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DESIGN FOR PEOPLE AFFECTED BY DUCHENNE MUSCULAR DYSTROPHY
Proposal for a new type of night AFO, Ankle Foot Orthosis, based on 3D indirect survey and 3D printing

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INDEX

The contents of the thesis are labeled in two :

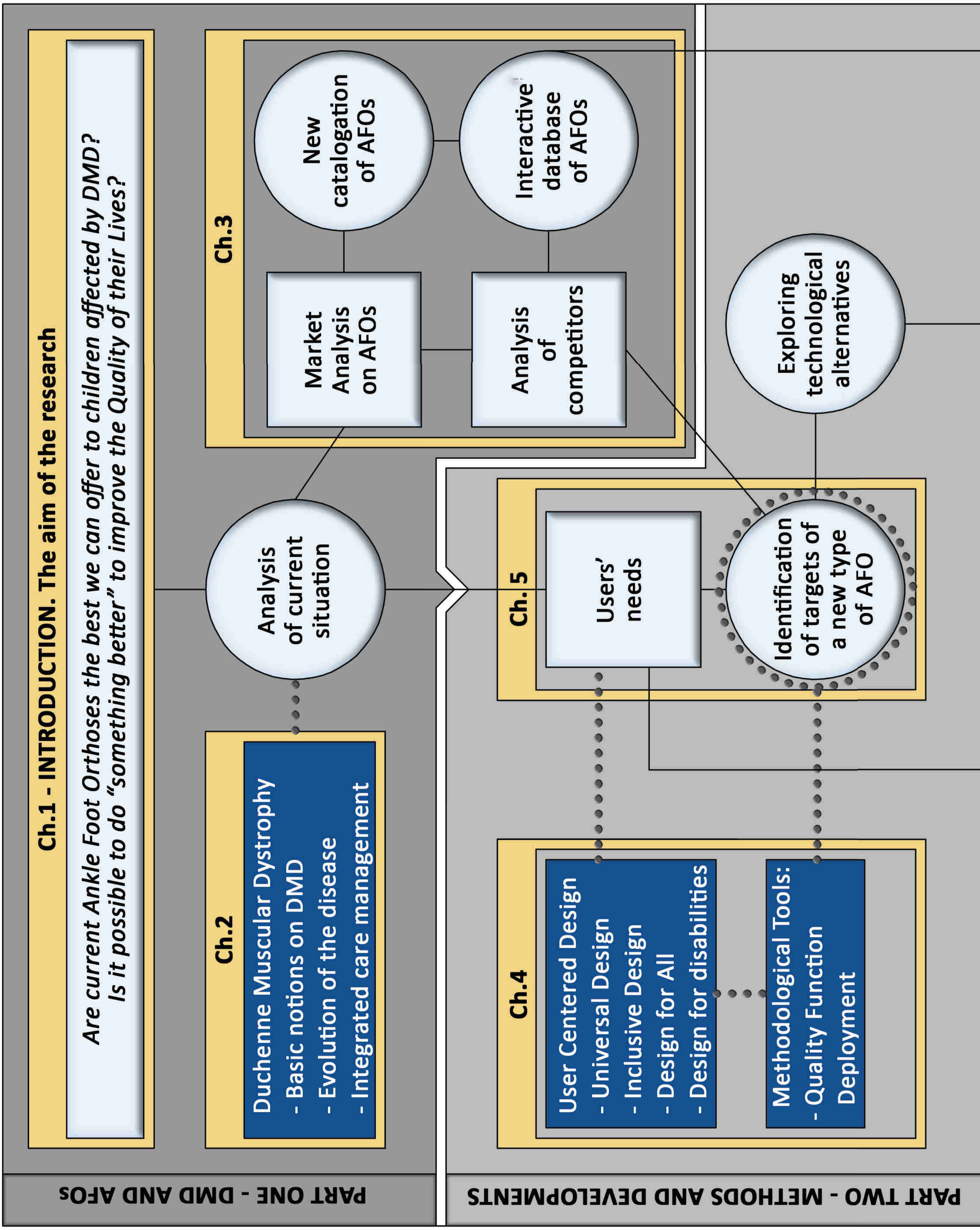
ANALYSIS	Dark blue indicates that the text is mainly a theoretical dissertation, a literature review that recaps and develops useful topics in the process of design
DESIGN	Light blue denotes original contents, personal data and word processing, tests on field and experimentations, innovative results, prototypes and final considerations.

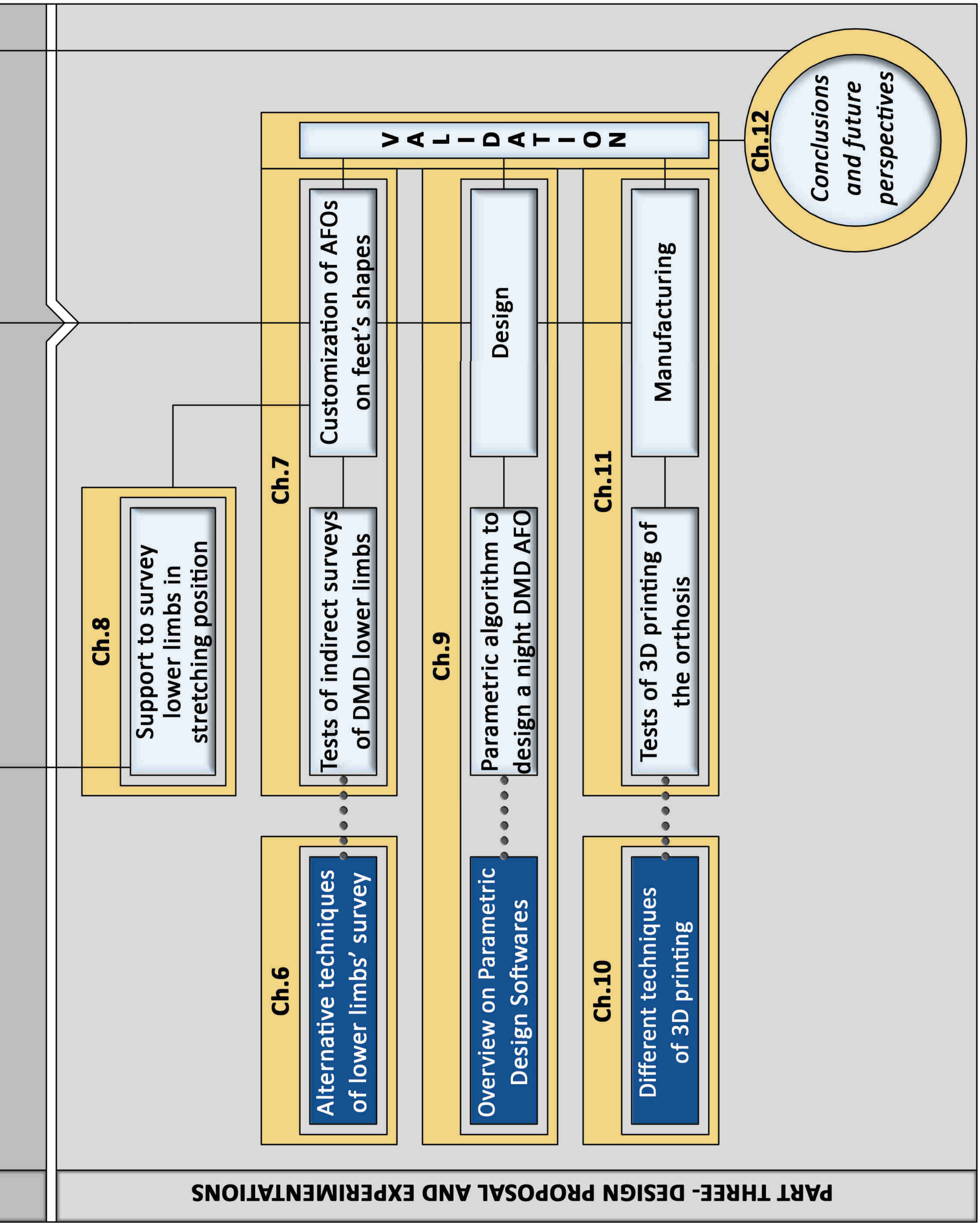
PART ONE

Duchenne Muscular Dystrophy and lower limb orthoses

PART TWO - METHODS AND DEVELOPMENTS

PART THREE - DESIGN PROPOSAL AND EXPERIMENTATIONS


Ch.1 - INTRODUCTION. The aim of the research
Are current Ankle Foot Orthoses the best we can offer to children affected by DMD?
Is it possible to do "something better" to improve the Quality of their Lives?
Ch.2
Duchenne Muscular Dystrophy
- Basic notions on DMD
- Evolution of the disease
- Integrated care management
Analysis of current situation
Ch.3
Market Analysis on AFOs
New catalogation of AFOs
Analysis of competitors
Interactive database of AFOs
Exploring technological alternatives
Ch.5
Users' needs
Identification of targets of a new type of AFO
Ch.4
User Centered Design
- Universal Design
- Inclusive Design
- Design for All
- Design for disabilities
Methodological Tools:
- Quality Function Deployment
PART ONE - DMD AND AFOs
PART TWO - METHODS AND DEVELOPMENTS


PART THREE- DESIGN PROPOSAL AND EXPERIMENTATIONS
Ch.6
Alternative techniques of lower limbs' survey
Ch.7
Tests of indirect surveys of DMD lower limbs
Customization of AFOs on feet's shapes
Ch.8
Support to survey lower limbs in stretching position
Ch.9
Overview on Parametric Design Softwares
Parametric algorithm to design a night DMD AFO
Design
Ch.10
Different techniques of 3D printing
Ch.11
Tests of 3D printing of the orthosis
Manufacturing
VALIDATION
Ch.12
Conclusions and future perspectives

1 INTRODUCTION

1.1 - ABSTRACT

The aim of this study is to investigate night Ankle Foot Orthoses, commonly prescribed to Duchenne Muscular Dystrophy patients to understand if there are margins to increase their comfort, aesthetic customization and psychological acceptance by the users, but even to improve their manufacturing process and to reduce costs.

Duchenne is a rare form of muscular dystrophy affecting 1 on 3.500 male children that, at about 8 to 12 years old progressively become wheelchair bounded and with an expectation of life on the late 20 or 30 years old, since usually cardiac or pulmonary complications occur. Due to muscles' weakening, Achilles tendon takes over on muscle tissue and starts to thicken and shrink, causing plantar flexion and retractions, while the function of AFOs is for applying a stretching force that can delay equine deformation of the feet. It is scientifically demonstrated that a constant use, of night Ankle Foot Orthosis, together with physiotherapy, can extend the independent ambulation by up to two years and delay the occurrence of other complications.

The PhD study was conducted from 2012 to 2014 thanks to a partnership between the Department of Architecture of Ferrara University and Parent Project Onlus for Duchenne and Baker. Moreover the thesis was endorsed by the Neuropsychiatric Department specialized in Duchenne of the Policlinico Gemelli in Rome, orthoses manufactures, experts in 3D survey, parametric design, and solid prototyping and, last but not least, by the direct contact with final users and their families.

The core of the thesis was organized in three parts. In the first one, after a brief recognition on the disease, a market analysis on all the lower limb orthoses available on European and North American market was essential to understand the state of art, the Italian picture and the most advanced innovations and ongoing experimentations. The second part focused on methodological approaches in the design of the AFO. After an overview on theories that frame the research, as Customer Centered and User Centered Design, as well as Universal Design, Inclusive Design, Design for All and Design for disabilities, a Quality Function Deployment process was chosen to translate theories into design directives. Relating user needs, technical requirements and comparison with the competitors, the scheme provides the guidelines for the design of a really innovative dorsal night AFO for DMD patients. The results of the research are exposed in the third part. Indirect survey techniques of photomodelling or laser scanner are used to accurately reproduce the shape of the leg, while the user is sitting on a particular bench designed to acquire the foot in a stretching position and to entertain the child as he was on a rocking horse. The 3D virtual reconstruction of the limb, combined with 15 control points, is elaborated in an algorithm of parametric design to obtain a customized AFO that can be 3D printed with complete freedom of personalization to meet the tastes of the child. The results are highly promising and deserve to be further developed in future experimentations on field.

1.2 – The reasons of the research

Duchenne is a rare form of muscular dystrophy affecting 1 on 3.500 male children. Symptoms usually appear at the age of two to five years old and lead to a complete muscular paralysis. When they are young, children are able to walk on their own but as soon as their muscular strength decreases, they need to sit on a wheelchair, at about 8 to 12 years old. Their expectation of life is on the late 20 or 30 years old, since usually cardiac or pulmonary complications occur. Nowadays medical frontier research is experimenting several new trials to extend the life of these children, but many things have still to be done in order to improve their ***quality of life***. It is scientifically demonstrated that in most of the cases a child affected by DMD begins assisted ambulation or a wheelchair confinement mainly due to feet deformation rather than for an effective lack of strength in lower limb muscles. Due to muscles' weakening, Achilles tendon takes over on muscle tissue and starts to thicken and shrink, causing plantar flexion and retractions.

For these reasons doctors prescribe, for patients affected by DMD, to wear Ankle Foot Orthoses all lifelong during the night, and, only in some phases of the illness, sometimes even during the day. The function of these "plastic boots" is to delay the equine deformation of the foot, applying a prolonged stretching activity. Scientific literature and clinic experiences agree that ***a constant use, every night, of night Ankle Foot Orthosis, together with proper and constant physiotherapy, can extend the independent ambulation by up to two years and delay the occurrence of other complications***.

However nowadays these AFOs present several **problems that could be improved**:

- **Technique of acquisition of the shape of users' lower limbs for the customization of the AFO**. Children's lower limbs in most of the cases are nowadays surveyed in a very "handcrafted way", with plaster cast as a mold for plastic casting, with an inaccurate result that could be easily improved thanks to modern technologies. Moreover as will be later explained, a survey of the foot in a stretching position could increase the clinical efficacy of the AFO;
- **Technique of manufacturing**. The handcraft manufacturing requires long time of production and, since its poor accuracy in the survey, it requires several reviews and handmade modifications;
- **Costs**. Current AFOs' price is by consent considered excessively high for a pair of children' shoes that needs to be changed at least every six months. High costs are not motivated by materials, since plastic is extremely cheap, but from the labour, manual skills and long time required to be produced.
- **Comfort**. Children and their families complain about AFO's discomforts. They proved to be really hot especially in summer season, bulky in natural night movements, the frontal straps are harmful and sometimes cause redness, callus and even ulcerations.
- **Aesthetics**. The possibility of an aesthetic personalization that manufacturers usually offers, especially in Italy, is generally limited to the choice of 5-6 patterns that are stitched or printed on the orthoses. A wider possibility of choice could be extremely important in the process of psychological acceptance of the orthoses by the child, since the child will consider them not only a top down imposition but he will feel himself part of the decision.
- **Clinical efficacy**. This aspect could be improved first acquiring the shape of

the foot at the maximum level of dorsiflexion the child can achieve and with the best alignment possible. In this way the orthoses will have not only a conservative role in maintaining the position of relax of the foot, but even in recovering that angular range of mobile retraction that, with a stretching activity is still possible to maintain. Moreover more comfortable and appreciated orthoses will be worn more continuously having an indirect effect on clinical efficacy.

- **Psychological acceptation**. This topic is another concern that the research suggests. The prescription of wearing night AFOs since the first childhood of the children isn't justified by a clinical urgency but more by a necessity to make the child get used and familiar with the orthosis and improve the process of psychological acceptance. These aids hurt, are bulky, are disturbing the sleep and make the child feel different from the others. As soon as he grows up, he tends to consider them an enforcement and he usually starts to refuse wearing them, but an irregular donning of the orthoses decrease drastically their efficacy.

All these considerations were at the basis of the decision of Parent Project Onlus for Duchenne and Backer to finance a study on DMD night Ankle Foot Orthosis aimed at investigating possible improvements to these difficulties. Parent Project wisely understood that the problems related with AFOs were not merely technical or biomedical. Especially since they are addressed to children, the main concern of this object is the approach to the design. Clinical efficacy guaranteed, these orthoses have absolutely not to look like hospital devices. Since they are a silent friend of Duchenne children for their entire life, it is extremely important that the design aims at creating something that should become part of their everyday life and not considered as an "intruder". Therefore the Onlus decided, instead of committing the research to a Bio-Engineering Staff, to turn to an Industrial Design Department, that has traditionally proved its attention to the themes of disability, Design for All and User Centered Design.

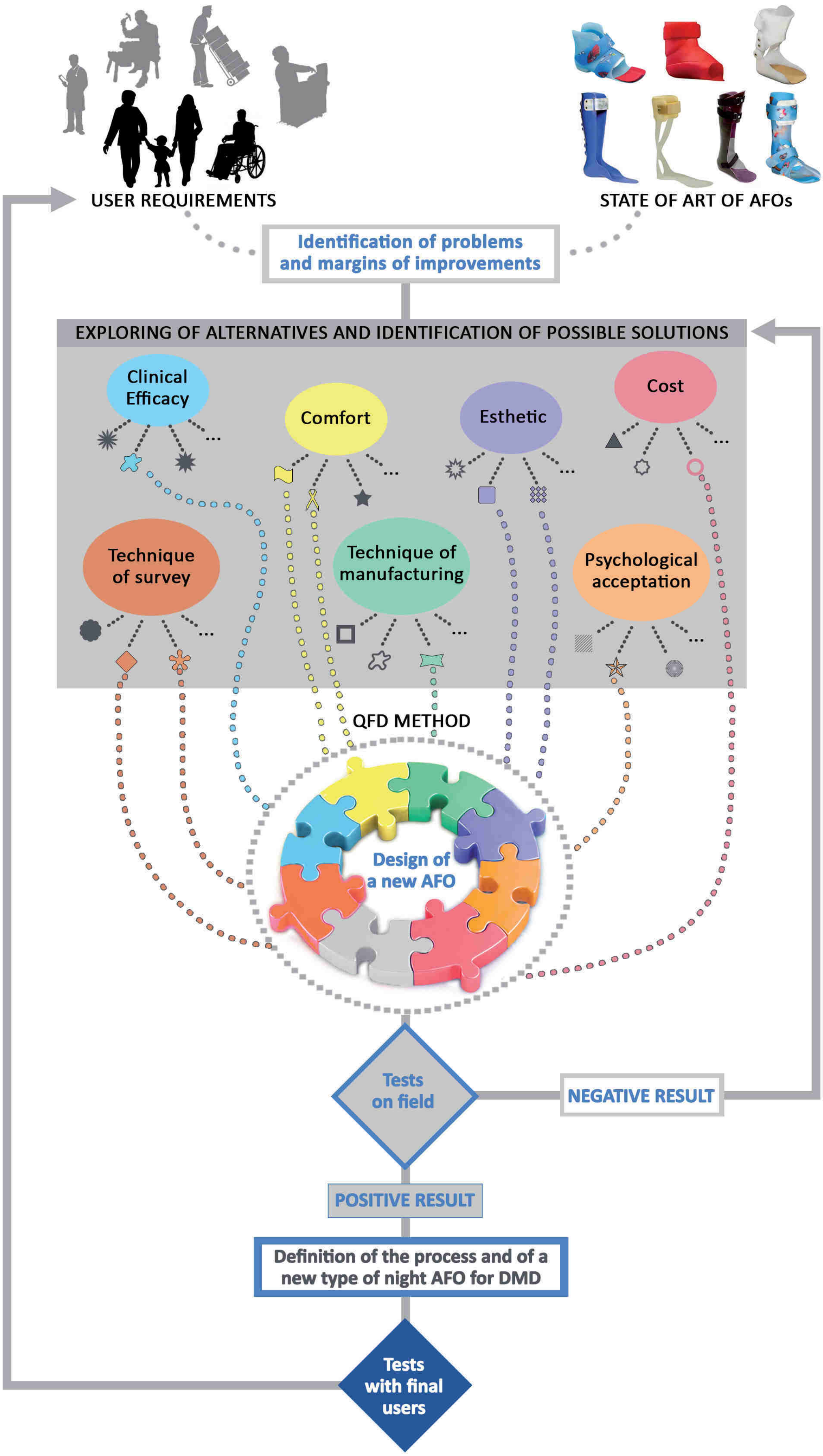
1.3 – The aim of the research and expected results

The aim of the project is to investigate the possibilities of improvements of night Ankle Foot Orthoses for children affected by Duchenne Muscular Dystrophy in order to design a new type of AFO. It has to be capable of grasping margins for improvements of existing products in terms of clinical efficacy, comfort, personalization, aesthetic and psychological acceptance by the users, while optimizing the process of production and marketing with a plausible cost reduction.

As it is illustrated in the previous paragraph, there are several aspects on which the research could explore meliorative alternatives. These involve not only the object itself. Also all the process around its manufacture, delivery and use must be considered as the core of the analysis. The aim of the thesis is to investigate the range of possible single solutions for each detected problem, even leveraging to the advantages of new technologies. All these solutions will be analysed and selected by their capability of effectively answer the specific need by themselves and by their predisposition of being arranged in an organic system.

Hopefully the application of contemporary technologies seems to be able to offer interesting solutions to the critical issue identified, as in the survey analysis of lower limbs, as in the manufacturing and accuracy and efficacy of the final result. However they have to be carefully evaluated, compared and selected. Moreover a technology couldn't be a solution if not in pair with a change of approach in the design that has to consider this object not as an hospital device anymore, but as an object part of DMD children daily routines.

This research will consciously not be able to solve all the criticalities encountered and no result will have to be considered definitive and unchangeable. Especially if we draw upon technology to improve some processes we have to consider that each solution, particularly in modern times is extremely temporary and while we are suggesting the adoption of one technology, we have the consciousness that somewhere in the world better solutions are coming available. This considered, it is clear how the aim of the research has to be most of all the indication of an optimized process and approach to the design of a new innovative type of night AFOs for DMD. Such an expected result would be more durable to the passage of time and more adaptive to contemplate technical and technological progresses.


USER REQUIREMENTS
STATE OF ART OF AFOs
Identification of problems and margins of improvements
EXPLORING OF ALTERNATIVES AND IDENTIFICATION OF POSSIBLE SOLUTIONS
Clinical Efficacy
Comfort
Esthetic
Cost
Technique of survey
Technique of manufacturing
Psychological acceptation
QFD METHOD
Design of a new AFO
Tests on field
NEGATIVE RESULT
POSITIVE RESULT
Definition of the process and of a new type of night AFO for DMD
Tests with final users

1.4 – Methodology and approaches to design process

The task of designing Ankle Foot Orthosis for people affected by Duchenne Muscular Dystrophy seems to be a mere functional commission. It has always been successfully dispatched by orthopedic technicians, biomedical professionals and orthopedic manufactures. These operators are certainly more skilled and trained on clinical and technical requirements that an orthosis has to fulfill in order to guarantee its efficacy. Despite these considerations, the products available nowadays on the market don't satisfy users, in this case personalized by Parent Project Onlus for Duchenne and Backer, that foresees the possibility of further studies on this product. Instead of recurring directly to the research of a better technological solution, they turned to a Design Faculty to deal with **a problem of method**:

*"Are the designs of our children's orthoses the bests we can offer them? Is it possible to do **something better to improve the quality of their lives**?"*

This request was incredibly demanding and required, if possible, even more respect, attention and responsibility in the approach to the issue, since it was demanded by parents of children affected by an incurable disease in order to improve the *Quality of Life* of their children.
"To find anything better" and *"to improve the quality of life"* were the first two milestones on which to build on the methodological approach of the thesis. In order to answer the first task, two questions need to be answered: what exists now and what are users' requirements, desires and aspiration related to AFOs. These goals highlighted the opportunity of recurring to product design methods that consider the *USER* the fulcrum of the entire design process.

Customer Centered and ***User Centered Design*** theories offered the appropriate frame to this topic.
However it must be noticed that the real complete reversal of the paradigm in the approach to this specific issue isn't the consideration of the user as the center of the design process *tout court*. As it is described in the text, most of contemporary orthoses are already built in single pieces, customized on user's feet and progressively adapted by doctors and technicians in order to improve their clinical efficacy. Besides standard orthoses, current ones are perfectly custom-tailored, as an handmade dress, completely thought and conceived around the final user. However this seems to be insufficient since still forms of dissatisfaction towards this product persist at the point of moving Parent Project in investing economical resources in the attempt to find a better solution.

The main change is to aim at designing an orthosis that doesn't only respond to "*how the user IS",* but attempts to give persuasive answers to *"**what users WANT**".*
On this concern a little clarification is needed on the acceptance of the term '**user**'. Main users of night Ankle Foot Orthoses are certainly children affected by Duchenne Muscular Dystrophy. The survey of their expressed, implicit and latent needs was a crucial step of the design process. But main users have to be considered by parents as well. Doctors suggest to start wearing AFOs since infancy, even in absence of a clinical urgency, in order to make the child get used to the orthoses. It is evident how, in this first stage, parents perform the main role in the process of commissioning, choosing and taking care of the orthoses. Only in a later stage they will be backed up by their child who, since his young age, will predictably be more

interested in the aesthetic aspects of the orthoses than in their clinical efficacy. This last goal is the main concern of his parents and of other “secondary users” of AFOs, other than doctors who cure the patient and orthopedic technicians. Their requirements and prescriptions have a direct influence on the workers who physically produce the object. Moreover the manufacture’s process they choose to lead has a direct repercussion not only on clinical efficacy, but even on the management of all the process of purchase of these shoes by the parents, on the rate of satisfaction of the children and, last but not least, on final price.
The cost factor is another key point that has to be carefully evaluated since an excessive cost will discourage parents from buying the orthoses or to their periodical renewal, following child’s growth and the progress of his retractions, with a comprehensible huge risk of invalidating clinical efficacy.

Primary and secondary users’ requirements have therefore to be considered as a whole system, trying to attribute the appropriate relative weight to each need and evaluating, in parallel, which of these needs are already satisfied by existing products, in which percentage, and which margins of improvement can be identified.
In order to propose a real innovative product, it has to be considered as a single unit, in its entire life cycle and as an integral part of patients’ lives. Afterward, when the current situation is clarified, the common process of prescription, manufacturing, use and renewal of the orthoses is clear and the roles of each protagonist of the process characterized, the design process *“of something better”* can start.

Only at this stage **technology** comes to the aid.
If we consider in particular Italian AFOs’ market, nowadays technology’s innovations influence the manufacturing of orthoses only marginally. Orthoses are made in light thermoplastic mold on a plaster, this material can be produced in different colors or various textures can be applied on them, but the entire process remains mainly handcraft and this factor deeply influences all the context. A User Centered design approach at this stage is translated in the criterion of ***selection of the best technology possible for the user.*** Even at a first sight it is perceivable that adopting modern techniques in all the phases of the manufacturing could produce immediate advantages. But technology couldn’t be considered a response by itself. The key point in each decision isn’t wondering if the adoption of a technology brings the best possible result. The chosen approach in each evaluation consists in pondering if that solution brings the best possible advantage to the user, starting from the main one: A Duchenne child.
For example, the adoption of the best vanguard laser scanner for an ultra-high resolution in the survey on child’s lower limb is definitely the best technological choice, but it would reflect in a dramatically high increment of AFOs’ cost, without a real consistent advantage for the user.

All the proposed solutions have therefore to be considered as a whole, as little tassels of a puzzle aimed at increasing the ***Quality of Life*** of the user.
Here the transition to the second goal of the research takes place. The drop out of a functionalist approach must involve not only technological choices. Reasonably nobody will ever consider an healthcare orthopedic device as an element capable of adding quality to his life. At least not if it is considered ONLY as an healthcare auxilium. A utilitarian approach optimizes clinical efficacy and production process, but risks to lose sight of quality of life of the child.
Even if it could be considered cruel and cynical it must be noticed that this increasing interest in the improvement of the quality of life of people affected by Duch-

enne Muscular Dystrophy is a great success not only of ethics and psychology, but of medicine itself. Unfortunately, until few decades ago, when the expectation of life for these children was extremely short, all the efforts in the care management were focused on pharmaceutical cures and in the prevention of complications. The dramatic health conditions of DMD children prevent from the consideration of all the other aspects of their life. Luckily scientific progress in the cure and containment of the most severe complications, has significantly extended the expectation of life of Duchenne people even if a specific cure seems to be closer but it hasn't been discovered yet. This success rebounds in a new consideration of all the aspects of life of a Duchenne child. It stimulates the fundamental awareness that even a Duchenne life is a life that has all the rights and modes of being fully lived.

This consideration has two main relapses on AFOs' issue.
Under this perspective, night orthoses couldn't be considered more as only an orthopedic device aimed at the delay of the equinus foot. Night Ankle Foot Orthoses become the instrument by which, if properly jointed with daily physiotherapy, as scientifically reported, a Duchenne child can extend his independent ambulation before sitting definitively on the wheelchair by up to two years. Moreover even once the child is wheelchair bounded, a further delay in retraction prevents contractures, complications and pains. The design of something that in any way, even with a very little contribution, is able to improve existing products in the reaching of this target, is probably the highest target we can conceive in order to increase the quality of life of these children.

Night Ankle Foot Orthoses aren't a cure for DMD patients and Achille tendons's retractions at the end will in any case take over muscular strength. But, once again, the aim of the design of the product isn't the mere achievement of a clinical result, but the ideation of something that, in any phase of the disease, can bring the highest benefit possible to the user, considering his personal conditions in that particular moment.

This reflection introduces the second relapse of considering AFOs as something different from a simple medical device. Almost everyone in our life proved at least once, at every age, the pleasure and satisfaction of choosing and buying a personal accessories, either a new cloth, a pair of shoes, a bag or whatever. It isn't a consumer consequence, neither an exhibitionist or narcissist feeling, but it is the natural human instinct, established since mists of time of owning something that belongs to us in some way, in which we reflect, that instinctively and most of the times unconsciously, improves the image we have of ourselves.
This is particularly true during adolescence when, the construction of the self-image, both psychological and physical-aesthetical, passes from these aspects too, especially in group dynamics to be considered a worthy part of the group. Duchenne child, during his adolescence lives his hardest period since all the most dramatic changes and consequences of the disease appear in a strong way and anything that could limit this feeling of diversity from his peers has to be put in place. If we injure one leg, or we break a foot's bone, we know that for a little period of our life we have to give up our favorite pair of shoes in order to do a bulky plaster or simply accept a bandage. We simply accept it because it's a temporary condition. But what if we are forced to wear them for our entire life and we are completely deprived of the ***pleasure of choosing what to do***? In this sense AFOs can't be considered just to lie a temporary plaster or whatever medical device, since it is a companion of

everyday's life of a child affected by Duchenne.
Furthermore, improving as much as possible the process of psychological acceptance of AFOs by the users has not only relapse in the immediate, in the pleasure of wearing something that he chooses and likes, but at the same time it is the best guarantee of a constant use of the orthoses, and, therefore, of the achievement of the best possible clinical results and in general of the improvement of his quality of life.

In order to understand which were the cornerstones that have to guide the design process, these reflections were framed in the internationally renowned theories of ***Universal Design, Inclusive Design*** and ***Design for all***, with a particular attention to the fundamentals of ***Design for disability***.

Afterwards, in order to translate these theories and methodological approaches in operative design suggestions, among all different design process methods, ***Quality Function Deployment*** process was considered the one that suited best with everything we've just said.

It was perfectly in harmony with the attention devoted on user needs by User Centered Design. Moreover it is proved that the QFD matrix, putting in relation user needs, technical requirements and an analysis of the response of the best competitor products to user needs, is one of the best instruments to obtain innovative design suggestions.

Of course, all this process doesn't discredit the work and professionalism of all the medical and technical figures currently involved in AFOs manufacture. The proposed methodology is just an added value on their technical background. In particular this phase of the research was conducted mainly in autonomy, even if supported and validated on the results by several specialists on different topics. However the final result isn't definitive and concluded and, in order to become a commercialized product it will require the establishment of a ***multi-disciplinary group able to guide the phase of testing and experimentations***. The application of the just described method lead to the formulation and realization of a prototype, but an integrated team work would be necessary to optimise all the phases of the process and to transform the prototype in a new product.

Concluding, the process of Quality Function Deployment proved to perfectly comply with the two initial requests that stimulated and oriented this research.

The relation between what is desired, what already exists and what needs to be done clearly evidences what could be done and which are the margins of improvement in order to create *"something better to improve the Quality of Life of Duchenne people."*

1.5 – Phases of the research process

Summarizing and illustrating the results of three years of research on night Ankle Foot Orthosis for people affected by DMD is quite a challenging task. Especially if we consider the experimental nature of the thesis, it can be easily figured out that the iter of the tests, analysis, prototypes, evaluation and insights was extremely complex and kept changing and developing throughout the process, without the organized structure of this text. Many activities, as the tests on surveys techniques and the acquisition of the basis of parametric design were developed in parallel and often it was necessary to stop a failed attempt and reconsider theoretical aspects or even the aim of the test itself.
However in order to provide an organic presentation on the results of the research, all the contents were organized and summarized in a logical sequence.
The core of the thesis was organized in three parts.

Part one – ***The DMD disease and context analysis on orthoses***, starts from a brief recognition on the disease, especially dealing with all the aspects that could have a relevant influence in the process of design of AFOs. More than on pharmacological therapies or genetic descriptions, the first chapter deals with the evolution of the disease, crucial to understand how the life of these children changes drastically in a short lapse of time, with all the related consequences. The system of integrated care management for children affected by DMD discusses all the cures and problems that globally involve the life of a patient, with a particular attention given to the orthopaedic management, essential to understand functions and effectiveness of the lower limb orthoses.

After having developed a consciousness of what is relevant and effective for a night DMD AFO, the research enlarges its field of view to a market analysis on all the lower limb orthoses available in Europe and North America not only the ones dedicated to Duchenne people. This step proves to be essential in the understanding of the state of art, to have a more documented idea on the Italian context on this regard and, most of all, to understand and discover the most advanced innovations and experimentations which are ongoing. Since DMD users' needs were previously carefully evaluated, a broad-spectrum research is extremely effective in suggesting technological transfers from an existing product to a not innovative one. Furthermore one of the most evident outcomes of this research was the extreme confusion in terminology related to lower limb orthoses, since a codified nomenclature is missing. This suggested the need of a personal cataloguing of the hundreds of different products found in the market as lower limb orthoses. An interactive and queryable data base was set that organizes all the orthoses by queries. These research keys were defined with a particular attention to the final user of the orthoses, relating not only technical and clinical data, but even techniques of manufacturing, marketing and possibilities of aesthetic customization. This database proved to be particularly effective, allowing the possibility of some evaluations and critical considerations on the state of art in orthoses manufacturing but at the same time to become aware of the most advanced ongoing research activity in course on this field and to address useful suggestions to the design of a new AFO.

Part two – *Methods and Developments* is articulated in a theoretical and operative section. In the first one the main theories that frame my research are briefly outlined in their general features and characteristics. Starting from a discussion on the value of a *Customer Centered* and *User Centered Design* that consider the user as

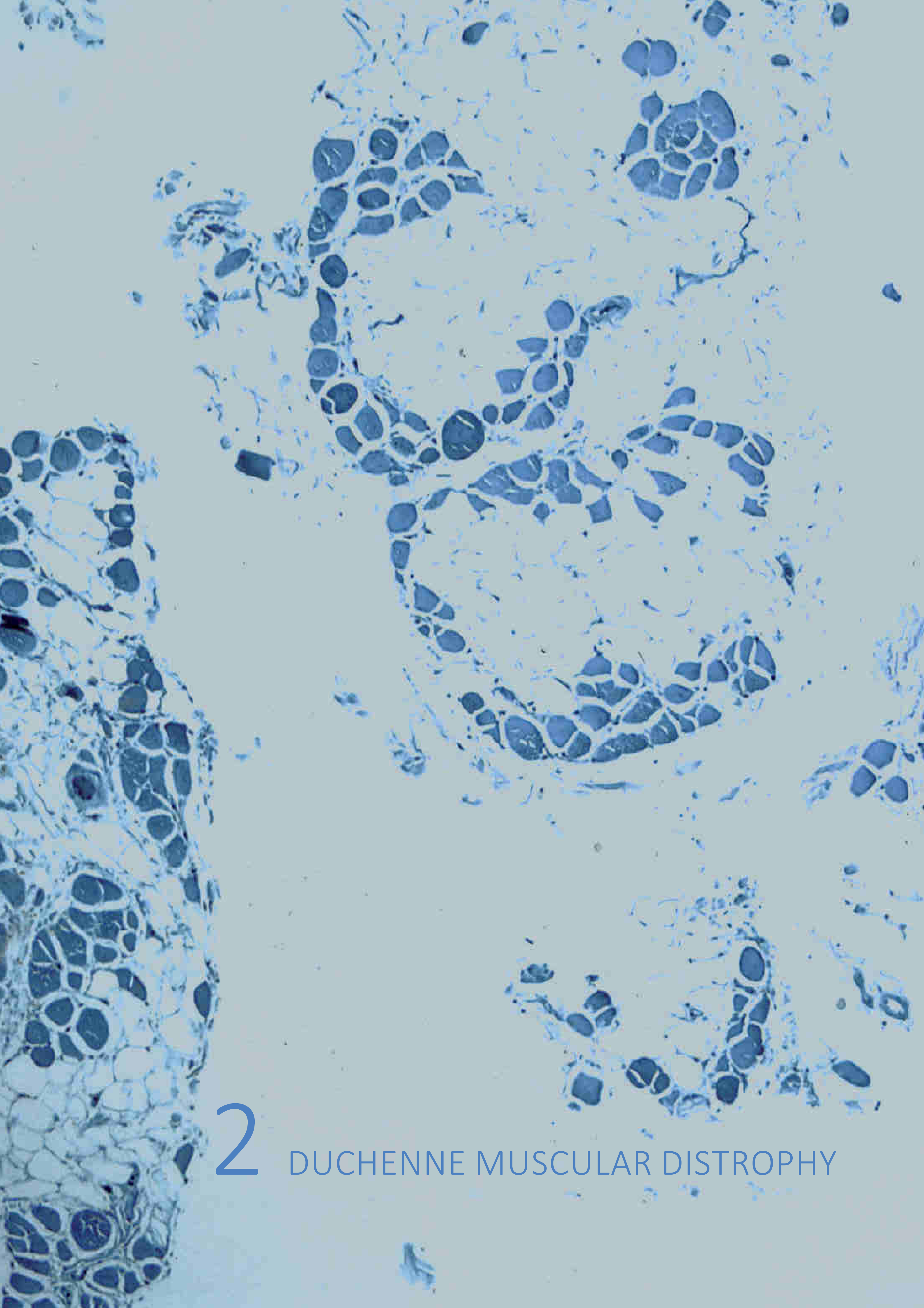
the starting point of each design process, the differences and similarities between the globally known theories of *Universal Design, Inclusive Design and Design for all are discussed*. Then the attention is turned to the more specific field of *Design for Disabilities*. Among all the operative methods available to translate a theoretical approach to operative design suggestions, Quality Function Deployment method, was considered the most coherent with the approach and the aim of the thesis. QFD is broadly adopted by forefront companies, especially if involved in innovative design and it was used for the design of a night Ankle Foot Orthosis for DMD. All the collected user needs, of all the users in relation with the orthoses, were put in relation with technical requirements and with the best examples emerged after a transversal comparison between all the possible competitive products emerged in market analysis, even if not directly addressed to DMD people but with some features that made them of some interest.
This complex process provided at the end the guidelines for the design of a really innovative and promising dorsal night AFO for DMD patients.

Part three – *Design proposal and experimentations* exposes the results of the research. Besides the market analysis of lower limb orthoses, that could be considered as a result by itself, the main outcomes of this thesis are:

- The setup of a process of acquisition of the shape of a child's lower limbs in order to have customized AFO, by the support of modern indirect survey techniques of photo-modelling or hand laser scanners. This theme is discussed with a brief overview on modern techniques of indirect body and foot survey and the final outcomes are illustrated through a summary of the main phases of survey tests, made applying different technologies and conditions, with a final conclusion on all the conducted experiences.
- The design of a particular bench designed to host the child while the technician has to survey his lower limbs. This prototype is something innovative and nothing similar was found on the market. It has the merit of being extremely flexible, light and transportable and, most of all, adaptable in its measures for a child from two to twenty years. Moreover it is provided by a sort of "pedal" in which one foot at a time is bounded and can be easily handled by the therapist in each space direction in order to position the foot in the best possible way for its clinical condition and with the higher range achievable of dorsiflexion. This device is extremely useful in the attempt of creating a boot that, stretching the foot, can recover the whole range of mobile retraction still present in the limb and it doesn't just almost maintain only the dorsiflexion of the foot in a relax position, as it happens nowadays with the traditional plaster cast.
- The design and realization of an innovative type of night AFO for DMD patients that benefits of new technologies to optimize critical issues and problems emerged in the analysis phase. The virtual reconstruction of the lower limb of the user and the identification of 15 control points are used as starting points in the elaboration of a parametric algorithm expressly designed. Starting from users' shapes, it elaborates the morphology of an innovative night dorsal AFO. Simply substituting the incoming data with the ones of another user, it automatically adapts to the new shape. This process speeds enormously the design phase, and enlarges the freedom of personalization of the AFO. This is made possible even thanks to the manufacturing process chosen. 3D printing technique, in fact, requires a minimum effort by the operator and gives excellent results with an exponentially enlarged possibility of esthetic personalization and customization of the AFO to meet the tastes of the child.

PART ONE

DUCHENNE MUSCULAR DYSTROPHY AND LOWER LIMB ORTHOSES



2 DUCHENNE MUSCULAR DISTROPHY

Histopathology of gastrocnemius muscle from patient affected
by pseudohypertrophic muscular dystrophy, Duchenne type.
Cross section of muscle shows extensive replacement of muscle fibers by adipose cells.
Dr. Edwin P. Ewing, Jr., Department of Health and Human Services, http://phil.cdc.gov/phil/home.asp

2 – DUCHENNE MUSCULAR DYSTROPHY

This chapter presents a theoretical dissertation on Duchenne Muscular Dystrophy. A literature review that illustrates the main features of the disease isn't only a compulsory step to frame and introduce the contents of the thesis. Even in inevitably marked on the side of the page as a "Research" chapter, a deep analysis and awareness of all the implications related with DMD were the first steps in the design process and in the consciousness of needs and difficulties that these children have to face in every stage of the disease.

Moreover it proves to be even more relevant since the nature and progression of the disease. DMD leads and forces the affected child through very different periods and conditions in his short life, from an apparently state of wellness to a complete immobilization. Each product designed for a DMD user has necessary to be faced with this evolution, and this is particularly true for the object of this thesis, Ankle Foot Orthoses, since their prescription and use are changing always, following the evolution of child's conditions.

For this reason this text briefly deals with genetic causes, diagnoses and pharmacological cures and focuses more on the system of integrated care management that globally involves the life of the patient. In particular in-depth analysis is dedicated to orthopaedic management, essential background to understand function and mode of operation of lower limb orthoses.

2.1 - BASIC NOTIONS ON DUCHENNE MUSCULAR DISTROPHY

Duchenne disease is a form of muscular dystrophy. It is part of a group of syndromes that have in common a progressive muscle weakness, a lost in muscle proteins and progressive death of muscle cells and tissues. Besides Duchenne other major forms are Becker, limb-girdle, congenital, facioscapulohumeral, myotonic, oculopharyngeal, distal, and Emery-Dreifuss[1].

In particular Duchenne and Becker are a recessive x-linked forms of the disease because the disorder is caused by a mutation on the *dystrophingene*, "the largest gene located on the human X chromosome, which codes for the protein *dystrophin*, an important structural component within muscle tissue that provides structural stability to the *dystroglycan complex* (DGC) of the cell membrane".[2] Since the Duchenne gene is found on the x-chromosome it primarily affects boys, it is passed from mother to child, but approximately 35% of cases occur because of a random spontaneous mutation[3].

While in Duchenne syndrome the dystrophin is absent, and so the muscle cells are easily damaged, in Becker muscular dystrophy the dystrophin is present, but in an abnormal form or amount, and this cause a less severe form of the disease.

DMD is the most common muscular dystrophy. It is a rare progressive illness that affects approximately 1 in every 3.500 live male births (about 20.000 new cases each year) and it occurs across all races and cultures.[4] In Italy around 5.000 people should

1 *Report to Congress on Implementation of the MD CARE Act*, Department of Health and Human Service's, National Institutes of Health, 2006, http://www.ninds.nih.gov/about_ninds/groups/mdcc/md_care_implementation.pdf (January 2015)

2 Genetics Home Reference, *Duchenne and Becker muscular dystrophy* (2012), http://ghr.nlm.nih.gov/condition/duchenne-and-becker-muscular-dystrophy, (May 2014)

3 EndDuchenne.org, *About Duchenne* (2014), http://www.endduchenne.org/, (May 2014)

4 Parent Project, *La patologia* (2013), http://www.parentproject.it/la-patologia/, (May 2014)

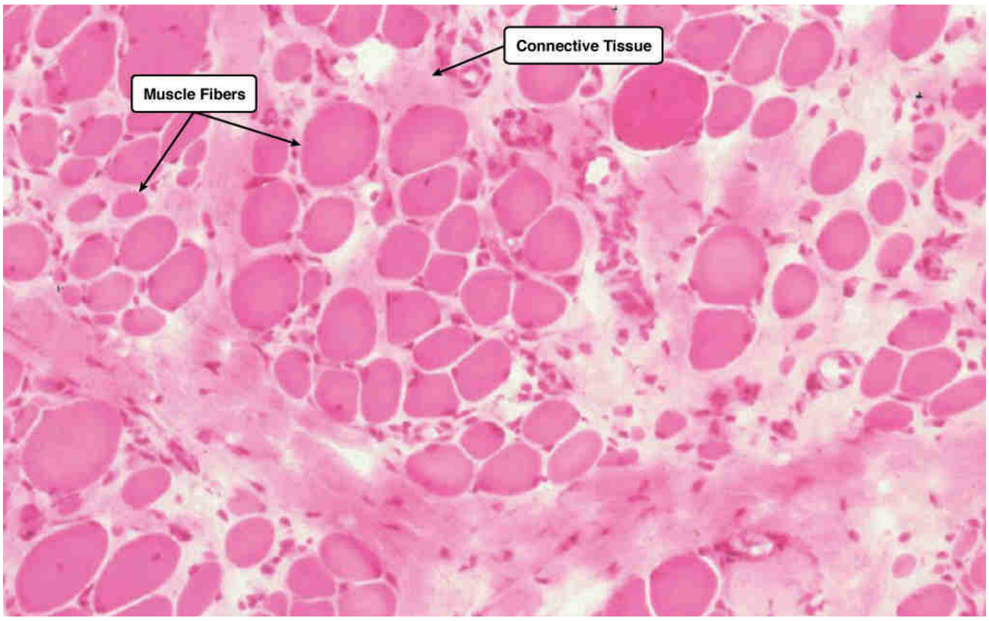
be affected by DMD but there are still no official data in this sense. [5]

The history of the discover of this disease is quite recent. “The disease was first described by the Neapolitan Physician Giovanni Semmola in 1834 and Gaetano Conte in 1836. However DMD is named after the French neurologist Guillaume Benjamin Amand Duchenne (1806 – 1875). The scientists, in the 1861 edition of his book “*Paraplegie hypertrophique de l’enfance de cause cerebrale*”, described and detailed the case of a boy who had this condition.

A year later, he presented photos of his patient in his “*Album de photographies pathologiques*”. In 1868 he gave an account of 13 other affected children. Guiltaume Duchenne was the first who did a biopsy to obtain tissue from a living patient for microscopic examination.”[6-7]

Since its discover, many aspects in therapies and treatments of DMD have evolved but there still isn’t a specific cure for it. Life expectancy exponentially grow up in the last years and is currently estimated to be around 25 years old, with a growing number of people that, with a proper cure management, succeed in reaching 30 and in very few cases even 40 years old. Human trials have started leading to the hope of definitive treatment, as the one based on gene modification or replacement, but what makes the difference until now is an effective prevention and management of complications[8.]

Finally it is proved that pharmacological treatments, especially corticosteroid, respiratory, cardiac, orthopedic, and rehabilitative interventions can drastically change not only the expectation of life but, most of all, the quality of life of a boy with DMD.



Cross section of muscles shows muscle fibers and connective tissue

@ http://medcell.med.yale.edu/histology/muscle_lab/duchenne_muscular_dystrophy.php

5 In Italy the 1% of the population is affected by neuromuscular disease. It was discovered in 1868 but still does not exist a complete list of all the affected people with DMD, even if many associations are working in this sense. UILDM Torino, *La Distrofia Muscolare,* (2014), http://www.uildmtorino.org/distrofia.htm#5, (May 2014)

6 Wikipedia, *Duchenne Muscular Dystrophy*. *History* (2014), http://en.wikipedia.org/wiki/Duchenne_muscular_dystrophy#cite_ref-6, (May 2014)

7 MedicineNet.com, *Definition of Duchenne Muscular Dysytophy* (2013), http://www.medterms.com/script/main/art.asp?articlekey=11686, (May 2013)

8 BUSHBY K, BOURKE J, BULLOCK R, et al., *The multidisciplinary management of Duchenne Muscular Dystrophy,* Current Paediatrics 15 (2005): 292-300, Elsevier, http://www.muscle.ca/fileadmin/National/Research/Other_research/The_multidisciplinary_management_of_DMD.pdf, (03/2013)

ANALYSIS

2.1.1 - Dystrophinopathies and disease transmission

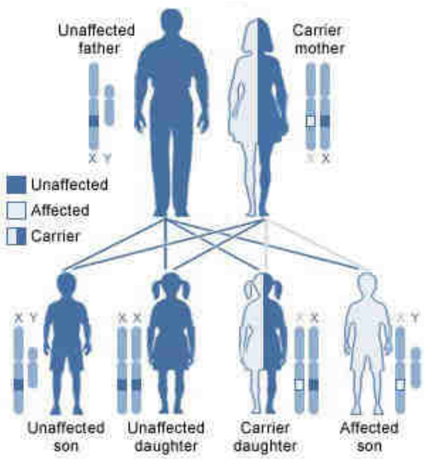
Duchenne Muscular Dystrophy is characterized by a mutation of *dystrophyn gene* at locus Xp21. Dystrophin is one of our largest known genes, it is responsible to link and stitch together muscle cells. Its deficiency, called *dystrophinopathy*, causes progressive neuromuscular disorders and progressive muscle degeneration[9] .

The lack of dystrophin makes outer membranes of cells of muscle fibers permeable to external substances that are not supposed to penetrate inside the cells. This causes the explosion of the cell itself and, of course, its death. As a consequence immunity system provides to *clean* the area of the muscle, even bigger than the necessary, causing a bigger and progressive damage. *Empty space* in the muscle is substituted by connective tissue which presses on sane cells and stifles them until their death[10].

Since it is located on X chromosome, it affects only boys, who have only one X-chromosome, while women, who have 2 X-chromosomes, make up with the other one for the damaged gene. For this reason DMD is inherited in an X-linked recessive patterns. It means that female are usually unaware carries of the disease. If a carrier woman has a child with a sane man, these are the possible scenario:

- 50% chance it is a man
  - 50% chance to be sane
  - 50% chance of inheriting the defective gene and be affected with DMD
- 50% chance it is a girl
  - 50% chance to be sane
  - 50% chance to be a carrier.

Unfortunately, once a child is born with DMD, there is still no way to stop the progression of the illness. However if there is a known case of DMD in the family, it is possible to carry out a prenatal diagnoses through genetic testing. For pregnant women this test can detect Duchenne with about 95% accuracy[11].



X-linked Recessive inheritance, carrier mother

@ *National Institutes of Health*
http://ghr.nlm.nih.gov

9 CASE L. E., *Physical therapy management of dystrophinopathies*, in *Parent Project Muscular Dystrophy Annual Conference*, Cincinnati, Ohio, 2006

10 SEJERSON T., BUSHBY K., *Standards of care for Duchenne muscular dystrophy: brief TREAT-NMD recommendation*, Advances in Experimental Medicine and Biology, 2009, 652:13-21, http://www.ncbi.nlm.nih.gov/pubmed?term=TREAT-NMD%20EU%20Network%20of%20Excellence%5BCorporate%20Author%5D, (05/2014)

11 EndDuchenne.org, *About Duchenne*, op. cit

2.1.2 - Symptoms and diagnosis

First step of evolution of the infancy are regular. As sane children, they start to have control of neck muscles at about six months, starts to stand up at 11 – 12 and to walk from 12 to 15 months. Sometimes parents or paediatrician notice some delay in movement or in speaking skills, but they still do not suspect DMD.
Most of the children affected with DMD present first symptoms of the illness at about 18 months, with a delay in walking capability. Between 2 and 5 years motor impairments related to the DMD become more evident and suggest parents to investigate the clinical reasons of muscle weakness.

As it is written in *About Duchenne* (2014) There is a combination of signals that make a boy to be supposed to have DMD:

- *"Has a hard time lifting his head or has a weak neck;*
- Is not walking by 15 months;
- Has a hard time walking, running or climbing stairs;
- Is not speaking well as other kids his age;
- Has calves that look bigger than normal (pseudohypertophy);
- Walks with his legs apart;
- Walks on his toes and waddles;
- *Walks with his chest pointed out;*
- *Needs help getting up from the floor or walks his hands up his legs in order to stay, with the so called Gower Maneuver".* [12]

Gower's sign is the typical way of standing of young child affected with DMD: "*Initially the child will roll onto his hands and knees in the prone position. He will then extend his knees, raising his buttocks upward. Next, he will use his upper limbs to "walk" his hands along his legs until the torso can be brought upright.*[13]"

In some cases parents discover DMD earlier thanks to a blood analysis, usually made for other reasons, that reveals really high value of transaminase (AST, ALT) or cheratine kinase (CK) from 21-250 U/l to > 9000 – 10000 U/L[14].
On the contrary the mean age of diagnosis of cases without a family history remains over four and half years of age[15].
Summarizing the diagnosis of DMD goes through several steps:

1. Clinical evaluation that underline problems with muscle function, Gowers's sign or speech delay;

2. Blood test with, as results, high levels of the muscle protein creatine kinase and "*liver enzymes*" AST and ALT;

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12 EndDuchenne.org, *About Duchenne,* op. cit

13 SUSSMAN M., *Duchenne muscular dystrophy*, J Am Acad Orthop Surg 2002; 10(2): pagg. 138–151.

14 D'ANGELO G., *Intervista alla dott.sa Grazia D'Angelo*, in Fondo DMD (2010), http://www.fondodmd.it/documenti/comunicato_190310.pdf, (05/2014)

It is an interview sponsored by the "Gli Amici di Emanuele" association, with Grazia D'Angelo, doctor in the Instituto di Ricerca e Cura IRCCS Eugenio Medea, in Lecco. The aim of the interview is to make people aware about Duchenne Muscular Dystrophy through ten comprehensive answer of the most common questions regarding the disease.

15 BUSHBY K, BOURKE J, BULLOCK R, et al., *The multidisciplinary management of Duchenne Muscular Dystrophy,* Current Paediatrics 15 (2005), op. cit.

3. *Neurological or/and neuropsychiatric examination* (possibly in a center specialized in neuromuscular diseases);

4. *Genetic testing*, for the child and for his mother. It is the main test because it can reveal genetic errors in the Xp21 gene. Moreover it will identifies the specific disease causing mutation and it will help to determine if the boy may be eligible for a number of mutation-specific clinical trials[16]. Mother's test that, as already said, can be done during pregnancy too, is required as well to have a precise frame of the clinical situation and to inform other family members;

5. *Muscle biopsy*. In some cases it is not required if the genetic test has given unique affirmative response on the presence of DMD. In other cases, if DNA testing fails to find the mutation, this test could give some useful information on the percentage or complete absence of dystrophin in muscle tissues. However, even if muscle biopsy proves the absence of dystrophin protein, a genetic test is always required for the reasons explained above.

Gower Maneuver

@ End Duchenne
www.
parentprojectmd.org

16 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 1: Lancet Neurol. 2010 Jan; 9(1), http://www.treat-nmd.eu/downloads/file/standardsofcare/dmd/lancet/the_diagnosis_and_management_of_dmd_lancet_complete_with_erratum.pdf (01-2015)

2.2 – EVOLUTION OF THE DISEASE

Duchenne muscular dystrophy is currently an incurable disease, but it is treatable and the differences in treatments, physiotherapies, medications and care management in general can change drastically its progression. Each patient and every clinical story is different and it's not possible to give precise times or to generalize fixed categories. There are too many variables involved and, as discoveries and new therapies are running so fast, it's not possible to have a "story" and a wide range of past experiences to have a reliable sample.

However, as the disease makes its tragic course, a boy with DMD will encounter in his life three important stages: independent ambulation, assisted ambulation and wheelchair mobility. In the following paragraphs all these stages will be examined, and in particular the last one has been divided in two stages. The last one deals with all the notes for the advanced state of the illness, were cardiac and respiratory complications become severe.

2.2.1 - Early ambulatory phase

As reported in the symptoms and diagnosis paragraph, boys with DMD have no specific evidences of the disease in the very first years, if not a slight delay in walking and speaking and a clumsy in movements. These signals are usually underestimated until when they become more evident or a blood analysis, carried for other reasons, reveals outlier results.

Therefore the early ambulatory phase largely coincides with the diagnosis moment. At this stage boys don't need particular help, parents have to provide education and instruments for them to gain independence equal as for all children of the same age.

This period is more crucial and stressful for parents who discover and have to accept the disease of their child and the bounded future that expects them. They have to find an integrated team of experts who can inform them regarding all the possibilities and the action they can put in place to be well prepared for their future. In particular it is the best time to analyze their house and to consider objectively if it could be suitable for a person who will require on a first period assistance in ambulation and then he will move on a wheelchair. If the house seems not to be adequate to the future needs of the family, they have to evaluate if it is modifiable, with restoration, construction works or works for abatement of architectural barriers or, in some cases, it could be kindly suggested to move to a more comfortable house that will solve many problems to all family members,the child with DMD, parents and care givers, for their future life.

It is important to take these decisions at this stage when the child can move easily and he is still too young to understand the reason of the changes and to feel guilty and responsible for that.

As the disease progress fibrofatty tissue replaces functional muscles and signals of DMD becomes more evident: Gowes'maneuver, strength deficits, pseudohypertrophy at calves, waddling type walking, walking on tip toes and weakness at the hip and knee extensors. The last one force the child to acquire a characteristic standing posture to balance and establishing passive hip stability: they assume a lumbar lordosis position and, as knee extensors become increasingly weaker, they rely more on active equinus posturing to move the weight line anterior to the knees, that establish a passive stability[17]. While hip and knee contractions remain mild during the ambulance stage, the equinism process becomes rapidly severe and has to be delayed from the very first moment after the diagnosis with proper physiotherapy and nightly foot orthoses. It's important to start a physiotherapy's activity since childhood for many reasons:

- to put in action an integrated care management of the child and prepare his body to the changes it is going to face;
- to constantly check the progression of the disease and to fix a "starting point" of complete strength, calibrated for his age, useful to compare future results;
- to make the child used to clinical environments and physiotherapist at an age in which similar process of acceptation are simpler compared to scholar and adolescence age.

The use of daily foot orthoses is not recommended since they add weight on leg muscles and can compromise ambulation and make it difficult to rise from the floor[18].

Throughout this functional stage long periods of immobilization, due for example to accidental trauma or illnesses, should be avoided because they irreparably accelerate muscle decay.

Hearth and breathing muscle does not present usually any complication at this stage but must be monitored at diagnosis and every two ages up to the age of 10.

As soon as the child stop to improve his physical results in test activity and starts the such called "*plateau phase*", of stasis, before starting the inverse process of muscle decay, doctors suggest to start the cure with steroids drugs.

In scholar period children with DMD could manifest a slight delay in learning and behavior, due to the effects of disease on the brain, to physical limitation and to the use of steroids. It is important to give to the child and to their parents adequate psychological support, in order to make them accept the illness of the boy and help him in the gain of a serene and equilibrate personality[19].

17 STEVENS P. M., *Lower Limb Orthotic Management of Duchenne Muscular Dystrophy: A Literature Review*, in "Journal of Prosthetics and Orthotics", Vol.18, Num. 4, 2006, pag. 111 – 119. Phillip M. Stevens is a Med CPO currently affiliated with Specialized Prosthetic and Orthotic Technologies in Salt Lake City, Utah. In this article he works out an exhaustive review on Orthotic Management of people affected by Duchenne Muscular Dystrophy in each phase of progression of the disease. He discusses themes like the use of orthoses during each of the stages, orthotic intervention and postoperative rehabilitation.

18 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 2: Lancet Neurol. 2010, http://www.treat-nmd.eu/care/dmd/diagnosis-management-DMD/ (01/2015)

19 LOPAPA S., *Vissuti di qualità. Accompagnare nel percorso di vita persone con distrofia muscolare di Duchenne,* Bologna, Pendragon, 2012, pag. 44

2.2.2 - Middle ambulatory phase

The progression of the disease leads to the amplification of all the symptoms appeared in early ambulatory stages: increased weakness in leg muscles, hip and knee extensor, augmented equinus deformation of feet, due to contraction of Achille's tendons, frequent risk of falls and walking capability that becomes harder and harder till the complete loss of independent ambulation.

"It has been observed that patients with DMD generally lose their ability to rise from the floor, climb stairs, and walk independently in that order, and at intervals of approximately one year between each functional deficit. " [20]

At this stage in some cases orthopedics suggest the use of daily Kafo, (Knee-Ankle-Foot-Orthosis), to give more stability to the knee joint, while the use of night splint is always recommended. Moreover, when independent ambulation is not completely lost yet, and the child is still capable of walking 3 – 4 steps in autonomy, the possibility of an orthopedic surgery can be considered. Opinions on the kind of surgery (the most common is Achille's tendon releases and its effectiveness are controversial and they are examined more in detail in orthopedic care management's paragraph. If the survey is made at the wrong time, too early or too late, or if it isn't followed by a proper, aggressive and rapid rehabilitation protocol, it could interrupt completely and definitively ambulation and anticipate wheel confinement. On the contrary, if there are all the clinical, psychological and motivational conditions to undergo surgery, it can prolong independent walking from 1 to 3 years[21].

One year is a long time for everybody, especially for a child with DMD, if we consider that it is about 20% of his entire life compared to his life expectations. Moreover prolonging ambulation has indubitable positive effects in delay scoliosis, cardiac and respiratory complications, and osteoporosis. Clinical conditions has even a higher advantage if the boy succeeds in having his puberty development when he's yet standing and not wheelchair bounded. It has a big effect on psychological side as well, even if, usually, when ambulatory becomes hard and clumsy, children prefer sitting on a wheelchair to move quickly and follow their friends, without fall behind. In all these considerations another element must be included: the use of steroids, together with an integrated care management is drastically prolonging ambulation even without surgery, and also for this reason the decision of orthopedic surgery must be deeply examined by all the staff who takes care of the boy, considering case by case advantages and risks.

Psychological care for a boy with DMD is essential at this age, since puberty is a difficult passage for everyone, in which our personality takes form, and moreover for a DMD boy it is the moment that he takes deep consciousness of his illness, he powerless witnesses of the daily transformation and strength degradation of his body, and he has to face the differences in physical and mental ability with his coetaneous at school. A boy with DMD at this stage has to confront an adaptation to a new condition, he must be able to constantly mourn over who he was in order to redefine and redesign at every stage, a new self-image.

All the instruments to promote integration in every scholar and ludic activities of the boy must be put in action, starting from the removal of architectural barriers.

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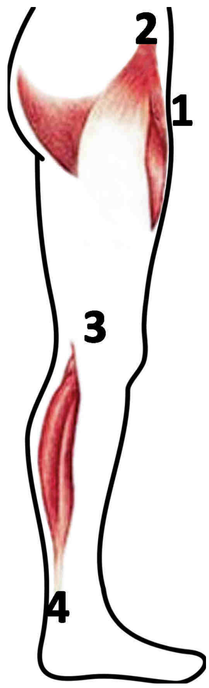
20 BROOKE M.H., FENICHEL G.M., GRIGGS R.C., et al., *Duchenne muscular dystrophy: patterns of clinical progression and defects of supportive therapy*. Neurology 1989; 39(4): pp. 475–481

VIGNOS P.J., ARCHIBALD K.C., *Maintenance of ambulation in childhood muscular dystrophy*, J Chron Dis 1960; 12: pp. 273–290

21 STEVENS P. M., *Lower Limb Orthotic Management of Duchenne Muscular Dystrophy: A Literature Review*, 2006, op. cit.

Psychological support at this stage is crucial for parents as well, since it is proved that, after the moment of the diagnosis, the child loss of ambulation is the hardest moment to face during the disease's history, because it signs a no-return point and makes the illness more evident. As Gardner-Medwin expressed, *"the loss of their boy's ability to walk confirms in a graphic and inescapable way the prognosis they (the parents) had been given and had been hoping against hope might be wrong*."[22]



Multiple Contracture Releases
To release multiple contractures in the leg, a surgeon can make small cuts in **(1)** muscles at the front of the thigh that flex the hip; **(2)** a muscle at the side of the hip, along with **(3)** connective tissue called the iliotibial band, at a point just above the knee; and **(4)** the Achilles tendon, also known as the heel cord, just above the heel.

@ WAHL M., *Understanding Heel Cord Surgery. Cutting the cord* (2001)

22 GARDNER-MEDWIN D., *Controversies about Duchenne muscular dystrophy (2). Bracing for ambulation*, in "Dev Med Child Neurol" 1979; num. 21(5): pag. 659

ANALYSIS

2.2.3 - Early non ambulatory phase

The starting of wheelchair confinement is one of the hardest change in daily routine of a DMD boy. "In absence of standing, flexion contractures of the hips and knees develop quickly. Equinovarus deformities are also common during this stage and can ultimately progress to painful subluxation of the midtarsal joints."[23] Orthopedic surgery is no longer functional to recover ambulation but, at least, if necessary, to relieve pain at the ankle, due to equinus deformity. AFO (ankle – foot – orthosis) are suggested during the day as well as the night, to delay this process and prevent pain related to deformities.

Strength in upper limbs starts to decay and he will be obliged to pass soon from mechanical to electric wheelchair. Physiotherapy has to focus on upper muscles in order to delay this process, that is really disabling for the patient, and at least preserve finger ability, to make them capable of moving by themselves electric wheelchair, to write and to use pc.

As for trunk muscle decay and are spending most of the day seating on the chair, they soon develop symptoms of scoliosis. Postponement in wheelchair confinement and the use of steroids are delaying severe complication due to scoliosis but, however, as soon as the child becomes wheelchair bounded he has to check his spine at least every 6 months, in absence of complications, because sometimes the progression of the illness can be really quick[24].

Cardiological and pulmonary examinations must be carried with the same frequency since at this stage start little health problems that will become crucial and vital in the late stage.

Despite the aggravation of his physical condition, this is the stage in which the boy with Duchenne, following his puberty and adolescence (from 7 to about 18 years), would like to acquire greater autonomy and independence from his parents[25]. In this sense it is crucial for them to encourage normal participation at school and fun activities, giving him all the support he requires without overprotecting him.[26]

With passing the time, he will require more and more help of parents and care givers for all his movements and activities and this will change drastically his daily routines, and that of all members of the family, besides their psychological conditions.

23 WILLIAMS E.A., READ L., ELLIS A., et al., *The management of equinus deformity in Duchenne muscular dystrophy,* in *J Bone Joint Surg Br*, 1984; 66(4): pp. 450-456

24 D'ANGELO G., *Intervista alla dott.sa Grazia D'Angelo*, op. cit

25 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 1, op. cit.

26 S. LOPAPA, *Vissuti di qualità*, p.84, op. cit.

2.2.4 - Late non ambulatory phase

Unlike the other stages, it's quite difficult to define the passage between early and late not ambulatory phase. This last stage is indeed characterized by the drastic deterioration of the patient's health conditions, especially concerning cardiological and pulmonary complications. It usually happens from 15 to 20 years old. The boy has almost lost all his autonomy and active muscle strength, and he could be hospitalized, also if modern techniques are trying to reduce to the minimum these periods and to effectuate most of the treatments at patient's house. The care management team has to work together to plan a proper personalized plan that includes all the auxilia that can help the boy to maintain the higher level of possible autonomy for his condition. Auxilium for moving, toileting, eating, sleeping well, transferring to and turning in bed, environmental controls, technological aids to make him in condition of using pc even if he doesn't have more strength in his fingers are all problems' categories that must be analyzed and taken in high consideration . Since the expectancy of life of a boy with DMD is continuously extending, since adulthood, it is important "to proactively plan for a life as a supported but independent adult, with all of the opportunities and challenges that this entails".[27]

Nutritionist has to control boy's diet, to avoid the risk of overweight, due to the continuing of steroid treatment, or on the contrary of a severe loss of weight, due to mandibular strength decay and risk of drowning, due to the loss of capability to cough.

Shortness of breath, fluid in the lungs and swelling in the feet and lower legs are severe complications, that are usually followed by a dilated cardiomyopathy, the main cause of death for a boy with DMD.

They usually pass away in their 20s or early 30s due to these complications[28].

27 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 1, op. cit.

28 EndDuchenne.org, *About Duchenne* (2014), op. cit.

2.3 - INTEGRATED CARE MANAGEMENT

"Incurable is not synonymous with untreatable."[29]

Duchenne Muscular Dystrophy, clinically, is one of the most predictable neuromuscular disorders found in pediatrics. This element is strategically important in the management of the cares. Since the moment of the diagnosis of the disease, we know how the muscles will weaken, how and when they will become thigh and the future comparison of contracture and deformities in a predictable sequences[30].

On one hand this means, of course, the ineluctability of the illness, but on the other hand it could become an opportunity, if well seized, to put in action a series of intervention and preventions that could radically change the life of a patient with DMD[31]. The aim of an inclusive, coordinated and integrated approach in the care management of people with DMD is to reduce if possible the predictable complication of the disease in each stage of its evolution, and to prepare to confront all the difficulties that people who leave with the DMD person could encounter[32]. Parents have always to be perfectly ahead of the events and well prepared in advance on the next stage of the disease. At the same time the staff who follow the patient must make them aware of all the possibilities, activities, adaption and adjustment enabling the boys/men to live a socially active life together with family and friends[33]. Furthermore, these measures are taken not only in order to lengthen the expectancy of life but, most of all reduce symptoms and to improve the quality of life.

Positive result of this approach are already in act and in about ten years the expectancy of life of a child with DMD has more than doubled, from twenty to forty years. In Italy the "Associazione Italiana di Miologia" [34] was one of the first research

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29 SIEGEL IM., *The management of muscular dystrophy: a clinical review*. Muscle Nerve 1978;1(6): pp. 453–460

30 CASE L. E., *Physical therapy management of dystrophinopathies,* op. cit.

31 "The predictable nature of the complications of DMD lends itself to the implementation of a planned programme of surveillance and management, which makes a real difference to survival and quality of life. Observation of the untreated natural history of DMD shows a predictable clinical course, although somewhat variable in severity from boy to boy." BUSHBY K, BOURKE J, BULLOCK R, et al., *The multidisciplinary management of Duchenne Muscular Dystrophy,* Current Paediatrics 15 (2005): 292-300, op. cit.

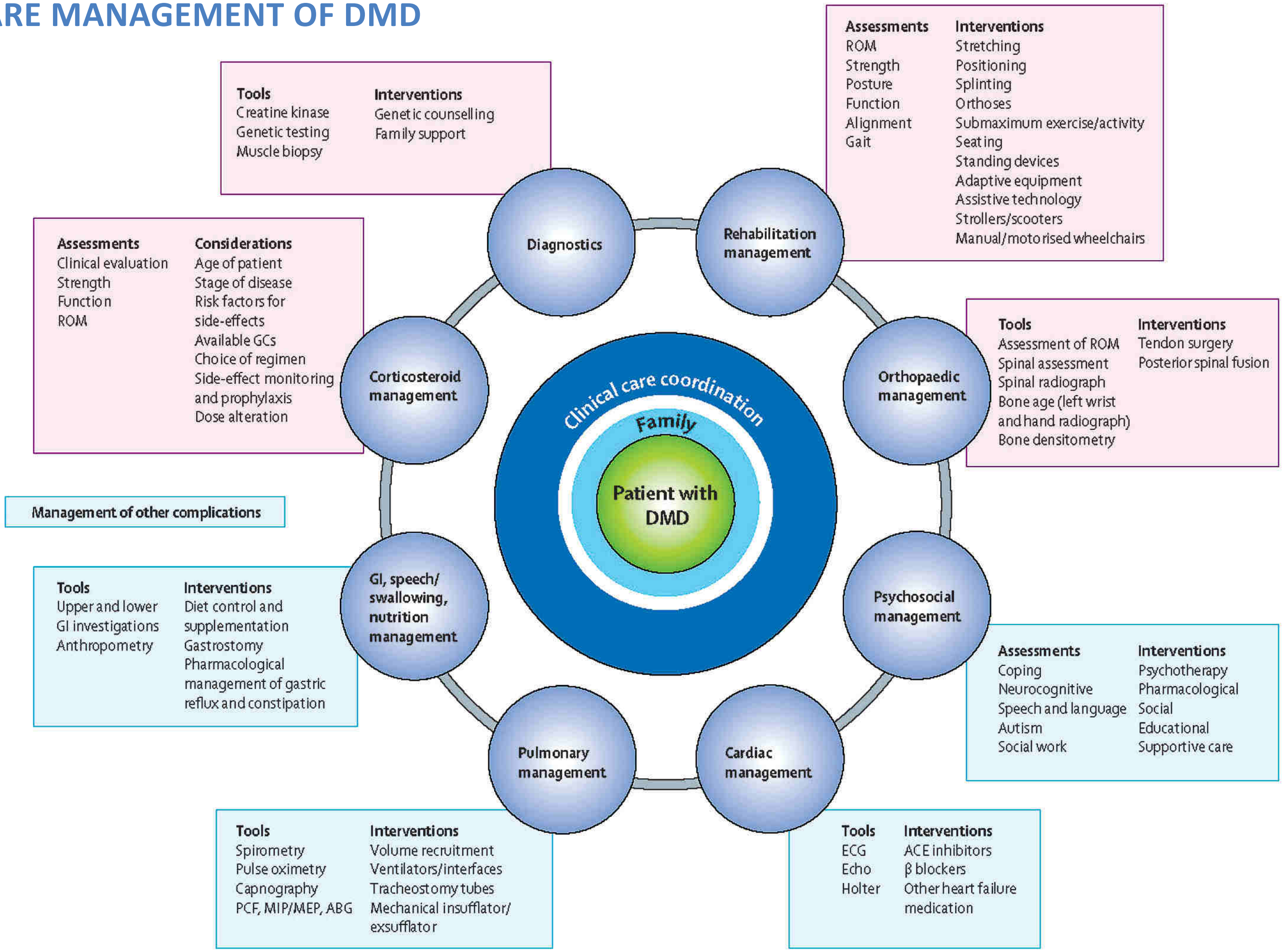
32 *"The optimal management of muscular dystrophy is multidisciplinary and aggressive in nature. Serial assessment aids in determining the functional stage of the disease and in indicating specific therapies. Physical therapy can augment strength through exercise and relieve contracture through passive stretching. Occupational therapy is employed to help the patient manage his activities of daily living within the restrictions imposed on him by his disease. Progressive disability can be delayed through a variety of physiatric and orthopedic techniques, including surgical release of lower-extremity contracture, repair of foot and ankle deformity, and correction of scoliosis. Appropriate orthoses are available, as are a variety of special devices to facilitate ongoing care for postambulatory patients. Physicians treating the muscular dystrophies should be aware of the complications of these diseases, particularly cardiomyopathy, pulmonary failure, and psychological and social problems."*
SIEGEL IM, *The management of muscular dystrophy: a clinical review, op. cit.*

33 *"Care for patients with Duchenne muscular dystrophy (DMD) is poorly standardized. There are many interventions in different systems which are known to improve outcomes in DMD but these are not uniformly applied. This leads to inequality in access to treatment, as well as problems for planning controlled trials of future therapeutics. A worldwide effort is underway to generate care guidelines for DMD, which involves the Centre for Disease Control in the USA and the TREAT-NMD network of excellence for neuromuscular diseases in Europe. In advance of the full consensus document, TREAT-NMD has worked on the generation of brief standards of care for DMD, which are presented here and are available via the TREAT-NMD website (http://www.treat-nmd.eu)."* SEJERSON T., BUSHBY K., *Standards of care for Duchenne muscular dystrophy: brief TREAT-NMD recommendation,* op. cit.

34 The *Associazione Italiana di* Miologia was born in October 2000 in Bologna, Italy, and it is opened to all the professionals who are in every level involved in the treatment of neuromuscular diseases. The aims of the association are: to become a scientific and multidisciplinary reference point on

ANALYSIS

INTEGRATED CARE MANAGEMENT OF DMD



"Coordination of clinical care is a crucial component of the management of DMD. This care is best provided in a multidisciplinary care setting in which the individual and family can access expertise for the required multisystem management of DMD in a collaborative eff ort. A coordinated clinical care role can be provided by a wide range of health-care professionals depending on local services, including (but not limited to) neurologists or paediatric neurologists, rehabilitation specialists, neurogeneticists, paediatricians, and primary-care physicians. It is crucial that the person responsible for the coordination of clinical care is aware of the available assessments, tools, and interventions to proactively manage all potential issues involving DMD. ABG=arterial blood gas. ACE=angiotensinconverting enzyme. DMD=Duchenne muscular dystrophy. Echo=echocardiogram. ECG=electrocardiogram. GC=glucocorticoids. GI=gastrointestinal. MEP=maximum expiratory pressure.
MIP=maximum inspiratory pressure. PCF=peak cough fl ow. ROM=range of motion."
BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* op. cit.

center, since 2000, that tried to connect and coordinate the practices of all the centers in Italy related with neuromuscular diseases. In 2001, in the USA, the *"Muscular Dystrophy Community Assistance, Research, and Education Amendments"*[35] was published. Multidisciplinary groups of experts in this field were founded in USA and Europe, promoted by clinicians and researchers, like TREAT-NMD, or by patients' associations, like MDA or Parent Project. In particular TREAT-NMD was founded in 2006, thanks to European Union funds, with the specific purpose of optimizing the circulation of information and the care management for people with neuromuscular diseases and promoting the constant upgrading of the Guide Lines *"The diagnosis and management of Duchenne Muscular Dystrophy"* [36].

Several multidisciplinary centers dedicated to DMD were born all over Europe and USA in these years and each one of them usually is composed, or it is in direct contact, with all these experts: pediatric, cardiologist, orthopedic, endocrinologist, gastroenterologist, genetic consultant, neurologist, surgeon, pulmonogist, nutritionist, occupational therapist, physiotherapist, psychologist, speech-language pathologist. The coordinator among all these professional figures should be of one expert who follows the patient all lifelong. He could be a neurologist, a physiotherapist, a pulmonologist, or the same family doctor if he/she has all the specific skills.

At last the four key areas in the management of the cure are the monitoring of the muscle strength and function, the prevention and management of spinal deformity, the control of respiratory complications and the prevention and treatment of cardiomyopathies[37]. From the moment of the diagnosis the boys have to be assessed once or twice a year by physiotherapists with special experience in neuromuscular disorders, and they have to do a complete checkup of the neurological, respiratory and cardiological system.

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neuromuscular diseases; to promote the drafting of clinical protocols and diagnostic and therapeutic guidelines; to divulge information on this topic, for example in dedicated conferences; to encourage the collaboration among different professionals involved in the treatment of these diseases; to become a reference for Ministerial structures and National Health Service; to become an important link among Italian and similar foreign associations and institutions.

MONGINI T., BERARDINELL A., RACCA F., POLITANO L., TOSCANO A., *Percorso assistenziale multidisciplinare per pazienti affetti da distrofia muscolare progressiva,* AIM – Associazione Italiana di Miologia [S.d.], http://www.miologia.org/index.php?option=com_content&view=article&id=66:percorso-assistenziale-multidisciplinare&catid=43:percorsi-assistenziali&Itemid=62, (May 2014)

35 The aim of this important law was "*To amend the Public Health Service Act to provide for research with respect to various forms of muscular dystrophy, including Duchenne, Becker, limb girdle, congenital, facioscapulohumeral, myotonic, oculopharyngeal, distal, and Emery-Dreifuss muscular dystrophies."* It is very important since it was the first legislation in the history of the US Congress that focused on muscular dystrophy. This legislation included 4 major points: NIH would support Centers of Excellence focused on muscular dystrophy. These Centers would have several components – basic research, extensive collaboration, shared resources, as well as, a clinical study. CDC would establish programs focused on Duchenne muscular dystrophy. This would include improving diagnosis, data collection, and care considerations. NIH and related government agencies would convene the research and clinical community to develop a research plan. NIH and related government agencies would establish a steering committee to oversee progress (MDCC).

H.R. 717-107th Congress (2001): MD-CARE Act, GovTrack.us in EndDuchenne.org, *2014 – Reauthorizing the MD-CARE Act* (2014), http://www.parentprojectmd.org/site/PageServer?pagename=Advocate_mdcare, (May 2014)

36 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy, Part 1* op. cit.

37 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 1, Ibid.

2.3.1 Pharmacological therapies

In the last ten years the life's expectancy of a person affected with Duchenne Muscular Dystrophy has grown from 20 to 28 years old. This progress has been reached thanks to the coexistence of multiples factors:

- steroid treatment;
- noninvasive assisted ventilation;
- progresses in the care managements;
- progresses in the management of complications and severe conditions in the late stage.

Steroids are the only drugs scientifically recognized that proves to be able to slow-down the muscle's strength and motor function decline.[38] This function is as important as it is demonstrated that prolonging the ambulation in a DMD child has huge psychological and physical benefits, it reduces the risk of severe scoliosis in late stage, it minimize breathing, heart and orthopedic problems. Their effect was known since 1974[39], they are also called corticosteroids and the two most common substances used nowadays are: prednisone and deflazcort. They have almost the same advantages and some differences on side effects.

They are usually prescribed between the age of 4-6 years old, when their motor function are at a so called "plateau phase", that is the moment in which the boy stops to improve his physical activities results, but his strength decay has not started yet. People who take steroids usually continue the therapy when they are no more ambulant, because it helps to maintain the functionality of the upper limbs, delay scoliosis and brings benefits to all the physical systems.

But besides the undoubted advantages of the use of steroids it has many contra-indications and side effects that have to be seriously managed from the very first moment of assumption of these substances[40]:

- behavioural changes,
- limitation to growth,
- tendency to gain weight,
- Cushingoid features,
- hirsutism
- osteoporosis, bone demineralization and increased fracture risk,
- hypertension,
- impaired glucose tolerance,
- immune/adrenal suppression,
- dyspepsia/peptic ulceration,
- cataract
- skin changes, acne.

38 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 1, Ibid.

39 STEVENS P. M., *Lower Limb Orthotic Management of Duchenne Muscular Dystrophy: A Literature Review,* op.cit.

40 SEJERSON T., BUSHBY K., *Standards of care for Duchenne muscular dystrophy: brief TREAT-NMD recommendation,* op. cit.

As a consequence, several tests have to be done before starting the therapies and all time long during the period of the cure, following the scheduled plan of controls draft by doctors. Before starting the cure, for example, immunity to chicken pox and all the vaccinations are required. After at least one check per month at the beginning of the therapy and one every 3 months later, in absence of any complications, are usually required.
However nowadays many side effects are dealt without dose reduction or suspension of the therapy. Doctors usually suggest people who use steroids to integrate the cure with gastro-protectors and vitamin D and calcium.

Scientific frontiers in the cure of DMD include the use of staminal cells, exon-skipping, analog up-regulation, gene replacement and supportive care to slow disease progression[41]. Clinical trials on new drugs are in place, each year new trials give little good responses to the progress towards a complete cure for DMD. Scientists' general feeling is that in very near future future important pharmacological changes and discoveries will happen, but, in reality, nobody can predict any time in which this hope will become reality, and this is the biggest challenge.

41 *Duchenne Muscular Dystrophy. Ongoing research* Wikipedia (2014), https://en.wikipedia.org/wiki/Duchenne_muscular_dystrophy#cite_ref-32, (May 2014)

2.3.2 – Legal management

The Italian legislation about care management for chronically sicknesses is quite old, many aspects are regulated individually by the Regions and very few has been done for specific disease, as Duchenne, which patients face different stages of disabilities throughout their entire life. Considering this state of things, the Associazione Italiana di Miologia has defined the adequate protocol of cares that should be carried out.

Italian Piano Sanitario Nazionale (PSN) promotes a net of sanitary and social services for disable people. Multidisciplinary centers, skilled on DMD, called (CdR – Center of Reference) have a crucial role at the moment of the diagnosis, because, together with the parents, set up a customized plan of care management (Piano Assistenziale Individuale – P.A.I.) and communicate it to the ASL, local center for sanitary assistance.

These documents contain the calendar of all the medical checks to monitor constantly his condition and the progression of the disease and the steps of cares that the child has to follow. Once received these documents, the ASL activate an UVM, a multidisciplinary evaluation unit that, together with the family doctor, will take care of the patient.

In particular this group of specialists has to:

- Specify in details the customized plan of cares;
- Facilitate the contact with care centers, orthosis and prosthesis producers;
- Guide parents in the bureaucratic practices with the government;
- Convey information from the CdR to local family doctor.

The guaranteed cares in the assistance program are organized in three stages:

- STAGE A – ambulant patient, low assistance care required
- STAGE B – non ambulant patient, medium assistance care required
- STAGE C – non ambulant patient with assisted ventilation, high assistance care required.

They usually start the stage B at an age that could vary from 9 to 12 years old, while the third phase starts from 15 to 20 years. Especially in the third phase of the progression of the disease, the ASL has to provide to the patient constant nursing care, neurologist, physiatrist, occupational therapist, anesthetist, pulmonologist, cardiologist, nutritionist, psychologist, orthopaedic, gastroenterologist and speech-language pathologist.

Tax breaks are in place for family with a child affected with DMD, with specific reductions per each category. They concern the purchase of a new car, all the means of transportation, lifters and wheelchairs required, house restructuring and construction works for removal of architectural barriers, the buying of orthosis and prosthesis, nursing and medicines and medical visits, at home or with hospitalization, medical analysis and eventually surgeries.

ANALYSIS

2.3.3 – Psychological management

The lack of dystrophin in people with DMD appears to have consequences in mental and psychological aspects as well. Problems amplified, of course, by the situation of disability in which the child lives, that force him on a wheelchair, and makes social inclusion more difficult for him. Furthermore the administration of some medicines, like the ones containing glucorticoids seems to make it worse[42].
Considering this clinical scenario and the higher risk for boys with DMD to run into psychological problems, prevention and early intervention could be the right approach to prevent complications.

"Difficulties in social functioning might be due to biologically based deficits in specific cognitive skills, such as social reciporocity, social judgment, perspective taking and affective discrimination, whereas the consequences of DMD (ie, physical limitation) might result in social isolation, social withdrawal, and reduced access to social activities. [...] Furthermore we have to consider the pattern of speech and language deficits, including those in language development, short-term verbal memory, and phonological processing, as well as cognitive delays, including impaired intelligence and specific learning disorders.[43]" In addition, there is an increased risk of behavioral and neurodevelopmental disorders and complication as dyslexia, dysorthography and dyscalculia that have to be cured as in people not affected with DMD[44]. At the end, cognitive deficits could cause anxiety, an overstated resistance to changes and depression. Understandably, most of the parents are even more worried about an eventual presence of such problems in their child more than physical effects of the disease, because they feel that this aspect can influence more the quality of their child's life. Therefore it is essential that they receive qualified service by skilled professionals who can guide both, the child and his parents, stage per stage, and to face all the unavoidable difficulties. Moreover recent researches report that parents as well are exposed to an high risk of depression and of couple issues and then psychological aids could be of great importance for them as well.

In a first time it is the father who seems to have the minor capacity of accepting and reacting to the diagnosis, but, as time goes by, the mother is the figure who usually needs more psychological help, also because she feels genetically responsible for the disease of her child. The staff of psychologist and occupational therapist help parents in discussing with them how to communicate with their son about his health's condition (depending on his age)[45], how to promote social inclusion, a customized school program and how to manage the relationship with other sane children[46], if present.

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42 ASTREA G., PECINI C., GASPERINI F., FIORILLO C., BRUNO C., CIONI G., POLITANO L., SANTORELLI F. M ., BATTINI R., *Neuropsychological profiles in children with Duchenne muscular dystrophy compared to dyslexic population,* in *Neuromuscolar Disorders*, Volume 21, Issues 9-10, Elsevier, 2011*:* pp.658–659

43 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 2, op. cit.

44 MONGINI T., BERARDINELL A., RACCA F., POLITANO L., TOSCANO A., *Percorso assistenziale multidisciplinare per pazienti affetti da distrofia muscolare progressiva,* op. cit.

45 POYSKY J., KINNETT K., *Facilitating family adjustment to a diagnosis of Duchenne muscular dystrophy: April 24-25, 3008, Miami, Florida,* in "Neuromuscular Disorders", (2009), doi:10.1016/j.nmd.2009/07/11, http://www.ncbi.nlm.nih.gov/pubmed/19736011 (January 2015)

"Fifteen participants representing clinicians and parents from Canada, the Netherlands, the UK, and the USA met in Miami on April 24–25, 2008 to attend a workshop that focused on facilitating family adjustment to a diagnosis of Duchenne muscular dystrophy (DMD). [...] The aims of the workshop were to (q) examine important factors that can have an impact on family adjustment and function following a diagnosis of DMD and (2) identify potential interventions and important windows of opportunity for affecting positive adjustment."

46 CROWE L., *Children with a Life Limiting Illness*, Queensland Health www.health.qld.gov.au/cpcre/

2.3.4 – Speech and language management

Latest scientific discoveries seam to prove that dystrophyn has a role in signaling molecules and in brain localization[47]. It is probably due to this cause that 30 – 50% of boys with DMD has some deficit in cognitive and learning capacity and manifest delay in the acquisition of language and language skills. For this reason it is crucial to recognize in time these symptoms, in order to start a planned program of rehabilitation with a speech-language pathologist. This professional figure will become essential in the late stages as well when the child will lose the ability of expressing emotions and of speaking with loud voice, due to visual muscle weakness and hypotonia. Specific exercises of the muscles involved in speech and in articulation are necessary when similar problems are identified. These difficulties become of course worst when the boy starts a daily assisted ventilation program.

Once he will have lost completely the ability of speaking, in a very late stage of the disease, medical staff will suggest the best communication aid, as, for example, eyes tracking movement.

2.3.5 – Nutritional and gastrointestinal management

The nutritional management of patients with Duchenne Muscular Distrophy has to take in consideration three topics[48].

Prevent under-nutrition/overweight – They are both common and likely to happen in different phases of the disease. Crucial steps are the beginning of the assumption of steroids, the period of loss of ambulation and, at the late stage, the difficulty of swallowing, due to muscle weakness. For this reason a balanced nutrition, with the right intake of calories, with a full range of food types, rich in particular with calcium and Vitamin D is essential all lifelong. Cardiac or respiratory complications may as well influence severe loss of weight. In the calculation of the ideal weight the loss of lean body mass must be considered.

Monitor and treat swallowing problems – Dysphagia, in a late stage, is due to weakness of the throat muscles. "Clinical and X-ray tests of swallowing are necessary when there are clinical indicators of possible aspiration (getting food in the windpipe) and poor movement of the swallowing muscles (food feels like it is getting stuck in the throat)."[49] Parents could start to worry about an ingoing of dysphagia if they realize that their child is unintentionally losing weight, if his meals start to last more than 30 minutes or it's accompanied with fatigue and couching. In the last period these complications can lead to the decision of feeding by tube or percutaneous endoscopic gastrostomy (PEG)[50].

Treat constipation and gastro-esophageal reflux – Constipation usually arise in adult age, as a consequence of muscle weakness and prolonged wheelchair con-

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pdf/chldrn_lifelim.pdf, (June 2014)

47 ASTREA G., PECINI C., GASPERINI F., FIORILLO C., BRUNO C., CIONI G., POLITANO L., SANTORELLI F. M ., BATTINI R., *Neuropsychological profiles in children with Duchenne muscular dystrophy compared to dyslexic population*, op. cit.

48 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 1, op. cit.

49 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 2, op. cit.

50 SEJERSON T., BUSHBY K., *Standards of care for Duchenne muscular dystrophy: brief TREAT-NMD recommendation*, op. cit.

finement, or after surgery. It is usually cured with laxative and other medicines, as reflux. A diet high in fluid fiber, fresh fruits and vegetables could help as well. Lengthening of the expectation of life in people with DMD has led to problems of gastric and intestinal swelling due to prolonged use of artificial ventilators. The important of oral care is something that is not present on the international care management of DMD but it has been usefully inserted by TREAT-NMD.

2.3.6 – Cardiac management

"By the age of 20, almost all patients with Duchenne muscular dystrophy have experienced dilated cardiomyopathy, a condition that contributes significantly to their morbidity and their mortality."[51]

Together with respiratory complication, cardiac problems are the main cause of death in children with DMD. This happen because the heart is itself a muscle, and for this reasons it is involved in the gradual process of replacement of muscle tissue in fibro-adipose tissue, with subsequent diminution of the strength of pulsing blood[52]. Myocardial fibrosis starts to affect first the free wall of the left ventricle. Moreover cardiac complications may occur also if provoked by respiratory wearing or by severe scoliosis that could cause direct cardiac compression[53].

The aim of cardiac management is the early diagnosis and prevention of complications related to cardiomyopathies. This aspect is even more important since the heart disease starts silently, without symptoms, and usually they appear when it is in an advanced state. An electrocardiogram (ECG) and echocardiogram is recommended soon at the diagnosis, to exclude the contemporary presence of other heart anomalies, and then once every two years in the ambulant phase. Afterwards the frequency must be reduced to once a year or even once every six months when abnormalities start to appear.

The most common diagnosis of the cardiologist is a dilated cardiomyopathy: the earth muscle become weaker and starts to enlarge, loosing efficiency. Ventricular arrhythmias could occur at any time, but they're more common in the late stage.

The standard prophylaxis contemplate ACE inhibitors (Angiotensin Converting Enzyme) as first-line therapy.[54] In this sense a long clinical trials prove the beneficial effects of an early use of this substance, since 5 years old, before the appearing of any sign. Then beta blocker are usually added, or they are dispensed together with ACE, and, following the progression of the disease, diuretics and anticoagulation therapy are necessary to prevent thromboembolic events.

People who take steroids need additional attention because these substances cause hypertension (high blood pressure).

51 RHODES J., MARGOSSIAN R., DARRAS B. T. , COLAN S. D., JENKIS K. J., GEVA T. and POWELL A. J., *Dilated Cardiomyopathy in Muscular Dystrophy*, in *Circulation – Journal of the American Heart Association,* 112, 2006, pp. 2799 - 2804

52 MONGINI T., BERARDINELL A., RACCA F., POLITANO L., TOSCANO A., *Percorso assistenziale multidisciplinare per pazienti affetti da distrofia muscolare progressiva,* op. cit.

53 CASE L. E., *Physical therapy management of dystrophinopathies,* op. cit.

54 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 2, op. cit.

2.3.7 – Respiratory management

Boys with DMD usually don't have problems of breathing in their ambulant phase, but as they get older and become wheelchair bounded, the respiratory muscle strength starts to decline. The aim of respiratory management is to put in action prevention and inhibition of complications.

During the ambulant period the boy has any specific treatment to do, if not exercises that could maintain in good conditions his pulmonary capacity and at least one FVC (measurement of forced vital capacity) per year to monitor the progression of the illness and to allow the child to become familiar with all the equipment. Immunization with pneumonia vaccine and influenza is always recommended, because of possible breath complications and because the permanence in bed of a child with DMD could be deleterious for his muscle strength.

Furthermore due to weakness in the diaphragm muscles, which is just under the lungs and is responsible for 70% of movements for respiration, DMD people have difficulty to cough. Due to an ineffective cough they lead to retention of secretion and for this reason they are highly exposed to lungs' infections or pneumonia. They start developing problems with their breathing during the night, when sleeping and, as time goes by, during the day as well.

"Once clinical signs of nocturnal hypoventilation develop or FVC drops to 1.25 l or <40% predicted value, then serial measurement of overnight oximetry allows the recognition of the development of nocturnal respiratory failure."[55]

In this case the team of doctors that are in charge with the boy usually prescribe non-invasive or invasive ventilation and associated techniques for increasing the amount of air that can enter in the lungs, manual and mechanically assisted cough[56]and daytime ventilatory support. Every 6 months the child has to do a FVC measurement and peak cough flow. Oxygen during sleep must be monitored but Oxygen therapy is not recommended and may be dangerous.

At the end 90% of the causes of death of people with DMD is respiratory insufficiency or its complications.

55 SEJERSON T., BUSHBY K., *Standards of care for Duchenne muscular dystrophy: brief TREAT-NMD recommendation,* op. cit.

56 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 1, op. cit

2.3.8 - Skeletal management

People with Duchenne often have spinal problems and poor bone health, due to decreased mobility, muscle weakness and steroid therapy, that has the downside of decreasing bone density. All these elements lead to osteoporosis, risk of fractures, scoliosis.

Osteoporosis

Osteoporosis “is a progressive bone disease that is characterized by a decrease in bone mass and density which can lead to an increased risk of fracture”[57]. A DEXA scan must be planned as soon as the child starts to take steroids, to fix the starting situation, and then it has to be done when required. Blood and urine tests give information on osteoporosis too.

Fractures

Boys with Duchenne are in a high risk of fractures, because of steroids and because of their muscle weakness that decrease their agility and rises the percentage of risk of falling. In ambulant phase usually fractures occur to upper limbs, in the attempt of protecting himself during the fall, while in non-ambulant phase the fractures concern more lower limbs, hit in wrong maneuvers with the wheelchair. In case a fracture occurs, it is essential that the boy restarts walking as soon as possible, even with a surgery, if it could make rehabilitation quicker. Contrariwise, if the boy is not more walking, there is no urgency and the broken leg can be plastered, just considering the possible development of contractures.[58]

Scoliosis

Scoliosis during the ambulatory stage is flexible and functional at maintaining a compensated gait pattern prior the loss of ambulation. But as soon as wheelchair confinement begins, the complications of scoliosis start to trouble DMD boys, because it could compromise pulmonary function, sitting ability, comfort and cosmetic integrity[59]. People with DMD who are not treated with steroids, have a 90% chance of developing a progressive scoliosis. But nowadays the common use of steroids has drastically reduced the risk of scoliosis for children with DMD. This risk became even lower if the child maintains an at least assisted ambulation with KAFO until his developmental age of about 13 years old. Spinal care includes clinical observation during ambulatory phase, a spinal radiography (X-ray) when the child becomes wheelchair-dependent, and at least one X-ray per year after this time to monitor the situation until the child is growing. During adult phase X-rays are required only if the clinical situation changes. Paramount is the comfort of the seating and the control of postural support. Surgery is indicated when the degree of the curve (known as the Cobb angle), is greater than 20° in ambulant boys who are not taking steroids, otherwise thanks to the steroid’s effect of reducing deterioration, the surgery can be postponed until the Cobb angle is greater than 40°[60]. In the decision of proceeding for a surgery the cardiac and respiratory conditions must be taken in proper account.

57 ALLDREDGE B. K., KIMBLE K., ANNE M., LLOYD Y.; KRADJAN W. A.; GUGLIELMO J. B., *Applied therapeutics: the clinical use of drugs,* Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2009, pp. 101–3

58 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy*, Part 2, op. cit

59 CASE L. E., *Physical therapy management of dystrophinopathies,* op. cit.

60 EndDuchenne.org, *About Duchenne,* op. cit.

2.3.9 – Orthopaedic management

The management of muscles, with all the associated orthopedic prescriptions, is one of the key point in the cure of DMD. Muscles allow us to move, stand, play, perform all the actions of our daily routine, but they let us breath and they make the heart pulse too.

Muscles are made of fibers that slide past one another producing a contraction that changes both their length and shape. They could be voluntary, as skeletal muscles, or involuntary, as the ones of digestive, respiratory and cardiac systems. The first type of muscles are attached to bones via tendons and are used to develop skeletal movements.

In Duchenne Muscular Dystrophy muscle fibers slowly break down and are replaced by fibrous and/or fatty tissue causing the muscle to gradually weaken[61]. If this process is not homogeny, it can upset the normal balance of strength and cause contractures. Progressively it is one of the causes of the loss of the capability of standing and walking. This process is not instantaneous, but it usually takes one year and half from independent mobility to wheelchair-bound, in most of the cases from about 9 to 10,5 years[62].

When a muscle is not used, it becomes weaker and the joints, the ligaments and tendons associated to it, become stiff and tight and lose their capability of stretching. It usually happens more in one direction than the other and when it becomes fixed it is called contracture and it causes deformities and pains[63].

These retractions in the first period occur at the ankles and hips and could have different causes:

- The progressive loss of ability to move a joint through its full range of motion[64];
- Static position, sit, in which they spend always more and more time in a day;
- Fibrotic changes in muscle tissue;
- The particular gait on tiptoe they acquire in order to maintain balance as the hip, knee and trunk muscles weaken. Once a child starts the habit of walking up on tiptoe he accelerate the development of contractures, because of the soft tissues around the joint who starts to shrink. “*The challenging is to separate the harmful contracture from a helpful one*.”[65]

61 Useful consideration on orthopedic management are reported in a guide edited by the Muscular Dystrophy Campaign, which reports all the practices of home physiotherapy for children and young people with Duchenne Muscular Dystrophy.

Muscular Dystrophy Campaign, *Physiotheraphy management for Duchenne Muscular Dystrophy* (2009), http://www.muscular-dystrophy.org/assets/0001/1477/Physio_booklet_web.pdf, (May 2014)

62 WILLIAMS E. A., READ L., ELLIS A., MORRIS P., GALASKO C. S. B., *The management of equinus deformity in Duchenne Muscular Dystrophy,* Royal Manchester Children’s Hospital, Manchester, British Editorial Society of Bone and Joint Surgery, 1984, http://www.bjj.boneandjoint.org.uk/content/66-B/4/546.full.pdf, (May 2014)

63 Muscular Dystrophy Campaign, *Physiotheraphy management for Duchenne Muscular Dystrophy* (2009), op. cit

64 BUSHBY K, et al. The Diagnosis and Management of Duchenne Muscular Dystrophy, Part 2, op. cit.

65 This article posted on the website Quest, of the Muscular Disease Associetion – Fighting Muscle Disease, reports the story of Tom Baker, a 14 guy affected with Duchenne Muscular Dystrophy and his story from the discovery of the illness through the decision of proceed into a heel cord tenotomy and its consequences.

WAHL M., *Understanding Heel Cord Surgery. Cutting the cord* (2001), http://quest.mda.org/article/understanding-heel-cord-surgery, (May 2014)

One of the firsts and serious contractures boys with DMD have to deal with is equinus deformity.

It's a deformation of the ankle joint, due to the retraction of Achille's tendon, that provokes a plantar flexion of the foot, making him tend towards toe walking.

It slightly starts to appear at about five years of age and reaches its final stages in the late teens [66]. Although if the deformity is diagnosable almost only clinically and the boy has an almost normal gait, it's important to start soon an activity of active and passive stretch. The contracture of the calf muscles increase progressively and when the foot starts not to be able to be brought more in a neutral position, it is clinically denominated "equinus deformity". Furthermore at this distortion follows a varus deformity of the ankle and foot, and, at the end, a subluxation of the mid-tarsal joints, with consequent pain.

For this reason it is strictly necessary that, as soon as possible, after the diagnosis of DMD, the boy starts a program of physiotherapy to try to put in action all the strategies aimed at preventing contractures, premature loss of ambulation, pains and avoidable complications. The aim of the physiotherapy is necessary to maintain the best physical, social and intellectual status in a boy with DMD as it is possible, considering his grade of evolution of the illness. Physicians have to teach the child how to preserve his muscles and how to perform all the activities and how to adapt them to his needs, in order to live a full social life with his family, at school and with his friends.

In view of this thesis, it is useless to report all the dates, exercises and rules given by many guides and internet sites and blogs dedicated to DMD cares. Each person is different and the activities have to be balanced considering all the elements that describe the patient clinical and social profile.

Nevertheless it is possible to delineate some general attitudes which I found in common among all the scientific reports:

- all the activities related to the stretching and musculotendinous units are strictly recommended in every phase of the illness. Active stretching, if it's possible, plus active-assisted stretching, plus passive stretching are all useful to delay the development of contractures and deformity;
- the use of positioning, splinting orthoses is as well recommended, in the modality prescribed for each phase, to assist stretching activities;
- high-resistance strength training is not only useless but harmful for muscles because it accelerates their deterioration. The cause and effect relationship between the muscles 'activity and the production of dystrophin is not so clear, because the mechanism of dystrophin itself is not fully understood until now. However it is for sure that overwork weakness must be avoid;
- gentle swimming-pool exercises is helpful both for muscle and respiratory systems and could be continued in non-ambulatory phase as well;
- breathing exercises and methods of clearing secretions must be practiced since early stages;
- sessions at a massage therapist could alleviate pains, if present;
- long periods of rest and immobility should be strictly avoided, even during illness or fractures and injuries, because it could cause functional losses.

66 GARDNER–MEDWIN D., *Controversies about Duchenne Muscular Dystrophy. Bracing for ambulation,* op. cit

Moreover, since Duchenne Muscular Dystrophy has an inevitable evolution, it is possible to define precise stages of "good practices" of orthopaedic management depending on the progression of the illness, also if the times are different for each boy.

Ambulation stage

At this stage the child has almost the energies of all the babies of his age. He will run, play, cycling, crawling as his peers but maybe he will become soon tired. Initially the priority of the physiotherapy is to prevent contractures and maintain symmetrical posture to delay scoliosis. Active, active-assisted and/or passive stretching and hydrotherapy are suggested at least 4 – 6 days a week, for each muscle group. Stretching could be done in clinic, at school or at home and regular use of night splints is highly recommended. Daily Afos (ankle – foot orthoses) are not recommended at this stage, but children can wear it when they are going to sit for long periods, as during school homework or if they're watching TV at night.

Assisted ambulation

Children with DMD usually lose their ability of independent ambulation in 1-2 years. In order to prolong ambulation, steroids are used, some people appeal to corrective surgery to lengthen the Achille tendons and some others use KAFO (Knee – Ankle – Shoes – Orthosis), also known as long leg callipers, to maintain balance and continue to walk for another while. Nights splints and daily Afo are recommended after the surgery too. Usually wearing KAFO does not allow children to achieve an independent ambulation, and for this reason they prefer sitting on a wheelchair. In most of the cases this passage is hardest for parents than for children who found the chair easier, less tiring and this allow them to participate better to their friend's social life. In this phase walking can be no more functional to "move from one place to another", but maybe just as physiotherapy or to do little transfers. Furthermore another cons highlighted in scientific literature is that at this point parents and therapists usually "force" the child to "make an effort", in prolonging ambulation even if at the end he will eventually inevitably fail, with all the predictable psychological consequences.

However it's important to underline that if the child succeed to stand until about the age of 13, he probably will have no need of a spinal surgery and severe contractions will be delayed too. Furthermore, as long as a human body is no longer walking, he will face bone loss, quick deterioration of remaining muscle strength, spinal contractures, weight gain, metabolic changes, constipation, fluid retention, cardiac and respiratory complications and psychological effects[67].

Therefore it is necessary to balance the use of the wheelchair for long distances, and try to make him exercise to stand when it's possible. It is crucial in this phase to maintain the highest possible level of functional independence, adapting all the situations to make him able to perform actions of his daily routine as much as possible. Particular areas in which strength is early lost are: neck flexors, abdominals, shoulder girdle musculature (like deltoids, latissimus, stabilizer), pelvic girdle musculature, especially gluteas, knee extensors, ankle dorsiflexors[68].

67 SIEGEL IM., *The management of muscular dystrophy: a clinical review. Muscle and Nerve*, 1978, op. cit

68 BUSHBY K, BOURKE J, BULLOCK R, et al., *The multidisciplinary management of Duchenne Muscular Dystrophy,* op. cit.

ANALYSIS

Heel cord tenotomy

When the youngster is at the point of sitting definitively on a wheelchair, doctors in some cases suggest the option of a surgery of Achilles tendon release. If done at the right time, and with the adequate post-surgery rehabilitation, this option could prolong the ability of walking for at least a couple of years. However scientist's opinions on this surgery for DMD are controversial, mainly because the use of corticosteroid medications is proving good effects in prolonging ambulation as well, without the possible complications of a surgery. Moreover an operation made at the wrong time could end prematurely the ambulation[69]. As we wrote, walking on tip toe is functional to increase the stability of the knee when muscles become to be too weak. A surgical operation who releases the tendon too much could break this mechanism irreparably. "The right time to do heel cord surgery in DMD is when the child is having considerable trouble standing and walking, with independent walking imminently threatened, but before he begins using a wheelchair[70]". It is a clinical decision that has to consider a multitude of factors, including boy's cardiac and respiratory status. Post-surgery rehabilitation is strategic: patients with DMD have to restart to stand and walk the same day of the surgery. Wearing AFO, casts or braces and night splints will be prescribed.

Ankle Foot Orthosis

@ BURGGRAAF N., *Funky or Vanilla?* http://cmtcreatesmusic.blogspot.it/2010/08/funky-or-vanilla.html

Wheelchair confinement

It is necessary to continue passive stretching at the legs, and to wear sitting AFO to prevent pains due to contractions, but even more important is active stretching of the upper extremities, of the hands and fingers, to maintain the boy able to drive the wheelchair by himself. The wheelchair has to promote freedom of movement and independency. It has to be flexible and customizable, with possibility of tilt and recline regulations[71]. In the first period it is better to use a manual wheelchair. When muscle's weakness will prevent the child from driving by himself the chair, he will use an electric one. Moreover standing frames or swivel walkers can delay contracture development in non-ambulant children, encourage spinal extension and offer psychological benefits as well[72].

69 WAHL M., *Understanding Heel Cord Surgery. Cutting the cord,* op. cit

70 SIEGEL IM, The management of muscular dystrophy: a clinical review. Muscle and Nerve 1978; 1(6), pag. 453-60, op. cit.

71 TREAT-NMD, *Linee guida del TREAT-NMD per la diagnosi e l'assistenza della distrofia muscolare di Duchenne,* 2013, http://www.uildm.it/docs/treat/LineeguidaDuchenne.pdf, (May 2014)

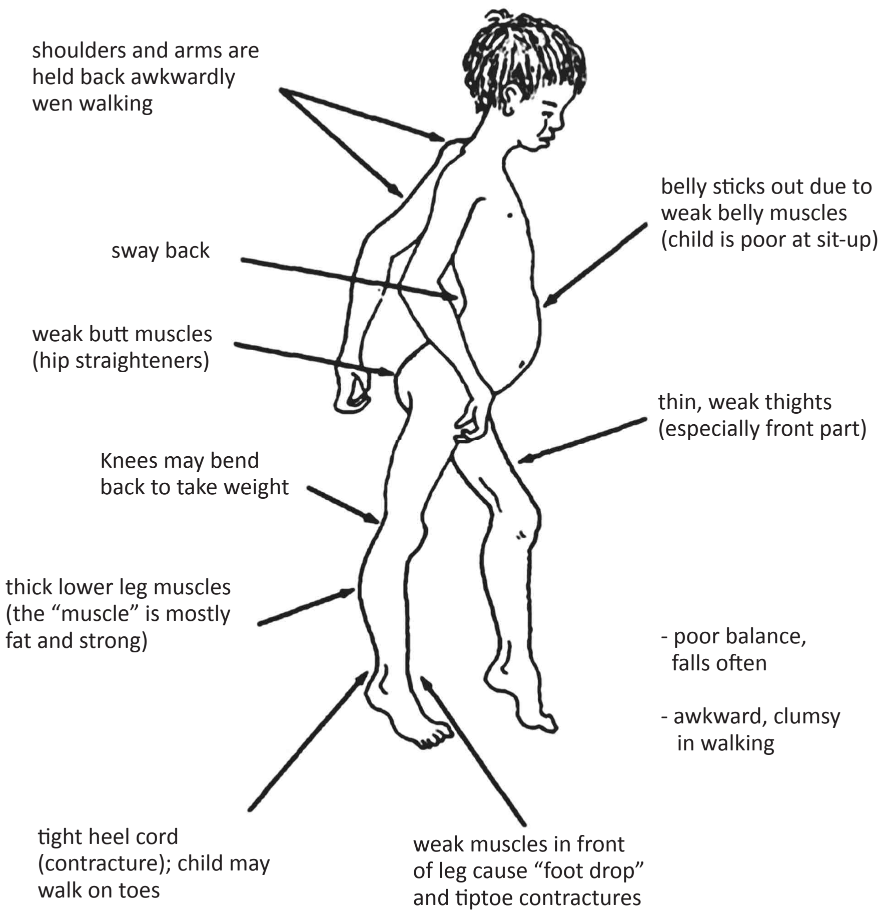
72 BUSHBY K, BOURKE J, BULLOCK R, et al., *The multidisciplinary management of Duchenne Muscular Dystrophy,* op. cit.

ANALYSIS

2.3.9.1 - Tests to monitor the orthopaedic condition in DMD

Unfortunately it is still not present an international protocol to test strength and agility in DMD people, who defines in detail the exercises that have to be done. Every clinic adapts the test depending on its boundary conditions and this element make the comparison of data very difficult.
Aspects that have to be assessed are:

- *strength*, measurable in different way to test if the strength in single joints is changing. Manual Muscle testing can be used, with the MRC scale[73]. It must be tested every 6 months: for lower limbs for ambulant boys, for upper limbs for non-ambulant boys, until they are in condition of driving a manual wheelchair;
- *range of joint motion*, to evaluate contractures and to plan a customized stretching programs for lower and upper limbs;
- *timed test*, as the time to get up off the floor, to walk a certain distance, the 6MWT (*Six Minutes Walk Test*), or to climb several steps;
- *motor function scales*, to monitor the progress of the disease following certain Scales, as the North Star Ambulatory Assessment Scale (NSAAS) for lower limbs or the Hammersmith Scale for upper limbs.
- *activities of daily living*, to estimate the grade of self-sufficiency. [74]



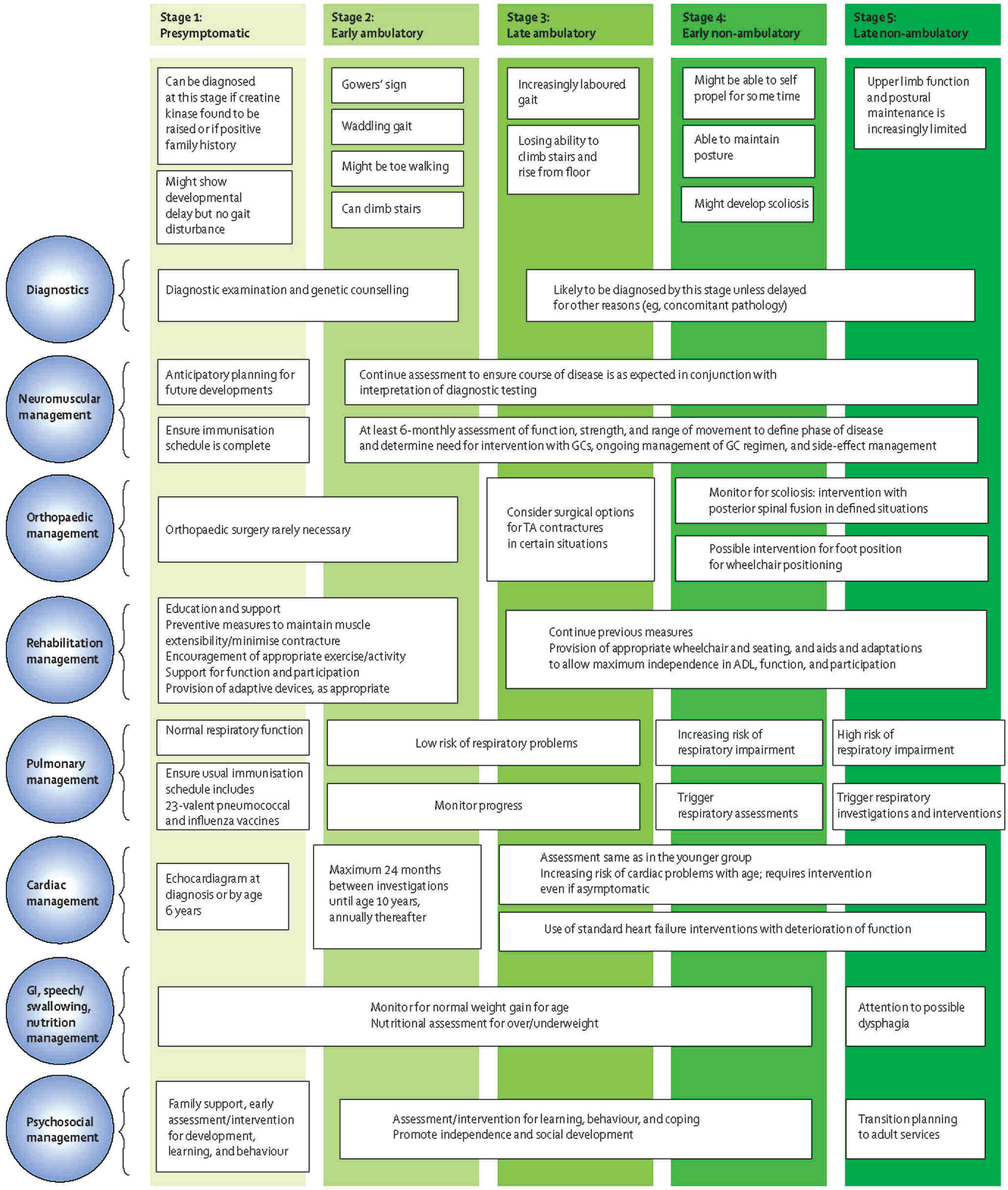
Symptoms exhibited in sufferers of Duchenne Muscular Dystrophy (DMD)

@Doctor tipster, *Duchenne Muscular Dystrophy*, www.doctortipster.com

73 MONGINI T., BERARDINELL A., RACCA F., POLITANO L., Toscano A., *Percorso assistenziale multidisciplinare per pazienti affetti da distrofia muscolare progressiva,* op. cit.

74 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 2, op. cit.

STAGES OF DISEASE AND CARE CONSIDERATION



@ BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy*, op. cit.

3 ANKLE FOOT ORTHOSES

3 – ANKLE FOOT ORTHOSES

The investigation on night Ankle Foot Orthoses for people affected by Duchenne Muscular Dystrophy started by a general framing on these lower limbs' orthoses. The International Organization for Standardization, in ISO 9999:2011 establishes a classification of all the assistive products for people with disabilities and, among the others, the subclass 06.12.06 identifies Ankle Foot Orthosis.

However medical advances, technological innovations and business strategies lead to the development of a multitude of different products and a subsequent confusion in technical terms, since a standard classification doesn't go further in detail on different types of AFOs.

An initial examination on scientific literature on AFO is followed by a broad market analysis on Ankle Foot Orthoses available in Europe and North America, with a special focus on Italian situation. This data collection includes several hundreds of different AFOs and it proved to be essential in the process of awareness on the state of art and to discover the most vanguard researches in course in this sector. Nevertheless the mentioned terminological confusion suggested the opportunity of a proposal of a new cataloguing of these scheduled products. This database doesn't only organize by category all the collected AFOs but it is a flexible and interrogable instrument with multiple keys of research. These information were organized with a particular attention to the user. Professionals and parents of DMD children could easily access to this document and examine not only technical and clinical characteristics, the related diagnoses for which each orthosis is recommended and the declared clinical effects. The system collects per each orthosis even information and contacts of the producing, materials, realization techniques, possibilities of aesthetic personalization, photos and available purchasing methods. In order to simplify and to present some of the results of this analysis, a schedule of each category of AFO, with the results of market analysis is presented. Moreover cross lectures combining different keys of research allowed a deepen understanding of this product in all its features.

Concluding, a focus on the specific requirements of AFOs for DMD allowed to individuate possible technological transfers from other products and load the way to future steps of DMD night AFO's design.

3.1 – ASSISTIVE PRODUCTS FOR PEOPLE WITH DISABILITIES

In 1980 the **World Health Organization (WHO)** organized the first ***International Classification of Impairments, Disabilities, and Handicaps***, or ***ICIDH*** in order to provide a unifying framework and a classification of the major health components of functioning and disability.
Afterwards, in 2001, the **WHO**, together with the **World Health Assembly** approved the ***International Classification of Functioning, Disability and Health*** and its abbreviation of ***"ICF"***. [1]
This classification is extremely important since it marks a completely new approach to the concept of handicap. *Disability is not more considered as an unalterable label, related to the disease or the individual, but as a classification of the functional status of each individual considered in his/her contest, independently by his/her health condition, disease or diagnosis.* It is applicable to all people, independently from his health condition, gender, sex, age, nation.

1 WORLD HEALTH ORGANIZATION, *International Classification of Functioning, Disability and Health*, Word Health Organi zation; 2001

The **ICF** considers functioning and disability as the interaction between:

- ***Body functions and structure***;
- ***Activities*** (related to tasks and actions by an individual);
- ***Participation*** (involvement in a life situation);
- ***Additional information on severity and environmental factors***.

The interrelation between all these elements produces a classification of abilities that is temporary and related to the person in that moment, in that context. Complications in these interrelationships can be expressed in a:

- limitation in the function,
- limitation in the activity
- limitation in the participation.

As Andrich refers in "*Consigliare gli ausili: organizzazione e metodologia di lavoro dei centri informazione* ausili"[2], the "rehabilitation", in its broad sense, can do a lot to change the personal state of condition and the potential of our personal abilities: in the prevention of compliances, in the treatments of the impediment of the harms, in the stimulation of a proper recovery, or in the compensation of the impairment.
We can think, for example, at how much a leg prosthesis can do to a person without a leg, making him in condition of performing actions and overall his personal physical limitation.
In this sense, **the concept of *"auxilium"*** is deeply much wider than the common sense of this word, since it **includes all the strategies, the products and the processes that can help to reduce a limitation**. Furthermore it has to be regarded not only as a mere physical rehabilitation, but also the removal of all the obstacles between the disable and the society in which he/she lives.
People affected by DMD, as all others physical and mental impaired people can take advantages of the use of a wide range of objects, techniques and solutions expressly designed for people with disabilities.

Everything that can help to overcome a difficulty can be defined as aid. This category includes elements of different nature:

- Personal care assistance, as nursing or caregivers;
- Animals' assistance (guide dog);
- Drugs and medications;
- Lip-reading;
- Implanted devices;
- Aids used exclusively by caregivers and medical staff;
- Financial support
- Assistive products and architectural design solutions for environmental improvements;
- Technical devices.

2 ANDRICH R., *Consigliare gli ausili: organizzazione e metodologia di lavoro dei centri informazione ausili*, Fondazione Don Carlo Gnocchi, Milano; 1996. It is an important guide line for all the professionals involved in the Italian Centro informazione ausili, promoted by SIVA equip. The aim of the volume is to offer suggestions and professional support to who is willing to improve personal autonomy, or the quality of life, by means of technological aids.

There are many methods to define the appropriateness in the recommendation and in the use of assistive technology.
The Institute for Matching Person & Technology[3], of NY, for example, proposes schemes and tests to evaluate the most appropriate device for each user in different fields:

- "**Assistive Technologies** – products for persons with physical disabilities designed to enhance independence and functioning (for examples wheelchairs, adapted utensils, communication devices);
- **Educational Technologies** - used to help students learn in classroom settings or at a distance (for examples multimedia delivery systems, self-instructional software programs);
- **Workplace Technologies** - designed to enhance job performance and productivity through multi-tasking, networking, telecommuting, and similar (examples are electronic scheduling devices, telecommunications software). General, everyday technologies to make our daily activities easier, more efficient and pleasurable (examples include automatic (bank) teller machines, VCR's)."

One of the main results of this method is to put in evidence how an apparently perfect and functional object may results inadequate if we consider personality preferences, psychological attitudes or environmental influences. This is particularly true for some users who have "particular needs" as physical or mental impaired people. Each sector is provided with two instruments, one for the provider of technologies, in our case the therapist or doctor, and the other for the direct users.

The **International European Standard for assistive devices** is the **ENN ISO 9999**. It ***"establishes a classification of assistive products, especially produced or generally available, for persons with disability."***[4]

The **ISO 9999:2011** makes use of the terminology and definitions of the ICF, the International Classification of Functioning Disability and Health[5]. The first drafting of the law was made in 1992 in collaboration with the ISPO (International Society for Prosthetics and Orthotics), RI (Rehabilitation International), UNECE (United Nations Economic Commission for Europe) and WHO (World Health Organization).

Assistive products aim at preventing, compensating, monitoring, relieving or neutralizing impairments, activity limitations and participation restrictions[6]. In particular the last two voices of the list above include devices, equipment, instruments, technology and software. It's a vast range of solutions, completely different in their nature, mechanical, hardware or software. It could be a simple or integrated solution, really low or extremely high tech, that is own by the disable or it is part of the

3 *Institute for Matching Person & Technology,* http://matchingpersonandtechnology.com/ (January 2015)

4 ISO 9999: 2011 http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=50982 (January 2015)

5 WHO Family of International Classification (FIC), *ISO 9999. Assistive products for persons with disability - Classification and terminology - ISO 9999, fifth edition, 2011*, http://www.rivm.nl/who-fic/ISO-9999eng.htm, (May 2014)

6 *Ausili: definizioni e normative. Tecnologie per la disabilità – A.A. 2010 / 2011*, Politecnico di Torino, ASPHI Fondazione Onlus, http://elite.polito.it/files/courses/01OQM/slide2012/12-ausili.pdf, (May 2014).

Introductory lesson and material for the course of Technologies for Disabilities of the Politecnico di Torino, held in the Academic Year 2011/2012. It discusses the meaning and function of technical aids, the contents of the ISO 9999:2011 and the Italian NHS.

activity he takes part to. As the definition declares, they have not to be necessary objects specifically designed for handicap people, but they could be as well products of the mass production market, maybe adapted to the needs of the user, or maybe used in an innovative way.
The **ISO 9999** classifies assistive products on the base of their function. It defines 12 functional "***classes***", each of which is subdivided into "***subclasses***", which list "***divisions***". Each product code contains: title, a brief explanation and some examples of included or excluded products. The 12 classes are:

04 – Assistive products for personal medical treatment

04 03 – Assistive products for respiration
04 06 – Assistive products for circulation therapy
04 07 – Assistive products for scar formation prevention
04 08 – Compression garments for body control and conceptualization
04 09 – Assistive products for light therapy
04 15 – Assistive products for dialysis therapy
04 19 – Assistive products for administering medicines
04 22 – Sterilizing equipment
04 24 – Physical, physiological and biochemical test equipment and materials
04 25 – Cognitive test and evaluation materials
04 26 – Assistive products for cognitive therapy
04 27 – Stimulators
04 30 – Assistive products for heat or cold treatment
04 33 – Assistive products to manage tissue integrity
04 36 – Assistive products for perceptual training
04 45 – Assistive products for spinal traction
04 48 – Equipment for movement, strength and balance training
04 49 – Wound care products
04 89 – Other products for personal medical treatment

05 – Assistive products for training in skills

05 03 - Assistive products for communication therapy and training
05 06 Assistive products for training in alternative and augmentative communication
05 09 Assistive products for continence training
05 12 Assistive products for training in cognitive skills
05 15 Assistive products for training in basic skills
05 18 Assistive products for training in various educational subjects
05 24 Assistive products for training in the arts
05 27 Assistive products for training in social skills
05 30 Assistive products for training in control of input units and handling products and goods
05 33 Assistive products for training in daily living activities

06 – Orthoses and prostheses

06 03 Spinal and cranial orthoses
06 04 Abdominal orthoses
06 06 Upper limb orthoses
06 12 Lower limb orthoses
06 15 Functional neuromuscular stimulators and hybrid orthoses
06 18 Upper limb prostheses

ANALYSIS

06 24 Lower limb prostheses
06 30 Prostheses other than limb prostheses
06 33 Orthopedic footwear
06 89 Accessories for orthoses and prostheses

09 – Assistive products for personal care and protection

09 03 Clothes and shoes
09 06 Body-worn assistive products for body protection
09 07 Assistive products for stabilization of the body
09 09 Assistive products for dressing and undressing
09 12 Assistive products for toileting
09 15 Assistive products for tracheostomy care
09 18 Assistive products for ostomy care
09 21 Products for skin protection and skin cleaning
09 24 Urine diverters
09 27 Urine and feces collectors
09 30 Assistive products for absorbing urine and feces
09 31 Assistive products to prevent involuntary urine or feces leakage
09 33 Assistive products for washing, bathing and showering
09 36 Assistive products for manicure and pedicure
09 39 Assistive products for hair care
09 42 Assistive products for dental care
09 45 Assistive products for facial care
09 54 Assistive products for sexual activities

12 – Assistive products for personal mobility

12 03 Assistive products for walking, manipulated by one arm.
12 06 Assistive products for walking, manipulated by both arms
12 07 Accessories for assistive products for walking
12 10 Cars, vans and trucks
12 11 Mass transit vehicles
12 12 Vehicle accessories and adaptations
12 16 Mopeds and motorcycles
12 17 Alternative motorized vehicles
12 18 Cycles
12 22 Manual wheelchairs
12 23 Powered wheelchairs
12 24 Wheelchair accessories
12 27 Alternative human propelled vehicles
12 31 Assistive products for transfer and turning
12 36 Assistive products for lifting persons
12 39 Assistive products for orientation

15 – Assistive products for housekeeping

15 03 Assistive products for preparing food and drink
15 06 Assistive products for dishwashing
15 09 Assistive products for eating and drinking
15 12 Assistive products for housecleaning
15 15 Assistive products for making and maintaining textiles

18 – Furnishings and adaptations to homes and other premises

18 03 Tables
18 06 Light fixtures
18 09 Sitting furniture
18 10 Accessories for sitting furniture
18 12 Beds
18 15 Assistive products for height adjustment of furniture
18 18 Support handrails and grab bars
18 21 Gate, door, window and curtain openers/closers
18 24 Construction elements in the home and other premises
18 30 Assistive products for vertical accessibility
18 33 Safety equipment for the home and other premises
18 36 Furniture for storage
18 89 Other products to adapt homes and other premises

22 – Assistive products for communication and information

22 03 Assistive products for seeing
22 06 Assistive products for hearing
22 09 Assistive products for voice production
22 12 Assistive products for drawing and writing
22 15 Assistive products for calculation
22 18 Assistive products that record, play and display audio, visual or audiovisual information using electronic media
22 21 Assistive products for face-to-face communication
22 24 Assistive products for telephoning and telematic messaging
22 27 Assistive products for alarming, indicating, reminding and signaling
22 30 Assistive products for reading
22 33 Computers and terminals
22 36 Input devices for computers
22 39 Output devices for computers

24 – Assistive products for handling objects and devices

24 06 Assistive products for handling containers
24 09 Assistive products for operating and controlling devices
24 13 Assistive products for controlling from a distance
24 18 Assistive products to assist or replace arm function, hand function, finger function or a combination of these functions
24 21 Assistive products for extended reach
24 24 Assistive products for positioning
24 27 Assistive products for fixation
24 36 Assistive products for carrying and transporting

27 – Assistive products for environmental improvement and assessment

27 03 Assistive products for environmental improvement
27 06 Measuring instruments

28 – Assistive products for employment and vocational training

28 03 Workplace furniture and furnishing elements

Orthoses that act on singular area

FO – Foot Orthosis

AO – Ankle Orthosis

KO – Knee Orthosis

HO – Hip Orthosis

Complex Orthosis

AFO – Ankle Foot Orthosis

KAFO – Knee Ankle Foot Orthosis

HKAFO
Hip Knee Ankle Foot Orthosis

THKAFO – Trunk Hip
Knee Ankle Foot Orthosis

Example of Orthoses as classified by the the ISO 9999, class 06.12, for Lower Limb Orthoses

ANALYSIS

28 06 Assistive products for transporting objects in the workplace
28 09 Assistive products for hoisting and repositioning objects in the workplace
28 12 Assistive products for fixing, reaching and grasping objects in the workplace
28 15 Machines and tools for use in the workplace
28 18 Devices for testing and monitoring in the workplace
28 21 Assistive products for office administration, information storage and management at work
28 24 Assistive products for protection and safety in the workplace
28 27 Assistive products for vocational assessment and vocational training

30 – Assistive products for recreation

30 03 Assistive products for play
30 09 Assistive products for sports
30 12 Assistive products for playing and composing music
30 15 Assistive products for producing photos, films and videos
30 18 Handicraft tools, materials and equipment
30 21 Assistive products for gardening and lawn care in private use
30 24 Assistive products for hunting and fishing
30 27 Assistive products for camping and caravaning
30 30 Assistive products for smoking
30 33 Assistive products for pet care

In particular, the **ISO 9999**, **class 06.12**, defines **Lower Limb Orthoses**, as:

"orthoses designed to modify the structural and functional characteristics of the neuromuscular and skeletal systems of the lower limbs.
The device may be custom fabricated to meet the functional needs of the individual user or prefabricated to meet a particular set of functional requirements.
The prefabricated devices may be adjustable to fit an individual user, or they may be ready to use so that adjustment is not possible or no adjustment is necessary for any user."[7]

Furthermore, the subclass of assistive products, ***06 12 Lower limb orthoses***, includes:

- **06 12 03 Foot orthoses**, orthoses that encompass whole or part of the foot. Included are, e.g., insoles and shoe inserts, pads, arch supports, heel cushions, heel cups and orthopedic inserts.
- ***06 12 06 Ankle-foot orthoses, orthoses that encompass the ankle joint and the whole or part of the foot.***
- **06 12 09 Knee orthoses**, orthoses that encompass the knee joint.
- **06 12 12 Knee-ankle-foot orthoses**, orthoses that encompass the knee and ankle joints and the foot.
- **06 12 13 Leg orthoses**, orthoses that encompass the lower leg, i.e. with fracture treatment.
- **06 12 15 Hip orthoses**, orthoses that encompass the hip joint.

7 *ISO 9999 – Subclass and Divisions. 06 12 Lower limb orthoses*, http://www.abledata.com/abledata.cfm?pageid=194672&Level1_number=06&Level2_number=12&level1_data_ob_id=170912&level2_data_ob_id=170953 (May 2014)

- **06 12 16 Hip-knee orthoses**, orthoses that encompass the hip and the knee joints.
- **06 12 17 Thigh orthoses**, orthoses that encompass the thigh, i.e. with fracture treatment.
- **06 12 18 Hip-knee-ankle-foot orthoses**, orthoses that encompass the hip, knee and ankle joints and the foot.
- **06 12 19 Thoraco-lumbo/lumbo-sacral-hip-knee-ankle-foot orthoses**, orthoses that encompass the lumbar regions of the trunk, the hip, knee and ankle joints and the foot with or without the thoracic part of the spine.
- **06 12 20 Foot-toe joints**, orthotic joints used as components of lower limb orthoses to allow or control motion of the foot and toe joints.
- **06 12 21 Ankle joints**, orthotic joints used as components of lower limb orthoses to allow or control motion of the ankle joint.
- **06 12 24 Knee joints**, orthotic joints used as components of lower limb orthoses to allow or control motion of the knee joint.
- **06 12 27 Hip joints**, orthotic joints used as components of lower limb orthoses to allow or control motion of the hip joint.

This classification is extremely useful and forefront. It is considered worldwide as a standard and the basis on which organizing and refer assistive products for people with disabilities. However, even if it is so detailed and encompassing, in the 06 12 03 it defines the assistive product of an Ankle Foot Orthosis but it doesn't go further in the definition of the various types of AFOs available on the market. In future analysis we'll see how this vagueness causes confusion in terminology in the orthoses' market and literature.

ANALYSIS

3.2 – DEFINITION OF ANKLE FOOT ORTHOSIS

An Ankle Foot Orthosis is a device that supports the ankle and the foot. It extends from below the knee and includes the foot. This device is used to control instabilities in the lower limb by maintaining proper alignment and controlling motion[8]. Moreover, it tries to prevent contractures, to protect and support the foot, to correct foot deformities and can be useful to reduce energy consumption in gait too, as for people affected with spastic hemiplegia[9].

It can be designed for wearing it only during the day, or either as a night splint or both during the whole day.

In 1990 Wu defines an **Ankle Foot Orthosis** as:
"***a medical mechanical device to support and align the ankle and foot, to suppress spastic and overpowering ankle and foot muscles, to assist weak and paralyzed muscles of the ankle and foot, to prevent or correct ankle and foot deformities, and to improve the functions of the ankle and foot.***[10]"

The thermoplastic molded Ankle Foot Orthoses were first described in 1958 by Yates, for the cure of flaccid drop foot and then used in children with cerebral palsy and muscular dystrophy[11]. Nowadays scientific literature is concordant in the recognition of the positive effects of a proper use of these orthoses, in static and dynamic conditions, depending on the diagnosis, if properly combined with active stretching and prescribed cures.[12,13]

In particular almost all the scientific articles analyzed, agree on asserting the **effectiveness of night splint therapy in various foot disorders**, as plantar fasciitis, foot drop, equinus foot, Achilles tendon disorders, ankle sprains, arthritis.[14] However the function of an AFO is often misunderstood.

The aim of a lower limb orthosis is not (only) to restore a normal gait as soon as possible, but includes a wide range of elements that have to be considered to achieve the best clinical and functional result allowed.
Furthermore the idea of "***normal gait***" must be rethought for these users, in particular ***for DMD patients***. Sometimes the aim of the orthosis ***is not to reproduce***

8 BUSHBY K, BOURKE J, BULLOCK R, et al., *The multidisciplinary management of Duchenne Muscular Dystrophy,* op. cit.

9 YINGQUI XING S., BHAGIA S. M., *Lower Limb Orthotics and Therapeutic Footwear*, Medscape Reference (2012), http://emedicine.medscape.com/article/314838-overview (May 2014)

10 ORTHO WORLDS, *Floor (Ground) Reaction Orthosis (FRAFO/GRAFO)*, http://www.orthoworlds.com/2010/01/floor-ground-reaction-afo-synonyms.html (May 2013)

11 LUCARELI P.R.G., de OLIVEIRA LIMA M., de ALMEIDA LUCARELLI J. G., SILVA LIMA F. P., *Changes in joint kinematics in children with cerebral palsy while walking with and without a floor reaction ankle-foot orthosis,* in *Clinics*, vol. 62 num.1, San Paolo, 2007, http://www.scielo.br/scielo.php?pid=s1807-59322007000100010&script=sci_arttext (May 2014)

12 ROMKES J., BRUNNER R., *Comparison of a dynamic and a hinged ankle foot orthosis by a gait analysis in patients with hemiplegic cerebral palsy,* Gait Posture, Feb (1) 2002: pp. 18-24

13 LEHMANN J.F., CONDON S.M., PRICE R., DELATEUR B.J., *Gait abnormalities in hemiplegia: their correction by ankle-foot orthoses,* Archives of Physical Medicine and Rehabilitation, Nov 68(11), 1987: pp. 763-771

14 SOBEL E; LEVITZ SJ; CASELLI MA, *Orthoses in the treatment of rearfoot problems*, Division of Orthopedic Sciences, New York College of Podiatric Medicine, NY 10035, NLM PUBMED CIT. ID: 10349286 SOURCE: J Am Podiatr Med Assoc 1999 May;89(5): pp. 220-338

Effective treatment of chronic plantar fasciitis with dorsiflexion night splints: a crossover prospective randomized outcome study. Powell M; Post WR; Keener J; Wearden S., Department of Orthopaedics, West Virginia University, Morgantown 26505, USA.

a standard gait similar to an unaffected person, but maybe only to compensate physical deficits ***to achieve the goal of the most efficient, optimized, healthy, safest gait***, that could not even include, for example, the values of speed of gait.[15]

On this regard, Bryan S. Malas suggests that the prescription of an AFO must include *"effects on the body's center of mass, considerations on the fatigue of use, on the area of contact, proprioception and preservation of balance outside of normalized ambulation"*[16], but even ***patients' expectation***.

As declared in the methodological approach to the research, the main function of any orthosis and aid for disable people, being DMD of any others, is improving the ***Quality of Life***. In the evaluation on the opportunity of prescribing an Ankle Foot Orthoses doctors have to evaluate not only the bio-mechanical efficacy of the aid for the user in that physical condition. A global and overall consideration of all the aspects related to the orthoses, to the nourishes expectations by users and their parents, their psychological acceptation of this device has to be carefully evaluated. These considerations are integral part of the prescription of an orthosis and their underestimation can even nullify completely the final result.

15 GRONER C., *AFO users must rethink concept of 'normal' gait*, in Lower extremity review, January 2011, http://lermagazine.com/article/afo-users-must-rethink-concept-of-normal-gait (January 2015)

16 MALAS B.S., *The effect of ankle-foot orthoses on balance: a clinical perspective*. J Prosth Orthot 2010;22(10), pp. 24–33

ANALYSIS

3.2.1 - Biomechanical function of AFOs

The functions of an Orthosis can be synthesized in[17]:

1. Immobilisation
2. Restriction of Motion (ROM)
3. Enhance Biomechanics
4. Force Re-distribution

These different goals can be time by time evaluated and pursuit intervening on the shape of the AFO. Since the functional nature of the object, all the significant differences in form or shape that we can notice among different products are motivated by the attempt of stimulating a particular biomechanical effect. The analysis and observation of all these differences is the first step in gain mastering in order to design a new orthosis.

Moreover through the analysis of the examined scientific literature, emerges the empiric and handcraft nature of this aid. Most of the what we consider standard solutions generated not from a theoretical calculation on force distribution but from empirical tests, initially on a few sample of people with the same pathology and then internationally adopted as a validated solution.

In general, the effects of an Ankle Foot Orthosis can be summarized in:

- Change in muscle tone, that can cause equinus foot and/or ankle inversion;
- Contrast the weakness of dorsiflexors muscles, that cause foot drop during gait, as in stroke or in severe peripheral neuropathologies. In these cases the AFO lifts the foot toes, improves balance and prevents retractions.[18]

For example, if a man is wearing a walking AFO, inside the shoes, the rigid part of the orthosis transfers the reaction force of the ground, towards the front of the leg, under the knee. This force against the head of the tibia, during the intermediate and final stage of the gait prevents and adjust the uncontrolled progress of the tibia. The AFO produces a plantar flexion movement that counters the ground reaction force of dorsiflexion of the ankle.

Furthermore, the calibration of the angle at the heel between the leg and the foot, is able to stimulate a flexor movement of the knee. This can be very helpful, for example, for people who have a weak quadriceps, because it gives more stability in the phase of gait.

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17 Two Orthotist/Prosthetist affiliated with The Australian Orthotic Prosthetic Association, propose a classification of lower limb orthoses.

GOODRICK R., NIELSEN B., *Prescribing MASS Funded Orthoses*, The Australian Orthotic Prosthetic Association Inc., 2013, http://www.health.qld.gov.au/mass/docs/resources/MGF/orthosesrdbn.pdf, (May 2014)

18 LEHMANN J.F., ESSELMANN P.C., KO M.J., SMITH J.C., DELATEUR B.J., DRALLE A.J., *Plastic ankle-foot orthoses: evaluation of function.* Arch Phys Med Rehabil Sept; 64(9) 1983: pp. 402-7

3.3 - MARKET ANALYSIS ON ANKLE FOOT ORTHOSES

3.3.1 - The aim of a research on all types of AFOs in Western market

The survey in edited scientific literature on Ankle Foot Orthosis offered the first necessary frame of the research. This study was particularly useful in defining the function of these orthoses and how they're use can affect gait and posture while they're don and in a long term evaluation. In a more critical way, the research highlighted at the same time the lack of a unified definition of the relation between diagnosis, prescription and desirable results. The overall impression is that, besides some fundamental rulers, there's a lot of overlapping between definitions and terms. An unitarian and codified approach to each single case in which a particular AFO is advantageous is lacking. The responsibility in the evaluation and choice of the better AFO for that patient is left to doctors who see the patient. This level of "uncertainty" and flexibility is reasonable if we consider the complex nature of the foot and how many completely different disease or temporary injuries can cause a great variety of similar deformations and that even the same physical problem requires different cures and actions depending on others boundary conditions. This evaluation lead to the conclusion that is impossible to draw up a complete and detailed records.

Nevertheless, since the substantial handicraft and empirical nature of the AFO, a deep study and analysis of a large number of examples and studies can evidence the most common approach. This lead to the decision of extending the research on all types of AFO and not only to the ones specifically indicated for DMD patient, in the believing that only through **analysis and observation of different solutions** and the learning of the **logics that guided each design decision** there could the possibility to hypothesize new meliorative proposals and approaches to the design of AFO. The aim of the thesis is creating a new type of AFO for Duchenne patients but nothing really innovative could be designed limiting the research to the exclusive observation of DMD's product.

These evaluation were at the basis of the decision of leading a **market analysis on Ankle Foot Orthoses available on European an North American market, with a particular focus on Italian situation**.

The aim of this research can be synthesized in:

- ***Providing an overall frame*** of AFO's market in Western countries;
- ***Understanding the Italian production of orthoses,*** its value, potential and criticality compared with other Western foreign countries
- ***Collecting the most various case studies as possible*** of Ankle Foot Orthoses, together with all the available information on that product.

DESIGN

3.3.2. Data acquisition

In order to finalize the results on the aim of the project, the acquisition of data in such a wide and complex research followed some criteria.

- **Manufacture's website with an on-line catalogue, photos or description of AFOs production**. Since the objective impossibility of personally visiting all the manufacturers, besides few of them that were personally visited or which products were exposed in trade fairs, a general criteria in this research was to consider **only the manufacturers that had an on line catalogue on their website** or at least an explanation of their production of Ankle Foot Orthoses.

- I analyzed over one by one the about **1675 Italian conventioned manufacturers** included in the list of 2013 issued by the *"Ministro della Salute, Dipartimento della programmazione e dell'ordinamento del Servizio Sanitario Nazionale, Direzione Generale dei dispositivi medici, del Servizio Farmaceutico e della sicurezza delle cure"*[19], from which you can buy sanitary and orthotic devices and aids taking advantage of a state subsidy. From this long list I selected only the ones who are producing in place boots and orthoses for lower limbs and even in this case I considered only companies that have an online catalogue of their AFOs. This restriction is quite severe and could influence the reliability of the research. However in the evaluation of the opportunity of this restriction we considered that this boundary could unfortunately exclude an high skilled handcraft technician who produces top-quality orthoses but addressed exclusively to a local market and therefore he wouldn't be interested in getting on line publicity. However nowadays it is difficult to imagine an high specialized and well equipped staff who recurs to vanguard technology that isn't provided with a website of their company. Therefore it had been concluded that probably the expected result of this restriction would have been the average preference of larger manufacturers, despite small handcraft producing and this eventual outcome was considered acceptable for the aim of the research. Moreover, as we'll see in the geolocation of manufacturers the ones that offer on their website a complete catalogue of their products were 37 and that they were spread on all the country, from North to South. Therefore this sample was considered sufficient to give at least a first general impression on the Italian state of art;

- A web research leads to the individuation of the first online websites for some states of the Western Europe, to have a general overview of the state of art in the production of foot Ankle Foot Orthoses in UE. The web research on foreign non-native English countries' manufacturers was carried out:

  - looking on Google search engine for research's keywords translated in country's language and then visiting local websites setting an automatic translation of the texts.

  - looking on Google search engine for research's keywords translated as in country's language as in English but limiting the research to the websites that have a web domain related to their country (for example ".de" for German manufacturers' websites)

  - looking for orthoses' manufacturers in local online phone books.

19 http://www.salute.gov.it/imgs/C_17_pagineAree_15_listaFile_itemName_19_file.pdf

- In the USA the legislation is different but I considered the list of 50 manufacturers provided by Able Data[20] for Ankle Foot Orthosis;

- The major international chains for the production of standard foot orthosis were selected in their head offices and their products distinguished in a separate category;

- I limited the scope of analysis only to the AFOs, the ankle foot orthoses, and in particular I excluded all the orthoses used to cure fractures, injuries, sport rehabilitations and similar, because of no interest as a term of comparison in the design of a new AFO for children affected by Duchenne Muscular Dystrophy.

At the end the database contains at the moment: **725 products of 129 manufacturers, 37 of which located in Italy and the others dislocated in 30 countries.**

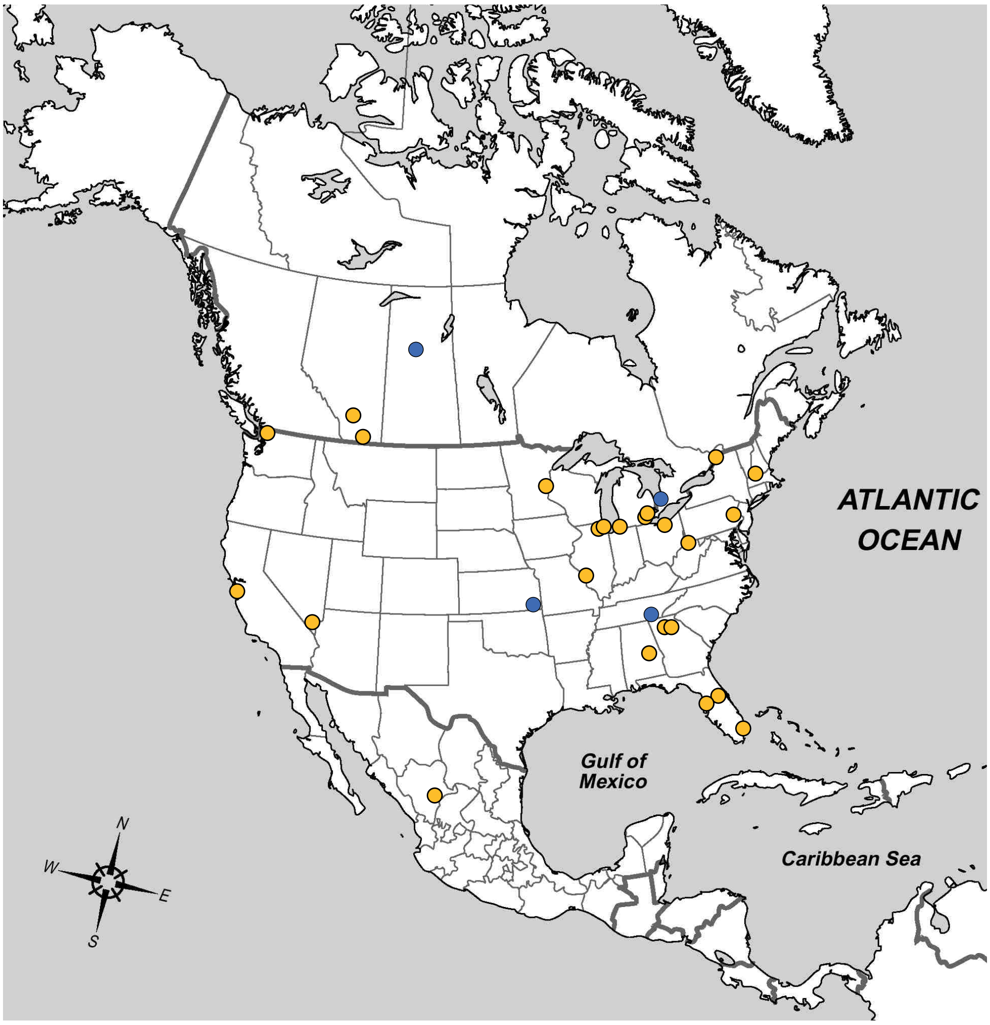
20 ABLE DATA is an American service that provides information on assistive technology and rehabilitation equipment. It is aimed at consumers, organizations, professionals and caregivers within the United States. They don't produce anything but provide information and contact on these products. http://www.abledata.com/abledata.cfm?pageid=19327&top=11769&ksectionid=0&productid=88855&trail=22,11768&discontinued=0 (January 2015)

3.3.3 - Geolocation of manufacturers

All the scheduled manufactured where reported on Google map pages to have a visual geographical synthesis of the research.

The results are presented in three different maps. The first two ones report the selected manufacturers in Western Europe and North America. The manufacturers who produce AFO are reported in red. In America the red dots are the ones indicated on Able Data website, integrated with other important ones found on the net. In Europe the red circles indicates the headquarters of the major brand of AFOs that have a website in which all the different products are clearly exposed and classified. The blue circles are the major retails of international chains of AFOs, the head offices of the multinational companies in each state.
While American and European manufacturers were chosen exclusively by their websites and their position in a Google Research, the Italian producers were chosen among a complete list of all the conventionned manufacturers by the NHS.

From this first analysis emerges how the region with higher interest in this productive sector are Piemonte, Lombardia, Emilia Romagna and Lazio, with specific industrial districts in Milan, Turin and Rome. On the contrary Molise, Basilicata and Calabria seem to be the regions in which it is harder to find a local producer of customized AFOs or, as we already said, if present, almost no information was found in this research.



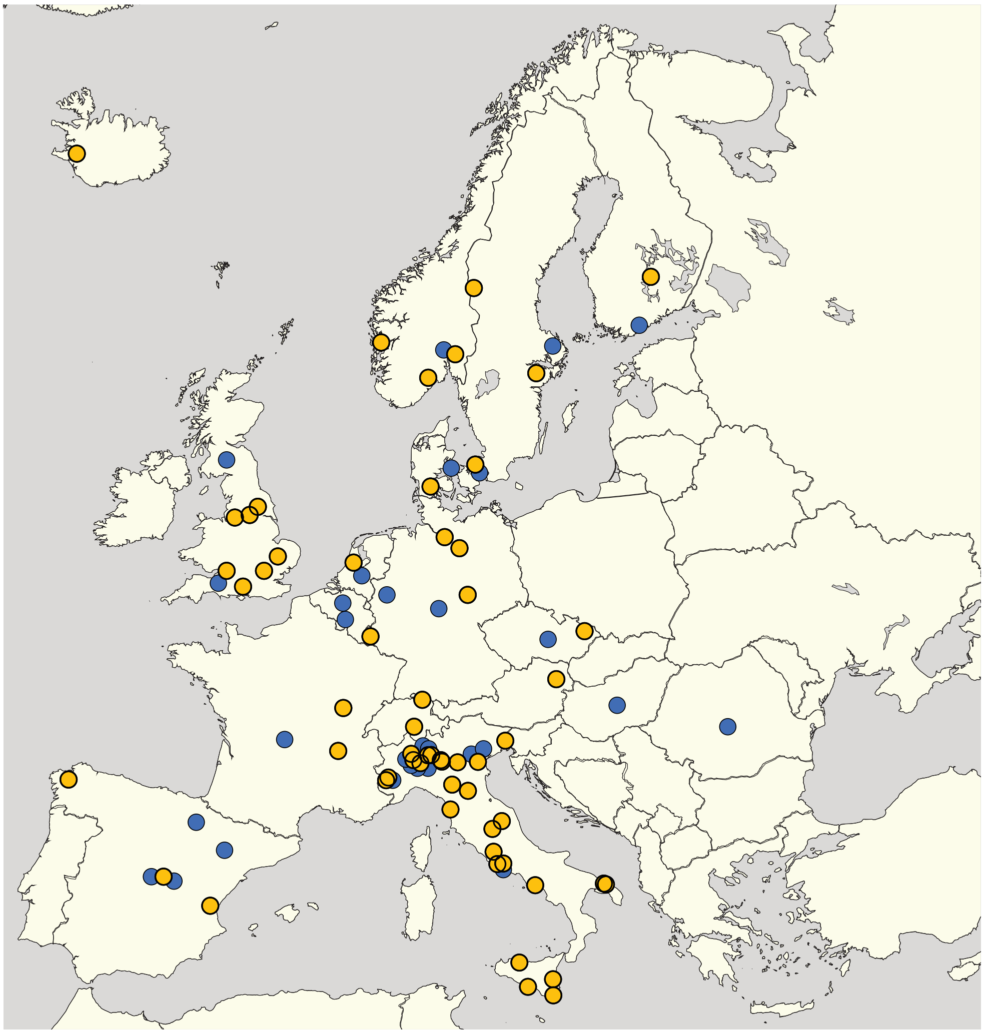
North American Manufacturers of AFOs

Main AFOs producers

AFOs international chains'retails

Therefore a zoom on Italy presents in detail all the scheduled companies. Excluding Italian headquarters of international chains, Italian manufacturers were organized in three groups, distinguished by different colours:

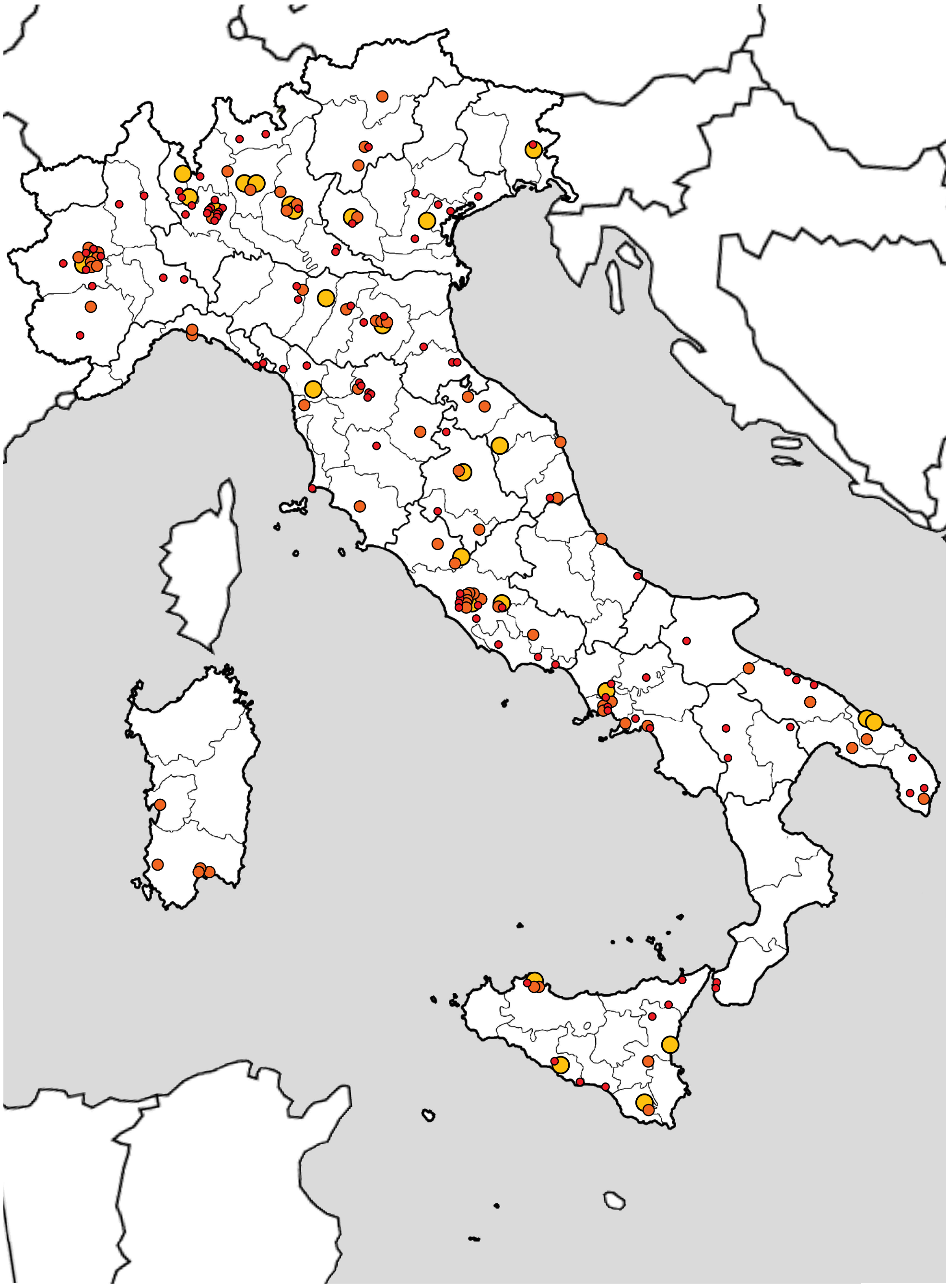
- in RED who provides a complete catalogue of products online, explaining differences and characteristics of each one;
- in ORANGE who declares its activity in custom manufacture of AFOs and encloses with the text one or two images of one product, of even their laboratory with the orthosis in phase of construction. It is made just to give an idea of the activity but usually few or none information is given on technical details of the AFOs;
- in YELLOW who only declares that customized ankle foot orthosis are made in their laboratory but there is no image published in the web page. In this case, it should be possible to call each company, one by one, to ask for information but the amount of cases found on the web were estimated sufficient to give a general idea on the trends of the market in this sector and, at least for the moment, the research didn't included these manufacturers in further analyses.



Western European Manufacturers of AFOs

Main AFOs producers

AFOs international chains'retails



Italian Manufacturers of AFOs

Complete catalogue of AFOs on their websites

One or two photos of their AFOs production on their websites

Companies that declare to have AFOs production but with no photo

3.3.4. Organization and classification of collected data on Ankle Foot Orthoses

The first difficulty that emerged in this market analysis of Ankle Foot Orthoses was the individuation of a uniform criteria to organize and catalogue all the products. As illustrated in 3.1 paragraph, the International Organization for Standards issues in the ISO 999:2011 all assistive devices for people with disability. However going through its organization in classes, subclasses and divisions we arrive to the class 06.12.06 which define Ankle Foot Orthoses but no more indications are provided in order to organize different types of AFOs.

This lack reflects in the huge confusion that we can find in the terminology and in the explanation of lower limb orthoses on scientific publications, catalogues of sellers, web sites and on line markets of these products.

Even scientific literature isn't unanimous in the definition of shared criteria of organization of AFOs.

Among the analyzed sources, one of the most appropriate classification found is proposal by the Goodrick and Nielsen in *Prescribing MASS Funded Orthoses* [21]. This cataloging is based basically on the use of the orthoses and it organizes them hierarchically in:

- **CLASSIFICATION**, that refers to the Nomenclature terms, based on the part of the body they embrace: FO, AFO, KAFO, HKAFO, THKAFO, AO, KO, HO and their joints;
- **STYLE**, it refers to a more specific adjective that characterize the "shape" of the orthoses, as, for example, AFO Life Spring Orthosis
- **DESCRIPTORS**, are related to design descriptors of components or characteristic features, or materials.

However, the attempt of using this hierarchy in the organization of the hundreds of products found between several Italian, European and American manufacturers evidences all its limits in the arbitrary collocation of some orthotic features as "style" or "descriptor".

Moreover it must be noticed that each manufacture, besides some general and recurrent terminology, tends to avoid to recur to standard terminology for a business strategy of presenting its product as unique.

To overcome this hindrance on a very first moment all the different classifications found were reported separately. This step was useful primarily to have a complete frame of all the terminology and most common types of AFOs currently produced. The comparison between different lists of products proved to be very valuable because it helped to focus the attention on the several different "**keys of lectures**" used to define categories, ***someone focusing more on the function, others on the dynamism allowed or locked, others pointing out more on different used materials and consequence performances.***

Hereinafter I report 44 different lists of terms considered useful for the aim of the research. The lists were divided in two groups: the ones discussed in scientific literature and the ones proposed by manufacturers. Products' names are referred in their original language as named on the website or publication.

21 GOODRICK R., NIELSEN B., *Prescribing MASS Funded Orthoses*, op. cit.

DESIGN

3.3.4.1 - Catalogations according to scientific publications

BENVENUTI E., *Analisi comparative dell'efficacia delle ortesi AFO: guida alla scelta e alla prescrizione*

AFO:
- ENGEN
- SEATTLE
- OTTO-BLOCK
- TEUFEL
- CODIVILLA
- CON ASTA METALLICA LATERALE E STOP POSTERIORE (o con molla di richiamo Jousto)
- A CALZASCARPA
- DI TIPO AVVOLGENTE (WRAP AROUND DESIGN)
- A CALZASCARPA
- IN LAMINATO PLASTICO RINFORZATO
- TOE-OFF
- PERO-MED

DAVIS J. R., ROWAN F., DAVIS R. B., *Indications for Orthoses to Improve Gait in Children with Cerebral Palsy*, in J Am Acad Orthop Surg, 15, 2007: pp. 178 – 188, http://www.jaaos.org/content/15/3/178/F8.expansion (May 2014)

CORAZZOL M., *Configurazione morfometrica del piede in relazione a condizioni patologiche*

AFO:
- STATIC
    - NIGHT SPLINTS:
        - AIR SPLINT
        - RIGID LINED NIGHT SPLINT
        - SLEEP SYSTEM
        - SOFT AFO
        - UFO
    - SOLID AFO
    - SERIAL CASTING AFO
        - TRI-PLANE ORTHOSIS
- DYNAMIC
    - LEAF SPRING
    - FOOT UP
    - HINGED
        - PULL OVER
    - SPIRAL
    - LYCRA
        - DYNAMIC MOVEMENT AFO
    - SILICONE
        - SAFO GO
    - DYNAMIC PLASTIC AFO
        - ADVANCED AFO
        - DYNAMIC SMO
    - FUNCTIONAL AFO
        - KIDDIE TOE OFF
    - NYLON AND SPANDEX AFO

CORAZZOL M., *Configurazione morfometrica del piede in relazione a condizioni patologiche*, Master's Thesis at the Faculty of Engineering, University of Padova, 2009-10

DAVIS J. R., ROWAN F., DAVIS R. B., *Indications for Orthoses to Improve Gait in Children with Cerebral Palsy*

- FLOOR REACTION AFO

DAVIS J. R., ROWAN F., DAVIS R. B., *Indications for Orthoses to Improve Gait in Children with Cerebral Palsy*, in J Am Acad Orthop Surg, 15, 2007: pp. 178 – 188, http://www.jaaos.org/content/15/3/178/F8.expansion (May 2014)

GOODRICK R., NIELSEN B., *Prescribing MASS Funded Orthoses*

ORTHOSES:

- USE
    1) CLASSIFICATION
        - BY NOMENCLATURE
        - BY THE BODY PART THEY INFLUENCED
        - BY FUNCTION
    2) STYLE
    3) DESCRIPTORS
        - ADDITIONS, COMPONENTS OR FEATURES
        - MATERIAL

LOWER LIMB ORTHOSIS:

- FO
- AFO
    - SOLID (SAFO)
        - SUPRA MALLEOLAR(style)
            - INTO SHOE
            - DIAGONAL STRAP
        - RWRAP (style)
            - INTO SHOE
            - TOP DIAGONAL STRAP
        - BIVALVED AFO
            - TONGUE
            - SOLE
            - LINING
        - LEAF SPRING
        - GRAFO (Ground Reaction AFO)
            - THERMOPLASTIC
            - LAMINATED CF COMPSITE
            - PROXIMAL ANTERIOR SHELL
        - COMBO AFO
            - Supra Malleolar combined with LSAFO, SAFO, AAFO, DAFO
    - ARTICULATED (AAFO)
    - DYNAMIC (DAFO)
        - GRAFO (Ground Reaction AFO)
            - LAMINATED CARBON FIBRE
            - PLASTIC - CF (HYBRID)
- KO
- KAFO
        - STANCE CONTROL (style)
- HKAFO

GOODRICK R., NIELSEN B., *Prescribing MASS Funded Orthoses*, The Australian Orthotic Prosthetic Association Inc., 2013, http://www.health.qld.gov.au/mass/docs/resources/MGF/orthosesrdbn.pdf, (May 2014)

DESIGN

HUGHES M., *The Silicone Ankle Foot Orthosis (SAFO)*

- SILICONE AFO

HUGHES M., *The Silicone Ankle Foot Orthosis (SAFO), a New Generation in Orthotics*, Dorset Orthopaedic Co Lts, in *Journal of Prosthetics and Orthotics* (JPO), 2006, http://www.oandp.org/publications/jop/2006/2006-34.asp (May 2013)

LUCARELI P.R.G., et al., *Changes in joint kinematics in children with cerebral palsy while walking with and without a floor reaction ankle-foot orthosis*

AFO:
- UCBI
- LEAF SPRING AFO
- SOLID AFO
- FLOOR REACTION AFO
- HINGED AFO

LUCARELI P.R.G., de OLIVEIRA LIMA M., de ALMEIDA LUCARELLI J. G., SILVA LIMA F. P., *Changes in joint kinematics in children with cerebral palsy while walking with and without a floor reaction ankle-foot orthosis*, in *Clinics*, vol. 62 num.1, San Paolo, 2007, http://www.scielo.br/scielo.php?pid=s1807-59322007000100010&script=sci_arttext (May 2014)

ORTHO WORLDS, *Orthopaedic Surgeons Community*

AFO:
- CONVENTIONAL
- DYNAMIC
- CUSTOM
  - SOLID
    - NIGHTSPLINTS
  - ARTICULATED
  - HYBRID
  - CUSTOM CARBON FIBER

http://www.orthoworlds.com/2010/01/floor-ground-reaction-afo-synonyms.html

PEDIATRIC ORTHOPEDICS

AFO:
- SOLID
- HINGED
- SPIRAL

http://www.pediatric-orthopedics.com/index.html

SACCHETTI R., DAVALLI A., ***Ortesi per l'arto inferiore ed ausili per il cammino***

ORTESI:
- ARTICOLAZIONE TIBIOTARSICA
    - ARTICOLARITA' TOTALMENTE LIBERA
    - ARTICOLARITA' CON LIMITAZIONE DEL CAMPO ANGOLARE FISIOLOGICO
- ARTICOLAZIONE AL GINOCCHIO
    - ARTICOLARITà MONOASSIALE O POLICENTRICA
    - CON ARTICOLAZIONE ARRETRATA
    - ARTICOLAZIONE LIBERA O CON ESCURSIONE ANGOLARE LIMITATA
        - CON ARTICOLAZIONE ARRETRATA
        - CON ARTICOLARITà CON BLOCCAGGIO/SBLOCCAGGIO
            - A PONTE
            - A CADUTA
- ARTICOLAZIONE ALL'ANCA
    - ARTICOLAZIONE MONOASSIALE
        - LIBERA
        - CON ESCURSIONE LIMITATA
            - BLOCCABILE/SBLOCCABILE
                - A PONTE
                - A LEVA

SACCHETTI R., DAVALLI A., *Ortesi per l'arto inferiore ed ausili per il cammino*, Centro Protesi INAIL Vigorso di Budrio (BO), http://www.inail.it/cms/Medicina_Riabilitazione/Riabilitazione_e_reinserimento/Centro_Protesi/Protesi%20e%20Ortesi.pdf (March 2013)

ZANI M., ***Progettazione e sviluppo di un'ortesi AFO innovativa in materiale composito***

AFO:
- AFO RIGIDE
    - PRESA ANTERIORE
    - PRESA POSTERIORE
- AFO ARTICOLATE
    - PRESA POSTERIORE
- AFO DINAMICHE
    - PRESA ANTERIORE

ZANI M., *Progettazione e sviluppo di un'ortesi AFO (Ankle Foot Orthosis) innovativa in materiale composito,*

Master's thesis at Politecnico di Milano, 2010, http://www.roadrunnerfoot.com/PRODOTTI/Tutori/Presentazione%20Tutori%20AFO.pdf (January 2015)

YINGQUI XING S., BHAGIA S. M.,
Lower Limb Orthotics and Therapeutic Footwear

ORTHOSES:
- SHOE ORTHOSIS
- FOOT ORTHOSIS
  - UCBL insert
  - HEEL CUP
  - SESAMOID INSERT
- AFO
  - TERMOPLASTIC
    - POSTERIOR LEAF SPRING
    - SPIRAL AFO
    - HEMI-SPIRAL AFO
    - SOLID AFO
    - AFO WITH FLANGE
    - HINGED AFO
    - TONE REDUCING AFO (TRAFO)
  - METAL/METAL PLASTIC AFO
    - FREE MOTION ANKLE JOINT
    - PLANTAR FLEXION, DORSIFLEXION AND LIMITED MOTION ANKLE JOINT STOPS
    - DORSIFLEXION ASSIST SPRING JOINTS
    - VARUS OR VALGUS CORRECTION STRAP (T-STRAPS)
- KNEE-ANKLE FOOT ORTHOSIS (KAFO)
  - DOUBLE UPROGHT METAL KAFO
  - SCOTT CRAIG ORTHOSIS
  - SUPRACONDYLAR PLASTIC ORTHOSIS
  - PLASTIC SHELL AND METAL UPRIGHT ORTHOSIS
- KNEE JOINTS
  - FREE MOTION KNEE JOINT
  - OFFSET KNEE JOINT
  - DROP RING LOCK KNEE JOINT
  - PAWL LOCK WITH BAIL RELASE KNEE JOINT
  - ADJUSTABLE KNEE LOCK JOINT (DIAL LOCK)
  - ISCHIAL WEIGHT BEARING
- KNEE CAPS AND STRAPS
- KNEE JOINT ORTHOSIS
  - FREE MOTION JOINT
  - OFFSET JOINT
  - OFFSET KNEE JOINT KNEE ANKLE FOOT ORTHOSIS
  - DROP RING LOCK KNEE JOINT
  - PAWL LOCK WITH BAIL RELEASE KNEE JOINT
  - ADJUSTABLE KNEE LOCK JOINT (DIAL LOCK)
  - ISCHIAL WEIGHT BEARING
- KNEE ORTHOSIS (KO)
  - KNEE ORTHOSES FOR PATELLA FEMORAL DISORDER
  - KO FOR KNEE CONTROL IN THE SAGITTAL PLANE
  - KO FOR KNEE CONTROL IN THE FRONTAL PLANE
  - KO FOR AXIAL ROTATION CONTROL
- HIP-KNEE-ANKLEE FOOT ORTHOSIS (HKAFO)
  - PELVIC BANDS
  - HIP JOINTS AND LOCKS
- TRUNK-HIP-KNEE-ANKLE-FOOT ORTHOSIS (THKAFO)
  - RECIPROCATING GAIT ORTHOSIS (RGO)
  - PARA WALKER
  - PARAPODIUM
  - STANDING FRAME
- SPECIAL PURPOSE LOWER LIMB ORTHOTIC
  - WEIGHTBEARING ORTHOSES
  - FRACTURE ORTHOSES
  - ANGULAR AND DEFORRMITY ORTHOSES
  - CONGENITAL HIP DISLOCATION ORTHOSES
  - SCOTTISH RITE, TORONTO AND NON SKELETAL BEARING TRILATERAL ORTHOSES

Medscape Reference, 2012,
http://emedicine.medscape.com/article/314838-overview

DESIGN

3.3.4.2 - Catalogations proposed by manufacturers*

* Manufacturers' details and references in bibliography

ACCELERATED CARE PLUS

AFO:
- STATIC
- DYNAMIC LOW LOAD
- PASSIVE NIGHT SPLINT
- STRETCH NIGHT SPLINT
- DORSAL NIGHT SPLINT

http://www.acplus.com/Pages/default.aspx

AUSILIUM

AFO:
- MOLLA DI CODIVILLA
- SOLID
- NOTTURNO DORSIWEDGE
- DORSALE DORFLEX

http://www.ausilium.it/

BALLERT ORTHOPEDIC

ORTHOTICS:
  - KINESCEPTIC
  - TONE BALANCING
  - DUCHENNE KAFO
  - FLOOR REACTION
  - FRAFO
  - TORONTO
  - SPOON STYLE AFO
  - LACE-UP
  - FOOT ORTHOTIC

Orthopedic immabolization lace-up

http://www.ballert.com/

BIONESS

- ELECTRIC ORTHOSIS

http://www.hitechbracing.com/products/

BOSH ORTOPEDIA

AFO:
- SOLID AFO
- DYNAMIC AFO
  - BOSH-O LIGHT
- SOLLEVATORE DI HEIDELBERG
- ARTICULATED AFO
  - SOLLEVATORE ORTHOFLEX

http://www.boesch-ortopedia.ch/

DESIGN

CAPSTONE ORTHOPEDIC

AFO:

- SMO
- CONVENTIONAL
- TOTAL SURFACE BEARING
- LOW PROFILE AFO - GAUNTLET
- SOLID ANKLE FOOT ORTHOSIS (SAFO)
- FLOOR REACTION ORTHOSIS (GROUND REACTION ORTHOSIS) (FRO/GRO)
- PATELLA TENDON BEARING ANKLE FOOT ORTHOSIS
- PATENT BOTTOM ANKLE FOOT ORTHOSIS
- DYNAMIC TYPE ANKLE FOOT ORTHOSES ARTICULATED = HINGED ANKLE FOOT ORTHOSIS (HAFO)
- POSTERIOR LEAF SPRING ANKLE FOOT ORTHOSIS (PLS AFO)

http://www.capstoneorthopedic.com/services/orthotic/index.php

CLINICAL ORTHOTIC CONSULTANTS OF WINDSOR

AFO:

- SEMIFLEXIBLE AFO
- PEDIATRIC HINGED AFO
- CONVENTIONAL METAL AFO

http://www.cocwindsor.com/

CRISPIN ORTHOTICS

AFO:

- POSTERIOR LEAF SPRING
- SOLID AFO
    - TONE INHIBITING AFO
- FIXED ANKLE AFO
- GROUND REACTION AFO
- CARBON FIBER AFO
- CONVENTIONAL AFO
- ARTICULATED AFO
- NIGHT AFO
- PRESSURE RELIEVING AFO
- SILICONE HYBRID AFO
- STOCK NIGHT AFO
- SUPRA MALLEOLAR ORTHOSIS (SMO)
- WALKER BOOT

Stock night AFO

http://www.crispinorthotics.com/orthotics/products/

DESIGN

CUSTOM COMPOSITE MFG

CARBON FIBER AFO:
- FLEXOR BAND AFO
- LATERAL STRUT AFO
- POSTERIOR LATERAL STRUT AFO
- SPIRAL AFO
- HYBRID MEDIAL STRUT AFO-STANDARD CALF BAND
- HYBRID MEDIA STRUT AFO-POSTERIOR CALF BAND
- PARTIAL FOOT TMA
- SOLID ANKLE ANTERIOR MEDIAL AFO (SAAM)
- SOLID ANKLE POSTERIOR AFO (SAP)
- PARTIAL FOOT PROSTHESIS

Solid Ankle Anterior Medial Orthosis

http://www.cc-mfg.com/

DORSET ORTHOPAEDIC

- AFO
- SILICONE AFO

http://www.dorset-ortho.com/contact/

ESSEX ORTHOPAEDICS

AFO:
- DYNAMIC AFO
- DYNAMIC FO
- AFO
- HINGED AFO
- ANTERIOR FLOOR REACTION ORTHOSIS
- SUSTENTACULUM - TALI -
- FUNCTIONAL FOOT ORTHOTICS
- KNEE ANKLE FOOT ORTHOSIS

Dynamic Foot Orthosis

http://www.essexorthopaedics.co.uk/

HI TECH BRACING

AFO:
- ANKLE BRACES
- WALKING BOOTS
- CUSTOM AFO
  - SOLID AFO
  - ARTICULATED AFO
  - MOLLA DI CODIVILLA
- NON CUSTOM AFO
- NIGHT SPLINTS
- CUSTOM FOOT ORTHOTICS

http://www.hitechbracing.com/products/

DESIGN

GEELONG ORTHOTICS

ORTHOSES:

- FOOT ORTHOSIS
  - PRE-FABRICATED
  - UCBL
  - SMO
- AFO'S
  - RIGID ANKLE
  - HINGED
  - TOTAL CONTACT DESIGN (total contact AFO)
- HIP ORTHOSES FOR DEVELOPMENTAL DYSPLASIA OF THE HIP
  - PAVLIK HARNESS
  - CUFF AND BAR
  - HIP SPICA-ABDUCTION BRACE
  - VON ROSEN BRACE
- CONGENITAL TALLIPES EQUINO-VARUS (CTEV)
  - BOOTS AND BAR
- TOE WALKING ORTHOSES
  - CARBON FIBRE TOE PLATE
  - SERIAL CASTING
  - NIGHT STRETCHING AFO'S CARBON FIBRE TOE PLATES

http://www.geelongorthotics.com.au/

J & J ARTIFICIAL LIMB AND BRACE

ORTHOSES:

- FO
- AFO
- DYNAMIC AFO
- KNEE ORTHOSIS
- KAFO
- HKAFO
- RECIPROCATING GAIT AFO

http://www.jandj.org/orthotics.html

KINETIC RESEARCH

AFO:

- SMO
- UCBL
- NOODLE AFO
- VALGA NOODLE
- ALIGNER AFO
- CARBON FIBER AFO
- SOLID ANKLE WITH LACER

Thermoplastic AFO

http://kineticresearch.com/contact.html

DESIGN

LANDRA PROSTHETICS

AFO:
- SOLID ANKLE AFO
  - CROW WALKER
  - COMPREHENSIVE FLEXIBLE SOLID ANKLE AFO/PLS
  - SURE STEP FIXED POSITION STIRRUP
- ARTICULATING ANKLE AFO
  - DORSI ASSIST AFO
  - ARTICULATING POSITION STIRRUP
  - AIRCAST GEL STIRRUP
- GAUNTLET
  - ARIZONA STYLE AFO
  - SWEDE-O ANKLE BRACE
- DYNAMIC
  - TOE-OFF
- CONTRACTURE BOOT
- NIGHT SPINT
  - PLANTARFLEXION NIGHT SPLINT


Dorsi Assist AFO

http://www.landrapando.com/Orthotics/LowerExtremities/AnkleFootOrthosis.aspx

LONDON ORTHOTICS

ORTHOSES:
- WALK ABOUT ORTHOSIS
- KAFO
- FREE WALK KAFO
- KNEE BRACING
- ANKLE FOOT ORTHOSIS
  - HINGED AFO
- ANKLE BRACING
- DYNAMIC AFO
- SILICONE AFO

http://www.londonorthotics.co.uk/orthotics/paediatric-orthotics/

NIGHTSPLINTS.COM

NIGHT SPLINTS:
- STANDARD BOOT
- SOFT NIGHT SPLINT
- DORSAL NIGHT SPLINTS
- SOFT SOCK NIGHT SPLINTS
- PLANTAR FXT

http://nightsplints.com/

DESIGN

ORTHOMERICA

ORTHOSES:

- HINDFOOT CONTROL ORTHOSES
  - SUB-MO OPEN (=FO)
  - SUB-MO WRAP
  - SUPRA MALLEOLAR ORTHOSIS (SMO)

- SAGITTAL CONTROL ORTHOSES
  - LEAF SPRING
  - LEAF SPRING COMBO
  - PLANTAR BLOCKER
  - FULL BLOCKER COMBO
  - FULL BLOCKER RESTING

- ARTICULATING ORTHOSIS
  - DORSI-FREE OVERLAP
  - DORSI-FREE STRETCH
  - ARTICULATING WRAP
  - ARTICULATING COMBO

- FLOOR REACTION ORTHOSES
  - FULL BLOCKER REACTOR
  - DORSI-BLOCKER REACTOR
  - TRANSFORMER

-PTBO

AFO WITH VARUS CONTROL
SOLID ANKLE FOAM LINED AFO
ARTICULATED AFO WITH MOTION LIMITER
POSTERIOR LEAF SPRING AFO
ARTICULATED FOAM LINED AFO

FUNZION AFO
GAUNTLET

http://www.orthomerica.com/

ORTHOTICS & PROSTHETICS NORTHEAST

AFO:

- SUPRA MALLEOLUS AFO
- POSTERIOR LEAF SPRING AFO
- SOLID ANKLE AFO
- FLOOR OR GROUND REACTION AFO
- ULTRAFLEX DYNAMIC STRETCHING AFO
- ARTICULATED AFO

http://www.northeastoandp.com/orthotics/lower/

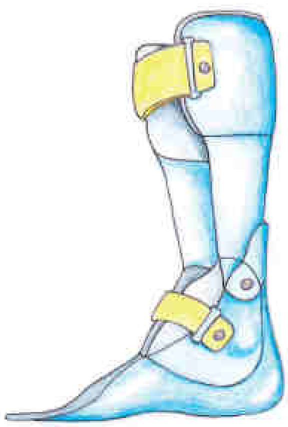
DESIGN

ORTHONOVA

AFO:

- SUB MALLEOLAR
- SUPRAMALLEOLAR
- MED DORSAFLEXIONS STOP
- MED PLANTAR FLEXIONS STOP
- PERONEAL DYNAMIC AFO
- PERONEAL METATARSAL

- DYNAMIC AFO WITH FREE ANKLE MOVEMENT
- ARTICULATED AFO
- AFO WITH FLEXIBLE ANKLE MOVEMENT
- HINGED AFO WITH PLANTAR FLEXIONS STOP
- FERRARI AFO
    - CARBON FIBER REINFORCED
    - COMPOSITE TOP
- STATIC LOWER LEG ORTHOTIC
- GRAFO
- FIBERGLASS SRING
- DYNAMIC SUPRACONDYLAR AFO
- LOWER LEG ORTHOSIS OF CARBON FIBER
- PREPREG AFO
- AFO WITH CALLIPER
- LOWER LEG ORTHOSIS WITH A DYNAMIC AFO
- LOWER LEG ORTHOSIS WITH AN INSERT
- DYNAMIC CARBON FIBER AFO
- SAFO
- SAFO WALK
- UNILATERAL AFO
- SAFO
- PERONEUS SUPPORT
- DICTUS-PERONEUS SUPPORT
- PP-PERONEUS SUPPORT
- TOE OFF
- WALK ON
- BLUE ROCKER
- YPSILON
- DEROYAL FUNCTIONAL ANKLE SUPPORT
- FOOT UP
- NAVIGAIT
- NIGHT SUPPORT PADDED
- NIGHT RAIL ADJUSTABLE
- KAFO NIGHT SPLINT
- DYNAMIC SPLINT FOR CLUBFOOT
- METATARSUS ADDUKTUS SUPPORT
- ULTRAFLEX AFO
- UFO UNIVERSAL PLANTAR FASCITIS ORTHOSIS
- CAROLI DYNAMIC AFO



Hinged AFO
with Plantar Flexion Stop

http://www.orthonova.fi/

ORTOPEDIA FERRANTI

- VALVA ANTERIORE ALLINEATO AI METATARSI DINAMICO PER LA MARCIA
- CON ARTICOLAZIONE TAMARAK ALLA TIBIOTARSICA DINAMICO PER LA MARCIA
- APPOGGIO SOTTOROTULEO ARTICOLATO ALLA TIBIOTARSICA
- CON ALETTE SOVRACONDILOIDEE NON ARTICOLATO ALLA TIBIOTARSICA

http://www.ortopediaferranti.it/

PEACHTREE

- THERMOPLASTIC AFO
- METAL AFO
- FRAFO
- KAFO
- MAFO

http://www.peachtreefab.com/orthotics.html

SCHECK & SIRESS

ORTHOSES:

- AFO
- CARBON FIBER IN BRACES
- FUNCTIONAL ELECTRICAL STIMULATION
- CAM WALKER
- FRAFO
- CROW WALKER
- KAFO

http://www.scheckandsiress.com/orthotics-lower-extremity.php

SRT PROSTHETICS & ORTHOTICS

ORTHOSES:

- FO
    - CARBON PLATE
    - FOOT ORTHOTIC
    - UCB
- SUPRAMALLEOLAR FO (SMO)
- AFO
    - SHORT ARTICULATED AFO
    - ARTICULATED AFO
    - DYNAMIC SHORT ARTICULATED AFO
    - POSTERIOR LEAF SPRING AFO (PLS)
    - SOLID AFO
    - CONVENTIONAL AFO
    - CHARCOT RESTRAINT ORTHOPEDIC WALKER
    - PATELLAR TENDON BEARING AFO (PTB)
    - FLOOR REACTION AFO
- KAFO

http://www.srtprosthetics.com/

SURE STEP

AFO:

- SMO
- BIG SHOT
- ADVANCED
- INDY 2 STAGE
- PULLOVER

http://www.surestep.net/

TREASURE STATE ORTHOTIC & PROSTHETIC

AFO:

- CONVENTIONAL
- DYNAMIC
- CUSTOM
  - SOLID
    - NIGHTSPLINTS
  - ARTICULATED
  - HYBRID
  - CUSTOM CARBON FIBER

Dynamic Gait Orthosis

http://www.treasurestateoandp.com/orthotics.php

ULTRAFLEX SYSTEMS

- SPASTICITY AFO WITH SMO
- DMD AFO
- ADJUSTABLE DYNAMIC RESPONSE (ADR)
- CARBON COMPOSITE FOR ADULT VERSION OF ADJUSTABLE DYNAMIC RESPONSE

http://www.ultraflexsystems.com/

360 ORTHOTIC & PROSTHETICS

AFO:

- SOLID AFO
  - SURESTEP ADVANCED
- ARTICULATED AFO
  - ULTRAFLEX ADJUSTABLE DYNAMIC RESPONSE

http://www.360oandp.com/contact-us.aspx

3.3.5 – Proposal of a new classification of Ankle Foot Orthoses

All the previous terminological label suggested the necessity of proposing a first attempt of standardization among all the classification previously illustrated. This normalisation was the first necessary step of a broader of organization of all the collected data on Ankle Foot Orthoses. The definition of a hierarchical list of terms, comprehensive of all the listed products provided a first AFOs' cataloguing, necessary to put further in order and organize all the other information.
The **definition of the criteria** that had to be followed in this normalization of terms was a demanding and treacherous task. ***Several alternatives were explored but too rigid criteria that consider exclusively the shape or the function of the AFOs, inevitably ended up to the exclusion of too many products that resulted where out of the proposed definition. Eventually the criteria of the maximum diffusion and frequency of the same term for indicating the same category of product was followed and, case by case, each product was located in the proposed category. In ambiguous cases an evaluation on the presence of products in one of the defined categories with comparable shape, function and material suggested the right collocation.***

Furthermore this has to be considered just as a first attempt of standardization and future researches and developments could certainly improve and perfection this first assay, even in view of a possible future standardization of therms.
The proposed classification is:

- **SMO**
    - **BEBAX**

- **SOLID AFO**
    - **TIPICAL SOLID AFO (daily or nightly)**
    - **COMBO (SOLID AFO or LEAF SPRING + SMO)**
    - **FRAFO**
    - **PATELLA BEARING**
    - **SILICONE AFO**
    - **PADDED BOOT**
    - **DORSAL AFO**
    - **CROW WALKER**
    - **AIR SPLINT**

- **DYNAMIC AFO**
    - **CONVENTIONAL AFO**
    - **LEAF SPRING**
    - **LEAF SPRING – WALK ON**
    - **LIFT SPRING**
    - **SPIRAL AFO**
    - **TOE-OFF**
    - **GAUNTLET**
    - **AIR STIRRUP**
    - **ELECTRICAL STIMULATOR**
    - **ELASTIC SOCK**

- **HINGED AFO**

As can be seen the main articulation is made on the *"type"* of orthosis. A detailed description of each category will be further illustrated in thematic sheets. However this organization was the first crucial step for the set up of a database able to organize all the acquired data.

3.3.6 – The set up of an interactive database for Ankle Foot Orthoses

The definition of the first level of hierarchisation of the collected products allowed the beginning of a loading data and the set up of an informatics database able to contain and organize all the information. The aim of this database goes even further the goals already illustrated of the market analysis. It doesn't limit to supply a frame of the state of art of AFO's marked.

The database is a useful, interactive instrument able to organize AFOs by several keys of research. The definition of the search words was oriented to optimise the consultation's easiness, intuitiveness and accessibility.

Following an ***User Centered Design*** approach, the selection of the research keys was extremely user oriented. They were designed taking in consideration the two main potential users of the database:

- *Professionals* - medical or technical staff, manufacturers that here can find all the information on the products available on the market and most vanguard technology, all collected in a single portal. In particular manufacturers could have in future an active role in this database by sending their catalogues and missing information for a business and proportional purpose;
- *Final users* - The user centred approach in the setting of this database consists in the definition of simple keys of research ad deducible even from a not insider in the sector. By this database the user can understand and observe the type of orthosis that doctors prescribed him, comparing and evaluating possible alternatives that don't affect with the clinical scope of the orthosis, such as techniques of production, aesthetic personalization, times of shipping, or localization of the nearest manufacture or if it provide remote orders.

The database organize each product by:

- ***Collocation in the proposed classification;***
- ***Commercial name;***
- ***Name of the manufacture;***
- ***City of the manufacture;***
- ***Country of the manufacture;***
- ***Website of the manufacture;***
- ***Address and contacts;***
- ***Photo of the product;***
- ***Description of the product given by the manufacture;***
- ***Diagnosis related to the prescription of that orthosis;***

DESIGN

- ***Declared clinical effects***
- ***Contraindications***
- ***Typology: Static/Dynamic/Articulated;***
- ***Main material or materials;***
- ***Techniques of acquisition/production;***
- ***Aesthetic alternatives;***
- ***Purchase order.***

In particular in the compilation of the database, some cell fills were extended responses, as the description of the products provided by manufacturers, other columns were provided with a multiple choice, created on the basis of the alternatives found among AFOs. This was useful to collect similar answers in single categories, to facilitate the consultation of the database. In particular these were the most interesting:

- **TYPOLOGY**
    - Static
    - Dynamic
    - Articulated
- **MATERIAL**
    - Carbon fiber
    - Carbon fiber and thermoplastic
    - Carbon fiber with soft padding
    - Elastic tissue
    - Electric stimulator
    - Leather
    - Plastic for outer structure with soft padding inside
    - PVC
    - Silicone
    - Steel
    - Thermoplastic
    - Thermoplastic components padded with other soft materials
    - Thermoplastic - Reinforced
    - Thermoplastic - Low
- **TECHNIQUE OF PRODUCTION**
    - Unique size
    - Standard sizes
        - 2 Sizes
        - 3 Sizes
        - 4 Sizes

    - 5 Sizes
    - 6 Sizes
    - 7 Sizes
    - 8 Sizes
    - 9 Sizes
    - 10 Sizes
  - Heated and trimmed after the delivery
    - Unique size
    - 2 Sizes
    - 3 Sizes
    - 4 Sizes
  - Remote order communicating measures on a pre-filled sheet
  - Remote order posting the cast of the lower limb to the manufacture
  - From plaster made in the same manufacture
  - From 3D scan
- **AESTHETIC CUSTOMIZATION**
  - None
  - Choice between two colours
  - Choice of colours
  - Choice between few given patterns (max 10)
  - Choice between many patterns (> 10)
  - Personalization with a texture given by the user
  - Personalization with 3D graphics
- **PURCHASE ORDER**
  - In fabric
  - Online

3.3.7 – The use of the database

In the description of the instrument we've already sketched some hypothesis of different uses of the database.
For example, using single keys of research, it is possible to select all the products realized by a single manufacture, or in the same way, all the lower limb orthoses belonging to a specific category, and comparing among the same product made by different brands. Likewise a research on a single material can be set, as all the carbon fiber orthoses found on the market, and thus having an overview of the possible existent applications of this material in lower limb orthoses.
However there's even a more interesting use of the database. The instrument is much more flexible since the keys of research, from the list above, can be added and intersected as desired. Here below some examples of possible specific researches.

Concluding it appears clear that this database proved to be extremely useful and, what's the most, liable of future integrations, with the possibility as of adding constantly new products as well as adding new keys of research and technical details on existing products. In this way it is possible to use a flexible instrument always upgraded with the newest outcomes on the market. It can be shared on the web and it could be implemented by manufacturers themselves, by adding personal reports of the users.

RESEARCH OF PRODUCTS MADE BY A SINGLE MANUFACTURER

CATHEGORY 1	CATHEGORY 2	CATHEGORY 3	FABRIC NAME	MADE IN	COMMERCIAL NAME	IMAGE	MATERIAL	ESTHETIC	PURCHASE ORDER	DECLARED CLINICAL EFFECTS	INDICATED FOR
			Childrens AFOs								
SOLID AFO	NIGHT SPLINT	PADDED BOOT	24 - CHILDRENS AFOS	Europe, United Kingdom, Manchester	UFO		Polyethylene outer structure with a foam inner layer	None	ON LINE	- Positions the foot and ankle in a optimal alignment to stretch the calf muscle while the patient is sleeping - Improve mobility - Reduce pain - Comfortable to wear	- for children with different neurological conditions including cerebral palsy, multiple sclerosis and stroke. - Toe walking - Drop foot - Soft tissue contractures at the foot and ankle - Altered positioning of the foot
SMO	BEBAX		24 - CHILDRENS AFOS	Europe, United Kingdom, Manchester	Tri-Plane Orthosis		\	\	on line	- Multi-directional hinge which adapts easily for correction in all 3 planes - Removable for stretching and hygiene - Increases passive range of motion - Reduces deformities - Promotes function and mobility	- for children with abnormal tone and soft tissue shortening secondary to neurological conditions such as cerebral palsy, multiple sclerosis, muscular dystrophy and charcot marie tooth (CMT) - Congenital forefoot deformities - Idiopathic toe walking - Spasticity - Soft tissue contractures
DYNAMIC AFO	LIFT SPRING		24 - CHILDRENS AFOS	Europe, United Kingdom, Manchester	Leaf Spring		Thermoplastic low	None	on line	support a drop foot	neurological conditions
DYNAMIC AFO	LEAF SPRING		24 - CHILDRENS AFOS	Europe, United Kingdom, Manchester	Paediatric Leaf Spring AFO		Thermoplastic low	None	on line	to help prevent soft tissue shortening allows a smoother gait pattern by lifting the foot up Improved gait pattern	children with spastic hemiplegia and diplegia Abnormal tone Muscle Weakness Soft tissue contractures Drop foot
DYNAMIC AFO	SPIRAL AFO		24 - CHILDRENS AFOS	Europe, United Kingdom, Manchester	Spiral AFO		Carbon fiber	None	\	Supports the foot and ankle when standing	Children with neurological conditions such as cerebral palsy, muscular dystrophy, charcot marie tooth (CMT), stroke and multiple sclerosis Difficulty With: Maintaining standing, Spasticity, Muscle weakness
SOLID AFO	SILICONE AFO		24 - CHILDRENS AFOS	Europe, United Kingdom, Manchester	SAFO Go		Silicone	\	\	Go replicates the normal movement pattern of the foot and ankle to help lift the foot when swinging the leg through in gait and preventing falls. SAFO Go covers the whole foot and lower limb which enhances stability as well as providing sensory feedback giving more control during gait. Improving mobility by replicating normal foot action giving more control when walking Improving awareness of the foot and ankle, i.e. sensory feedback	children of all ages with different neurological disorders including Foot drop Muscle weakness Altered positioning of the foot and ankle Involuntary tone/spasm
SOLID AFO	TIPICAL SOLID AFO		24 - CHILDRENS AFOS	Europe, United Kingdom, Manchester	Dynamic plastic AFO - Dynamic Supra Malleolar Orthosis		Thermoplastic	\	in fabric	maintain a neutral heel position while also supporting the arches of the foot. Provides stability, while maintaining the position of the foot during gait to facilitate functional activities. Improves balance, Increases stability Allows natural movement of the foot and ankle Improves alignment and positioning of the foot and ankle Prevents muscle fatigue Reduces stress on the knees and hips	Moderate to severe pronation when standing and/or mobilising short distances. Hypotonia (low tone) General instability when pulling to stand and during gait Difficulty reaching developmental milestones, e.g. late in learning to advance beyond short distances.

Extracts from the table of catalogation of AfOs. Output of a research on the products made by a single manufacturer

RESEARCH OF PRODUCTS INCLUDED IN THE SAME CATEGORY

CATHEGORY 1	FABRIC NAME	MADE IN	COMMERCIAL NAME	IMAGE	MATERIAL	ESTHETIC	PURCHASE ORDER	DECLARED CLINICAL EFFECTS	INDICATED FOR
SOLID AFO									
SOLID AFO	08 - ORTHOMERICA	United States, Florida, Orlando	Plantar Blocker Sagittal Control Orthosis		Thermoplastic	Choice of given patterns (file)	ON LINE	Recommended for: - Restriction of plantarflexion (or dorsiflexion and plantarflexion when tibial strap is used) - Knee hyperextension secondary to excessive plantarflexion - Toe walking - Transfers for non-ambulatory patients when used with a proximal strap Not recommended for: - Patients who benefit from having more sagittal plane flexibility	\
SOLID AFO	19 - LONDON ORTHOTICS	Europe, United Kingdom, London	Ankle Foot Orthosis, Fixed and Hinged (AFO)		Thermoplastic	Choice of few patterns	In fabric	to treat mild weakness in the dorsiflexors when combined with significant collapse of the foot and ankle. It allows dorsiflexion and plantar flexion (toes up and toes down) but eliminates mediolateral movement.	SDR patients
SOLID AFO	24 - CHILDRENS AFOS	Europe, United Kingdom, Manchester	Dynamic plastic AFO - Dynamic Supra Malleolar Orthosis		Thermoplastic	\	in fabric	maintain a neutral heel position while also supporting the arches of the foot. Provides stability, while maintaining the position of the foot during gait to facilitate functional activities. Improves balance, Increases stability Allows natural movement of the foot and ankle Improves alignment and positioning of the foot and ankle Prevents muscle fatigue Reduces stress on the knees and hips Comfortable to wear	Moderate to severe pronation when standing and/or mobilising short distances. Hypotonia (low tone) General instability when pulling to stand and during gait Difficulty reaching developmental milestones, e.g. late in learning to advance beyond short distances.
SOLID AFO	31 - BOSCH ORTOPEDIA	Europe, Switzerland	Ortesi di scarico del tallone		Thermoplastic	None	in fabric	Scarico del tallone	Fratture del calcagno
SOLID AFO	33 - LANDRA PROSTHETICS	United States, Michigan, Southgate	Solid Ankle AFO		carbon fiber	None	\	Provides triplanar ankle/foot motion control Medial/lateral ankle stability Post-operative support/protection Knee stability during stance Mild knee hyperextension control	
SOLID AFO	47 - HI TECH BRACING	Canada, Alberta, Lethbridge	Rigid AFO		Thermoplastic	Choice of few given patterns	In fabric	provides functional alignment for flaccid (weak) extremities, resistance to mild extensor spasticity and it also provides mediolateral support for ankle instability	or people who have types of dorsal or anterior nerve injury. They are also useful in treating Charcot conditions and Dropfoot.
SOLID AFO	64 - Sure Step	United States, Indiana, South Bend	Advanced		Thermoplastic	Choice of given patterns (file)	on line	increased sagittal plane stability to help children find their ideal standing position	ideal device for pre-walkers INDICATIONS Pronation Low muscle tone (hypotonia) Joint hypermobility Delayed standing Inability to stand for p0rolonged times

Examples of research of Solid AFOs. It is possible to observe how the same type of AFO can include slightly different products by materials, number and position of straps, shapes

MULTIPLE KEYS OF RESEARCH - CASE STUDY 1

If, for example, we want to discover the manufacturers closer to our city or the one that offers a wider choice of alternative aesthetic solutions, we can set specific query on the city and on the aesthetic customization. Hereinafter another example, that investigate Italian manufacturers that are currently applying a 3D scan acquisition. We set as key options:

* Collocation in the proposed classification: Solid AFO

* Techniques of acquisition/production: From 3D Scan

* Country of the manufacture: Italy

CATHEGORY 1	CATHEGORY 2	FABRIC NAME	MADE IN	COMMERCIAL NAME	IMAGE	MATERIAL	TECHNIQUES OF PRODUCTION	ESTHETIC	PURCHASE ORDER
☑ SOLID AFO			☑ Europe, Italy				☑ From 3D scan		
SOLID AFO	TIPICAL SOLID AFO	137 - officina tecnica ortopedica catanese	Europe, Italy, Lucca	Tutore gamba piede		Thermoplastic	From 3d scan	choice of few patterns	in fabric
SOLID AFO	TIPICAL SOLID AFO	138 - orthogea	Europe, Italy, Ostuni (BR)			Thermoplastic	From 3d scan	From few examples	in fabric
SOLID AFO	TIPICAL SOLID AFO	145 - ORTOPEDICA SCALIGERA	Europe, Italy, Lugagnano di Sona (VR)	ORTESI PER ARTO INFERIORE		Thermoplastic	From 3d scan or from plaster	None	in fabric
SOLID AFO	TIPICAL SOLID AFO	145 - ORTOPEDICA SCALIGERA	Europe, Italy, Lugagnano di Sona (VR)	ORTESI PER ARTO INFERIORE		thermoplastic	From 3d scan or from plaster	From given pattern	in fabric

As we can see from this preview of the results, even if the manufacturers are applying vanguard technologies in the phase of the acquisition, the final aspects of the orthosis and the manufacture technology remain traditional.

DESIGN

MULTIPLE KEYS OF RESEARCH - CASE STUDY 1

Similarly, if we hypothesize to be American citizens and we want to explore which manufacturers allow a remote order of a customised solid AFO in thermoplastic, it contemplates the options of sending a plaster made in another medical centre or sending just a pre-filled form completed with user' measures. In this case we type:

* Collocation in the proposed classification: Solid AFO

* Country of the manufacture: America, State

* Main material or materials: thermoplastic

* Techniques of acquisition/production: From plaster plus measures

From measures

*Purchase order: online

CATHEGORY 1	CATHEGORY 2	FABRIC NAME	MADE IN	IMAGE	WEBSITE	MATERIAL	TECHNIQUES OF PRODUCTION	ESTHETIC	PURCHASE ORDER
☑ Solid AFO			☑ United States			☑ Thermo-plastic	☑ From cast plus measures ☑ From measures		
SOLID AFO	COMBO (AFO + SMO)	08 - ORTHOMERICA	United States, Florida, Orlando		http://www.orthomerica.com/product/1609140-leaf-spring	Thermoplastic	From cast plus measures (file)	Choice of given patterns (file)	ON LINE
SOLID AFO	COMBO (AFO + SMO)	08 - ORTHOMERICA	United States, Florida, Orlando		http://www.orthomerica.com/product/1609141-leaf-spring-combo	Thermoplastic	From cast plus measures (file)	Choice of given patterns (file)	ON LINE
SOLID AFO	FRAFO	56 - PEACH TREE	United States, Georgia, Monroe		http://www.peachtreefab.com/itemDetail.asp?id=103	Thermoplastic	From cast plus measures (file)	Choice of few given patterns	in fabric and online
SOLID AFO	TIPICAL SOLID AFO	64 - Sure Step	United States, Indiana, South Bend		http://www.surestep.net/advanced.php	Thermoplastic	From measures (file)	Choice of given patterns (file)	on line
SOLID AFO	TIPICAL SOLID AFO	98-19 - Cascade	United States, Washington, Ferndale		http://www.dafo.com/products/jumpstart-kangaroo/	Thermoplastic	From measures (file)	Choice of colors	on line

This is an extract of the list of manufacturers that produce the required orthosis and allows the user to remain in whatever city he lives without moving to the manufacture and to receive his AFOs at home.

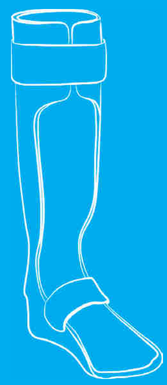
3.3.8 – Classification of AFOs

The following section is composed by single schedules on each type of Ankle Foot Orthosis. A scheme on the right define the orthosis as a Static, Dynamic or Articulated Orthosis. The blue box illustrated the general features of the type of orthosis, while the grey lateral one refers all the names of the surveyed companies that produce that type of AFO.

DESIGN

SMO

A Supra Malleous AFO is prescribed to give additional medial lateral stability in paediatric users.
Some of the SMOs can be used in an addition to the AFOs in COMBO solutions. It can be solid or hinged. It may extend to the ball of the foot or to the end of the foot depending on individual requirements. The SMO is cut over the ankle bones but the upper trim line could slightly change. The shell could be cut away at the posterior portion, over the instep or at the heel to allow the ankle to move up and down and facilitate the walking.
Number and position of the straps are variable.



Static AFO

DIAGNOSES[22]

- Pronation and/or supination
- Low muscle tone (hypotonia)
- Developmental delay
- Delay in acquiring gross motor skills
- Poor coordination or balance, triplanar instability in weight bearing
- Mild toe-walking
- Meningomyelocele
- For ensuring the correction of feet abnormalities after surgery or after the application of a circular plaster cast[23]
- Diplegia
- Hemiplegia
- Results from pci (cerebral palsy child)
- Neuro-muscular disease [24]

CONTRAINDICATIONS

- High muscle tone
- Spasticity
- Tight heel cords
- Tight peroneals
- Knee flexion or extension instability
- Severe toe-walking

DECLARED CLINICAL EFFECTS

Provides controlling forces to stabilize the foot position.
Increase balance and stability.
The thin material provides information to the nervous system through proprioception.

RESEARCH DATA:

Num. of scheduled products:
22

Num. of manufacturers:
12

Italian Manufacturers
- ITOP
- Orthogea

European Manufacturers
- Chrisofix (Sw)
- Crispin Orthotics (UK)
- Essex Orthopaedics (UK)
- Orthonova (Fin)

American NHS Manufacturers
- Cascade
- Insightful products

American Manufacturers
- D - Bar
- Morgantown
- Orthomerica
- Sure Step

Cascade Orthotics

22 *Sure Step*, http://www.surestep.net (May 2013)
23 *Chrisofix*, http://www.chrisofix.ch (May 2013)
24 *ITOP, www.itop.it* (May 2013)

ITOP

Chrisofix

Essex orthopaedics

Orthomerica

MATERIALS

SHELL: Thermoplastic, polypropylene.
INNER FINISH: padding, leather, silicone[25]

TECHNIQUES OF PRODUCTION

In Italy, as well as in Europe in general, among all the manufacturers that publish a catalogue of this type of Ankle Foot Orthosis, we can notice that most of them realize SMOs starting from a foot cast. Few examples declare the application of a laser scanner technique for an indirect survey. On the contrary in America the manufacture of SMOs can occur in three ways:

- *Plasters of children's feet are made in the same fabric* where the orthosis will be manufactured;
- *Plasters of children's feet are made in whatever clinical centre* chosen by user's parents and they are posted to the orthotic manufacture together with a pre-filled form that reports all the corrective measures that have to be applied to the cast;
- *A pre-filled schedule, is filled out on line* with all the measures of child's feet that are required. Each measure is carefully explained, sometimes even with a video, in order to put parents in condition of acquiring the rights measurements. Then the company provides a customized SMO with the reported measures and they send the final product directly to the user.

AESTHETICS

Usually Italian products have a limited range of alternatives of patterns applicable on a SMO. Little attention seems to be dedicated as well on European products, as appears on the analysed websites that even if some of them seems from the pictures that they provide different textures, they usually don' t describe in detail this topic. In America manufacturers seem to have developed a deeper sensibility on the aesthetic aspects of the SMO, giving the users the possibility of choosing their favourite patterns from a wide range of alternatives, of even creating their own pattern and choosing colours and drawings on secondary elements of the shoes, like the straps or the sole. This different approach could be motivated by an higher awareness of American companies of the role of aesthetic features in the process of psychological acceptation of the orthoses by the user. However it must be noticed that American Manufacturers work on a large scale market and that an higher attention is put in their websites and on line purchasing of products, compared to a more local European catchment area. For this reason it is predictable that in some European companies a more varied supply could even be present and it isn't illustrated on their website but directly to the users who personally go to the fabric.

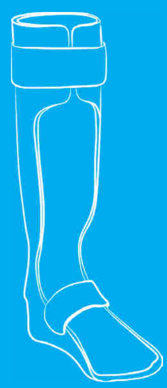
25 *Sure step,* http://www.surestep.net (May 2014)

SMO - BEBAX

Worn as night splint or during the day but the aid cannot be used when walking.

Multi-directional hinge which adapts easily for correction in all 3 spatial planes.

Tielle Camp Group is the main producer of this type of orthosis. The other products found are usually handcraft imitations of the main one.



Static AFO

DIAGNOSES

- For children with abnormal tone and soft tissue shortening secondary to neurological conditions such as cerebral palsy, multiple sclerosis, muscular dystrophy and Charcot Marie Tooth (CMT)
- Congenital forefoot deformities
- Idiopathic toe walking
- Spasticity
- Soft tissue contractures

DECLARED CLINICAL EFFECTS

- Increases passive range of motion
- Reduces deformities
- Promotes function and mobility

MATERIALS

Soft leather, lined with a polyethylene foam.

TECHNIQUES OF PRODUCTION

10 different sizes.

AESTHETIC PERSONALIZATION

None.

RESEARCH DATA:

Num. of scheduled products: 8

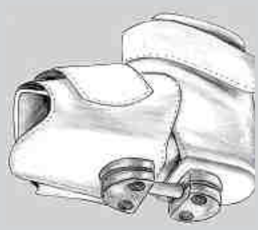
Num. of manufacturers: 8

Italian Manufacturers
- Centro Ortopedico 2000
- Centro Tecnico Ortopedico
- Ortjomedica Variolo
- Ortopedia Grassini
- Tielle Camp*

European Manufacturers:
- Basko (NL)
- Childrens Afos (UK)
- Orthonova (FI)

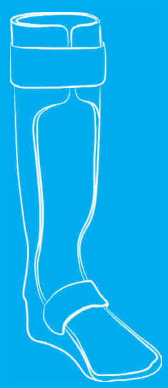
* International company

Tielle Camp



Orthonova

DESIGN



Static AFO

SOLID AFO – TIPICAL SOLID AFO

A Solid AFO is an orthosis that provides stability and immobility to the ankle. It allows for maximum stability during stance, while controlling the foot and ankle in all spatial planes throughout ambulation.[26]
It prevents plantar flexion of the foot in swing phase and improves ground clearance "by applying a system of three forces to the posterior calf, the plantar surface of the foot near the metatarsal heads and the dorsum of the foot near the ankle joint."[27]
A disadvantage of the solid AFO is its limitation of normal movement of the tibia forward over the weight bearing foot resulting in decreased ankle dorsiflexion and early heel rise in stance.
However it must be rigid to contrast the force of gravity in plantar flexion of ankles. The required resistance must be evaluated considering the high and the weight of the user that reflex proportionally on the thickness of the plastic, or eventually in the decision of inserting reinforcements in carbon fiber, glass fiber or metal fiber[28].

RESEARCH DATA:

Num. of scheduled products: 81

Num. of manufacturers: 43

Italian Manufacturers:
- Centro Ortopedico 2000
- Centro Tecnico Ortopedico
- Corpora
- ITOP
- Laboratorio Ortopedico Di Mauro
- Medical Ortopedia Vergati
- Medical Support
- Officina Ortopedica Buonumori
- Officina Tecnica Ortopedica Catanese
- Orthogea
- Orthomedica Variolo
- Ortopedia Burini
- Ortopedia Fagiani
- Ortopedia Ferranti
- Ortopedia Garibaldi
- Ortopedia Grassini
- Ortopedia Novarese
- Ortopedica Scaligera
- Progettiamo Autonomia

DIAGNOSES

- Restriction of plantarflexion or dorsiflexion
- Knee hyperextension secondary to excessive plantarflexion
- Knee flexion instability
- Quadriceps weakness
- Toe walking
- Non-ambulatory positioning of foot/ankle complex
- Post-operative positioning
- Spasticity[29]
- Diplegia
- Hemiplegia
- Myelomeningocele
- Results from PCI (child cerebral palsy)
- Neuro-muscular disease
- Duchenne Muscular Dystrophy

CONTRAINDICATIONS

- Patients who benefit from having more sagittal plane flexibility and dorsiflexion
- Patients with knee flexion instability (when proximal strap is removed)

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26 TREASURE STATE ORTHOTIC & PROSTHETIC, *Common Orthotic Devices*, Orthotic & Prosthetic Clinic, Inc, http://www.treasurestateoandp.com/orthotics.php (May 2014)

27 ORTHO WORLDS, *Floor (Ground) Reaction Orthosis (FRAFO/GRAFO)*, op. cit.

28 OCCHI E., *Le ortesi per il cammino del paraplegico*, Portale SILVA Fondazione Don Carlo Gnocchi, 2004, http://portale.siva.it/files/doc/library/a405_1_Occhi_02_TA_2004.pdf (January 2015)

29 *"Spasticity is a disorder of the body's motor system in which certain muscles are continuously contracted. This contraction causes stiffness or tightness of the muscles and may interfere with gait, movement and speech."*
Hi tech bracing, http://www.hitechbracing.com (May 2014)

- Ambulant patient with severe hypotonia

DECLARED CLINICAL EFFECTS

- Increases passive range of motion
- Reduces deformities
- Prevents ankle dorsiflexion and plantar flexion, as well as varus and valgus deviation
- Promotes function and stability
- Stabilizes the foot and ankle joint complex
- Prevents the Achille tendon from tightening

MATERIALS

Most of the products are made in thermoplastic, in polyethylene or in resins. The thickness could vary from 2 to 6 mm, depending on the function of the AFO and the age and the weight of the user it is made for.
New lines propose Solid Afo in carbon fiber.
One producer propose a solid AFO with outer coating in leather[30].
Internal paddings are in hypoallergenic cotton fiber, synthetic materials or in leather.

TECHNIQUES OF PRODUCTION

Most of Solid AFOs, either made in Italy, in Europe, or in USA, are produced starting from a plaster of the foot. Some American products allow to realize the plaster in another clinic and to send it to the manufacture together with a prefilled sheet of the required changes that have to be applied to the cast. In some cases, for simpler mold of AFOs, few direct measures, taken directly on user's foot are sufficient to proceed in the manufacturing of a Solid AFO. On the contrary very few America products offer a standard solution, in 3 or 6 sizes, for this type of orthosis. 3D laser scanner and indirect survey of the foot is increasingly been using and it probably will be used more and more in the future.
However, in my opinion, it is significant to notice how almost half of the catalogued Italian and European product do not describe on their website how the Solid AFOs are made. It is probably imputable to the consciousness that they are made from plaster tout court, but we have no information on this regard.

AESTHETIC PERSONALIZATION

The first data that emerges from the observation of the database on the aesthetic personalization of Solid AFOs, is the high percentage of Italian and European manufacturers who don't declare on their website the possibility of aesthetic personalization of lower limb orthoses, while almost all the scheduled American products are offering online a catalogue of alternative textures.

- Rizzoli Ortopedia
- Sanitar Farma Officina Ortopedica

European Manufacturers:

- Bandagist (DK)
- Bosh Ortopedia (CH)
- Children AFOs (UK)
- Crispin Orthotics (UK)
- Innovation Rehab (UK)
- London Orthotics (UK)
- Orthonova (FI)
- Orthopadie Technik (DE)
- OVL (NO)
- Proteor (FR)
- RSL STEEPER (UK)
- Teamolmed (S)

American Manufacturers:

- Braceworks
- Hi Tech Bracing
- Landra Prosthetics
- Morgantown Orthotic & Prosthetic Center
- Orthomerica
- Sure Step

American NHS Manufacturers:

- Acor
- Cascade
- Maramed
- Wheaton Brace

Cascade

30 *Teamolmed*, http://www.teamolmed.se (May 2014)


Acor Orthopaedic


Landra Prosthetics

NOTES ON DIFFERENCES AMONG THE PRODUCTS INCLUDED IN THIS CATEGORY

One of the most common differences among the analyzed products is the length of the footplate. Two are the alternatives: it is until the metatarsal heads if the orthosis is intended to promote ambulation, while it is until the toes if it is made to facilitate the standing.
"The position of the ankle indirectly affects the stability of the knee, with ankle plantar flexion providing a knee extension force and ankle dorsiflexion providing a knee flexion force".[31]
Different shapes and trim lines offer greater stability if they embrace more the ankle and the foot or are aimed at promoting an easier ambulation if they leave higher freedom of movement to the ankle. If it is necessary to resist to high tone, an ankle strap can be positioned in order to resist to the ankle force, at approximately 45°degrees. Solid Ankle Foot Orthoses can vary in the height of the boot, higher in case of knee instability, and in the number and position of the straps. Few of them use even laces instead of straps. Bearings and pads often complete the inner sole to provide the right alignment and proprioception of the foot. They could be both daily or night orthoses, in products thought for stasis or ambulation and therefore they can be wore alone or inside shoes. Different types of padding suggest to wear them with or without socks.
A particular type of Solid AFO is the ***R-Wrap Afo***. It is usually worn inside the shoes and it's characterized by a thin thermoplastic tongue that embrace completely the foot in the frontal side too, in order to guarantee a total contact design. It immobilizes foot and ankle and it is indicated for hypertonicity, spasticity, highly unstable ankle complex.[32]


Bosh Ortopedia


R-Wrap AFO


Orthomerica


Medical Ortopedia Vergati


R-Wrap AFO


Orthomerica

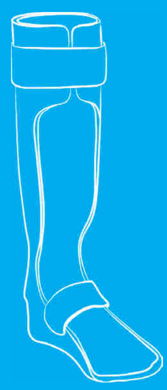
31 YINGQUI XING S., BHAGIA S. M., *Lower Limb Orthotics and Therapeutic Footwear*, op. cit.

32 GOODRICK R., NIELSEN B., *Prescribing MASS Funded Orthoses,* op. cit.

COMBO
(SOLID AFO OR LEAF SPRING + SMO)

Combo AFO is an orthosis made by the combination of two different orthoses. It has different dynamic function depending on the exact shape of the orthosis. It changes in the length of the foot and among the scheduled products these combinations were found:

- a classic Solid AFO plus a SMO, a FO or an UCBL;
- a Leaf Spring plus a SMO, in order to leave higher freedom to ankle movements compared with the Solid one;
- a Floor Reaction AFO and a SMO.



Static AFO

DIAGNOSES

- Severe pronation that cannot be managed with a single SMO
- Hypotonic feet
- Equinus foot
- Paediatric Cerebral Palsy
- Myelomeningocele
- Muscular Dystrophy
- Proprioception difficulty
- Weakness in both sagittal and coronal planes

CONTRAINDICATIONS

- Knee flexion or extension instability

DECLARED CLINICAL EFFECTS

- Assisting dorsiflexion without completely limiting plantar flexion
- Clearance in swing and positioning of the foot for heel strike
- Increases stability of the foot and ankle during the swing phase
- Facilitates independent standing

MATERIALS

Carbon fiber and/or thermoplastic. If composed by both materials, carbonfiber is used in the "leaf part", to provide more flexibility and elasticity to the orthosis, while thermoplastic is used when an higher stabilization and wrap of the foot is required. On thermoplastic orthoses, the material of the two components is thin enough to be worn one inside the other.

TECHNIQUES OF PRODUCTION

The technique of production of combo AFOs is the same of the one used to produce Solid AFOs. All the identified manufacturers start

RESEARCH DATA:

NUM. OF SCHEDULED PRODUCTS: 11

NUM. OF MANUFACTURERS: 7

EUROPEAN MANUFACTURERS:
- CHILDRENS AFOs (UK)
- CRISPIN ORTHOTICS (UK)
- TEAMOLMED (SW)

AMERICAN NHS MANUFACTURERS:
- CASCADE

AMERICAN MANUFACTURERS:
- ORTHOMERICA
- MORGANTOWN ORTHOTIC & PROSTHETIC CENTER
- SURE STEP

Sure Step

DESIGN

from a positive model of the plaster of the foot or few of them adopt CAD-CAM system of indirect survey.

AESTHETIC

Besides one manufacture among the American NHS ones, who offers a complete range of alternatives of patterns, it seems that few attention is posed in the personalization of combo AFO. However even if manufacturers do not declare on line if there is any possibility in this sense, we can reasonably suppose that it will follow the Solid Afo trend.

NOTES ON DIFFERENCES AMONG THE PRODUCTS INCLUDED IN THIS CATEGORY

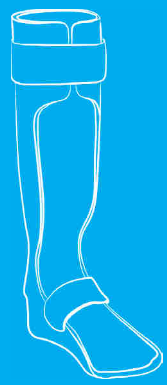
In this category were included both as orthoses with removable FO, UCBL or SMO hooked to the leaf spring as one piece orthoses but composed by these two elements stitched together.

Kinetic research

Cascade

FRAFO OR GRAFO
FLOOR OR GROUND REACTION ANKLE FOOT ORTHOSIS

"The FRAFO is designed to have contact with the entire plantar aspect of the foot from the hind foot to the distal trim line extending to the forefoot. The anterior trim line extends to the proximal third of the tibia segment". [33]



Static AFO

The first FRAFO was focused in 1980, analyzing the mechanism of floor reaction principles on a Saltiel's patellar tendon bearing orthosis.

A FRAFO "can help the child to lock his knee by causing posterior movement of the tibia during stance phase of gait. A FRAFO is fabricated by taking an impression in the same way as for a normal thermoplastic solid AFO, except that the impression is taken with the patient's foot in 5 to 10 degrees of plantarflexion."[34] It must be considered that patients that need a FRAFO usually already have a plantarflexion rigid contracture of at least 5 – 10 degrees.

DIAGNOSES

- Cerebral Palsy
- Crouch Gait
- Weak hip and knee extension
- Lack of plantarflexion strength
- Spina Bifida
- Duchenne Muscular Dystrophy

CONTRAINDICATIONS

- Recurvatum or unstable knee
- Knee extension moment compromised with external foot rotation in excess of 25 degrees.
- Presence of knee flexion contractures exceeding 15 degrees
- It must be able to get ankle to neutral or slight plantar flexion.
- Minimum of fair quadriceps strength needed if applied bilaterally (because the sound side allows the patient to know where they are placing the effected side).
- Presence of some trunk balance needed or ability to use walking side.

RESEARCH DATA:

Num. of scheduled products: 9

Num. of manufacturers: 9

American NHS Manufacturers:

- Cascade
- Ortho Rehab Designs

European Manufacturers:

- Crispin Orthotics (UK)
- Essex Orthopaedics (UK)
- London Orthotics (UK)
- Orthopadie Technik (DE)

American Manufacturers:

- Capstone Orthopedic
- Morgantown Orthotic & Prosthetic Center
- Peach Tree

Crispin Orthotics

33 DAVIS J. R., ROWAN F., DAVIS R. B., *Indications for Orthoses to Improve Gait in Children with Cerebral Palsy*, in J Am Acad Orthop Surg, 15, 2007: pp. 178 – 188, http://www.jaaos.org/content/15/3/178/F8.expansion (May 2014)

34 *Ballert Orthopedic*, http://www.ballert-op.com/muscular_dystrophy.asp (March 2013)

DESIGN

Capstone Orthopedic

DECLARED CLINICAL EFFECTS

- The design of the FRAFO is very rigid and allows for minimal movement of the ankle joint during gait.
- It is often used to try and maintain the length of the hamstring and prevent crouch gait
- It applies forces to assist the knee in extension (straightening) and in walking, stabilizing the ankle/foot complex.
- This can be an excellent alternative to a KAFO for patients with weak quadriceps. Wearing FRAFOs, he can achieve knee stability while maintaining efficiency by reducing weight and bulkiness.
- Pressure against the innervated area of skin just anterior and distal to the knee joint provides proprioceptive feedback.[35]

MATERIALS

FRAFO orthoses are usually made in thermoplastic but for older patient or for who exceeds a certain weight, a carbon fiber reinforcement is required.
New products made entirely in carbon fiber are proposed.

TECHNIQUES OF PRODUCTION

From plaster or from plaster plus measures.

AESTHETIC

These orthoses, despite their particular shape and biomechanical function are similar to Solid AFOs in material and techniques of production. Usually if a company produces FRAFOs it produced Solid AFOs as well and for this reason the possibilities of an aesthetic personalization of the orthoses are the same we already discussed about Solid AFOs.

London Orthotics

NOTES ON DIFFERENCES AMONG THE PRODUCTS INCLUDED IN THIS CATEGORY

All the products have full length plate to improve functional gait. They can or cannot have a strap depending if they are thought to be worn alone or inside the shoes.

BIOMECHANICAL FUNCTIONING

The biomechanical principle of a FRAFO is based on the Third law of Newton which asserts that for every action there is an equal and opposite reaction. The Ground Reaction Force is determined by the sum of the body weight and the acceleration of the center of mass which acts downwards and create an equal and opposite reaction

35 ORTHO WORLDS, *Floor (Ground) Reaction Orthosis (FRAFO/GRAFO)*, op. cit.

upwards[36]. The point of application of the force is on the sole of the foot and, since it passes at a distance from the center of a joint, it creates an external moment. It creates an opposing internal extension moment of the quadriceps that, if not supported by muscular strength it is supported by the orthosis. The lever of this force is equal to the length of the foot and for this reason it is important that the AFO has a foot length plate.[37] To conclude, plantarflexion plus knee extension cause a knee extension moment that help to support weak quadriceps and plantarflexor muscle.

Peach Tree

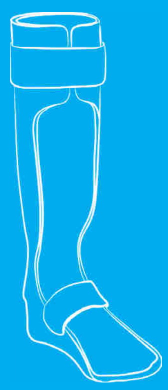
The anterior trim line (blak arrow) extends to the proximal third of the tibia segment and discharge on the ground. The Frafo plantarflex the ankle and the reaction force from the ground slips the foot through its proximal and posterior margin (red arrow).

Ortho Rehab Designs

36 The Ground Reaction Force is equal to the force discharged from the body on the ground, in the opposite direction. In standing, it coincides with the gravity. During gait, the GRF changes constantly in intensity and direction and creates external moments in the joints that need to be controlled by muscles and joints.

In 67: OCCHI E., *Le ortesi per il cammino del paraplegico.* Portale SIVA Fondazione D. Gnocchi ONLUS, 2004

37 ORTHO WORLDS, *Floor (Ground) Reaction Orthosis (FRAFO/GRAFO),* op. cit.



Static AFO

PATELLA BEARING

Patella bearing orthosis has the structure of a Solid AFO but it completely embraces the tibia in order to guarantee a better stiffening and control of lower limbs.
Padding on posterior and anterior shells is optional. It is available with various style and joints for fixed, variable and free range of motions.

RESEARCH DATA:

NUM. OF SCHEDULED PRODUCTS: 2

NUM. OF MANUFACTURERS: 2

AMERICAN NHS MANUFACTURERS:

- ACOR

AMERICAN MANUFACTURERS:

- CAPSTONE ORTHOPEDIC

Acor

DIAGNOSES

- Fracture management
- Arthritic joints
- Painful conditions of the heel
- Problems with ulceration

CONTRAINDICATIONS

- Conditions of skin and peripheral circulation which cannot tolerate the pressure of the PTB
- Unstable knee joint

DECLARED CLINICAL EFFECTS

Unload the foot-ankle complex with major weight bearing forces at the patellar tendon and tibial condyles.

MATERIALS

Thermoplastic.

TECHNIQUES OF PRODUCTION

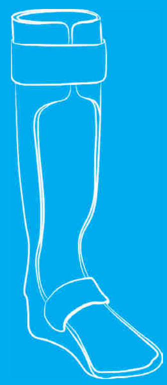
From plaster.

AESTHETIC

None.

SILICONE AFO (SAFO)

The SAFO is a total contact silicone AFO that was introduced few years ago on the market in the attempt of substituting Solid AFOs. It is reinforced along the anterior part of the of the leg and on the *dorsum* of the foot to lift the toes during the gait.[38]
Silicone AFOs, compared to traditional one, allows better fit, proprioception and freedom for challenging foot deformation. They usually extend from approximately mid-calf to the ball area of the foot. The material allows to wear the orthoses alone, indoors, for nocturnal positioning control, in the shoes or even at the bath.



Static AFO

DIAGNOSES

- Pediatric and adult patients
- Flaccid Drop Foot
- For patients who cannot undergo surgery
- Spastic Plantarflexion Control
- Hind Foot Varus or Valgus Instability
- Cerebral palsy
- Charcot Marie Tooth (CMT)
- Guillian Barre syndrome
- Polio
- Multiple sclerosis
- Hemiplegia or Diplegia
- Stroke (CVA)

DECLARED CLINICAL EFFECTS

- Encapsulates the foot and leg with greater control and comfort
- The complete wrap of the SAFO orthosis collaborates with the straps in the correct positioning of the foot
- Lifts foot toes during walking gait
- Provides a better sensory feedback and proprioception
- Improves balance
- Reduces risk of pressure areas.

MATERIALS

Silicone.

RESEARCH DATA:

Num. of scheduled products:
11

Num. of manufacturers: 8

European Manufacturers:
- Children Afos (UK)
- Crispin Orthotics (UK)
- Dorset Orthopaedic (UK)
- London Orthotics (UK)
- Orthonova (FI)
- Sophiesminde (NO)
- Teamolmed (SE)

American Manufacturers:
- Orthomerica

Childrens Afos

38 HUGHES M., *The Silicone Ankle Foot Orthosis (SAFO), a New Generation in Orthotics*, Dorset Orthopaedic Co Lts, in *Journal of Prosthetics and Orthotics* (JPO), 2006, http://www.oandp.org/publications/jop/2006/2006-34.asp (May 2013)

The paper discusses the effects and patients feedbacks after the use of Silicone Afos for an year of trial period. The research was made with the help of five young Cerebral Palsy patients, from 7 to 16 years, through Yeovil NHS Trust in UK.

Orthomerica

TECHNIQUES OF PRODUCTION

Since the limited number of cases identified who produce Silicone AFO, it difficult to elaborate a reliable statistical data. However we can see that they are usually made from plaster, as well as thermoplastic AFOs, with someone who elaborates them starting simply from some direct measures or thanks to the application of new technologies like scanner 3D. Scientific literature reports that usually the positive mold of a silicone AFO should be created by a negative cast on which a slight dorsiflexion of 5 degrees was impressed.

AESTHETIC

As for thermoplastic AFO we can detect the trend of a higher sensitisation of England and American Manufacturers on aesthetic personalization of foot orthoses, while European manufacturers have a limited choice of options.

Teamolmed

NOTES ON DIFFERENCES AMONG THE PRODUCTS INCLUDED IN THIS CATEGORY

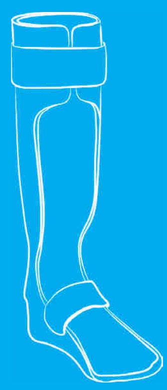
It could be made with heat adjustable plastic for a better customization of the product.
Bi-valved and tongue options are available. It could open along the back section of the leg and at the heel.
They can differ one from the other for the number of straps, colours and reinforcements.
All the scheduled manufacturers that produce silicone AFOs I found were settled in UK, Nordic Countries or USA.

Dorset Orthopaedic

DESIGN

DORSAL AFO

Dorsal AFOs are prescribed to control equinus foot deformity. The most common orthosis of this category is available on the mass market and it is designed mainly to cure temporary injuries than severe incurable diseases or deformations. However users' response on this type of orthosis assert that they are the most comfortable among the splints prescribed to counteract equinus deformity.



Static AFO

Common Ankle Foot Orthoses are not always well tolerated by patients, due to their compression of the calf muscles and the sole which can cause annoying stimulation and skin compressions.

Moreover, in ambulant patients, they limit the possibility of anterior translation of the tibia in the sagittal plane, in phase of stance. This causes a strong interference in the dynamic function of the foot and a resulting significant energy consumption. Dorsal AFO avoids most of these problems. Night Dorsal AFO limits the contact with the skin and it is less bulky, while daily dorsal AFO limits skin stimulations and allows a better stability to the ankle and a more fluid dynamic gait.

DIAGNOSES

- Ankle injury
- Plantar fasciitis

DECLARED CLINICAL EFFECTS

- Hold the foot in the proper position or of dorsiflexion
- Passive stretch to the plantar fascia and Achilles tendon
- Foot drop
- Toe off

MATERIALS

Foam padding, rubber and plastic.

TECHNIQUES OF PRODUCTION

Dorsal AFOs commonly in commerce usually don't require particular attention in the customization of the shape of the orthosis. For this reason all the analyzed products were made in standard sizes (from unique to 4 different sizes) among which the user can choose depending only on the dimension of the feet lenght.

RESEARCH DATA:

Num. of scheduled products: 15

Num. of manufacturers: 15

Italian Manufacturers:

- Centro Ortopedico 2000
- DJO*
- Ortopedia Sanitaria
- Ossur*
- Tielle Camp*

European Manufacturers:

- Night splints.com

American NHS Manufacturers:

- Footsmart
- Insightful products
- Patterson (DJO*)

American Manufacturers:

- Cascade Orthotics
- Orthotic Solutions
- Rehabmart

* Internationa company

Ortopedia Sanitaria

DESIGN

DJO Global

Alteor

Orthotic Solutions

Foot-up. Orthotic Solutions

Patterson

AESTHETIC

The standard nature of the orthosis reflects in a low attention on esthetic features. Standard dorsal AFOs are usually sell in a unique aspect, that is not possible to personalize. In few standard dorsal AFOs is possible to choose among two colours.

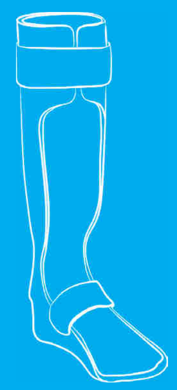
NOTES ON DIFFERENCES AMONG THE PRODUCTS INCLUDED IN THIS CATEGORY

Depending on inner padding, dorsal AFO can be suggested to be worn barefooted or with socks. The most sophisticated ones present the possibility of gradually adjust the grade of dorsiflexion thanks to adjustable wraps, or thanks to an elastic put on the front of the foot

A particular type of dorsal Afo is the "*Foot up*". It is a brace at the ankle in leather or elastic tissue, provided with a rubber band. This one is first donned at the ankle and then it is attached at the shoes' laces. The longer the rubber band sits on the shoe, the more lift the toes. A variant of this Foot up is the one that instead of the ankle brace is provided by an orthosis that embrace the lower limb at the ankle and under the knee to guarantee a better stability.

PADDED BOOT

Padded boots are standard AFOs that extends from the top of the calf to the end of the foot. Most of them are considered as night splints, or as splints for minimal household ambulation. Their use is recommended not only in case of severe diseases but even for injuries or post-surgery recovery periods.
Adjustable straps to ensure the right amount of stretching.



Static AFO

DIAGNOSES

- Plantar fasciities
- Heel spur
- Toe walking
- Drop foot
- Altered positioning of the foot
- Different neurological conditions, including cerebral palsy, multiple sclerosis and stroke, muscular dystrophy, Charcot Marie Tooth
- Range of Motions dysfunctions

DECLARED CLINICAL EFFECTS

- Applies a controlled amount of dorsiflexion
- Stretch the plantar fascia, the calf and Achilles tendon

MATERIALS

Padded boots are mainly composed by a plastic outer structure with a foam inner layer or by a thermoplastic skeleton but completely coated with a soft padding.

TECHNIQUES OF PRODUCTION

All of them are built in standard sizes, from unique to a maximum of 6 Sizes.
Few of them, the ones made in low thermoplastic, allow the user to cut the sole with scissors to customize them on their feet's length.

AESTHETIC

The hospital and cumbersome aspect of the Padded Boot AFO and its use, mainly during the night, produce very little attention on esthetic aspects. Almost all of them are proposed by the manufacturers in one single version, only an American brand allows to choose the material of the external padding and a Swedish one proposes them in two colours.

RESEARCH DATA:

Num. of scheduled products: 36

Num. of manufacturers: 24

Italian Manufacturers:

- Centro Ortopedico 2000 srl
- Eumedica
- ITOP
- Ossur*
- Otto bock *

European Manufacturers:

- Alteor (FR)
- Childrens AFOs (UK)
- Chrisofix (CH)
- Crispin Orthotics (UK)
- Farmaortopedia Penalver (ES)
- Innovative Rehab (UK)
- Nightsplints.com
- Nordicare (SW)
- Orliman (ES)
- Orthonova (FI)

American NHS Manufacturers:

- Footsmart
- Patterson
- Swede-o

American Manufacturers:

- ACP
- Heelspurs
- Hi Tech Bracing
- Landra Prosthetics
- Orthotic Solutions
- Rehabmart

* Internationa company

DESIGN


Rehabmart

NOTES ON DIFFERENCES AMONG THE PRODUCTS INCLUDED IN THIS CATEGORY

Three-quarters of the examined products presented side straps to adjust ankle dorsiflexion.
Few of them are equipped with a system to control varus and valgus foot.
One of the products presents a mechanical piston on the back for gradual control of dorsiflexion.
Another product is provided with an external removable sole to use it in a double version, during the night or, hinging the sole, for minimal household ambulation.


Centro Ortopedico 2000

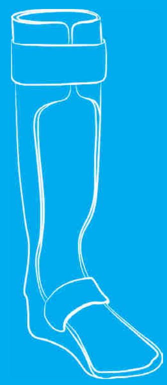

Orliman


Nightsplints.com

CROW WALKER

CHARCOT RESTRAINT ORTHOTIC WALKER

A CROW Walker[39] is a walker designed for patients with ulcers on the plantar aspect of the foot and for Charcot Marie Tooth disease or fractures.



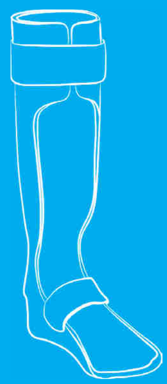
Static AFO

It consists of a fully enclosed ankle/foot orthosis with an outer shell made in plastic or fiberglass and a customized inner boot for unique conditions made with the positive of a cast. It offers maximum control of motion/volume with unloading the weight. The CROW supports the entire foot. Charcot neuroarthropathy (CN) causes deformities to the feet that could provoke ulcers which can develop into infections. The function of the boot is to distribute equally pressure throughout the leg and the foot.

Crow Walker
Landra Prosthetics

AIR SPLINT

The air splint AFO is an orthosis made of washable PVC divided in sectors. Thanks to the regulation of air pressure it provides tension on the lower limb and on the foot to stretches muscles.

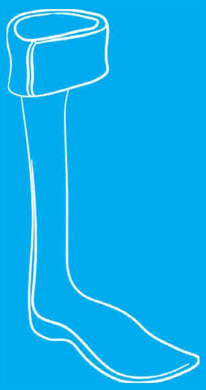


Static AFO

It is indicated to treat abnormal muscle tone and foot drop, neurological disabilities or cerebral palsy. It inhibits spasticity and reduces oedema. It doesn't require a perfect fit with the foot's shape of the users and for this reason it is produced in few sizes, even only two, for children and adults.

Air Splint
Childrens Afos

39 AMERICAN ORTHOPAEDIC FOOT & ANKLE SOCIETY, *CROW – Charcot Restraint Orthotic Walker*, http://www.aofas.org/footcaremd/treatments/Pages/CROW---Charcot-Restraint-Orthotic-Walker.aspx (May 2013)



Dynamic AFO

CONVENTIONAL AFO

The Conventional AFO is made by one or two metal struts which are locked into the footwear. The strut/s are fixed with a metal band which encompass the calf and are covered with an adjustable padded which extends around the front leg. It is indicated when a custom plastic device would be detrimental to the patient.[40]

Conventional AFO can be made with one strut on the back of the heel or two lateral struts. They can have another brace around the ankle for a better positioning of the lower limb. The insert of an ankle joint in the stirrups controls directly desired range of motions of plantar flexion and dorsiflexion.

RESEARCH DATA:

Num. of scheduled products: 7

Num. of manufacturers: 6

Italian Manufacturers:
- Centro Ortopedico 2000

European Manufacturers:
- Crispin Orthotics (UK)
- Orthonova (FI)

American Manufacturers:
- Capstone Orthopedic
- Clinical Orthotic Consultants
- Peach Tree

Centro Ortopedico 2000

Capstone Orthopedic

DIAGNOSES

- Recommended when the thermoplastic AFO is not indicated.
- Fluctuating oedema
- Paralysis of backbone extensor muscles
- Neurological diseases

DECLARED CLINICAL EFFECTS

The stirrups lifts the foot up in phase of gait and stimulates dorsiflexion.

It allows the patient to step forward without swiping the tips.

MATERIALS

Metal struts with different padding in leather, foam, elastic tissue.

TECHNIQUES OF PRODUCTION

It is usually made in a really handcraft way. The unique size of the stirrups is customized on measures of user's lower limbs. They have a really hand craft production and usually each manufacture produced them in a single version.

AESTHETIC

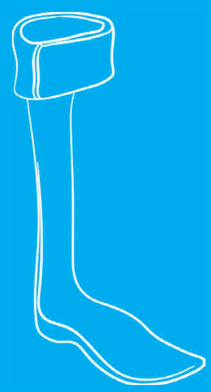
The cosmesis of a conventional AFO is probably its weaker aspect. Moreover their use make the changing of the shoes quite difficult.

40 TREASURE STATE ORTHOTIC & PROSTHETIC, *Common Orthotic Devices,* op. cit.

LEAF SPRING

Leaf Spring AFO extends from the upper calf to underneath the foot. Usually the calf section is secured with a Velcro strap.

It is made in thin materials because it is designed to be worn inside shoes. The word “spring” is related with the biomechanical function of the orthosis of stimulating an elastic reaction to the legs force during the gait. The cut of the plastic at the heel and at metatarsal heads improve proprioception, thereby restoring a degree of sensory feedback to the patient.



Dynamic AFO

Similarly, some orthoses present an open heel cut that allows patients to wear any shoes comfortably without heel contact. These are called **Kinesceptic Ankle Foot Orthosis**[41] and are designed specifically for patients with Myotonic Dystrophy or Charcot Marie Tooth Syndrome.

DIAGNOSES

- Dropfoot
- Diabetes
- Abnormal tone
- Muscle weakness
- Lack of medial/lateral control or stability at the ankle
- Soft tissue contractures
- Peripheral Nerve Trauma
- Talofibulare anterior ligament injuries at the ankle
- Myelomeningocele
- Multiple Sclerosis
- Cerebral Palsy
- Cerebrovascular Accident (CVA or Stroke)
- Polyomelitis
- Spinal Stenosis
- Spastic Hemiplegia and Diplegia

CONTRAINDICATIONS

- Patients requiring control of dorsiflexion
- Footplate with very little medial/lateral support

DECLARED CLINICAL EFFECTS

- Control of the foot drop

41 BERARDONI G., *New Orthotic Applications for Neuromuscular Disease*, http://www.ballert-op.com/index.php/articles/new-orthotic-applications-for-neuromuscular-disease-part-1

An article written by the CO-Founder of Ballert Orthopedic Manufacture that analyses several different types of orthoses and describe how he adapted orthotics to the needs of patients with neuromuscular disease.

RESEARCH DATA:

Num. of scheduled products: 41

Num. of manufacturers: 33

Italian Manufacturers:

- Ausilium
- Centro Ortopedico 2000
- Centro Tecnico Ortopedico
- Dual Sanity – Dr. Gibaud*
- Flaminio
- ITOP
- Medical Support
- Ortopedia Fagiani
- Ortopedia Michelotti
- Ortopedia Novarese
- Ortopedica Scaligera
- Otto bock* - Italia
- Rizzoli Ortopedia
- RO+TEN*
- Sanitar Farma Officina Ortopedica

European Manufacturers:

- Alteor (FR)
- Children Afos (UK)
- Crispin Orthotics (UK)
- Essex Orthopaedics (UK)
- Innovation Rehab (UK)
- Nordicare (SW)
- Orthonova (FI)
- Ortopadie Technik (DE)
- OSSUR * (IS)

American NHS Manufacturers:

- ACOR
- Maramed
- Wheaton Brace

DESIGN

American Manufacturers:
- Capstone Orthopedic
- Cascade Orthotics
- Clinical Orthotic Consultants
- Hi Tech bracing
- Kinetic research
- Landra Prosthetics

* Internationa company

ITOP

Molla di Codivilla
Medical Support

- Provides foot and ankle stability
- Prevents soft tissue shortening in children with spastic hemiplegia and diplegia
- Allows a smoother gait pattern by lifting the foot up

MATERIALS

Thermoplastic. Carbon fiber.
Due to the properties and machinability of carbon fiber, the shapes of these orthoses can be much more varied than thermoplastic AFOs.
Inner lining can be made of leather, fabric or synthetic hypoallergenic materials.

TECHNIQUES OF PRODUCTION

Many of the thermoplastic leaf spring orthoses are made with a thin and flexible foot section, easy to trim with a pair of scissor, after heated.

AESTHETIC

Compared with a Solid AFO, Leaf Spring AFOs are usually made as well in thermoplastic or carbon fibre but it emerges a lower attention in the possibilities of aesthetic personalization of the orthoses. Only few manufacturers offer more than one version of the same leaf spring AFO of among which you can choose following users' aesthetic tastes.

NOTES ON DIFFERENCES AMONG THE PRODUCTS INCLUDED IN THIS CATEGORY

It usually extends for the full footplate, but sometimes it stops at the ball of the foot to encourage a better proprioception.

Kinesceptic Leaf Spring Orthosis
Dual Sanity Dr Gibaud

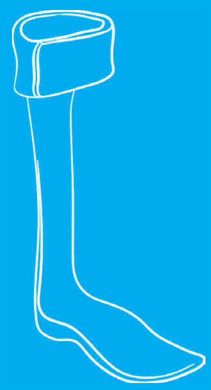
Ro+Ten

Landra Prosthetics

LEAF SPRING – WALK ON

Regarding the overall aspect and its mechanical principle, the Walk-On AFO behaves like a common Leaf Spring AFO.

However the carbon fiber material allows thigh profiles and an higher energy in return during gait. Walk-On orthosis is a patent of Otto Bock, but it is delivered worldwide and has been replicated similarly by many other manufacturers.



Dynamic AFO

DIAGNOSES

- Foot drop with functional plantar flexion strength
- Knee hyperextension control
- Weak dorsiflexion
- Mild Achilles tendon tightness – equinovarus
- Children with neurological conditions as cerebral palsy, stroke, and multiple sclerosis
- Children with hemiplegia, diplegia

CONTRAINDICATIONS

- Severe ankle foot deformities
- Severe spasticity
- Fluctuation oedema
- M-L instability
- Extreme activity

DECLARED CLINICAL EFFECTS

- Encourages a more upright standing position and improves the quality of the gait pattern
- Limits plantar flexion
- Offers high energy return
- Reduces involuntary movements
- Reduces walking efforts
- Provides toe pick-up

MATERIALS

Carbon fiber.

TECHNIQUES OF PRODUCTION

Most of the Walk-On AFO has been made in standard sizes, from 3 to 8 sizes. However some more sophisticated products were manufactured starting from measures, from plaster or even from 3D scan.

RESEARCH DATA:

Num. of scheduled products: 22

Num. of manufacturers: 17

Italian Manufacturers:

- Centro Ortopedico 2000
- ITOP
- Ortopedia Fagiani
- Ortopedia Michelotti
- Ortopedia Scaligera

European Manufacturers:

- Bandagist (DK)
- Bosh Ortopedia (CH)
- Childrens Afos (UK)
- Fior & Gents (DE)
- Innovation Rehab (UK)
- Orthonova (FI)
- Ossur* (IS)
- Proteor (FR)

American Manufacturers:

- Hi Tech Bracing
- Kinetic research
- Morgantown
- Otto bock*

* Internationa company

Ossur

DESIGN

Otto Bock

AESTHETIC

Very little attention is put on aesthetic possibility of personalizing Walk-On orthoses. This ascertainment is probably due to carbon fiber material, as well as to the standardization of the making process of the product, as to the tight profile of the orthosis, which expresses its features by its simple shape.

NOTES ON DIFFERENCES AMONG THE PRODUCTS INCLUDED IN THIS CATEGORY

Few differences may be noticed between analysed products. They can have a single spring by one side or two springs that embrace better the ankle. If two springs are present, they start from the bottom of the arch of the foot. On the contrary, if the AFO is made by a single spring, it can starts from the middle of the sole or from the bottom of the heel, on the back side.

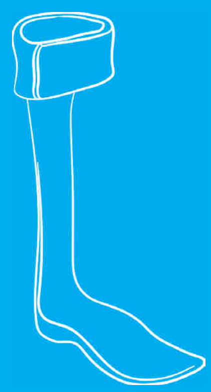
Walk On
Otto Bock

Childrens Afos

LIFT SPRING

Lift Spring AFO is a standard low profile and lightweight orthosis with a thin and flexible foot plate that fits well in shoes. The posterior half of the AFO extends from the top of the calf to underneath the foot. The calf section is secured with a Velcro strap.

Some manufacturers define it as ***Molla di Codivilla***, for its action as a spring. Another type of lift spring orthosis is called ***ENGEN***[42] and it is characterized by a corrugated back and by a thickening of the material along its lines of force.



Dynamic AFO

DIAGNOSES

- Neurological conditions
- Foot drop
- Equinus foot
- Peroneal paralysis

CONTRAINDICATIONS

- The orthosis can be used only if the ankle is sideway stable.

DECLARED CLINICAL EFFECTS

- It provides a lifting force to the foot as the leg swings through during walking to prevent catching of the toes on the ground which can cause tripping.
- It maintains the foot in desired angle of dorsiflexion

MATERIALS

Polypropylene or carbon-reinforced polypropylene. Injection moulded polypropylene allows different thicknesses throughout the orthosis, thicker on the vertical aspect for rigidity, thinner at the footplate for an easier trimming, comfort and flexibility.

TECHNIQUES OF PRODUCTION

Almost all the products were realized in thin polypropylene that could be easily trimmed to adapt to the feet's length.

RESEARCH DATA:

Num. of scheduled products: 37

Num. of manufacturers: 26

Italian Manufacturers:

- Ausilium
- Centro Ortopedico 2000 SRL
- Centro tecnico ortopedico
- Corpora
- FGP*
- Flaminio
- Lab. Ortopedico Di Mauro
- Mapis
- Medical Support
- Officina Tecnica Ortopedica Catanese
- Ortopedia Grassini
- Ortopedia Sanitaria
- RO+TEN*
- Tenortho*
- TIELLE*

European Manufacturers:

- Alteor (FR)
- Basko (NL)
- Bosh Orthopedia (CH)
- Childrens Afos (UK)
- Crispin Orthotics (UK)
- Farmatopedia Penalver (ES)
- Innovation Rehab (UK)
- Nordicare (SW)
- Orthonova (FI)
- Ossur* (IS)
- RSLSTEEPER (UK)

* Internationa company

42 BENVENUTI E., *Analisi comparative dell'efficacia delle ortesi AFO: guida alla scelta e alla prescrizione*, Tesi finale presso il Corso di perfezionamento "Tecnologie per l'autonomia", A.A. 2001-2002, Fondazione Don Carlo Gnocchi, Università Cattolica del Sacro Cuore, http://portale.siva.it/files/2002_benvenuti.pdf (March 2013)

DESIGN

Officina Tecnica
Ortopedica Catanese

Bosh Ortopedia

OSSUR

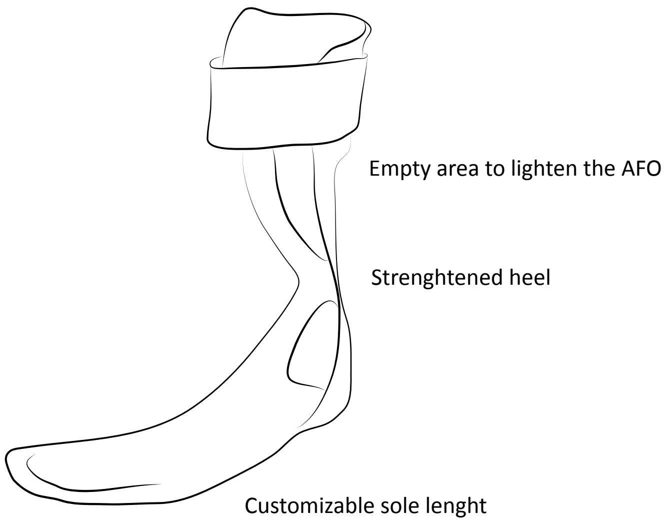
Innovation Rehab

AESTHETIC

This type of AFO is maybe one of the less sophisticated from an aesthetic point of view, in particular regarding the possibility of choosing different colours, models or patterns. This element could be explicated considering this orthosis like a very “standard device”, that you can buy, even online, in standard size and then it has to be heated and trimmed to adapt to user’s measures.

NOTES ON DIFFERENCES AMONG THE PRODUCTS INCLUDED IN THIS CATEGORY

Lift Spring Orthoses the orthosis can have a predefined angle of dorsiflexion or plantarflexion to prevent dropfoot or to adapt to fixed ankle retractions.

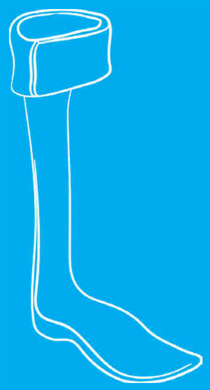


DESIGN

SPIRAL AFO

The name Spiral AFO is given by its characteristic shape.

The Spiral AFO embraces the lower limb and consists in a shoe insert and a spiral that goes around the back of the leg, then round the front, to finish with a calf band, usually made in Velcro.



Dynamic AFO

DIAGNOSES

- Equinus foot
- Valgus pronation or varus supination
- Pediatric Cerebral Palsy (Dyplegia, Hemiplegia, Quadriplegia)
- Myelomeningocele
- Spasticity of the foot

DECLARED CLINICAL EFFECTS

- Limits the range of movement of the ankle joint in all directions.
- Supports the foot and ankle when standing
- Stabilizes the ankle-foot complex in three spatial planes: frontal, sagittal and transversal.
- Transmits ground pressures to higher skin and provides proprioceptive cues[43].

MATERIALS

Polypropylene or carbonfiber.
Inner padding in foam or soft pads.

TECHNIQUES OF PRODUCTION

All the scheduled manufacturers who declares the technique of fabrication of Spiral AFOs, produce them starting from a plaster and then creating a positive model. Spiral AFOs have to be carefully built "on the leg" on the user. It's a quite demanding process and for this reason it requires high experience and they are hard to find.

AESTHETIC

The possibility of esthetical personalization of a Spiral AFOs is reasonably the same of a thermoplastic solid AFO, since the process

43 PEDIATRIC ORTHOPEDIC, *Walking AFO,* http://www.pediatricorthopedic.com/Topics/Walking-AFOs/Braces/braces.html (March 2013)

RESEARCH DATA:

Num. of scheduled products: 11

Num. of manufacturers: 9

Italian Manufacturers:

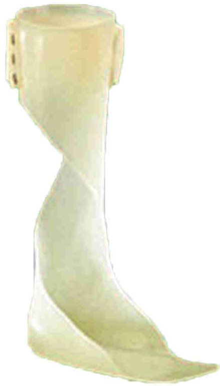
- Centro Ortopedico 2000
- Centro Ortopedico Essedi
- Flaminio
- ITOP
- Medical Ortopedia Vergati
- Ortopedia Michelotti
- Rizzoli ortopedia
- Sanitar Farma Officina Ortopedica

European Manufacturers:

- Childrens Afos (UK)

Rizzoli

Pediatric Orthopedics



Sanitarfarma

Childrens Afos

to produce them are the same. In particular most of the identified Italian manufacturers offer the possibility of a limited range of alternatives between few given patterns that could be applied on the orthoses.

NOTES ON DIFFERENCES AMONG THE PRODUCTS INCLUDED IN THIS CATEGORY

Spiral AFOs can be made with a foot length plate, to improve the standing, or with a sole aligned with metatarsal heads to improve proprioception and agility in the gait. It could be an "*anti-varus supination AFO*", if the spiral of the AFO donned at the right leg runs in clockwise or "*anti-valgus pronation afo*" if the spiral of the orthosis of the dx leg runs in counterclockwise.
Another element which differentiates spiral AFOs is the angle between the leg and the sole, that can vary depending on the disease and on specific necessities of the user. It extends from less than 90°, for example for myelingocele's patients, to encourage equilibrium in standing and in gait, to more than 90°, as for pediatric cerebral palsy's patients, to compensate retractions and equinus feet.
The so called Double Spiral AFOs are characterized by the possibility of a separate control of varus and valgus deformities.
Otherwise in the Hemi-Spiral AFO the spiral starts on the lateral side of the shoe insert, passes up the posterior leg and terminates at the medial tibia, at the attach of the calf band. This type of Spiral AFO is used for achieving better control of equinovarus deformation[44].

44 YINGQUI XING S., BHAGIA S. M., *Lower Limb Orthotics and Therapeutic Footwear*, Medscape Reference, op. cit.

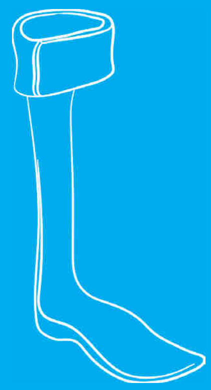
DESIGN

TOE - OFF

In the cathegory of Toe – Off Orthoses three different types of orthoses were included: Ypsilon Orthosis, Toe-Off, Blue Rocker.

Walking AFOs in carbon fiber, they can be fitted together with a SMO in case of spasticity.

Some products have, besides the possibility of trimming the feet's sole, even the chance of adjusting the height of the front part.



Dynamic AFO

- ***Ypsilon Orthosis*** among the Toe Off Orthoses is the one that offers greater flexibility and dynamic assistance to the ankle. It controls dorsi-plantar flexion but at the same time allows a natural ankle movement. The "Y" shape provides better fixation of the tibia, giving freedom to the tibial crest. Ypsilon can be used by people with foot drop but only if the ankle and the tibia are stable.

- ***Toe – Off*** balances the Ypsilon and Blue Rocker effects, allowing movements but giving medium support to the ankle. The design absorbs energy at heel strike and returns it at toe-off. ToeOFF is a better option compared with Ypsilon Ortosis if the ankle is unstable.

- ***Blue Rocker*** is the stronger AFO of this category. It gives the highest stability to the ankle and it guarantees a better balance in stance and gait, especially in patients with weak quadriceps. It is usually recommended to patients who have other disease besides the equinus foot.

DIAGNOSES

- Foot Drop
- Clubfoot from neurological disorder: stroke, polio, multiple sclerosis, spinal cord strains
- Clubfoot from neuromuscular disorder: cerebral palsy, muscular dystrophy, myelingocele
- Medium ankle instability neuromuscular deficit or traumatic conditions
- Spasticity

CONTRAINDICATIONS

- Gross deformities of the foot
- Acute edema
- Moderate to severe spasticity
- Contracture of anterior and posterior tibial muscle cannot be solved with a simple device posture

RESEARCH DATA:

Num. of scheduled products: 39
Num. of manufacturers: 25

Italian NHS Manufacturers

- Centro Ortopedico 2000
- Centro Tecnico Ortopedico
- Flaminio
- Medical Ortopedia Vergati
- Oddicina Ortopedica Buonumori
- Ortopedia Grassini
- Ortopedia Michelotti
- Ortopedia Sanitaria
- Ro+Ten*
- Tielle Camp*

American NHS Manufacturers

- Allard

European Manufacturers

- Bandagist (DK)
- Basko* (NE)
- Bosh Ortopedia (CH)
- Camp Scandinavia (SE)
- Childrens Afos (UK)
- Nordicare (SE)
- Orthonova (FI)
- Ossur* (IS)

American Manufacturers

- ACP
- Cascade Orthotics
- Hi Tech Bracing
- Kinetic Research
- Landra Prosthetics
- Orthotic Solutions
- Ossur* (IS)

* Internationa company

DESIGN

Ypsilon
Tielle Camp

DECLARED CLINICAL EFFECTS

- Control of Foot Drop
- Provides foot and ankle stability
- Enhances a dynamic response in gait
- Provides support and stability of the lower leg

MATERIALS

Toe-Off AFOs are made in Carbon Fiber. This material has the property of reflecting energy during gait and returns it to lift feet toes.

TECHNIQUES OF PRODUCTION

Most of the Toe-Off AFOs are made in standard measures, more or less detailed. If the sole is thin, they can be easily heated and trimmed with scissors to suit to user's feet length. More sophisticated products are shaped on a plaster or a 3D scan of user's limbs.

AESTHETIC

Toe_Off orthoses are usually made in Carbon Fiber without any possibility of an aesthetic customization. Among scheduled companies, only a Scandinavian manufacture pads Toe-Off orthoses with foam and coloured tissues with different patterns.

Toe-Off
Tielle Camp

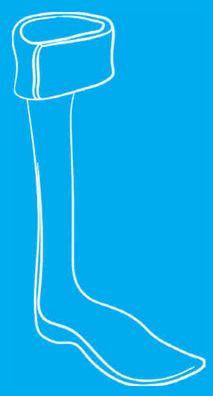
Camp Scandinavia

Stability Scale of the ToeOFF family of products - *Allard USA*

Blue-Rocker
Tielle Camp

GAUNTLET

Gauntlet AFO are tied orthoses. Their resistance and ankle support vary depending on the material of inner padding. However since they provide a lower profile of resistance and aren't indicated for muscular dystrophy patients, my research on this kind of AFO was made only marginally.
The gauntlet is usually made with a sole that extends until the standard metatarsal length but it can have a fool length sole as well. Some differences in the system can be noticed. Some orthoses designed to be worn inside the shoes present a cut at the heel in order to increase proprioception.



Dynamic AFO

DIAGNOSES

- Tendinitis of the ankle
- Ankle Sprains
- Posterior Tibial Tendon Dysfunction PTTD
- Charcot foot
- Equinus or drop foot
- Pes planus Talocalcaneal valgus
- Tibialis Tendonitis
- Subtalar, midtarsal ankle trauma
- Ankle arthritis and degenerative joint disease

CONTRAINDICATIONS

Offers less support and stability than other options such as CROW walker or Solid AFOs.

DECLARED CLINICAL EFFECTS

- Offers medium firmness to the ankle
- Increased stability for varum or valgum at the knee
- Night time contracture control

MATERIALS

Gauntlet AFOs are usually made in leather, elastic materials and synthetic fibers. More structured ones are composed by a thin polypropylene inner structure covered with leather or by elastic tissue, polyester.

TECHNIQUES OF PRODUCTION

Gauntlet AFOs are usually made in standard sizes, calibrated only on feet lengths since the softness of the fabric allows good adaptability to most of users' feet shapes. Only in case of a thermoplastic inner shell, the orthosis is made starting by positive mold of the plaster.

RESEARCH DATA:

Num. of scheduled products: 9

Num. of manufacturers: 9

Italian Manufacturers:

- Ortopedia Sanitaria
- Centro Tecnico Ortopedico
- Tielle Camp*
- Dual Sanity Dr Gibaud

American NHS Manufacturers:

- ACOR
- Insightful Products

American Manufacturers:

- Ballert Orthopedic
- Landra Prosthetics
- Capstone Orthopedic

* Internationa company

Ballert Orthopedic

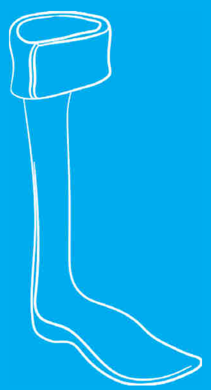
Landra Prosthetics

AESTHETIC

Standard products don't provide any possibility of personalization. Few manufacturers offers the possibility of choosing among few different colours (2 – 3 alternatives).

Insightful Products

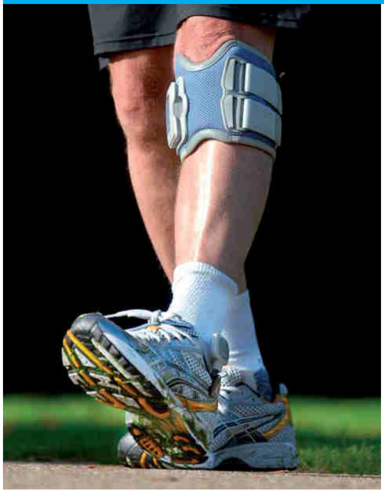
Centro Tecnico Ortopedico



Dynamic AFO

ELECTRICAL STIMULATOR

The electrical stimulator is called ***"Neural Prosthesis"*** and it uses a tilt sensor and an accelerometer to determine the position of the lower leg during gait. The device is carefully customized on each user in order to proper stimulate dorsiflexor muscles in patients affected by foot drop.[45] The aimed result of the use of an electric stimulator is a more natural walking pattern combined with enhanced stability and confidence.[46]



Electrical Stimulator. Hi Tech Bracing

It could be recommended for cerebrovascular accident, multiple sclerosis, traumatic brain injury, cerebral palsy and other neurological disorders. But it is contraindicated for people with muscular diseases, because it stresses the muscles, as well as for people with nerve diseases or with pacemakers, fractures and cancer in the legs.

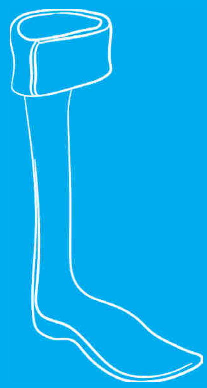
45 *Cascade Orthotics,* http://www.cascadeorthotics.com/html/walkaide.html (May 2014)

46 *Bioness,* http://www.bioness.com/Home.php (May 2014)

DESIGN

ELASTIC SOCK

This product is maybe one of the most used aids to treat plantar fasciities during the day or at night. The sock gently stretches the Plantar Fascia, Achilles Tendon and Calf Muscle.



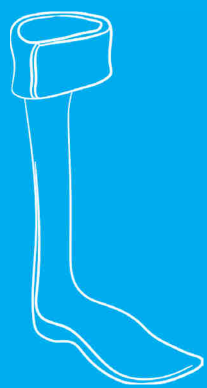
Dynamic AFO

It positions the ankle, assists dorsiflexion and improves the ankle range of movement in gait. It doesn't require any particular attention in the customization of the product and it is usually sold in any orthopedic shop. However since it's low resistance to severe deformation, it isn't treated in details in this analysis. It can be made in elastic tissue, flexible, foam lined nylon and spandex material.

Elastic Sock
Hi Tech Bracing

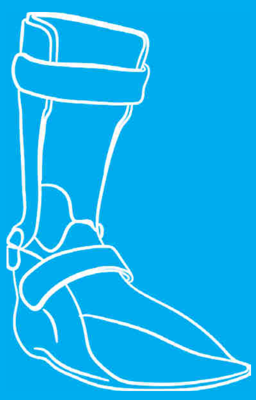
PERO-MED

PERO-MED orthosis is made in plastic, it's really light and cosmetic. It helps to stabilize the ankle, providing better balance during gait. It can be recommended in case of light spasticity.



Dynamic AFO

Elastic sock
Childrens Afos



Articulated AFO

HINGED AFO

"There are many variations of the hinged AFO which incorporate a variety of hinges at the ankle joint to allow free motion or assist motion. Some hinges have a 'control arc' to limit the degrees of movement at the ankle joint."[47] A simple hinge, if the stirrup has a completely circular stop, allows the foot to dorsiflex freely while controlling plantarflexion and lateral movements of the ankle and foot. By adding an adjustable motion stop, the amount of plantar-flexion or dorsiflexion can be monitored.

RESEARCH DATA:

Num. of scheduled products: 89

Num. of manufacturers: 43

Italian Manufacturers:

- Biomedica su misura
- Centro Ortopedia Bennica Carmelina
- Centro Ortopedico 2000 srl
- Centro Tecnico Ortopedico
- Corpora
- ITOP
- Officina Ortopedica Buonumori
- Officina tecnica ortopedica catanese
- Orthogea
- Orthomedica Variolo
- Ortopedia Ferranti
- Ortopedia Garibaldi
- Ortopedia Novarese
- Ortopedica Scaligera
- Rizzoli ortopedia
- Sanitar Farma Officina Ortopedica

European Manufacturers:

- Bandagist (DK)
- Bosh Ortopedia (CH)
- Childrens Afos (UK)
- Crispin Orthotics (UK)
- Drevelin (NO)
- Fior & Gentz (DE)
- Innovation Rehab (UK)
- London Orthotics (UK)
- Orthonova (FI)
- Orthopadie Technik (DE)
- Proteor (FR)
- Sophiesminde (NO)

The plantar flexion stop has a posterior angulation at the top of the stirrup that restricts plantar flexion but allows unlimited dorsiflexion. This system, in particular, is used in patients with weakness of dorsiflexion during swing phase and flexible equinus foot.
On the contrary, in the dorsiflexion ankle joint stop the stirrup has a pin inserted in the anterior channel of the ankle joint or has a flattening of the anterior lip of the stirrup's circular stop. The dorsiflexion stop has an anterior angulation at the top of the stirrup that restricts dorsiflexion but allows unlimited plantar flexion.[48] This solution is preferred when the user suffers with weakness or plantar flexion during late stance.
Consequently, in order to limit both plantar flexion and dorsiflexion ankle movements, both anterior and posterior angulations at the top of the stirrup are required, with a pin in the anterior and posterior channel.
A locked hinge can be used, for example, to fix the position of the foot gradually following the recovery of the user in his range of movement or, on the contrary, his retractions.
If, instead of a pin, a spring is located in the posterior channel, it helps dorsiflexion during swing phase.

DIAGNOSES

- Dorsiflexion weakness and mid-foot deviations with no knee flexion instability
- Toe walking
- Knee hyperextension due to plantarflexion
- Severe mid-foot and forefoot deviations (no plantar stop used)
- Multiple Sclerosis
- Cerebrovascular accident
- Poliomyelitis
- Spinal Stenosis

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47 *Children's AFOs*, http://www.childrensafos.co.uk/types-of-afos/dynamic/hinged/index.html (March 2013)

48 YINGQUI XING S., BHAGIA S. M., *Lower Limb Orthotics and Therapeutic Footwear*, op. cit

CONTRAINDICATIONS

- Knee flexion instability
- Crouch gait pattern
- Patients with range of motion limitation due to bony blocks

DECLARED CLINICAL EFFECTS

Hinged AFOs are commonly used for children who can dorsiflex and plantarflex their ankles but need additional lateral and medial support. Moreover hinged AFOs help to limit toe walking and maintain stretch on the calfs while providing stability.
These orthoses are prescribed even in order to increase or maintain dorsiflexion range with precise foot/ankle control and to guarantee a control of varum and varus foot.

MATERIALS

Hinged AFOs, as Solid AFOs can be made in thermoplastic or Carbon Fiber.

TECHNIQUES OF PRODUCTION

From statistic data on analysed hinged AFOs emerge that most of the orthoses, both Europeans or Americans are made with starting from a cast and then elaborating a positive mold. American Manufacturers allow as well to create the cast in wherever clinic and to post it together with a prefilled module of corrective measures. Other American products are engendered starting only from measures. An European brand, thanks to a thin low thermoplastic sole, allows you to heat and trim the sole of the foot after the delivery.
3D scanner of the feet and CAD-CAM methods are just starting to be applied in very few cases.

AESTHETIC

The possibility of an aesthetic personalization of hinged AFOs follows the trend of Solid AFOs. In Italy, if a choice of external finish is present, it concerns only the possibility of an alternative among few given patterns. A progressive large range of options is given by European Manufacturers and American ones, especially if not included in NHS. However there is a large percentage of manufacturers of every country that doesn't declare in their website the aesthetic options for their orthoses.

NOTES ON DIFFERENCES AMONG THE PRODUCTS INCLUDED IN THIS CATEGORY

Articulated orthoses can be designed to be worn inside the shoes or alone and they can be both daily or night orthoses. Usually the calf and instep sections are secured by a Velcro strap except some types that are completely closed on the front and opened on the back in case of crouched gait, to prevent the ankle to roll forward.
A particular type of hinged AFO is the so called "*preloaded orthosis*".

American NHS Manufacturers:

- ACOR
- Allard
- Cascade
- Insightful Products

American Manufacture:

- Braceworks
- Capstone Orthopedic
- Cascade Orthotics
- Clinical Orthotic Consultants
- Essex orthopaedics
- Hi Tech Bracing
- Kinetic research
- Landra Prosthetics
- Morgantown Orthotic & Prosthetic Center
- Orthomerica
- Peach Tree
- Sure Step

* Internationa company

Ortopedia Garibaldi

Landra Prosthetics

DESIGN

ACOR

The manufacture who produces it declares that it is biomechanically more energy efficient, since it allows for good plantar flexion at heel strike. *"It provides resistance to plantarflexion the instant the heel hits the ground. Some other designs need to be plantarflexed before the resistance is high enough to be effective. By then […] the shock of hitting the ground has already damaged the foot and ankle."* Pre-loaded orthosis, instead, controls deceleration at contact.
Another type of articulated AFO is the one provided with a twin screw extender that allows to gradually correct the equinus foot.
Some night products are provided with a crossed Velcro that lifts the foot toe and is adjustable to control dorsiflexion.
Inner padding and trim lines are usually customized to the user.

Different joints* of hinged AFO. From the left:

- Knee or ankle articulation to be applied on plastic AFO. Screw and counter screw in stainless steel;
- Tamarack, flexible joints for dorsiflection control;
- Kit for ankle articulation for the control of dorsi-plantar flection.

* *M.T.O. S.p.A. Meccanica Tecnica Ortopedica*, www.mto.it

Bandagist

Centro Ortopedico 2000

Ortomerica

London Orthotics

ITOP

Insightful products

Innovation Rehab

3.3.9 Considerations on research keys of market analysis

3.3.9.1 - TYPOLOGY

Maybe one of the most relevant distinguish that has to be made talking about lower limb orthoses is if they are designed to be a static or a dynamic device.

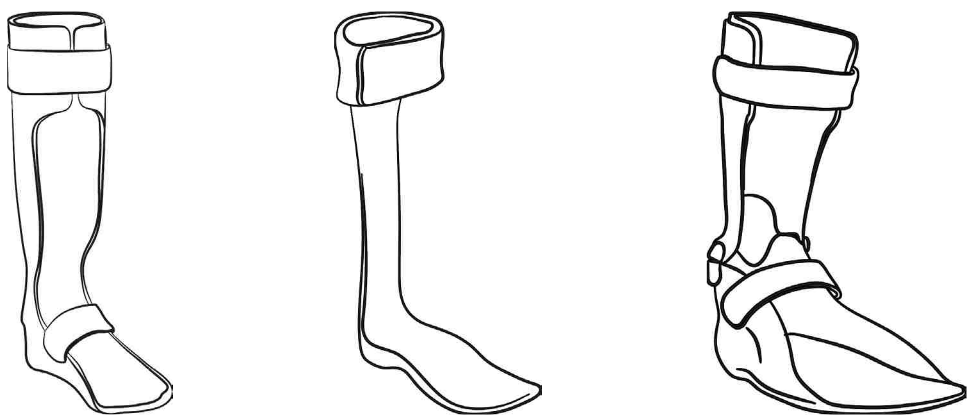
A ***Static Orthosis***, both daily or nightly is thought to inhibit a movement, to counteract a force or a natural deformation, to prevent future contractures, to immobilize the limb waiting, for example, the recomposing of the fractures, to protect limbs from accidental movements, to stabilize limbs and to put articulations in a proper position. To accomplish these functions, they are made in more solid materials, more resistant and usually with a "single block" appearance.

On the contrary, a ***Dynamic orthoses***, of whatever class, is thought for following the lower limb during gait. It provides mobility to the articulation, that can be completely free or partially inhibited. It is usually made in light and thin material to burden as little as possible on muscles, especially if it is addressed to dystrophic patients.

Furthermore dynamic lower limb orthoses are designed in order to "allow controlled movements in sitting and standing, which provide more sensory feedback that supplies information for balance and postural control."[49] If prescribed by a doctor or a physiotherapist it can provide significant improvement, , in active standing and walking balance, hip-knee-trunk control, leg separation and gait pattern.

In my classification of Ankle Foot Orthoses, I considered them "dynamic" *to cour*, if they simple help the movement but they are not able to control actively the articulation range of movement.

A particular case are ***Articulated Orthosis***. They can be considered as a static as dynamic orthosis depending on how it is set. In fact, it is provided with a joint that can lock or unlock the articulation. If it is used only to inhibit the movement to specific range, it maintains all the characteristics of a dynamic AFO, but it's usually heavier, because of the joint. On the contrary, if it is used to fix the ankle in a specific position or angle it has the role of a static AFO. To customize a valve thermoformable articulated AFO it is important to evaluate, in static or dynamic conditions, the range of movement that is possible to correct with the use of the orthosis. Both metallic and thermoformable articulated orthoses can control the flexion-extension of the feet[50].



Solid, Dynamic and Articulated AFO

49 *Childrens Afos*, www.childrensafos.co.uk (May 2014)

50 *Centro Ortopedico 2000*, http://centroortopedico2000.reha-group.it/ortopedia/ortesi_arti_inferiori/ (May 2014)

3.3.9.2 - MATERIALS

Orthoses' materials can be really various and new materials are continuously coming on the market. Moreover this is probably the feature that is liable to change more in the next years. **Polypropylene, Carbon fiber, Ethylene vinyl acetate (thermoplastic material), Lightweight aluminum, Lycra, Leather, Silicon or even PVC (in air splints)**, are the most common materials used in analyzed products[51].

The choice of a material is extremely important for the result of the orthosis, determining its mechanical characteristic, strength performances, endurance, weight, but also aesthetic and cosmetic finishing. In particular cosmetic finish must be evaluated with high attention. An orthoses that cause pains, ulcerations, flushing, allergies, itches and discomfort will not be used with regularity by the patient and it will lose its functionality and clinical efficacy. [52]

Leather is pleasant at the touch, it conducts heat and absorbs water well, but it has low mechanical resistance. **Metals**, such as **stainless steel** and **aluminum** are extremely shapeable, but they have an high specific gravity and they are not pleasant at the touch. Their use in direct contact with the skin is usually avoided.

Silicone AFOs seem to be common especially in UK. They are really flexible and with a wide possibility of customization in shape and aesthetic. However they seem to have lower values of strength resistance and some problems on breathability.
Regarding plastics, a distinction has to be made between

- **thermosetting materials**, which can be molded into permanent shape after heating and do not return in their original shape if reheated;
- **thermoplastic materials**, which soften when heated and harden when cooled. They are usually heated at *high temperature*, usually about 180°, and molded on positive stamps of plaster. These materials are resistant and durable and, if thin and flexible, return perfectly in the original shape after the strain. On the contrary, *low-temperature* thermoplastics can be molded simply with hot water or hot air and cut with scissor. They are increasingly been using in health care, but primarily for low stress activities.[53]

On this regard, an interesting paper that compares pros and cons between thermoplastic AFOs and metal ones is *"Ankle Foot Orthoses: Metals vs Plastic"*[54].
The author discusses the advantages of thermoplastic AFOs in 1983, when they just came on the market, but his considerations are still valid, or even more since the improvement of the quality of this material during last years.
The main advantages of **thermoplastic AFO**s are:

- **Light Weight**, extremely important especially for dynamic AFOs since it causes a decrease in energy expenditure;
- **Higher Elasticity**, that in some cases can sign the limit between being or not able of performing movements. It promotes more efficient gait cycle;

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51 *Childrens Afos*, www.childrensafos.co.uk (May 2014)

52 SACCHETTI R., DAVALLI A., *Ortesi per l'arto inferiore ed ausili per il cammino*, Centro Protesi INAIL Vigorso di Budrio (BO), http://www.inail.it/cms/Medicina_Riabilitazione/Riabilitazione_e_reinserimento/Centro_Protesi/Protesi%20e%20Ortesi.pdf (March 2013)

The thesis, after a brief analysis on lower limb orthoses, analyses in deep the main characteristics of foot orthosis, materials, components, techniques of productions, functions.

53 YINGQUI XING S., BHAGIA S. M., *Lower Limb Orthotics and Therapeutic Footwear*, op. cit.

54 KLOPE SHAMP J. A., *Ankle Foot Orthoses: Metals vs Plastic,* O&P Library, Clinical Prosthetics & Orthotics, 1983, Vol. 7, n.1, pp. 1-3

- **Higher Hygienicity**, since they're washable with water and soap, alcohol or any disinfectant;
- **Possibility of a total contact orthosis**, that proves to be particularly effective in case of insensitive feet to prevent decubitus ulcers;
- **Higher flexibility of use**, allowing the patient to easily interchange shoes compared with conventional metal AFOs;
- **Versatility**, in their possibility of being integrated with metal hinges and being designed to create an incredibly vast number of completely different orthoses. It allows to manufacturing new types of AFOs unconceivable before, as spiral or hemi-spiral AFOs;
- Noise-free orthosis, extremely important as an element of social integration;
- Easiness of aesthetic customization, as we'll see in the following paragraph.

In last years all these advantages of thermoplastic were obtained and in some features even improved by the diffusion of Carbon Fiber orthoses.

The introduction of **carbon fiber** and **Kevlar** in the orthoses is significantly changing this production.
They are usually made with a process of vacuum lamination and are equipped with joints in high resistance Stainless steel[55]. They have high resistance and are placed in epoxy resins with a very light and high resistance result. Due to the weight reduction of the orthoses, the user expends less energy, and then they allow him to walk faster or for longer distances.

"Carbon fiber AFOs have also has excellent storage and return properties too. Whilst walking the force created by an individual's momentum is stored and as one moves forward this energy is released giving the user a "push" start."[56]
Last but not least it fit a wider selection of footwear, and this element is considered crucial for most of the patients when choosing their orthoses.

Thermoplastic for Lower Limb Orthoses

JMS Plastics Supply http://www.jmsplastics.com/

55 SACCHETTI R., DAVALLI A., *Ortesi per l'arto inferiore ed ausili per il cammino*, op. cit.

56 *London Orthotic Consultancy*, www.londonorthotics.co.uk (May 2014)

DESIGN

3.3.9.3- TECHNIQUES OF PRODUCTION

The techniques of production of the orthoses are clearly strictly connected with the type of orthoses, with the material they are made of, and with the technique of customization of the AFO on foot's shape.
Among the analysed products these alternatives were observed:

- by mold, especially to produce FO. This technique is even common in the personalization of wheelchair saddles;
- by plaster, through negative shapes of a cast made in the same manufacture where the orthosis is produced;
- by plaster, made in another center and posted to the manufacture integrated with a prefilled module of measures that reports eventual desired corrections at the shape of the plaster;
- by measures, completing a prefilled form, even on line, with direct measures of the limb, specifically indicated;
- by standard foot measures of the sole length;
- by unique size. After the delivery of the orthosis the patient cuts with scissors the sole of the AFO to make it conform to the users' size;
- by unique size for that fits everyone.

The **traditional manufacture of the most common FO, AFO or KAFO** is handcraft processes. Technical staff makes a plaster impression of the foot of the user in as close to a neutral position as possible and from that a positive impression with a plaster slurry is made. At this stage some firms are recently substituting plaster with fiberglass because it gives a better adhesion in the acquisition of the shape.
At the same time, in some cases, if a special attention to the shape of the sole is required, an impression of the full plantar surface of the foot is made on firm durometer foam or cork, particularly important for FO and for foot orthoses with a full length foot plate. Then a metatarsal pad can be added under metatarsal heads, while a toe crest can be located *"distal to the metatarsal heads, to causes the formation of a metatarsal well."*[57] Many thermoplastic AFOs have this custom foot plate that it's pasted into the AFO after the thermoforming and trimming.
This process makes possible a series of "post production" corrections, to better adapt to the shape of the foot, to release pain, to stimulate corrective positions, to follow the progression of deformations and retractions.
However this common practice of "continuously adapting" AFO, make it even more difficult to classify orthoses, since the same orthoses could acquire different purposes, depending on the pads, sulcus and toe crests inserted inside. This praxis has another critical point: it delegates enormous power to the experience and skills of orthopedics and clinicians who visit the patient.

After an evaluation of childrens'conditions, in reference with physician suggestion or prescription and users'needs, techniques made the mold of feet for the production of AFO.

@ Holly Gray, *Caleigh's Corner*, www.caleighscorner.com/

57 *Ballert Orthopedic*, www.ballert-op.com (May 2014)


Then, the cast is corrected and the plaster is poured into the cast to create a mold that replys the users'lower limb. This mold is then adjusted to ensure a good fit and to provide the required angle of correction of dorsiflexion.


The plastic is heated in a special infra-red oven so that it can be molded around the mold of the client's body part. The escess of plastic is removed from the mold with a special cast saw. The Afo is checked before fitting and given to the user to a first fit to control everything works. Usually several pads and bearings can be added to acquire the desired outcome.

@ Morgantown Orthotic & Prosthetic Center, *How we make the device*, www.mgtnop.com

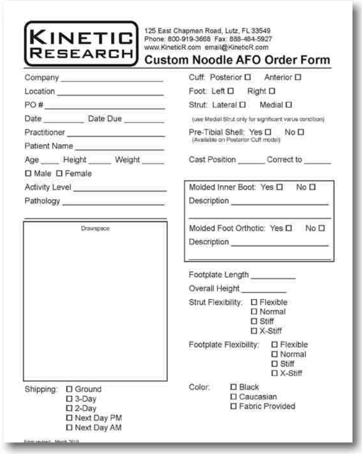
This factor is highly predictably advantageous only if the medical staff is well trained and really meticulous in the observation of the patient. In all the other cases it could generate confusion and difficulties in the monitoring and comparison of the results and regarding the effectiveness of the orthoses.
Only very few manufacturers are starting to propose new techniques of indirect survey of the feet, applying for example the technology of indirect survey that makes use of a **3D laser scanner**, while this technique seems to be more common in the production of prostheses and wheelchair backs.
Furthermore many firms, especially in America, are encouraging on line purchase orders. User indicates some **key measures of the foot on a pre-filled form on line.** Manufacturers usually explain carefully by drawings, photos or even uploading videos on youtube channel, how users have to take these measures. This procedure is simpler and it decomposes the design of an AFO to a parametric model liable to change and to adapt simply inserting customized measures.
An sample of a prefilled form could require, as an example:

- the general features and type of the desired orthosis,
- the desired number and positions of the straps,
- the degree of dorsiflexion or plantarflexion that has to be impressed to the AFOs on sagittal plane,
- the degree of pronation or supination, that has to be impressed on AFO along frontal plane,
- brace height,
- foot length,
- external posting,
- forefoot diameter,
- ankle diameter,
- distal tibia circumference.

This approach is a good idea to simplify the process of purchasing orthoses, to speed it up, but parents have to be really careful in taking measures, and there is no expert who controls the correctness of the process.

Required measures for on line purchase orders

KINETIC RESEARCH



KINETIC RESEARCH
125 East Chapman Road, Lutz, FL 33549
Phone: 800-919-3668 Fax: 888-484-5927
www.KineticR.com email@KineticR.com

Custom Noodle AFO Order Form

Company ____
Location ____
PO # ____
Date ____ Date Due ____
Practitioner ____
Patient Name ____
Age ____ Height ____ Weight ____
☐ Male ☐ Female
Activity Level ____
Pathology ____

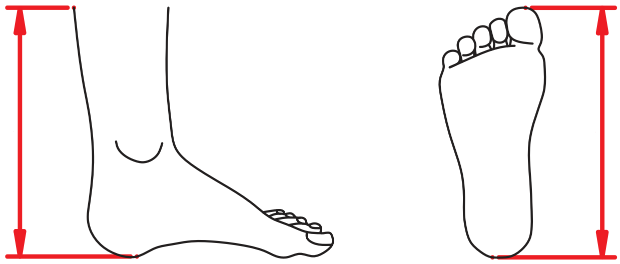
Drawspace

Shipping: ☐ Ground ☐ 3-Day ☐ 2-Day ☐ Next Day PM ☐ Next Day AM

Cuff: Posterior ☐ Anterior ☐
Foot: Left ☐ Right ☐
Strut: Lateral ☐ Medial ☐
(use Medial Strut only for significant varus condition)
Pre-Tibial Shell: Yes ☐ No ☐
(Available on Posterior Cuff model)
Cast Position ____ Correct to ____

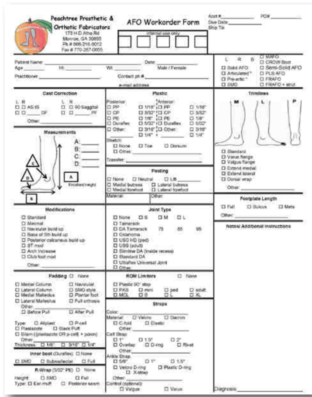
Molded Inner Boot: Yes ☐ No ☐
Description ____
Molded Foot Orthotic: Yes ☐ No ☐
Description ____

Footplate Length ____
Overall Height ____
Strut Flexibility: ☐ Flexible ☐ Normal ☐ Stiff ☐ X-Stiff
Footplate Flexibility: ☐ Flexible ☐ Normal ☐ Stiff ☐ X-Stiff
Color: ☐ Black ☐ Caucasian ☐ Fabric Provided



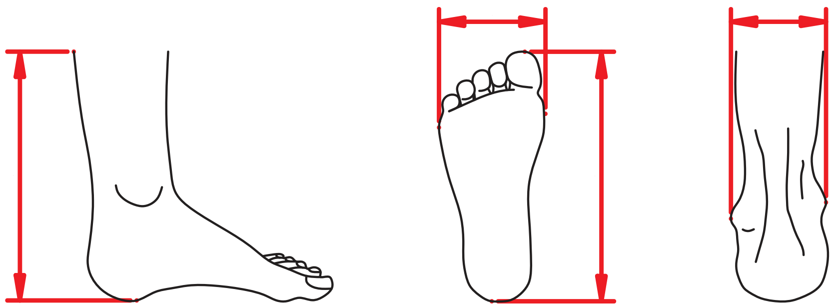
http://www.kineticresearch.com

PEACH TREE PROSTHETIC



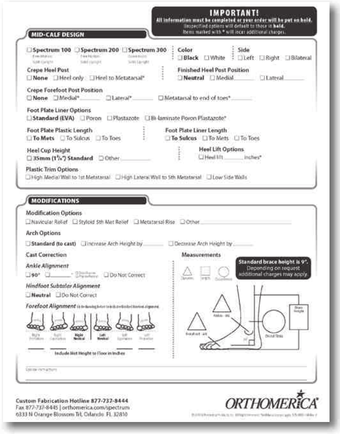
Peachtree Prosthetic & Orthotic Fabricators

AFO Workorder Form



http://www.peachtreefab.com/

ORTHOMERICA



IMPORTANT!

MID-CALF DESIGN

☐ Spectrum 100 ☐ Spectrum 200 ☐ Spectrum 300

Color ☐ Black ☐ White

Side ☐ Left ☐ Right ☐ Bilateral

Crepe Heel Post

Finished Heel Post Position

Crepe Forefoot Post Position

Foot Plate Liner Options

Foot Plate Plastic Length

Foot Plate Liner Length

Heel Cup Height

Heel Lift Options

Plastic Trim Options

MODIFICATIONS

Modification Options

Arch Options

Cast Correction

Measurements

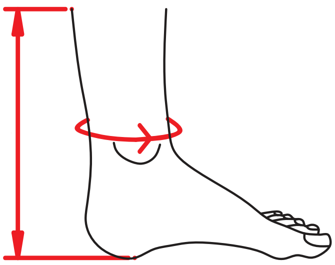
Ankle Alignment

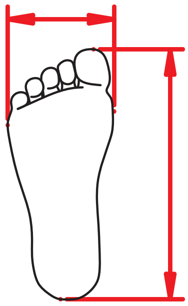
Hindfoot Subtalar Alignment

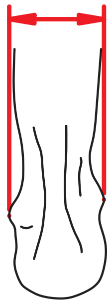
Forefoot Alignment

Custom Fabrication Hotline 877-737-8444

ORTHOMERICA

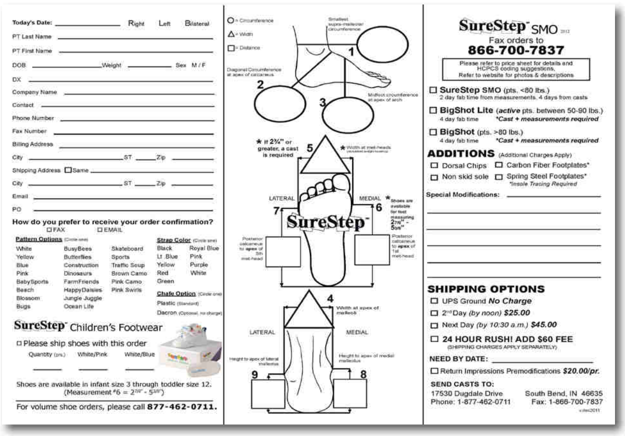






http://www.orthomerica.com/

SURE STEP



Today's Date: Right Left Bilateral

PT Last Name

PT First Name

DOB Weight Sex M / F

DX

Company Name

Contact

Phone Number

Fax Number

Billing Address

City ST Zip

Shipping Address ☐ Same

City ST Zip

Email

PO

How do you prefer to receive your order confirmation?
☐ FAX ☐ EMAIL

Pattern Options: White, Yellow, Blue, Pink, BabySports, Beach, Blossom, Bugs, BusyBees, Butterflies, Construction, Dinosaurs, FarmFriends, HappyDaisies, Jungle Juggle, Ocean Life, Skateboard, Sports, Traffic Soup, Brown Camo, Pink Camo, Pink Swirls

Strap Color: Black, Lt. Blue, Yellow, Red, Green, Royal Blue, Pink, Purple, White

Chafe Option: Plastic, Dacron

SureStep Children's Footwear

☐ Please ship shoes with this order

Shoes are available in infant size 3 through toddler size 12.

For volume shoe orders, please call 877-462-0711.

LATERAL MEDIAL

SureStep SMO

Fax orders to 866-700-7837

Please refer to price sheet for details and HCPCS coding suggestions. Refer to website for photos & descriptions

☐ SureStep SMO (pts. <80 lbs.) 2 day fab time from measurements, 4 days from casts

☐ BigShot Lite (active pts. between 50-90 lbs.) 4 day fab time *Cast + measurements required

☐ BigShot (pts. >80 lbs.) 4 day fab time *Cast + measurements required

ADDITIONS (Additional Charges Apply)

☐ Dorsal Chips ☐ Carbon Fiber Footplates*

☐ Non skid sole ☐ Spring Steel Footplates*

Special Modifications:

SHIPPING OPTIONS

☐ UPS Ground No Charge

☐ 2nd Day (by noon) $25.00

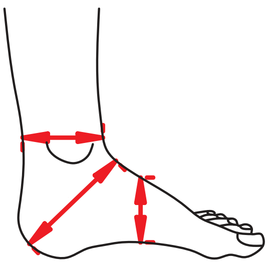
☐ Next Day (by 10:30 a.m.) $45.00

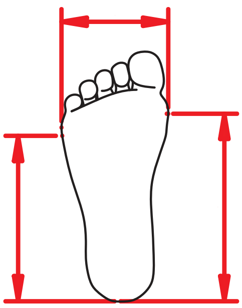
☐ 24 HOUR RUSH! ADD $60 FEE

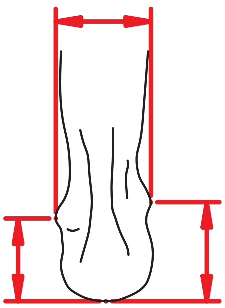
NEED BY DATE:

☐ Return Impressions Premodifications $20.00/pr.

SEND CASTS TO:
17530 Dugdale Drive, South Bend, IN 46635
Phone: 1-877-462-0711 Fax: 1-866-700-7837







http://www.surestep.net/

DESIGN

Peachtree Prosthetic & Orthotic Fabricators
173 H D Atha Rd
Monroe, GA 30655
Ph # 866-216-8012
Fax # 770-267-0655

AFO Workorder Form

internal use only

Acct #____________ PO# ___________
Due Date:___________
Ship To:

Patient Name: ______________________________ Date: ____________
Age _______ Ht: ________ Wt: ________ Male / Female
Practitioner ____________________ Contact ph # ____________________
e-mail address

L R B
☐ Solid AFO ☐ Articulated " ☐ Pre-artic " ☐ SMO
☐ MAFO ☐ CROW Boot ☐ Semi-Solid AFO ☐ PLS AFO ☐ FRAFO ☐ FRAFO + strut

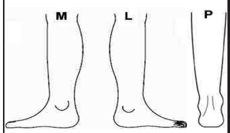
Cast Correction

L R ☐ ☐ AS IS ☐ ☐ _____ DF
L R ☐ ☐ 90 Saggital ☐ ☐ _____ PF
Other: ____________

Plastic

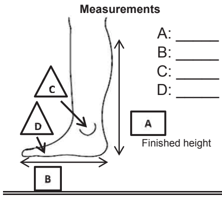
Posterior: ☐ PP ☐ CP ☐ PE ☐ Duraflex ☐ Other: ______ ☐ 1/16" ☐ 3/32" ☐ 1/8" ☐ 5/32" ☐ 3/16" ☐ 1/4"
Anterior: ☐ PP ☐ CP ☐ PE ☐ Duraflex ☐ Other: ______ ☐ 1/16" ☐ 3/32" ☐ 1/8" ☐ 5/32" ☐ 3/16" ☐ 1/4"
Stretch: ☐ None ☐ Toe ☐ Dorsum ☐ Other: ____________
Transfer: ____________

Trimlines



☐ Standard
☐ Varus flange
☐ Valgus flange
☐ Extend medial
☐ Extend lateral
☐ Dorsal wrap
Other: ____________

Measurements



Posting

☐ None ☐ Neutral ☐ Lift ________
☐ Medial butress ☐ Lateral butress
☐ Medial forefoot ☐ Lateral forefoot
Material: Other:

Footplate Length

☐ Full ☐ Sulcus ☐ Mets
Other: ____________

Modifications

☐ Standard
☐ Minimal
☐ Navicular build up
☐ Base of 5th build up
☐ Posterior calcaneus build up
☐ ST mod
☐ Arch Increase
☐ Club foot mod
Other: ____________

Joint Type

☐ None ☐ S ☐ M ☐ L
☐ Tamarack
☐ DA Tamarack 75 85 95
☐ Oklahoma
☐ USG HD (ped)
☐ USS (adult)
☐ Slimline DA (inside recess)
☐ Standard DA
☐ Ultraflex Universal Joint
☐ Other:

Notes/ Additional Instructions

Padding ☐ None

☐ Medial Column ☐ Navicular
☐ Lateral Column ☐ SMO style
☐ Medial Malleolus ☐ Plantar foot
☐ Lateral Malleolus ☐ Full orthosis
Other: ____________
☐ Before Pull ☐ After Pull

Type: ☐ Aliplast ☐ P-cell
☐ Plastazote ☐ Black Puff
☐ Bilam ({plastazote OR p-cell} + poron)
Other ____________
Thickness: ☐ 1/8" ☐ 3/16" ☐ 1/4"

Inner boot (Duraflex) ☐ None
☐ SMO ☐ Submalleolar ☐ Full

R-Wrap (3/32" PE) ☐ None
Height: ☐ SMO ☐ Full
Type: ☐ Ear-muff ☐ Posterior seam

ROM Limiters ☐ None

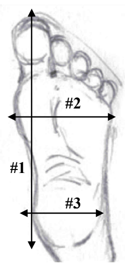
☐ Plastic 90° stop
☐ PAS ☐ mini ☐ ped ☐ adult
☐ MCL ☐ S ☐ L ☐ XL

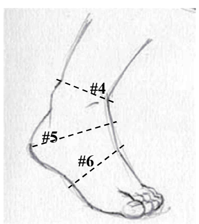
Straps

Color: ____________
Material: ☐ Velcro ☐ Dacron
☐ C-fold ☐ Elastic
Other: ____________
Calf Strap:
☐ 1" ☐ 1.5" ☐ 2"
☐ Overlap ☐ D-ring ☐ Rivet
Other: ____________
Ankle Strap:
☐ 5/8" ☐ 1" ☐ 1.5"
☐ Velcro D-ring ☐ Plastic D-ring
☐ X-strap
Other: ____________
Control (optional):
☐ Valgus ☐ Varus

Diagnosis:____________

CLUBFOOT AFO
MOLD AND MEASUREMENTS
REQUIRED





City_______________ State ________ Zip _________

Billing Address ____________________________

City_______________ State ________ Zip _________

Phone____________________________

Device Type **Size**

Description	Sm.	Rg.	Qty.
DCB – Free Motion Dobbs Bar			
DCBMD – w/ Mitchell Attachment Bar			
QDCB- Quick Release w/ Spring Assist Bar			
Clubfoot AFO with molded inner boot			
Shipping Method: (*Ground /Second / Next*)			

Payment Method:
☐ Check ☐ Visa ☐ Master Card ☐ Discover

☐ CC# ____________________________

☐ PO # ______________ Exp. Date ______________

AFO Pattern & Colors (circle one)

Lavender Butterfly	Pink & Purple Bunnies	Fly & Drive
Ice Age	Military Camouflage	Tornado
Green Soccer	Handprints	Dinosaurs
White *(no pattern)*	Black *(no pattern)*	Ladybug

Number	Right	Left	Circle One	Type
Measurement 1			Inch / cm	Length
Measurement 2			Inch / cm	M-L
Measurement 3			Inch / cm	M-L
Measurement 4			Inch / cm	Cir.
Measurement 5			Inch / cm	Cir.
Measurement 6			Inch / cm	Cir.
Measurement 7			Inch / cm	M-L
Shoulder Width			Inch / cm	Width

Ankle Set At: Neutral (90°) or Dorsiflexion _____°

Special Instructions: ____________________________

Call (314) 968-8555 for Questions Fax (314) 968-3561

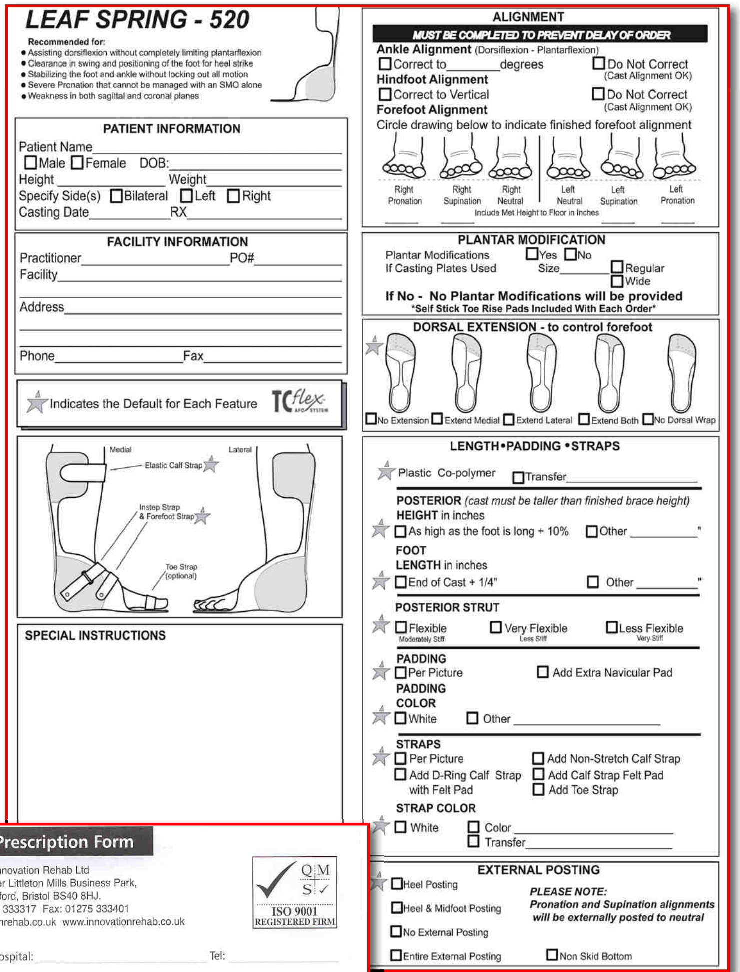
Send Cast and this Form to:
D-Bar Enterprises, LLC
748 Marshall Ave.
Webster Groves, MO 63119
www.dobbsbrace.com

Order forms of Afos of different manufacturers made by plaster plus corrective measures

@ Peachtree
www.peachtreefab.com

@ D-Bar Enterprises
www.dobbsbrace.com

DESIGN



LEAF SPRING - 520

Recommended for:
- Assisting dorsiflexion without completely limiting plantarflexion
- Clearance in swing and positioning of the foot for heel strike
- Stabilizing the foot and ankle without locking out all motion
- Severe Pronation that cannot be managed with an SMO alone
- Weakness in both sagittal and coronal planes

PATIENT INFORMATION
Patient Name
☐Male ☐Female DOB:
Height Weight
Specify Side(s) ☐Bilateral ☐Left ☐Right
Casting Date RX

FACILITY INFORMATION
Practitioner PO#
Facility
Address
Phone Fax

Indicates the Default for Each Feature

Medial | Lateral | Elastic Calf Strap | Instep Strap & Forefoot Strap | Toe Strap (optional)

SPECIAL INSTRUCTIONS

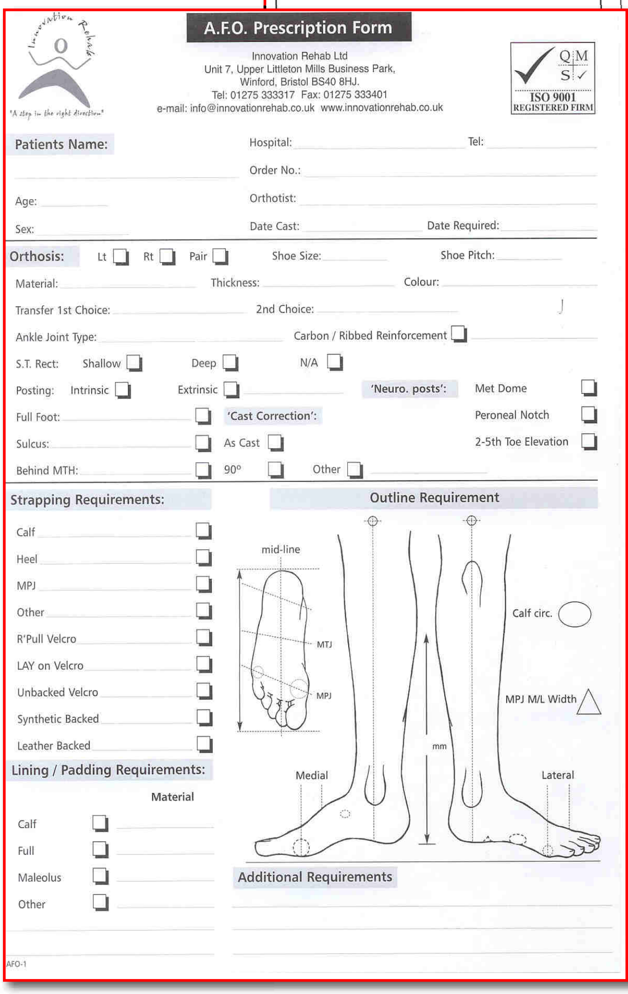
ALIGNMENT
MUST BE COMPLETED TO PREVENT DELAY OF ORDER
Ankle Alignment (Dorsiflexion - Plantarflexion)
☐Correct to ______ degrees ☐Do Not Correct (Cast Alignment OK)
Hindfoot Alignment
☐Correct to Vertical ☐Do Not Correct (Cast Alignment OK)
Forefoot Alignment
Circle drawing below to indicate finished forefoot alignment
Right Pronation | Right Supination | Right Neutral | Left Neutral | Left Supination | Left Pronation
Include Met Height to Floor in Inches

PLANTAR MODIFICATION
Plantar Modifications ☐Yes ☐No
If Casting Plates Used Size ☐Regular ☐Wide
If No - No Plantar Modifications will be provided
Self Stick Toe Rise Pads Included With Each Order

DORSAL EXTENSION - to control forefoot
☐No Extension ☐Extend Medial ☐Extend Lateral ☐Extend Both ☐No Dorsal Wrap

LENGTH•PADDING•STRAPS
Plastic Co-polymer ☐Transfer
POSTERIOR (cast must be taller than finished brace height)
HEIGHT in inches
☐As high as the foot is long + 10% ☐Other "
FOOT LENGTH in inches
☐End of Cast + 1/4" ☐ Other "
POSTERIOR STRUT
☐Flexible (Moderately Stiff) ☐Very Flexible (Less Stiff) ☐Less Flexible (Very Stiff)
PADDING
☐Per Picture ☐ Add Extra Navicular Pad
PADDING COLOR
☐White ☐ Other
STRAPS
☐Per Picture ☐ Add Non-Stretch Calf Strap
☐ Add D-Ring Calf Strap with Felt Pad ☐ Add Calf Strap Felt Pad
☐ Add Toe Strap
STRAP COLOR
☐ White ☐ Color
☐ Transfer

EXTERNAL POSTING
☐Heel Posting
☐Heel & Midfoot Posting
☐No External Posting
☐Entire External Posting ☐Non Skid Bottom
PLEASE NOTE: Pronation and Supination alignments will be externally posted to neutral



A.F.O. Prescription Form

Innovation Rehab Ltd
Unit 7, Upper Littleton Mills Business Park,
Winford, Bristol BS40 8HJ.
Tel: 01275 333317 Fax: 01275 333401
e-mail: info@innovationrehab.co.uk www.innovationrehab.co.uk

QM ISO 9001 REGISTERED FIRM

"A step in the right direction"

Patients Name: | Hospital: | Tel:
Order No.:
Age: | Orthotist:
Sex: | Date Cast: | Date Required:

Orthosis: Lt ☐ Rt ☐ Pair ☐ | Shoe Size: | Shoe Pitch:
Material: | Thickness: | Colour:
Transfer 1st Choice: | 2nd Choice:
Ankle Joint Type: | Carbon / Ribbed Reinforcement ☐
S.T. Rect: Shallow ☐ Deep ☐ N/A ☐
Posting: Intrinsic ☐ Extrinsic ☐ | 'Neuro. posts': | Met Dome ☐
Full Foot: ☐ | 'Cast Correction': | Peroneal Notch ☐
Sulcus: ☐ | As Cast ☐ | 2-5th Toe Elevation ☐
Behind MTH: ☐ | 90° ☐ | Other ☐

Strapping Requirements:
Calf ☐
Heel ☐
MPJ ☐
Other ☐
R'Pull Velcro ☐
LAY on Velcro ☐
Unbacked Velcro ☐
Synthetic Backed ☐
Leather Backed ☐

Lining / Padding Requirements:
Material
Calf ☐
Full ☐
Maleolus ☐
Other ☐

Outline Requirement
mid-line | MTJ | MPJ | Calf circ. | MPJ M/L Width | mm | Medial | Lateral

Additional Requirements

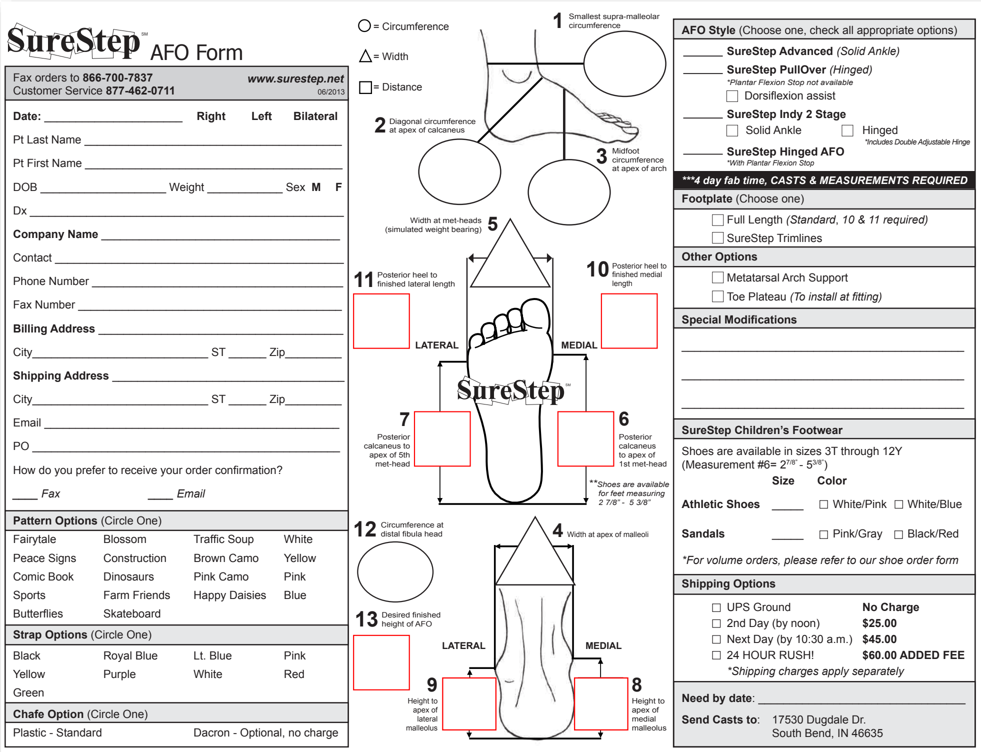
AFO-1

Order forms of Afos of different manufacturers made by plaster plus corrective measures.

@ Orthomerica Products, www.orthomerica.com

@ Innovation Rehab www.innovationrehab.co.uk

DESIGN



SureStep™ AFO Form

Fax orders to 866-700-7837 www.surestep.net
Customer Service 877-462-0711 06/2013

Date: ____________ Right Left Bilateral
Pt Last Name ____________
Pt First Name ____________
DOB ____________ Weight ____________ Sex M F
Dx ____________
Company Name ____________
Contact ____________
Phone Number ____________
Fax Number ____________
Billing Address ____________
City ____________ ST ______ Zip ______
Shipping Address ____________
City ____________ ST ______ Zip ______
Email ____________
PO ____________
How do you prefer to receive your order confirmation?
____ Fax ____ Email

Pattern Options (Circle One)

Fairytale	Blossom	Traffic Soup	White
Peace Signs	Construction	Brown Camo	Yellow
Comic Book	Dinosaurs	Pink Camo	Pink
Sports	Farm Friends	Happy Daisies	Blue
Butterflies	Skateboard		

Strap Options (Circle One)

Black	Royal Blue	Lt. Blue	Pink
Yellow	Purple	White	Red
Green			

Chafe Option (Circle One)
Plastic - Standard — Dacron - Optional, no charge

AFO Style (Choose one, check all appropriate options)
______ SureStep Advanced (Solid Ankle)
______ SureStep PullOver (Hinged)
*Plantar Flexion Stop not available
☐ Dorsiflexion assist
______ SureStep Indy 2 Stage
☐ Solid Ankle ☐ Hinged
*Includes Double Adjustable Hinge
______ SureStep Hinged AFO
*With Plantar Flexion Stop
***4 day fab time, CASTS & MEASUREMENTS REQUIRED

Footplate (Choose one)
☐ Full Length (Standard, 10 & 11 required)
☐ SureStep Trimlines

Other Options
☐ Metatarsal Arch Support
☐ Toe Plateau (To install at fitting)

Special Modifications

SureStep Children's Footwear
Shoes are available in sizes 3T through 12Y
(Measurement #6= 2 7/8" - 5 3/8")

	Size	Color	
Athletic Shoes	____	☐ White/Pink	☐ White/Blue
Sandals	____	☐ Pink/Gray	☐ Black/Red

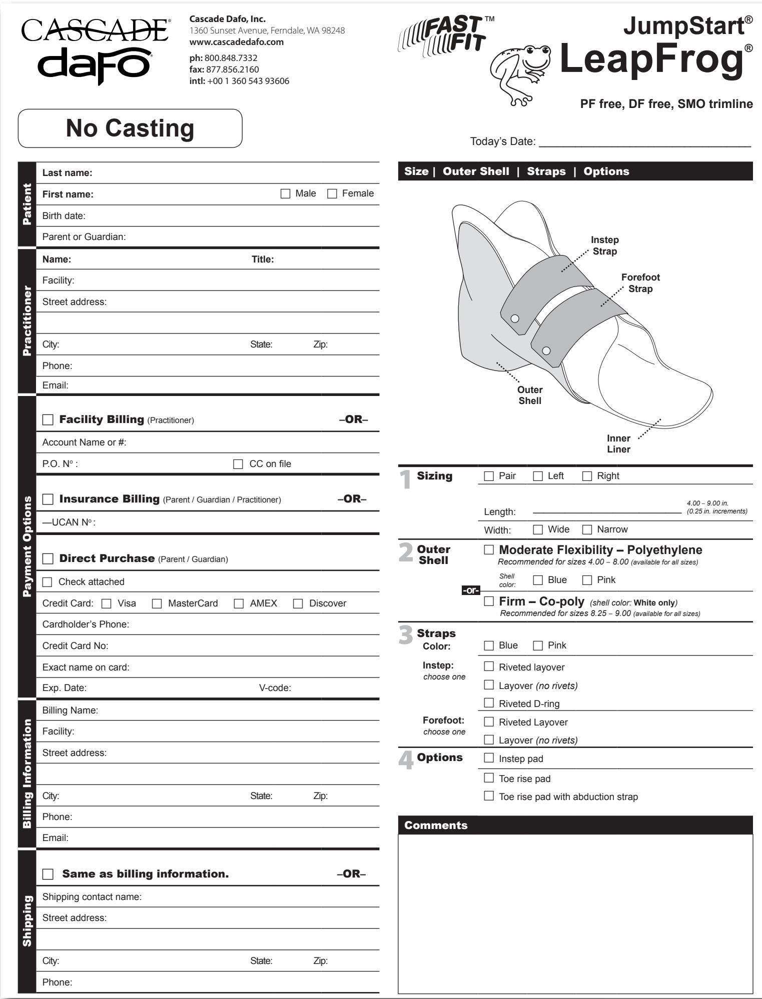
*For volume orders, please refer to our shoe order form

Shipping Options

☐ UPS Ground	No Charge
☐ 2nd Day (by noon)	$25.00
☐ Next Day (by 10:30 a.m.)	$45.00
☐ 24 HOUR RUSH!	$60.00 ADDED FEE

*Shipping charges apply separately

Need by date: ____________
Send Casts to: 17530 Dugdale Dr.
South Bend, IN 46635



CASCADE dafo
Cascade Dafo, Inc.
1360 Sunset Avenue, Ferndale, WA 98248
www.cascadedafo.com
ph: 800.848.7332
fax: 877.856.2160
intl: +00 1 360 543 93606

FAST FIT™ JumpStart® LeapFrog®
PF free, DF free, SMO trimline

No Casting

Today's Date: ____________

Patient
Last name:
First name: ☐ Male ☐ Female
Birth date:
Parent or Guardian:

Practitioner
Name: Title:
Facility:
Street address:
City: State: Zip:
Phone:
Email:

Payment Options
☐ Facility Billing (Practitioner) –OR–
Account Name or #:
P.O. N°: ☐ CC on file
☐ Insurance Billing (Parent / Guardian / Practitioner) –OR–
—UCAN N°:
☐ Direct Purchase (Parent / Guardian)
☐ Check attached
Credit Card: ☐ Visa ☐ MasterCard ☐ AMEX ☐ Discover
Cardholder's Phone:
Credit Card No:
Exact name on card:
Exp. Date: V-code:

Billing Information
Billing Name:
Facility:
Street address:
City: State: Zip:
Phone:
Email:

Shipping
☐ Same as billing information. –OR–
Shipping contact name:
Street address:
City: State: Zip:
Phone:

Size | Outer Shell | Straps | Options

1 **Sizing** ☐ Pair ☐ Left ☐ Right
Length: ____________ 4.00 - 9.00 in. (0.25 in. increments)
Width: ☐ Wide ☐ Narrow

2 **Outer Shell**
☐ Moderate Flexibility – Polyethylene
Recommended for sizes 4.00 – 8.00 (available for all sizes)
Shell color: ☐ Blue ☐ Pink
–or–
☐ Firm – Co-poly (shell color: White only)
Recommended for sizes 8.25 – 9.00 (available for all sizes)

3 **Straps**
Color: ☐ Blue ☐ Pink
Instep: choose one
☐ Riveted layover
☐ Layover (no rivets)
☐ Riveted D-ring
Forefoot: choose one
☐ Riveted Layover
☐ Layover (no rivets)

4 **Options**
☐ Instep pad
☐ Toe rise pad
☐ Toe rise pad with abduction strap

Comments

Order forms of Afos of different manufacturers made just by measures.

@ Surestep
www.surestep.net

@ Cascade Dafo
www.dafo.com

3.3.9.4 - PURCHASE ORDER

Another interesting element of evaluation on AFOs' markets is the way you can order the orthosis. Until a few years ago the only way to purchase an AFO was to go to the manufacture, to make the plaster of the patient's lower limb, and to wait some weeks after coming back to the manufacture to withdraw the AFO.

Nowadays more and more manufacturers are developing forms of remote purchase orders. We already saw the two possibilities of making a plaster in a local clinic and sending it together with corrective measures or obtaining a customized AFO simply communicating to the manufacture the measures they require.

These possibilities expand exponentially the potential suppliers of orthoses but it must be noticed that a direct contact with expert technicians that evaluates the perfect fit of the AFO is often crucial and inevitable and offers a better guarantee on the efficacy of the result, especially in more critical clinical cases.

Hereinafter some example of order forms are reported.

Ankle-Foot Orthosis (AFO) Also available as Blanks (Untrimmed, No Strap)

Standard AFO design pre-fabricated from polypropylene to a 1/8″ thickness for necessary rigidity and comfort. Indicated for flaccid or spastic foot drop. Can be heated to customize fit. Very versatile design.

- Posterior ribs for increased support
- Velcro® strap

Size	Model # Left	Model # Right	Shoe Size	Brace Height	Calf Circ.	Footplate Length	Calf Band Width
Small	**3540**	**3545**	Size 6 or less	12″	13½″	6¼″	8″
Medium	**3541**	**3546**	Men 5-7, Women 6 or less	13½″	14″	6¾″	8″
Large	**3542**	**3547**	Men 7½-10, Women 6½ up	14″	14½″	7″	9″
X-Large	**3543**	**3548**	Men 10½-13	14″	15″	7″	9″

To order blanks use **.01** suffix, (e.g., 3541.01)

An example of an order form of a Solid Afo. The choice is among 4 different sizes but you can heat and trim the foot sole to customize the orthosis on the user's foot.

@ Orthomerica Products, www.orthomerica.com

3.3.9.5 - AESTHETIC CUSTOMIZATION OF AFOS

Aesthetic issue of orthoses is strictly linked with their psychological acceptation. Since their shape is dictated mainly by their function, to intervene on aestetic aspects is the only way to attempt to improve their psychological acceptation. This is a problem that involves people of each age and sex but this issue will be treated more in detail in the following paragraph.

Here we'll focus more on different approaches and differences surveyed in aesthetic aspects among the scheduled products. One of the first problem experienced is that these orthoses, expecially the cheapest ones, too many times have an *"hospital guise, a sanitarium appearance".*

The diffusion of plastic orthoses encouraged drastically the attention on the aesthetic of orthoses, but this is mainly true for strong high thermoplastic AFOs, while **low thermoplastic AFOs** are always produced only in a standard white or transparent version. **High thermoplastic AFOs**, especially if designed for children, are often printed in different colours or textures, trying to meet their taste in fashion. As a first sight the choice is various: their name, their favorite colour, cartoon characters, football team, superhero could be printed on plastic, elastic bands or even on the padding. Other American web sites allows users directly to create their own pattern and uploading online the images in high resolution that will be printed on AFOs. One brand even allows to add LED flash lights on orthotic device, with long battery life and waterproof. Another one to creates 3D stamps and graffiti with, at instance, the user's name.

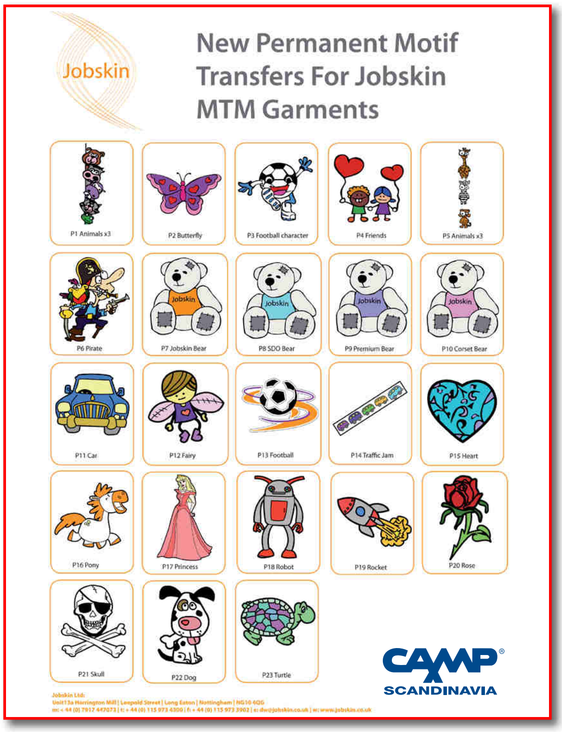
Carbon fiber AFOs, on the contrary, are usually not refined, lightweight and their characteristic functional aspect is considered as an aesthetic language. They don't provide for aesthetic customization if not, in very few cases a Scandinavian manufacture that pads the frontal part of Toe-Off AFOs with foam and tissue and allows to chose the colours and texture of the textile.

However, besides this first apparent variation, some observations have to be done.

- **AFOs variation involves just their skin** - Except few isolated manufacturers, in most of the cases this aesthetic alternative concerns exclusively the choice between patterns that can be indiscriminately applied on a shape that remains always the same. Modern technologies as additive technology can enormously enlarge the possibility of personalization and manufacturing and the creation of unique products without problems of creating molds, stamps, or economical advantages in mass scale production. A new idea of orthosis could be ideated, an AFO where personalization isn't limited only to the skin, but involves all the shape, different materials and colours of the orthosis, exploring expressive possibilities, customizing one by one the product on the patient.
- **Textures are only for children** - The analysis of the patterns proposed by manufacturers evidence an higher attention to young children. The images are funny, coloured and childish. Very few patterns, except maybe some abstract textures, seem to be thought or suitable to adolescents or adults. It appears as the texture issue involves only children and that adolescent and adults don't require such attentions since they are fully satisfied by standard anonymous products. But we'll see in the following paragraph that this consideration isn't true;
- **No dress-code for orthoses** - Among the selected manufacturers, even the most vanguard ones propose orthoses with a very informal, sportive look.

People who have to wear daily orthoses claim the absence on the market of products that could be don, if necessary, even in a formal situation, with a look more appropriate with elegant dresses. It could appear a futile request, but this element, if the orthosis is visible, is often caused by feelings of frustration and auto-exclusion from formal social occasions.

- **Uneven attention on aesthetic issue among different countries** - as it will be subsequently analysed.



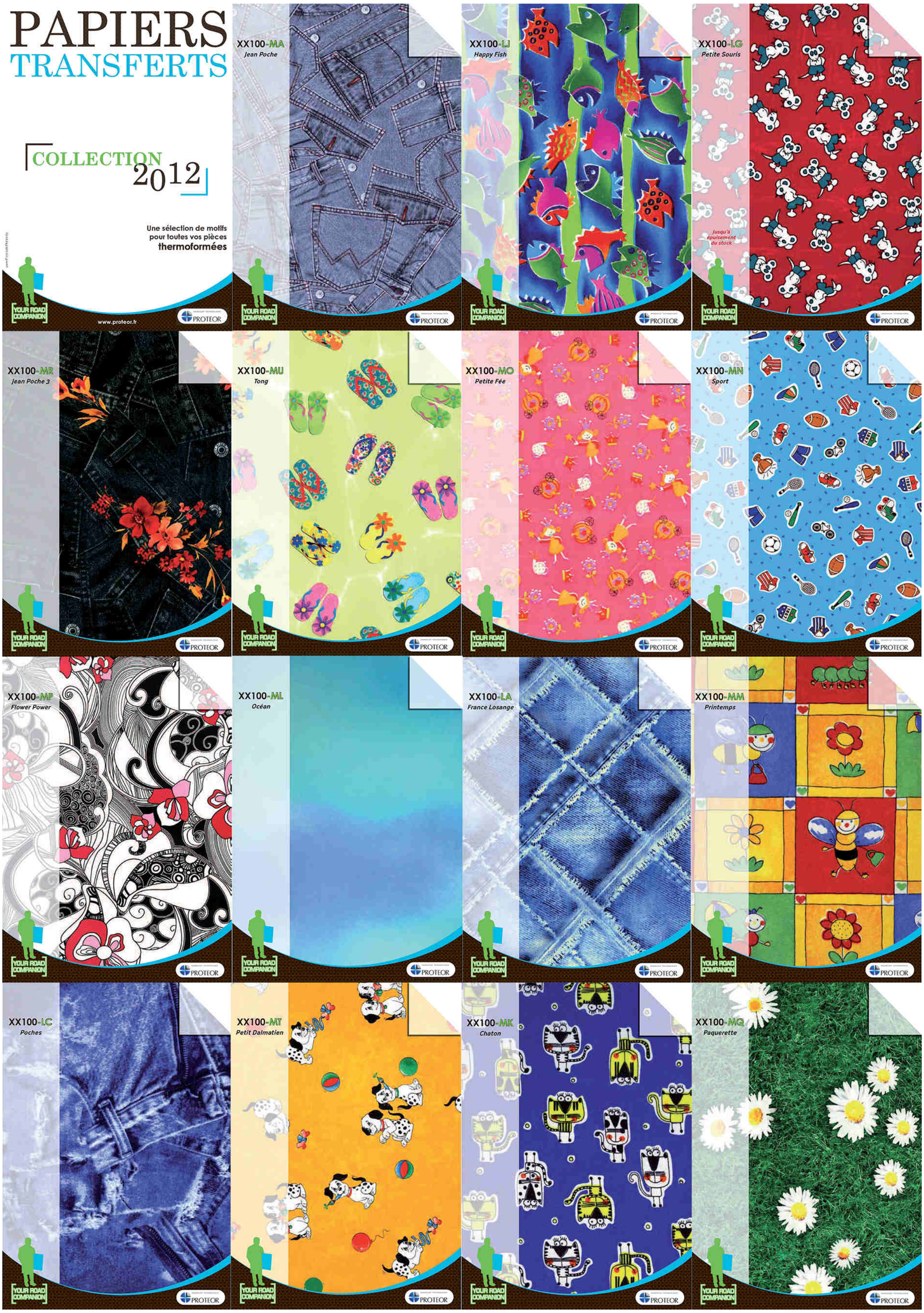
Examples of two patterns guides to chose the decoration to be applyed on orthosis.

Above on the right
3d customizable graffixs on AFOs.

In the lower left
Insert of small motion sensitive LED lights on AFOs.

On the next pages
An extract of a thermoplastic AFOs'pattern guide.

Companies (clockwise):
Sure Step
Innovation Rehab
CAMP Scandinavia,
Algeos.
On the next page:
Proteor


PAPIERS
TRANSFERTS
COLLECTION
2012
Une sélection de motifs
pour toutes vos pièces
thermoformées
www.proteor.fr
YOUR ROAD COMPANION
PROTEOR
XX100-MA
Jean Poche
XX100-LJ
Happy Fish
XX100-LG
Petite Souris
XX100-MR
Jean Poche 3
XX100-MU
Tong
XX100-MO
Petite Fée
XX100-MN
Sport
XX100-MP
Flower Power
XX100-ML
Océan
XX100-LA
France Losange
XX100-MM
Printemps
XX100-LC
Poches
XX100-MT
Petit Dalmatien
XX100-MK
Chaton
XX100-MQ
Paquerette


XX100-JJ
Petit Ours
XX100-JE
Fleurs Sixty
XX100-JC
Faux Uni Bleu
XX100-MB
Visage
XX100-MH
Dalmatiens
XX100-LP
Seventies
XX100-JF
Peace & Love
XX100-MI
Camouflage Gris
XX100-JG
Escargot
XX100-MF
Girlie
XX100-MJ
USA
XX100-LS
Camouflage Vert
XX100-LH
Nounours
Jusqu'à épuisement du stock
XX100-LM
Jungle
XX100-ME
Champignons
XX100-MC
Engines
YOUR ROAD COMPANION
PROTEOR

DESIGN

3.3.9.6 - PSYCOLOGICAL ASPECTS RELATED TO THE USE OF THE ORTHOSES

"What we wear reflects who we are or, at the very least, what we want to project of ourselves. That is why fashion is such a powerful and ever-changing industry. Practitioners who work with patients that need orthotic or prosthetic devices need to understand this to provide the best care."[58]

The moment of the prescription of an orthosis is crucial not only for the expected clinical effects and because it's necessary to choose the exact type who fits best with users diagnosis and conditions. The phase of prescription requires a huge attention on psychological aspects too. Medical staff has to evaluate carefully user needs, expectations, daily routine, social and cultural contest, before suggesting their solution.

But's that not enough. Clinicians have to be trained to explain to children the purpose and the function of an AFO, in order to improve as much as possible the process of psychological acceptation of the orthoses.

Orthoses usually result necessary uncomfortableness for the user, since they have to contrast a natural wrong position or attitude of the lower limb and of the foot or reallineate the foot in a correct position after an injury, trauma or surgical intervention.

However if we consider the AFO as an hospital device, a temporary aid useful for recovery from an injury, the orthoses is generally accepted as a "badly needed", but even in this sector many improvements could be done.

Karen Nolan, PhD researcher at the Kessler Foundation in West Orange, NJ, asserts that the 61% of the interviewed people who regularly uses AFO is unsatisfied of the appearance of the orthoses and found them unaesthetic.

"Just because you've had a stroke, it doesn't mean you're no longer concerned about how people view you and how you look," she said. *"It's vanity."*[59] And this aspect is particularly true if we consider women and children.

But what do the orthosis accompaniment do for the user for his entire life? We all have tested on ourselves how sometimes could be rewarding for our spirit (especially for women, it seems), to buy a new pair of shoes, to have the possibility of choosing them because of their style that is not simply the exterior finish. In juvenescence it is even more important because a dress style could underline a "status symbol", mark the belonging of a group or, on the contrary, to be cause of irony and even scorn if they don't correspond with the trend of the moment.

According to Delzell E.[60], one of the main causes of psychological refusal of Ankle Foot Orthoses is not so much comfort as an aesthetic problem. Wearing an orthoses is a visible indicator to all the people of their own infirmity, it's a sort of label that inevitably tends to be intrusive in the self-image that the patient would have lied to transmit to other people. Most of the patients who regularly wear AFOs complain that the orthosis, for strangers or acquaintances tends to take over on their identity, labeling them as *"the man/woman who wear orthoses"*. Moreover the necessity of wearing an AFO limits clothing and footwear options and this is source of frustration for users of each age, but in particular adolescents. Each one of us tends to

58 MARSHALL J., Pediatric specialist at Shrines Hospital for Children in Tampa F.L., interview in: DELZELL E., *Sensitivity to self image boots O&P outcomes*, Lower Extremity Review Magazine, April 2011, http://lermagazine.com/article/sensitivity-to-self-image-boosts-op-outcomes, (January 2015)

59 MALAS B.S., *The effect of ankle-foot orthoses on balance: a clinical perspective*, op. cit.

60 DELZELL E., *Sensitivity to self image boots O&P outcomes*, ibid.

use different dress codes for various occasion, informal or celebratory occasions. The few available options between orthoses and shoes that can be worn together with the orthoses is instead felt as an high limitation of feeling comfortable and adequate in a social situation.

Therefore it appears clear how the option of choosing the texture, the colour applied on the orthoses or even the possibility of a complete personalization of the AFO has an extreme relevance in the process of psychological acceptation of orthoses.

“Incorporating elements of patients’unique personality helps them better to identify with their pathology.”[61]

The possibility of choosing a drawing, a shape, or symbol that represents the user and in which he identifies, himself can change the approach towards the orthosis from something to hide to a work of art that the user is proud of to show.

This is if possible even more important for young or adolescent users, in a phase of building of their self-image. For most of them, the choice of the aesthetic aspect of their orthoses is the only moment in which they are involved actively in the prescription of the AFOs. For this reason it is valorizing this moment as much as possible to involve young users in the choice. It is important to listen to their concerns and educate them about therapeutic benefits and discuss their expectations.

The psychological response of a boy who complains of the esthetic of the AFO must not be ignored since an orthosis that satisfy the users, will be worn with more acceptation, maybe even unconsciously, and the prolongation of the use will have direct clinical effects.

Images of children wearing their AFOs taken from their personal blogs on internet

61 DELZELL E., *Sensitivity to self image boots O&P outcomes*, ibid.

It is extremely important for every patient being understood, feeling that the medical or technical staff is interested in his problems, even the ones that will be apparently judge futile compared to the clinical efficacy of the orthosis. This moments tends to create a partnership between them, essential to instil confidence to the patient. For this reason it is so important to listen to their concerns and educate them about therapeutic benefits of AFOs and to discuss their expectations. Patients have to perfectly understand, with a terminology adequate to their age and culture, the function of AFOs and why they're so important for their health, in order to be well motivated and to accept them. At the same time doctors must be careful in avoiding any possible exaggerated expectation, since a disappointment would inevitably lead to a complete refuse of AFO.

Concluding, on this topic several blogs and forums on line discuss this double approach on the design of the AFO but without an unanimous response. In order to improve the psychological acceptation of an orthosis two alternative approaches are debated:

- to look for an orthosis as light and thin as possible as to be hided under trousers and to be fitted inside every pair of shoes, and this is of course a desirable characteristic especially of daily orthoses.
- to be as cool as possible in order to agree the user willing to wear them just because he likes them.

3.3.9.7- NOTES ON COMFORT

Unfortunately isn't possible to hierarchise AFOs by their level of comfort, even if this element is strategic in the definition of the rate of acceptation of the orthoses. Too many subjective factors influence the judge, related as to clinical conditions of the patients and its diagnosis as to personal degree of endurance of pain. However as blogs as users and technical staff, I personally met complaining that most users find AFOs uncomfortable, especially night splints, because, the orthoses result bulky and limit their natural movements. This is particularly true, for example, for DMD patients and their night AFO. For this reason doctors often suggest to start wearing orthoses gradually, first for some hours, or one leg by time, or initially only in the evening when watching TV, or while they're sitting doing their homework.

However a surveyed widespread thought among users is a **better evaluation on the comfort of night dorsal AFOs**. If prescribed for a short time as post-surgery recovery, after an injury or trauma, or as daily worn for more severe diagnosis. The use of dorsal AFOs, if their clinical effect is compatible with the diagnosis result more comfortable for the users.

Complications related to the use of AFO are mostly due to compression of tissues. Rednesses, bruises, calluses or bruises should be carefully monitored and communicated to medical staff. They will decide if it's time to change orthosis, to modify it or to add some pads inside in strategically positions.[62]

Another critical issue that drastically influences the perception of comfort of an orthosis is its level of **breathability**. This element depends mainly from the extension of contact surface between the skin and the orthosis and from the characteristics of the material. At this level of analysis there were too many data missing to calculate or express documented opinions on different behaviors but the level of breathability of any orthosis could be one interesting element that could be implemented in the future.

Concluding, in order to improve comfort and reduce skin contact with the orthosis, many orthotics are suggested to be worn with knee **high socks in cotton and stretch**, without ridges that can lead to skin breakdown[63].

3.3.9.8 - NOTES OF AFOS' PRICES

In this analysis the economic element wasn't taken into consideration but absolutely not because it is considered non important. On the contrary it is a crucial aspect that often addresses parents on one product more then another, especially considering the children's necessity of a frequent renovation of AFOs, following their growth. However, since worldwide products were compared, the prices are changing too much from one country to the others and the reasons of these differences were often non imputable to technical characteristics of orthoses. Subsequently cataloging AFOs by their prizes would have seemed misleading in its result.
However as an overall consideration on the prize of an AFO, it is decisively influenced by the technique of production and by the time required to produce it. Reasonably, a customized AFO which starts from the making of the plaster of user's leg

62 BASAGLIA N., *Trattato di medicina riabilitativa – medicina fisica e riabilitazione.* Napoli, Idelson, Gnocchi, 2000

63 *Braceworks,* www.braceworks.ca (March 2014)

at the manufacture, and following all the traditional phases of production and final controls with medical staff affiliated to the center itself, will cost much more than an AFO you can order online, in base on your foot size, and it is delivered directly at your home.

In general, however, appears that carbon fiber AFOs have an higher cost than thermoplastic AFOs and the ones produced in low thermoplastic are the cheapest.

3.3.10 – INTERPRETATIONS OF DATABASE INFORMATION

The cataloguing of products of their organization is done by type, with the compilation of a descriptive form for each category proved to be very useful. A so vast research among hundreds of products gave not only information on "what is on the market", but also "what is in trend on the market", which are the most common products, where new materials, technologies or types are developing faster and how all the features of an AFO can be reciprocally linked.
This consideration suggested the opportunity of synoptic tables, linked with the database as pivot sheet in Excel software, able to give in time real **transversal overall lectures on the result and facilitate critical interpretation of data**.
These sheets were even linked with the formulation of graphs which reassumes all collected data in a more comprehensive and attractive way. These graphics were very useful in the compilation of typological schedules just illustrated and to understand general trends among AFOs. However they weren't significant enough to be reported here, considering the aim of the thesis. They were too specific and in some cases they could even be misleading. This could happen in the cases in which the sample of a specific product is too small to give a reliable result on the state of art. However they are here included and presented just to give an idea of the great potential of the instrument and of the possibilities of future developments.

Relation between types of AFOs and their material

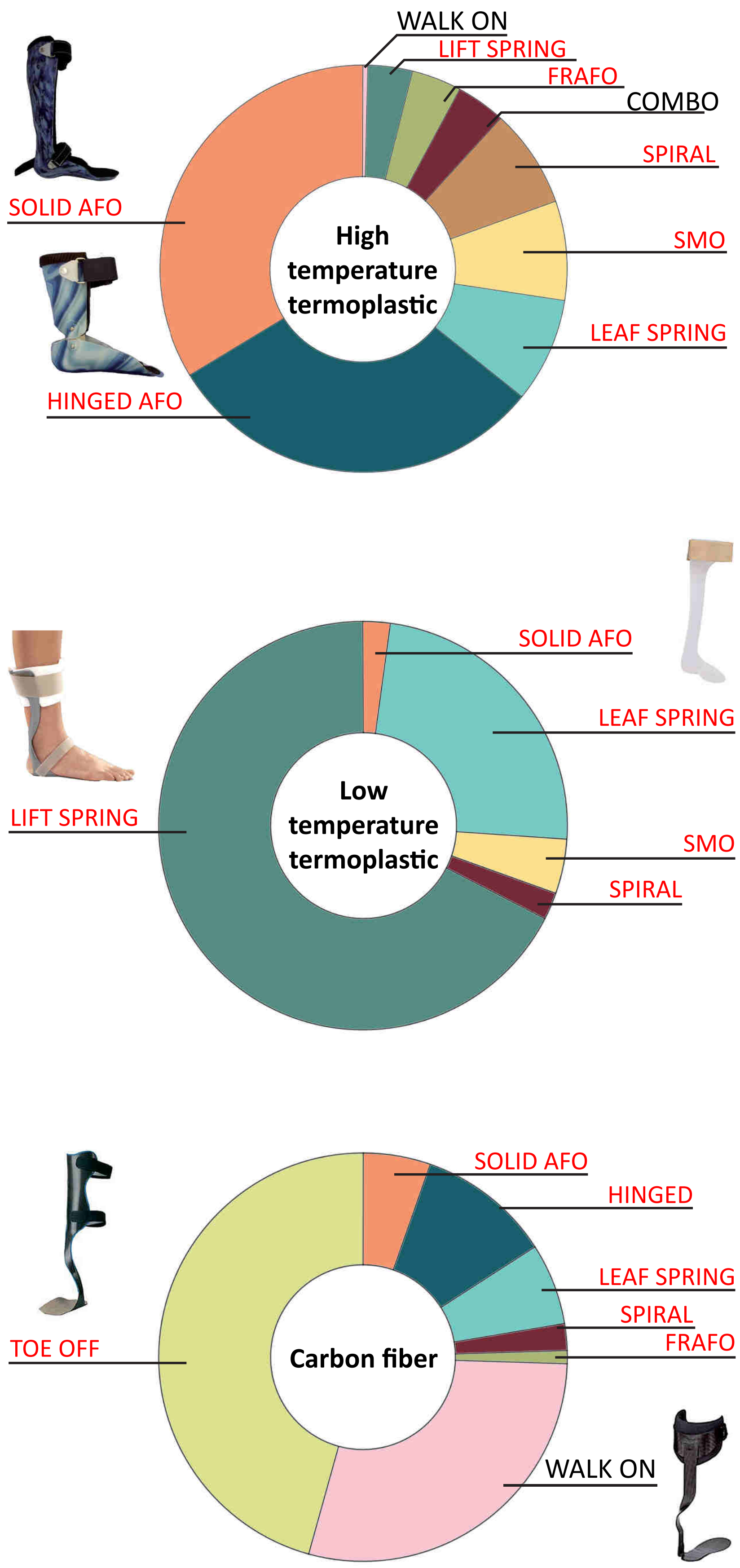
The first graph analyses the relation between materials and types of AFOs. It appears that most of the AFOs can be made used as well as thermoplastic as carbon fiber. However the image shows that the major trend, at the moment, is to adopt high thermoplastic especially to manufacture Solid and Hinged Afos. Some Solid and Hinged AFOs are built as well in carbon fiber while very few of Solid and none of Hinged are built in Low temperature thermoplastic, because the material doesn't offer enough resistance to strength. This material is used most of the time to create Leaf Spring and Lift Spring AFOs. Usually orthoses made in low temperature thermoplastic can be heated and trimmed after the deliver to customize on users' feet length. Carbon fiber is a quite new material that is going to be used more and more in the future for its advantage in terms of weight and energy return during the gait and for this reason it is preferred on dynamic orthoses.
Nowadays the most common products made in this material are the one belonging to the Toe-OFF Family, Blue Rocker, Ypsilon and Toe-Off and Walk-On orthoses, a type of leaf spring AFO. However it is interesting to observe how this material seems to be suitable to almost all kind of lower limb orthoses. Silicone and Gauntlet AFO in leather were not considered in this analysis since their application was found only to one type of product.

Relation between AFO's material and its possibilities of an aesthetic customization

The second graphic elaboration extracted from AFO's database puts in relation the material used to manufacture the AFO with its appearance. From this elaboration emerges clearly how low thermoplastic and Carbon fiber AFOs are usually made in one version only, without any possibility of customization.

If on low thermoplastic AFOs a technical problem in the manufacture could be glimpsed, on Carbon fiber product the possibility of using sticker or coloured pad-

DESIGN



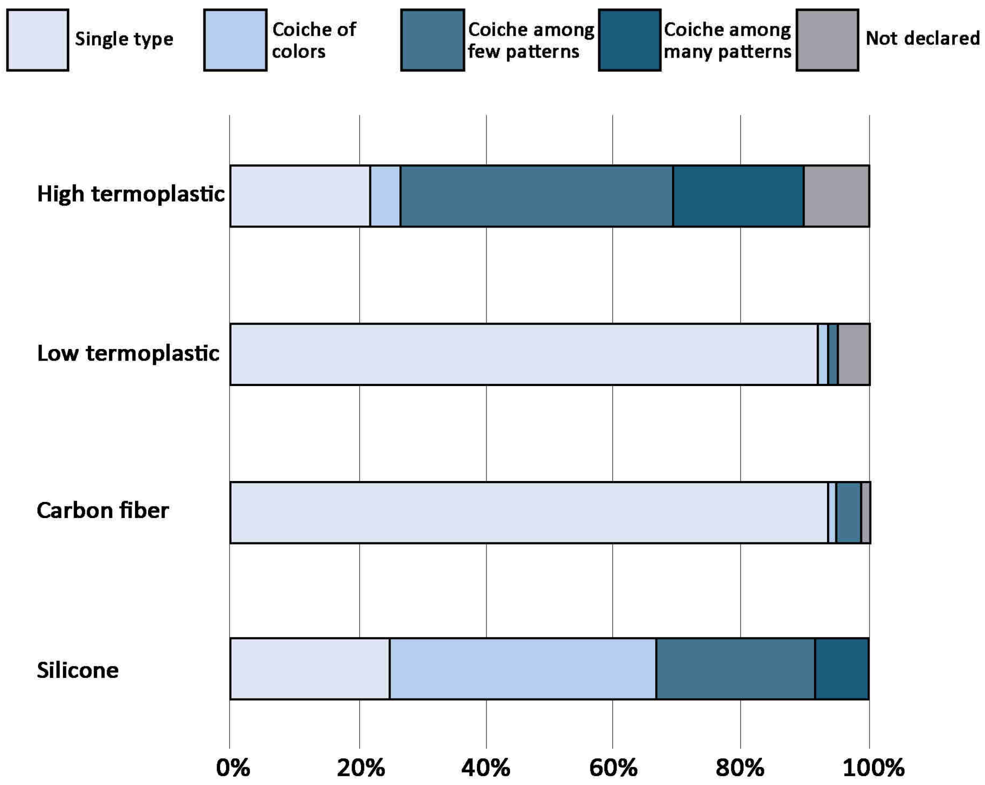
Relation between the type of AFO and the material it is made of ding to meet children taste shouldn't require particular effort and cost. It could be particular important if we supposed that AFO, since its advantages in return energy during gait, could be used more and more in the future. Nowadays only few Finland and Sweden companies, among the ones selected, offer similar possibilities. High thermoplastic AFO, on the contrary, are the most flexible and susceptible of aesthetic customization. Silicone AFOs as well are quite versatile, especially in the choice or colours more than among patterns but if their use will increase in future, probably their aesthetic features will expand as well.

Possibilities of aesthetic customization in different countries

The last illustration visualizes how different possibilities of an esthetic personalization are offered by manufacturers of different countries. In order to give a unitarian and synthetic view of all the results, I considered all the North American products together, as if they were included in Able Data catalogue as if they were not, the Italians, the UK's product and the others rest Europeans.

All the other European products were considered together mainly to have a numerical sample comparable with the other categories. Inside this last group, however, it is possible to notice how the behaviour of AFOs manufacture on aesthetical aspects of Scandinavian products (Norway, Sweden, Finland, Denmark) is similar to UK ones, while all the other European products have a possibility of customization most of the time even lower than Italian orthoses.

The first data that emerges from the observation of the graph is the high percentage of European manufacturers who don't declare online on their website the possibility of aesthetic personalization of lower limb orthoses, while this number drops to almost zero if we consider American products.



Connection among the choice of the material of an AFO an its possibility of anesthetic customization

In my opinion this could be read in different versions:

- European Manufacturers are more intended to a local user base and therefore buyers are supposed to go to the establishment and to choose at the place the covering they prefer;
- There is a general higher sensibility on this topic in USA, also because, since the customer base is definitively larger, this element can make the difference in the user or parents' user choice of the manufactory. Therefore it becomes important to show all the possibilities starting from the websites, because they probably consider than the first selection among manufactories occurs online;

NO PERSONALIZATION

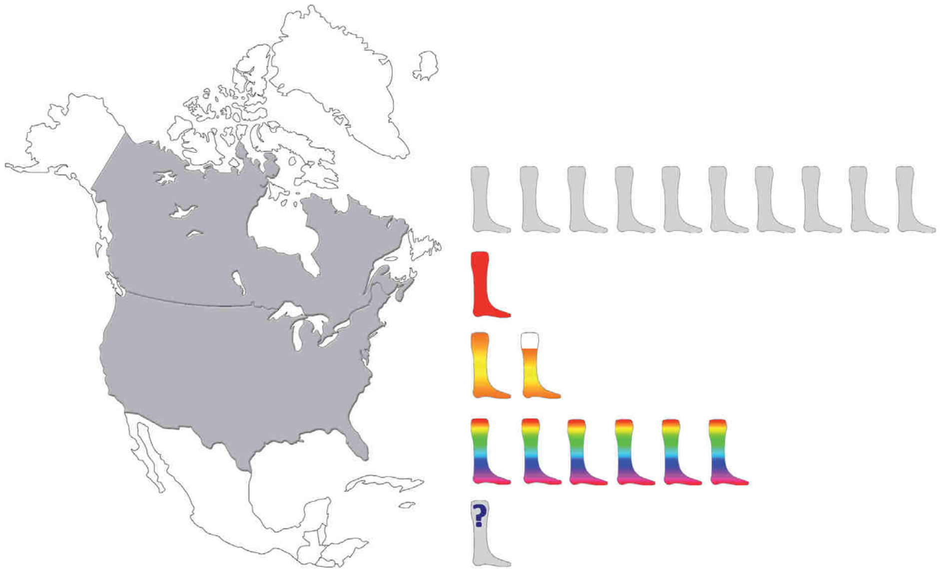
CHOICE OF COLORS

CHOICE AMONG FEW PATTERNS

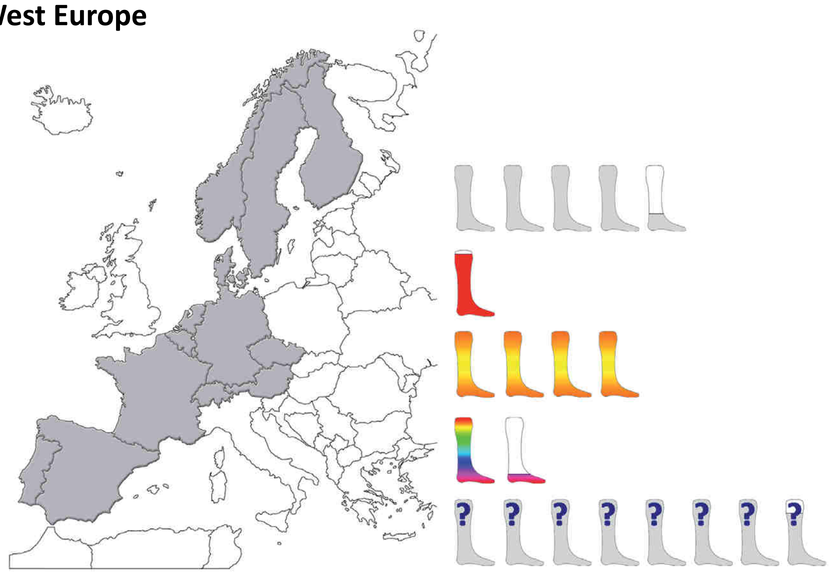
CHOICE AMONG MANY PATTERNS

NOT DECLARED

North America



West Europe

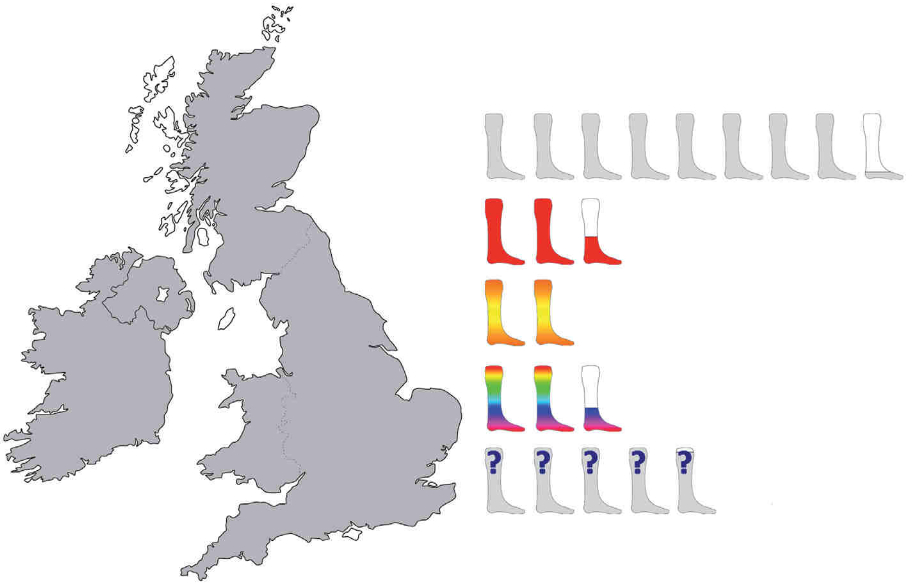


Percentages of options, when buying an AFO of chosing, maintaing the same clinical caractheristics, among more possibilities of esthetic customizations

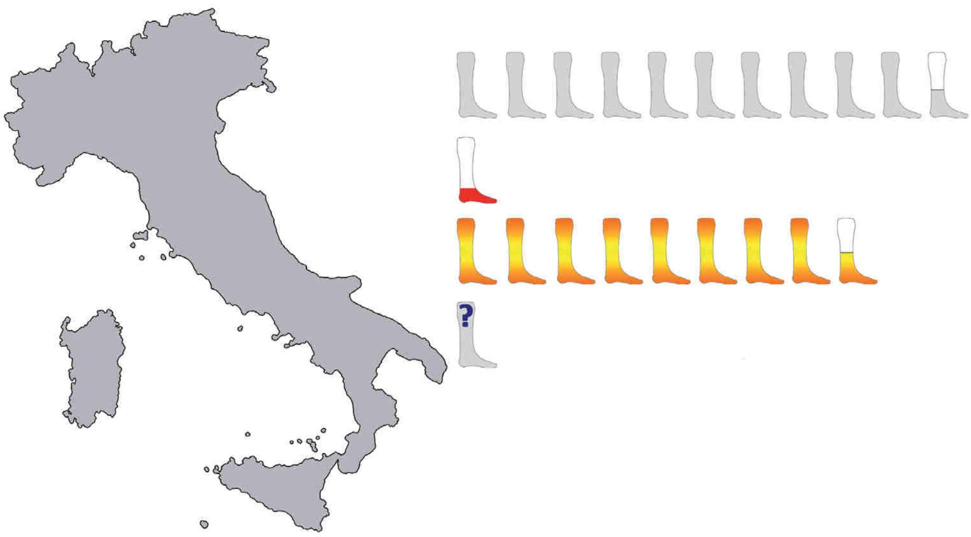
- The low percentage of Italian companies who don’t declare any possibility of aesthetic personalization is not significant since among all the Italian manufacturers we are considering only the ones who had a complete catalogue online with a full description of the products and therefore were more oriented to this kind of communication.

In particular among American manufacturers it is offered sometimes the possibility not only of choosing among a wide range of products, but even of upload online an high quality image that will be applied on thermoplastic AFOs.
On the contrary there is a large market of standard orthoses with no possibility of any aesthetical choice that is sell through internet and home delivered.
In Italy the situation seems to be quite uniform. Despite standard products and the ones in low thermoplastic who usually do not present any personalization, the main manufacturers offer the possibility of a range of 5-10 alternative patterns.

England



Italy



Percentages of options, when buying an AFO of chosing, maintaing the same clinical caractheristics, among more possibilities of esthetic customizations

3.3.11 - FINAL CONSIDERATIONS ON MARKET ANALYSIS

One of the most evident aspects that emerges in the analysis on Ankle Foot Orthosis, is the relevant ***discretion and freedom of action of all the staff who is involved in the manufacture of AFOs*** from the very first moment of the prescription to the phase of test of the orthoses.

Especially for daily AFO, used for the gait, a **more accurate gait analysis**, conducted taking advantages of new technologies will bring more precise prescriptions. A ***database that register periodically the evolution in the morphology of the feet,*** the advancement of dorsiflexion retractions in relation with the annotation of the use of AFOs, the frequency and type of stretching therapy and pharmacological cures will help in the understand the condition of the patient, his clinical history and, what's can be even the most, to have comparable results and reliable statistics. These data could be useful, for example, a***s to observe the evolution of the disease in patient with DMD, as to compare different solutions and effect among comparable cases***.

A Netherlands research in support of this thesis affirms that *"for every ankle orthosis there is an optimal stiffness associated with the lowest energy cost of walking for a given get set of gait-related impairments"*[64].

The scientific link between **mechanical AFO functioning** and benefits for the patient **in terms of energy consumption** is one of the keys to achieve the best optimization of the medical device. The analysis evaluated the gait of a group of seven patients with and without leaf spring AFO. One of the results of this research, for example, is to prove that carbon fiber AFO require 40% energy less during gait, compared to polypropylene AFO. Moreover the research put in evidence the relation between the mechanical functioning of the AFO and the benefit perceived by the patients during gait. However, besides specific result, the most relevant aspect is to highlight the importance of a better design of the AFO that takes in consideration scientific and comparable parameters and not only handcraft experiences.

With regard to night splints, for example, a value of the muscular strength of the calf of pushing the foot and moving it from its stretching position inside the AFO could have a direct effect in determining the resistance that the material of the AFO has to counteract and consequentially to determinate the thickness of thermoplastic.

It is highly desirable a better objectification of the AFO prescription process. In world market is evident how foot orthoses are characterized by forms and materials rather than function and mechanical properties. A change of perspective in the design of the product will certainly produce more effective orthoses and, most of all, objective and comparable information on AFO's properties. But to achieve this result, the phase of acquisition of data must be standardized, as in gait analysis, as in the lower limb force measurement, as in range of motion, fixed retraction or required angles of dorsiflexion.

Furthermore the advantages of a user centered process must be bilateral, on the definition of customized technical requirements and on a change in the psychological approach to the issue. The application of modern technologies could allow complete freedom in personalizing the shape, patterns and colours to be applied on AFOs and we have already put in evidence how this element can become crucial in the process of acceptation and personalization of the orthoses.

64 BREGMAN D. J. J., *Finding a formula for the optimal AFO*, in *Lower Estremity Review*, March 2012

Concluding it can be noticed that all the analysis that compare orthoses for all the aspects beside their clinical efficacy, such as marketing strategies, choice of aesthetic alternatives, on line purchasing and similar, penalize European manufacturers compared to American ones. My personal perception is that this result is due not only, by a real difference in the production, but it has to be related also with the choice of considering manufacturers that only have a catalogue of their products published online. This survey disadvantage can be motivated by:

- an higher level on computerization in America, a greater attention in website communication and on line marketing strategies;
- different purchasing methods in America with a broader diffusion of remote orders without the necessity of personally moving to the establishment but simply acting through company's website.

However the proposed interpretations of data are just some of the possible transversal lecture that can be extract and visualized from the database. An integrated online portal dedicated to orthoses will certainly come in aids of technicians and patients. The one proposed is just a first attempt that has been proved to be useful at the aim of the thesis and secondarily to test possible results of similar analysis.

Further evolutions of this first idea are desirable in future with a direct contact and collaboration with manufacturers that will be interested in being involved in the project. For the aim of the thesis this information were essential in guiding design process. They allowed to acquire deep knowledge and understanding with the product, obtaining useful suggestion to guide every future choice.

However, as it was said at the beginning, market analysis involved all types of AFOs, while a focus on AFOs indicated specifically for DMD patient, at this moment of the research, is the necessary future step to address market analysis' suggestions to DMD needs.

3.4 - ORTHOSES FOR DUCHENNE MUSCULAR DYSTROPHY

People affected by Duchenne Muscular Dystrophy are suggested to use a wide range of orthoses during their life, depending on the stage of evolution of the disease. They will follow the person with DMD since the moment of the diagnosis and for their entire life, becoming objects of their daily routine. Unfortunately AFOs aren't able to "cure" the disease or to make some of the disease's effects regress.

However scientific literature and clinic experiences are undoubtedly sure that a constant use of Ankle Foot Orthoses, suited to user needs, to his age and stage of evolution of the disease, it can prevent severe problems and delay the occurrence of other complications.

As we saw in the orthopedic management of people affected by DMD in chapter 2, one of the most early and visible effect of the disease is the progressive equinus deformity of the feet. This deformity is one of the firsts to appear, at about 5 years. Progressive muscular weakness of lower limbs causes a retraction of Achille's tendon, that is no more hampered by the muscle they are bounded with. This distortion antedate the moment in which the boy is no more able to walk independently of only two years, even if muscular strength should be still enough to stand. Besides the already discussed effect of delaying wheelchair confinement, *"the dorsiflexion weakness coupled with the atrophy of the intrinsic muscles, causes foot pains with thick callous formation under the metatarsal heads and calcaneus. The pain is caused by the foot slapping, which in turn is due to the lack of normal dampening action of the pretibial muscles at heel strike in conjunction with the lack of normal padding around and under the metatarsal heads due to the intrinsic atrophy. This combination of atrophies and weaknesses causes the patient to develop a rigid equinocavovarus foot."*[65]

Moreover, since the progressive nature of the disease, the function, use and types of AFOs change significantly during the life of a DMD patient and for this reason they will be carefully analyzed separately.

3.4.1 - Use of AFOs in different stages of the disease

EARLY AMBULATORY PHASE

Tightness of dorsiflexion of the ankle could be clinically detected since about three years old, although the gait pattern is normal. Fixed equinus and contractures appears progressively by the age of six, when the foot usually couldn't be brought anymore into a neutral position[66]. Night splint orthoses, in conjunction with a passive stretching regimens, are recommended throughout life since the moment of the diagnosis of DMD because they can help to prevent or minimize progressive equinus

65 *Ballert Orthopedic*, http://www.ballert-op.com/muscular_dystrophy.asp (March 2013)

66 WILLIAMS E. A., READ L., ELLIS A., MORRIS P., GALASKO C. S. B., *The management of equinus deformity in Duchenne Muscular Dystrophy* , op. cit.

This paper reports a tryal conduct on 69 Duchenne patients, (age range 4 to 17 years) to prove the effect of surgery at the ankle to correct equinus deformity. It proves that, if made in the correct time and with a quick post-operative riabilitation, it could bring several benefit to the patients. Furthermore it proves the importance of a constant use of nightsplints for the management of the equinus foot.

contractures[67]. They can be worn at night or during the day when the child is resting and not walking, for example during his homework in the afternoon or in the evening when he's on the sofa watching television. It is important to start wearing AFO even before the appearance of first retractions in order to maintain normal joint range of motion at feet and to make the child used to night splints since his infancy. Establishing as soon as possible an orthotic stretching routine will make easier the process of acceptation of orthoses.

On the contrary, at this stage, daytime AFOs are uniquely discouraged, since they add excessive weight to a progressively weaker knee extensor during the loading response phase. Furthermore a constant use of daily AFO can even be more harmful since recent literature evidences *"the susceptibility of dystrophic muscles to permanent injury when subjected to eccentric contractions."*[68] It would be counterproductive, further weakening the quadriceps and potentially shorten the period of independent ambulation.

MIDDLE AMBULATORY PHASE

Knee-angle-foot-Orthoses (KAFO), or callipers, can be suggested by physiotherapist in the late stage of ambulation or early no ambulatory stages to allow standing or little ambulation. The function of the KAFO is to lock the knees to substitute the weak quadricipeps. Despite nightsplints, in KAFOs a slight plantarflexion of the foot, as well as heel wedges can be functional to facilitate the boy's balance during gait. KAFO can be provided with ischial shelves, to allow the boy to "sit" into the orthoses[69]and it has been proved that a footplate that extend until the metatarsal heads[70] is more effective.

During this phase a surgery can occur to lengthen Achille's tendon. If so, it is crucial that the boy starts to walk even on the same day of the operation, first with walkers, until he doesn't recover stability and a new equilibrium and then with the help of callipers. Detailed information on the opportunity of such a surgery are discussed in the Orthopedic Management paragraph, in chapter 2.

"Swing phase is compromised by the locked extension of the knee joints bilaterally, necessitating lateral trunk lean over the stance limb to lift the swing leg. Initial contact is instigated by the heel, translating into forward progression of the locked limb. Hyperlordosis of the lumbar spine and trunk hyperextension persist, keeping the child's weight line posterior to the hip, thereby providing passive stability at that joint"[71].

67 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy,* Part 2, op. cit.

68 CHILDERS M.K., OKAMURA C.S., BOGAN D.J., et al., *Eccentric contraction injury in dystrophic canine muscle*, Arch Phys Med Rehabil 2002; 83(11): pp. 1572–1578

69 SIEGEL I.M., *Pathomechanics of stance in Duchenne muscular dystrophy*, Arch Phys Med Rehabil 1972; 53(9): pp. 403–406

70 HECKMATT J.Z., DUUBOWITS V., HYDE S.A., et al., *Prolongation of walking in Duchenne muscular dystrophy with lightweight orthoses: review of 57 case*, in "Dev Med Child Neurol", 1985; 27 (2): pp. 149–152

71 HSU J.D., FURUMASU J., *Gait and posture changes in the Duchenne muscular dystrophy child,* in "Clin Orthop Relat Res" 1993; 288: pp. 122–125

SPENCER G.E., VIGNOS P.J., *Bracing for ambulation in childhood progressive muscular dystrophy*, in *J Bone Joint Surg Am* 1962; 44: pp. 234–242

SIEGEL I.M., *Maintenance of ambulation in Duchenne muscular dystrophy. The role of the orthopedic surgeon.*, in "Clin Pediatr" 1980; 19(6): pp. 383–388

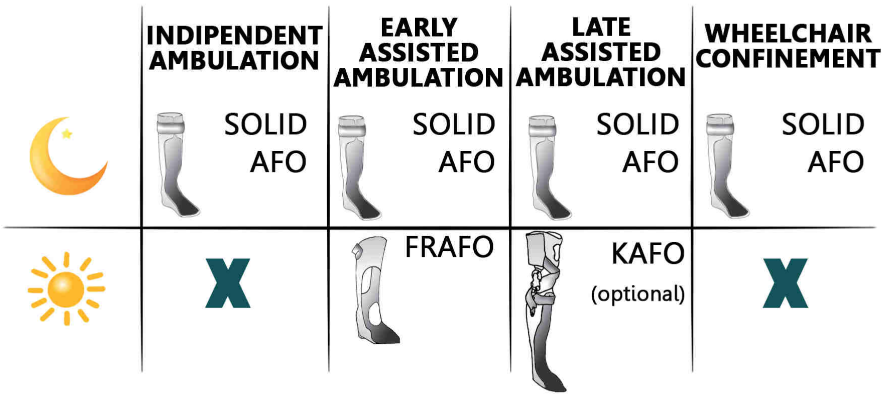
In this phase the function of daily orthoses for DMD children isn't to give them the possibility of recovery a "normal gait", similar to an unaffected person. At this stage the aim of the orthoses is only to try to prolong as much as possible an assisted ambulation, in order to delay complications related to a wheelchair confinement. AFOs goal is to compensate physical deficits *"to achieve the most efficient, optimised, healthy, safest gait, that couldn't even include, for example, the value of speed of the gait."*[72]

NON AMBULATORY PHASE

When ambulation is inhibited and the boy is wheelchair bounded, the use of daily AFO and night splits is suggested as well by scientific literature, even if this practice seems not to be common in Italy. Their use at this stage is useful to deter the progression of deformities and all the complications related with it. However, it is important not only to prevent cramps and deep pain due to fixed deformities, but also to allow children to be capable of continuing wearing common shoes of the ordinary market, as his pairs, without be forced for resourcing to the special market of orthopedic shoes.

"A passive standing device for patients with either no or mild hip, knee or ankle contractures is necessary for late ambulatory and early non ambulatory stages. Many advocate continued use of passive standing device or a power standing wheelchair into the late non-ambulatory stage if contractures are not too severe to restrict positioning and if devices are tolerable."[73]

In summary, the use of KAFO in standing transfers of a boy with DMD can be functional for little movements in or out home, as long as general health conditions, height and weights allows it.[74]



Use of nightly and daily Ankle Foot Orthoses during the phases of the evolution of DMD

72 GRONER C., *AFO users must rethink concept of 'normal' gait*, op. cit.

73 BUSHBY K., et al., *The Diagnosis and Management of Duchenne Muscular Dystrophy*, Part 2, op. cit.

74 HSU J., *Management of foot deformities in Duchenne pseudohypertrophic muscular dystrophy*., in *Orthop Clin North Am* 7 (4) 1976: pp. 979-984

3.4.2 - Specific psychological aspects related to the use of the orthoses for people affected by DMD

In the life of a Duchenne child and his family there will be two moments in which the medical and technical staff will have a crucial role in determining the first approach to psychological acceptation of the orthoses. The first one will occur between professionals and parents, when the child is too young to have an active role in the moment, and doctors have carefully and technically to explain the aim of wearing AFOs for DMD people and why their constant use is so important for the health of their child. Afterwards, when the child will grow up, medical staff and parents will have to explain the same contents, but with a language appropriate to the child, the value of his orthoses. In case of Duchenne Muscular Dystrophy these moments are if possible even more delicate. For these children Ankle Foot Orthoses in any case will be a cure or a solution for their disease and their constant use, at least considering current medical discoveries, will only delay an inevitable worsening. Giving the child false expectations only to persuade him in the immediate of wearing his AFO could be extremely dangerous with the passage of time. The inevitable worsening of their clinical conditions will be experienced as a personal failure despite all his efforts in donning AFOs even against his will, and this strong feeling of frustration has to be avoided as much as possible.

Moreover in the psychological approach to orthoses for people affected by DMD, an important role is played by child's parents too. In a first stage, when children are infants, they carry out the main role in choosing, ordering, taking care and wearing AFOs for their children. Then, even in the passage to adolescence, parent's role remains crucial in supporting and motivating the child at the constant use of AFOs. Once independent ambulation becomes difficult and when the doctors suggest the use of daily AFOs or KAFO, the role of parents is determining again in comforting and encouraging the child.

However, when ever these orthoses will be no more sufficient to guarantee a safe standing, parents shouldn't force excessively the child and accept the passage to the wheelchair. As described in chapter 2, on psychological effects of DMD, this is one of the worst passage for parents even more than for the children. They indeed usually feel relieved by not being forced more to wear painful and bulky orthoses. A KAFO in anyway allows a normal gait and it risks to prevent the child from the possibility of a walk out with classmates and to keep their pace.

Concluding, it is important to underline that, particularly for DMD users but in any case, the main function of Ankle Foot Orthoses before even to obtain a clinical result, is **improving the Quality of life of patients**. If obtaining an even minimum clinical result can effectively improve the life of the patient, it is important to encourage him. But if the obtainment of an orthopedic result goes to detriment to psychological sphere, without a real chance of improvement, it must be remembered that the aim of every cure must be only the improvement of the Quality of Life.

ANALYSIS

PART TWO

METHODS AND DEVELOPMENTS

4 PRODUCT DESIGN METHODS

@ Ping Li
https://www.flickr.com/photos/heckler06/1550136913/in/photostream/

4 – PRODUCT DESIGN METHODS

Market Analysis on Ankle Foot Orthoses evidenced the lack of an overall design process in the design of the AFOs that took in consideration not only technical requirements but all the system, including ***users' needs and expectations***. Even in the cases in which an aesthetic attention was noticed, it was something "annex" on a medical device, but an integrated evaluation on the product was still missing.

This observation suggested to broad the research to ***User Centered Design*** methods and to the main schools of thoughts and theories that characterized these last decades that were born inside an UCD approach, connoted by a particular attention to social inclusion, enhancement of differences, disability: ***Universal Design, Inclusive Design, Design for All, Design for Disability***. Even if the design of AFO was certainly a problem of Design for Disability the analysis of the other theories gave the appropriate frame to focus main problems and better strategies to adopt in the design process.

But this phase required another intermediate step, since from the theoretical approach it was necessary to individuate the right rational tools to transform users' requirement in reliable design suggestion. Among the comparison of several different methodologies and the evaluation on their suitability for the aim of the research, ***Quality Function Deployment*** proved to be the best process to guide the design of a new type of Ankle Foot Orthosis for people affected by Duchenne Muscular Dystrophy.

4.1 - FROM CUSTOM-MADE TO USER-CENTERED ORTHOSES

Market analysis on Ankle Foot Orthoses was an occasion to survey not only final products of manufacturers but even to collect a first general impression on manufacturers' organization and approach to the production of orthopaedic orthoses.

The level of insight of this study doesn't allow to elaborate statistical reliable data, but what clearly appeared was a dichotomy between:

- small companies, with an handicraft structure, composed by few workers and with a one-by-one contact with patients;

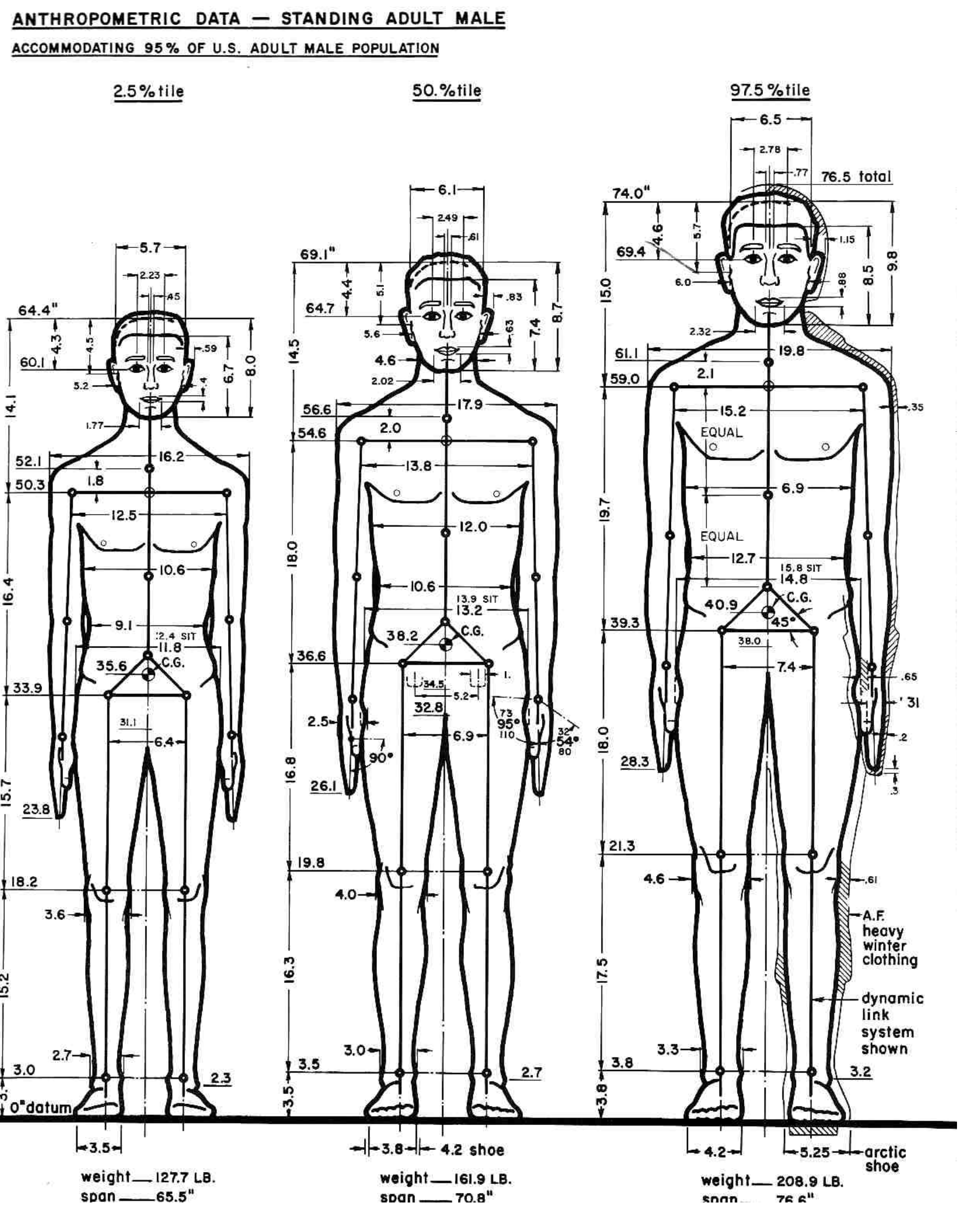
- multinational companies, with an industrial production of standard AFOs.

In the last situation, in most of the cases the presence of a research staff is evidenced, but its activity is addressed to experimentation on new material or technologies. An overall feeling is that this sector of product design is developed and managed almost exclusively as a medical problem that gives a functional answer, even if sometimes concealed by coloured textures. This configuration could motivate the perceived absence of a real "design process" related to the object. This hypothesis is even supported by a research, *"Effective design methodologies for rehabilitation equipment - The CACTUS Project"*[1], that claims the low quality of rehabilitation equipment in general and the absence of a more global and integrated design process, able to efficaciously interprets user participation and information provision *"in*

1 BAMFORTH S., BROOKES N., *Effective design methodologies for rehabilitation equipment - The CACTUS Project*, in Design Applications in Industry and Education. 13th International Conference on Engineering Design, ICED01 Glasgow - Professional Engineering Publishing, 2001 pp. 219 - 226

order to improve customer satisfaction through increased product quality.”[2]

In the lasts years many progresses took place to make products more effective, lighter, stronger and cosmetically more appealing, but a lot can still be done. Besides standards ones, orthoses are custom-made, but this concept is not synonymous of user-centered. This concept implies the development of a design that considers the patient as the centre of the process, it doesn’t limit to evaluate his feet’s shapes or his tendons’ retraction, that are even important and fundamental to assure clinical efficacy. A user-centered design approach considers the user in all his components, and his fears, and his expectations. Until assistive production will remain a medical industry issue, these products will inevitably remain just a functional aid. A shift of these orthoses to design field is desirable in order to enhance the attention on the user as modern theories, methods, tool and approaches are suggesting.
Hereinafter a brief excursion on **human centered design theories** is presented to explore different alternative design methods and individuate all the instruments that could enhance the production of Ankle Foot Orthoses.



Henry Dreyfuss, *The Measure of Man*

@ Human Factors in Design

2 BAMFORTH S., BROOKES N., *Effective design methodologies for rehabilitation equipment - The CACTUS Project*, ibid.

4.2 - USER CENTERED DESIGN

In 1959 **Henry Dreyfus**[3], with his ***"The Measure of Man"*** was one of the firsts to put the attention on human measures and anthropometry in design process against the mass products' idea based on the concept *"one size fits all"*. The ***Vitruvian man*** stereotyped man, young, tall, healthy, white, renewed in modern design by Le **Corbusier** with his ***Modulor***, who gave measures and proportion to all manufactured goods, from objects to architectural spaces, has proved to be a failure.

A broader tendency, as opposite to some self-celebrative fashion designers, or to some common scholastic approaches is to put greater attention to the user, to his interaction with the product, not only functional but even emotional and in terms of awareness of its potential of use. The goal of responding user needs is no more seen as a limitation of creativity but as a spur to innovation.

The classic design method is the ***product centered design***. It is focused on the definition of the functional and aesthetic properties of the product. It begins with what already exists and tries to adapt it to new functions or users, and for this reason it is defined as a "*reactive*" process. The ***user-centered design***, on the contrary, has no shape, materials or spatial morphology pre-defined in mind. It starts from user needs to develop step by step an innovative product. It begins each time from the definition of the product's user to guide the design process, and therefore it can be considered as a "*proactive*" method.[4]

Human factors are increasingly becoming milestones of the product design process. Users are no more seen as mere consumers but in an holistic way, taking care of their cognitive, emotional and physical components as well as their hopes, fears, dreams and values. As Patrick W. Jordan says in his *"Designing Pleasurable Products"*, the aim of product design must be creating something that for the user "*is a joy to own*"[5].

In the production of industrial goods the aim of the process is creating something that is desirable from the market and therefore from the larger amount and typology of users possible. But in reality this condition happens rarely due to mistakes in the design process, in the deep knowledge of user needs and information. The process of users' inclusion requires more efforts but considering users' emotional and psychological factors in the ideation of a new product guarantees a better commercial competitively of the final product[6].

The term "***User-Centered Design***" originated in **Donald Norman**'s research laboratory, at the University of California in the 1980s[7], which became widely used after the publication of the book entitled *"User-Centered System Design: New Perspectives on Human-Computer Interaction."*[8]
First of all he defines Users not only who uses the final product or artifact.

3 DREYFUS H., *The Measure of Man: human factors in design*, Whitney Library of Design, New York; 1960

4 STEPHANIDIS C., *Universal Access in Human-Computer Interaction. Users Diversity. 6th International Conference,* UAHCI 2011

5 JORDAN P. W., *Designing Pleasurable Products,* Taylor & Francis, London, 2000

6 MINCOLELLI G., *Design Accessible*, Esperienze progettuali e didattiche sul tema del *Design for all*, Maggioli, Rimini, 2008

7 ABRAS C., MALONEY-KRICHMAR D., PREECE J., *User-Centered Design*, in Bainbridge W., *Encyclopedia of Human-Computer Interaction*, Thousand Oaks, Sage Publication, 2004

8 NORMAN D.A., DRAPER S.W., *User-Centered System Design: New Perspectives on Human-Computer Interaction*, Lawrence Earlbaum Associates, Hillsdale, NJ, 1986

"Eason[9] identified three types of users: primary, secondary and tertiary. Primary users are those persons who actually use the artifact; secondary users are those who will occasionally use the artifact and those who use it through an intermediary; and tertiary users are persons who will be affected by the use of the artifact or make decisions about its purchase."[10]

The **ISO standard Human-Centred design for interactive systems ISO 9241-210, 2010** issues the six rules for a user centered design:

1. *"The design is based upon an explicit understanding of users, tasks and environments.*
2. *Users are involved throughout design and development.*
3. *The design is driven and refined by user-centered evaluation.*
4. *The process is iterative.*
5. *The design addresses the whole user experience.*
6. *The design team includes multidisciplinary skills and perspectives."*[11]

Useful tools in this analysis can be:

- **Persona,** or **personas**, fictional character that collect the features of a possible user of the object. They can be even more than one person if it is difficult to imagine a single ideal consumer. An "anti-persona" can be added if defining a character who personifies a person for who the product isn't addressed and can be useful in the conceptualizing the process. Focusing on one or more "typical" stakeholders, instead of "average" ones helps in empathizing with the characters and in getting in tune with their emotions.
- **Scenario,** the invented "daily life of" the persona. It can involve all his day or only the events that put him in relation with the product or service that is object of analysis. There can be even more scenarios that figure out the best possible way of things to turn out, as well as an average scenario or the possible worst one, assuming that everything goes wrong and trying to figure out why, in order to avoid all possible causes.
- **Use case**, a short episode that put in relation the user, the object and the rest of the world, described in every tiny detail, step by step, to analyse in every single moment how the story can evolve or change and if and when the object or service, in relation with its user, proves its tops and worst moments.

Moreover, in User-centered design (UCD), the phase of ideation of a product is at least as important as the phase of testing. In an iterative process this step is crucial since it allows designers and experts to observe final users on the job with their product and highlight weakness and improvable features.

Nowadays User-centered design is a broad term that describes as a philosophy as a variety of methods associated by the involvement of the user, with any role or in any phase, in the design process.

Users' participation since the very first steps of the ideation of a product or service, has been put in act since 1970 in the **Scandinavian tradition**[12] and soon after

9 NORMAN D.A., DRAPER S.W., *User-Centered System Design: New Perspectives on Human-Computer Interaction*, Lawrence Earlbaum Associates, Hillsdale, NJ, 1986

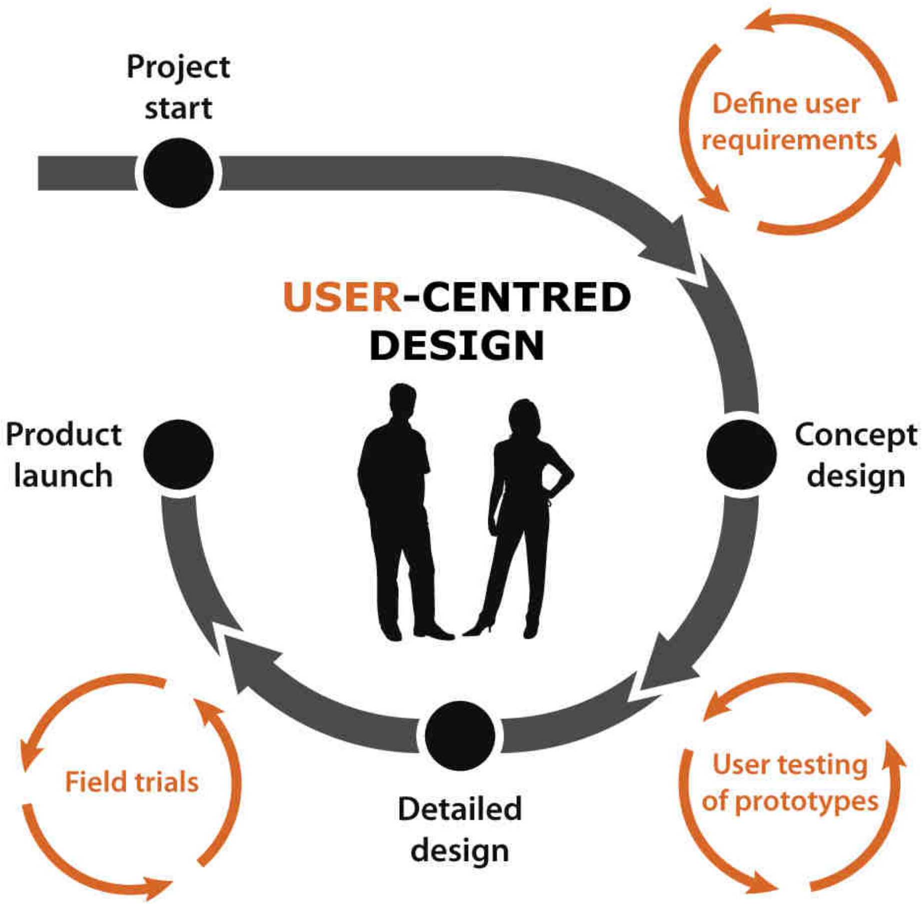
10 ABRAS C., MALONEY-KRICHMAR D., PREECE J., *User-Centered Design*, op. cit.

11 EASON K., *Information technology and organizational change,* Taylor and Francis, London 1987

12 GREENBAUM&KYNG (eds), *Design At Work,* Cooperative design of Computer Systems, Lawrence

in North America, applying the methods that have been called as ***Cooperative or Participatory design***[13]. It is based on the listening of users by interviews, questionnaires, observation, statistical analysis or similar. However in all cases in which the user is regarded as a co-designer it is important to consider cultural differences and diverse professional backgrounds compared to professional designers[14]. Due to this factor the user probably will not understand designer languages, as well as he will not be able to express all his needs, even the more latent ones in a comprehensible and clear way. There are indeed several ways in which users can be involved in the process, from requirements gathering and usability testing until the design process. Concluding, the major advantage in this approach is a deeper understanding of the psychological, social and ergonomic factors that affect the users. Designers can survey or foresee their expectations and this guarantee a better satisfaction of the end user, more effectiveness and safety.
The major disadvantage of user-centered design is that it can be quite costly because the users' needs analysis, as well as the testing phase, requires more time and it demands a team of experts in different professions to interpret correctly all data.

Some of the most relevant theories that can be included in the User Centered Design approach are the Universal Design, the Inclusive Design and the Design for All. In the following paragraph these theories will be singularly discussed.



A typical UCD process. The definition of the concept of the design comes as a conquence of the definition of users' requirement, involved in every phase of the project, included the phase of testing that precedes the definition of the details and the final field trials before the launch of the product.

@ Emotive Systems

Erlbaum, 1991

13 SHULER&NAMIOKA, *Participatory Design*, Lawrence Erlbaum, 1993

14 EHN P., KYNG M., *Cardboard computers: Mocking-it up or hands on the future.*, in Grenbaum J., Kyng M., *Design at work*, Lawrence Erlbaum Associates, Hillsdale, NY, 1991

ANALYSIS

4.3 - UNIVERSAL DESIGN

The idea of an universal access to goods took its origin from the need of free access for wheelchair people and the demand for a "barrier-free" space. Thereafter the idea evolved by incorporating the concept of free access to all goods and services.

In 1985 the American architect and product designer **Ron Mace**, a wheelchair user, promoted the term ***Universal design*** and in 1989 he established the Center for Accessible Housing at the College of Design at North Carolina State University, later renamed the Center for Universal Design. One of the great Mace's merits was to point out that wheelchair accessibility, ramps, turning spaces and accessible toilets, are only the tip of the iceberg of the concept of ***user-friendliness that includes all our interactions with the designed world***.

The Center defined a set of seven principles[15] to guides design community through this method. *"Universal design was defined as: the design of products and environments to be usable by all people, to the greatest extent possible, without adaptation or specialized design."*[16]
In this sense it goes further beyond the idea of accessible design or design for disable people since "*it provides permanent, attractive features that everyone would find acceptable in their home"*.[17]
The premise is that anyone in our life lives a condition of physical or mental impairment at leas once, for a trauma, or even a temporary condition due to external factors and almost anyone of us knows a physical or mental disable. Moreover the probability of loosing physical, sensory or cognitive abilities grows with the age and the average age of the world's populations is continuously growing. And then, the globalization of marketplace is exponentially enlarging the consumer base, including people of different cultures, language and the design has to consider these new incoming requirements[18].
These considerations highlight the importance of this theory in stimulating a new approach to a new form of design aimed to be usable by the greatest variety of people. Architect and designers started to observe that the necessity of providing "special" solutions, environment, object for people with special needs most of the time lead to ugly solution, while an integrated design of a unique solution usable by

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15 "The seven principles are:

1 – **Equitable use**, the design is useful and marketable to people with diverse abilities.

2 – **Flexibility in use**, the design accommodates a wide range of individual preferences and abilities.

3 – **Simple and intuitive to use**, use of the design is easy to understand, regardless of the user's experience, knowledge, language skill or current concentration level.

4 – **Perceptible information**, the design communicates necessary information effectively to the user, regardless of ambient conditions or the user's sensory abilities.

5 – **Tolerance for error**, the design minimizes hazards abs the adverse consequences of accidental or unintended actions.

6 – **Low physical effort**, the design can be used efficiently and effectively with a minimum of fatigue.

7 – **Size and space for approach and use**, appropriate size and space is provided for approach, reach, manipulation and use regardless of user's body size posture or mobility."

CENTER FOR UNIVERSAL DESIGN, College of Design, *The principles of Universal Design,* NC State University, 1997

16 CREWS D. E., ZAVOTKA S., *Aging, Disability, and Frailty: Implications for Universal Design,* in *Journal of Physiological Antropology*, num. 25, 2006: pp. 113-118

17 NULL R., *Universal design: creative solutions for ADA compliance*, Professional Publications, Belmont, 2001

18 STORY, FOLLETTE M., MUELLER, JAMES L., MACE, RONALD L., *The Universal Design File: Designing for People of All Ages and Abilities,* NC State University, The Center for Universal Design, 1998

everybody was often a less expensive, attractive and even marketable solution. In this sense Universal Design differs from Assistive Technology or Design for disabilities, since it aims at integrating disable needs in ordinary products and not creating specific goods addressed only to them. It involves Accessible Design but is not only identified with that. It can be applied to objects, to architecture, urban planning, but even web design and interfaces and, especially American movement of Universal Design leading many battles for the assertion of user consumer rights.

Claudine Casabonne, *88's new visual designer on Universal Design,* 88 Creative

4.4 - INCLUSIVE DESIGN

Simultaneously in England the idea of an "*Inclusive design*" was developing. It originated from the same principles but it is more focused in orienting businesses to respond to the needs of a modern society, among which a design for all kind of users takes a vital role.

"In this context, Inclusive Design is seen as a progressive, goal oriented process, an aspect of business strategy and design practice, rather than a genre of design or a performance measure." [19]

This means that in Europe the focus has been on social inclusion while in the US on individual rights.
The aim of an *Inclusive design* approach, developed in UK, is to enlarge the target of users of a product or a service to include as many consumers as possible, without compromising people's satisfaction as business profit. It was initiated by a collaboration between industry, designers, researchers and educators.
The attention is more on an inclusive social level rather than a design dedicated for disable or elderly people. An important practice in this method is to consider not only who is the final user of the designed product, but also who is excluded by its access due to physical, mental, social limitations of every kind[20]. This approach is a completely change of point of view compared with traditional practices in this field and highlights immediately the limits of the product if the result is carefully evaluated with the maximum catchment area estimated. Focusing on who cannot use the product and why, high spot immediately latent weaknesses of the object and aspects that could be improved to achieve a larger users' base. But this process requires accurate methods *"of assessing the features of a product and users' interaction with it to establish the capability demands placed upon the end-user"*[21].

"An inclusively designed product should only exclude the end-users who the product requirements exclude."[22]

That means that one product shouldn't have any capability demands to the user that is not necessary and that is just the result of an arbitrary designer's decision.

Product Design and design management can be really crucial in determining the rate of inclusivity. Their potential have to be carefully taken in consideration. However, if the user we would like to include has too much specific needs, his inclusion could generate a too high compromise and for this reason it has to be evaluated attentively.

Every decision has to take in consideration even the marketability of the product that cannot be sacrificed completely to inclusion features, risking the economic failure of production.

Moreover it must be noticed that **pursuing the inclusivity in a product does not correspond directly with users' satisfaction**. Users usually don't notice at all that one object is properly designed to encounter his ability or that it can ben equally used by other different categories of consumers, since it is taken for granted. On

19 CLARKSON J., COLEMAN R., KEATES S., LEBBON C., *Inclusive Design. Design for the whole population*, Springer, London 2003

20 IMRIE R., HALL P., *Designing and Developing Accessible Environments,* Spon Press, 2001

21 CLARKSON J., COLEMAN R., KEATES S., LEBBON C., *Inclusive Design. Design for the whole population*, ibid.

22 CLARKSON J., COLEMAN R., KEATES S., LEBBON C., *Inclusive Design. Design for the whole population*, ibid.

the contrary a user would probably don't like to realize that he is using a product designed specifically to meet his eventual physical or mental limitation and that the same object cannot be used by the rest of the population.
Concluding, inclusivity, in the design of mass product, has to be pursuit but it has not to be evident or it can be counterproductive[23].

The international design company IDEO[24], as an example, developed an innovative method to guide the design process based on storytelling. Trying to understand and observe potential users, they recreated plausible scenarios that involve the relationship between the user and the product[25].
The phase of a design of a new product completed, a crucial step for the success of the final result is the review of the project. At first it involves the general functionality of the object, but then a deep evaluation embraces its accessibility, aesthetically pleasure and social acceptability.

Designers are currently more and more trained in user centered design methods. The real challenge is now to change manufacturers' approach to these issues and to manage how legislation will accelerate this process. But, what is more important, it is necessary to make user demand aware of their huge role in pushing the market.

23 MINCOLELLI G., *Design Accessible*, op. cit.

24 MOGGRIDGE B., *Design by story-telling,* in *Applied Ergonomics* 24.1, Butterworth-Heinman, London, 1993: pp. 15-18

25 COLEMAN R., *Design strategies for older people. Designing for our future selves,* Royal College of Art; London, 1993: pp. 43-56

4.5 - DESIGN FOR ALL

In 1993, thanks to an European Program Horizon aimed at promoting projects able to improve the quality of life of disable people, the EIDD European Institute for Design and Disability was founded. It follows Universal and Inclusive design theories but with innovative and personal contributes and presenting more as a methodology than a theory. It considers as cultural references the Scandinavian tradition of participatory design, ergonomic design of the 60s and the Declaration on the Equalization of Opportunities for Person with Disabilities[26] issued by ONU in 1993, as well as American Disabilities Act[27]. In 1998 the organization defined its mission statement, ***Enhanching the quality of life through Design for All,*** but it is the Declaration of Stockholm of 2003 that added crucial elements to identify the uniqueness of DfA compared with other theories: ***"Design for All is the design for human diversity, social inclusion and equality".***[28] This Declaration was the forerunner of an important event for DfA, significant in symbolizing its content, it loosed the specification of Disability and in 2006 the EIDD became Design for All Europe.

DfA aims doesn't involve indeed only people with disabilities, but it must be considered as an instrument to promote social inclusion enhancing human diversity. It starts from the survey of user needs in an holistic and multidisciplinary approach and in this sense it is more close to Inclusive design than Universal Design, more aimed at the product design. It can involve each type of design, environment, everyday used products, services, culture and information[29].

The breakfast mug with two handles is a typical example of Design for All, useful for young children, for people with little strenght in the hands ... and for simmetrical design victims!

26 *Although not a legally binding instrument these Standard Rules were a strong moral and political commitment of Governments to take action to attain equalization of opportunities for person with disabiliti es. It was composed by 22 rules concerning persons of disabilities: preconditions for equal participation, target areas for equal participation, implementation measures, and the monitoring mechanism - and cover all aspects of disable persons.*
Standard Rules on the Equalization of Opportunities for Persons with Disabilities, General Assembly on 20 December 1993 (resolution 48/96 annex), http://www.un.org/disabilities/default.asp?id=26 (2015-01)

27 By a legislative point of view another important step in the recognition of disable rights was the Americans with *Disabilities Act* of 1990, that was followed by the T*elecommunications Act* of 1996, that extends for the first time the access to communications including people with hearing, speech and vision disabilities.

28 *The EIDD Stockholm Declaration*, Annual General Meeting of he European Institute for Design and Disability, 9 May 2004, http://www.designforalleurope.org/upload/design%20for%20all/sthlm%20declaration/stockholm%20declaration_english.pdf (2015-01)

29 ACCOLLA A., *Design for All. Il progetto per l'individuo reale*, FrancoAngeli s.r.l., Milano, 2009

ANALYSIS

An enlighten simple example of what could be a DfA product could be a breakfast mug. Why, if my grip is limited and I need to hold the cup with both the hands, I have to renounce directly to all the thousands and millions of different fashionable cups offered on general market and I can only choose among the very few alternatives of special market products, in special shops, located often only in major cities, were I can find a cup with two handles[30-31]? Doubtless a small differentiation in the production could be pleasantly accepted not only by disabled people, but even from very small children or whoever likes, for example, a symmetric design.

Furthermore what characterizes DfA from other User Centered approach is the passage from User to Beneficiary. All the other approach are aimed at making every people, including disable people able to USE an object, a space or whatever. DfA goes slightly further issuing that what it is not important only to use something but to take pleasure in using that product, living that space, etcetera. For example DfA doesn't consider sufficient that a public building is equipped with an accessible entrance if it is located far from the main entrance, in a service area, dirty and isolated that inspire bad feelings, frustration and margination in who is forced to use that entrance. Moreover this new concept of user/beneficiary doesn't only includes all the people that in any way, from the ideation to the use and disposal come in relation with the object but consider even each one of them in what they define an *"autopoietic system".* It is something in continuous evolution, always free of changing, following its natural development.

This relevance given to good feelings, to the desiderating and not only to requirements is the quality leap that includes emotions and aesthetic involvement. *Beauty inspires a proactive reaction in approaching a new object and therefore it automatically enhance the capacity of comprehension of stimulus reactions and, concluding, it improves its usability.*

30 CLARKSON J., COLEMAN R., KEATES S., LEBBON C., *Inclusive Design. Design for the whole population*, ibid., p. 66

31 BANDINI BUTI L., *Design for All - Aree di ristoro - Il caso Autogrill*, Maggioli Editore, Rimini 2013

ANALYSIS

4.6 – DESIGN FOR DISABILITIES

As it is clear by their names Design for All is different from Design for disabilities. Design for All has to include in its attention all the products in a broader sense that can be experienced from all people. The ones used exclusively by people affected with a temporary or permanent physical or mental impairment concern the Design for Disabilities. However in a synergic effect this last one takes big advantage from DfA, since better is the level of general inclusion and flexibility of the DfA project, easier will be the integration with Design for Disabilities requirements.

In the last decades disable or their parents' consciousness on their rights and "*social dignity"* is luckily becoming more assertive, especially in Western countries and this led to higher users claims on their dedicated products. At the same time institutions adapted to this new emerging consciousness and new legislations and regulations took in higher considerations physical or mental impaired people needs. Hereinafter a brief overview of the main step of this process.

At the end of the Second World War, in all Europe and USA the number of mutilated people was huge, as well as psychologically traumatized. An increasing attention was demanding on human and civil rights, on social justice, on the respect for each individual. In America this common scent became even more important after the Vietnam War and its tragic effects on population.

In 1963 the UK architect Selwyn Goldsmith published a guideline titled *"Designing for the disabled"*[32] In 1976 the American designer Victor Papanek gave a lecture at the Royal College of Art in London with the title "*Design for Need*", which anticipated most of modern thinking on design for disability[33].

One of the first official Acts for the recognitions of Disable was the *World Plan of Action Concerning Disabled Persons* written in 1982. However, since in 1988 it was not effective yet, Italian and Swedish delegates suggested an international human right convention for disabled people that finalized in 1993 with the UN *a tutel*. One of the first countries to receive and advance in legislation protecting handicap people was Australia that enacted in 1991 the *Disability Discrimination Act* and in 1995 the *Australian Adaptable Housing Standard*. In a chain effect all the developed countries started to adopt measures in this sense. Europe, UK and Holland were the driving countries.

Although these undeniable progresses, there was a common feeling that these laws lead inevitably to a new form of discrimination more than inclusion, explicated through the adoption of dedicated services, passages, toilets and so on. A first attempt to overcome this flaw was the US *Rehabilitation Act* of 1998.

However the real change of paradigm is merit to the I**nternational Classification of Functioning, Disability and Health**, also known as **ICF**, published in 2001, after nine years of collaboration between the World Health Organization (WHO) and the World Health Assembly. In the chapter 3, at the paragraph *Assistive products for people with disabilities*, we've already seen the great innovation marked by this classification that consider disability no more related to a particular disease or individual but as a result of the relationship between individual functional status and his context. Hereinafter I reported their last definition of "Disabilities"

32 GOLDSMITH S., *Designing for the disabled*, Royal Institute of British Architects, London, 1963

33 BICKNELL J. , MCQUISTON L., *Design for need: The social contribution of design: an anthology of papers presented to the symposium at the Royal College of Art,* Published for ICSID by Pergamon Press, London, 1977

"Disabilities is an umbrella term, covering impairments, activity limitations, and participation restrictions. An impairment is a problem in body function or structure; an activity limitation is a difficulty encountered by an individual in executing a task or action; while a participation restriction is a problem experienced by an individual in involvement in life situations.

Disability is thus not just a health problem. It is a complex phenomenon, reflecting the interaction between features of a person's body and features of the society in which he or she lives. Overcoming the difficulties faced by people with disabilities requires interventions to remove environmental and social barriers.

People with disabilities have the same health needs as non-disabled people – for immunization, cancer screening etc. They also may experience a narrower margin of health, both because of poverty and social exclusion, and also because they may be vulnerable to secondary conditions, such as pressure sores or urinary tract infections. Evidence suggests that people with disabilities face barriers in accessing the health and rehabilitation services they need in many settings."

Concluding, in the 2008 the U.N. Convention on the Human Rights of People with Disabilities (CRPD), added the third supplement to the International Human Rights Treaty, adding detailed guidance for protecting the human rights of people with disabilities. They started with the base of the WHO/ICF and codifies design as a human right. This act, the CRPD, was adopted in almost all the country of UN and it evidences the pervasive common understanding of accessibility as a shared commitment.[34]

4.6.1 - Features of Design for Disabilities

"One of the main concerns on design for disabled people is the "tendency to focus on "special need", rather than lifestyle aspirations, and so it risks to remained trapped in equally narrow markets where turnover and profitability are too low to justify adequate investment in design itself, giving rise to a plethora of stigmatizing and poor quality aids and adaptations."[35]

The common thought is used to consider design for disabled people as a distinct sector of production, ruled by completely different needs and expectations. However if we consider that each one of us could prove a lifetime, or even just a short period or moment of physical or mental impairment, the approach to the subject starts to acquire new meanings.

The assistive production is now a prerogative of the medical industry, it is considered primary a subset of rehabilitation engineering for short term recuperation from injury or illness or long-term functional support. But it will have low chance of improvement if it remains relegated to this sector since there will be always more founds addressed to cures than to cares. **A shift of this production sector to design field, on the contrary, could ensure better inclusion and attention to users in the future.**
It is what happened, for example, as Graham Pullin in *"Design Meets Disability"*

34 FLETCHER V., *Human-centered design/design for all*, in STEFFAN I.T., *Design for all - Il progetto per tutti*, Maggioli Editore, Rimini, 2012: pp. 11-14

35 CLARKSON J., COLEMAN R., KEATES S., LEBBON C., *Inclusive Design. Design for the whole population*, op. cit.

ANALYSIS

recounts, with glasses that evolved from medical aids to fashion accessories. *"It has been reported that up to 20 percent of some brands of glasses are purchased with clear nonprescription lenses, so for these consumers at least, wearing glasses has become an aspiration rather than a humiliation".*[36]
On the contrary, in most of orthopaedic items, their aim is not to research a pleasant aspect but not to have an image at all, trying, unsuccessfully, with transparent or colour skin material to camouflage with the body. But the psychological effect related unconsciously with this attitude is that these aids are something of which being ashamed, to hide as a personal blame.
As already said, people usually in charge of Design for Disabilities have more a culture of *problem solving* and fashion issues may appear in contrast with their theories. For this reason fashion designers should be required and paradoxically, when this collaboration took place they were even more effective when the designer had no experiences in medical product since it brought more innovative ideas.[37]
Many of the aids already present on the market don't need a further "problem solving". Nevertheless designers could re-examinate these projects, material, explore their aesthetic potential and even if apparently it could not be perceived as the solution of a problem, in practice it could be so and it could make the difference in the process of psychological acceptation of an aid for disable people.
However the problem has to be considered bilaterally and, if from one side the market is usually occupied by bio-mechanical engineers, at the same time university culture taught at the university, beside few exceptions, don't train designers on this topic or don't educate them on its value and potentialities. A new equilibrium and balance between the two professional figures could solve this cultural gap.
Design for disability means trying a new cooperation between clinical and cultural issues.
An over attention on capability deficit, does nothing but strengthen the medical features and reflects the semantic of hospital equipment. This is mainly the reason why disable's aids are frequently rejected from the users. An inclusive approach, on the contrary, needs a rethinking that starts from the mainstream of design and considers disabled people as valuable consumers as all the others. In this sense, some progresses have already been made: fashionable clothes are available in a wider range of sizes, technology and domotic solutions offer greater possibilities of

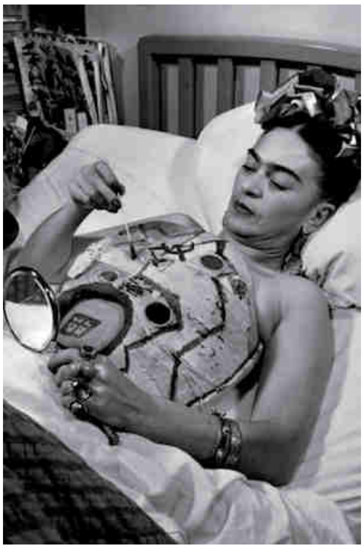
The model, athlete and actress Aimee Mullins photographed by Alexander McQueen with her carbon-fiber prosthetic legs for the *Dazed and Confused Magazine*

36 PULLIN G., *Design meets Disability,* MIT PR, 2009
37 PULLIN G., *Design meets Disability,* ibid.

remote control of household appliances and, as predictable, these products don't effect only disabled people. As Design for All approach states, isn't important only that one object for disable is *usable*, it must be *beautiful*.
It is necessary to acquire a deep knowledge on the wider group of people excluded from design thinking, on their lifestyles and expectations in order to propose a customized business and design strategy.
What it has to be balanced is low cost with high quality, standardization versus personalized design and user demand versus manufacture's offer[38].

Some of the 12 pairs of legs that the model Aimee Mullins owns. On the right the elaborately carved elm woods leg that McQueen custom designed for the model

But in this sense design for disability approach differs from inclusive design since it is more focused on impaired user needs. Moreover the survey of user need is even more complicated since the amount of "*latent needs*" that users aren't able to clearly express is bigger. This happens not only in case of mental impairments, the lack of awareness and consciousness on their deep rights and potentials make disable people often resigned to their conditions and to the conditions their society offers them, just because they often simply can't really see an alternative solution. In this sense the role of the designer can be crucial if he/she is able to express latent user needs and transform them in products and services.



Frida Kahlo wore plaster corset for most of her life because her spine was too weak to support itself and she was used to décor corsets painting them with her personal style

38 CLARKSON J., COLEMAN R., KEATES S., LEBBON C., *Inclusive Design. Design for the whole population*, ibid., p. 180

ANALYSIS

4.6.2 - Prosthetic and Orthotic Design

"The term 'prosthetic' is now attributed to the branch of surgery dedicated to replacing missing or defective limbs, but to the Ancient Greeks it was an altogether more assertive concept meaning 'to add', 'to advance' or 'to give power to'."[39]

Following new theories and user centered approaches, modern designers are more and more becoming interested in orthoses and prosthetics technologies, for their strong relationship with human body, health, functionality and beauty. More and more people are starting to realize that standard hospital looking devices cannot be the right answer for user needs, when he/she is in condition of wearing some orthopedic aids. These auxilia are starting to be no more conceived only under the prospective of function and low cost, but as an integrant part of human daily life and for this reason they're worthy of all designers attention. Examined in that light prosthetics can become devices for "*enhancing, remoulding the body and reshaping identity in ways that force a rethinking of associations between disability and devaluation*"[40].

The history of the evolution of prosthetics reflects the relationship humanity had with their body in that period. A great development in this sector happened in the sixteenth century, especially in France, were sophisticated facial, nose prostheses, iron breastplates and limb prostheses were produced. The French surgeon Ambroise Paré described his prostheses as a work of art, masterpieces of handcraft, realized with luxurious materials.

This tendency developed during the late eighteenth and early nineteenth centuries in Britain and prostheses of people of higher classes were an instrument to emphasize their nobility. They were not only prostheses to substitute amputated body part, but even simply products to improve female posture.

"They were marked not just as the means of an inestimable blessing to its user, but as an object of admiration."[41]

Nowadays many contemporary artists are exploring the aesthetic and artistic expressivity of prostheses and orthoses but, most of the time, their results are relegated just as a work of art and few of them have direct consequences on the market of these products. However even this solution that proposes an innovative and personalized orthoses have not to be considered as a substitution of existing devices but more a necessary alternative that patients have the right of pretending. There will be who prefers prosthesis as an overt tool, who will feel more comfortable wearing no prosthesis at all, who will continue to prefer a cosmetic prothesis and moreover even who will be free to choose one of these solutions every day depending on its mood. The dichotomy between aesthetic (field of the designer) and function (field of the bio-mechanical engineer) is something that has to be overcome and substituted by integrate and team proposals.

An interesting exception is the work of the Lanzavecchia+Wai Studio of design[42]. They revisit disability artifacts in an original and interesting way. They realized, for example, back braces molded with 3d printing that perfectly fit the user's body shape. Othoses become from an intruder, a cause of discomfort into objects of desire. Perforated patterns improve breathability, funny pockets add new functions, an attention on colours, materials and patterns enlarge enormously the possibility

39 *SHOWCABINET: PROSTHETICS*, http://showstudio.com/shop/exhibition/showcabinet_prosthetics (July 2014)

40 TURNER D., *Form or Function? Prosthesis past and present,* SHOWstudio, http://showstudio.com/project/prosthetics_conversations/david_turner (July 2014)

41 TURNER D., *Form or Function? Prosthesis past and present,* op. cit.

42 LANZAVECCHIA F., *Proaesthetics*, 2008, http://lanzavecchia-wai.com/projects/proaesthetics-orthosis/ (July 2014)

of personalization. Thermoplastic neck braces that evoke a Victorian collar, or accessorised with hooks to hung everyday objects, coated with the right textile and pattern can appear like a fashion object and reduce the strong visual impact that hospital devices usually have.

Concluding, a stimulating point of view offered by a disable person underlines the differences that occur between how non-disable people see prothesis and how who dons that feels them for themselves:

"The experience or use of a prosthetic does not determine whether a user feels that his or her body is disrupted. Indeed, in common use, artificial limbs do not disrupt amputees' bodies, but rather reinforce our publically perceived normalcy and humanity [...] artificial limbs and prostheses only disrupt [...] what is commonly considered to be the naturally whole and abled body."[43]

This perception is common even about wheelchairs. An enable device that helps people to gain mobility and independence, is seen by abled people as an additional impediment, that adds complications to normal mobility.

Design could have a crucial role in changing this state of things.

Francesca Lanzavecchia, *Proaesthetics Orthosis as personal canvas*, 2008

43 BOYS J., *Doing disability differently,* Routledge, New York, 2014

4.3 – FROM THEORIES TO METHODOLOGICAL TOOLS

In this brief excursus we've outlined the main principles that characterize some of the most important theories that can be included in the group of the **User Centered** methods. Starting from what is called the **Voice Of Customers** each theory develops its peculiarity and has personal and historical approaches and programs.
The design of a new type of night Ankle Foot Orthoses for people affected by Duchenne Muscular Dystrophy is for sure a problem of Design for Disabilities. It is an orthopaedic device addressed exclusively to these people and therefore it has not the necessity of being influenced by inclusive requirements. In this sense the main challenge seems the one issued by Pullin[44]: glasses were born as an aid for visual impaired people, but thanks to designers experimentations on this object they became a fashion accessory that sometimes even people without any problems desires to use. Is it possible to hazard a similar outcome for the orthopaedic orthoses? How are the tools available on current market that could lead to the transformation of users' requirements and prescriptions in design suggestions without betraying all the principles we've just exposed? Unfortunately survey in an effective way user requirements doesn't guarantee the efficacy of the result. First of all **is difficult to understand in deep user requirements,** without misunderstandings
User needs can in fact be classified in[45]:

- **Expressed needs**, are the ones clearly expressed by the user, the ones he/she is perfectly aware of. These requirements guide the shopping and goods purchasing and for this reason they have to be carefully analysed from the market;
- **Implicit needs**, are the ones the user usually takes for granted. They are usually referred to the main function of the object (es. I take for granted that a can opener opens tins), or security aspects that I cannot expect or anticipate and for this reason an eventual dissatisfaction of an implicit need is highly disabling in the judgment of the product;
- **Latent needs** are the ones the user is not aware of. It could happen, for example, if on the market there isn't a similar object capable of satisfying this need or if a technology progress allows something that was impossible in the past.

Being able of catching these needs can be really crucial in determining the success of a product but, as can be predictable, it is really hard to translate this indications in design suggestion and this imply that, at the end, a verification is necessary to evaluate the correspondence to original users' desires. As Elisabeth Sanders declares in *A New Design Space*[46]*,* in a user-centered approach to the project, the aim of the design should be:

- *Fit to the body,* with the contribution of ergonomic science;
- *Fit to the mind,* the field of information and interaction design;
- *Fit to the social*, the ethnography environment or in a smaller range, his local context;
- F*it to the emotional*, with the always heavier contribute given by psychologists in these processes;
- *Fit to the dreams*, aspirations and expectation, both conscious and latent.

44 PULLIN G., *Design meets Disability,* op. cit.

45 RAINEY D., *Product Innovation. Leading Change through Integrated Product Development*, Cambridge University Press, 2005

46 SANDERS E.B.N., *A New Design Space*, Proceedings of ICSID 2001 Seoul: Exploring Emerging Design Paradigm, Oullim, Seoul, Korea, 2011, pp. 317- 324, http://www.maketools.com/articles-papers/NewDesignSpace_Sanders_01.pdf (January 2015)

And moreover, even if all these conditions are verified, it still could not be sufficient. *Designing new products and innovation processes requires more than satisfying customer needs.* Once all users' requirements are clear defined it is still necessary another step forward to ideate something that can really make the difference.
In order to help designers in such a demanding goal a wide range of models, tools, schemes and procedures were defined. The choice between the adoption of one method instead of another is not irrelevant, it deeply affect all the phases of the ideation of the product, from basic research, to the development of design, its prototyping, testing, and obviously the final result. Companies are highly aware of the potential and the crucial role of the design method they decide to follow and for this reason almost each company tends to personalize it and to adapt to its own necessities. The process of ideating and developing a new product in any method is however made by several phases and in most of the cases it's an iterative process in the attempt of verifying and improve each stage. In particular the ***Product Development & Management Association*** **(PDMA)** defines New Product Development as *"the overall process of strategy, organization, concept generation, product and marketing plan creation and evaluation, and commercialization of a new product. […] It is a disciplined and defined set of tasks and steps that describe the normal means by which a company repetitively converts embryonic ideas into salable products or services."*[47]
In the difficult selection among all the surveyed design methods, I decided to select:

- Most common design methods, as selected by Cross N. in *Engineering Design Methods*[48]*;*
- Methods that were suggested by scientific texts and prominent authors as appropriate tools for the User Centered Design.

Then, at the end, after having analysed these methods in detail, I'll chose the one I'll apply. The more appropriate method for an innovative product, and for the aim of the thesis.
General aims of all these methods are to suggest good practices to externalize design thinking, to ***enlarge the field of investigation,*** going beyond the first idea that came as solution, and to facilitate team work, providing to all the members of the group, all the required elements to carefully evaluate each proposal. Therefore they must be considered more as ***a tool to guide creativity and intuition*** than an instrument that limits ***innovative thinking***.

- **Conventional methods**
  - **Handcraft**
  - **Design by drawing**, the method often conducted individually by most of designer. It is an iterative activity that, as by names, goes through a series of sketches and drawing. This traditional method is usually composed by: exploration, generation, evaluation and communication. If the evaluation isn't positive, the process comes back to the generation phase.
- **Creative Methods**
  - **Brainstorming**, starting from a specific problem statement, a small group of various skilled people propose in turn, in a short time laps, of usually 20-30 minutes the largest amount possible of different, even crazy ideas. No one can critic the other but he can implement his proposal. At the end all the ideas, written on different sheets are selected and evaluated.

47 ROSENAU M.D., *The PDMA HandBook of New Product Development,* Wiley, 1996

48 CROSS N., *Engineering Design Methods. Strategies for Product Design.*, John Wiley & Son Ltd, Fourth Edition, http://home.iitj.ac.in/~ug201210024/book/c/2.pdf (January 2014)

- **Synectics**, it is similar to brainstorming, but longer and all the members of the group are in turn working and proposing on the same first idea given at the beginning, recurring to an analogical thinking.

- **Enlarging the Search Space,** is not a single method but the collection of a series of dialect methods (transformation, random input, *why?why?why?*, counter-planning) that helps in the process of generating idea.

- **Rational methods**
  - **Checklist**, is the simplest one, a list of what has to be done;

  - **The objectives Tree Method**, aims at clarifying objectives and their relations. Usually users manifest a problem, not a statement of design objectives, that has to be understood by the designer. Objectives have to be listed and then ordered in a tree graph from the more general to the specific ones and the tree structures evidences even the transversal relationship between aims;

  - **Function analysis**¸ establishes functions and system boundary of a new design focusing on what has to be achieved and not how. The functions are expressed as blocks that transforms inputs into outputs and organized in sub-functions while the system boundary defines the field of action, that could be limited by management policy, client requirements or other external factors;

  - **Performance specification**, useful to define the specification of each performance required and to transform it in a design solution. It starts from the definition of the range of alternatives between of which the designer is free to move, between alternatives, types or features and then at least all the performance requirements for each attribute in the most possible objective way, with numbers, definitions or intervals;

  - **Quality Function Deployment**, relations user requirements and marketing strategies with technical specification and engineering characteristics to set targets for the design of a new product. It is a complex and comprehensive of many other methods, it can be used at different stages of the design and it includes even the comparison with concurrent products;

  - **Morphological chart or Strategic Design**, generates all the possible alternative solutions for a product. It starts from the list of the essential product's features or function, then specify the relative means required, surveys all the possible sub-solutions and, at the end, evaluate feasible combinations of proposals;

  - **Weighted objectives**, evaluates alternative design proposal differently weighting all the goals;

  - **Value engineering**, increase or maintain the value of a product trying to reduce costs. It considers as the value of the product to its purchaser as the cost of a product to its producer. It can be considered a *pre-planned strategy*[49], more suited to modify existing products than to create an innovative one;

49 JONES J. C., *Design methods: seeds of human futures,* John Wiley & Sons, New York and Chichester, 1970

- **Concurrent engineering**, *"is a systematic approach to the integrated, concurrent design of products and their related processes, including manufacture and support. This approach is intended to cause the developers, from the outset, to consider all elements of the product life cycle from conception through disposal, including quality, cost, schedule and user requirements.*"[50] It's key words are: Voice Of Customer, Multidisciplinary Teams, Automated Tools and Process Management.

This list, as we said, was just an extremely brief selection of some of the possible methods and tools applicable to transform User Needs in Design Specifications. I've already said the criteria that I followed in this selection. Among these**, I focused more on the Design for All or Design for Disabilities peculiarities**, trying to figure out which of these processes could be more appropriate to be conjunct with that theoretical frames. In particular I went even deeply **in the approaches suggested by scientific literature for innovative rehabilitation and orthopaedic manufacturers**. On this regard, the requirements that emerged in the choice of the most appropriate design method for a rehabilitation Industry were[51]:

- Provide a cheap and cost effective development process;
- Require limited marketing/development skills to implement;
- Give designers a full understanding of the need of the customer;
- Provide a guide to the most appropriate marketing method to use for each stakeholder;
- Deal with multiple customers' requirements effectively;
- Enable the development of cheap to manufacture products;
- Require limited man hours to utilize;
- Structure the problem without restricting freedom to develop solutions;
- Enable the development of customer satisfying products.

Following these two criteria, four were the selected methods:

- ***Objective Tree***, for the merit of leaving completely free the development of design ideas considering only the achievement of the target;
- ***QFD***, for its versatility of use and for its merit in combining users and market's requirements with engineering detail, clearly identifying conflicting elements;
- ***Strategic Design***, for the credit of evaluating many design alternatives;
- ***Concurrent engineering***, for its optimization of all the phases of the design and production.

Below I reported a comparison of customer focused design tools as proposed by Bamforth S. and Brookes N. in *Effective Design Methodologies for Rehabilitation Equipment*[52]. Among the four methods individuated, ***the table doesn't include concurrent engineering***. However considering the aim of the thesis and the starting stage of the design process in which I would like to lean on a design method this

50 Definition of the Department of Defense/Institute of Defense Analysis (DoD/IDA) Report R-338 in WALKER J. M., BOOTHROYD G., *Product Development,* in CROWSON R., WALKER J., *Handbook of Manufacturing Engineering*, Second Edition, CRC Press, 1996

51 BAMFORTH S. E., BROOKES N. J., *Customer-focused design methodologies and their suitability for the rehabilitation industry*, in PHAM D.T., DIMOV S. S., O'HAGAN V., *Advances in Manufacturing Technology XV,* 17 National Conference on Manufacturing Research, Professional Engineering Publishing Limited, 1998 pp.69-74

52 BAMFORTH S., BROOKES N., *Effective design methodologies for rehabilitation equipment. The CACTUS Project*, in CULLEY S.,13th International conference of Engineering Design, ICED 01, Glasgow, John Wiley & Sons, 2001

exclusion isn't relevant, even considering that ***Concurrent Engineering can be composed by different methods, among which all the other three and in particular Quality Function Deployment.***

The table[53] evidences the qualities and potentials of Quality Function Deployment method compared to the others, it's upside in doesn't giving any predefined solution in response of users' requirements and in being extremely open in collecting and balancing all kind of requests.

Considering the multidisciplinary approach required for this specific theme and strikingly underlined in the theory of Design for All, ***Quality Function Deployment seems the more able to collect all these different inputs and it better elaborates the Voice Of Customer***, weighting each requirement and giving response related to technical requirements. In the following paragraph this method will be discussed more in detail.

53 BAMFORTH S., BROOKES N., *Effective design methodologies for rehabilitation equipment. The CACTUS Project*, op. cit.

A comparison of customer focused design tools

	Characteristics	Objective Three	Strategic Design	QFD
Attributes	Highly visual	■	■	■
	Directly identifies relationships between domains	●	▲	■
	Competitive benchmarking	●	▲	■
	Uses cross-functional team members	●	■	■
	Customer requirements are ranked	●	■	■
	Indicates importance & visibility of technical solutions	●	▲	■
	Tanks customer needs	●	■	■
	Brings upstream, to the design stage, down stream issues	●	■	■
	Display customer requirements	■	▲	■
	Identifies product solutions that meets most requirements	●	■	▲
	Effective for prioritising customers	●	▲	■
	Sets targets	■	■	■
Benefits	Reduce design costs	●	■	■
	Reduce design time	●	■	■
	Enhances communication among team members	■	■	■
	Increases efficiency	●	■	■
	Reduces pre-launch time	●	■	■
	Lead to increased customer satisfaction	■	■	■
	Improves product quality	■	■	■
	Provides Documentation	■	■	■
	Quick tool to use		■	■
	Balances customer needs with the company's	●	■	▲
Limitations	Difficult to know if the VOC has really been understood	■	■	■
	Difficult to know if total VOC has been gathered	■	■	■
	Difficult to know if the "hows" are the best solution	●	■	■
	Requires the input & analysis of a large amount of data	■	▲	■
	Can show ambiguity in customer demands	■	■	■
	Subjective	■	■	■
	Qualitative	■	■	■
	Can produce large and complex charts	■	▲	■
	Seeks solutions to a limited number of requirements	●	■	▲

4.4 – QUALITY FUNCTION DEPLOYMENT

A User-Centered Design practice define an ideological approach to the process of design that can be declined in different way. One of the most internationally recognized methods is the **Quality Function Deployment**, or **QFD**. It was elaborated for the first time in 1966 in Japan by Dr. Yoji Akao and it was defined as "*a method to transform qualitative user demands into quantitative parameters, to deploy the functions forming quality, and to deploy methods for achieving the design quality into subsystems and component parts, and ultimately to specific elements of the manufacturing process.*"[54]

It is important to highlight that the USER is intended not only the final one who uses the product but all the people that interact with it during its entire life, from the manufacturing, to the selling, the use, until its disposal.

The aim of the method is to transform the "***Voice Of the Customer***" VOC, customer needs, into engineering characteristics of a product or service, yielding a series of charts and matrices. The VOC can be apprehended in various ways: direct discussions or interviews, surveys, focus groups, customer specifications, observations, warranty data, field reports, etc.[55]

QFD method can be applied in a great variety of fields and it has been included in the ISO 9000:2000. It was brought to the United States in the early 1980s and it gained its first great popularity in the automotive industry, starting from Japan automotive market.[56] Here the binomial ***Quality-Innovation*** was considered one of the keys of their success that still continues nowadays. When the industrial production of goods started, in the 30s and 40s the term Quality was associated with the absence of defects in the final product. Nowadays, quality is defined as a "*multidimensional function that involves each aspect of the product in order to make it more desirable from the consumer*", while, Innovation is "*that action that is capable of change the market, even slightly.*"[57] It means that Quality is the sum of all the characteristics of the product that makes it desirable, while Innovation is the mean by which it is possible to do that, according to economical and manufacturing constraints.

The effect of Innovation is increasing product's quality, but it usually isn't directly perceived from the users. For this reasons economists define it as "Perceived Quality", that is different from "Expected Quality", defined by markets' standards for that product, that itself is different from the concept of quality produced by the manufacturers. Its aim is to change ***perceived quality*** in order to make it coincide or even get over ***expected quality***[58]. Innovation-based companies may risk to focus on pushing a technology into the marketplace without truly understanding customer needs. Marketing staff sometimes have the feeling of user needs but usually the fabric managements lacks of a direct communication among them and the design team.

54 AKAO Y., *Development History of Quality Function Deployment. The Customer Driven Approach to Quality Planning ad Deployment*, Asian Productivity Organization, Minato, Tokyo 107, Japan, 1994: p.339

55 KENNETH C., *Customer-Focused Development with QFD*, DRM Associates, 2002, http://www.npd-solutions.com/qfd.html (July 2014)

56 REVELLE J., *Quality Essentials: A Reference Guide from A to Z*, ASQ Quality Press, Milwaukee, 2004: pp. 152-155

57 FRANCESCHINI F., *Quality Function Deployment*, Il Sole 24 ORE, Milano, 1998: p. 2

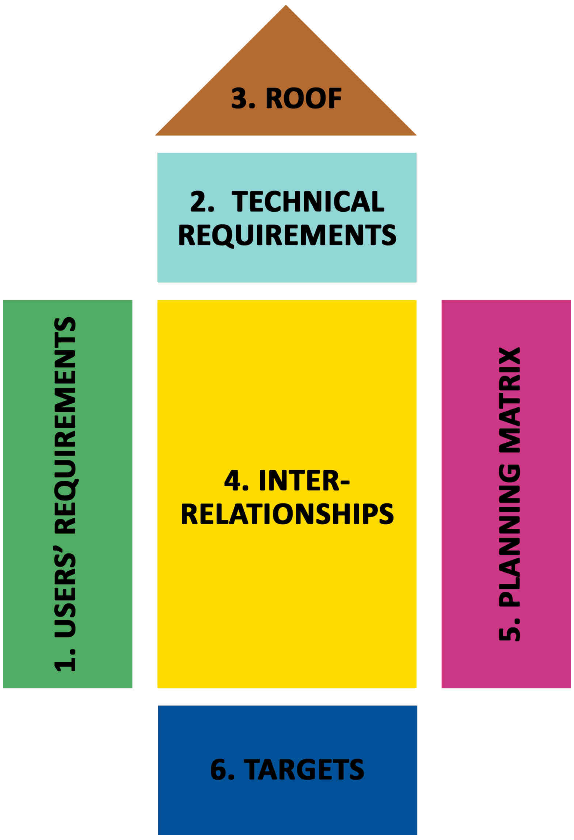
58 GARVIN D.A., *Competing on the Eight Dimensions of Quality,* Harvard Business Review, 1987: v.65, n.6, pp. 101-109

Quality Function Deployment Method is oriented at involving all the figures collaborating in product development, from Marketing to Design Engineering, Quality Assurance, Manufacturing, Engineering, Test Engineering, Finance, Product Support and so on. Akao defines QFD as a means through which *"responsibilities for producing a quality item must be assigned to all parts of a corporation."*[59]
It proved to be particularly effective in the understanding of customer needs, both spoken and unspoken, but from the customer's perspective. What's the most these needs are directly linked to design characteristics, leading to a deeper control of the project and a conscious development of its potential.
The development of the process takes place starting from user requirements. Then technical characteristics are defined, firstly in a general scale and more and more in details. Subsequently the process of production is analysed and, at the end, all the specifications are put in place to ensure the quality of the final product.

Overall it can be articulated in two phases: the first step is what is it called "***The House of Quality***", and it focuses on the most important product or service attributes or qualities. Secondary, others schemes, ***"Waterfall relationship of QFD"*** allow you to transform prioritised attributes in organized functions and actions.

The **House of Quality** is composed by six parts:

1. **User Requirements;**
2. **Planning Matrix;**
3. **Technical Requirements;**
4. **Roof;**
5. **Interrelationships;**
6. **Targets.**



House of Quality of Quality Function Deployment

59 AKAO Y., *Foreword*, in KING B., *Better Designs in Half the Time,* Goal/Qpc, Methuen (Ma), 1989

1. USER REQUIREMENTS

Some information on the correct approach to user expressions of their needs have already been expressed in the User Centered Design Chapter. Operatively this table contains a list of all the users' needs, categorized by topics or related requirements. They have to be really specific, expressed in users' language, identifying "what" is the need and not "how" can it be satisfied, otherwise it will give an anticipation on what can be the final solution and preclude other alternatives. Unspoken needs can be added by the staff by observing consumers, products or services and recognizing opportunities for improvement.

Customer priorities. On the right of Customer Requirements table is located a column that expresses customer priorities. It is expressed as a rating from 1 to 5 for each requirement filled in a row, and it indicates the user's importance of the satisfaction of that need. It is called ***Importance Weighting*** as well and some authors allocates it in the planning matrix. [60]

2. PLANNING MATRIX

This matrix is allocated on the right side of the House of Quality and it serves several purposes. First of all it compares and analyses selected existing products on the base on their capabilities of satisfying user requirements, expressed on the first table. This phase is extremely important since it allows to focus on competitors strengths and weaknesses compared to users' priorities and to identify any gaps that could be covered by the new product. This comparison is extremely useful to define the design strategy and avoid the tendency of the design team of exceeding all product's performances parameters in each area, leading to a more costly product[61].
Other evaluations that can be part of the planning matrix are:

- ***Planned Satisfaction Rati ng***, dedicated to the expected performance of the designed product in fulfilling each specific requirement;
- ***Improvement Factor***, obtained subtracting the score of the existing product from the planned performance, multiplying by an improvement increment, ex. 0.2 and added to 1[62]. This operation put in evidence the rate of improvement in each need acquired by the new product;
- ***Sales Point*** can be used to add weight to those requirements which can be utilized to market the product, as environmental impact.

3. TECHNICAL REQUIREMENTS

This matrix is composed by a tree chart that identifies all the technical details that can be useful to describe and design the product. They have to be organized in categories and characteristics must be really specific, unequivocal and measurable. They have not to imply any specific technical solution, or a predefined material, in order not to constrain designers in their ideation process.
An additional row is added under the requirements that includes arrows pointing up and down. If the arrow allocated under a technical requirement is pointing up it means that an higher value of that characteristic is considered as an improvement

60 LOWE A. J., *QFD*, http://www.webducate.net/qfd/qfd.html (July 2014)

61 CROW K., *Quality Function Deployment: What, Why & How*, DRM Associates, 2004, http://www.npd-solutions.com/whyqfd.html (August 2014)

62 LOWE A. J., *QFD*, op. cit.

in product performance.
An important principle of this method is "garbage in, garbage out", useful to strengthen the crucial role of the choice of the elements to be put in the matrix. If they are chosen properly, the result will be useful, otherwise the entire development effort will be useless.

4. ROOF

In the House of Quality the triangular roof matrix expresses the relationships among technical requirements. In particular it analyses them in pairs and expresses, through symbols, if the variation of one feature has a strong, medium or null effect on the other. In the proposal of an innovative product it is crucial to consider these relations that can be exploited enhancing the factor that has more positive effects on the other or, on the contrary, to control undesired consequences.

5. INTERRELATIONSHIPS

It is the core of the matrix, where requirements and characteristics match to provide useful instructions to designers. The interrelationship is expressed in a four point scale and associated with a numeric value, from 0, equivalent to None, to 1 – 3 or 9, the maximum score, and then multiplied by the importance rating.
Analysing the matrix it is possible to develop the product strategy and understand what could be the strengths of the project. In order to be able to conceptualize and to read the result of the interrelations' matrix it is important to contain the row of requirements and the column of technical details in an equal number between 20 and 30 maximum. Larger values should be to the detriment of comprehensibility.

6. TARGETS

It is the final step of the House of Quality matrix and it summaries all the collected data. It is made of:

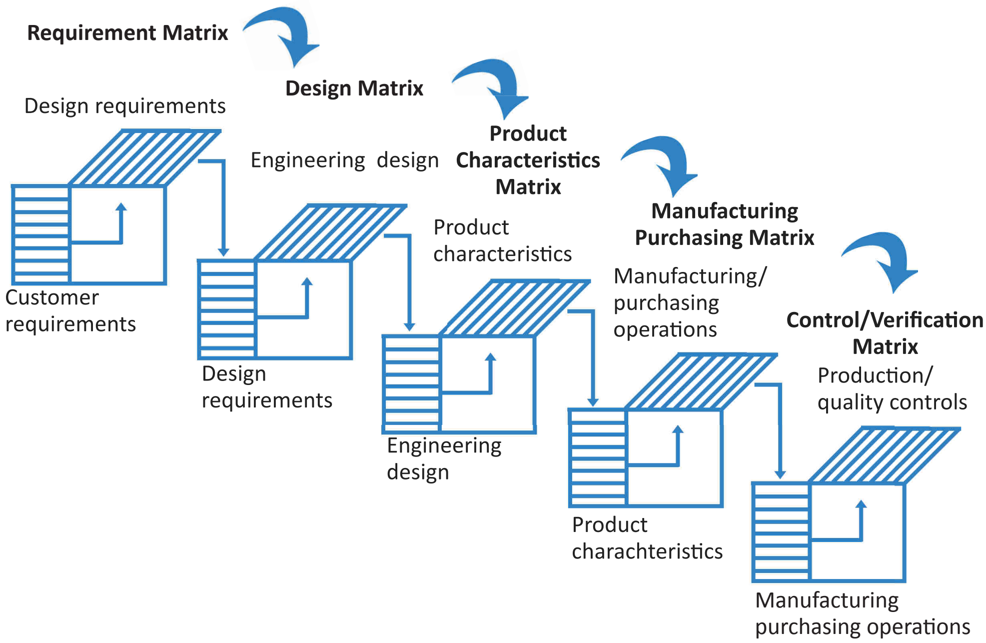
- ***Technical Priorities***. It expresses the relative importance of each technical requirement of the product in meeting customer's specified needs. It is calculated by multiplying each value in the Customers Priorities with the ones in the planning matrix and summing all the results of a single column, corresponding to a single technical requirement. This sum represents the priority of each technical requirement.

- ***Competitive benchmarks.*** It is a comparison of technical requirements between the new product and existing ones. It helps to identify clearly technical existing products strengths and weakness compared with the new project.

- ***Targets***. It is the final output of the matrix and it expresses the design staff goals in the ideation of the new product. It is expressed singularly by each technical requirement and it has to take in consideration all the other parts of the matrix, prioritizing them on the base of customer needs relevance, competitors' performance and aims of the new product. The strategy should reflect where the team will focus its development effort to achieve the customer value proposition. The definition of the targets is not necessarily the end of QFD process. These results can become the first steps for future matrix that drive the product development process until the end of the production process. Product targets help the definition of parts deployment and parts target, until the planning of the process per each component. It is called as a Waterfall relationship of QFD.

The ***Waterfall relationship of QFD*** is composed by:

7. **Deployment Matrix**
8. **Planning Matrix**
9. **Quality Control Matrix**



Waterfall relationship of QFD

7. DEPLOYMENT MATRIX

This phase ultimated gives the possibility to draw up the first product plans, overall design hypotheses. The following phase is, in fact the concept selection matrix, that allows to compare design alternatives according to users' requirements and their importance ratings. Proceeding with all the matrices that represent the definition of all the elements we contribute to the definition of the deployment matrix of the product. This matrix is very similar to the product planning one, but progressively all the technical characteristics are substituted with the real ones of the product to evaluate them critically and in terms of performance, quality and reliability perspective.

8. PLANNING MATRIX

This matrix can be used to evaluate different manufacturing process approaches and select the better one. On the top of the table are allocated all the elements that constitute the product, while on the left critical process steps take place.

9. QUALITY CONTROL MATRIX

"In addition to planning manufacturing processes, more detailed planning related to process control, quality control, set-up equipment maintenance and testing can be supported by additional matrices."[63]

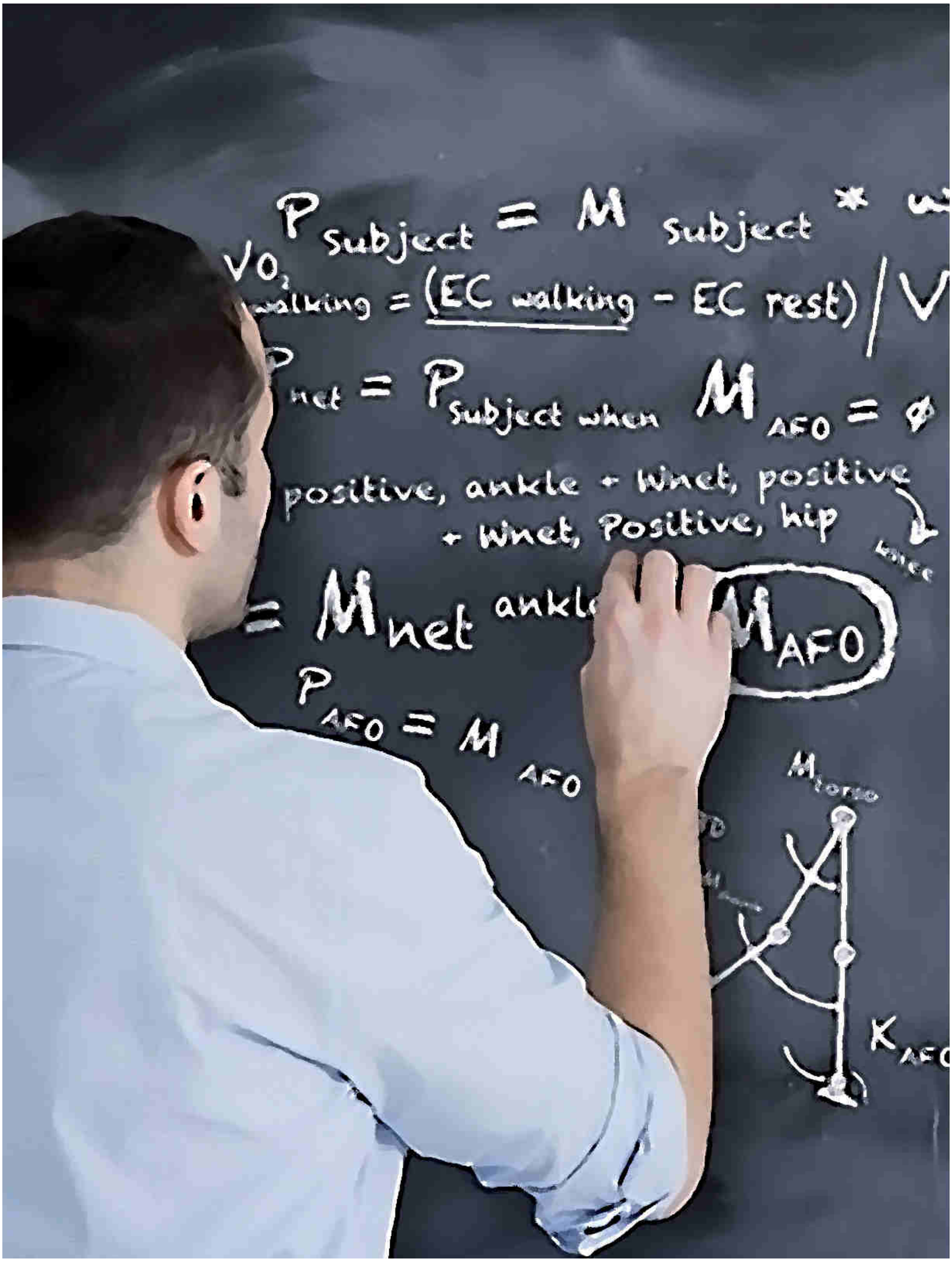
At the end of this series of matrix the product is defined in all its processes, dimensions and characteristics, in order to meet consumers' needs.

63 KENNETH C., *Customer-Focused Development with QFD*, op. cit.

4.4.1 - Conclusion

Reassuming, Quality Function Deployment starts with product planning, continues with product design and process design and finishes with process control, quality control, testing, equipment maintenance and training. The entire project requires much more time than traditional methods in the planning of the design, but it is largely recovered in the phase of testing and evaluation of the prototype, because the result is much more checked in each single element since the beginning. It is an extremely useful methodology to facilitate communication, planning and decision-making in a product development and it reduces times and costs in the process. It bridges the gap between Marketing, Engineering, Manufacturing and Quality department of a manufacture. Furthermore, it reduces to the minimum the arbitrary of the designer of enhancing technical requirements without a specific response of user need but, on the contrary, there is a rigorous consideration of a variety of factors in objectively developing requirements and specifications.

Quality Function Deployment Matrix proved to be one of the best approach to introduce innovative technologies, materials, processes or solutions, since no predefined choice are made at the beginning and many alternative solutions are considered. The intent of this method is exactly to identify and promote a better, innovative and even break-through solution. Moreover it proved its flexibility and openness to multidisciplinary requirements, one of the most relevant quality of the method.
In the following chapter the method of Quality Function Deployment will be applied in the design process of night Ankle Foot Orthoses for people affected by Duchenne Muscular Dystrophy.



5 DMD NIGHT AFO'S DESIGN

5 – DMD NIGHT AFO'S DESIGN

Among the ***User Centered Theories*** exposed, ***Design for All*** and ***Design for Disabilities*** were the two that provided better insights and useful directives for the development of the design process.
The definition of the targets to be followed in the design of a new type of orthoses was lead through the application of the ***Quality Function Deployment*** method, chosen, as we saw in the previous paragraph, among several alternatives, since it proved to be the one that best suits the aim of the research. In particular this methodology was adopted in its first part, the ***House of Quality***. Composed by six parts, this matrix puts in relation users' needs, technical requirements and a comparison of the best concurrent products on the market, in order to individuate priorities and possible improvable elements in the design of the orthoses.

In particular the phase of ***survey of users' requirements*** was highly extensive, it was made through different modalities, by literature analysis, interviews, web researches on blogs, simulations, experts and it involved all kinds of users, not only the boys affected by DMD but all the people that come in relation with the orthoses. To synthesize all these needs and expectations and complete the first part of the House of Quality the UCD tricks of ***"imaginary personas"*** was adopted and each requirement was marked for its importance weight.

Completed all the matrix with technical details and with the analysis and ***comparison between the best products found on market analysis***, the final targets that have to guide the design process emerged. These targets are the aim of all the projects and what characterize the night AFO for DMD proposed as an ***innovative product***. These new features aren't referred exclusively to the shape of the AFO but they deeply involve its process of manufacturing, with the application of ***new technologies of indirect survey, parametric design and 3D printing*** and even probable marketing consequences. All the innovation elements proposed are then discussed illustrating all the difference and the improvement elements compared with traditional products.

5.1 – INTRODUCTION

AFOs' market analysis developed in Chapter 3 revealed how these orthoses are currently considered mainly a medical device and that, if research and experimentations in course are implementing technological solutions and the application of new material, an overall analysis and "Design" of the product in all its features, its process of manufacturing, use and its implication for all the people who come in relation with it is still lacking. This dearth of a design process in the conception of the AFO lead to an analysis, in Chapter 4 of User Centered Methods in the believing that starting from user requirements could bring to innovative and effective solutions. The comparison among Universal, Inclusive Design, Design for All and Design for Disabilities highlighted common problematic and pointed out how, even with different histories and approaches, in the last decades a widespread sensibility is growing on the issues of social inclusion, enhancing of differences, and disability. In particular Design for All theories and Design for Disabilities, despite the obvious differences of approaches, since the first is addressed to all the population and the second one is applied only to specific solutions for disable people, presented some common features and principles of particular interest for the aim of the thesis. Hereinafter a synthetic table is presented to briefly illustrate what are the **main principles of Design for All and Design for Disability that I would like to transfer in my project.**

PRINCIPLES	SUGGESTION FOR THE DESIGN PROCESS
Engagement of all the "users", in a broader sense	Analysis of all the figures that came in relation with the orthoses during their Life Cycle and survey of all their requirements
Terminological shift from user to beneficiary	AFOs aren't only a medical device but a daily experience for all the people affected by DMD. It has not only to function, but also to be as pleasant as possible.
Holistic approach	Importance of considering all AFOs' Life Cycle, from even before its manufacturing, until its disposal, considering all the phases in an integrated system
Multidisciplinary method	The overall analysis of the product implies the necessity of multidisciplinary contribution and support of different professionals in all the phases of the development of the project, from the needs' survey to the manufacturing and management of the final product.
Multisensory approach	AFOs can be perceived with all the senses. Children uses all their senses to know the world around them and they live every night with their AFOs, so it is important to evaluate them under any sensorial perception.
Ergonomics	AFOs have to be customized since each man is different but this is particularly true for DMD boys, which limb are continuously changing in shape for their growth and their disease.
The right of beauty	Beauty isn't only something prerogative of fashion but fashion and beauty have to permeate the object, not only its surface finish, its final dress, but its substantial, used as an expressive language. A beauty object is used more appropriately and more gladly and this is the best guarantee for its efficacy.
The right of change	As any other accessory, or dress, AFOs have to be proposed in several versions, to allow boys of every age to choose their AFOs or to change them depending on the mood of the day or the occasion
Economic affordability	Since these AFOs aren't a luxury and ergonomy, beauty and variety intrinsic parts of orthoses and not a plus extra, the new type of AFO has to satisfy all these requests and be economic too, in order to be afforded by everyone.

Once theoretical frame was defined, in chapter 4, among several tools surveyed, Quality Function Deployment proved to be the best method to translate users' requirements in design indications.
After the identification of the users and the survey of their needs and expectations, the House of Quality Matrix of Quality Function Deployment will be applied in order to define priorities and suggestions for the design phase of the AFO.

5.2 – IDENTIFICATION OF THE USERS AND REQUIREMENTS' SURVEY

The first step for the survey of users' needs is the identification of the users. But who is the user? According to the Product Development Management Association,

"User is any person who uses a product or service to solve a problem or to obtain a benefit, whether or not they purchase it."[1]

This definition marks a difference between who is the USER of a product and who BUYS it and can be defined as a customer. In my case these two figures can be identified with the child who personally dons the AFOs and the parents that, together with their child, order the orthoses from the manufacture. But in this scenario there are even others crucial role: medical staff who prescribe orthoses and can address the family towards one product despite another and manufacturers who physically built and sell the product that, in some cases, is bought with a government subsidy and therefore for these product the State can be considered a buyer too. Each one of them has presumably different roles, requirements and expectations from the AFOs and for this reason it is important to start from a general analysis of all the process.

As Kumar V. declares in the *Second Principle for a successful innovation*[2], it is important to think **innovation as system**. In the specific case this means to not consider only product's performances, but placing it in the context of the overall healthcare system, analysing AFOs in relation to all the figures, environments and processes that are involved in the life cycle of the object. This method is extremely useful not only to understand system-level implications for the design of the product but even to enlighten new possibilities of innovation.

The survey of users' requirements was conducted in several ways, it took a long time and efforts and took place in numerous places and occasions, with different modalities depending on the interlocutor and the situation. To organize all these data I subdivided all of them in three categories, following the indications given by Holt et al. in *Need assessment: a key to user-oriented product innovation*[3]. This book organizes all the methods of collecting needs related information in three groups:

- **Utilization of existing knowledge**, based on edit literature, scientific papers or information published by manufacturers or government.;
- **Generation of new information**, throw direct contacts, interview and talks;
- **Provision of need information by other methods**, as informal approach or sector analysis.

In particular, among the methods suggested by the authors, and here reported with the same names, these were the ones I put in place.

1 ROSENAU M.D., *The PDMA HandBook of New Product Development,* Wiley, 1996

2 KUMAR V., *101 Design Methods. A structured Approach for Driving Innovation in Your Organization*, John Wiley & Sons, 2013

3 HOLT K., GESCHKA H., PETERLONGO G., *Need assessment: a key to user-oriented product innovation*, Wiley 1984

Existing Information	
Customer Information	In this category can be considered all the information that I received directly in the moment in which I was selected by *Parent Project Onlus,* an association of children's parents affected by DMD to develop a project to improve the design of current AFO.
Competitor Information	Market Analysis described in Chapter 3 was a crucial step in the collection of useful information and requirements for the design of a new type of orthosis. Moreover the comparison with competitors is an integrant part of the House of Quality of PhD.
Government Information	It concerned all the current legislative procedure to obtain a pair of AFOs with a government subsidy and all the procedure and the required documents to include a new product in this list.
Trade Fairs	Trade fairs like the annual Handimatica that keeps every year in Bologna or also meetings organized by the Ausilioteca in Bologna too were special occasions to meet in a single place several AFOs producers, to talk with them, compare products, collecting their technical brochure and discover the most vanguard products and research in course.
Literature	Books, Normative, specialized scientific journals, reports
Experts	Precious technical support of all the staff of the Policlinico Gemelli in Rome that gave precious information and made its experience on the field available to the aim of the research.

Generation of New Information	
User Questioning	The annual international conferences held in Rome, organized by Duchenne Parent Project, were precious occasions to meet patients affected by Duchenne Muscular Dystrophy, their parents, doctors and technicians, as well as counseling centers' operators on Duchenne Dystrophy and to discuss with all these different figures of "users" about the main topics and issues regarding the AFOs through questionnaires or direct interviews.
User Observation	The conferences in Rome were a good occasion not only to talk with people but even to observe with discretion DMD children in all their aspects, starting from the ones that equate them with all their peers to the ones caused by the disease.
Multivariate Methods	As the application of Quality Function Deployment method to relate user perceptions with product's characteristics.
Simulation	Tests made at the Policlinico Gemelli in Rome with Duchenne boys and the medical staff and many other tests with other children where a real-life situation was reproduced.
Active Need Experience	FUTURE DEVELOPMENT OF THE RESEARCH
User Projects	FUTURE DEVELOPMENT OF THE RESEARCH Purpose of a future project cooperation with users to develop and experiment on field the research

Other Methods	
Informal contacts	Direct interviews were integrated by the lecture of the numerous blogs opened to discuss online problems related to the management of DMD and in particular on the use of AFO for DMD or disease with similar effects that require the use of these orthoses. This practice of opening a web blog to discuss topics and seek for advices from people who are facing same difficulties is very diffused especially in America and these information were important since they were communicated in a real informal and colloquial way. Web communication allows in fact to expose personal doubts or feelings without the fear of being judged.

On the first meeting **in February 2012, 31 people were interviewed with a questionnaire** on the use of Ankle Foot Orthoses from their child. Useful information were collected but most of all **direct talks** with the parents who could frankly express their opinions and exchange views with the others **proved to be more interesting in let latent needs emerge**.

What clearly emerged as a first impression was that usually as users, as their parents and medical staff, are **used to consider the object only in its utilitarian aspect, as a tool, a medical device**, and in most of the cases they accept it as a medical prescription, **without even questioning whether it would be possible to improve it.**

Once completed this phase of collection of data the amount of requirements expressed was huge and it became necessary to give them an order and to select and evaluate the most relevant ones.

For this reason, this complex scenario is exemplified with the User Centered Design method of ***Personas***, powerful imaginary people who help in the identification of specific users' needs. These personas are imaginary but highly detailed and they reassumes and express all the surveyed needs. This method allowed to concentrate needs and expectations in few hypothetical figure but able to reassume all the needs expressed by the same group of people. It allowed at the same time to discover eventual contradiction that two users of the "same category" expressed on this topic and evaluate the reasons of this discrepancy.

Personification of expectancies immediately visualizes who I'm designing to, avoiding the risk, lost in a multitude of opinions, of opting for a "self-centered design", without considering anyone. Focusing on "real" people, as **the creator of the notion of *personas*, Alan Cooper says "*Convey information about users to your product team in explicit ways that other artifacts cannot.*"**[4]

The imaginary characters were:

Of course they don't represent all the users, all people that came in relation with the AFO but they proved to be a good starting point to focus, elaborating all the acquired data, the list of requirements that each person could express. It must be considered

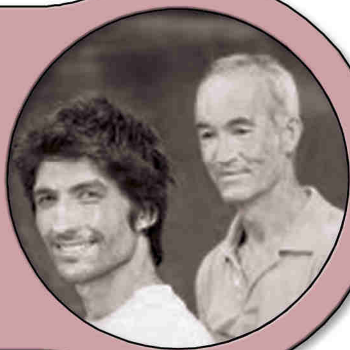
4 COOPER A., *The Inmates are Running the Asylum: Why High Tech Products Drive Us Crazy and How To Restore The Sanity*, Que, 1999, cit. in PRUITT J., ADLIN T., *The Persona Lifecycle: Keeping People in Mind Throughout Product Design,* op. cit.

LUCA – He is 8 years old, he is from Sassari, in Sardinia and he is affected by Duchenne Muscular Dystrophy. He wears night splints AFO since he was 4 years old but almost every evening he discusses with his parents since he would prefer to sleep without orthoses and, at the end, he dons AFOs only 3 – 4 days a week. He attends the third year of elementary schools, he loves video games and to watch TV in the evening on the sofa with all his family.

MARIA and **PIETRO** – are Luca's parents. They discovered Luca's disease at three years old, when they noticed that he had some difficulties in standing up from the ground and went to the hospital for some medical findings. They tried to convince Luca each night to the necessity of wearing AFOs but sometimes they give up not making him cry. Luca's retractions are becoming evident, he's starting to have difficulties in independent ambulation and they're really worried about his future.

GIOVANNI and **MARTINA** – are Luca's doctor and physiotherapist. They knew Luca since his parents discovered his illness. They see him really frequently for his physiotherapy routine and medical check-ups. They suggested Luca's parents to wear AFOs, they explained its function first to them and, since Luca has been 5, even to him. Giovanni and Martina recommended to Maria and Pietro an orthopaedic manufacture they knew since they made all the orthoses for their little patients and they've always been satisfied of the results.

FILIPPO and **RICCARDO** are the owner and the worker in an orthopaedic manufacture. Their establishment is in Oristano, two hours far from Sassari but Filippo inherited this activity from his father, they're really very well known in the sector since they produce high quality orthoses and in Sardinia there aren't so many other manufacturers so skilled. Filippo has 5 employees in his manufacture, they are few people but they do all their best to meet all requirements. Last year he invested in new machines to mold thermoplastic and apply colored textures on it to meet child tastes.



* Images are purely indicative

in particular that, while needs and expectation of all the other people maintain almost unchanged through the years, **Luca's requirements drastically changes over time** since his natural growth and since during his life since the progression of the disease visibly changes his daily life and his clinical conditions. Hereinafter a brief elaboration of all the surveyed data expressed by my imaginary personas.

LUCA

1. I want to understand why I have to wear these boots and my parents don't have to.
2. I want to sleep well.
3. I always move during the night but AFOs are uncomfortable when I sleep face-down.
4. My mom makes me wear AFO sometimes even in the afternoon if I'm sitting doing my homework or on the sofa but I am ashamed if other friends are with me because I don't like them.
5. I would like Winnie Pooh AFOs but manufacture hasn't got them.
6. I hate when I need a new pair of AFO making the plaster, I get bored.
7. If I wake up in the night and I have to go to the toilet I don't want to put off and on AFOs.
8. AFOs make me sweat.
9. I want to wear my AFOs alone without the help of my parents.
10. AFOs get tangled sheets.
11. I want anyone but my parents see me wearing AFOs.
12. AFOs don't have to hurt and leave scratches on the skin.
13. I don't want to wear always the same AFOs every night.
14. AFOs shouldn't weight too much since I get tired soon.
15. I want to wear and put off AFOs easily.

MARIA and **PIETRO**

1. We want to understand deeply the function of the AFO and how and when Luca has to wear them.
2. Luca's AFOs have to be clinically effective and delay his foot drop.
3. AFOs have to be efficient but they don't have to hurt Luca too much.
4. AFOs don't have to stink.
5. AFOs have to be easily cleanable.
6. We would like a closer manufacture since every time we have to ask for a day off to go to the manufacture to make a new pair of shoes.
7. They are too expensive and Luca is growing quickly so he needs to change AFOs frequently.
8. Luca has to walk safety in house even if he's wearing AFO, without risk of slipping.
9. We want to be sure to wear AFOs correctly.
10. We don't want to see Luca crying every time he had to wear AFOs.
11. We don't want to wait a long time after reservation of a new pair of AFOs.
12. We don't want that Luca feels his AFOs as a punishment, neither a medical device.
13. Luca has to be free of wearing AFOs with or without socks.
14. We want to involve Luca in the moment of the choice of his new pair of AFOs and please his tastes and desires.
15. We would like to find a trick to convince Luca in quietly wearing his AFO every night.

GIOVANNI and **MARTINA**

1. We want to be sure that the manufacture builds the AFOs as we ordered them
2. AFOs have to be clinically effective and delay plantarflexion
3. AFOs should control not only plantarflexion but every other possible contextual deformation
4. AFOs have to fit perfectly to every patients
5. AFOs have to apply the strongest stretching possible to the child in that moment but without causing pains
6. AFOs have to assist during the night to our physiotherapy activities during the day
7. AFOs have to be light not to burden on DMD children's weak muscles
8. AFOs have to be worn daily to guarantee their clinical efficacy
9. AFOs have to follow the inevitable progression of plantarflexions over the time
10. AFOs have to be in hypoallergenic materials
11. We want to choose the best type of AFO that suit best for every patient in terms of shape and material
12. AFOs have not to move from their original position during the night
13. AFOs have to be transpiring to reduce the risk of infections and blisters
14. We want to indicate personally to the manufacture how AFOs have to be made to meet child's clinical requirements.
15. It must not leave redness, scratches or bruises for more than 20 min after removing the AFOs

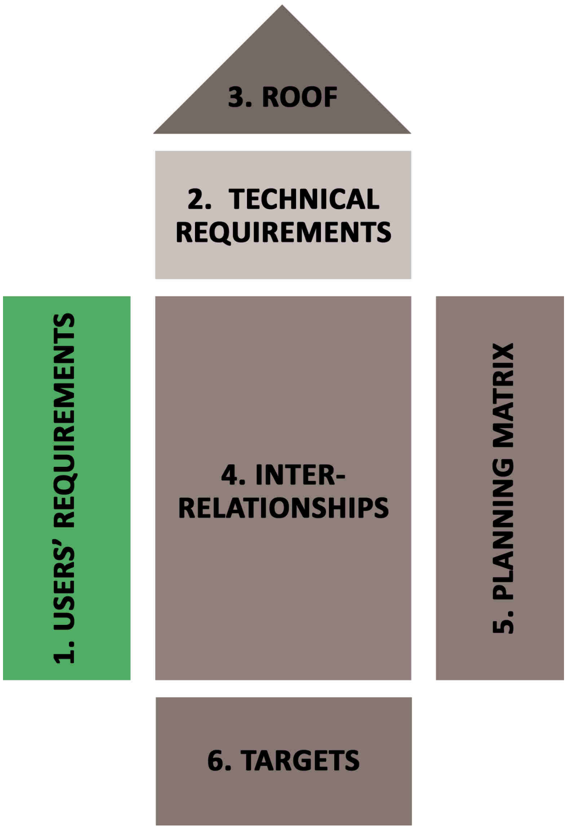
FILIPPO and **RICCARDO**

1. We want to respond to all the orders of orthoses in time.
2. We want to satisfy our customers.
3. We want to produce clinical effective orthoses to meet medical requirements.
4. We want to produce beautiful orthoses to meet children's requirements
5. Our orthoses have to be competitive on the market.
6. We would like to be always upgraded on the last technologies available to make better our work.
7. We would like to reduce costs and increment earnings.
8. I want to make orthoses in less time possible.
9. I want to make orthoses in safety.
10. We would like to enlarge our catchment area
11. We want to produce certified AFOs that respond to all the request to be included in government subsidies list.
12. AFOs have not to break risking to impair children
13. We would like to optimize energy and material consumption in the production process, reducing waste materials.
14. We would enlarge our catalogue with other types of orthoses but it is costlier
15. We would be able to manufacture orthoses for people of every age and every complication.

The recourse to these persona proved to be an efficient trick to organize and synthetize all the collected data in the phase of survey about requirements on Ankle Foot Orthoses. These explicit and latent needs were expressed with the same language they have been or could have been referred from each user.

5.3 – ANALYSIS OF CUSTOMER REQUIREMENTS

This phase concluded all these needs were further synthesized to the arrangement of the first part of the House of Quality scheme, the first step in the application of the Quality Function Deployment. Similar needs were reassumed in a single expression and an effort of interpretation was made to translate too specific gripes, related to a single product or event, into the correspondent general need that in that occasion, for that user, was unsatisfied. This phase completed, all the needs were collected in five main categories and sub-categories. This classification created a tree diagram of needs, that constituted the first part of QFD Matrix, known as *User Requirements*, that described the ***"Voice of the Customer".***



Position of Customer Requirements Table in the House of Quality Matrix of the QFD.

Efficacy - The first requirement, obviously expressed by all users in any role to Ankle Foot Orthoses is their clinical efficacy. AFOs have to contain, reduce, delay and **prevent the foot drop** of the foot. It is their fundamental and essential function, the reason why they are prescribed by doctors and therefore this is their inalienable requirement. However this general principle includes specific factors, and sub cause or consequences, as the requirement, for the foot, **not to move during the night** from the original position at the time when the AFO is dressed. Tendon retractions will naturally tend to move the foot in a dorsiflexion position that has to be countered. Furthermore a desire, expressed in particular by user's parents is the possibility of the AFO to follow the evolution of dorsiflexion retractions by the time. On standard markets of AFOs I found similar products, with the **possibility of a "registration" of the range of dorsiflexion**, like in many hinged AFO, or in other Dorsal AFOs with a regulation on the front. However my analysis tends to the observation that a change in dorsiflexion involves all the overall posture of the foot and therefore it would be better if any changes were prescribed by doctors and not autonomously by users.

Safety – This requirement is clearly understandable but it can be included in implicit needs since it is rarely expressed in a direct way, especially by users and their caregivers. My impression is that they take for granted that the AFO does not break and that it is designed to be perfectly safe for their children, both mechanically and hygienically . This is, at least in theory, always true but it must be remembered that the orthosis is subjected to strain, even strong, of tensile or compressive. Furthermore even if the AFOs that are object of my analysis are night orthoses, it has to be assumed that the child, or boy, may use them even for few steps at home. Hygiene safety is simply satisfied if the AFOs are easily washable and tumble and if a proper breathability of the orthoses is guaranteed.

Comfort – It is probably the most crucial point of discussion regarding Ankle Foot Orthoses. It seems that the binomial clinical efficacy and comfort cannot be anything if not an oxymoron. Comfort dorsal AFOs available on the market result the most comfortable but have low resistance, rigid solid AFOs are painful, non-breathable, bulky and heavy. Everyone interviewed point out some considerations on this issue. To organize and simplify these requirements five sets were organized.

- *Comfort of movement,* as in natural unconscious movements during the sleep as if the user takes few steps in the house.
- *Breathability* is crucial especially in hot seasons, when Solid AFOs in thermoplastic offers no way for the transpiration of the skin, causing sweats, rashes and discomfort.
- *Weight* considerations are particularly important in daily AFOs, the ones, if prescribed by a doctor, that have to be worn during the gait, since they have not to weight on weak muscles. For night AFOs this concept has to be in consideration only considering the possibility of short walks of the user in the house and has to be related with the concept of bulkiness that could obstacle simple movements during the night.
- *Touch* is related to the feeling of comfort when AFOs slips between the sheets or pajamas and of security of absence of edges and tips.

Usability – This category collects all the requirements that involve the process of order, production and delivery of an AFO. Among all the gathered needs on AFOs' usability, a huge discrepancy was noted among Italian's and American's ones. Italians are more focused on economic problems of cost of AFOs. On the other hand American blogs, beside the cost, discuss on the facility of ordering, manufacturing and receiving the AFO without moving far from home.

Appearance – In order to improve the feeling of acceptation and affection of the user toward this object that accompanies every night of his life we've already explained why aesthetic factors are crucial and it is extremely important to give the appropriate relevance to expressed or latent needs related to the appearances of AFOs.

This phase concluded, a crucial step in the compilation of the House of Quality Matrix is the attribution of ***Customer Priorities*** per each need. Not all the identified users' requirements have the same importance. A careful analysis of users' interviews and web letters lead to the attribution of a mark per each need from 1 to 5. The maximum mark identifies a requirement whose fulfillment is considered of extreme importance by the user.

USER REQUIREMENTS

EFFICACY 	Clinically effective	
	They have to prevent the foot drop	
	The foot has not to move from the correct position	
	They can follows evolution of retraction or dorsiflexion by the time	
SAFETY 	Mechanical safety	You don't have to fall If taking some steps wearing night AFOs
		It must not leave redness, scratches or bruisees for more than 20minutes after removing the AFO
		They must not break easily
	Hygiene	They have to be easily washable
COMFORT 	Movement	I want to decide how to sleep
		It has to be worn in the afternoon too when he is sitting on the sofa or is making his school homework
		I want to take few steps also if I'm wearing night splint AFO
	Breathability	I need to wear them in all the seasons of the year
		They must not make me sweat
		In winter I want to wear them with my socks
	Weight	Lightweight
		They have not to be bulky
	Touch	They must be pleasant at the touch
		Comfortable
		The AFO must not entangle to sheets or pyjamas
	Easy to don and don off	
USABILITY 	They have to be cheap to change them easily when his foot grows or change	
	You don't have to wait a long time to receive AFOs after reservation.	
	Once you received it you don't need further adjustment and tests	
	Orderable on line without moving from home	
	You don't have to move so far from your house to order a new pair of AFO	
APPEARANCE 	You have to be able to chose the style of your night AFO.	
	The wider choice of aesthetic customization has not to increase exaggeratedly the price of the AFOs.	

Identification
of customer
requirements

5.4 – TECHNICAL REQUIREMENTS

The first part of the matrix regarding user requirements composes what it is called as the "*Voice of Consumers*". The top of Quality Function Deployment is made by **Technical Requirements**. It expresses the ***"Voice of the Engineer"***. The aim of this portion of the House if Quality Matrix is to translate user requirements expressed in a subjective way, related to a single specific product into a technical description of the product or service. It has to be a physical requirement, a characteristic or a parameter clearly identifiable, it has to be expressed in a way that does not limit or prefer a particular design solution or technology. T**hese engineering characteristics represent the *HOWS*** of the designer. Some authors define them as *Substitute Quality Characteristics,* since they substitute users' requirements and form the input of the project.

The selection of technical requirements of the AFOs was a really hard task. It was particularly difficult since, surprisingly, even if it is a mainly functional product, **very few technical details were provided by manufacturers**. A great confusion in the given information was detected on the description of the material, usually generically defined as thermoplastic or polypropylene, only in very few cases a general thickness was reported while no manufacture communicated the characteristics of strength and resistance to stress forces of an AFO. The absence of technical details in market products complicated the definition of the characteristics, since it was almost completely lacking any terms of comparison. Each one of the technical detail was thought in relation with one or more special needs. Identified technical requirements were:

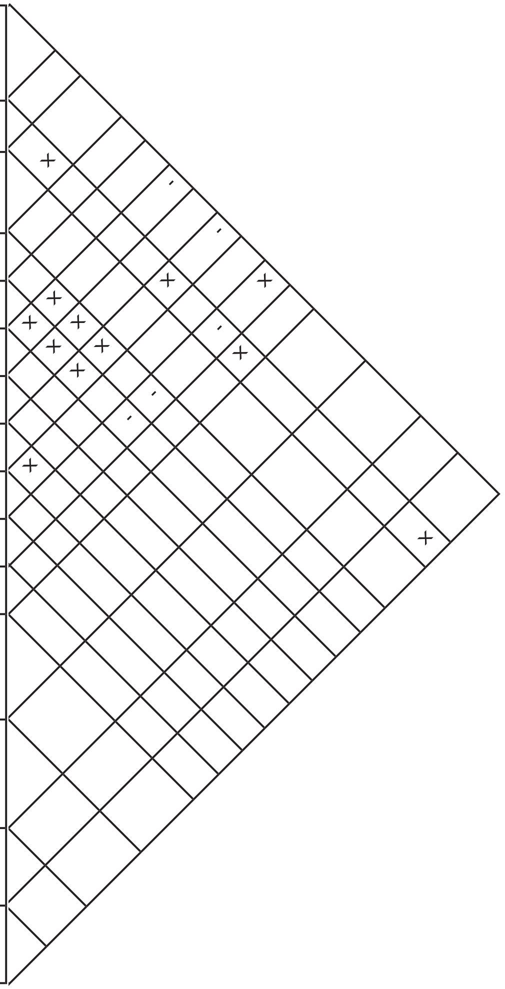
- Percentage of open surface on the general encumbrance of the shoes;
- Number of buckles;
- Number of pieces in which it can be decomposed;
- Maximum and minimum thicknesses;
- Breaking strength;
- Flexural strength of the sole;
- Total weight;
- Specific weight of the material;
- Breathability (g/m^2/die);
- Webbing strength;
- Number of days spent since the acquisition of the form for a new AFO to the first day of use;
- Number of revisions of the AFOs required after the manufacture, before its perfect fit;
- Number of different colours or textures available.

This list was completed with a row on the bottom, containing arrows pointing up or down. If it points out it means that an higher value of that characteristic is considered as an improvement in the design of the product. If the cell is left empty, it indicates a characteristic which variation cannot be directly linked with an improvement or worsening of the AFO.
Furthermore the roof of the matrix is a triangle table that links and crosses all the technical requirements between each others. If a plus sign is placed at the cross of two rows related to two details, it means that an improvement in one characteristic will automatically cause an improvement in the other. Consequentially a minus sign

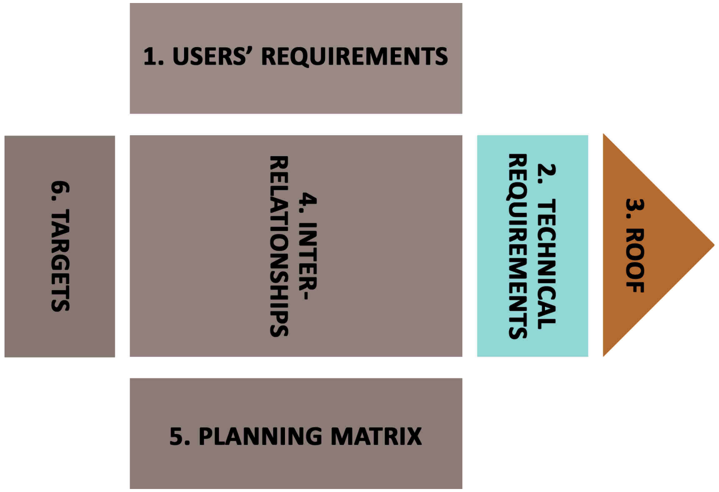
means that if a value of a technical requirement improves, the other characteristic will have a worsening, while an empty cell means that those two characteristics are not linked with each other. For example an increment of thickness causes an increase in breaking strength, and this is a positive feature, but proportionally it increases weight as well, while this value has to be as lower as possible.

Morphology	Percentage of open surface on the general encumbrance of the shoes
	Number of buckles
	Number of pieces in which it can be decomposed
Technical details	Maximum thickness
	Minimum thickness
	Breaking strength
	Flexural strength of the sole
	Total weight
	Specific weight of the main material
	Breathability ($g/m^2/die$)
	Webbing strength
Production process	Number of days spent since the acquisition of the form for a new AFO to the first day of use
	Number of revisions of the AFOs required after the manufacture, before its perfect fit
	Number of different colors or textures available
	Average time in seconds to wear an AFO

▶	Percentage of open surface on the general encumbrance of the shoes
	Number of buckles
	Number of pieces in which it can be decomposed
◀	Maximum thickness
◀	Minimum thickness
▶	Breaking strength
▶	Flexural strength of the sole
◀	Total weight
◀	Specific weight of the main material
▶	Breathability (g/m2die)
	Webbing strength
◀	Number of days spent since the acquisition of the form for a new AFO to the first day of use
◀	Number of revision of the AFOs required after the plaster cast, before using a new AFO
▶	Number of different colors or texture available
◀	Average time in seconds to wear an AFO



Technical Requirements Table with Roof in the House of Quality Matrix of the QFD



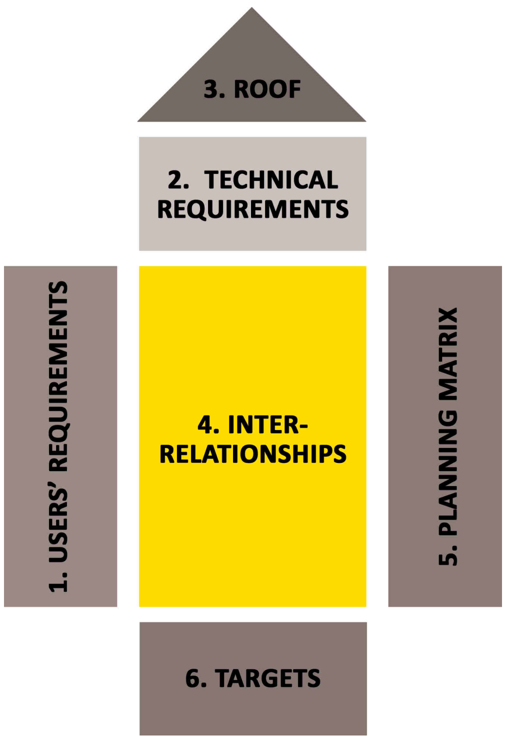
Position of Technical Requirements Table in the House of Quality Matrix of the QFD

5.5 – CORRELATION MATRIX AMONG NEEDS AND CHARACTERISTICS

The main part of the House of Quality is the Interrelationship Matrix. It indicates the way in which each technical requirement is satisfied by a user requirement.

It means that each cell located at the cross of a technical requirement with a users' need answer to the question: "How a technical characteristic may affect the quality expected by the user and his/her degree of satisfaction?" Four levels of interactions have been codified:

- *empty cell*, if the need and the technical performance are not related to each other;
- *white circle* represents a low relation between the elements and in the numeric count it corresponds to value 1;
- *black circle* identifies a medium relation and it is equal to the value 3;
- *full black round with a circle on the outside* symbolizes a strong relationship between need and technical property and it is associated with the number 9.



Position of Interrelationship Table in the House of Quality Matrix of the QFD

CORRELATION MATRIX

○ low relation = 1

● medium relation = 3

◎ high relation = 9

			Morphology			Technical details								Production process			
			Percentage of open surface on the general encumbrance of the shoes	Number of buckles	Number of pieces in which it can be decomposed	Maximum thickness	Minimum thickness	Breaking strength	Flexural strength of the sole	Total weight	Specific weight of the main material	Breathability (g/m2die)	Webbing strength	Number of days spent since the acquisition of the form for a new AFO to the first day of use	Number of revisions of the AFOs required after the manufacture, before its perfect fit	Number of different colors or textures available	Average time in seconds to wear an AFO
			▲	▼	▼	▼	▼	▲	▲	▼	▼	▲		▼	▼	▲	▼
EFFICACY	Clinically effective							◎	◎				◎				
	It has to prevent the foot drop		◎			○	○		◎				◎				
	The foot has not to move from the correct position			○									◎				
	It can follows evolution of retraction or dorsiflexion by the time			◎					◎			○	◎				
SAFETY	Mechanical safety	I don't have to fall if I take some steps wearing night AFOs		●					○	◎	◎		◎				
		It must not leave redness, scratches or bruisees for more than 20minutes after removing the AFO	●	◎								◎	◎				
		They must not break easily	●		◎	◎	◎	◎	●		◎						
	Hygiene	They have to be easily washable			○							●					
COMFORT	Movement	I want to decide how to sleep	◎														
		It has to be worn in the afternoon too if he is sitted on the sofa or is making his school’s homeworks	◎							●	○	●				●	
		I want to take few steps also if I’m wearing night splint AFO		●				◎		◎			◎				
	Breathability	I need to wear them in all the seasons of the year	◎				●					◎					
		They must not make me sweat	◎	◎			○					◎					
		In winter I want to wear them with my socks	●									◎	●				
	Weight	Lightweight	◎		○	◎	●			◎	◎						
		They have not to be bulky			○	◎	●										
	Touch	They must be pleasants at the touch	◎	◎													
		Comfortable	◎									◎					
		The AFO must not entangle to sheets or pajamas		◎	○												
	Easy to don and don off			◎						○			●				◎
USABILITY	They have to be cheap to change them easily when his foot grows or change													◎	◎	◎	
	If I need to change them I don’t want to wait a long time to receive them after reservation				○									◎	◎		
	Once I received it, I don’t have to make further adjustaments and tests													◎	◎		
	Orderable on line without movimg from home														◎		
	You don’t have to move so far from your house to order a new pair of AFO													◎	◎		
APPEARANCE	You have to be able to chose the style of your night AFO			●	○											◎	

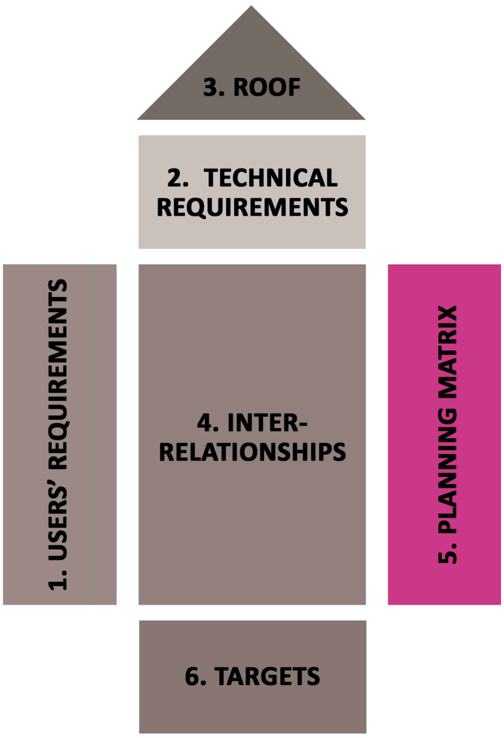
Position of Interrelationship Table in the House of Quality Matrix of the QFD

DESIGN

5.6 – ANALYSIS OF COMPETITORS

The 5th part of the House of Quality is the ***Planning Matrix***. The analysis of competitors is the continuation of the inquiry on market products explained in the third chapter. Among all the hundreds of scheduled products, only 18 AFOs were selected for a further analysis. This selection was made according to criteria of best possibility of use of the orthosis as a night splint. Among similar products, with the same response to users' needs, even if slightly different, only the best type was selected. Each product was then analysed following users' requirements table, assigning a mark from 1 to 5 to each capacity of a single product to satisfy that need. In order to better visualize the results of this comparison, the cells were filled with a range of colours, darker to indicate better results, white if the need was unresolved by that product. Intermediate results per each category of requirements were indicated with another scale of colours but with the same criteria. At the end all these marks were proportionally summed considering the relevance of each need expressed in ***Customer Priorities Column***. **The four AFOs that had the best scores were included in the House of Quality Matrix.**

This phase is called ***benchmarking on perceived quality***. The four AFOs that accessed the House of Quality were completely different each other: diverse typology, materials, usability and appearance. They were a thermoplastic solid AFO with Velcro straps; an hinged AFO with the possibility of locking the articulation to the required range of dorsiflexion, a standard dorsal AFO and a silicone AFO.



Position of Planning Table in the House of Quality Matrix of the QFD.

The first two types offer the best clinical efficacy, locking the foot in the correct position and moreover hinged AFO allows to follow the evolution of retraction of dorsiflexion by the time. Silicone AFO has an intermediate resistance, it depends on the thickness of the material but, in general, it gives up a bit of its function of containment of the position for a better comfort. Standard dorsal AFO, as the one in the picture, provides the lowest control of the foot but the best comfort. This is

DESIGN

the reason why it isn't usually prescribed to Duchenne's patients but more to cure simpler problems like plantar fasciitis or tendons' inflammations.

None of selected AFOs has significant problems with security or hygiene, but the best is silicone orthosis, thanks to its soft material and easy washability. Even in terms of comfort silicone AFO has good performances except from breathability, deeply compromised since the nature of the plastic material. It sticks as a glow to the foot, making it sweat. Similar problems of lack of breathability defects thermoplastic orthoses that, what's the most, have some problems even due their encumbrance, since they result bulky and heavy. As already said, dorsal AFO offers the best comfort possible among these four products. It allows multi-positions of the lower limbs during the night, it leaves a large part of the legs' skin uncovered to improve breathability and its soft padding prevents redness, bruises, calluses and pains.

Evaluations on different products' usability are quite difficult to be made since too different techniques are compared. Thermoplastic and silicone AFOs are made from plaster and then the material, in a liquid state, is cast in a negative mold. This require that the user has to move to the manufacture to make plaster casts of the lower limb, then technicians have to work on the mold and then the user has to come back one or more time to adapt and perfect fit the AFO to achieve the maximum clinical result and comfort possible.

The selected Dorsal AFO among the other products, on the contrary, is made as a standard product. Its morphology does not require any particular attention on the user's foot shape and it can even fit feets of slightly different measures. This characteristic made this product extremely flexible in the use, it is produced in only three sizes (small, medium, large) and when you need it you can go to a seller of orthopedic aids, sometimes even a pharmacy, and buy the product.

But if we compare these four products on their possibility of an esthetic personalization we notice a complete change of perspective. This analysis undoubtly rewards thermoplastic AFO thanks to their predisposition of being printed with different patterns and colors. Silicone Afos can as well be made in different colors and with drawings stamped on it but so far this attention in the personalization of silicone Afos is not yet broadly developed. On the other hand selected dorsal AFOs are made in a single standard version.

The analysis of competitors suggested to create a new product combing the best performances of each of the four selected products. Thermoplastic material proves to guarantee the best clinical efficacy and possibilities of aesthetic personalization, dorsal AFO results as the most comfortable orthosis, especially as a night splint, silicone AFO the best customization on user's feet.

I fear it will be difficult to combine the flexibility of an hinged AFO in following children's retraction by the time in the process of manufacturing of a new AFO without causing an exponentially increment of the total weight.

PRODUCTS' COMPARISON AMONG 20 SELECTED PRODUCTS			**IMPORTANCE**				
EFFICACY		Clinically effective	5	5	5	5	5
		It has to prevent the foot drop	5	4	5	5	5
		The foot has not to move from the correct position	5	4	5	4	5
		They can follows evolution of retraction or dorsiflexion by the time	2	0	0	0	0
Percentage of satisfaction				**76,47**	**88,24**	**82,35**	**88,24**
SAFETY	**Mechanical safety**	You don't have to fall If taking some steps	3	4	4	4	4
		It must not leave redness, scratches or bruisees for more than 20minutes after removing the AFO	5	2	2	2	3
		They must not break easily	3	4	4	3	5
	Hygiene	They have to be easily washable	2	5	5	5	5
Percentage of satisfaction				**67,69**	**67,69**	**63,08**	**80,00**
COMFORT	**Movement**	I want to decide how to sleep	4	2	2	2	2
		It have to be worn in the afternoon too if he is sitted on the sofa or is making his homeworks	3	5	5	5	5
		I want to take few steps also if I'm wearing night AFO	3	4	4	4	4
	Breathability	I need to wear them in all the seasons of the year	4	2	2	2	3
		They must not make me sweat	4	2	2	2	2
		In winter I want to wear them with my socks	2	3	3	3	3
	Weight	Lightweight	3	3	3	3	4
		They have not to be bulky	4	3	3	3	3
	Touch	They must be pleasants at the touch	4	3	3	3	3
		Comfortable	4	2	2	2	2
		The AFO must not entangle to sheets or pajamas	3	3	3	3	3
	Easy to don and don off		3	3	3	3	4
Percentage of satisfaction				**56,59**	**53,95**	**53,95**	**58,60**
USABILITY		They have to be cheap to change them easily when his foot grows or change	4	3	3	3	1
		You don't have to wait a long time to receive AFOs after reservation.	3	2	2	3	3
		Once you received it you don't need further adjustament and tests	2	0	0	0	3
		Orderable on line without movimg from home	1	0	0	3	0
		You don't have to move so far from your house to order a new pair of AFO	2	1	1	5	0
Percentage of satisfaction				**25,00**	**25,00**	**42,50**	**23,75**
APPEARANCE		You have to be able to chose the pattern on night AFO	5	3	4	4	0
	Percentage of satisfaction			**60,00**	**80,00**	**80,00**	**0,00**
TOTAL				**57,15**	**62,98**	**64,38**	**50,12**

										
5	5	5	4	4	4	5	2	4	4	1
5	5	5	4	5	5	3	3	4	4	3
5	5	5	3	4	4	4	3	3	4	3
4	0	4	0	4	4	0	3	3	0	1
97,65	**88,24**	**97,65**	**64,71**	**85,88**	**85,88**	**70,59**	**54,12**	**71,76**	**70,59**	**43,53**
4	4	4	4	1	3	4	0	5	5	5
3	3	3	2	4	4	2	5	4	5	4
3	3	3	4	5	5	4	4	5	5	5
5	5	5	5	4	4	5	2	5	5	5
70,77	**70,77**	**70,77**	**67,69**	**70,77**	**80,00**	**67,69**	**63,08**	**92,31**	**100**	**92,31**
1	2	1	2	3	1	2	3	5	5	4
3	5	3	5	4	3	5	1	5	5	4
4	4	4	4	1	3	4	0	5	5	5
3	2	3	2	3	1	2	4	4	1	4
2	2	2	2	2	1	2	3	5	0	3
3	3	3	3	5	5	3	0	5	0	1
2	2	2	3	4	1	3	5	4	4	4
2	3	2	3	3	0	3	0	5	5	5
0	2	0	1	2	0	3	0	4	4	5
2	2	2	2	4	3	2	0	5	4	4
2	3	2	3	2	1	3	4	5	5	5
2	3	2	3	2	2	3	4	5	4	4
39,53	**50,70**	**39,53**	**50,23**	**54,42**	**29,77**	**53,95**	**38,14**	**90,23**	**67,44**	**78,14**
2	2	2	3	4	4	3	5	5	4	4
2	2	3	2	5	5	2	5	5	3	4
3	3	3	0	5	5	3	5	5	5	3
0	0	3	0	5	5	0	5	5	0	0
1	1	5	1	5	5	1	5	5	0	1
27,50	**27,50**	**45,00**	**25,00**	**70,00**	**70,00**	**32,50**	**75,00**	**75,00**	**43,75**	**45,00**
4	4	4	0	0	0	5	0	0	4	4
80,00	**80,00**	**80,00**	**0,00**	**0,00**	**0,00**	**100,00**	**0,00**	**0,00**	**80,00**	**80,00**
63,09	**63,44**	**66,59**	**41,53**	**56,21**	**53,13**	**64,95**	**46,07**	**65,86**	**72,36**	**67,80**

PRODUCTS' COMPARISON
AMONG THE 4 BEST PRODUCTS
WITH SIGNIFICANT DIFFERENT CHARACTERISTICS

			CUSTOMER IMPORTANCE	PLANNED SATISFACION RATING	N°1 	N°2 	N°3 	N°4 
EFFICACY	Clinically effective		5	5	5	5	4	4
	It has to prevent the foot drop		5	5	5	5	4	4
	The foot has not to move from the correct position		5	5	4	5	3	4
	It can follows evolution of retraction or dorsiflexion by the time		2	3	0	4	3	0
SAFETY	Mechanical safety	I don't have to fall if I take some steps wearing night AFOs	3	5	4	4	5	5
		It must not leave redness, scratches or bruisees for more than 20minutes after removing the AFO	5	4	2	3	4	5
		They must not break easily	3	4	3	3	5	5
	Hygiene	They have to be easily washable	2	5	5	5	5	5
COMFORT	Movement	I want to decide how to sleep	4	5	2	1	5	5
		It has to be worn in the afternoon too if he is sitted on the sofa or is making his school's homeworks	3	5	5	3	5	5
		I want to take few steps also if I'm wearing night splint AFO	3	4	4	4	5	5
	Breathability	I need to wear them in all the seasons of the year	4	4	2	3	4	1
		They must not make me sweat	4	4	2	2	5	0
		In winter I want to wear them with my socks	2	4	3	3	5	0
	Weight	Lightweight	3	5	3	2	4	4
		They have not to be bulky	4	4	3	2	5	5
	Touch	They must be pleasants at the touch	4	2	3	0	4	4
		Comfortable	4	3	2	2	5	4
		The AFO must not entangle to sheets or pajamas	3	3	3	2	5	5
	Easy to don and don off		3	4	3	2	5	4
USABILITY	They have to be cheap to change them easily when his foot grows or change		4	5	3	2	5	4
	If I need to change them I don't want to wait a long time to receive them after reservation		3	5	3	3	5	3
	Once I received it, I don't have to make further adjustaments and tests		2	5	0	3	5	5
	Orderable on line without movimg from home		1	4	3	3	5	0
	You don't have to move so far from your house to order a new pair of AFO		2	5	5	5	5	0
APPEARANCE	You have to be able to chose the style of your night AFO		5	5	4	4	0	4
TOTAL				86,14	64,38	66,59	65,86	72,36

ANALYSIS OF COMPETITORS

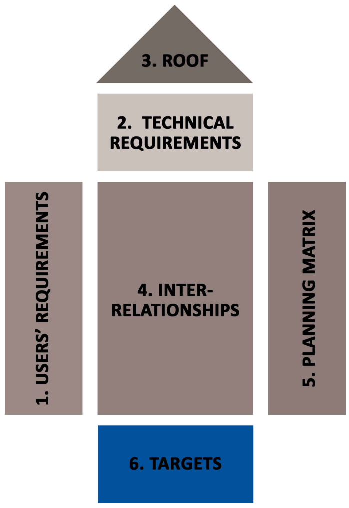
The four selected products

in the House of Quality Matrix

			Morphology			Technical details								Production process									
			Percentage of open surface on the general encumbrance of the shoes	Number of buckles	Number of pieces in which it can be decomposed	Maximum thickness	Minimum thickness	Breaking strength	Flexural strength of the sole	Total weight	Specific weight of the main material	Breathability (g/m2die)	Webbing strength	Number of days spent since the acquisition of the form for a new AFO to the first day of use	Number of revisions of the AFOs required after the manufacture, before its perfect fit	Number of different colors or textures	Average time in seconds to wear an AFO	CUSTOMER IMPORTANCE	PLANNED SATISFACION RATING	COMPETITOR N°1 	COMPETITOR N°2 	COMPETITOR N°3 	COMPETITOR N°4 
			►			►	►	►	►	►	►	►		►	►	►	►						
EFFICACY	Clinically effective							9	9				9					5	5	5	5	4	4
	It has to prevent the foot drop		9			1	1		9				9					5	5	5	5	4	4
	The foot has not to move from the correct position			1					9				9					5	5	4	5	3	4
	It can follows evolution of retraction or dorsiflexion by the time			9					9			1	9					2	3	0	4	3	0
SAFETY	Mechanical safety	I don't have to fall if I take some steps wearing night AFOs		3					1	9	9		9					3	5	4	4	5	5
		It must not leave redness, scratches or bruisees for more than 20minutes after removing the AFO	3	9								9	9					5	4	2	3	4	5
		They must not break easily	3		9	9	9	9	3		9							3	4	3	3	5	5
	Hygiene	They have to be easily washable			1							3						2	5	5	5	5	5
COMFORT	Movement	I want to decide how to sleep	9															4	5	2	1	5	5
		It has to be worn in the afternoon too if he is sitted on the sofa or is making his school's homeworks	9							3	1	3				3		3	5	5	3	5	5
		I want to take few steps also if I'm wearing night splint AFO		3				9		9			9					3	4	4	4	5	5
	Breathability	I need to wear them in all the seasons of the year	9				3					9						4	4	2	3	4	1
		They must not make me sweat	9	9			1					9						4	4	2	2	5	0
		In winter I want to wear them with my socks	3									9	3					2	4	3	3	5	0
	Weight	Lightweight	9		1	9	3			9	9							3	5	3	2	4	4
		They have not to be bulky			1	9	3											4	4	3	2	5	5
	Touch	They must be pleasants at the touch	9	9														4	2	3	0	4	4
		Comfortable	9									9						4	3	2	2	5	4
		The AFO must not entangle to sheets or pajamas		9	1													3	3	3	2	5	5
	Easy to don and don off			9						1			3				9	3	4	3	2	5	4
USABILITY	They have to be cheap to change them easily when his foot grows or change													9	9	9		4	5	3	2	5	4
	If I need to change them I don't want to wait a long time to receive them after reservation				1									9	9			3	5	3	3	5	3
	Once I received it, I don't have to make further adjustaments and tests													9	9			2	5	0	3	5	5
	Orderable on line without movimg from home														9			1	4	3	3	5	0
	You don't have to move so far from your house to order a new pair of AFO													9	9			2	5	5	5	5	0
APPEARANCE	You have to be able to chose the style of your night AFO			3	1											9		5	5	4	4	0	4
																			88,86	**64,38**	**66,59**	**65,86**	**72,36**
	Percentage of satisfaction of each need by each characteristic		15,47	13	2,35	5	3	5	8,3	5	4	9	13	4,96	5,41	5	1,4						
		Technical priorities	**309**	**227**	**47**	**95**	**69**	**99**	**165**	**93**	**84**	**188**	**267**	**99**	**108**	**90**	**27**						

5.7 – AFO'S TARGET AND CONSIDERATIONS ON THE DESIGN OF AN AFO

The planned matrix is composed not only by the analysis of competitors but even by the targets that the team decides to pursuit in the design. At this stage the AFO doesn't exist yet as a shape or as a solid, but this is the moment in which, from the results of the House of Quality it is possible to define the aims of the design of a new product. Customer priorities and marketing strategies have now to be carefully evaluated. Trying to achieve the best mark in all the needs indistinctly can be counterproductive, since it could make the cost grow too much, leading its economic competitively.



Position of Target Table in the House of Quality Matrix of the QFD.

The results of this process of **translation of design targets in proposed solutions** is illustrated in the following scheme.

The QFD matrix evidenced which were the user requirements considered of higher importance for people who are in relation with the orthoses and, at the same time, it evidenced which technical characteristics should be modified in order to aim at an improvement of existing products. The scheme starts from the five categories identified to organize users requirements, edged in dark blue. For each category a synthesis of the needs that will be considered as targets in the design of a new type of orthoses is written in grey rectangles that come out from the coloured circles.

An accurate evaluation of these needs suggested some possible solutions. Each one of these is still just a suggestion, an embryonic idea that still communicates in which direction will move the research in order to try to satisfy users' requirements. As noticed, all these suggestion were organized in three levels, depending on the feature that was of interest in the design process:

- ***Production Process*** - This is one of the elements that soon appeared as the weakest in the observation of AFOs in all their features. Even if made with thermoplastic materials, we've seen how current process of manufacturing AFOs is really handcraft. Modern technology could do a lot to improve this situation, starting from the phase of survey.
    - ***Indirect survey in stretching position*** - An indirect survey made positioning feet in the best position they can achieve in terms of alignments and dorsiflexion could be useful in optimizing clinical efficacy, The aim is to create an AFO with the higher level of correction as

DESIGN

possible, exploiting the mobile retraction still present in that moment in boy's feet and therefore applying a customized and calibrated stretching force. Moreover an indirect survey could allow to easily collect and **monitor over time the progression of plantarfexions**, to have measurable data dated in time and scientifically comparable to evaluate the progression of the disease compared with the physiotherapy and AFO's stretching activities. Furthermore an **indirect survey could be easily done in the same clinical centre where the boy usually does his physiotherapy.** These conditions have a double advantage: firstly the therapist that positions the child's foot would know perfectly how to do that and what level of dorsiflexion the boy is able to achieve; secondly parents would not be obliged to physically move to the manufacture, that can even be in another city, since the 3D virtual model of the feet on which model the AFOs can be mailed and the final AFOs posted.

- ***Parametric modelling*** - The hypothesis of approaching a parametric design to model the geometry of the AFO directly on the shape of the foot could bring several advantages. First of all the complete automatization of the process. The geometries that determinates the shape of an AFO wouldn't build in general and then suited to the leg but would originate directly from the 3D model of the child's limb. Moreover, in case of a parametric design, if I would asset the algorithm with the sequence of operation required to model an AFO, every time would be necessary exclusively to substitute the reference model from which starting the process. This could extremely simplify all the process in terms of time, manhours and therefore costs. Concluding, a parametric design would enlarge enormously the possibility of an aesthetic personalization of the shoes, even choosing parametric textures or motives that could be applied on the orthosis.
- ***3D printing AFO*** - The idea of recurring to an additive technology for the manufacturing of the AFO is related to the choice of a parametric design and in view of the best optimization of the process in terms of quality, time and costs. This technology could indeed be able of printing even the most complex AFO's shape, given simply a minimum thickness, and therefore exponentially it would enlarge the possibility of creating aesthetic pleasant and personalized orthoses that would meet the tastes of the users. Concluding, if this solution will be effectively applied, high resistance and hypoallergenic thermoplastic will be required to guarantee solidity and hygiene.

- ***Morphology -*** The second group of solutions to create an innovative AFO with improved characteristics compared with traditional orthoses involved the shape itself of the AFO, its morphology.
  - ***Dorsal AFOs*** - Market analysis evidenced that this type of AFO is the one with better scores in terms of comfort and of good responses from the users to its use. However nowadays there aren't any dorsal AFO that can be suited for Duchenne people. This observation lead to the idea of investigate this typology of AFOs to understand if, increasing its strength resistance and customization could be possible to use this scheme of orthoses.
  - ***Increment percentage of open surfaces*** - this element could drastically improve the breathability of the orthosis and this could be a relevant improvement in terms of comfort. Moreover it would be easily made

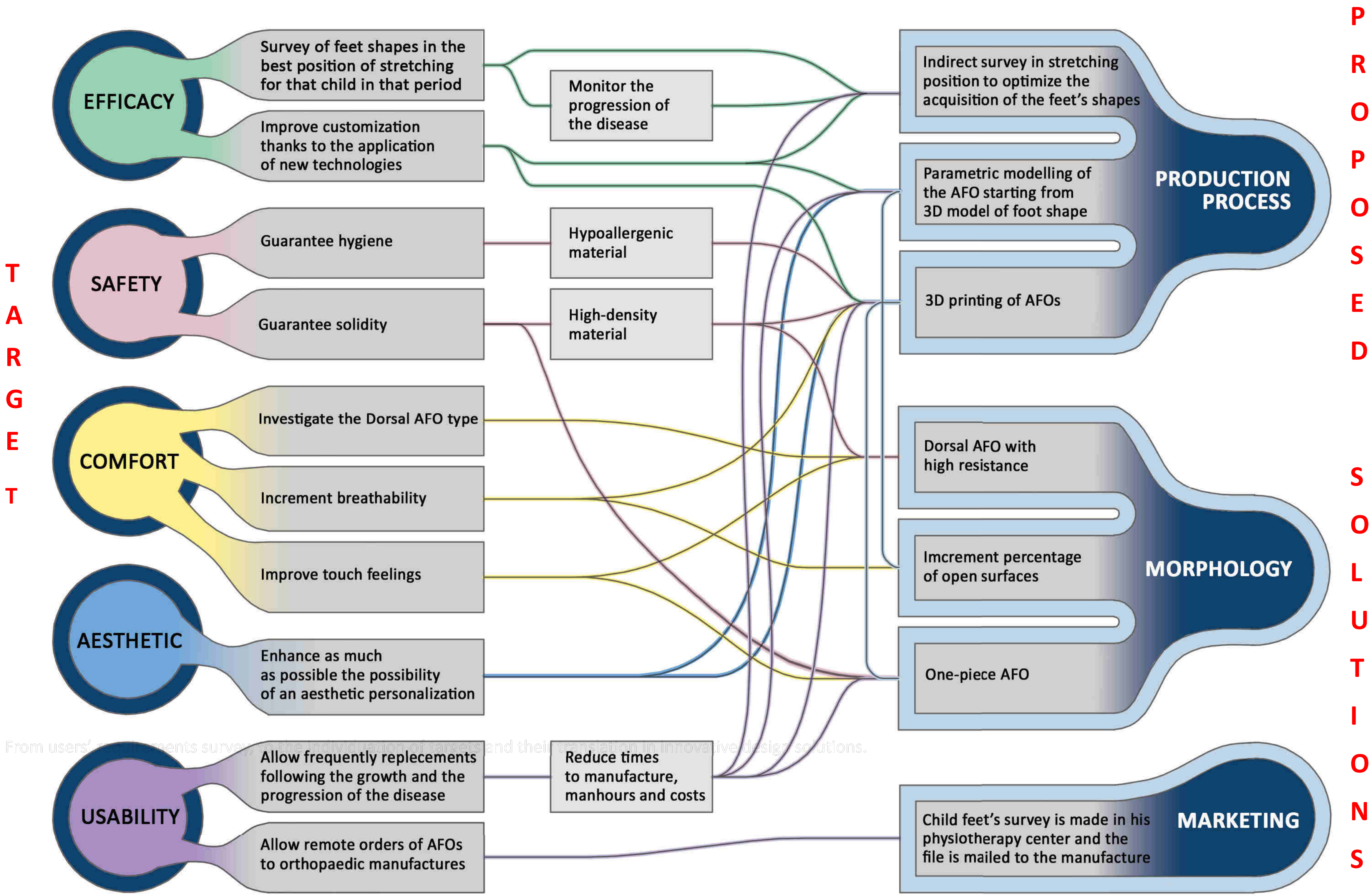
DESIGN

possible by the choice of a 3D printing technique, that could allow even microperforation of the surface.

- ***One piece AFO*** - The idea is to try to produce the AFO in a single piece. This element could improve touch feelings, since the absence of junctions, and contextually increase solidity. Moreover this could be obtained even with traditional techniques, but the application of an additive technique of 3D printing could make this passage easy, automatic and economically convenient.

- ***Marketing***
  - ***Remote orders*** - Indirect survey technique would allow technicians who take in care the DMD patient to made by themselves the survey of child's limbs and to mail the virtual reconstruction to the manufacture, even if they are far, and to receive back the customized AFOs, once it is 3D printed.

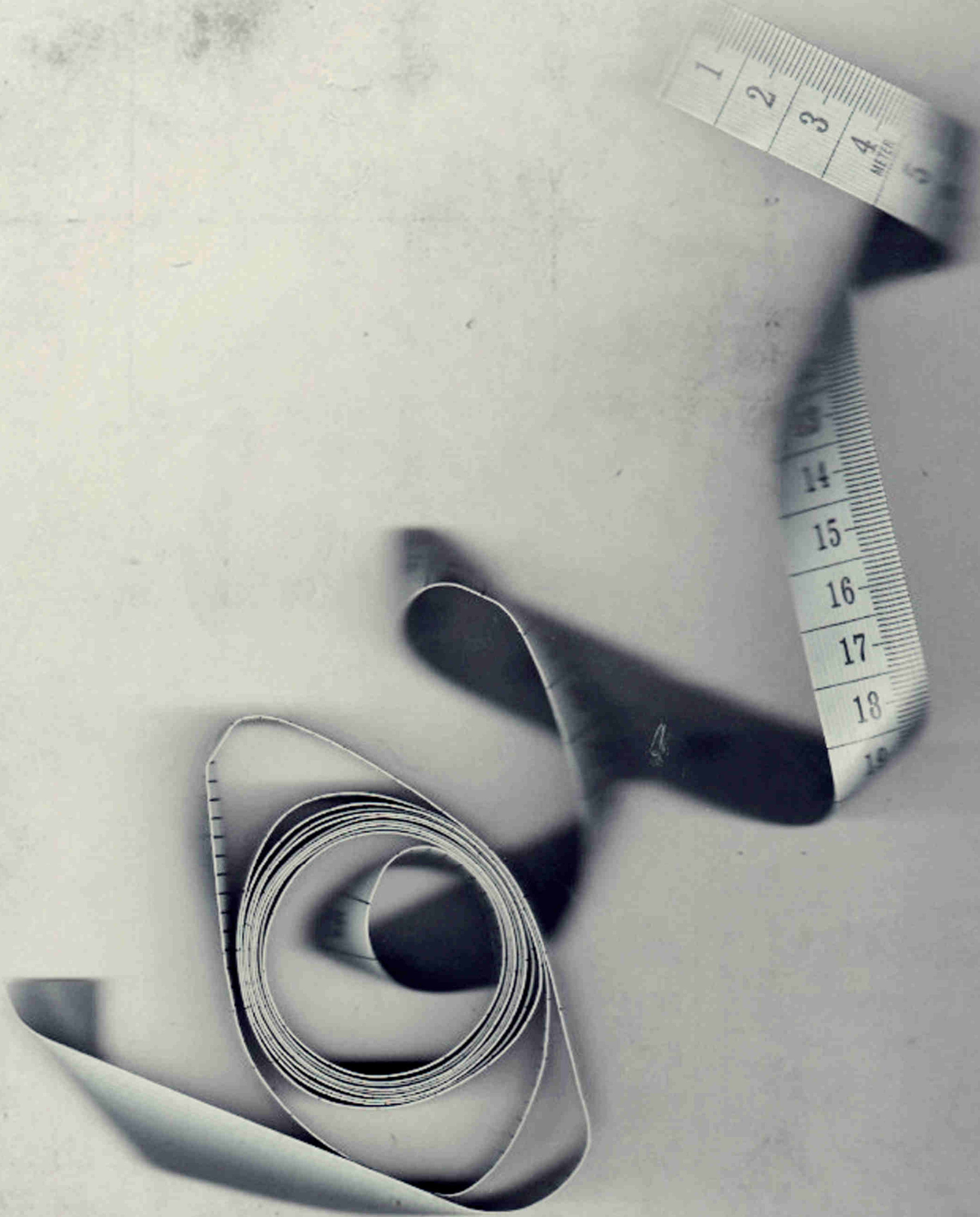
All these solutions are the starting point of the design process of a new type the orthoses, innovative and which main characteristics aren't arbitrary but the rational and analytical consequence of the application of the method of Quality Function Deployment. In following paragraphs all the phases of the design of this new innovative type of night orthoses for people affected by Duchenne Muscular Dystrophy will be carefully analysed.



From users' requirements survey, to the individuation of targets and their translation in innovative design solutions.

PART THREE

DESIGN PROPOSAL AND EXPERIMENTATIONS



6 OVERVIEW ON ALTERNATIVE TECHNIQUES OF LOWER LIMBS' SURVEY

@ Measuring tape. by Therese Tjernstrom
https://www.flickr.com/photos/tescho/7035440467

6 – OVERVIEW ON ALTERNATIVE TECHNIQUES OF LOWER LIMBS' SURVEY

The application of the ***House of Quality Matrix of the Quality Function Deployment*** highlighted which were the priorities that have to be followed in the design of a new orthosis in order to provide improvements on existing products and a better response to users' requirement.

This third part is dedicated to the implementation of the design process. The proposal of an innovative new type of Ankle Foot Orthosis for people affected by Duchenne Muscular Dystrophy doesn't effect only the research of a new shape. On the contrary it is a project that involves all the aspects related to the object, from its conception, the techniques of acquisition of the shape of children's limbs, the veritable design of the shape, its physical manufacturing and all the consequences that each choice could have in the marketing and use of the orthoses.

The main steps of the design process are:
- ***Acquisition*** of the shapes of DMD children's lower limbs;
- ***Parametric design*** of the orthosis starting from the surveyed 3D model of user' leg;
- ***Manufacturing*** of the orthosis by the application of the additive technology of 3D printing.

Each phase contemplates a first phase in which all the alternatives offered by current market and innovative technologies are taken in consideration, compared and evaluated. Then the final choice or choices are applied to the aim of the research to move a step forward in the design process.

In this chapter, in particular, all the ***alternative technique of survey*** are taken in consideration, with a particular attention to indirect techniques of survey for medical applications and lower limbs.

6.1 – INTRODUCTION

The third part of the thesis illustrates the implementation of the design of an innovative Ankle Foot Orthosis for people affected by Duchenne Muscular Dystrophy. The application of the method of the House of Quality Matrix of Quality Function Deployment indicates targets and operative suggestions that have to be developed in the following design phase. In particular the last scheme of the previous chapter ***proposes solutions for the identified mayor requirements***. These were organized in three categories: ***Production Process, Morphology and Marketing***. Among these three, the third part of the thesis will focus mainly on process issues, since morphological choices are influenced by results of market analysis and by comparison of products or they are, as marketing possibilities, a direct consequence of the manufacturing process.

The phase of implementation of the night AFO has been divided in three main phases. The first step is a focus on the ***alternative possibilities of customizing the AFO on the shape of DMD child's leg***, comparing pros and cons of different survey techniques. The second stage involves the morphological design of the AFO and the ***passage from a virtual reconstruction of a lower limb, to a 3D solid model of an orthosis*** that suits perfectly with the shape of the foot acquired in its best position of stretching and alignment possible. Concluding the last phase illustrates the ***passage from a virtual model to a solid object***, the realization of the first prototypes and future developments of the research.

For each of these main steps, the methodological approach adopted was the same: once that the frame of the issue was clear, through the analysis of current situation and the evaluation of special needs related to that phase, an overview on mains technological alternatives possible was presented. Then, among described different possibilities, the most suitable for the scope, or even more than a single solution, were selected, tested and operatively applied in the process of design of the orthosis. In next chapters we'll see how these criteria were specifically applied in each phase that will be illustrated as follows:

PART THREE:

- ***Acquisition***:
    - CAP. 6 - Overview on alternative techniques of lower limbs' survey.
    - CAP. 7 - Tests of indirect survey of lower limbs with different technologies and comparison of the results.
    - CAP. 8 - Design of a support to survey DMD children's lower limbs.
- ***Parametric design***
    - CAP. 9 - Overview on parametric design and its application in the design of a night AFO for people affected by DMD starting from a 3D model of user's lower limb.
- ***Manufacturing***
    - CAP. 10 - Overview on 3D printing techniques.
    - CAP. 11 - 3D printing of a night Ankle Foot Orthosis for DMD, realization of the first prototype and future developments.

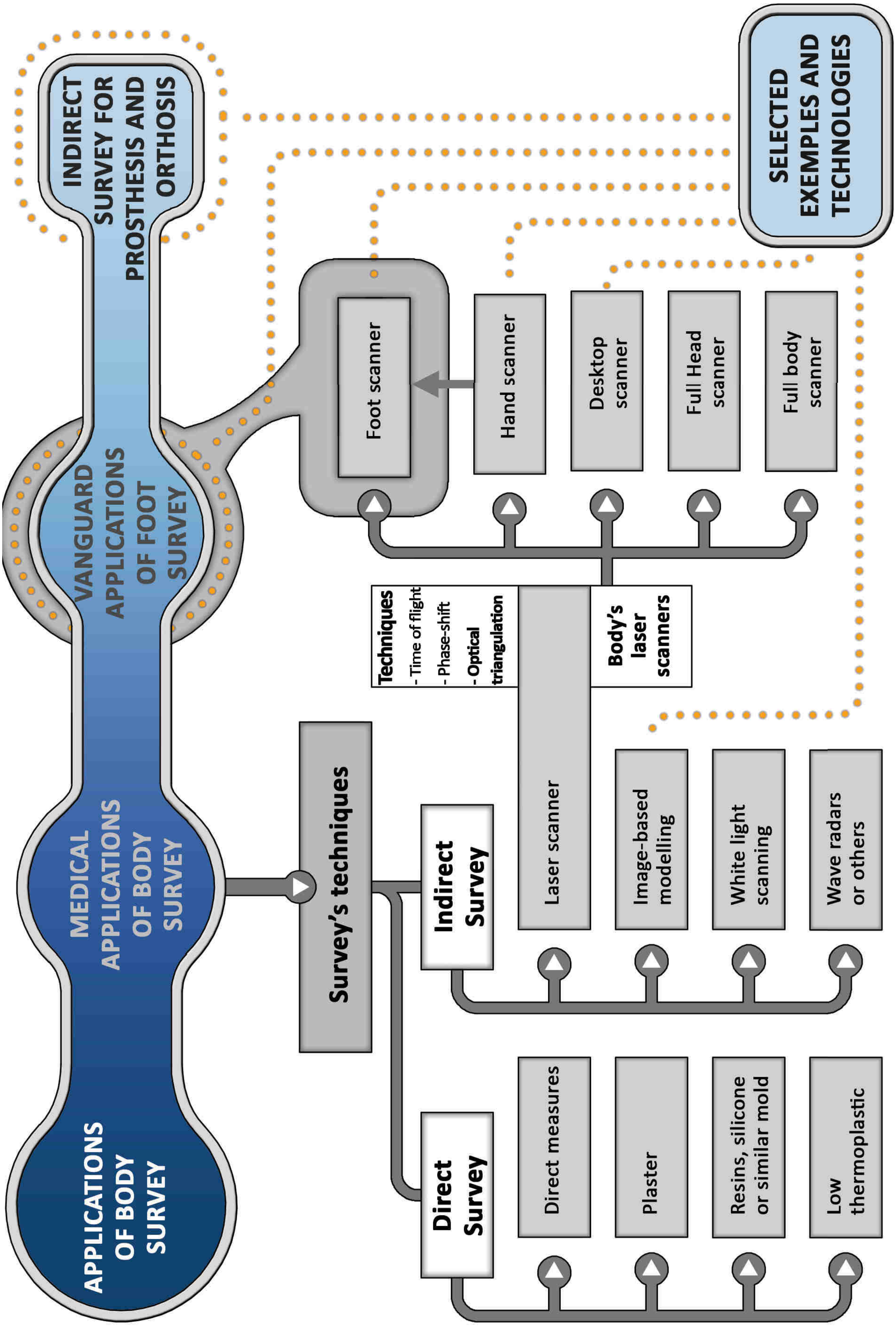
Moreover the phase of acquisition involves not only the survey of the lower limb but even the design of a completely innovative object, not found on current market, that is a sort of bench, with the feature of a rocking horse, on which children can sit and accommodate their foot in a adjustable pedal that is regulated by the therapist to impress the appropriate stretching and alignment for each single child in that moment.

Chapter 6 begins the Acquisition Issue with an overview on alternative techniques of lower limbs' survey.
In Market Analysis revealed how, especially in Italy, almost all the customized AFOs are made, starting from the plaster of child's leg, on which it is mold a thermoplastic shell. We've already seen how this choice is a weak point, since the shape of the foot is acquired in an almost relaxed position and then an arbitrary range of dorsiflexion is applied in order to press a stretching force. However the empiricism of this technique doesn't take in consideration the real extension of mobile retractions still present in the patient's foot. This observation lead to the conclusion that the application of an ***indirect survey of the limb, locked in the best position possible taking in consideration his current ligamental flexibility, could improve clinical efficacy of the AFO.*** It would apply to the foot the highest level of correction as possible in every direction and will have a better correspondence with the exact shape of the foot. Starting from this analysis and proposed solution, hereinafter a brief overview on survey's techniques is presented.

DESIGN

As it is illustrated in the scheme, two levels of insights are lead in parallel, the application issue and the technical one. Regarding the first topic, a progressive deepening is illustrated, starting from general ***applications of body survey***, then focussing more on ***medical applications*** of these technique, especially ***indirect techniques of visible body parts.*** Then, a focus on ***indirect foot survey*** highlighted how this technique isn't applied only in medical field but even to improve shoes' fitting in luxury or sportswear shoes. This in-depht analysis concluded with something strictly related with the theme of the research, that is applications of body survey for prosthesis and orthotic items.

Contextually another research develops more alternatives ***techniques of survey*** available, with a first sketchy distinction among direct and indirect techniques and then, focussing in particular on Image-based modelling and Laser Scanners. This technology is applied in various different instruments specifically thought for body survey, among which, in particular several different types of ***foot scanners***.


APPLICATIONS OF BODY SURVEY
MEDICAL APPLICATIONS OF BODY SURVEY
VANGUARD APPLICATIONS OF FOOT SURVEY
INDIRECT SURVEY FOR PROSTHESIS AND ORTHOSIS
Survey's techniques
Direct Survey
Direct measures
Plaster
Resins, silicone or similar mold
Low thermoplastic
Indirect Survey
Laser scanner
Image-based modelling
White light scanning
Wave radars or others
Techniques
- Time of flight
- Phase-shift
-Optical triangulation
Body's laser scanners
Foot scanner
Hand scanner
Desktop scanner
Full Head scanner
Full body scanner
SELECTED EXEMPLES AND TECHNOLOGIES

DESIGN

6.2 – THE AIM OF THE RESEARCH ON SURVEY TECHNIQUES

In the first phase of the developing of the research, one of the first problems that emerged clearly, as from scientific literature as from direct contacts with parents of children with DMD and all the medical staff, was the necessity of improving the phase of survey of the feet of children with DMD in order to simplify the process of making the plaster and improving the results, too often and too much depending on handcraft ability of the technician.

The application of modern technologies could bring interesting improvements in this field. Nowadays most of the custom-made orthosis are made by: non weight bearing impression or casting, partial weight bearing foam impression, computer -aided design and computer-aided manufacturing (CAD-CAM). Even if, especially in Italy, we've seen that most of the AFO are made with the first technique, the CAD-CAM method is increasingly gaining popularity.

"The first CAD-CAM system for the production of orthoses was the Orthocan system and was introduced in 1988 by the American Digital Technology. The second system was released by the Ammon Production system through Ammon Corporation and was manufactured by the Bergmann Orthotic Laboratory."[1]

In particular, in the traditional method, during the bandage for the plaster nowadays technicians try as much as they can to stretch the foot in a dorsiflexion position and to correct the alignments of the limb making the most of the mobile retractions still present in the user. With the progression of the disease, in fact, the thickening of the Achille's Tendon, along with the decrease of muscular strength, causes retractions and deformations. However in a first moment, these can be corrected and compensated with a stretching activity. Handicraft methods, even if conducted by expert technicians, tend to loose precision in the direction and range of movement, losing precious angles of recovery during the passive stretching activity of the AFO. From these premises it started a deepening on all the techniques of body survey available nowadays on the market, in order to find the best solution to improve the production's process of night ankle foot orthoses for people affected by Duchenne Muscular Dystrophy.

A full body scan at Manchester Airport in England

@ PAUL ELLIS. AFP. Getty Images

1 GRUMBINE N., *Computer-generated orthoses. A review,* in *Clin Podiatr Med Surg 10, 1993: pp.377 - 391,*

DESIGN

6.3 – BODY SURVEY. POTENTIAL AND APPLICATIONS

The study of human proportions and measures has interested humankind since the dawn of time. From the Vitruvian man, to all the principes of RenaissanceHumanism, to the nineteenth-century theories on anthropometry, human shapes have been surveyed, catalogued, analysed and interpreted. Modern techniques have simply made this process simpler and quicker, allowing a rapid acquisition of humans, with an extreme accuracy and high detail, in a static or even dynamic position.
It is this technical simplification that has expanded wildfire the possible fields of applications of human shape.
Furthermore 3D human scans are much more than just a 1-D measuring tools, since they provide, for example, shape, contour, volume, location, comparative locations over time or under different conditions or between two people[2].
Body scanners are now used in:

- *cinematography*, to create effects, especially in science fiction or animation;
- *computer games*, with the recreation of human features characters;
- *art, sculpture, 3D printing*;
- *security*, as the ones used in airports;
- *biometry*, as biometric recognition used in prisons or in anti-theft systems;
- *forensic*, as an application of a scientific method and technique for the investigation of a crime[3];
- *anthropometry*;
- *clothing*, shoes or accessories to create personalized and customized clothes, virtual try-on or virtual make over, hairdressing;
- *industrial design*, as a new frontier of customization, ergonomics and personalization;
- *sport and fitness*, as for the design of sport clothes or customized shoes for top sportsmen as for the design of equipment, as Formula 1 car cockpit or the interior of a bob, where each little space has to be optimised;
- *health*, in diagnostic analysis
- *cosmetics*, dermatology
- *orthopedic and prosthetic*, with body survey for the design of personal aids as orthoses, prosthesis, or orthopedics customized aids in general, as wheelchair backs.

Creaform, Geomagic and WYSIWYG 3D come to the aid of Australia's kayak team. The customized inside of the kayak was built starting from a scan, with an hand laser scanner, of the athlete in position.

@ geomagic.com

2 ROBINETTE K.M., *2D Body Scanning, Past and Future,* in *Proceedings of the 4th International Conference on 3D Body Scanning Technologies*, Long Beac, CA, USA, 19-20 November 2013; p. 11

3 DIAPREM, *Corpo Spazio e Architettura. Rilievo di morfologie e geometrie corporee tra scena del crimine e metaprogettazione*, DIAPReM Departmental Center of the Department of Architecture of the University of Ferrara, 2005, http://www.unife.it/centri/diaprem/archivio-progetti/corpo-spazio-e-architettura (January 2015)

The potential of these instruments are enormous if we think that a whole-body scanner can capture highly accurate 3D body maps in 1 to 10 seconds. From this virtual reconstruction it is possible to extract every desired measure, eliminating manual measurements, transcription errors, or long time of acquisition, since all the measures can be extracted even afterwards, in absence of the physical subject[4]. The techniques of acquisition can vary depending on the instrument and most of all on the aim of the scan. Some criteria for the choice of the instrument can be:

- ***Area of application***: they can survey the complete body or just a part;
- ***Quality and type of result:*** accuracy, resolution, it is required a 3D model with surfaces or a point cloud, with or without texture or colours;
- ***Process of acquisition:*** time of acquisition, reliability at the first time;
- ***Background knowledge*** required for the use of the instrument;
- ***Location:*** surrounding environment requirements, dimension of the instrument, transportability, light conditions;
- ***Cost:*** it has to include the cost of the instrument, of the software for processing data, of operators, maintenances, and of the entire system. Some of them, based on photo-scan can be very cheap, others can reach 200.000 euros or even more.

The differences between a scan of an inanimate object and a human scan is of course connected with the time of acquisition and the impossibility of completely stop human motions, due to natural movements, breathing, hairs, whip of the lashes and similar. For this reason it is important to define the posture during the scanning, and the environment. Preventive security measures have of course to be put in place. The survey has to be not harmful and eye safe, but even psychological issues on the property and data protection, have to be taken in consideration. This topic becomes even more important since the possibility of 3D body scanning in the very next future will become accessible to all, instrumentations' cost is set to fall, open-source software are coming on the market and the process technique is becoming quickly simpler. Furthermore the capability of 3D body scanner of recreating faithful virtual reconstructions has a great potential of radically change a wide range of processes of design of products and even the way they are conceived[5]. This can be true not only for customized products designed specifically for a single person but it can really bring a step forward to the theory of ***User Centered Design***. ***Anthropometric measures*** have been used since ancient Greek times but a 3D database of "real" humans is a completely change of point of view:

- the database is not based on standard measures, on a model of "average man", but on real people, with all their differences and characteristics.
- the representation is no more a bi-dimensional drawing but a 3D model evaluable in all its feature, queryable in every moment depending on necessities.
- 3D scanner is able to register in a measurable mode human body in motion and in stress conditions, while all the representations of human body in the history for anthropometric scopes represented him in static positions[6].

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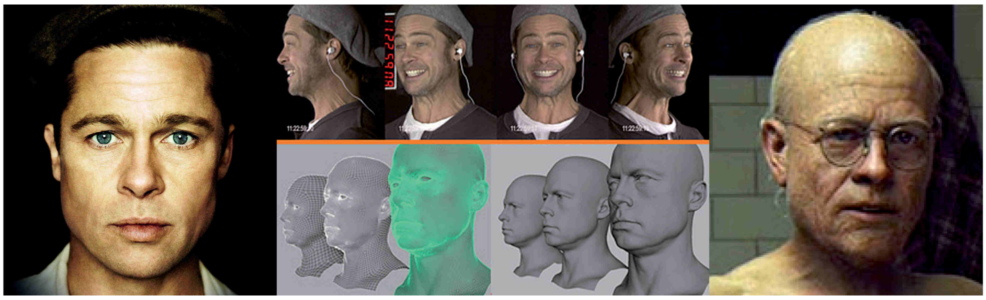
4 TRELEAVEN P., *3D Body Scanning and Healthcare Applications*, Computing Practices, University College London, IEEE Computer Society, 2007, discovery.ucl.ac.uk/13462/1/13462.pdf (September 2014)

5 New legislations are collecting ideas and potentials of new technologies and are translating the results into references measures to define new standards in industrial design. The ISO 7250-1:2008 provides a description of anthropometric measurements which can be used as a basis for comparison of population groups. It is intended to serve as a guide for ergonomists who are required to define population groups and apply their knowledge to the geometric design of the places where people work and live.

6 TELFER S., WOODBURN J., *The use of 3D surface scanning for the measurement and assessment of the human foot*, in *Journal of Foot and Ankle Research*, 2010, 3:19, http://www.jfootankleres.com/content/3/1/19 (August 2014)

The ***Civil American and European Surface Anthropometry Resource, CAESAR***, has carried out many studies in the collection of anthropometric measures associated with dynamic movements.

The so called ***4D scanning*** are already a reality that is going to grow rapidly in the future. 4D ultrasound scans, for example, has completely revolutionized the way we can visualize, examine and see the developing baby in uterus[7].



a. Brad Pitt acted out the first half of Benjamin Button standing still and moving only his face and head. Animators used his performance as reference when moving his digital puppet.

@ www.forbes.com/forbes/2010/0315/entertainment-hollywood-cameron-movies-star-reborn.html

b.

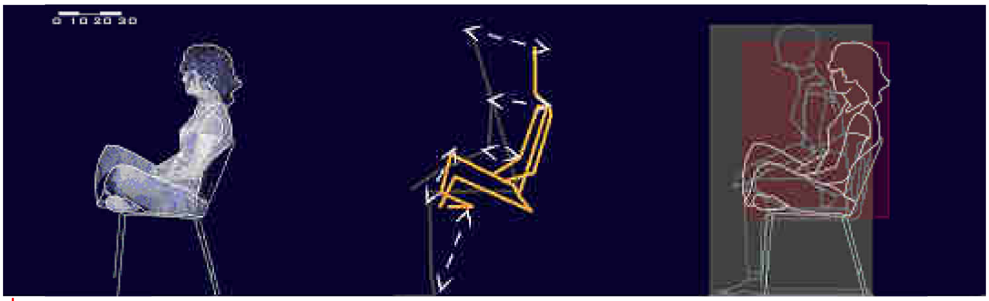
b. 3D/4D ultrasound sessions performet at InfantSee4D

@ 3dand4d.com/before-after-photo-gallery

c.

c. Personalized avatars as gadgets at Tryeco, Ferrara

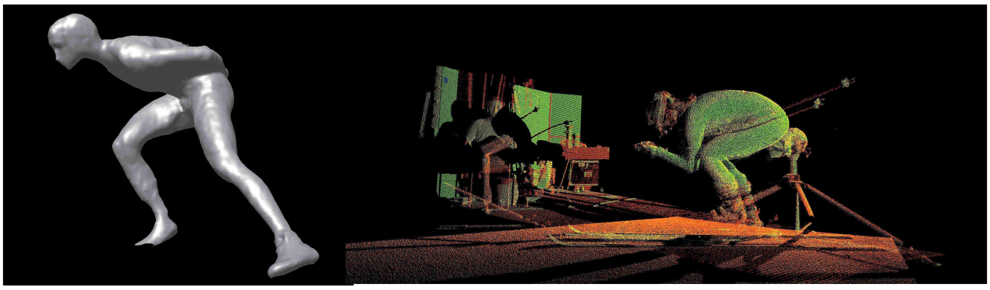
@Tryeco.com



d.

d. Body, space and architecture. DIAPReM center of the Department of Architecture of the university of Ferrara developed a study on body survey. The body as a changing element that can offer suggestions for design activity.

@ diaprem.unife.it



e.

e. The research, developed by the Department of Architecture of the University of Ferrara is part of "Coni-Ferrari: insieme per vincere" project. The aim of the study was the 3D body survey of Olympic's athletes to study new bobs and race tutes.

BALZANI M., TURSI A., FERRARI F., *Methodologies and digital morphometric survey applicationsfor optimization of postural and ergonomic interaction among body, tool, vehicle and sport actions"* in *Acts of Congress of "MIMOS II Decennale"* - Session: *"Medicine Meets Virtual Reality Italy", 2012*, http://lnx.mimos.it/mimos_decennale/index.php?option=com_content&view=article&id=53&Itemid=166, 2012 (January 2015)

7 BRAYFORD STUDIO, *4D Baby Scanning. 3D & 4D Ultrasound Scanning*, http://www.4dscanning.co.uk/4d-baby-scan/ (September 2014)

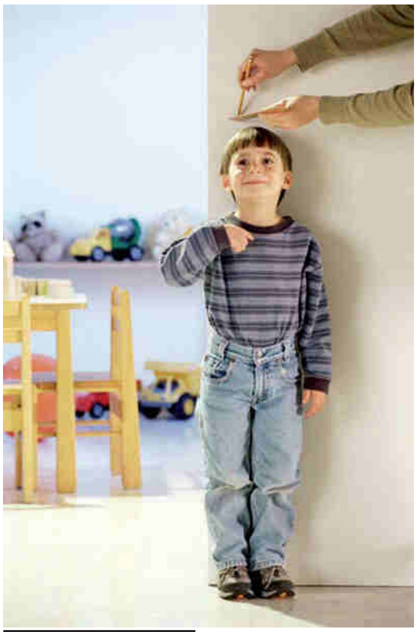
6.4 – MEDICAL APPLICATIONS OF BODY SURVEY: DIRECT SURVEY

Doctors of all times have faced with the necessity of measure body's sizes and shapes to assess health status and guide treatments. Since we are born, during the first years, the relationship between our height and weight is an important factor in the evaluation of our good health. Among all the possible techniques of direct survey I particularly focus in on these techniques, because of special interest for my analysis:

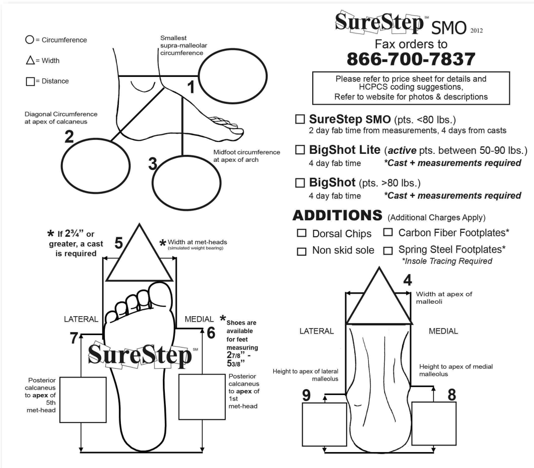
- survey by direct measures;
- survey by plaster;
- survey by resin mold;
- survey by low thermoplastic.

Direct survey is of course the oldest technique and the most intuitive one. Regarding the possibility of application of this technique in the manufacture of AFOs, as described in chapter 3, nowadays it is mainly used for those orthoses that are ordered online, mainly on American market, simply filling a form that indicates carefully which measures are required to design a customized AFO and how the measure has to be taken.

However until now lower limb prosthesis and orthoses have been designed and manufactured with *handicraft methods*. Traditional ankle foot orthoses, for example, are made by taking a negative ***plaster cast*** of the lower limb and making a positive plaster cast of it by filling the negative cast and then moulding the orthoses around this cast. The traditional process consists of two phases: in a first moment the technician has to mould manually some plaster bandages and can slightly manipulate the foot. This alteration of the original shape is required because the plaster surveys the foot in a relaxing position, while a slight dorsiflexion is manually and empirically added later to increase the stretching function of the AFO. After the bandages' solidification, the obtained shape is used for the final plaster cast[8].



a.



SureStep SMO 2012
Fax orders to
866-700-7837
Please refer to price sheet for details and HCPCS coding suggestions, Refer to website for photos & descriptions
☐ SureStep SMO (pts. <80 lbs.) 2 day fab time from measurements, 4 days from casts
☐ BigShot Lite (*active* pts. between 50-90 lbs.) 4 day fab time *Cast + measurements required*
☐ BigShot (pts. >80 lbs.) 4 day fab time *Cast + measurements required*
ADDITIONS (Additional Charges Apply)
☐ Dorsal Chips ☐ Carbon Fiber Footplates*
☐ Non skid sole ☐ Spring Steel Footplates*
*Insole Tracing Required
○ = Circumference
△ = Width
☐ = Distance
1 Smallest supra-malleolar circumference
2 Diagonal Circumference at apex of calcaneus
3 Midfoot circumference at apex of arch
4 Width at apex of malleoli
5 * Width at met-heads (simulated weight bearing) — * If 2¾" or greater, a cast is required
6 Posterior calcaneus to apex of 1st met-head — * Shoes are available for feet measuring 2 7/8" - 5 3/8"
7 Posterior calcaneus to apex of 5th met-head
8 Height to apex of medial malleolus
9 Height to apex of lateral malleolus
LATERAL MEDIAL
SureStep

b.

c.

a.
The measure of the growth of a child is one of the firsts and more common techniques of direct body survey

b.
Order form of an AFO made just from measures

c.
Arm in a plaster cast
@ www.amoils.com

8 COLOMBO G., BERTETTI M., BONACINI D., MAGRASSI G., *Reverse Engineering and Rapid Prototyping Techniques to Innovate Prosthesis Socket Design*, in CORNER B. D., LI P., TOCHERI M., *Three-Dimensional Image Capture and Applications VII*, SPIE-IS&T Electronic Imaging, SPIE Vol. 6056, 2006

In most cases the positive cast is further modified by orthopedic technician that adds or remove material in order to control the pressures' forces of the foot on the orthosis.[9]
This practice is empirically functional but it leaves most of the responsibility on the final result to the skills of the orthopedic technicians.

Furthermore new materials allow innovative techniques of making a plaster of body parts. **Lower limb molds** can be possible in several new materials, ***silicone, resin, rubber, foam***. A ***Silicone mold,*** for example, is made dispensing the material into a cup and brushing it carefully onto the body part until a coverage over all parts is achieved. It can even built up in layers until a mold thickness of about 1cm is achieved. After about five minutes a rigid support shell is built, made of medical bandages and they have to cure approximately for 15 minutes and then both the supports can be removed and the first mold carefully cut.

This is a negative mold, but if a positive one is required the outside shell is ready to be filled with resin that, after 10 minutes can be removed from the casting. Following this process the final model reproduces all the details of the original human part[10].

Otherwise in the ***Foam System***, the subject stands on a box of foam that slowly collapses under his weight and, when the leg is removed, its footprint remains printed on the foam. Afterwards this footprint can be filled with plaster to obtain a positive mold or, in most of the cases, it is directly 3D scanned to properly design the orthotic.[11]

However a research developed by the Hong Kong Polytechnic University, compares the results provided by CAD CAM and foam impressions and demonstrates that *CAD-CAM solution proves to be more effective than Foam impression*, especially in the evaluation of the peak pressure in the mid forefoot region[12].

Silicone Rubber to Make a Mold of a Head

@ http://www.smooth-on.com/

9 TELFER S., WOODBURN J., *The use of 3D surface scanning for the measurement and assessment of the human foot,* Journal of Foot and Ankle Research, 2010, 3:19, http://www.jfootankleres.com/content/3/1/19 (August 2014)

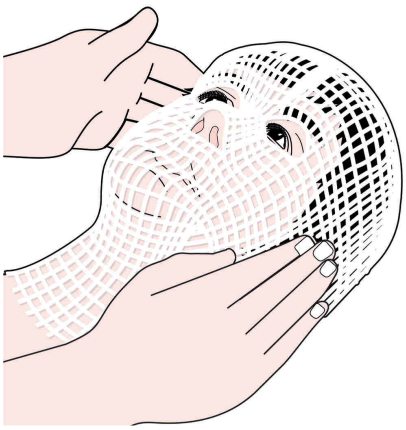
10 SMOOTH-ON, *Using Body Double® FAST SET Silicone to Make a Mold of a Head,* http://www.smooth-on.com/gallery.php?galleryid=307 (September 2014)

11 GUNDELMOND N.A., LEFFERS P., SANDERS A.P., EMMEN H., SCHAPER N.C., WALENKAMP GHIM, *Casting Methods and plantar pressure: effects of custom made foot orthoses on dynamic plantar pressure distribution,* J Am Podiat Med Assoc 2006, 96: pp. 9-18

12 Ki S.W., Leung A. K. L., Li A. N. M., *Comparison of plantar pressure distribution patterns between foot orthoses provided by the CAD-CAM and foam impression methods*, Prosthetics and Orthotics International, SAGE Pubblications, September 2008; 32 (3): pag. 356 - 362

Another interesting option of direct survey offered by new technologies are ***low thermoplastics***.

The use of this material in biomedical applications is quickly increasing but it characterizes mainly products that don't require high resistance to strains. In one application, for example, it is perforated in thermoplastic sheets. These are introduced in a tank with hot water at a proper temperature (depending on the brand, usually from 70° to 80°C. After waiting the heating time indicated on the product's manual the thermoplastic becomes really soft and it has to be pulled out from the water and placed on the body part of the patient. It is carefully docked onto the baseplate and after few minutes, when it cools down it returns solid and rigid, assuming the shape of the body part. Until now this technology is applied mainly in radiotherapy centers where these masks, for example of the head, or of the breast, or hips are intended to hold the body part reducing movements to less than two millimetres. This allows to directionate the radiation in a more accurate way, avoiding unwanted radiations in other unnecessary parts[13].



Thermoplastic mask for radiotherapy. It is warmed in hot water and then gently put on the body to fit it perfectly. In few minutes it becomes hard and is ready to be used in the treatment.

@ http://www.macmillan.org.uk/

13 CIVICO Medical Solutions, *Guide to Thermoplastics for Enhanced Positioning & Immobilization*, www.civico.com (2014-09)

6.5 – MEDICAL APPLICATIONS OF BODY SURVEY: INDIRECT SURVEY

If we consider medical applications of body survey the most relevant discoveries and innovations are among indirect survey techniques. In this field, the advantages of an indirect survey compared with a direct one are undoubtable[14]:

- shorter time of acquisition;
- non-invasive technique;
- less consumption of materials;
- less problems of security, safeness;
- less problems of hygiene;
- easy adaption of the instrument to every human shape or dimension[15];
- detail of acquisition;
- possibility of calibrating the accuracy of the result depending on the needs;
- possibility of integrating the results of indirect survey carried out with different techniques in a single 3D virtual model that reproduce the complete body part, interior and exterior, visible and invisible[16];
- cost.

Visia Face Scanner.

Different wavelenghts of light produce lectures of the condition of the skin, its damages caused by exposure to UV light, wrinkles, spots, skin texture, bacterial load, inflammation and vascular areas.

@ http://www.dermalclinic.co.uk/visia-facial-scan-edinburgh-scotland/

14 RYDMARK M., BRODENTAL J., FOLKESSON P., KLING-PETERSEN T., *Laser 3D scanning for surface rendering in biomedical research and education*, Goeteborg University, Sweden, Stud Health Technol Inform, Pub Med, 1999; 62: pp. 315 – 320

15 GUGGIA S., *Scanner Laser 3D per applicazioni biomediche*, op. cit.

16 An example of this new frontier comes from a research developed by the Politecnico di Milano, Mechanical Engineering Department. It aims at optimizing lower limb socket prosthesis design, integrating different techniques of indirect survey in order to reconstruct a 3D geometric model of the foot integrating the outside shape with the bones, soft tissues, muscular masses and dermis. The external shape is acquired with laser scanner, and integrated with Computer Tomography and Magnetic Resonance Imaging technologies for the internal structure, respectively for bones and soft tissues and muscles. *"Aim of our activity is to propose a computer aided design methodology, based on digital models and numerical simulations in order to obtain the physical mock-up of the stump on which socket's lamination could be made, applied to the trans-tibial prosthesis case. The proposed methodology has three relevant technical features: first, the reconstruction of a 3D geometrical model of the residual limb, then the numerical simulation of the structural behavior of the stump, and finally the rapid manufacture of a physical mock-up of the stump."* -

COLOMBO G., BERTETTI M., BONACINI D., MAGRASSI G., *Reverse Engineering and Rapid Prototyping Techniques to Innovate Prosthesis Socket Design*, op. cit.

Indeed technological advances in recent years have allowed the possibility of an external and internal survey of human body aimed at diagnostics studies. X-rays, Magnetic Resonance Imaging(MRI), Ultrasounds, Computer Tomography (CT) scanners are able to produce 3D internal images of a patient body, while 3D laser scanners survey the body surface at an accuracy never seen before, with the possibility of evaluating sizes, shapes and volumes. Considering the aim of the thesis we will focus only on techniques of indirect survey able to acquire exterior body shapes.

The field of application of indirect survey of visible body parts can be[17]:

- *deformity detection*; changes in external visible part of human body in size or shape have implications for a variety of diseases;
- *anthropometric surveys*;
- *prescription of some drugs* or in the determination of assays;
- *in case of burns or traumas and damages of skin*, where a quickly calculation of the injured surface can be useful to calculate the extension of the damage;
- *skin analysis*, as wrinkles, porphyrins (bacteria in pores that can lead to acne), skin moles, melanomas, evenness, photo-damages, evenness;
- *cosmetic surgery*, to assess risk and guide health management but even to interact with the patient, providing simulations of his/her image after the surgery;
- *odontology*;
- *epidemiology* of some disease, as obesity;
- *dietetics*, to evaluate progresses and evolution of eating disorders and diets;
- *orthopedic evaluations*, as scoliosis;
- *prosthesis and orthose*s.

Moreover all these applications and body surveys can be easily periodically repeated, overlapped and compared with the previous ones, giving a significant monitoring of the conditions over time. More than a plaster, these information almost don't occupy space and for this reason they can be easily stored in order to constitute a virtual database of the patient, queryable in every moment, if required.

17 TRELEAVEN P., *3D Body Scanning and Healthcare Applications*, op. cit.

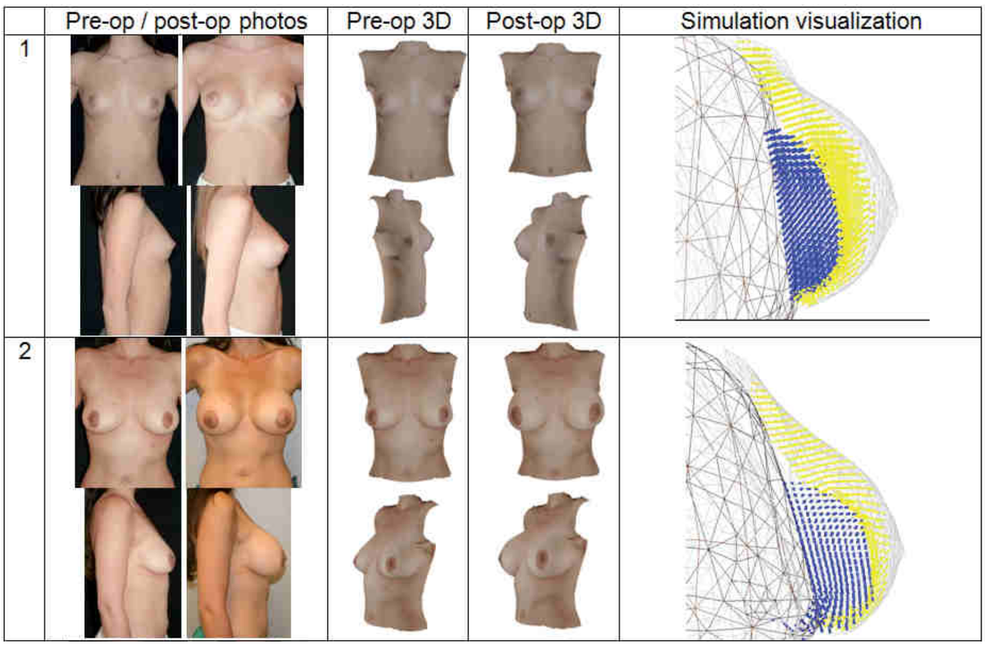
6.6 – TECHNOLOGIES FOR INDIRECT VISIBLE BODY SURVEY

3D indirect survey of visible body parts can be realized recurring to different techniques. In this paragraph a brief overview on the most used technologies of indirect survey is presented. As already said, the application of one technology despite another one is in most of the cases motivated by the aim of the survey. However other factors influence this decision and for this reason a general overview on the most common available technologies is presented. The aim of this summary is to identify the solutions that can offer a migliorative althernative in the acquisition of the shape of lower limbs of Duchenne patients compared to the traditional ones. Regarding the technologies currently employed for indirect survey of human body, the most common are:

- Laser scanner;
- Image-Based Modelling;
- White light scanner
- Others, as millimetre wave radar or contact scanners.

AutoScan3D Dental Scanner. Shining 3D

@ www.shining3dscanner.com



Pre- and postoperative photos, pre- and postoperative dimensional 3D reconstruction and implant simulations.

@ http://www.jmir.org/2012/1/e21/

These instruments and technologies are rapidly becoming extremely common in medical application. In most of the cases their ***cost*** can apparently be considered high. however it has to be carefully evaluated ***in the comparison between traditional handcraft techniques and indirect survey***, especially in some fields as 3D body survey aimed at the production of prosthesis and orthosws. Once the cost of the instrument to scan the body part is amortized, indirect survey proves to be much cheaper than traditional plaster cast, because of the saving of material, but most of all in terms of time of work of the operators. Furthermore, in many cases, these casts are made in a clinic and then posted to the manufacture, with other additional costs. On the contrary, in case of an indirect survey, a simple email of the virtual model can solve all the problems.

However the high cost of the initial investment of the acquisition, for example, of the scanner and 3D printer joint with the upgrade of all the knowledge required for the management of the machines and relative software is still sometimes discouraging manufactures in the adoption of these new technologies in production process[18].

18 TELFER S., WOODBURN J., *The use of 3D surface scanning for the measurement and assessment of the human foot*, op. cit.

ANALYSIS

6.6.1 – Laser Scanner

Among all the techniques of indirect survey used to accurately acquire visible 3D shapes, the most used, is **laser scanner survey**. Its use is quickly increasing and it is preferred because the survey is quick, it acquires a huge amount of data in a short time, it is harmless and not influenced by environment light. Laser scanners are becoming easier to be used and in particular specific software for medical applications are incoming on the market. Moreover the cost of one scanner is far less than CT's or MRI's one.

All types of 3D laser scanners have basically the same functioning: a laser beam is deflected by a mechanism of rotating and oscillating mirrors which vary with the azimuth and zenith angles and illuminates all the surfaces around the instrument. The scanner receives the retuning beam and measures the distance of the hit surface in that point. The number of points the instrument can measure is enormous, it can acquire even more that tens of thousands of points per second and each x,y,z coordinate is graphically represented with a point. At the end, a point cloud is generated that describes the scanned area.

Time of flight laser scanner. ScanStation. Leica Geosystem

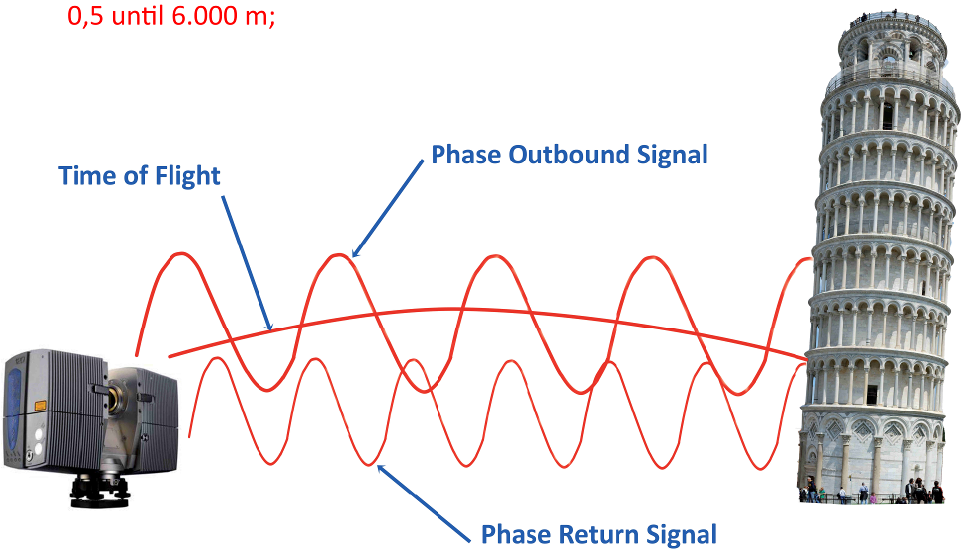
Talking about laser scanner a first distinction has to be made among the terms of Accuracy and Resolution.

We define ***Accuracy*** the exactness of correspondence between the 3D point in the virtual model and the real position of each point on the surface, while ***Resolution*** is intended as the minimum distance achievable with a single scan between one point and the other in the final point cloud.

Resolution depends from mechanical limitations *"how precisely they can encode angles of the laser projector".* Since it is a measure of angles, it depends from the distance between the scanner and the object, the farther the subject, the lower the resolution.

There are basically three measurement techniques in which laser scanner can elaborate the coordinates of each point:

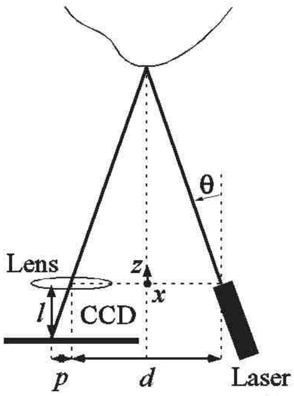
- **Phase-shift**: it calculate the shift in the electromagnetic wave of laser scanner and it is suitable for medium-large objects, about from 0,6 to about 330m;
- **Time of flight**: it measure the time for the beam to go, reach the object and come back. It is useful to scan big and far objects, at a distance about from 0,5 until 6.000 m;



Phase-shift and Time of Flight comparison

- **Optical-triangulation**: for high resolution surveys of small objects, from about 0.2 m to 25 m. This type of scanner fire a laser beam on the object and measures the direction of the reflected ray to calculate the distance between the sensor lens and the incident surface.

  Knowing the location and orientation of the sensor, that is fixed by the moment of construction and calibration, it is possible to calculate the Cartesian coordinates of the point in space[19].



a.

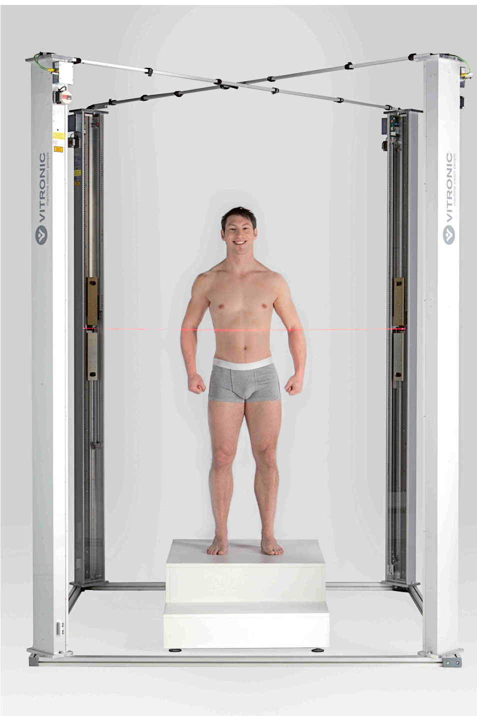
a. Laser-based triangulation involves projecting a thin ray of laser light onto an object, capturing the reflected light by a charge-coupled device (CCD), and inferring depth from the pixel position of the reflected point and from the geometric relationship between the position of the laser source and the CCD.

@ www.bic.mni.mcgill.ca

b.

b. Triangulation scanner Konica Minolta Vivid V19

@ http://www.scottishten.org/



c.

d.

c. Vitus 3D Body Scanner generates a precise 3D image of a full body in 12 seconds

@ http://www.vitronic.de/

d. Head & Face Color 3D Scanner @ Cyberware

19 TRELEAVEN P., *3D Body Scanning and Healthcare Applications*, op. cit.

Reasonably, laser scanners used for body surveys adopt optical-triangulation technique. Among laser scanner specifically intended for body survey, the number of different products available in the market is enormous but, just to have a general panorama on the available technologies we can mention these five categories, and briefely illustrate just some of the available models for that category:

- **Full body scanner,** composed as an example by
  - 4 scanner units that moves vertically along 4 pillars. Average total scanning time: 12 seconds;
  - or 6 scanner units located in pairs on 3 pillars;
- **Full head scanner**. It can be made, for example, by one scanner unit that moves horizontally all around a person in few seconds.
- **Desktop scanner**, if combined with optical triangulation technology, offers the best result, both in terms of accuracy and resolution and for these reasons they are usually preferred in the survey of small objects where high quality of the 3D virtual model is required.
- **Hand held scanner**. It is composed by a single scanning unit, it is light and can be easily helded with one hand. It moves around the subject for a complete acquisition or it can be fix and the subject moves around it. It is composed by four components: a camera, a projector, a light and the center of the camera. It is a box that serves as center of reference for scanner movements. As long as the technician moves the hand scan all around the body part, the instrument measures the relative distance in terms of spatial coordinates between the “center of the camera” and the hand scan and, thanks to these measures, it is able to reconstruct its spatial position;
- **Foot scanner**. Since of particular interest for the aim of the research foot scanners will be analysed in details in the following paragraph.

The *Accuracy* of a hand held or arm-based laser scanner might be 0.2 mm (for a 10 cm object), or an high-precision desktop scanner might have 0.01 mm accuracy for object up to 1 m. A large-area tripod-mounted unit might have 5 mm accuracy (for objects up to 50 m size). Regarding distance ranges, desktop and hand-held scanners are designed for a smaller range (usually between 5 cm and 1 m) compared to tripod-mounted scanners with a range variable from 2 m to 50 m. [20]

Hand Scan for body survey. GoScan3D

@ http://www.goscan3d.com/en

20 Walford A., *A New Way to 3D Scan. Photo-based Scanning Saves Time and Money*, Eos Systems Inc., 2009 http://info.photomodeler.com/blog/new-photomodeler-whitepaper/ (2014-09)

6.6.2 Image-based modelling

Photo-based scanning, or photogrammetric scanning is a technology that allows to create a 3D point cloud of a physical object or of an environment, using only a common digital camera in combination with specific softwares. This methods permits lower costs and time, since it substitutes, in most of the cases, for a medium resolution of the object, laser scanner technology.
Scientific literature reports four main techniques of passive 3D photography:

- ***Stereo Photo Matching***: also called ***Computer Vision***, applies human vision process, where the double vision of the eyes allows the perceiving of the depth. The amount of displacement, alternatively called *parallax* or *optical flow* is inversely proportional to distance and may therefore be used to compute 3D geometry[21]. The theory has been asserted by Marr and Poggio[22] in 1970's and gradually developed to modern photo-based 3D scanning. It takes advantages of the accurate measurement of the photogrammetry and of the advanced matching algorithm techniques from Computer Vision. A crucial step in this process is the camera calibration, that means having precise knowledge of camera position, orientation, focal length and all the internal parameters of the camera.
- ***Structure for motion***: it reconstructs 3D model extracting sequences from a single moving camera that moves around the object on a known path.
- ***Shape from Shading***: recovers the shape of an object from the analysis of a single image, given the intensity of a point in the image and a known directional light source.
- ***Photometric Stereo***: simplify the previous process acquiring two or more images of the object under different illuminations.

Photo-based scanning has its historical feet in two camps:

- Stereo matching or computer vision.
- Photogrammetric topographic Digital Elevation Model (DEM) creation;

The photogrammetric technique allows to calibrate position and orientation of cameras. Photo-based scanning software compares and overlaps similar parts of the photos giving orientation information to compute the 3D orientation.
In this process, helpful elements that guarantee better results are:

- a good resolution of the camera
- a sufficient numbers of points of view in order to acquire the entire geometry;
- possibility of free motion all around the object, to take photos from every position.
- a good and uniform lighting of the object or the environment;
- an evidence texture or pattern that facilitates the overlapping;
- easily identifiable elements on the object, as corners, tips, grooves or targets;
- an appropriate number of digitalized points in the processing phase.

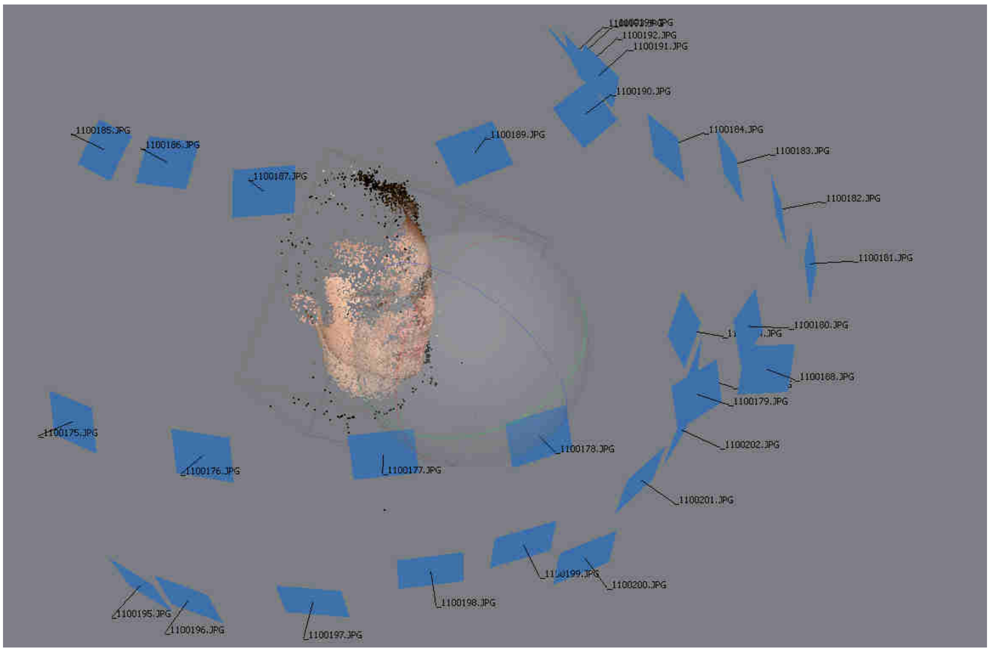
Laser scanner acquisition isn't sensible as photo-based scanning to the texture of the object. In this technique a uniform texture, monochromatic, without recognizable elements on the surface, like metal objects or newly painted glossy surfaces, can

21 SEITZ S. M., *An Overview of Passive Vision Techniques*, op. cit.

22 MARR D., POGGIO T., *A Computational Theory of Human Stereo Vision,* The Royal Society, 1979, http://rspb.royalsocietypublishing.org/content/204/1156/301.article-info (January 2015)

Image Based Model of a face. Recognition of spatial positions of cameras and elaboration of point cloud.

@ Agisoft Photoscan http://1k0.blogspot.it/



seriously influence on the result of the process. Once the set is defined, the acquisition has to be made with a series of photos (minimum a pair), being close to parallel but slightly separated. After the acquisition, the set of photos is uploaded in the photo-based scanning software that proceeds to the orientation and disposition of the images, recreating the spatial coordinates of the camera from which each photo was taken. Afterwards the software compute the scanning/matching phase of the photos and at the end of this automatic process a 3D point cloud is generated.

"A photo-based scanner's accuracy and resolution are affected by the resolution of the camera being used, the distance of the camera to the subject and the nature of the texture and pattern on the surface."[23] If we desire to improve the quality of the 3D point we can move the camera closer or use an higher-resolution camera. Usually forcing exaggeratedly the software in generating a denser point cloud without changing, these two factors lead to inaccurate 3D points and noise.

"For a surface with a good texture pattern you can usually get one 3D sample per image pixel. For example, a 10MP camera viewing a 1m object has each pixel viewing approximately 0.3 mm of surface. Here the resolution of the 3D sampling would be approximately 0.3 mm. Stepping back so the camera now views a 10 m object, the point cloud resolution falls to 3 mm."[24]

Photo-based scanning system has undoubted advantages in terms of mobility. If you want to test immediately the good result of your acquisition, all you have to carry to the place where the object you want to survey is located, is a camera and a laptop, with the photogrammetric scanning software installed, otherwise even just a camera can be sufficient and the photos can be processed in a second time.

Moreover image-based modelling has no limits in distance range, if you can take photos of it, it can be photo scanned, from very small objects to large natural environment. At the same time with a camera you have almost completely eliminated the time to set up the machine before the acquisition.

One of the great potential of photo-based scanning is the possibility of reducing to the minimum the time of acquisition. Modern laser scanners acquire an enormous quantity of points in a very short time. This is an huge job but, after this time, you usually need to move the scanner in one or more other positions in order to have a complete geometry of the object without shadow cones. These movements require

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23 WALFORD A., *A New Way to 3D Scan. Photo-based Scanning Saves Time and Money*, Eos Systems Inc., 2009 http://info.photomodeler.com/blog/new-photomodeler-whitepaper/ (September 2014)

24 WALFORD A., *A New Way to 3D Scan. Photo-based Scanning Saves Time and Money*, ibid.

time to switch off, transport, switch on and re-calibrate the instrument, beside the time of a new acquisition. Therefore the object has to be motionless for all this time, until all the required scans are finished. This necessary condition causes a reduction of the field of application of laser scanner technologies. Even in photo-based scanning technology it is required some time to move all around the object to have a complete vision of it from all the points of view but the scans have an instant acquisition and can catch even really far objects. Furthermore the lower cost of the machine allows, if necessary, to prepare a set where more cameras are located in a good position to cover all the required views of the object. These cameras can be put on a net and a simple command can be operated on a device to make them all shoot at the same time. In this way synchronized multiple cameras allow an instant scan of an object even if it is moving very fast.
In economic terms **photo-based scanning system has a lower cost**, incomparable with the purchasing or leasing and maintenancing of a laser scanner machine. Even in most of the cases in which a simultaneous camera acquisition is put in place, photo-based scanning system remains overall the most effective cost. As a comparison among photo-based scanning and other laser scanners techniques I report an extract taken from *A New Way to 3D Scan*[25].

- "**Tripod-mounted laser scanners** might do a better job than photo-based scanning in situation involving:
  - *Poorly lit areas, night time scanning;*
  - *Textureless surfaces (manufactured parts, newly painted surfaces, etc.);*
  - *Surfaces with large and abrupt depth changes;*
  - *Surfaces at very shallow angle to the scanner;*
  - *Processing time at the office must be a minimum;*
  - *Very high densities and millions of points are required per scan.*
- **Desktop laser or structured light scanners** might be better suited when the characteristics are:
  - *Small objects with high detail and high density requirements;*
  - *Textureless surfaces or a surfaces where texture is not dense or random;*
  - *Where processing time at the office must be a minimum.*
- **Photo-based scanning** might do a better job than laser or white-light scanners where considerations include:
  - *Equipment and maintenance costs;*
  - *Wide variety of ranges and high versatility;*
  - *Easy transport and low equipment weight;*
  - *Quick field setup and minimal field time;*
  - *Easy set up of multiple-scans in consistent coordinate system;*
  - *Scanning of moving subjects (with synchronized cameras)"*

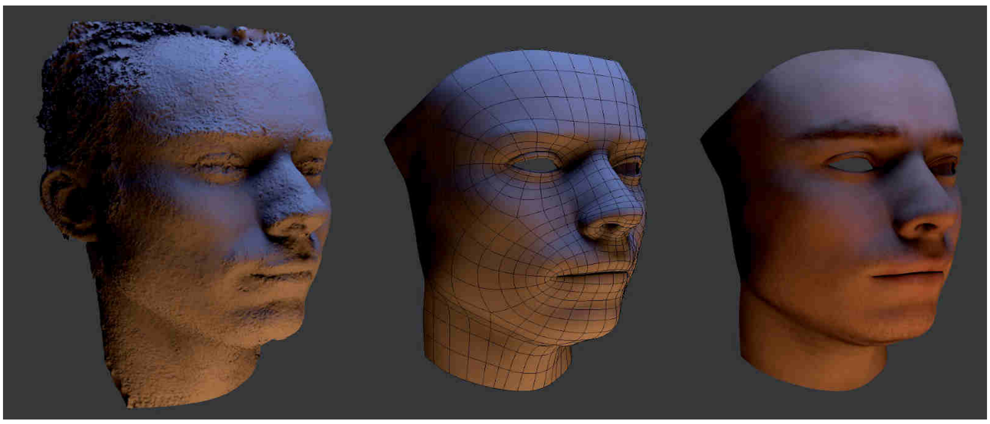


Image Based Model of a face. Optimization of the mesh and texturization.

@ Agisoft Photoscan
http://1k0.blogspot.it/

25 WALFORD A., *A New Way to 3D Scan. Photo-based Scanning Saves Time and Money*, ibid.

ANALYSIS

6.6.3 - White Light Scanner and others

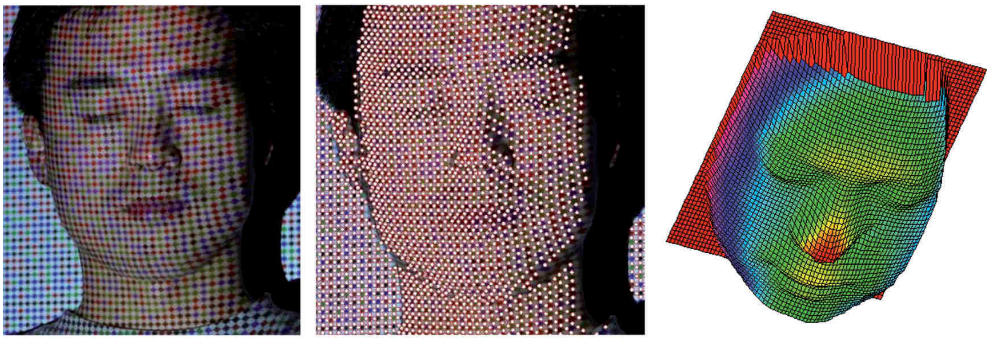
A White light scanner projects a light with a pattern on the human body part that has to be surveyed. A camera acquires the scene and thanks to an optical triangulation process and a coding system, it is able to determine the tri-dimensional position of each point on the surface. The pattern projected on the skin contains several information: binary code, vertical, horizontal, shifted, colour code, each line is different and for this reason it is possible to virtual reconstruct the original geometry.

Applications of this technology can be seen in all the types of scanners already described, as full body scanner, face scanner or hand-held scanner.

Other techniques of 3D indirect survey of visible body parts are Visual Hull and Wave Radar.

Visual Hull – It is obtained setting up several cameras, minimum 8, located at the same high but uniformly distributed at an about equal angle all around the subject. From all the cameras body silhouettes are extracted. Then the 3D model is obtained by projecting the cones from the camera to the profiles, considering the focal points of the camera, and interpolating the results. The advantages of this technique is its speed of use and the possibility of acquiring even a body in motion. However the 3D surface elaborated is still outlined and rough, without details and therefore rarely applicable.

Millimeter – wave radar – These 3D scanners use linear-array radio-wave technology to scan a subject’s body, and they can scan through clothing. The person steps inside a cabin where a rectangular vertical panel containing the emitter of radiation slides along the edges and records the reflected signal. This instrument is able to acquire up till 200.000 points located on human body, with an accuracy of 6 mm.



A projector illuminates with dark and light bars with different spatial frequencies and orientations. Two differently oriented cameras acquire the images and the software computes the deformation of the bars with respect to a flat reference to determine the 3D point cloud.

@ http://www.cis.rit.edu/prospective-students/application-based-curriculum

White scanner survey of a foot.

@fablab.waag.org

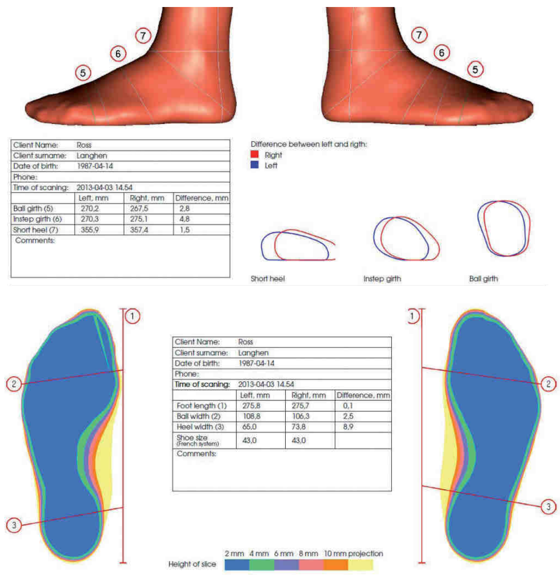
6.6.4 - Foot Scanners

Nowadays an increasing number of different instruments of foot scanning are already on the market, with a huge potential of easily obtaining 3D digital representations of feet. These solutions are diffusely been using in medical, ergonomic and footwear applications. Regarding ***Foot scanners***, many instruments of different brands and various software are available on the market and they can differ in accuracy, resolution, but even in the modality of acquisition, in the type of result and, obviously, in the price. For example there are scanners configured to acquire exclusively the foot sole, while others are able to survey the entire lower limb.

The carried research on foot scanners revealed the presence of four major categories:

- Automatic 3D Foot Scanner;
- Portable 3D Foot Scanner;
- 2D plantar Foot Scanner;
- Contact Foot Scanner.

The **Automatic 3D footscanner** is a box equipped with a laser scanner, divided in three units, one per each side, and a video camera. One foot by one is located inside the box and it is scanned up to 15 – 25 cm in height. Once the leg is placed in the correct position the software produced automatically a 3D model in few seconds. Regarding accuracy and resolution no differences are notable between desktop scanner and foot scanner. The relevant difference in terms of accuracy and process optimization is between a laser technique and a direct survey[26].



Automatic Foot scanner
Collected measuremet of data Footing3D Measures Right & Left

26 This paper compares simulated measurements of feet acquired using 3D laser scanner (SM), with manual measurements (MM) and the output of a commercially available automated foot measuring system (CP). Eighteen dimension of each foot were compared and each manual measure was taken twice. After establishing a linear correction to adjust for systematic errors, the differences between the three methods were reduced. However manual measures depends significantly from the operator, while automatic measurement with scanned data can give replicable information.

WITANA C.P., XIONG S., ZHAO J., GOONETILLEKE R.S., *Foot measurements from three-dimensional scans: A comparison and evaluation of different methods,* in *International Journal of Industrial Ergonomics*, Volume 36, Issue 9, September 2006; pp. 789 – 807

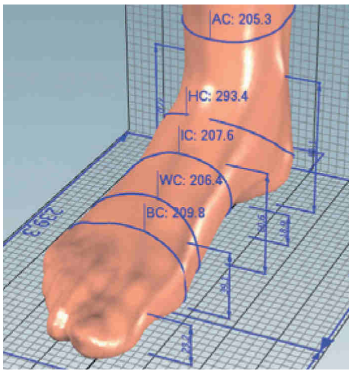
Automatic 3D Foot Scanners differs from desktop scanners exclusively in the customization of the product to improve the process in terms of comfort and simplification for the patient and in the software to interpret foot scan data. It can be indeed used as a stand-alone machine for foot measuring and size estimation or used in conjunction with specific software calibrated for foot surveys, for a deep shape analysis and evaluation of acquired data.

Portable 3D foot-scanner, is equal to all the other hand-scanners except on the software that elaborates data that is calibrated to scan and analyse feet. It has the flexibility of being handled easily to scan whatever surface located at a short distance. Gripped the instrument, the therapist moves it around the object and in real time he observes, on the monitor of the computer it is connected with, the 3D virtual reconstruction of the real object. Furthermore this type of scanner is light and can be easily transported.

2D Plantar Foot Scanning is a footboard, that can be set in horizontal or vertical position, on which the user climbs. A dual LED illuminator located inside that illuminates the feet sole for a photographic capture that allows to analyze the posture and contact points of the plantar surface of the feet.

Contact footscanner is an array that uses a technology borderline between a direct and indirect survey. It is composed by 500 mobile sensors, that slide lowly down when they are pressed by the foot weight. The electronic measure of this displacement gives the data required for a 3D scanning of the foot plantar.[27]

a.



b.

c.

a.
Hand Scan with associated a software for the recognization and processing data for foot analysis. GoScan3D @ http://www.goscan3d.com/en

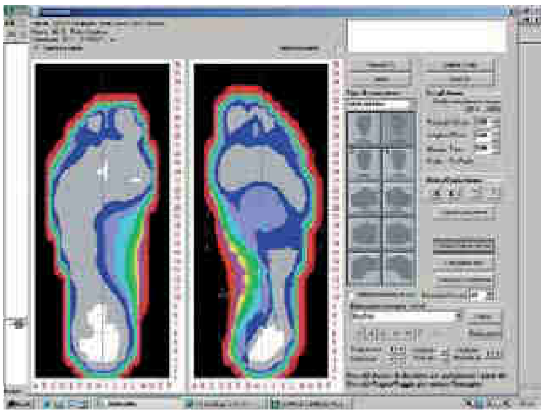
b.
Footscan Measurments elaborated with an hand scan @ http://www.shoemaster.co.uk/

c.
Plantar Foot Scanner. The Associate Platinum @ http://excelsiorchiropractic.com/

27 AMFIT INCORPORATED, *Contact digitizer*, http://www.amfit.com/products/contact-digitizer (January 2015)

Plantar Foot Scanner.
TOM-CAT 3D Foot Scanner

@ www.aolabs.com



Contact foot scanner:
- 3D measuring
- Corrections
- Fabrication
- Plaster model
Orthopadie Sharer

@ www.orthoweb.ch

In conclusion, the International Journal of Industrial Ergonomics published a research that attests, in particular, the efficacy of 3D laser scan as a method to extract foot measures compared with manual measurements and with the commercially available foot measuring systems. Manual measurements are in fact too dependent on the measure, while automatic measurements with laser scanner offer replicable information even if depending from the scanning system and the computational algorithm[28].

However while for 1D measures of foot, standard protocols are fixed, regarding the interpretation of a digital model, we have to refer to the **International Standard ISO 20685 of 2010** that *"addresses* ***protocols for the use of 3-D surface-scanning systems in the acquisition of human body shape data and measurements****"*[29]. It refers to the **ISO 7250-1:2008**[30] and establishes that the maximum mean difference between the traditional and 3D scanning derived values is 2 mm, even if most of the modern foot scanners have a submillimetre accuracy.
At the end, what is lacking, is a standardised protocol describing the preparation of the foot, the processing of data and how the measurements should be taken from. If to carry a static survey of feet laser scanner instrument that is used, both in loaded, half loaded or unloaded situations, for a dynamic analysis of gait computer vision technologies is preferred. Common analysis of movements are made by the recognition of pasted landmarks on the body, but new experimentation are proving the potential of a full 3D reconstruction of the shape of the foot in the different phases of gait. In particular, one of the researches included in the ***European CEC Made Shoe project***[31] aims at the definition of a method of stereo acquisition to obtain 3D foot shape deformation during the gait cycle.[32]

28 WITANA C. P., XIONG S., ZHAO J., GOONETILLEKE R.S., *Foot measurements from three-dimensional scans: A comparison and evaluation of different methods*, in *International Journals of Industrial Ergonomics*, op. cit.

29 ISO 20685: 2010. *3-D scanning methodologies for internationally compatible anthropometric databases*, 2010, http://www.iso.org/iso/catalogue_detail.htm?csnumber=54909 (January 2015)

30 ISO 7250-1:2008. Basic human body measurements for technological design, 2008, http://www.iso.org/iso/catalogue_detail.htm?csnumber=44152 (January 2015)

31 European Commission, *CEC MADE SHOE: Custom Environment and Comfort made shoe*, project launched in 2004 and ended in 2006 by the European Confederation of the Footwear Industry. http://cec-footwearindustry.eu/en/projets/past-projects (November 2014)

32 COUDERT T., VACHER P., SMITS C., VAN DER ZANDE M., *A method to obtain 3D foot shape deformation during the gait cycle,* in *Ninth International Symposium On the 3D Analysis of Human Movement*, June 28th - 30th, 2006 http://www.univ-valenciennes.fr/congres/3D2006/Abstracts/117-Coudert.pdf (2014-11)

In this test two experiments of foot survay during gait were conducted, one wearing coloured socks and in the second case paint drops were projected on the skin and the results were exposed and evaluated.

6.7 VANGUARD APPLICATIONS OF INDIRECT VISIBLE FOOT SURVEYS

In the previous paragraph the most common types of foot scanners were illustrated. The proliferation of all these different instruments designed to survey the foot is a clear sign of the potential of this technology and of the advantages that its application can bring, compared to traditional methods, to all the fields in which an accurate survey of such a complex shape is necessary or, at least, desirable.

The new application offered by feet indirect surveys are moving in different directions:

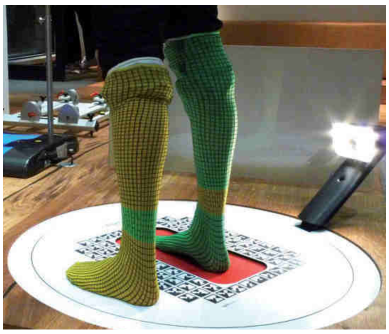
- Remote shoes' fitting researches;
- Clinical studies on gait and posture;
- Shoes design for luxury brands or sports champions' shoes;
- Prosthetic and orthotic applications.

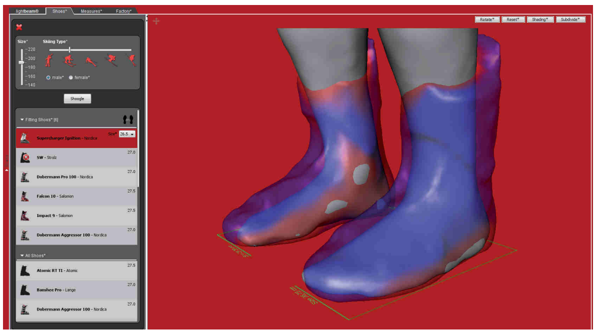
6.7.1 - Shoes' fitting and shoes' customization

"A good fitting shoe should be free of any high pressure points and at the same time should have the right "feel" and support."[33]

User adaption of shoes is not simple because the foot has soft and deformable parts and it has a complex 3D shape. One of the main difficulty is in fact related to the nature of the foot itself as a part of the human body, due to "*its capacity of deformation which depends on the movement ranges of its numerous joints and its physiognomy when is shod*"[34].

How is it possible to create a product more comfortable without knowing the standards for comfort or discomfort for that single user?





a-misura - One of the several brands that are sperimenting foot survey to offer an evaluation of virtual fitting or the design of a customized footwear.

@ www.a-misura.com

33 QUIMBY H. R., *The Story of Lasts*, New York: National Shoe Manufacturers Association, 1994

34 NÁCHER B., ALCÁNTARA, ALEMANY S., GARCÍA – HERNÁNDEZ J., JUAN A., *3D foot digitizing and its application to footwear fitting*, Istituto de Biomecánica de Valencia, http://www-ieem.ust.hk/dfaculty/ravi/papers/caes.pdf (September 2014)

ANALYSIS

Goonetilleke and Luximon declare that *product compatibility is necessary for a person to experience comfort and satisfaction during use."*[35]
But even the idea of compatibility changes so much among different populations: it is proved that women give more weight on fashion than fit, while men pose more attention on comfort. At the same time, "*when buying footwear for children, parents may be prepared to pay a high price for fit and comfort, thereby giving protection to the development of children's feet"*[36].

Furthermore the feeling of comfort is inclusive of many different factors such as size, shape, flexibility, style, weight, inside, shoe climate (temperature, humidity), materials, tread, cushioning, and more[37]. Considering all these items, emerges how a complete understanding of the 3D shape of the foot can give precious information in the calibration of these elements.
Until recently the ergonometric measures for the foot were based on 1D and 2D measures, while a 3D scan of the foot has an enormous potential of offering a more detailed information on the spatial shape of the foot, and on shoes' fitting, even associated with dynamic movements.
Foot orthotics, insoles and all the studies of foot deformities and of foot deformations in stress condition can take great advantages form virtual 3D reconstruction of the foot[38]. A scientific publication written by Laughton, Davis and Williams, for example, compares different techniques of acquisition of the shape of the foot and demonstrates, as an example, that plaster casting reproduces similar measures to clinical measurements for the forefoot to rearfoot relationship, but laser scanner acquisition proves to be the best system to analyze a weight bearing foot[39].

3-D laser scan for a custom fit service of luxury men shoes. *@ http://www.wallpaper.com/gallery/lifestyle/lodger-shoes/17050771#YWDUI6kGe3PoHmyw.99*

The shoes of the fastes man in the world, Usain Bolt, were made starting from a scan of his feet.

Another theory was proposed by Luximon A. and Goonetilleke R.S. of the Hong Kong University of Science and Technology. They developed an algorithm able to predict the foot shape using foot length, foot width, foot height and a measure of foot curvature. The aim of the research was to develop a technique for custom footwear without the necessity of an expensive 3D scanning of feet. The results show that each individual foot shape may be predicted to a mean accuracy of something more than 2 mm but this research shows all its weaknesses if we are talking of more "problematic feet", with congenital or subsequent deformations.[40]

35 GOONETILLEKE R. S., LUXIMON A., *Designing for Comfort: A footwear Application,* Hong Kong University of Science and Technology, Clear Water Bay, Hong Kong, 2001, published on Computer-Aided Ergonomics and Safety Conference '2001, edited by Das B., Karwowski W., Mondelo P., Mattila M., 2001

36 CLARKS, *Manual of Shoemaking,* Clarks Training Department, UK, 1976

37 GOONETILLEKE R. S., LUXIMON A., *Designing for Comfort: A footwear Application, cit.*

38 TELFER S., WOODBURN J., *The use of 3D surface scanning for the measurement and assessment of the human foot, op. cit.*

39 LAUGHTON C, DAVIS IM, WILLIAMS DS, *A comparison of four methods of obtaining a negative impression of the foot,* J Am Podiat Med Assoc 2002, 92: pp. 261-268

40 LUXIMON A., GOONETILLEKE RS, *Foot Shape modeling,* in *Hum Factors*, 2004, 46(2): p. 304 – 15
"The prediction model was generated using 40 Hong Kong Chinese men and the model was validated

International researches discuss ***the relation between the foot and the shoes, trying to elaborate the formula of the perfect fitting***[41,] even when the shoes are not directly tried on[42,43].
However, when loaded, there are several anthropometric changes that occur in the feet. An entire line of research is dealing with the changes that occur to foot shapes between non-weight bearing and weight bearing states. These studies evidences in particular that *"the increases in length and breadth between unloaded and half loaded are greater than those found between half and full weight bearing."*[44]

6.7.2 - User Oriented Footwear

"In 1970 there were only 5 unisex models of running shoes on western market, compared to the actual 285 models (167 men and 118)."[45]

Historically there has always been an inclination of manufactures towards product variety in order to better encounter customers' wants and tastes. However it must be considered that providing variety can be highly costly, since the manufacture cannot take advantage of the economies of scale in production and that a typical user, usually, doesn't desire several types of shoes between to choose, but only the right one. Therefore it is proved that if the market place is very competitive, there may exist a greater need for a high level of customization[46], otherwise it could be economically counterproductive.

All these studies on remote shoes' fitting starting from an indirect survey of the foot converged naturally to a new tendency of shoes' customization.

Until now, regarding **User Oriented Footwear** a double attituted can be perceived:

using a different group of 25 Hong Kong Chinese men. The results show that each individual foot shape may be predicted to a mean accuracy of 2.1 mm for the left foot and 2.4 mm for the right foot."

41 ZHAO J., XIONG S., BU Y., GOONETILLEKE R.S., *Computerized girth determination for custom footwear manufacture,* in *Computers & Industrial Engineering*, Volume 54, Issue 3, April 2008, pp. 359-373

42 HERNÁNDEZ J. G., HERAS S., JUAN A., PAREDES R., NÁCHER B., ALEMANY S., ALCÁNTARA E., GONZÁLES J. C., *The MORFO3D Foot Database*, in J.S. MARQUES ET AL. (Eds.), I*bPRIA, Lecture Notes in Computer Science*, 3523, Springer-Verlag, Berlin Heidelberg, 2005: pp. 658-665

This paper reports a research developed by the University of Valencia who acquired a foot database of more than 300 people **to study footwear fitting**. INFOOT laser scanner was used for the acquisition and 14 adhesive markers were located on bony prominences or critical zones for shoe fitting. The scanning process was carried out while the participant stand upright with equal weight on each foot.

43 LUXIMON A., GOONETILLEKE R.S., TSUI K-L, *A Fit Metric for Footwear Customization*, in *Proceedings of World Congress on Mass Customization and Personalization,* Hong Kong, 2001
It is another reseach that illustrates a 3D methodology for quantifying footwear fit through an evaluation of the level of match or mismatch between foot and sole.

44 OLADIPO G., BOB-MANUEL I., EZENATEIN G., *Quantitative comparison of foot anthropometry under different weight bearing conditions amongst Nigerians*, in *Internet J Bio Anthrop* 3:1, 2009

45 COX M., W. And Alm R., *The Right Stuff-America's Move to Mass Customization*, Annual Report, Federal Reserve Bank of Dallas, 1998

46 LUXIMON A., GOONETILLEKE R. S., TSUI K-L, *A Fit Metric for Footwear Customization*, Department of Industrial Engineering and Engineering Management of Hong Kong University of Science and Technology, Clear Water Bay and School of Industrial and System Engineering, Georgia Institute of Technology, Atlanta, Georgia http://www-ieem.ust.hk/dfaculty/ravi/papers/mcpc.pdf

- an application of ***best fitting systems*** that, starting from the 3D survey of the foot, compare the shape with the already available models of existing shoes, using shapes' comparison and algorithms that take in consideration the rate of satisfaction of previous users;
- a ***complete footwear customization*** that starts from a 3D survey of the foot and designs the correspondent unique shoes.

The first approach is becoming increasingly important with the success of e-commerce for shoes, or, for example, to study footwear fitting with children or with people with a decreased sensibility, as diabetics[47].

On the other hand a complete footwear customization nowadays is still quite costly and time consuming and therefore it is mainly achieved for elite sports, for "personalized shoes" of famous brands for very rich people, for vanguard experimental manufactures, or for medical applications. Nowadays the real challenge is to bring successful results from luxury market to mass production. As Jiao and Tseng declared in "*An Information Modelling Framework for Product Families to Support Mass Customization Manufacturing"*:

"Mass customization begins with understanding individual customer requirements and ends with the fulfilment process of satisfying the target customer with near mass production efficiency."[48]

These studies prove indeed to be particularly effective in the research for design of shoes for people subjected to ulceration, like diabetic patients, or for people with varus feet[49]. A wider application of this technique to problematic feet could definitively help in the management of critical situations provided that these products maintain an accessible cost for the mass market.
Furthermore the customization of the shoes, the perfect fit with the human shape especially in children with difficult feet and retraction forces, is unfortunately not a guarantee of comfort. Several studies have already been made to try to quantify mismatches that may cause discomfort as a result of skin compression. *"Using what is known in the sensation and pain literature, useful measures can be developed to better understand comfort and also their underlying mechanism in an effort to design the interface between feet and footwear optimally."*[50]

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47 NÁCHER B., ALCÁNTARA E., ALEMANY S., GARCIA-HERNANDEZ J., JUAN A., *3D foot digitizing and its application to footwear fitting*, op. cit.

The purpose of this study is the elaboration of a model of footwear fitting prediction from foot geometrical characterization data and perceptions from users. 15 wemen of the same foot size were used as testers, their feet were surveyed with a 3D laser scanner and they were asked to express feeling of comfort or pain wearing 8 different types of shoes. The foot was divided into 19 zones, in order to make assessment of pains more objective and less influenced by psuchological factors. Then the information provided by foot dimension variables of the 15 females was correlated with the results of the fitting trials to create an algorithm able to predict which shoe, selected among the set of samples, causes less discomfort to a specific foot.

48 JIAO J., TSENG M., *An Information Modelling Framework for Product Families to Support Mass Customization Manufacturing,* Annals of the CIRP, 48/1:93-98

49 CHEN MJL, CHEN CPC, LEW HL, HSIEH WC, TANG SFT, *Measurement of Forefoot Varus Angle by Laser Technology in People with Flexible Flatfoot*, in *American Journal of Physical Medicine & Rehabilitation*, 2003, Volume 82, Issue 11: pp. 842-846

"The purpose of this study was to measure the forefoot varus angles in subjects with and without flexible flatfoot (FF) by using laser foot-scanning technology. [...] A total of 100 positive casts were obtained by having their subtalar joints kept in a neutral position. The plantar surface of the positive cast was scanned by a Yeti 3D Foot Scanner. A straight line was drawn between the first and the fifth metatarsophalangeal joints. The forefoot varus angle was measured from this line in relation to the line parallel to the ground. [...] The laser foot-scanning technique offers fast and accurate measurement of the forefoot varus angles."

50 GOONETILLEKE R. S., LUXIMON A., *Designing for Comfort: A footwear Application,* op. cit.

An increasing number of manufactures foresee the huge potential of the application of this technology compared with traditional processes and are starting to apply them in their productions. In particular these instruments proved to be particularly effective with problematic feet, when the use of mass products is often denied or inhibit. The manufacturing of customized orthoses and orthopedic shoes that take advantages of indirect 3D survey seems to be destined to increase exponentially in the very next future as soon as the time of production of a good and the price of the entire process will become lower than products on ordinary market[51].

Partial foot prosthesis of silicone made starting from a 3D Laser survey of the sane foot

@ www. protesiinsilicone.it

51 TELFER S., WOODBURN J., *The use of 3D surface scanning for the measurement and assessment of the human foot,* op. cit.

6.7.3 - Body survey for prosthetic and orthotic applications

One of the first attempts of defining an integrated system for the manufacture of a personalized orthosis was reported in the BAO HP, Soundar P., Yang T., *Integrated approach to design and manufacture of shoe lasts for orthopaedic use*[52]*,* a real milestone in this field, cited in most of the papers on this topic.
Several studies have proved the more effectiveness at reducing pain and redistributing pressure of customised foot orthotics compared with the standard "off the shelf" products[53].
What's the most virtual survey of the foot allows a constant monitoring of the evolution of progressive diseases that cause deformities, reducing the necessities for the patients to be exposed to radiations from x-rays.
The average supremacy of CAD CAM techniques for orthoses customization on traditional techniques is asserted by most of international papers on this topic.

Ki, Leung and LI[54], for example, compared handcraft orthoses, foot orthoses provided by the CAD-CAM method of design and manufacturing and foot orthoses provided by the foam impression method. The orthoses were divided in eight regions and examined in the conditions on maximum peak pressure, maximum force, pressure-time integral and contact area.

An analogue research was conducted by Pallari, Dalgarno and Woodburn who compare 3D scanned and 3D printed orthoses, produced by the CAD CAM method, with those produced using the foam impression and demonstrates that the firsts proved to be "*more effective at redistributing pressure away from the forefoot region and supporting the transverse arch*". [55]

52 BAO H., SOUNDAR P. YANG T., *Integrated approach to design and manufacture of shoe lasts for orthopaedic use*, in *Computers and Industrial Engineering*, 26 (2), 1994: p.411-421

53 Hawke F., Burns J., Radford JA, du Toit V: *Custom-made foot orthotics for the treatment of foot pain*, Cochrane Database Syst Rev 2008, 16:CD006801

54 KI S. W., LEUNG A- K., LI A. N. M., *Comparison of plantar pressure distribution patterns between foot orthoses provided by the CAD-CAM and foam impression methods*, in *Prosthetics and Orthotics International*, September 2008; 32 (3): pp. 356-362

55 PALLARI JHP, DALGARNO KW, WOODBURN J., *Mass customisation of foot orthoses for rheumatoid arthritis using selective laser sintering,* IEEE Trans Biomed Eng 2010, 57: pp.1750 - 1756

6.8 CONSIDERATIONS ON THE OVERVIEW ON SURVEY TECHNIQUES

The overview on survey techniques highlighted how many different alternatives are currently available. This panoramic, even if extremely brief and sometimes forcedly inaccurate for synthesis' requirements, proved to be useful in the individuation of a set of technologies that could be tested in order to understand if they can improve on current process.

This method aims at justify every technological choice in a scientific method. Technology could quickly vary over time, this sector is currently in continuous evolution, but once the criteria by which one technology is preferred to another, in this particular application and context, even the incoming of new instruments could vary just the tool, but not the approach and the aim of that action. Moreover in the opt of one technology the reasons are never only technical or functional. A ***User Centered Design approach*** was crucial even in this phase since ***every technology was evaluated considering first of all pros and cons for the final user***.

In each phase, among the available options many element of evaluation were considered as:

- ***the suitability of the technology for the aim of the research***;

- ***the costs*** for eventual new machines, materials, manhours, softwares and maintenance summed all together have to be inferior to the analogue current solution. Otherwise the adoption of a new technology has to bring so big advantages in some features that the eventual superior cost will be motivated by and undoubted advantages and will be recovered by the choice of other more economic solutions, or even the initial investment, in a reasonable business plan, will be recovered in a certain lapse of time.

- ***the easiness of use***. The choice of an economic and simple solution is the best guarantee for its further development and experimentations. If we chose one technology that with no experience or with a low training can be used by all, this is a crucial factor to maintain low cost and to promote its widespread adoption.

- ***its smartness of the technology and its integrability with the other phases*** of the process;

- ***its psychological impact*** first of all on the final user, on the DMD child, and then on all the other users or workers;

- ***its safety*** during its application and its safety implications in the final result;

- ***its environmental impact***;

- successful case studies that use the same technology.

At the end four were the technologies considered of particular interest that were selected in order to investigate their applicability in the design process of the design of the orthosis:

- ***Desktop scanner***, since its characteristic of acquiring high-resolution data from which elaborate accurate 3D models of small objects;
- ***Hand scanner***, there are several types on the market, for different applications but they seem to be extremely useful and comfortable to use, since they can be held in one hand, freely moved all around the object and in real

time the virtual reconstruction of the object takes shape on the computer the scanner is connected with.

- ***Foot scanner.*** Not all types of foot scanners were considered of interest for the aim of the thesis. In fact, most of them contemplate to allocate the foot on a plane surface in a resting position. Only the foot scanners that take part of the family of hand scanners will be considered in the phase of tests, since they would be compatible with the position of stretching of the foot.
- ***Image-based modelling.*** The recurs to this technology for survey pourposes is rapidly growing in number and in wide of field of application. It is extremely interesting for its flexibility of use, in the phase of acquisition it requires almost no technical background and the cost of the instrumentation of survey, a simple camera or even a smartphone, is minimal and in most cases, it is already in possess of the technician in charge for the survey.

In the following chapter these techniques will be applied on field to evaluate their applicability for the aim of the research.

7 TESTS OF DMD LOWER LIMBS' SURVEY

7 – TESTS OF DMD LOWER LIMBS' SURVEY

This chapter illustrates **all the tests personally conducted in the acquisition phase** in order to define the ***best process to acquire the shape of the foot***, useful for the customization of night Ankle Foot Orthosis for people affected by Duchenne Muscular Dystrophy.

Cameras, hand scanner, optical triangulation scanners were all used to compare results and evaluate their applicability in the process, not only in terms of best technical performance but in an ***User Centered approach*** of overall convenience in the frame of the project. A chalk mannequin's leg, sane people, and Duchenne boys gentle offered as testers and acquisitions were made as in laboratory, as at the Policlinico Gemelli in Rome, as in a garden, in order to evaluate how a pleasant environment could effect on the children's will of collaborating to the survey.

In order to allocate and maintain the feet in a stretching position during the minutes of acquisition ***a special support, a bench with a resemblance of a rocking horse was designed***. It will be carefully described in the following chapter but here we'll see how it was used many times in several tests.

Final results and an overall considerations among the proved technology will be made in the last paragraph.

7.1 - INTRODUCTION

The overview on the possible alternative techniques of body survey highlighted which were the best that, at least theoretically could be applied for the acquisition of lower limbs of boys affected by Duchenne Muscular Dystrophy in order to customize their Ankle Foot Orthosis on the shape of their feet. Moreover we started from another crucial technical observation that is the opportunity of acquiring the morphology of the foot in the best position possible the patient is able to achieve counteracting his mobile retractions of the Achille's tendons, through the application of a stretching force.

The Ankle Foot Orthosis is in fact a device that has to counteract as much as possible the retraction of Achille's tendon and the deformation of dorsiflexion of the foot that evolves to an equinus of the foot. These retractions evolves by time and since for the moment of their outbreak they present an angle of dorsiflexion that constitute a "fixed retraction", mostly no more recoverable if not with a surgery, and an angle of "mobile retraction", that an action of stretching of the calf and of the tendon made by a therapist, can temporary recover, until he doesn't stop to exert a force on the foot. Nowadays the range of mobile retraction is only partially recovered trying to apply a stretching force at the moment of wrapping with bandages the foot to make the plaster.

Allocating the foot in a stretching position could be advantageous but to do so we started to suppose the possibility of designing a particular bench on which the child could sit and allocate his foot in a pedal that could lock his position as desired by the therapist. This prototype will be carefully described in chapter 8 but it will be used to survey tests here illustrated.

Desktop scanner, hand scanner and image-based modelling technique are tested in the survey of a mannequin chalk leg and on real people but, besides the technical evaluation of the acquired data, each test include a consideration on all the implication of the adoption of a certain technology and an evaluation on the quality of all the process, considering even psychological and environmental conditions. Each test is presented as a data sheet, it describes the development of the training and compares the result in relation to the aim of the test.

7.2 – SCAN OF A LOWER LIMB IN RESTING POSITION BY OPTICAL TRIANGULATION SCANNER

AIM OF THE TEST

The first test was made in order to understand potentials, limits and eventual complications of a foot scan made with an optical triangulation scanner. Two triangulation scanners, ownership of the Departmental Center of the Department of Architecture of the University of Ferrara, were tested, thanks to the collaboration of a sane boy, to evaluate their appropriateness for a body survey.

ENVIRONMENT SETUP

The test was made in the photographic laboratory of the Department of Architecture of the University of Ferrara. One student who offered as a tester was sitting on a table in a relax position, slightly of dorsiflexion. The skin of his lower limb was covered with talcum powder to make the surface matter. It was asked to the student to maintain that position unmoving as much as possible.
The Range 5 Scanner and Vivid 910 Scanner were alternative mounted on a tripod and the space all around the table where the tester was sitting was left empty in order to facilitate the movements of the scanner between different positions.

Konica Minolta RANGE 5 Non-Contact 3D Digitizer

Konica Minolta Non-contact 3D digitizer Vivid 910

INSTRUMENTS:

Konica Minolta RANGE 5 Non-Contact 3D Digitizer

MEASURAMENT METHOD: Triangulation by light sectioning

OBJECT DISTANCE RANGE: 45cm to 80 cm

ACCURACY: ± 80 µm

MAX RESOLUTION: ± 80 µm

PRECISION: 8 µm

OUTPUT FORMAT: 3D data 1280x1024 pixel

DIMENSION: 295X190X200 mm

WEIGHT: Approx. 6,7 kg

Konica Minolta Non-contact 3D digitizer Vivid 910

MEASURAMENT METHOD: Triangulation, light stripe method

DESIGN

OBJECT DISTANCE RANGE: 60 cm to 250 cm

CAPABLE OF SCANNING: 307.000 points in 2,5 seconds or 77.000 points in fast mode.

ACCURACY: 220 microns (0.0087 inches)

MAX RESOLUTION: 400 microns (0.0016 inches)

OUTPUT FORMAT: 3D data 640x480 pixel

DIMENSION: 213x413x271mm

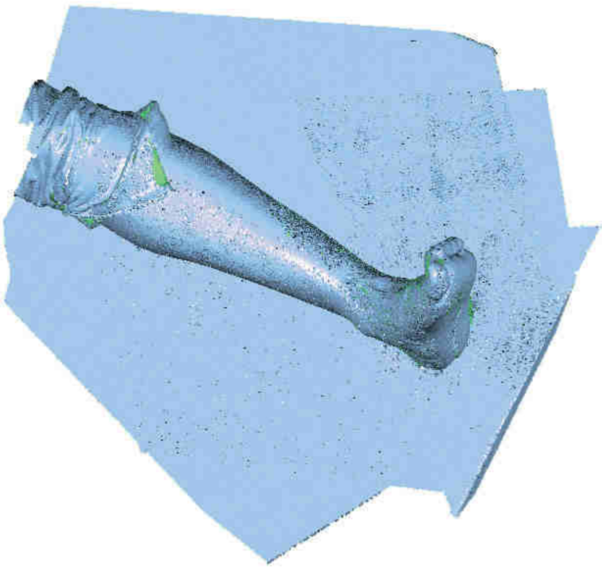
WEIGHT: Approx. 11 kg

CARRYING OUT OF THE TEST

Five scan's stations were made all around the lower limb doing a time of about 10 minutes. Each scan acquired all the points referred to the visible surfaces from that point of view. The five scans were necessary in order to acquire the complete geometry of the leg.

PROCESSING OF DATA

- **Registration**: each scan had its own reference system that considered the center of the scanner as the axis origin. To automatically registered each scan with the others, in this case, surface matching algorithms were used. To make this process properly work an overlapping of at least 30% is required.
- **Cleaning**: it was done both automatically and manually and it was aimed at the elimination of all the "rumors", mistaken points that had no correspondence with the real surface. They can be due to some problems of direction of the laser beam or other disturbing elements.
- **Alignment:** once all the scans were cleaned, a further automatic registration was processed in order to refine the registration. It was conducted using the Iterative Closest Point algorithm, until the angular deviation between the scans was reduced to the minimum.
- **Blending** of the single scans to obtain a single point cloud representing the object from all the points of view. Usually the level of accuracy that can be achieved adopting a surface matching technique is lower than through a target registration. However the difficulty in the positioning of the targets, together with the evaluation of the comparison between the two results, made the automatic surface matching technique acceptable for this process.
- **Triangulation** of the point cloud to transform points into a mesh.



Snapshot of the acquired point cloud

ACQUIRED DATA

INSTRUMENT: Konica Minolta Non-contact 3D digitizer Vivid 910

NUMBER OF STATIONS: 5

POINTS ACQUIRED: 1.576.144

AVERAGE NUMBER OF POINTS PER EACH SCAN: 315.229

EXECUTION TIME: 10 minutes

LOCATION: Department of Architecture of the University of Ferrara

DATE: 29 - 05 - 2012

CONSIDERATION ON THE RESULTS

Vivid 910 3D was preferred in the continuation of the test since it proved to be more flexible in the simultaneous acquisition of points located at different distances from the scanner. Vivid scanner, with a single acquisition, proved to acquire a surface almost double compared with the Range 5's one. The resolution of the scan made with Range 5 scanner was definitively higher but, for the aim of the survey, the resolution of Vivid 910 scanner was considered more than sufficient. As it can be seen in the snapshots of the 3D model, the final result presents a quite high resolution, absolutely adequate to be used as a support for a customized shoes. Some slight imperfections can be seen along jointing lines between different scan positions but they can be due to natural small movement of the lower limb since it was not locked but simply resting on the table. The back of the leg, part of the calf and of the heel was of course missing since it was lying on the table, but this was considered not important for the aim of the test. This process was useful to understand and define how to optimize the acquisition before repeating the same experiment at the Policlinico Gemelli with a child affected by Duchenne Muscular Dystrophy.

Virtual reconstruction of the lower limb surveyed with Konica Minolta Non-contact 3D digitizer Vivid 910

DESIGN

7.3 – SCAN OF A LOWER LIMB OF A DUCHENNE CHILD PUT IN A STRETCHING POSITION BY A THERAPIST AT THE POLICLINICO GEMELLI IN ROME

AIM OF THE TEST

The aim of this test was to try if an indirect survey of a lower limb of a child affected by DMD could be possible in a condition of stretching for his foot provoked by an active force of the therapist. We've already seen all the advantages of a survey made with the foot in a stretching position, but in this case we would test if the presence of the therapist and her hands on the foot of a Duchenne boy, at the Policlinico Gemelli in Rome, allowed to acquire the minimum surface required to obtain a reliable 3D model of the lower limb.

INSTRUMENTS:

Konica Minolta Non-contact 3D digitizer Vivid 910

MEASURAMENT METHOD: Triangulation, light stripe method

OBJECT DISTANCE RANGE: 60 cm to 250 cm

CAPABLE OF SCANNING: 307.000 points in 2,5 seconds or 77.000 points in fast mode.

ACCURACY: 220 microns (0.0087 inches)

MAX RESOLUTION: 400 microns (0.0016 inches)

OUTPUT FORMAT: 3D data 640x480 pixel

DIMENSION: 213x413x271mm

WEIGHT: Approx. 11 kg

ENVIRONMENT SETUP

The test was made at the Department of Child Neuropsychiatry directed by the Prof. Eugenio Maria Mercuri at the Policlinico Gemelli in Rome. The test was made thanks to the collaboration of an 8 years old child affected by DMD, a physiotherapist and another man who helped me in the handling of the scanner. Even if the patient was quite young, his retractions were already severe and he was wheelchair bounded since two years. With the help of his mother and the physiotherapist, the boy was lined on an exam table.

CARRYING OUT OF THE TEST

The therapist embraced his leg and started a procedure of Achilles' tendon stretching, trying to recover as much as possible the angle of mobile retraction that was still present and to correct other misalignments. This phase concluded, the therapist locked with her hands the foot at the maximum level of dorsiflexion possible and tried not to move for the following minutes. In the meanwhile I made in a time of 4 minutes 4 scans all around them.

ACQUIRED DATA

INSTRUMENT: Konica Minolta Non-contact 3D digitizer Vivid 910

NUMBER OF STATIONS: 4

POINTS ACQUIRED: 370.494

AVERAGE NUMBER OF POINTS PER EACH SCAN: 92.624

EXECUTION TIME: 4 minutes

PROCESSING OF DATA

The raw data acquired from the scanner was processed following the same steps of the previous test: registration by surface matching, cleaning, alignment, blending, triangulation. However in this case the phase of cleaning was particularly demanding since all the

Stations of acuisition of the shape of the limb of a child affected by Duchenne Muscular Dystrophy. At 12 years old the one seen in the first photo is the higher level of dorsiflexion it can be achieved applying a stretching force

ACQUIRED DATA

INSTRUMENT: Konica Minolta Non-contact 3D digitizer Vivid 910

NUMBER OF STATIONS: 4

POINTS ACQUIRED: 370.494

AVERAGE NUMBER OF POINTS PER EACH SCAN: 92.624

EXECUTION TIME: 4 minutes

LOCATION: Policlinico Gemelli in Rome

DATE: 04-06-2012

environment and the body of the therapist had to be removed in order to isolate the lower limb. Many shadows' cones were present and, the smallest ones were closed by an algorithm of automatic "Fill Holes".

CONSIDERATION ON THE RESULTS

The acquired surface was not complete. The position of the therapist who was stretching the child's foot necessarily covered important parts of the body of the child and ***the resultant shape was considered insufficient to be used as a model for an Ankle Foot Orthosis***. Moreover ***the stretching of the heel for DMD patients is unavoidably at least slightly harmful*** and the test was unintentionally made on a child who had some serious psychological problems as well. Even if the time of the acquisition was reduced to the minimum, only four minutes, for the whole period the child complained to the therapist and tried to move from that position. Furthermore the child was not so young and quite chunky compared to the therapist's physiognomy and ***she complained an excessive physical exertion*** during the minutes of acquisition, in the attempting of stretching child's lower limb and immobilize him. These factors made the registration of the single scans more difficult and we

stopped the test before acquiring the view from the fifth position in order to not stress anymore the child.
However this test was extremely useful to focus, together with the physiotherapist needs and **problems that could emerge in these situations:**

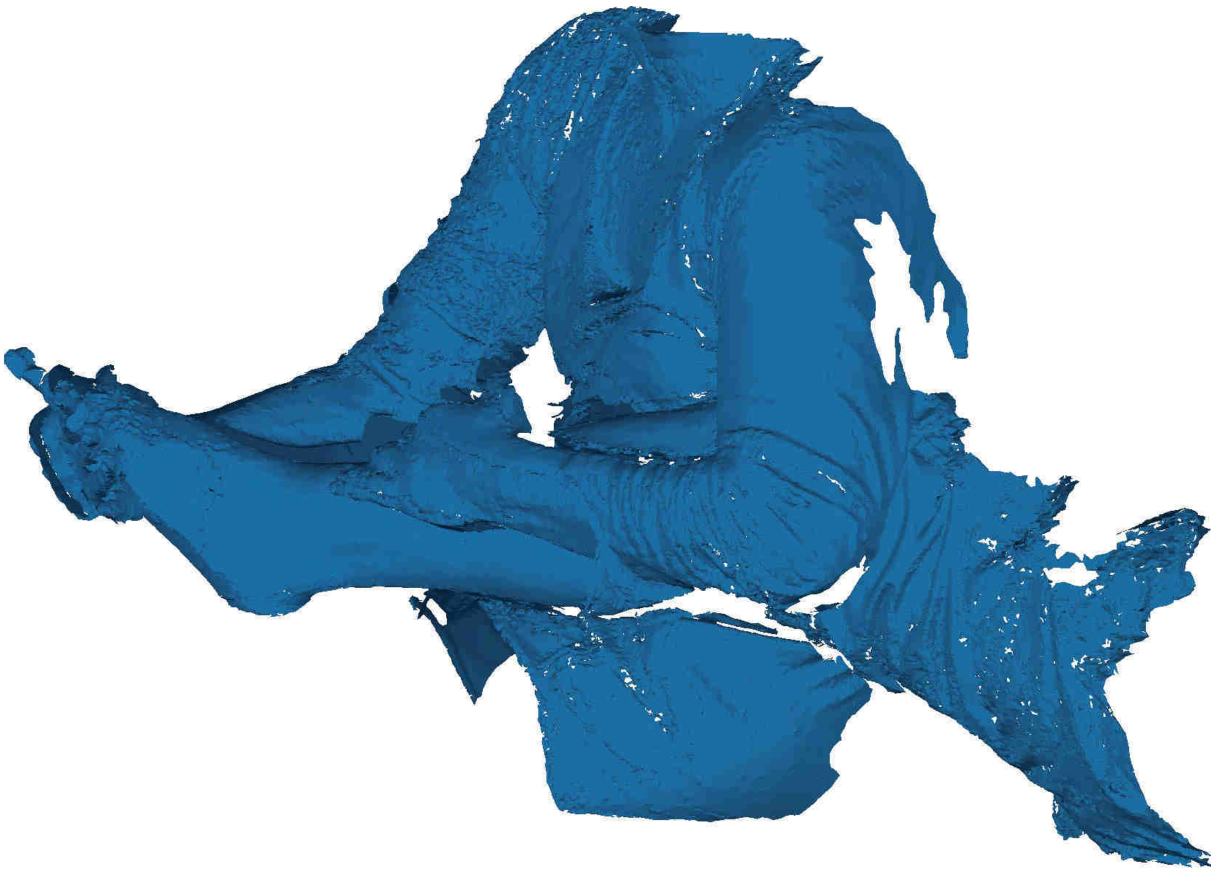
- ***the positioning of the foot in a stretching position can be crucial in adding a curative additional factor to Ankle Foot Orthosis*** and not only of maintenance of the actual situation without considering mobile retractions;

- ***a specific support for the leg***, had to be designed in order to maintain the foot in the best position possible and to lock the foot, reducing to the minimum shadows' cones.

- in the hypothesis of a specific support for the leg, ***the role of the technician would be reduced only to the correct positioning of the foot on the support*** and in its secure locking in a way that would prevent all the movements but, at the same time, it would be less harmful possible. However the role of the therapist is crucial and it would be better if the survey would be done by the same technician who has in care the boy since he perfectly knows the mobility's possibilities of the child.

- The psychological aspect of this phase of survey is crucial. The boy was scared even before entering in the room about the idea of something new related to his stretching activity. He was nervous and immediately got bored. For the good result of the process it will be extremely important to try to create a relaxed atmosphere and to make the child feel comfortable.

3D Mesh obtained by the elaboration of data of all the stations acquired with Konica Minolta Non-contact 3D digitizer Vivid 910. The result is incomplete and inadequate to the scope



7.4 – FIRST TESTS OF PHOTO-SCAN OF A CHALK MANNEQUIN'S LEG

AIM OF THE TEST

The goal of this test was to develop a procedure for the elaboration of a 3D model of an object starting from a set of photo. These first series of tests of photo-scanning were made using a trial version of the software Photomodeler. In order to compare the accuracy of different results the tests were made on a leg of a child mannequin in gypsum.

ENVIRONMENT SETUP

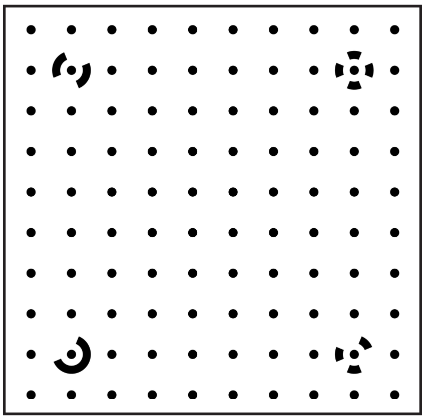
The acquisition of photos was made in the photographic laboratory of the Department of Architecture of the University of Ferrara. The gypsum leg was firstly located simply on a table in front of a white wall, located in a light tent cube. The nylon fabric of the tent diffuses the external light source, softening shadows and reducing glare, creating the perfect set for photographing the object with a uniform background. In particular we first tried with a white tent, then we preferred a blue background in order to create an higher separation between the white of the leg and the setting. Moreover the mold was located on a tv turntable to make it rotate gradually while the camera was fixed in front of the box on a tripod.

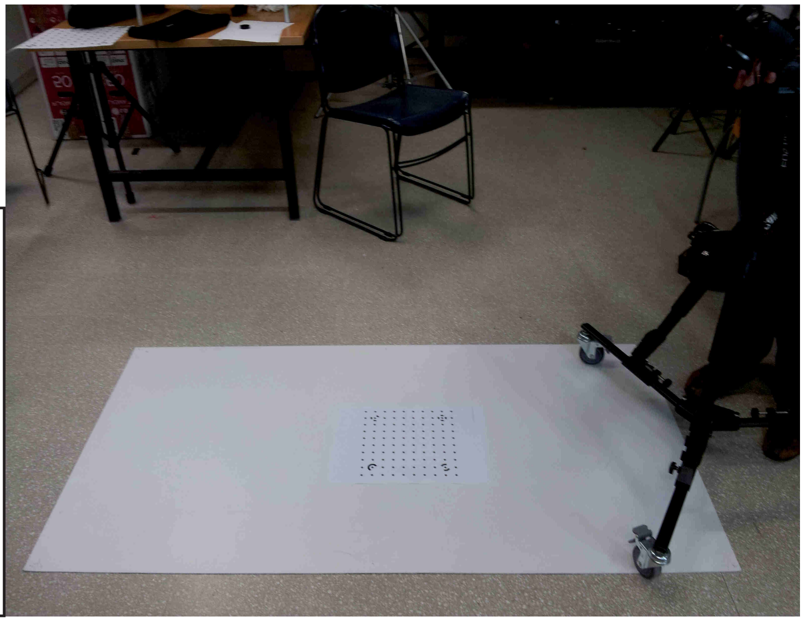
CARRYING OUT OF THE TEST

Calibration of the camera

The first step suggested by Photo Modeler for an accurate image-based modelling was camera calibration. The aim of the calibration is to determine the values, such as focal length and lens distortion typical of each camera. As a first step of the process the PhotoModeler Calibration Grid was printed as a square with a side of about 28 cm, in a size similar to the sole length. The software's tutorial suggested in fact to print the grid in a scale similar to the dimension of the object that has to be photo-scanned. The camera was mounted on a tripod and the target was placed on a larger white paper fixed on the floor so that all the photos didn't catch other textures or specular surfaces that could disturb the process. Twelve photos were necessary, three photos for each of the four sides. The first set of photos was made with the camera in a landscape position, horizontal. The camera was stationary and I moved around the grid. Then the camera was rotated, remaining fixed on the tripod, 90° right and another set of four photos was taken and, at the end, the camera was rotated on the tripod, positioning it vertically after a rotation of 90° left and the last group of four photos was taken. All camera settings, image resolution, zoom, focal length remained the same during all the process. The distances between the camera and the grid were set up so that the grid fills up the photos as much as possible.

Camera Calibration
and Calibration Grid





This phase concluded, the photos were uploaded in the software and then processed with an automatic camera calibration procedure. It recognized on each photo the 100 points of the grids, including the 4 control points. At the end, the software recognized the focal length used, the format size and all the parameters it required to identify the camera and recognize how it recorders images. A final report of the process presented all the values and the total error calculated. This is an important value since it indicates the minimum thresholds to consider the process acceptable. Several tests were made until a valid result was achieved. In particular I noticed that a particularly reflectance floor disturbed the process and for this reason in the final set, I put the Camera Calibration Sheet on a larger white paper.

Mannequine's photographic acquisition

the photographic acquisition of the leg followed camera calibration. Hereinafter we can see some short sheets that reassume the main tests conducted until an acceptable result was achieved.

FIRST SERIES OF TESTS - FAILED

The first set of photos was made allocating the mannequin on a desk against a wall. The leg was photographed by each side, leaving the camera hooked on a tripod and slightly rotating the object in a 360° turn.
This photoshoot failed in the elaboration of a 3D model starting from this set of photos. The causes could be several: the tripod was too far from the object and the leg occupied a small part of the frame. Moreover due to this element, the resolution of the targets was inadequate for their identification for the 3D matching.

ACQUIRED DATA

INSTRUMENT:
SONY DSLR-A350

NUMBER OF PHOTOS: 20

F-stop: f/5.6

Time of exposition:
1/60 sec.

Focal lenght: 18mm

Diaphragm: 3.61

Dimension:
4592 X 3056 pxl

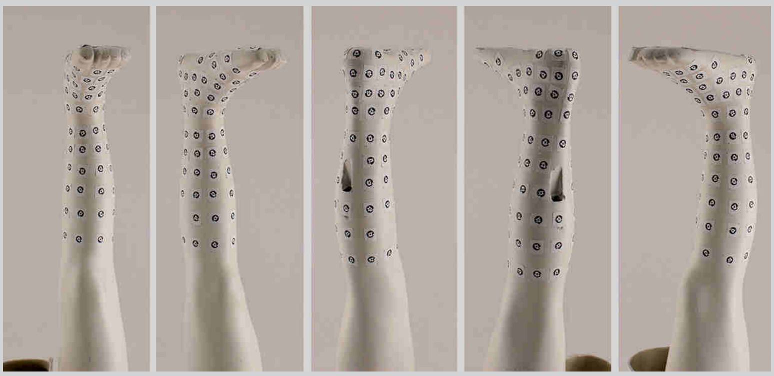
EXECUTION TIME:
2 minutes

LOCATION: Department of Architecture of the University of Ferrara

DATE: 05-02-2013

SECOND SERIES OF TESTS - FAILED

The second test was made in the photographic laboratory and the mannequin's leg was allocated in a white photographic tent. A better illumination and a shorter distance between the object and the camera drastically improved the quality of the photos. However it seemed that the software had some difficulties in the matching of the photos to obtain a 3D model.
It was supposed that this error was due to the little contrast between the leg and the background. Several targets were recognized and matched but the general result wasn't acceptable.



ACQUIRED DATA

INSTRUMENT:
SONY DSLR-A350

NUMBER OF PHOTOS: 20

F-stop: f/4.5

Time of exposition:
1/100 sec.

Focal lenght:
18mm

Diaphragm: 3.61

EXECUTION TIME:
4 minutes

LOCATION: Photographic Laboratory of the Department of Architecture of Ferrara

DATE: 05-02-2013

LAST SERIES OF TESTS

Treasure the experiences of the previous tests, this last series was made allocating the mannequin in a blu tent, in order to have an higher contrast between the dark background and the white of the chalk.
13 photos were made from a fixed position of the camera while the leg slightly rotated in a 360° turn on the turntable. Each photo was fulled for most of its frame by the leg and between each photo there was an overlapping of about the 60%. the distance from which the leg was framed.
The leg was framed in order to cover at least 2/3 of the photos. Moreover a shorter distance increased the resolution of the leg and it was more simple for the software to recognize targets. However these changes made more difficult the focusing of the photos, since the deep of field was definitively shorter.

ACQUIRED DATA

INSTRUMENT: SONY DSLR-A350

NUMBER OF PHOTOS: 13

F-stop: f/22

Time of exposition: 1/2 sec.

Focal lenght: 18mm

Diaphragm: 3.61

Dimension: 4592 X 3056 pxl

POINTS ELABORATED: 579.398

EXECUTION TIME: 3 minutes

LOCATION: Photographic laboratory of the Department of Architecture of the University of Ferrara

DATE: 07-03-2013

PROCESSING OF DATA

The software allows different procedures of photo-scanning, in this case we used the automatic recognition of the surface. Since it was a really smooth surface and without textures, several targets were applied randomly on the surface of the leg to facilitate the process of recognition of the three-dimensional shape.

An automatic recognition of the shape was applied but, if necessary, with this method, we can add also reference points between same targets by a manual recognition on pairs of photos.

All the images were imported into the software, the camera calibration file was associated to the set of photos and processed in 4 stages in order to recreate the textured 3D model:

- **Point cloud creation**; starting from the photos, the software calculates the positions of the camera in each shot in relation to the object and recreates a 3D point cloud of the objects framed in photos. Features are detected on each image and then matched across images.
- **Multi-view stereo system for dense point cloud and its texturization**; thanks to a multi-view stereo system an high density point cloud is generated and each point is associ-

ated with its RGB colour extracted from the photos.

- **Elaboration of the mesh from the point cloud**; triangulation of the point cloud in order to obtain a solid 3D mesh;
- **Texturization of the mesh**, elaborating a texture starting from the original photos. This last step is purely visual; it won't change the shape of the mesh or affect measurements. If an exact measure is known and clearly visible on the photo, the 3D model can be scaled and it can be used for taking measures.

INSTRUMENT:

Camera Sony Alpha DSLR-A350

RESOLUTION: 14.20 Megapixel

LENS:

3.88x zoom

18-70 mm

VIEWFINDER: Optical / LCD

ISO: 100-3200

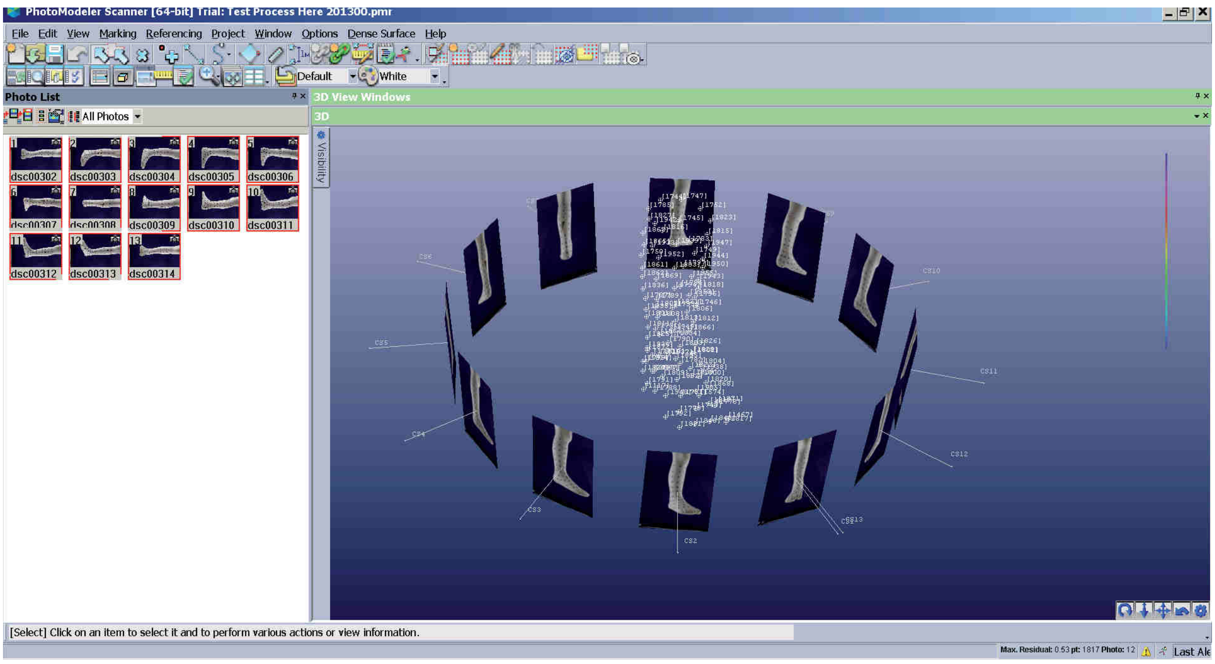
SHUTTER: 30-1/4000

Mannequine's photographic shooting

CONSIDERATIONS ON THE RESULTS

The results of these first attempts of photo-modelling were quite partial and incomplete. The final model was quite coarse, with a severe loss of the detail of the surface. In particular the point cloud was more accurate and dense in the areas closer to the targets, while the software had more difficulties in the individuation of common points among photos in the blank parts of the gipsy. The causes can be attributed to inexperience in the management of the software, in the choice of an automatic procedure of auto-matching instead of a probably more accurate manual registration in the density and disposition of the targets, or even in the type of surface, too uniform and smooth to be accurately recognized. However the result couldn't be considered sufficient for the aim of the test.

Point cloud generated by the
 Image-based process
of survey of the mannequine



7.5 – TEST OF PHOTO-SCAN OF A CHALK MANNEQUINE'S LEG AT THE BRUNO KESSLER FOUNDATION OF TRENTO

AIM OF THE TEST

In May 2013 another test of Image-Based Modelling was repeated thanks to the help of the Fondazione Bruno Kessler of Trento, specialized in accurate measurements and reality-based 3D reconstruction problems. Before moving to Trento, a 3D scan of the lower limb was made in order to compare the results between the photo scanned model of the chalk leg and the one obtained by a triangulation scanner. The goal of this test was to prove that a photo-scan process can be applied in substitution of a triangulation scanner for the aim of acquiring a 3D virtual reconstruction of a lower limb, useful as a mold on which modelling a customized Ankle Foot Orthosis.

ENVIRONMENT SETUP

The mannequin was locked on the top of a projector table in order to fix it in a stable position raised with respect to the floor at an height that allowed an easy framing in the photos of the lateral sides of the leg but, at the same time, to acquire the foot sole. The space all around the table was left empty to be able to take photos from every direction. At one side of the table was located a tripod on which was fixed a metal ruler, in order to have a known metric measure to scale the reconstructed virtual model in a 1:1 scale.

CARRYING OUT OF THE TEST

The test was preceded by a long briefing with the FBK team to explain them generally the aim of my research and in detail the process of photo acquisition I already made and all the problems I encounter in these tests. In order to avoid some of the problems we decided to randomly colour, with markers of different colours and different shapes, the entire surface of the mannequin. This operation simplify the recognition of correspondent points between photos. 24 photos were taken: two series of 9 photo each all around the leg at a double high and 6 photos dedicated to the sole, from the four diagonal points of view and two frontal ones.

DATA PROCESSING

The photos were processed with a trial version of the software ***Agisoft PhotoScan***[1]. In this case that Camera was already calibrated, we recognized it and started the alignment process. At this time, the coverage of the surface with drawings and sketching and the better set up of the program gave at the first attempt a good result. The number of photos was even exceeding since from the report we can read that in the medium all the points that compose the point cloud were taken at least by 9 photos.

1 Agisoft Photoscan, www.agisoft.com (January 2015)

INSTRUMENT:

Camera Nikon Digital SLR Camera D800

RESOLUTION:
36.30 Megapixel

SENSOR SIZE:
35,9 x 24 mm

VIEWFINDER:
Optical / LCD

ISO: 100-6400

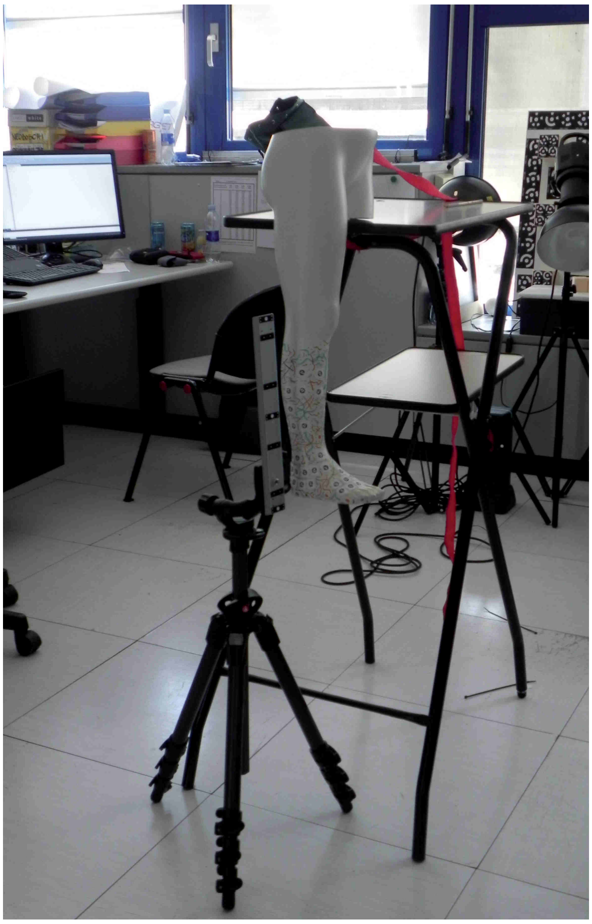
DIMENSION:
146 X 123 X 81.5 mm

WEIGHT:
1 kg

The first stage was the upload of all the photos in the software and then the "*Align Photos*" process, with the highest accuracy possible, was activated. At the end a sparse point cloud was generated, surrounded by symbols that indicate the locations of the cameras. Then, based on the estimated camera positions, the program calculates depth information for each camera to be combined into a ***single dense point cloud***.

After dense point cloud was obtained, it was transformed into a polygonal mesh model.
Photo-scanning method doesn't recognize, reasonably, the scale of the photos. Therefore, once the model is transformed into a solid mesh, is necessary to ***scale*** it in order to operate in real scale. Minimum two markers have to be added in the model and a related Scale Bar, with the exact distance of the two points. If the distance between several more markers is known, several scale bars can be added for a more accurate scaling of the model.
At the end the model was exported in .obj format to be imported into the software of customized parametric modelling of the AFO.

Photoshooting of the mannequine's leg at the Bruno Kessler Foundation in Trento



ACQUIRED DATA

INSTRUMENT:
Nikon D800E

NUMBER OF PHOTOS: 23

F-stop: f/13

Time of exposition:
1/250 sec.

Depth of field:
from 0,60cm to 1m

Focal lenght: 35 mm

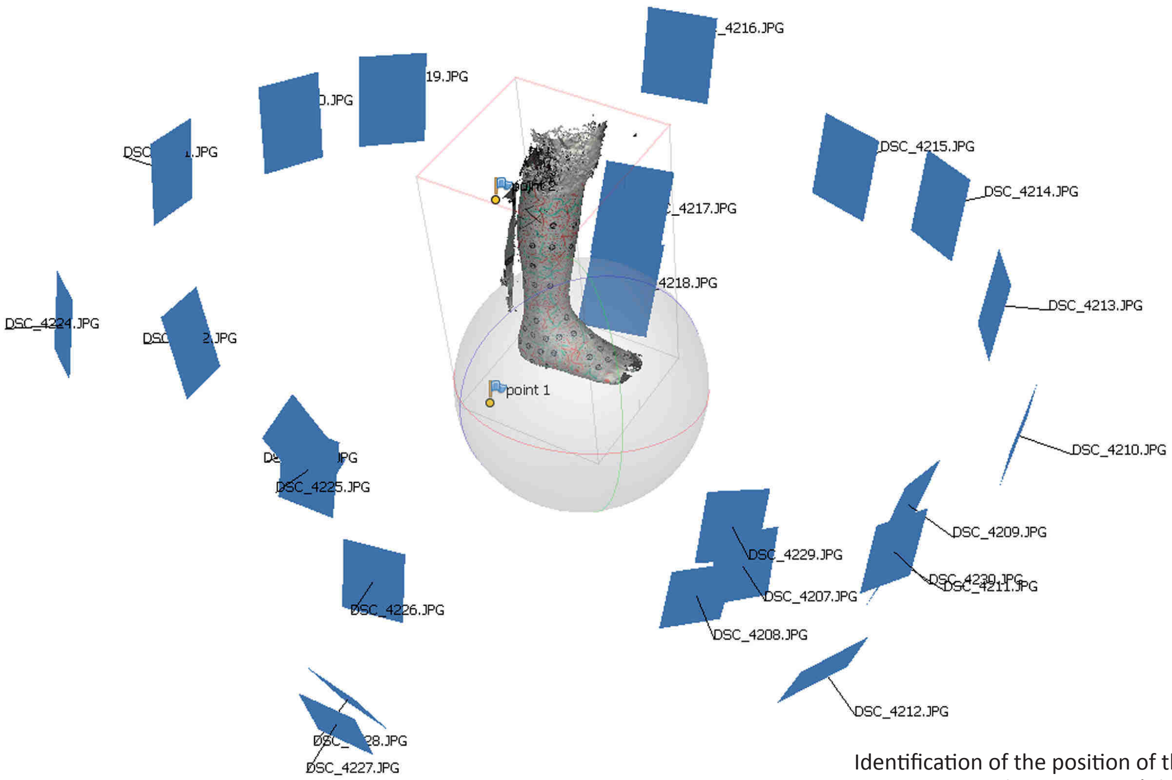
Dimension:
7360 X 4912 pxl

POINTS ELABO-RATED: 493.051

EXECUTION TIME:
5 minutes

LOCATION: FBK Foundation, Trento

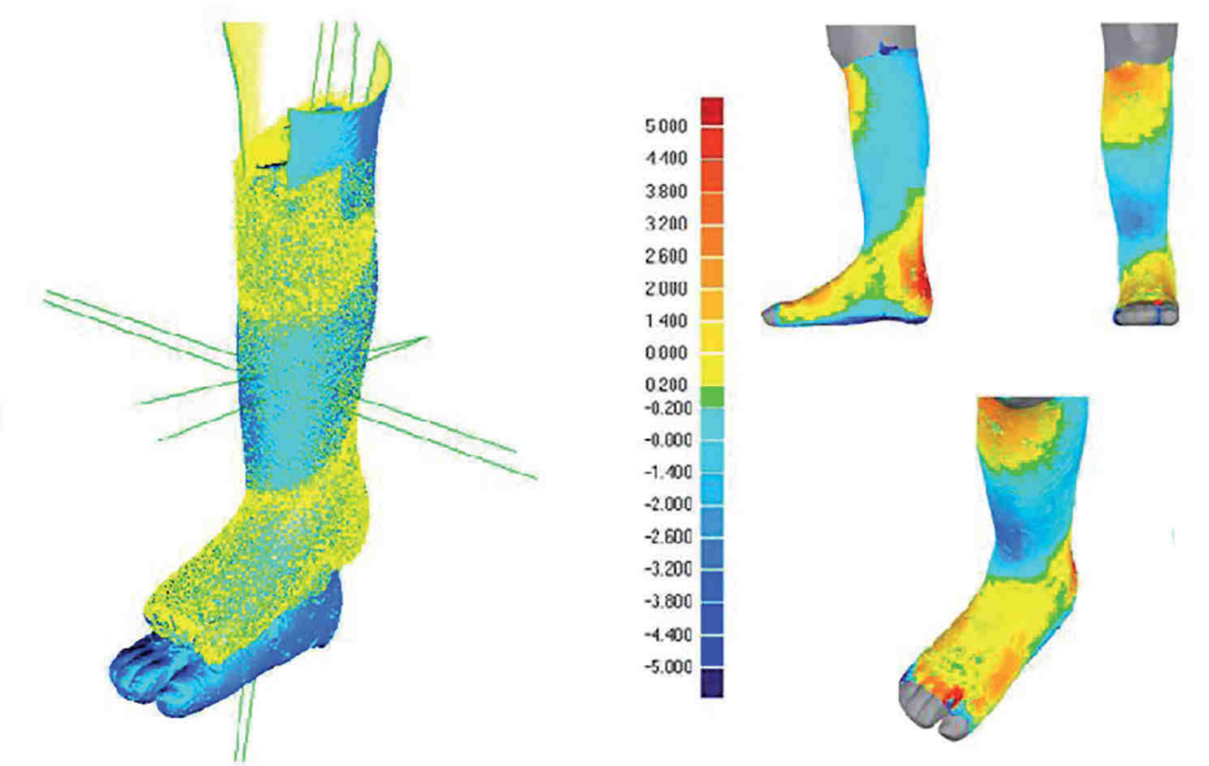
DATE: 28-05-2013



Identification of the position of the cameras around mannequine's leg

COMPARISON OF DATA AMONG DIFFERENT SURVEYS' TECHNIQUES

To test the accuracy of the virtual reconstruction of the gypsum leg, the resultant 3D model was compared with the one obtained by processing data acquired with the triangulation 3D scanner Konica Minolta Range Viewer. This comparison was achieved with a trial version of the software Geomagic Qualify 2013[2]. The two models were imported in an unique space of the software and then aligned first with a roughly manual registration, to have a similar collocation of the two object in the virtual space and then processed with an automatic global registration to refine the results. This step concluded the two shapes were once more aligned with the ***"Best Fit Alignment"*** process. 100.000 points were taken as sample size, that is the number of points on the surface of each object that will be compared during the alignment process. It is the higher value allowed by the software, set to obtain the most accurate possible result. Then statistic data and a visualization on the 3D model illustrated the results. **The average distance among the two figures was of 2,22 mm**, while the largest deviation amount to 5 mm and it was located mainly at the heel and in the posterior part of the ankle.



Registration, Best Fit Alignment and Comparison among the 3D model obtained by Image-Based modelling and the one surveyed with otical triangulation laser scanner.
The maximum relative distance is of 5mm but several expedients were noticed to improve this result in the following tests

2 Geomagic Qualify, http://www.geomagic.com/it/products/qualify/overview (January 2015)

CONSIDERATION ON THE RESULTS

The first important result of this test is to prove that this technique is applicable in substitution of laser scanner survey with all the predictable and already explained advantages. The same acquisition was then repeated with two instruments of a lower quality, as Canon EOS 500D in automatic set and with a camera on a smartphone Samsung S2 and in both cases the results continued to be considered acceptable.

Furthermore one annotation on the results is that the graph of relative deviation does not show the error of Image Based Method, but the relative difference among the two instruments considering the accuracy of a triangulation 3D laser scanner as a point of reference. Moreover the most relevant errors were located at the heel and, observing the positioning of the camera in the photos that frame the heel, some improvements can be made.
In the evaluation on the acceptability of the result several elements have to be considered:

- ***The noticed error is acceptable.*** The orthosis will be made in a rigid material and therefore broader tolerance margins have to be considered. The lower limb is a living body that changes not only due to the natural grow of the child, but even for temperature variations, the functioning of peripheral circulation, positioning, and several other possible causes as food or activities lead in that day;

- ***The dislocation of the error has to be put in relation with the shape of the AFO.*** For example it is useless to focus on the accuracy of the survey of the foot fingers since the orthosis doesn't involve that part;

- ***Padding.*** Little irregularities during the survey and processing of data are partially compensated by the 4 mm of inner padding.

If, besides these considerations, the error is still non acceptable, a coloured light nylon sock, or markers, better if in relief, could be applied on the leg to facilitate the phase of photo-matching[3].

INSTRUMENTS:

Konica Minolta RANGE 5 Non-Contact 3D Digitizer

MEASURAMENT METHOD: Triangulation by light sectioning

OBJECT DISTANCE RANGE: 45cm to 80 cm

ACCURACY: ± 80 µm

MAX RESOLUTION: ± 80 µm

PRECISION: 8 µm

OUTPUT FORMAT: 3D data 1280x1024 pixel

DIMENSION: 295X190X200 mm

WEIGHT: Approx. 6,7 kg

3 A special thanks for the precious technical support to Eng. Fabio Remondino, Eng. Alessandro Rizzi, Fabio Menna and all the staff of the 3DOM - 3D Optical Metrology Unit, of FBK - Bruno Kessler Foundation, Italy (http://3Dom.fbk.eu/en/home) and to the FBK researcher Alessandro Rizzi of the SMART3K, spin-off of FBK, (http://www.smart3k.it/).

7.6 – TESTS OF PHOTO-SCAN: FROM A CHALK MANNEQUIN'S LEG TO A REAL ONE

AIM OF THE TEST

These tests of Image-Based Modelling were collected in a single paragraph since they had a common goal: testing the process of survey of a lower limb located on a special bench designed to lock the foot in a stretching position. The test aimed at optimizing it as much as possible, trying to forecast all the possible drawbacks and complications.

It must be considered in fact, that even if most of the process of acquisition was processed in real time, the all processing of data develops when the child is no more in the healthcare building. Furthermore it must be considered that mistaken a survey could be really inconvenient since the technician would have to re-call the family of DMD child to carry out a new survey. Beside the availability of the parents it must be considered even the disposability of the child of being patient, calm and motionless again for other five minutes, especially if he is young. The situation is often complicated, talking about Duchenne's boys, by a restlessness and nervousness related to pharmacological cures or common psychological complications.
Therefore all the following tests were aimed at proving the reliability of the process and in highlighting all the possible errors that can be avoided.

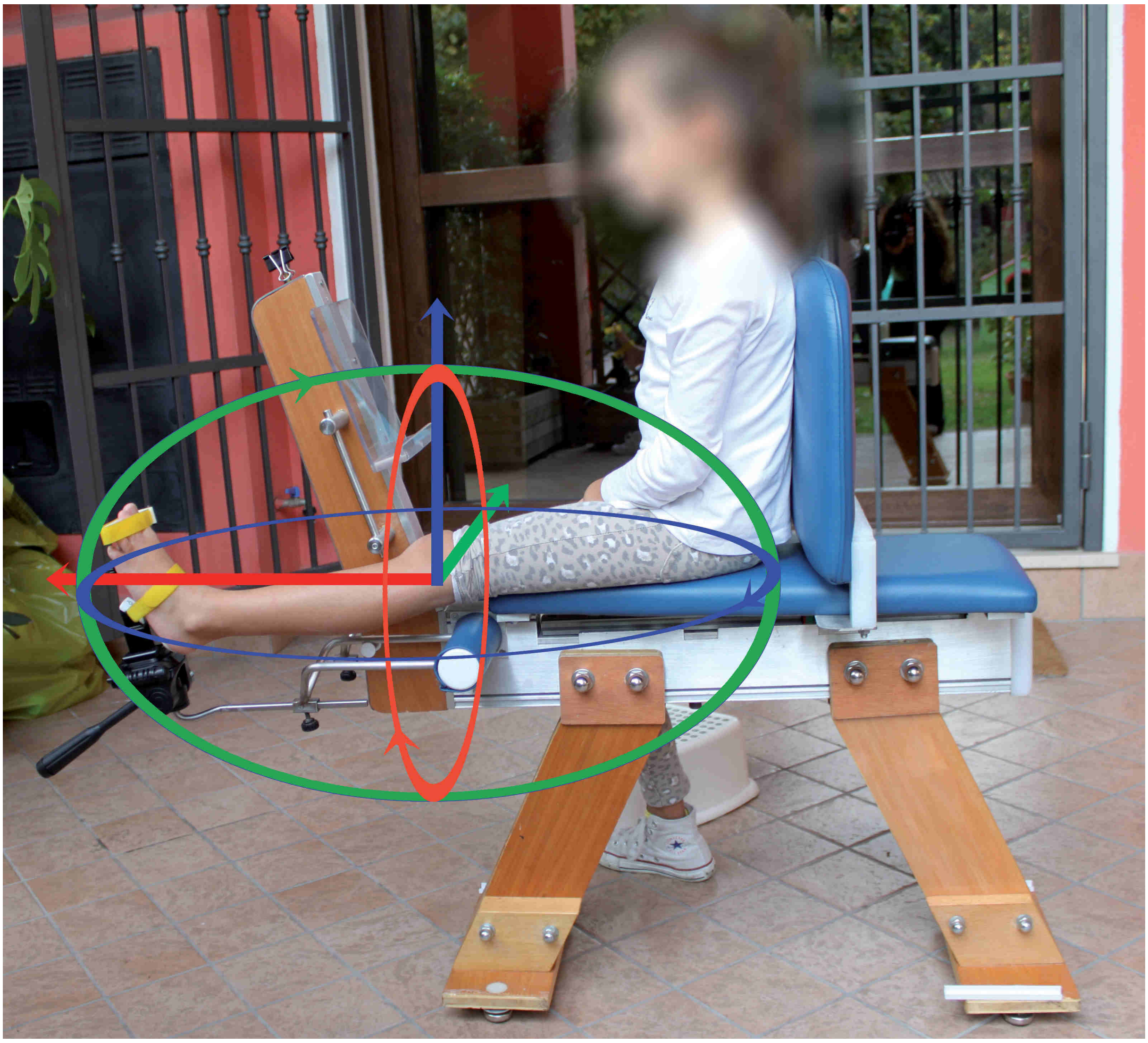
ENVIRONMENT SETUP

The tests were carried in different conditions of lightening, from a photographic set, to an indoor situation with a diffuse illumination to an open air situation. Each set had pros and cons but in general what is important is to have an environment with a good diffuse illumination, trying to avoid strong light reflections on the scene as well as shadows cones. One of the main mistakes made in the acquisition performed in a photographic set, for example, was the arrangement of photographic headlights: they were dislocated all around the body to provide as much as possible a uniform lighting. However two errors were committed. Firstly the lights were too strong and this causes an overexposure of some parts and some strong reflection of the lights on lucid surfaces like the plastic of the support, with subsequent dark cone shadows in some hidden parts. Secondary the spot lights were too many and it was quite difficult to avoid them during the photo shooting. In particular this element was underestimated in phase of acquisition, but a strong light in the image, even if the leg was properly highlighted by a headlight on the back of the camera, damage irremediably the frame and causes the elimination of that picture by the automatic matching of the software.

CARRYING OUT OF THE TEST

The series of tests suggested to mentally standardize the sequence of photos to be sure, at the end of the acquisition, to have a complete set of images. The center of a world coordination axis was ideally located at the center of the knee of the leg that had to be surveyed. From this center the 3 axes were supposed along the leg, perpendicular towards the other leg and vertical. The photos have to follow these circles of rotation with a frequency of about one shoot every 30 – 40 degrees on the ideal circle. This density proved to have the best efficacy even in case one photo has to be eliminated since the others can eventually cover the entire surface. Hereinafter a brief review of the most important tests.

In order to have the best acquisition possible, without shadows' cones, photo shooting all around the leg has to be done following the three revolution axes as in the picture



ACQUIRED DATA

INSTRUMENT:
Canon EOS 650D

NUMBER OF PHOTOS: 20

F-stop: f/5.6

Time of exposition:
1/160 sec.

Focal lenght: 18mm

ISO: 1600

Dimension:
5184 X 3456 pxl

EXECUTION TIME:
3 minutes

LOCATION: Photo-graphic Laboraratory

DATE: 29-10-2013

TESTS OF SURVEY IN PHOTOGRAPHIC LABORATORY

Several tests of acquisition were made in the photographic laboratory. The results of these tests weren't satisfying mainly because of problems of illumination of the environment. If a strong light source was taken in the picture, 3D matching didn't work.

ACQUIRED DATA

INSTRUMENT:
Canon EOS 650D

NUMBER OF PHOTOS: 20

F-stop: f/2.2

Time of exposition:
1/33 sec.

Focal lenght:
18mm

ISO: 1600

Dimension:
5184 X 3456 pxl

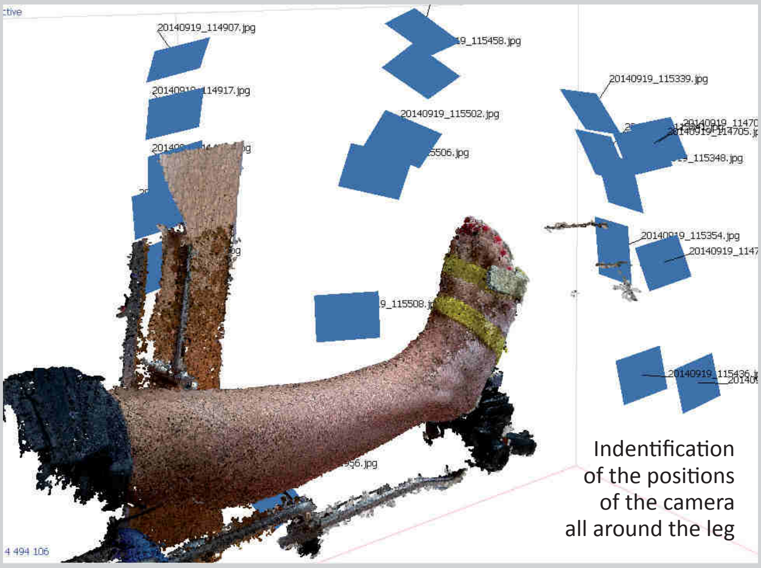
EXECUTION TIME:
5 minutes

LOCATION: Out-door garden

DATE: 19-11-2013

OUTDOOR ACQUISITIONS WITH I.B. MODELLING N.1

These tests were conducted outdoor in order to avoid all the problems of light reflections of a photographic set and to test if it was possible to carry a survey in a more friendly environment.



Indentification of the positions of the camera all around the leg

DESIGN

OUTDOOR ACQUISITIONS WITH I.B. MODELLING N.2

This series made thanks to the collaboration of an 8 years boy failed because the photos at the heel were out of focus. This was a common error that had carefully to be checked during acquisition.

ACQUIRED DATA

INSTRUMENT:
Canon EOS 650D

NUMBER OF PHOTOS: 17

F-stop: f/4.5

Time of exposition:
1/33 sec.

Focal lenght:
18mm

ISO: 160

Dimension:
5184 X 3456 pxl

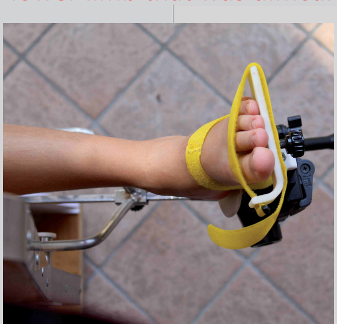
EXECUTION TIME:
4 minutes

LOCATION: Outdoor garden

DATE: 25-11-2013

OUTDOOR ACQUISITIONS WITH I.B. MODELLING N.3

Several tests were made with the collaboration of a 6 years old girl in order to perfect several details of the protocol of the acquisition. In particular one of these series failed for another problem of illumination. As can be seen from the image below, the natural ligh t coming from the exterior part of the leg wasn't enough balanced by an artificial one on the internal side and the image-modelling gave as a result two different shells of the lower limb that was difficult to accurately merge.



ACQUIRED DATA

INSTRUMENT:
Canon EOS 650D

NUMBER OF PHOTOS: 33

F-stop: f/5

Time of exposition:1/50 sec.

Focal lenght: 35mm

ISO: 400

Dimension: 5184 x 3456 pxl

INSTRUMENT: Samsung S4

Dimension: 5312 x 2988 pxl

EXECUTION TIME: 5 min.
LOCATION: Outdoor garden
DATE: 29-11-2013

INSTRUMENT:

Camera Canon EOS 500D

RESOLUTION: 15.10 Megapixel

FOCAL LENGHT:
1,6x zoom
18-70 mm

VIEWFINDER:
Optical / LCD

ISO: 100-6.400

SHUTTER: 30-1/4000

Smartphone Samsung S4

RESOLUTION: 13 Megapixel

DATA PROCESSING

The phase of processing of data didn't involve particular changes from the first test at the Fondazione Bruno Kessler in Trento. The process remained almost the same, but an higher attention was put on the individuation of common markers between the photos and in the definition of metric scale. In particular in these cases the measure of the pieces of the bench that support the child and the pieces of the pedal which stops the foot were used to scale the object.

ACQUIRED DATA

In this context it is considered useless to report all the single acquired data per each test, considering the aim for which they were carried out. However the most relevant information are report in the tests' boxes. Nevertheless it is interesting to notice how the acquisitions were made with different instruments from a professional camera to the basic camera of a smartphone and both proved to work.

CONSIDERATION ON THE RESULTS

An interesting conclusion of this comparison is that a **top quality camera is not synonymous of guarantee of a better result**. On the contrary managing a professional camera can be more tuff for a clinical technician without any experience in photography. The calibration of the proper focal length, combined with the correspondent distance between is crucial to determine the result of the photo-acquisition. Moreover, as already said, the software computes better the frame in which the leg occupies at least 2/3 of the photo. This element instinctively lead to prefer a shorter focal length to have a wide angle lens, but this factor imply a larger barrel deformation along the edges of the picture, that are exactly the ones on which the software works to match the photos. Furthermore if we reduce the focal length and open the diaphragm the depth of field will drastically decrease and we'll have a central area of the photo that is focused, but the further parts of the leg will be defocused, causing problems in matching with other photos.
On the contrary the optical of a smartphone is drastically simpler and tends to focus all the parts of the photo. Moreover it proved to be simpler to be used, especially during the acquisition of the back of the leg. Concluding, modern smartphones have an image resolution definitively adequate for the aim of the survey.

7.7 – TESTS OF SURVEY OF A CHALK MANNEQUIN'S LEG USING AN HAND SCAN

AIM OF THE TEST

The aim of this test was to verify the applicability of hand scanners for the aim of the research. In particular this first test was made on the same mannequin leg in order to have comparable results and to avoid other possible causes of errors due to a living body survey.

ENVIRONMENT SETUP

The mannequin's leg was resting on a table with empty space left all around the table to be free to move all around during the acquisition in an indoor laboratory.

CARRYING OUT OF THE TEST

The first step for the acquisition contemplates the setting of the instrument. Once the scanner is connected with the computer, its software was launched and here we defined the acquisition settings: the scene, that we configure as a body with a bounding box of 0,6x0,6,0,6 meters, with a normal aspect ratio, an high feedback quality and a continuous *"all frames recording"*. Then the acquisition was carried moving slowly the scanner all around the leg in every direction. A great advantage of the instrument is that in the same time you survey you can check on the computer the progress of the acquisition.

DATA PROCESSING

The phase of recording concluded, the first step of data processing was the reconstruction and elaboration of acquired information. It was done by the same software related with the scanner and it was possible to decide if we wanted to prioritize the speed of the process, with a lower involvement of CPU, or we desired a more accurate result. We preferred this last option and set for an High Fidelity. At the end of this process a 3D mesh was elaborated that described three-dimensionally the shapes we acquired in a 1 to 1 scale.

At this point the software allowed further elaborations in order to improve the quality of the mesh, to colourize it developing a texture, but we preferred to export the mesh into Geomagic Studio to finish the last optimizations of the surface .

CONSIDERATION ON THE RESULTS

The final model proved to be really accurate in the leg part, while, some errors can be detected at the tip toe, at foot fingers, maybe because the child moved during the acquisition and his foot needed to be locked squeezer. However this test proved how handy scan is technically the best solution among the ones we tested, in terms of

INSTRUMENT:

3D SYSTEMS 3D Sense - Scanner 3D

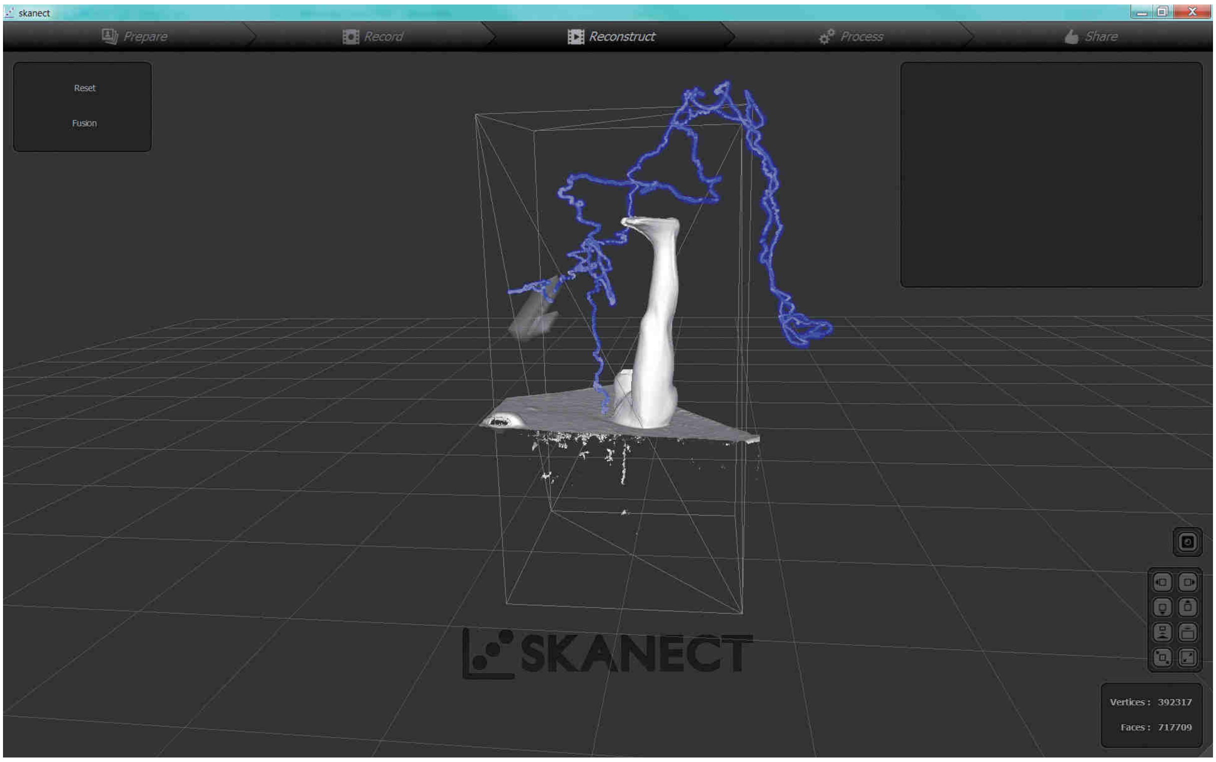
POWER CABLE:
USB cable

SOFTWARE:
Skanect

DIMENSION:
17,8 x 12,9 x 3,3 cm

The line marked in blue shows the path made by the and scanner all around the mannequine's leg (below)
The final 3D model obtained by an hand scanner survey

accuracy, immediately response on the accuracy of the result and short time of acquisition. The motion of the technician is continuous, slow and regular and if an area isn't acquired at the first round, a second one is possible with an automatic matching of the two shapes.



ACQUIRED DATA

INSTRUMENT:
3D Systems Sense scanner3D

OPERATING RANGE:
0,35m to 3m

SPATIAL X/Y RESOLUTION
@0,5m: 0,9 mm

EXECUTION TIME:
4 minutes

NUMBER OF MESH TRIANGLES ELABORATED:
483.652

LOCATION: Indoor

DATE: 28-09-2014

7.8 – TEST OF SURVEY OF A CHILD'S LEG USING AN HAND SCAN

AIM OF THE TEST

In occasion of the final test carried on a child sit on the bench it was made a double acquisition, with a handy scan and with photo-image, in order to have a direct first comparison on the accuracy of the results. Starting from the successful results of the survey with hand scan of the mannequin's leg this test proves the application of this technology on a lower limb of a child sitting on the support that allocates his foot in a stretching position.

ENVIRONMENT SETUP

The acquisition was carried in an outside environment, under a porch that prevents from direct rays of the sun and with an artificial light from the closed side of the veranda, to compensate and uniform the lighting.

The child was sitting on the bench and a table was located nearby to hold the computer, to which with a long USB cable, was attached the handy scan. The space all around the bench was left empty to allow a free movement to frame the patient from each side.

CARRYING OUT OF THE TEST

The test was very simple. For about two minutes the hand scan was rotate slowly all around the leg from all the points of view and at the same time the images on the computer verified the proceeding of the test.

DATA PROCESSING

The acquisition concluded, the software elaborated in few minutes all the survey and gave as a result the 3D model of the leg with the possibility of associating a coloured texture on the mesh for a more photorealistic effect.

CONSIDERATION ON THE RESULTS

This test gave soon optimal results. The scanner is extremely simple to use, it requires almost no training and the final 3D model had a uniform and smooth surface and with an average level of details' accuracy. Moreover, from the observation of the path described handling the scanner in hand and moving all around the leg, we can evaluate as soon as we finish if we moved properly or if we ignored some parts or linger too much on others.

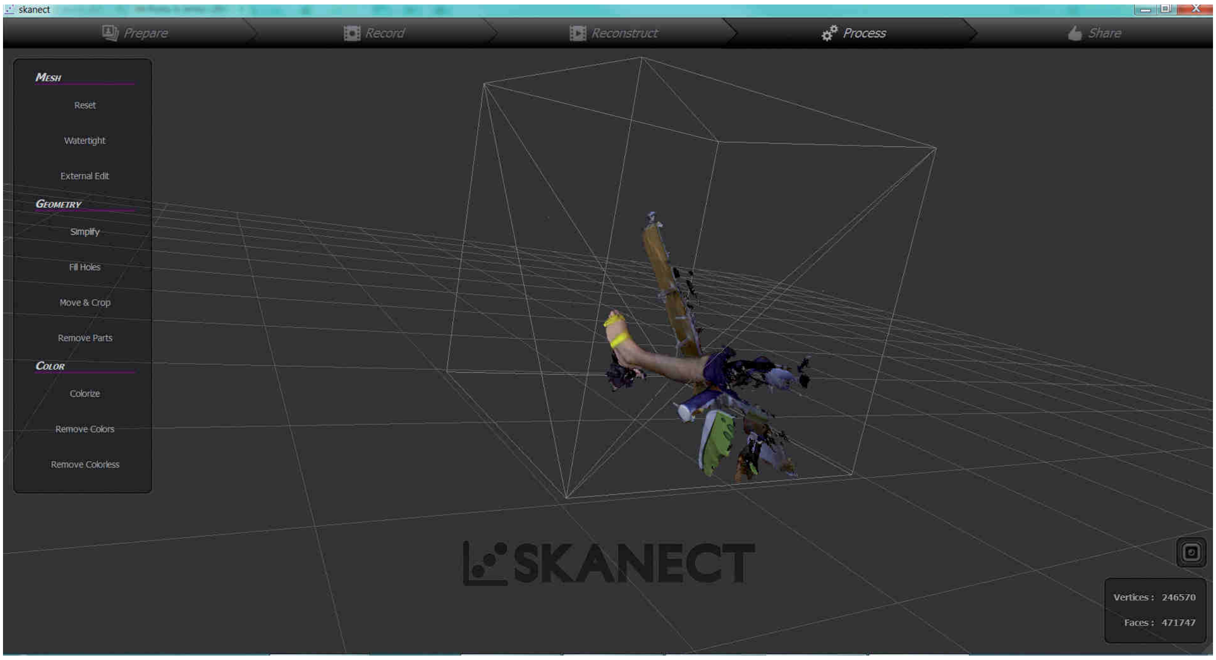
INSTRUMENT:

3D SYSTEMS 3D Sense - Scanner 3D

POWER CABLE:
USB cable

SOFTWARE:
Skanect

DIMENSION:
17,8 x 12,9 x 3,3 cm



The line marked in blue shows the path made by the and scanner all around the mannequine's leg

The final 3D model obtained by an hand scanner survey

ACQUIRED DATA

INSTRUMENT:
3D Systems Sense scanner3D

OPERATING RANGE:
0,35m to 3m

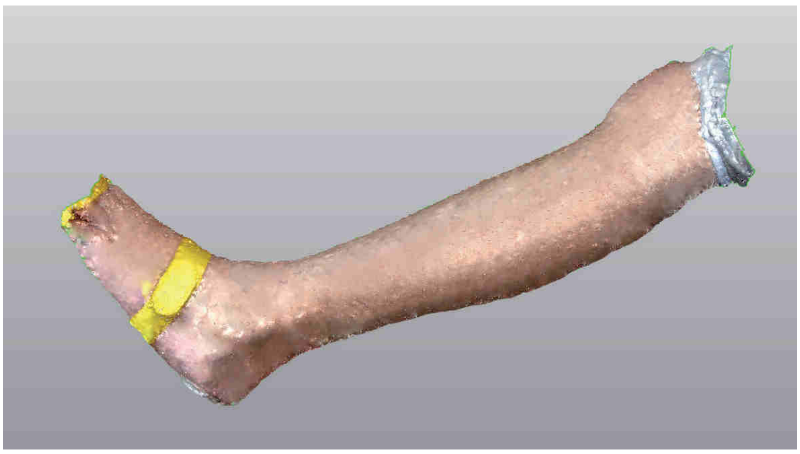
SPATIAL X/Y RESOLUTION
@0,5m: 0,9 mm

EXECUTION TIME:
5 minutes

NUMBER OF MESH TRIANGLES ELABORATED:
67.316

LOCATION: Indoor

DATE: 29-11-2014



DESIGN

7.9 – Final test of survey of a child's leg using Image-Based modelling and Hand Scan

AIM OF THE TEST

The goal of the last test is to reassume and put in practice all the gained experience in Image Based Modelling and Hand Scan, to prove the efficacy of the processes and their applicability in this context. In occasion of the test carried on a child sit on the bench it was made a double acquisition, with a handy scan and with photo-image, in order to have a direct first comparison on the accuracy of the results. In the previous chapter we illustrated the hand scan acquisition. Hereinafter the Image.Based modelling is presented and the comparison among the two results.

ENVIRONMENT SETUP

For the final test we choose an open air environment, a porch completely open from one side, shielded from direct sunlight and illuminated from the closed side with artificial light to compensate the brightness and to provide the leg of a uniform and vivid light. Moreover we discovered that it was simpler to persuade children to collaborate at the test in a garden when many other toys were present and where my bench seemed just one of the others. The child was relaxed, we recreated a playful atmosphere, she chose the character of the exterior panels of the "rocking horse" and we asked her to sit on the bench, we fixed her foot at the pedal in the correct position and we started with the set of photos.

INSTRUMENT:

3D SYSTEMS 3D Sense - Scanner 3D

POWER CABLE:
USB cable

SOFTWARE:
Skanect

DIMENSION:
17,8 x 12,9 x 3,3 cm

CARRYING OUT OF THE TEST

The set of photos was taken proceeding following the three circles of orthogonal system of axis centered in the knee and aligned with the leg, taking a picture every 30 – 40 degrees. Maintaining the same focal length we put some marks on the floor to keep averagely constant the distance between the camera and the closer point on the leg.

DATA PROCESSING

All the photos were imported in the software. To facilitate the process of photo-matching on each photo it was created a mask that put in evidence all the relevant part that needed to be virtual reconstructed in 3D and covered all the part that were considered irrelevant for the aim of the test. At this stage it was important to leave visible even all the elements that were not part of the leg but would be useful in the determination of the scale of the model. Then, common markers were placed to individuate reference points visible in more photos. This step was a support for the software to proceed in a first alignment of all the photos. Once it was done, the automatic process calculated the position of each camera and created a sparse point cloud containing common point visible in more than one frame. Then, thanks to the markers we inserted, we calibrated the scale of the object, optimized the alignment, build a dense cloud and eventually its relative mesh.

(on the next page)
Acquisition of the images of the leg, postprocessing of the 3D point cloud, mesh and comparison between this 3D model and the one obtained by hand scan survey

CONSIDERATION ON THE RESULTS

The results of the test fulfills the aim for which it was arranged. The 3D reconstruction elaborated from photo-modelling has a detail and accuracy sufficient to be used as a basis to elaborate a customized orthosis. The most difficult part of the process remains the phase of acquisition since it’s easy to shoot out of focus images especially with a professional camera, and in the photos that frames the back of the leg. The solution of a good smartphone or a proper setting of the camera to maintain in focus all the elements in the picture could solve this problem and improve the results. Moreover those tests were even the occasion for testing the bench for stretching the foot. Some problems appeared and this lead to the decision of changing some of its features in the passage from the prototype to the final model.

COMPARISON OF DATA AMONG DIFFERENT SURVEYS’ TECHNIQUES

The shape acquired with the method of Image-Based Modelling was composed with the one obtained by hand scan survey. The comparison among the two shapes was carried out with the support of the software dedicated specifically to this aim Geomagic Qualify 2013. The 3D virtual reconstruction of the morphology acquired by an hand scan and the one obtained with Image – Based – Modelling were imported in a common space, manually rough registered, than automatically arranged by a Global Registration and at the end a Best Fit Alignment was processed in order to have the best matching possible between the two shapes, taking in consideration a correspondence of 100.000 points on each surface. At the end of this process a coloured representation shows the results of the analysis illustrating the deviation between the two surfaces. It appears that the maximum deviation is of five millimeters near the knee and the tip toe, but it can be due to natural movement of the child between one acquisition and the others. What is important is that the average standard deviation is less than 3 mm and that the area where the most relevant errors are located will not be interested in the modelling of the orthosis.

ACQUIRED DATA

INSTRUMENT:
Canon EOS 650D

NUMBER OF PHOTOS: 20

F-stop: f/5

Time of exposition:
1/60 sec.

Focal lenght:
50 mm

ISO: 1600

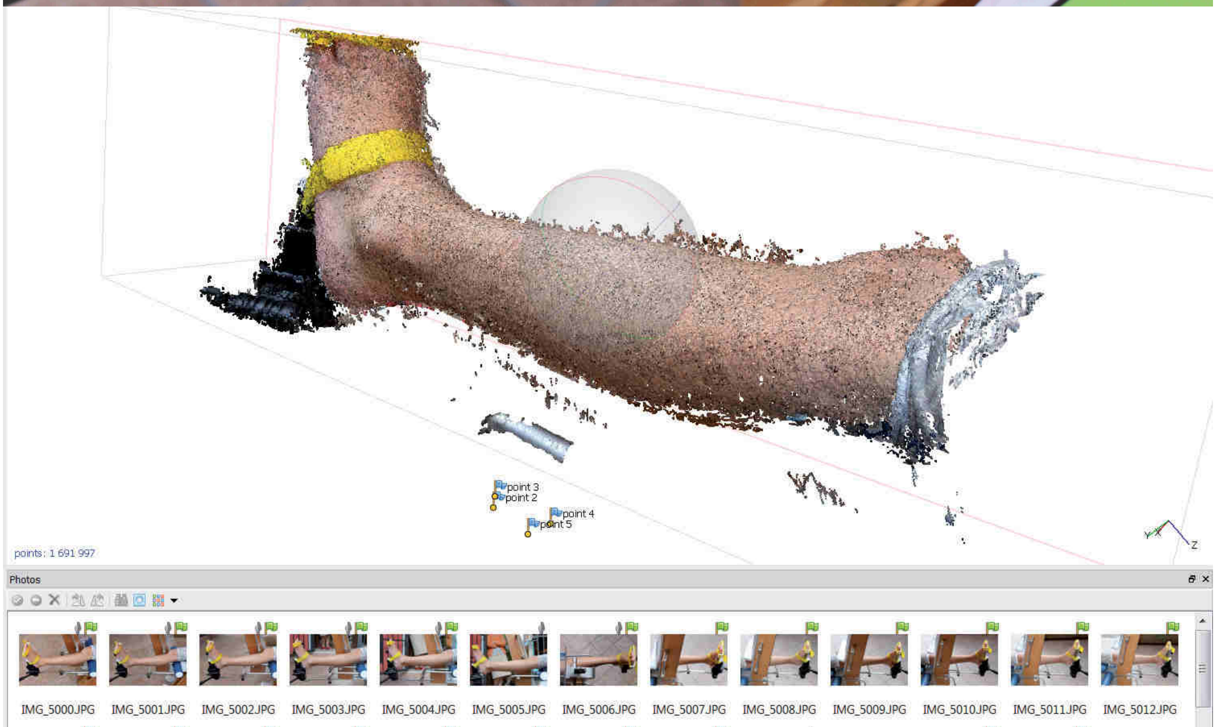
Dimension:
4752 X 3168 pxl

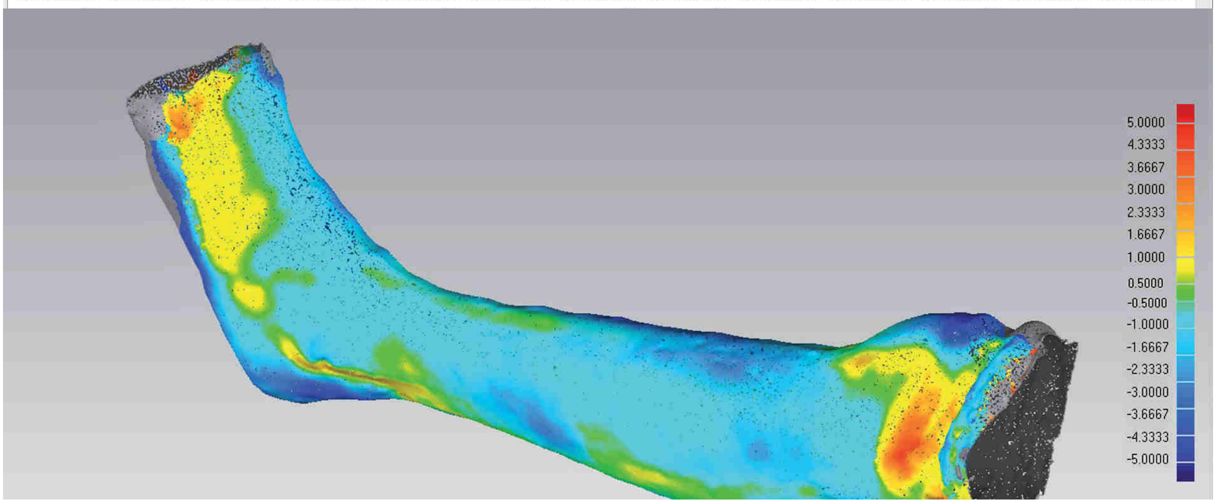
Number of mesh triangles elaborated:
67.316

EXECUTION TIME:
5 minutes

LOCATION:
Outdoor garden

DATE: 19-11-2013


point 3
point 2
point 4
point 5
points: 1 691 997
Photos
IMG_5000.JPG
IMG_5001.JPG
IMG_5002.JPG
IMG_5003.JPG
IMG_5004.JPG
IMG_5005.JPG
IMG_5006.JPG
IMG_5007.JPG
IMG_5008.JPG
IMG_5009.JPG
IMG_5010.JPG
IMG_5011.JPG
IMG_5012.JPG


5.0000
4.3333
3.6667
3.0000
2.3333
1.6667
1.0000
0.5000
-0.5000
-1.0000
-1.6667
-2.3333
-3.0000
-3.6667
-4.3333
-5.0000

7.10 - CONCLUSIONS OF SURVEY TESTS' PHASE

The phase of testing of the several alternative techniques of survey reached a satisfactory level of definition but it can't be considered concluded. First of all it demonstrated that it is possible to survey the foot in a stretching position but at the same time acquiring all the measures required to create a customized orthosis on the shape of the lower limb. Then it proved the efficacy, at least as a principle of the designed bench that supports the child during the minutes of acquisition, even if will see in the next paragraph how these tests on field evidenced some weak points of that prototype too that lead to the design of a second prototype.

On regard of the three technology tested we can make some observations:

- ***Desktop scanners*** guarantee the highest resolution and accuracy compared with the other techniques. However it is a static technology that proceeds by steps. Between one station and the other it is necessary to move the machine and the tripod in a new location and reset the scanner. Even if it is done quickly, it loses precious minutes that could affect the final result since the boy in the meanwhile could voluntary or involuntary move. This type of technology are more suited for small objects than living bodies and for this reason they are not indicated for this research.
- ***Hand scanners*** are probably the best solution tested until now. It is extremely simple to be used even without a specific background knowledge in laser scanner survey, it reveals in real time if the acquisition is successful or if some parts are lacking and it would be better to integrate them, it is light, transportable and easily manoeuvrable all around lower limb. The one that was tried in this research was a really "basic one", economic and with few adjustable parameters, but it still gave very interesting results. Moreover the costs of an hand scanner is usually quite affordable for every healthcare center, even a real professional one usually don't get over 1.000 euros. In this phase hand scanners with a software for the interpretation of feet weren't tested. However, in the illustration of the algorithm that gives shapes to the AFO, we'll see how everything was set in the eventually of an application with this technology too.
- ***Image-based modelling*** is a technology which application is rapidly increasing and that gives good results even in this case. Its greater advantage is undoubtably the low cost of the instrument, since we proved that even the photos made with a medium quality smartphone gave acceptable results. However this is paid with a slighter longer and a little bit more difficult process of elaboration of images and with a manual scale of the model that could be even very accurate but it has to be done manually.

However the aim of this research is not only finding the best technical solution possible since technology developments are so quickly that for sure, in the meanwhile we're discussing this thesis new better instruments are coming on the market. For this reason both the techniques, of hand scanner and image-based modelling can be considered acceptable and case by case it can be decided which one is more suitable for the context.

In the following paragraph the process of design of the support for the child during the indirect survey of his feet is illustrated.

8 DESIGN OF A SUPPORT TO SURVEY LOWER LIMBS IN STRETCHING POSITION

8 – DESIGN OF A SUPPORT TO SURVEY LOWER LIMBS IN STRETCHING POSITION

Previous chapter on survey techniques evidenced how the application of new technologies of 3D indirect survey can improve the process of customization of the AFO on the foot shape. Moreover the research highlights the possible advantage of an indirect survey made positioning the foot at the best stretching possible position for the user in that moment.

In DMD patients' feet retractions and deformation are progressive but for any range of dorsiflexion that becomes rigid and no more recoverable, if not with surgical lengthening of Achille's tendon, there's another range of dorsiflexion that can be reached applying a stretching force on the foot. Therefore designing an AFO that arranges the foot not just in its relax position but with the best alignment the child can still achieve, improves the clinical efficacy of the orthosis.

In order to achieve this result a special bench was designed to host children during the minutes of their limbs' survey. It is an innovative product and nothing similar was found on the market. It looks like a rocking horse, to stimulate children's fantasy and creating a playful atmosphere and it is designed to be used from infancy to adolescence. But this prototype is even provided by a sort of "pedal" that bounds a foot at a time in the position fixed by the therapist for the minutes of the acquisition. This pedal allows to regulate and control the position of the foot in each direction and apply the required and possible stretching force.

This experimentation on this support went through two different prototypes in the attempt of improving functionality and aesthetic and all the design process is hereinafter illustrated.

8.1 – CONCEPT

The observation of the most common processes of realization of a night AFO for people affected by Duchenne Muscular Dystrophy lead to the conclusion that the phase of survey of the foot's shape was one of the first weakest point on which the application of modern technologies of indirect survey could bring interesting improvements.

As we know, with the progression of the disease the thickening of the Achille's Tendon, along with the decrease of muscular strength, causes retractions and deformations. However this is a progressive evolution of the equines foot and, while small ranges of plantarflexion are progressively lost, there are always at the same time ranges of movement that can still be reached through proper stretching movements. The aim of the stretching activity exerted regularly by the therapist on DMD lower limbs is indeed to work on this range of flexibility, in the attempt of maintaining that range of movements for the larger time possible. It is a quite painful activity for the patient but it is one of the best techniques to delay the progression of Achille's tendon retractions.

The function of night AFO is to prolong in a passive way the exercise made by the therapist and stimulate dorsiflexion, while stretching the calf. With traditional techniques of AFO's manufacturing the plaster is made while the foot is in a relax position and only subsequently the therapist communicates, to the technician that will realize the orthosis, an empirical range of dorsiflexion that has to be impressed on the mold. In this way the AFO will haven't only a function of maintaining the dorsiflexion of the foot but even of applying a little stretching force. However it can be easily observed how this handicraft method, even if conducted by expert technicians, tend to loose precision in the direction and range of movement, and risk to lose precious angles of dorsiflexion that the patient is still able to reach.

In the previous chapter I've illustrated all the potentials of modern technologies of optical indirect survey that allows to acquire high detailed reconstructions of the foot's shape without recurring to direct techniques. But to make this acquisition effective, during the minutes of the survey, the foot has to be placed in the best position possible of stretching considering his specific retractions and needs in that moment. It is a really delicate task and it has to be made by a physiotherapist or a member of the medical staff that has knowledge and skills with this topic. During the first test at the Policlinico Gemelli in Rome we supposed that a technician could lock the foot in the correct position during the phase of acquisition but we observed that this choice wasn't practicable since the boy tends to move during the acquisition and the therapist cannot bear such a strain for all the time of acquisition without moving himself.
Moreover the presence of the technician person near the user causes unavoidable shadows cones, causing an incomplete acquisition of the foot's shape and compromising the success of the result, as in the photo-based modelling as in the laser scanner acquisition.

All these considerations lead to the evidence of a need of a sort of **bench for the child, on which hanging a device able to control and lock the foot during the minutes of the indirect survey**. I looked further for similar devices on the web but I didn't find anything comparable and therefore I started with the design of a completely new and innovative object.

A boy of 12 years old affected by Duchenne Muscular Dystrophy in his maximum stretching of dorsiflexion

DESIGN

8.1.1 – Users’ needs

As for the design of the AFO, even for the design of this bench the first step of the design process was the individuation of its main users and, subsequently, their needs on this regard. The individuation of the users was very simple:

- the therapist, or trained technician, can be a man or a woman, young or old and therefore I had to consider that he could not be able to carry heavy objects or to perform complex operation of assembly and disassembly. Each procedure he has to made must be really simple and quick;
- users: male children from infancy to adolescence. His age could vary from a very little child, of two-three years old to a boy of 18-20 years who is no more able to stand alone and is wheelchair bounded but who still wears AFOs to counteract the progression of feet’s deformation and their painful consequences.

The drawing up of the list of user needs was quite demanding since I almost cannot rely on someone since the object doesn’t exist and the user cannot refer the experience to almost anything similar. However I tried to interpree and hypnotize their requirements towards the design of the bench and I collected them in a table, organized by categories. In particular I marked with an orange dot therapist’s eventual requirements, while the blue dots are referred to possible expression and desires expressed by the child.

Efficacy requirement were supported by literature research and by the direct contact with the medical staff of the Policlinico Gemelli in Rome. The surveyed need was the necessity of extending the problem of dorsiflexion and considering the necessity of a device able to control the foot in any direction in order to include the possibility of contextual other deformations or misalignments. Once the therapist regulates the optimal position for one leg, it has to be tightly bound in order not to move from that position for the minutes of the acquisition. Regarding this, it must be noticed that the limb is fixed in a stretching position and this could be even slightly painful for the child. For this reason it is extremely important that the acquisition lasts as less time as possible. It has to be contemplated that the child could become intolerant to the situation or that involuntary jerks could occur and invalidate the result of the acquisition. Unfortunately until now we don’t have scientific data that attest the amount of strength and pressure that DMD children can apply on the pedal and therefore we’ll proceed in an empirical way. In order to acquire the entire shape of the limb, the surface has to be completely free and visible from all points of view. Feet locking systems has to be as small as possible and their location must be carefully designed. Moreover in the following chapter of the parametric design of the AFO starting from the 3D model of the limb, we’ll see that in order to develop the algorithm, besides the overall shape of the foot, 15 control points have to be absolutely visible and easily identified on the virtual surface.

Furthermore to make this bench suitable for different techniques of indirect survey, it is important to locate a metric reference on the support, visible and high contrasted, in order to scale photos in case of an imaged-based survey.

Ergonomic issue is one of the other main concern in the design of support, it will be better illustrated in the following paragraph but as a hint we can say that the aim of this design is creating something adjustable and adaptable. The range of age broadly indicated is from 2 to 20 years, it is probably an estimation by excess, but it is a precautionary measure that takes in consideration even the possibilities of a very short or tall boy.

Other concerns have to be considered on the overall **functionality** of the process. The necessary speed of the acquisition has to be evaluated in any phase. Since boys are young it's very simple to pick them up and sit on the support. But when they grow, they become heavier, they start to loose control of their muscles and to be wheelchair bounded. In this condition the transfer of the boy from the wheelchair to the bench has to be programmed in the safest and agile way possible. The child has to be able to stop on the side of the rocking horse and, with the same transversal movement he usually does to sit on the toilet, be laterally dragged on the bench. But to accomplish this manoeuvre, two conditions have to be satisfied. First of all the bench has to be stable, without risk of tipping over or slipping on the floor. Then, the bench has to be at the same high of the sit of the wheelchair. Then if the boy lost its trunk control or he is too young to stand alone, it has to be easily and safety secured at a back. Last but not least, since this object is supposed to be located in a clinic, an hospital or even an orthopaedic manufacture, if equipped with skilled and qualified technical staff, there will be used each time a Duchenne boy, or someone with his same needs, who has to order a new pair of AFOs. Therefore its use will probably not be daily and it could be desirable if it could be packed and stored in a small space, but easily and quickly mountable if necessary. Moreover among the eventual requirements the possibility that this support has to be moved to other structures or to some patient's house if he is unable to move, must be considered. This imply that the bench should be light, compact and easily transportable.

EFFICACY	CLINICAL	It has to put the child's foot at the higher range of dorsiflexion he can achive whitout pain, starting from 90°
		It has to control the varus foot
		It has to control the valgus foot
		It has to control the plantar flexion
		It has to control the equinus deformity
		It has to be graduated in order to control the evolution in time of the position of the leg and of the foot of every child
	IN FIXING THE POSITION	It has to lock perfectly the leg during the acquisition
		It has to lock the knee
		It has to lock the ankle
		It has to lock the foot
		I need to move and fix the position of the foot in every direction in the space.
	IN THE ACQUISITION OF THE SHAPE	The surface of the lower limb must be as much visible as possible, from every angle, to have a complete virtual reconstruction from which extract the required measures of the AFO
		The 15 key point useful in the parametric diagram for the reconstruction of the AFO must be absolutely visible.
		I need to move freely all around the leg during the acquisition
		If I survey the foot with an image-based modelling process, I need to see something appropriate that can be used as a metric reference in the scale of the 3D reconstructed model.

ERGONOMICS	🟠	It has to fit with the size of my foot
	🟠	It has to fit with the circumference of the thight
	🟠	It has to fit with the lenght of my leg
	🟠	I It has to be adaptable to all the children
	🟠	The transfer from the wheelchair to the bench has to be as much simple as possible.
FUNCTIONALITY	🟠	I would easily adjust it after the child is sit on it
	🔵	I don't want to wait so long until the technician finish to put my leg in the right position
	🟠	I want to carry it easily from one room to the other in the hospital, or even by car if I have to made a survey
COMFORT	🟠	If the sit is comfortable it will be easier for me to keep the child calm without moving the leg during the acquisition
	🔵	I would like a soft sit and back
	🔵	I don't want all the process last too much
	🔵	It has not to hurt
SAFETY	🟠	It has to be safe in the use
	🟠	It has to be without any element that could scratch the skin of a baby
	🟠	It has not to break easily
	🔵	I don't want to fall
	🟠	The back of wheelchair bounded boys must be carefull tied at the back of the chair since they can't control more their own equilibrium
	🟠	It has not to tip over
HYGIENE	🟠	It must be hygienic
	🟠	It has to be easily cleaneable
	🟠	Every tissue or padding present must be hypoallergenic
ECONOMY	🟠	It has to be cheap
	🟠	Every hospital should be in the condition of buying this support
	🟠	It has not to break easily
	🟠	It has to be durable
	🟠	It has to be simply built and with cheap material so that every medical center that needs it, could built it easily and with a cheap expenditure
ESTHETIC	🔵	I want it to look like a joke
	🟠	The child must not be scared by the aspect of the support
	🟠	It has to be considered cool and pleasant by the children of every age

🔵 CHILD'S NEEDS

🟠 TECHNICIAN'S NEEDS

Classification of users needs regarding the support of the baby for the 3D foot acquisition

Safety is indeed another imperative requirement that implies that any parts of this bench have to break or could hurt neither the boy nor the doctor and this requirement for some issues, especially since we're talking of an object located in an hospital is closer to **Hygiene** requirements, since it will be used by different people. Assuring the Comfort of the technician that can easily move and operate all around child's lower limbs is important but, of course guaranteeing the comfort for the children is a condition that could directly affect the predisposition of the child of collaborating with the therapist. This trust and peaceful atmosphere is extremely important for the obtainment of a good result.

Psycological factors play even in this context a crucial role. The bench has not to be designed as an isolated object but all the situation and the process has to be evaluated. Even if maybe in a clinical context, in that moment the child isn't doing anything related to his cures. Indirect survey offers many advantages in this sense, is less intrusive compared to a plaster and doctors can stimulate children's curiosity in a playful atmosphere. This bench hasn't to look like an hospital device, its reassuring aspect has to invite the boy of approaching it even without considering its use.

Bench **Aesthetic** has to be considered pleasant, playful and cool by children of every age. Children, especially the youngest ones, are not interested in the aim of the bench, they have just to feel curious and amused by the object to the point of accepting that, while they're imaginatively riding this horse, or car, or motor, or animal, or whatever character, doctor lock one by one their feet.

Concluding, it must be cheap. **Economic** issue can never be ignored and a cheap, durable, simply built product has always more chance of being adopted and become common. Every clinic, without a great effort or expenditure has to be able for adopting this method, including not only the bench by itself, but all the technologies required to conduct the indirect survey and, more generally, to manufacture the AFO.

Ultimated this step of overall survey of users' possible requirements towards this new object, the attention focussed to the most difficult and characterizing part of the bench, the pedal that, arranged by a skilled technician, collocates the foot in the best position possible before its virtual acquisition.

8.1.2 – TECHNICAL REQUIREMENTS: Foot spatial control

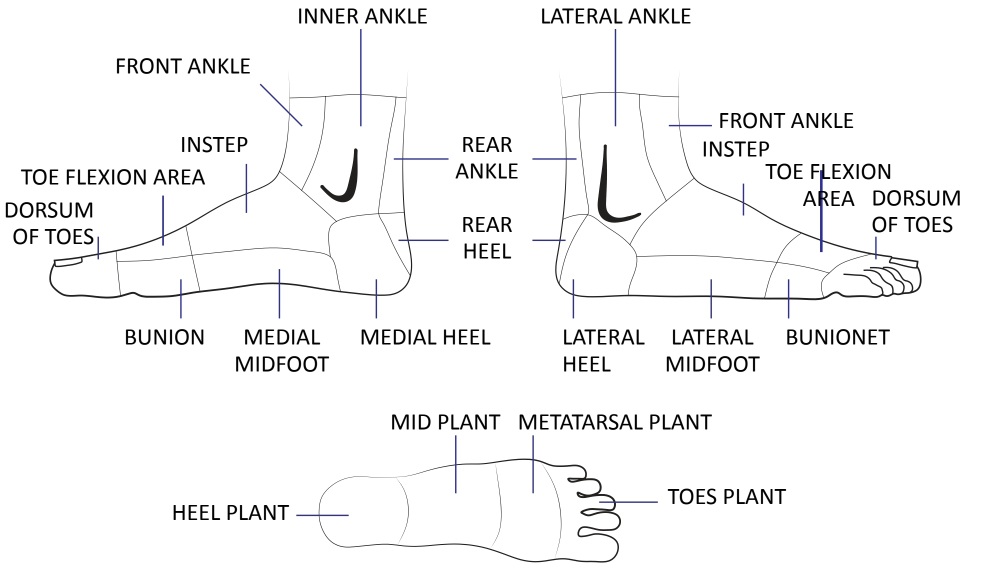
Technical and functional requests aimed at the operation of the support were addressed mainly in two fields: the design of the spatial control system for the foot and the ideation of all the accommodations and devices that makes the support usable by children from 2 to 20 years.

The first device has the function of locking the foot in a stretching position and to correct all the mobile deviations, and retractions, but also to restore the best alignment possible for that particular foot. It has basically to substitute the hands of the therapist and to maintain firmly that position for the minutes of the acquisition. In order to develop skills, knowledge and terminology necessary for the ideation of a similar device I started from scientific literature that described anatomically the different parts that compose the foot.

It is one of the most complex part of our organism, it is composed by 28 bones, 33 articulations and 20 different muscles. It can be generally divided in three parts: ***forefoot, midfoot***, ***hindfoot.***

Its function can be compared to a truss, where the traversal arch is located at the metatarsal heads and the vertex at the heel generating two external and internal longitudinal arches. The last one is the most important from a static or dynamic point of view since it is more elastic than the external one[1].

I reproduce here below the scheme I followed in the individuation of the areas of the foot. It was particular important especially in order to acquire specific terminology to adequately interface with the medical staff that supported and validated the project.



Foot's zones

NACHER B. et al., *3D foot digitizing and its application to footwear fitting*

The study of the anatomy of the foot was even useful in order to quantify the morphometric of the foot and which parameters had to be controlled.

One element that had to be carefully evaluated was the great variety of measures and shapes that occur between feet of different people, of the same person in different age, or even in different days and positions. In theory the feet grow until the average age of 14, but scientific papers report that even after that period the

1 CORAZZOL M., *Configurazione morfometrica del piede in relazione a condizioni patologiche,* Master's Thesis at the Faculty of Engineering, University of Padova, 2009-10

shape of the foot continues to change in the relationships between the parts. Furthermore, in a DMD person the retractions, if not properly cured, could continue in parallel with the progression of the disease. Moreover the plantar flexion of people with DMD can be even associated with other deformities of the feet, that could be caused by different factors and that requires to be analysed case by case. For this reason I didn't study the different pathologies of the foot, but only the deformations and the possible movements in the ankle joint, that provoked that defomation.

The main movements that were codified are:

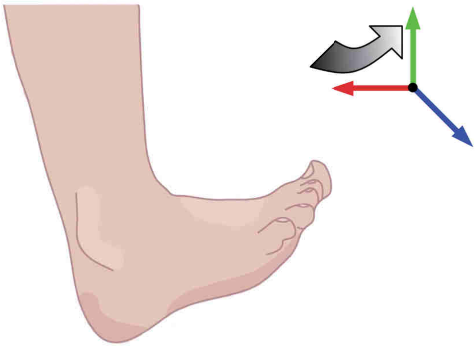
- ***dorsiflexion, or flexion,*** upward movement caused by the ankle that brings the foot toward the anterior tibia bone;
- ***plantar flexion, or extension,*** downward movement caused by the ankle that brings the foot away from the tibia
- ***abduction,*** turning the ankle and the foot outward, away from the midline but the weight is on the medial edge of the foot
- ***adduction,*** turning the ankle and the foot inward, away from the midline but the weight is on the medial edge of the foot
- ***eversion,*** turning the ankle and the foot outward and the weight is on the internal edge of the foot
- ***inversion,*** turning the ankle and the foot inward and the weight is on the external edge of the foot
- ***toe flexion***, movement of the toes toward plantar surface of the foot
- ***toe extension***, movement of the toes away from the plantar surface of the foot
- ***pronation***, is composed by eversion, abduction and dorsiflexion
- ***supination***, is composed by inversion, abduction and plantar flexion[2].

These observations and the study of the movement of the ankle and the foot were essential in the design of the fixing system for the foot during the 3D virtual acquisition. The analysis of foot complications by the decomposition of the direction of the movements of deformation allowed to focus more on the effect that has to be counteract, more than on the trigger pathology, which is a medical concern.

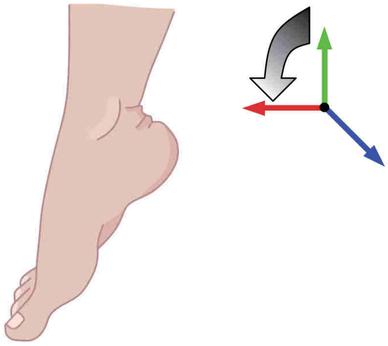
2 MAGEE D. J., *Orthopedic Physical Assessment*, Elsevier Health Sciences, 2008, pp. 872 - 914

MOVEMENTS OF ANKLE AND FOOT

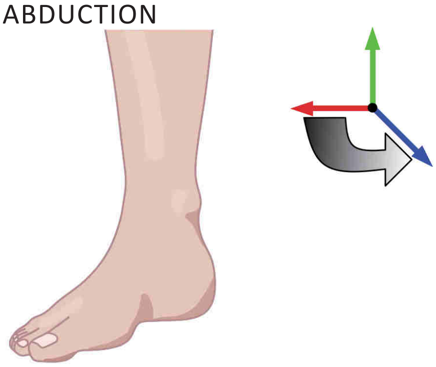
DORSIFLEXION



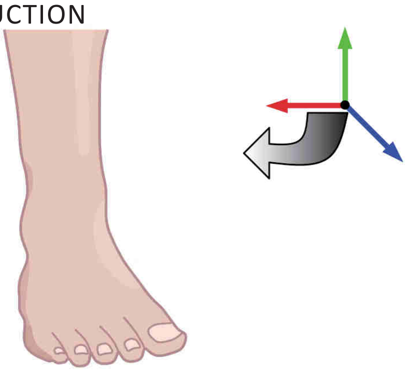
PLANTAR FLEXION



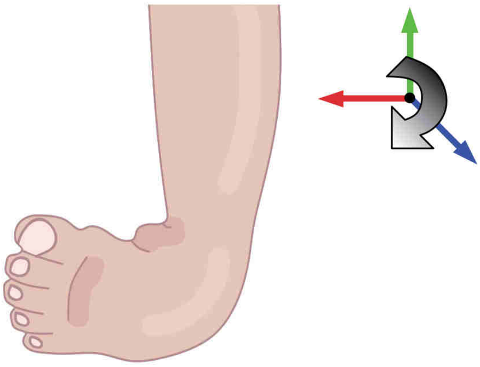
ABDUCTION



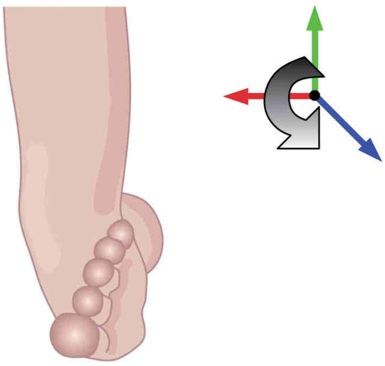
ADDUCTION



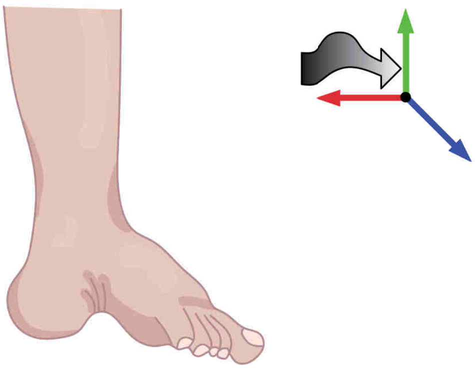
PRONATION

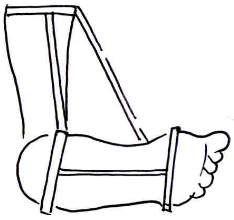


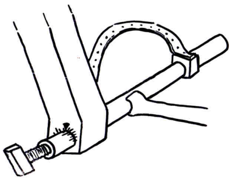
SUPINATION

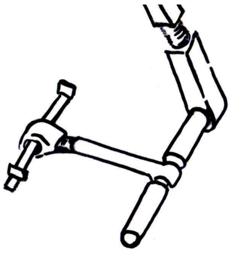


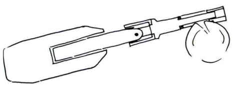
CLUBFOOT

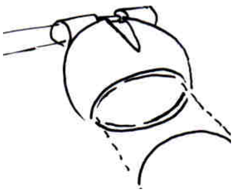


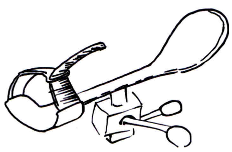


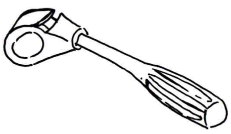


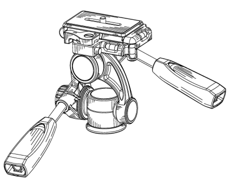










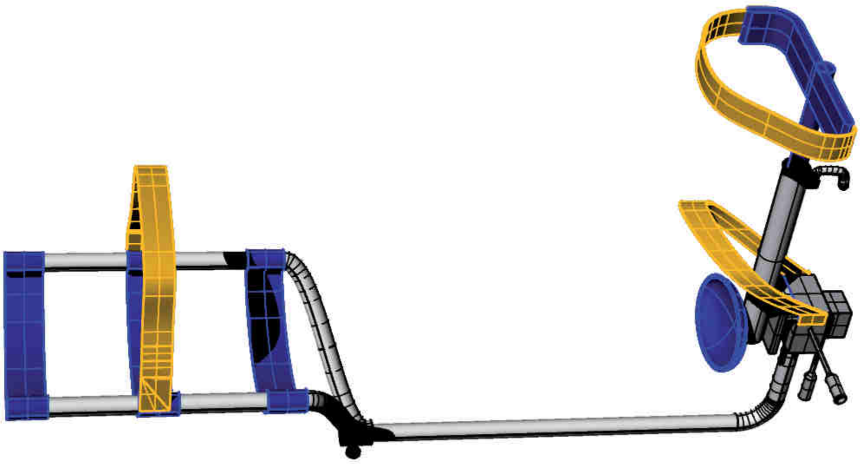


8.2 FROM THE DESIGN TO THE REALIZATION OF THE PROTOTYPE

8.2.1 The pedal

The process of design of the support for the children during the phase of acquisition started from the design of the lock for the foot in a stretching position.
Starting from the user needs and technical requirements expressed above the aim of the design was to create something that:

- can be regulated in every direction and angles with a continuous movement, in order to be more accurate;
- can be regulated not only in the directions of movement but even in its main dimensions to suit feet of children of different ages;
- to look cool and funny such a motorcycle pedal or a stirrup of a horse saddle in order to don't scare the baby.



These premises after having explored several alternatives, lead to focus on a simple device composed by a rigid part on which is located a support for the heel, and another extension that flows inside the first one, to guarantee a perfect regulation with the length of the foot. This last one ends with a transverse support for the metatarsal heads, adjustable in the angle to correct inversion or eversion tendency of the foot.
The support for the heel and for the metatarsal plant was made in thermoplastic, ABS, and was designed and 3D printed expressly for this prototype. Then this pedal was locked to a head of a camera tripod that guarantees a simultaneous control on the three axis of rotation with a continuous movement that can be firmly locked at any time. A padded cylinder as a support for the knee and two straps, at the tip toe and at the long circumference of the heel[3] completed the design of the object. Once built, it was tested in several virtual acquisitions of lower limbs and it proved to be extremely effective in the regulation of the length of the tibia and of the child's foot sitting on the support, as well as in the control of the angles of rotation to correct, and, if any if possible, of misalignments. It's main fault was the coverage still of a vast area of the sole that, in the virtual acquisition of the limb, was missing since hidden by the pedal.

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3 The long circumference of the hell is defined as the circumference from the point of the instep until the rear heel. Corazzol M., *Configurazione morfometrica del piede in relazione a condizioni pato-logiche,* Master's Thesis at the Faculty of Engineering, University of Padova, 2009-10

Images of the first prototype of the pedal

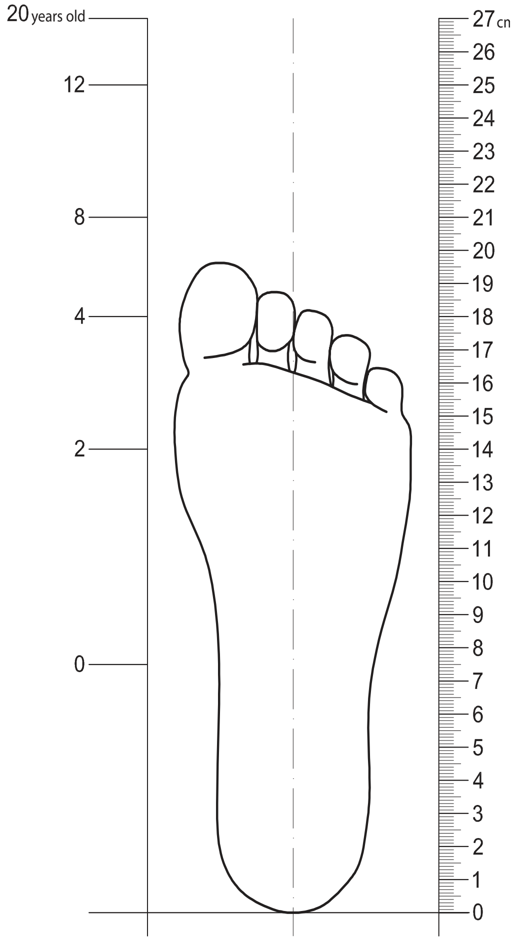
(previous page) Concept sketching of the pedal and evolution of the design idea

3D model of the prototype

8.2.2 – TECHNICAL REQUIREMENTS: Hergonomics

One of the main challenges in the design of the support for the 3D virtual acquisition of the lower limb of a person affected by Duchenne Muscular Dystrophy was to create a unique object that could be indifferently used by a child as soon as his parents diagnose the disease and his doctors prescribes him the use of night splint orthoses, until doctors consider them useful to delay negative consequences of plantar flexion, usually in adolescence.

As can be noticed there isn't a specific range of age in the use of AFOs and therefore, trying to be as much inclusive as possible, I considered in the design, as potential users, children from two to twenty years old.
At this regard scientific literature refers that from the birth until the end of the growth of a child's foot (at about 14 years), it could vary from about 7,5 cm until 27 cm, in the tallest cases. However even when he grows, he remains usually shorter than the average of his age due to pharmacological cure, and many of them tends to obesity, especially if they sit on the chair before their physical and sexual development during adolescence. This measure was receipt in the design of the pedal that, as we just saw, had a heel and metatarsal stops, connected by two bars that flow into each other to allow this range of variation.



Standard growth of the foot of a child, from 0 to 20 years old

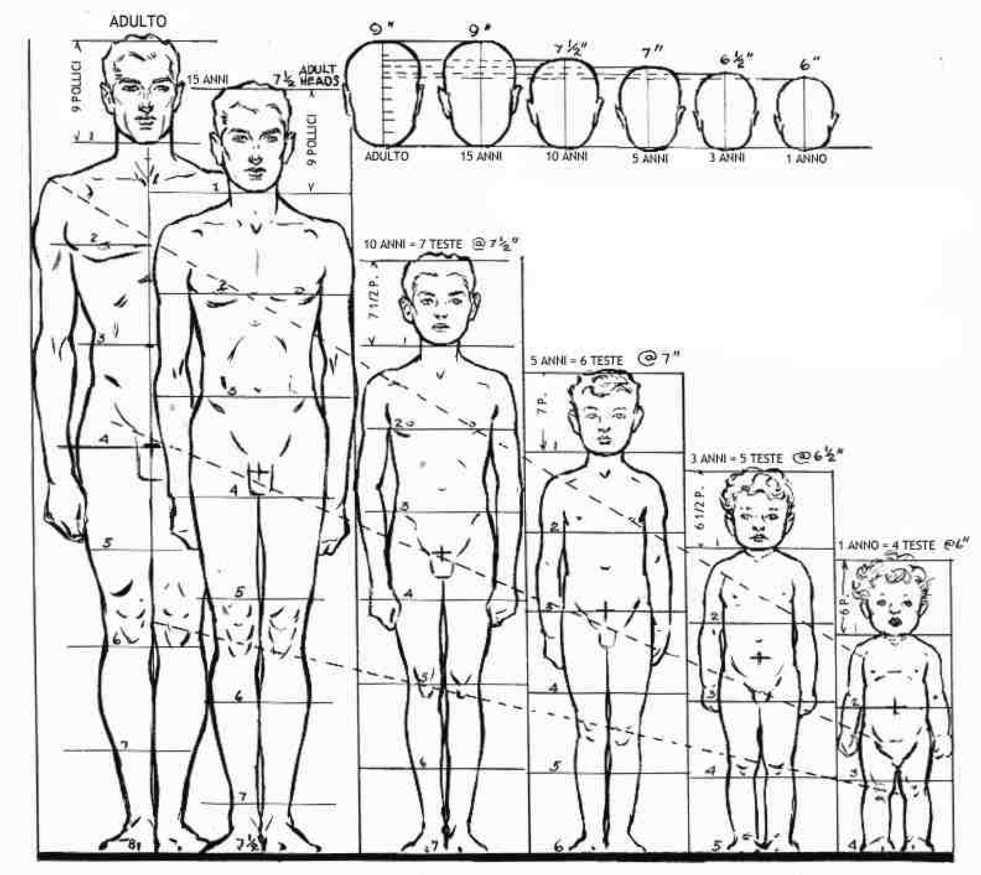
@ LOOMIS A., *Figure Drawing Dor All It's Worth*

Similar evaluations were made in the design of the support. It had to take in consideration child growth standards, At this regard two considerations have to be made. First of all it must be considered that one of the main contraindications in the constant use of corticosteroids (cortisone), at the moment at the basis of the Duchenne pharmacological cure, is to inhibit growth, and, in most of the cases, it is combined

DESIGN

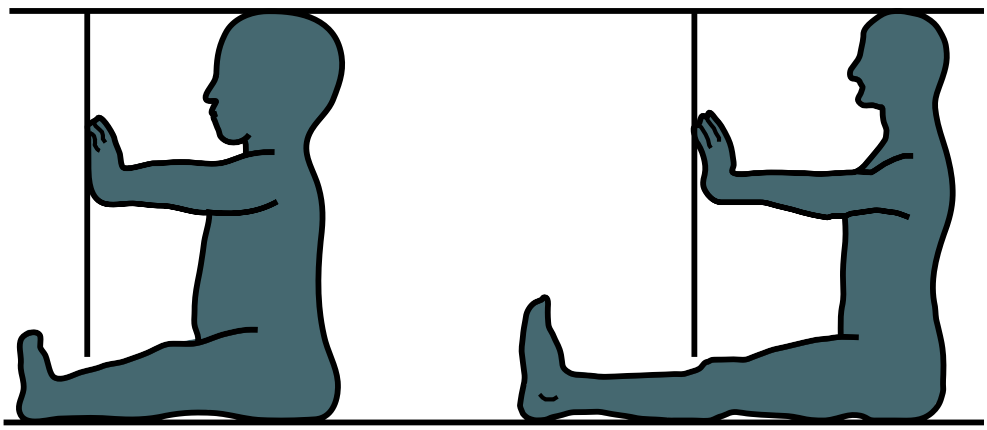
with a fattening. However I didn't find at the moment any reliable statistical data on this regard, even if a research is just starting now with the aim of collecting these measures and parameters of Duchenne children growth. In the absent of scientific growth standards, specific for DMD, common ones where followed, but maintaining a range in the age of the possible users probably slightly bigger as a safety margin.

Secondly it must be considered not only human measures as single lengths of body parts or total heights, but even the relationships between parts. In human body in a sitting position, as can be seen from the scheme below, it must be considered how the relationships between the trunk, the arms and the legs changes by the time, in the passage from infancy to adolescence[4]. Furthermore a little child needs to be carefully tied at the seatback to prevent accidental falls, and similarly it is required for wheelchair bounded children, once they lost their strength in the trunk.



Ideal proportions at various ages

@ LOOMIS A., *Figure Drawing Dor All It's Worth*

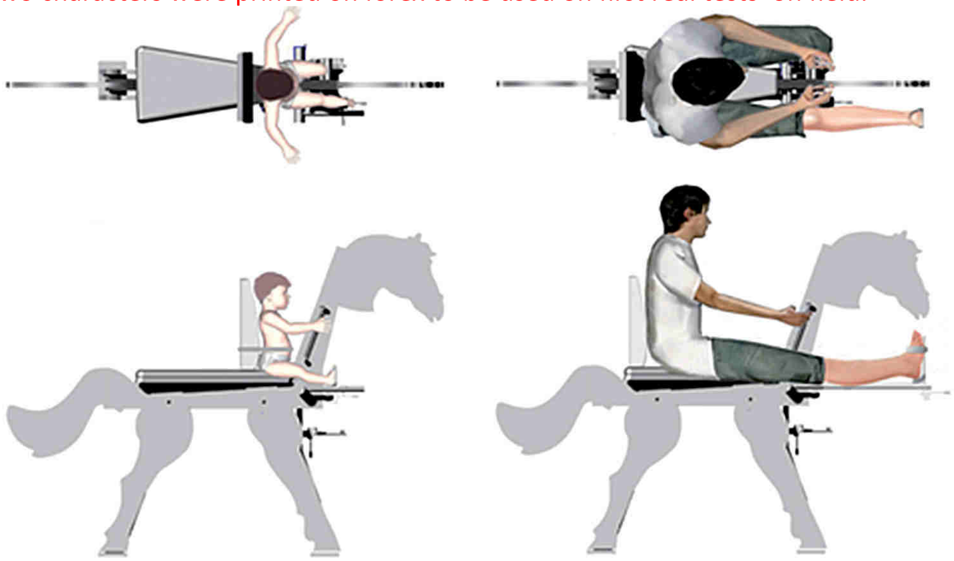


Proportions between arms and legs in a sitting position between a child of six months and a man of twenty years.

4 DREYFUSS H., *The Measure of Man and Woman: Human Factors in Design*, John Wiley & Sons Inc; Har/Cdr, 2001

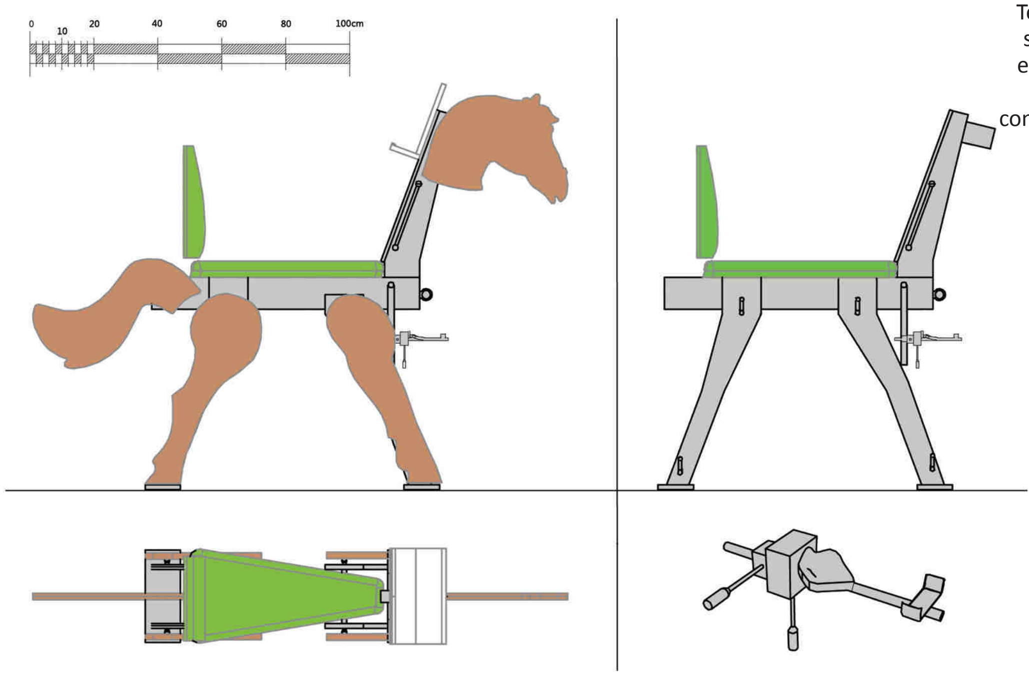
8.2.3 – FROM THE DESIGN TO THE REALIZATION OF THE PROTOTYPE: the support

The design of the support was as well quite demanding, and explored several alternatives and prototypes. To encounter user needs it has to be something light but stable, adjustable depending on the stature of the child, with a chair at the height of the wheelchair and with an overall aspect that makes it looks like more as a joke than an hospital device.
Ergonomic problems were solved with a trapezoidal chair that enlarges on the back to fit with the major size of adults' hips and with a long handle where children of every age could hang at their own high. All the other technical ergonomic requirements were absolved by the pedal. In the attempt of transforming this device in a joke it was decided to make it looks like a rocking horse on which the baby mounts for the minutes of the acquisition. All these first ideas related to this first prototype were then based on the concept of a minimal skeleton of the support, on which the child, with the help of the therapist, could hang light panels that represent cartoon characters. The matching of the right combination of legs and tail, as well as trunk and head was considered as a first moment of leisure in which the child can relax, without thinking at the stretching activity that expects him and in this way he will be hopefully more psychological prepared to collaborate with the technician. Moreover a small table in Plexiglas was added to support a tablet to watch cartoons or jokes and stay without moving during the minutes required for the indirect survey. The firsts sketches represented a slight structure in iron shrouded by light panels.
In the physical realization of the first prototype the steel was reduced only to the central bar with a sliding track system to regulate the position of the backrest thanks to a loop under the seat. When the loop is pushed down the backrest thanks to a loop under the seat can slide freely on the rail, when the loop is released the back is fixed in that position. The chair, the backrest and the supports under the knees were padded and clothed with blue leather for a better comfort. The legs and "the neck" were realized in wood and locked with the trunk. The two front legs, as well as the two back legs were fixed on two basis in order to guarantee better stability. Moreover these bases hold the slots for the inferior lock of external panels, while the upper slots are located under the backrest. In a first moment it was thought to divide each character in 5 – 6 different panels: the four legs, the head and, eventually, the tail. Afterwards, this process was simplified in just three panels, two laterals and the head, to optimize the overall encumbrance of the device. Several samples were drawn and among them, with the suggestion of 10 children of different ages, two characters were printed on forex to be used on first real tests on field.

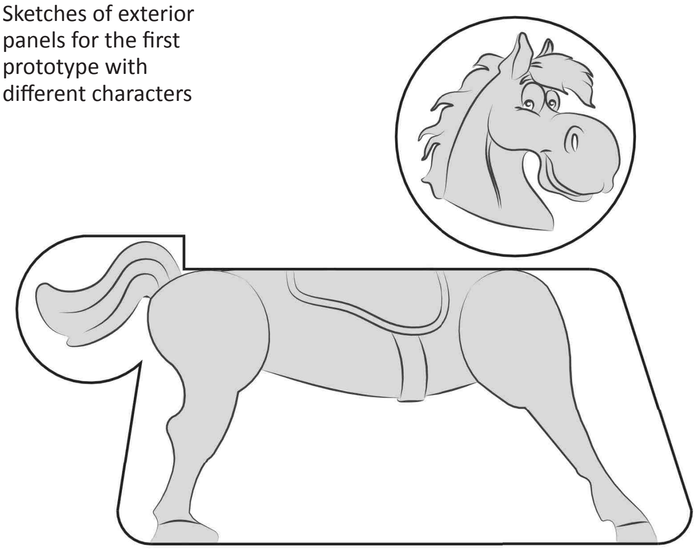


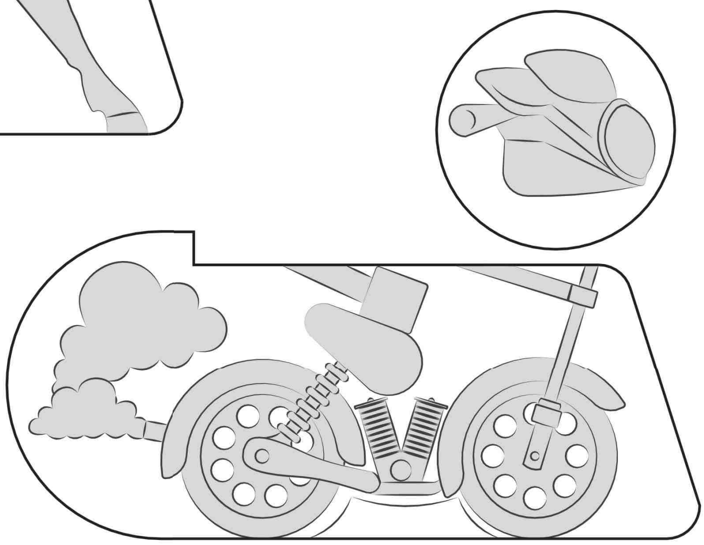
The support is designed to be adaptable for children of every age

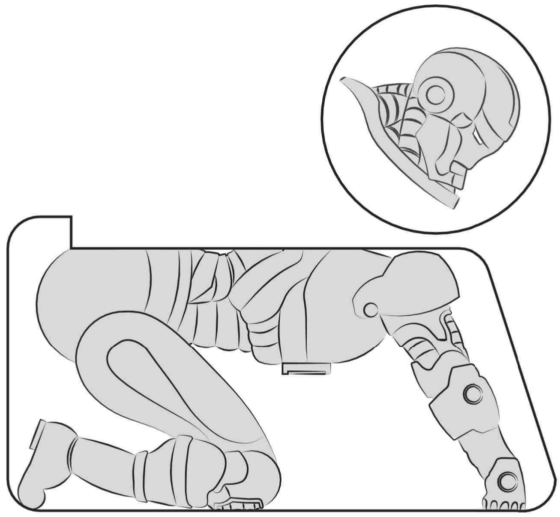
Technical drawings, sketchs of possible exterior panels and render of the first concept of prototype

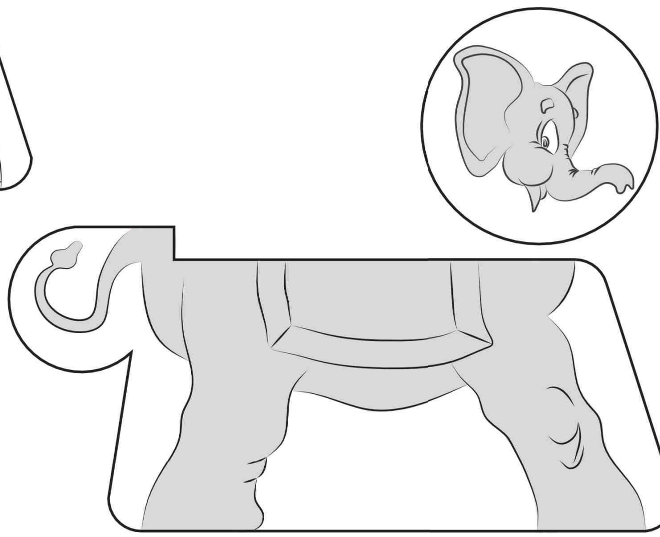


Sketches of exterior panels for the first prototype with different characters

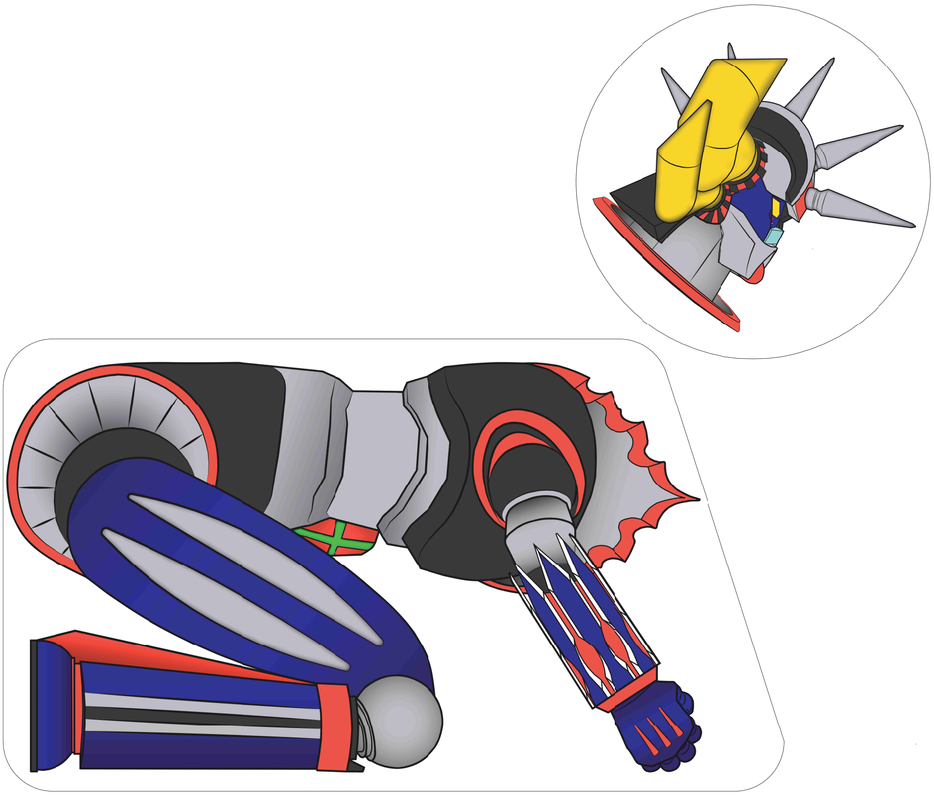


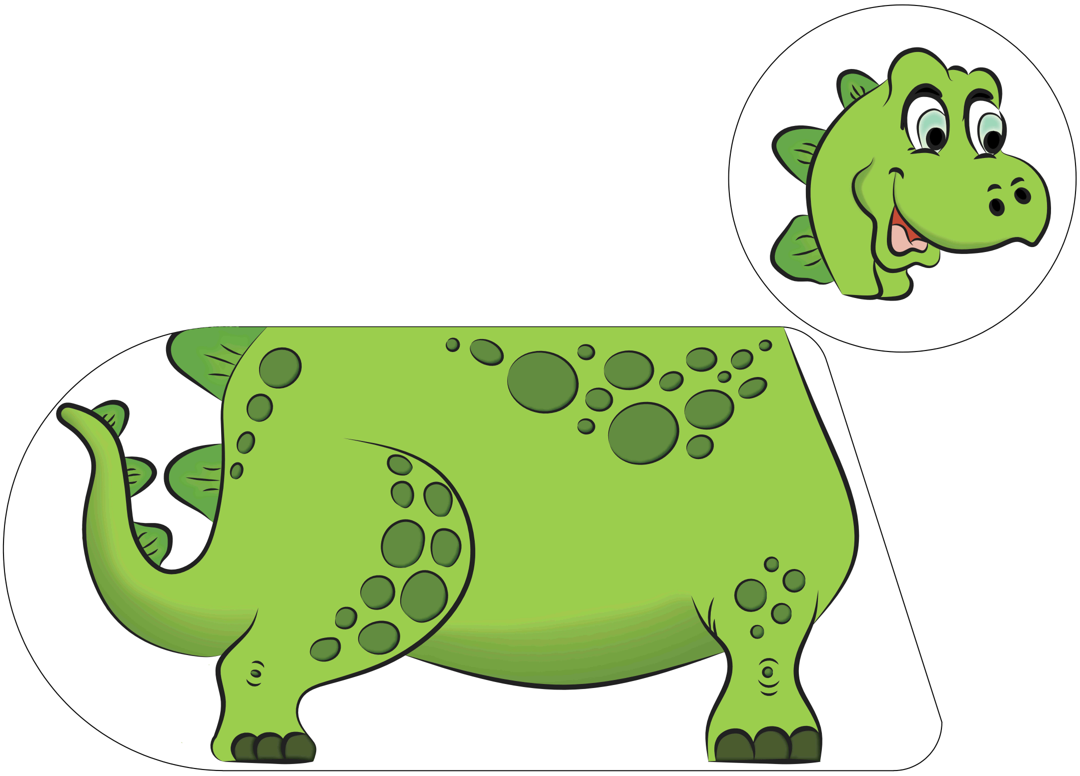






Sketches of exterior panels for the first prototype with different characters





First prototype of support for the child during the minutes of their lower limbs' indirect survey

First prototype of support for the child during the minutes of lower limbs' indirect survey

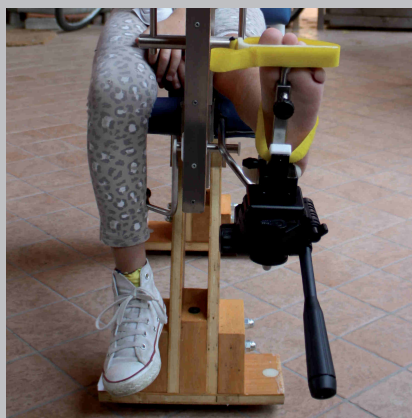
8.2.4 - Evaluation on field of some possible improvements of the first prototype

The physical realization of the prototype and all the tests of lower limbs acquisition made using the “horse bench” were essential in the evaluation of the support and in testing all the proposed solutions. This phase concluded, all the photos and impressions related to the support were collected and the device was again evaluated, as it was done during the design phase, for its response to user needs.
In the evaluation on field of the first prototype, the results were quite satisfying but still improvable. It proved to be adaptable from very little children to small adults, until about 1.65 m, but that this range could be easily enlarged to include taller boys.

This range limitation of this first prototype was in fact due only to the decision of using, since it was simply a test, a recycled piece. Its versatility and manageability in positioning and locking the foot was one of its greater **strengths**, together with its stability and safety from tipping. Even the psychological impact on children was quite good, especially if the structure was covered with exterior panels and if they were involved in the choice of the character.
Nevertheless, some important **weaknesses** were surveyed. These considerations convey in the decision of designing and realizing a new prototype in the attempt of solving these critical issues.

Partial coverage of the inner part of the calf

this was maybe the most important fault of the first prototype: the neck of the horse bench covered an important part of the leg, causing some difficulties in the process of acquisition, both with image-based modelling or hand scan. During the tests I succeeded in remedy to this problem but it would be better to eliminate this visual obstacle.



Partial coverage of the sole

the design of the pedal to lock the foot in a stretching position was extremely difficult but once it was realized and tested it proved to properly function. However some further improvements could be done to improve the final result and leave more visible the sole of the foot. In particular it was observed that the connection between metatarsal heads and the heel, in stretching position, presses on the sole and this was an undesired result.

Lack of a support

for the foot that is not being acquired. This lack tends to cause an imbalance, especially if the child's leg at rest is close to reach the ground. As it can be noticed in the image, in this case the child, in order to rest the foot on the floor, assumes an incorrect position.

Location of the knees' rests

as can be seen from the photos of the tests it was located too low respect to the sit and it was almost never used. However this observation lead to the consequence that maybe it isn't necessary or it could be substituted with something that locks the leg under the knee.

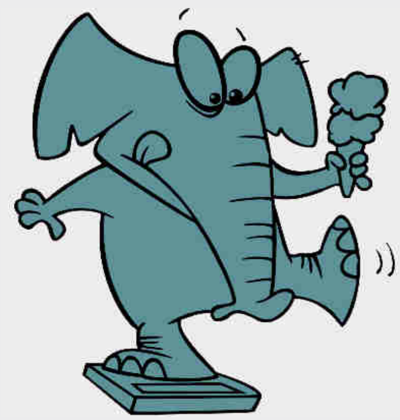
Lacks of belts

but they can be easily added. In particular they would be necessary for very young child that still can't stand alone and for wheelchair bounded adolescents that lost the control of the upper trunk.

Uselessness of the handles

In that location they are useful only for young boys, but for children from about 4-5 years on, they're too far from the sit, unusable and positioned too much in the lower, where they can be cumbersome for lower limbs.

DESIGN



Excessive weight

it was extremely stable, but maybe this was at the same time one of its weakest point, since this stability was due to extra unnecessary material and it was paid with an extra weight that makes it hardly transportable.

Washability

a little bit difficult since the presence of some hardly reachable points in which dust deposits.

Aesthetic of the "skeleton"

It was of something heavy, hard looking, with too many materials concurring to the final result, it was mostly functional but something had to be done for its aesthetic.

Difficult manufacturing

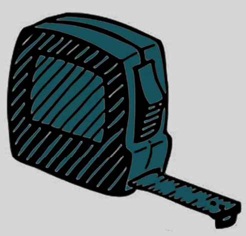
since it requires joints between different materials, unique pieces and final finishes, as chair, back and knee rests paddings.

Safety

Risk of get hurt with some protrusion and joints.

Difficult decomposition

since it was thought as a one piece device.



Lack of a reference measurement, in a first time it was supposed that this element wasn't necessary, since each visible element can be considered as a reference measurement is completely visible. The presence of a modular repeated known measure on the bench, instead, could be an advantageous device in the case of an image based modelling, since any visible portion could be useful to give dimension information.

DESIGN

8.3 - FROM THE DESIGN TO THE REALIZATION OF THE SECOND PROTOTYPE

All the considerations reached for the design of the first prototype were addressed to the design of the second prototype. One of the main care in the design of the second prototype was a different weight given to the requirement of transportability. A general consideration on the design of aids for Duchenne Muscular Dystrophy patients and their caregivers, as for personal aids as for environmental ones, lead to the conclusion that the keyword for everything that has to come in relation with them is flexibility. Their needs are continuously in evolution, they change day by day and everything around them has to follow their conditions. Therefore if we analyse the first prototype under this lens we observe that ***it behaves appropriately in its possibility of customization depending on the age and height but it was difficulty transportable, since it was heavy and bulky, it was made by a single piece and it wasn't possible to separate for transport it if necessary.*** We can imagine several situations in which this bench would travel. Since its use is not daily, but only when, after an appointment, a child needs to change his AFOs, we could imagine that it could be stored in another room and transferred where required at the moment of the acquisition or when, for example, more institutes have to share it or, even more probably, it could happen that one technician has to move to the child's house since he is unable to move.
Therefore the new prototype was designed with the aim of ***creating something different, light and transportable, maintaining all the advantages of the previous one***.

It is made in birch plywood, it refers to the looking of a rocking horse and it is composed by four main parts:

- ***hinged legs as a sawhorse***. Frontal legs are perforated to host a footrest. It is made in a single sample since it host one foot by time while the other one is fixed on the pedal in order to be surveyed. Three holes allow to regulate the position of the footrest depending on the height of the child.
- ***a trapezoidal bench with two foldable side wings*** is wedged between the legs. Its shape follows medium hip widths of children from two to twenty years to guarantee comfort and ergonomics. Six slots on the central part and similar ones on each wing are designed to host the backrest.
- ***a backrest with two foldable side wings*** is provided of three double lugs, one under each part of the backrest. They are made by two parts, one that wedges in the bench hole and one under each side wing that turns, hinged with the upper piece, to lock the backrest. This backrest can be easily moved from one slot to the other on the bench in order to fit with the sizes of the children. Moreover it is equipped with two belts that wrap the child. These equipments can be particularly useful as for a very young child, to keep them stable, quiet and give them a sense of safety, as for adolescents that have already lost the control of the upper trunk, who are wheelchair bounded and need help to stand upright.
- ***the head with the U-bar on which is hooked the pedal***. This part is probably the second great innovation of this prototype compared with the previous one. We've already discussed how, in the first model, the neck occluded too much the internal part of the limb during the indirect survey. This new solution hooks the neck to a U-bar that slides forward to fit with the length of the child. With this solution the head moves away from the foot and leaves the sight of the lower limb completely free without any shadow cones. The U-bar slides in two bushes and the scroll ends thanks to a travel stop on the track.

- The pedal hooked on the iron bar can be easily unhooked, turned and locked on the other side. It follows the same ploy previous described. The head of a photographic tripod moves the pedal in every spatial direction to control all possible deformations and, most of all, impresses the higher dorsiflexion possible to the foot. The pedal is the device that stretches the calf muscle and therefore all the system has to be really stable and fix the lower limb during the minutes of the acquisition. It differs from the first model just for one detail: the support for metatarsal heads and for the heel is no more aligned with the central bars that slides one inside the other at the middle of the sole to fit with children's feet length. The two supports are slightly moved forward of 8 cm. This change brings three advantages.
    - First of all it lives more visible the entire sole of the foot, allowing a better indirect survey, with every technique.
    - Secondly it reduces the contact between the pedal and the foot in undesired parts and this contact between the skin and the metal bar is unpleasant due to different thermal conductivities.
    - Since the foot is in a stretching position, it tends to press on the bar causing undesired deformations of the foot sole that haven't to be reported in the shape of the AFO.

When it has to be carried, the operator:

1. pushes the neck with the pedal towards the bench;
2. extracts the backrest and closes its wings,
3. closes the wings of the bench;
4. overlaps the backrest to the bench;
5. with the two belts, ties everything together assuring transportability;
6. closes the hinge of the legs.

Renders of the second prototype of support for the child during the minutes of their lower limbs' indirect survey

DESIGN

The iron bar slides under the seat to fit with the legs' lenghts

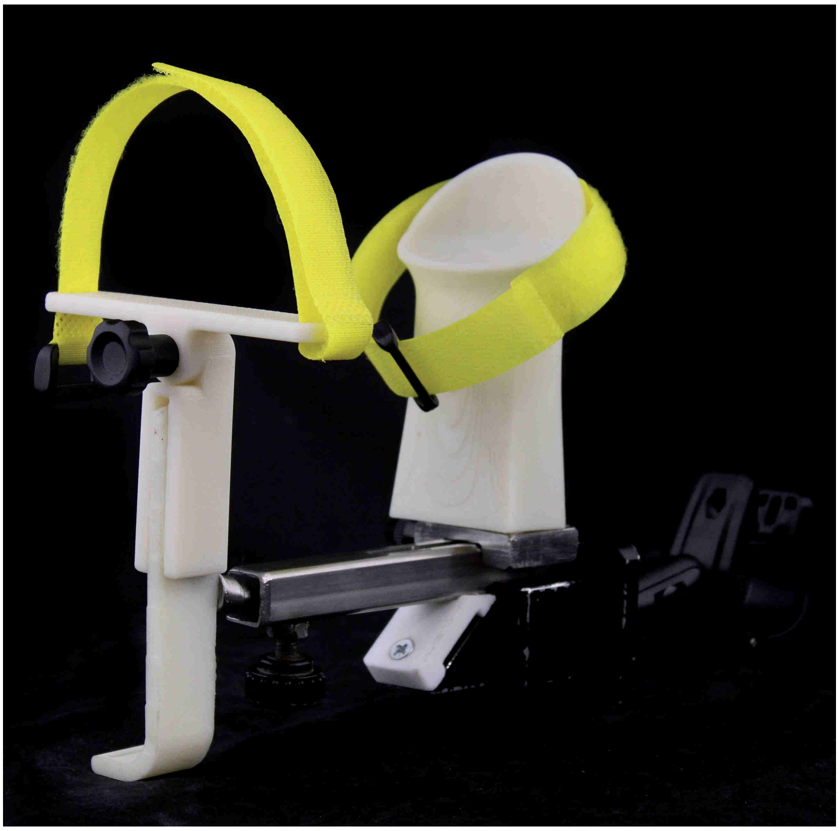
DESIGN

The foot rest supports the leg that is not being surveyed

Photos of the first prototype

The foot is allocated in this special pedal and can be oriented by the therapist in its best position possible

Frontal view.
The foot rest can be easily moved from one side to the other and regulated in its high depending on the age of the boy



The pedal allows a complete spatial control of the foot in all directions and can be regulated to fit with children of every age

Backside view
The backrest can
be easily allocated
in various position
inside the seat to fit
with child's height

Even without the
pedal, the support
can be used
as a toy, or a bench
by children that
can sit on it

The support can lenghten in order to match with legs of children of every age

The set of the test of the second support for the child for the virtual acquisition of his leg

Second prototype of support for the child during the minutes of his lower limbs' indirect survey

8.4 - FINAL CONSIDERATIONS ON THE PROTOTYPE

This second prototype proved to solve many criticities compared to the first model. It proved to be more effective in allowing a better survey of the limb, it has a more unitary and coordinate aesthetic image and its improvements in weight and transportability could have a crucial role in the usability of the product. However this second prototype should still be more widely tested, especially to fully verify the resistance of the head of the pedal and the risk of slipping.

Probably this solution sacrifices a bit the ludic phase of choosing the character the child wants to ride and it eliminates the support for tablets to reduce weight as much as possible. However it is important to notice that the main result of this bench is not in the design, that could be still improved and modified in various aspects and that could take infinite looks and shapes. Its strength is in the proposed solution of acquisition of the shape of the foot in a stretching position, with the possibility guaranteed to the technician of positioning the foot and regulating and correcting as much as possible the alignments of the limb without being actively present at the moment of acquisition. Furthermore the choice of an object that recalls the features of a rocking horse and that can be easily moved in an outdoor garden, as well as in a playroom, contributes in the perception of the moment of the acquisition of feet's shapes as a ludic moment. The technique of the impression of the lower limbs sape through plaster is mainly a clinical procedure, highly intrusive for children, since the skin comes in contact with other materials and the process could remember painful moments, as when we break one leg's bone.

The prototype demonstrates how it is possible to achieve the same result but in a playful atmosphere. Moreover the child can be even involved in the observation of the final result, in the recognition of his foot virtually reconstructed on computer. Hereinafter we'll see how the acquired 3D mesh of the lower limb is used as the basis of the design of customized AFOs.

With the elaboration of the 3D model of child's lower limb the phase of acquisition is concluded and in the following paragraph the design of the morphology of the orthosis will be described.

9 PARAMETRIC DESIGN OF A NIGHT DMD AFO

9 – PARAMETRIC DESIGN OF A NIGHT DMD AFO

The morphometric definition of the new type of night Ankle Foot Orthosis for people affected by Duchenne Muscular Dystrophy originated by the surveyed mayor needs and requirements emerged by the application of the House of Quality of the Quality Function Deployment method and started by the 3D virtual reconstruction of the lower limb of the child sitting on the designed prototype that allocates its foot in a stretching position and with the best alignments possible related to his clinical condition.

Among several alternatives, parametric design proved to be the approach that suites the best with the requirements of the project. An overview on parametric design softwares and specificity allowed to select Grasshopper, plug-in of Rhinoceros.

Once it is set the algorithm with all the steps to elaborate a 3D orthosis starting from the mesh of the user's lower limb and 15 points accurately selected on the surface of the foot, this process maintain its great advantage of automatic change propagation. It means that it is sufficient to reload a new mesh and new control points on the leg to make the shape of the relative AFO automatically reshape on the other patient.

This solution has many great advantages: a greater customization, since every AFO originates exactly by an offset of the user's limb and a significant reduction in times and cost of working hours. Moreover parametric design enlarge exponentially the possibilities of an aesthetic customization of the orthosis, since many parametric textures, motives, drawings, sign or similar can be easily applied on the surface that can even have differentiate thicknesses following the discharge force lines.

9.1 – INTRODUCTION

Giving shape and morphology to the new type of night Ankle Foot Orthosis for people affected by Duchenne Muscular Dystrophy was only one of the last steps of the design process. The shape of the object isn't the result of a personal taste or artistic sign but only the consequence of the analysis of a series of requirements. However this consideration doesn't imply an exclusively functional response, since psychological, aesthetical, marketing issues and everything related with the users' experiences of the product were integral part of the design process.

Before starting the phase of design, the incoming data at this point were:

- ***a 3D model of the user's lower limb;***
- a list of ***main requirements and proposed solution proceeded by the application of the House of Quality*** of the Quality Function Deployment Method to the project:
    - suggestion of investigating the type of dorsal AFO, since market analysis reveals that it is the most comfortable type, but be aware that the ones currently on the market offer low resistance and aren't suitable for Duchenne people;
    - requirement of breathability and therefore of reduction as much as possible of the contact surface between the skin and the AFO
    - demand of improving morphological customization

- expectation of an AFO with high level aesthetic and a broader possibility of personalization
- hopefulness of a reduction of times and costs in the manufactory of the AFO.

As done in occasion of the choice of the best technique of body survey, even for the choice of the best method to deign a customized orthosis starting from the 3D model of the leg, different alternatives were evaluated in order to find the one more suited to the aim of the project. Three different options were hypothesized:

1. ***Manufacturing of the 3D model of the lower limb and thermoforming of the AFO on the mold of the user's lower limb;***
2. ***Manual Solid modelling of the AFO on the 3D mesh of the limb.***
3. ***Parametric modelling of the AFO on the 3D mesh of the limb.***

The first alternative substantially maintains unaltered current techniques of manufacturing, except for the survey phase. The manufacturing of the limb could be done by an additive technology or even in a more empiric way by reconstruction from bi-dimensional drawings. It could work but uselessly maintains the introduction of new technology only to the phase of survey, without involving the design of the AFO that remains substantially as it is actually manufactured.

Manual Solid modelling of the AFO, on the contrary, leaves a definitively higher level of freedom in the design of the orthosis. It proceeds with the traditional instruments of this technique by the elaboration of primitives, curves, surfaces, solids, by extrusion or revolution. Any model is a one-piece elaboration. If we imagine the process of realization of a manual 3D model, from its conceptualization to the realization of the prototype in a traditional way we can observe how concept sketching is a dynamic tool. Sketching is definitively not a rapid technique of representation, but it is a dynamic and evolutive one, since, while I'm sketching, I have the time needed to think about my project and develops ideas until the final one. However in the common process of design, once this step is concluded, it is required a further step of definition of details and of three-dimensional representation. It can be discrete, with 2D representations, or continue, with a virtual 3D model or a physical prototype. In this schematization we can see how the 3D model, at this stage, is the most rigid tool we're using. With non-parametric softwares the dynamism is relegated to the possibility of moving the object in the 3D space, changing points of view and positioning cameras to fix some positions and extracting pre-defined views.

The aim of parametric design is to introduce dynamism in 3D models. This is possible if we transform each element in an input that establish relations with other inputs, so that the output isn't a fixed solid feature anymore, but becomes the result of a function which parameters can be changed, causing a chain effect on all the others. If we want to reassume parametric design main advantages, we can synthesize them in[1]:

- ***Automatic change propagation.*** This feature is maybe the most important characteristic that brings together all the parametric design softwares on the market. In traditional *non-parametric softwares* if we want to operate a single change, we need to singly modify all the features and the shapes that are directly connected to the area where the change elapses. On the contrary, as Geisberg says on parametric design: *"The goal is to create a system that*

1 SHAH J. J., *Designing with Parametric CAD: Classification and comparison of construction techniques*, in *Geometric Modelling. Theoretical and Computational Basis towards Advanced CAD Applications*, edited by Fumihiko Kimura, 2001: pp.53-68

DESIGN

would be flexible enough to encourage the engineer to easily consider a variety of designs. And the cost of making design changes ought to be as close to zero as possible. In addition, the traditional CAD/CAM software unrealistically restricted low-cost changes to only the very front end of the design-engineering process.[2]" Therefore it is clear how **its application is particularly advantageous when the design has to minimize the efforts and the costs of creating design variants.** Creating an algorithm of pre-defined processes reduces not only the time spent in repeating each single task more and more times, but even the possibility of human errors and the discretion of the result[3]. Dimensions and variables are linked in such a way that when the value changes, the geometry is capable to change accordingly and automatically[4]. Furthermore an easy and quick response on all the possible changes caused by a variation in the inputs, or in the relations between them, often lead to the discovery of unimagined outcomes and different and innovative solutions[5].

- ***Geometry re-use***. Once one algorithm to produce one product is defined, the whole process can be easily archived and recycled every time we need a similar feature, starting from that procedure and simply changing just the values required to adapt the new object on our desires. Its value is much more than a saving of time. It means that a parametric designed object is able to conserve into its features not only the final result, but all the steps that were required to reach that result. This clearness and objectivity make this knowledge easily exchangeable, reproducible and implementable by all users.
- ***Embedding of design/manufacturing knowledge with geometry.*** At the moment this is the less developed aspect of parametric design softwares and not all the softwares are featured with this application. It consists in applying to the model real material properties in order to analyse its technical characteristics even exporting the final model in software of simulation of working models.

This analysis evidence the great potential of parametric design and how it will perfectly feet the needs of a virtual geometry that can quickly adapt from one user to the other, maintaining its general feature and morphology and the logic of construction, but adapting case by case on the surveyed 3D mesh. In the following paragraph an overview on different available software of parametric design will guide the choice of the one that will be applied for the design of the orthosis.

2 GEISBERG S. P., *Interview on Industry Week 1993*, in TERESKO J., *Parametric Technology Corp: Changing the way Products are Designed*, in *Industry Week*, December 20, 1993

3 PARAMETRIC CAMP, *Parametric design and generative modeling workshop*, op. cit.

4 ABDULLAH H. K., *Parametric design procedure: an approach to "Generative Form" and exploring the design instances in architecture*, http://www.academia.edu/1529999/Parametric_design_procedure_an_approach_to_Generative-form_and_exploring_the_design_instances_in_architecture (November 2014)

5 JABI W., *Parametric Design for Architecture*, King Publishing, Laurence, 2013

9.2 – BASIS OF INDUSTRIAL DESIGN SOFTWARE OF PARAMETRIC DESIGN

"When humans acquired language, we learned not just how to listen but how to speak. When we gained literacy, we learned not just how to listen but how to write And as we move into a digital reality, we must learn not just how to use programs, but how to make them."[6]

As the American media theorist Douglas Rushkoff states, we live in an époque where almost all of us is able to use a computer, but almost none of us is aware of its mechanisms and functions. It happens in design field as well. In about twenty years nearly all the studies of design equipped with computers that became essential in the workflow of the design, but just in the last decades, with the disclosure of ***parametric design***, their application is going beyond its role of a technological drawing board.

The term *parameter* originates from mathematics and it is defined as: *"one of a number of auxiliary variables in terms of which all the variables in an implicit functional relationship can be explicitly expressed"*[7]. If we translate this concept in a design context, we could define parametric design as a process based on algorithmic thinking able to generate a certain design through a hierarchy of mathematical and geometric relations[8]. The algorithm encodes the relationships between design intents and design responses and, what's the most, it makes incredibly simpler to explore all the range of possible solutions that the variation of input data can allow.

One of the firsts rudimentary physical examples of application of parametric design in architecture that are reported in literature were building's mockups made by the world-famous Spanish architect Antoni Gaudi. For his most complex projects he created upside down models, made by strings weighted down with birdshot to create complex vaulted ceilings and arches. Changing the length of the strings or the weights on each arch he could observe how this change propagated on all the arches related to it. Therefore he was able in time real to explore different solution of his design, without the necessity of complicated static mathematical calculations.

When progresses in computer programming lead to the conjunction between ***computational geometry***, the study of algorithms for geometrical computations and ***computer graphics***, the software and hardware development to display geometry on computer screens, parametric design software developed their great potential.

One of the first rudimentary application of parametric design dates 1963 and it is related with the PhD thesis of Ivan Sutherland and its software **Sketchpad**. It can be considered as an ancestor of modern CAD (Computer-Aided Design) programs. Even if it allowed to draw just in 2D space, it had some features typical of a parametric approach, as the possibility of drawing lines and arcs that could be related to each other using constraints[9].

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6 RUSHKOFF D., *Program or be programmed. Ten Commands for a digital age*, Soft Skull Press, 2011

7 *Parameter*, Collins English Dictionary, Collins, 2007, www.collinsdictionary.com

8 PARAMETRIC CAMP – *Parametric design and generative modeling workshop*, http://www.parametriccamp.com/en/what-is-parametric-design/ (November 2014)

9 *"Sketchpad was the first program ever to utilize a complete graphical user interface, using an x-y point plotter display and the recently invented light pen. The clever way the program organized its geometric data pioneered the use of "objects" and "instances" in computing and pointed forward to object oriented programming. The main idea was to have master drawings which one could instantiate into many duplicates. If the user changed the master drawing, all the instances would change as well. Another major invention in Sketchpad was that it let the user easily constrain geometric properties in the drawing—for instance, the length of a line or the angle between two lines could be fixed."*

Pro/Engineer was the first commercially successful parametric modelling software. It was released in 1985 by the Parametric Technology Corporation, founded by Samuel Geisberg in 1985 and unlike Sketchpad the geometry was three-dimensional[10].

CATIA and **Digital Project** were the firsts important applications of parametric modelling in architecture and found one of the mains and more important promoter in the architect Frank Gehry who used these algorithms for the defining of the fascinating shapes of the Barcelona Fish of 1991, as well as the famous Guggenheim Museum in Bilbao (1993-97). It *imposes a strong abstract structuring of data with access to a constraint solver and sophisticated graphical debugging methods[11].*

Revit, as well as ArchiCAD, were subsequent developments of parametric building modeler, specifically thought to help architects in the design process since they contain intelligent building components, views and annotations. The name itself Revit is to signify an instant revise of all the project contextually with the modify of any of its feature.

SolidWorks is nowadays almost a standard in mechanical engineering but it isn't commonly used in design and architecture's application.

Autodesk 3DSMax is another sophisticated parametric 3D modeling software designed to provide animations, simulations and rendering solutions for games, film and motion graphic artists. Its workflow is based on modifiers and wired parameters that control the shapes and make them parametrically modifiable.

However it must be noticed a crucial difference between these last softwares and the previous: Pro/ENGINEER, CATIA or Sketchpad were managed through the scripting of equations, in this generation of softwares, the algorithms are "hidden" behind the pre-defined tasks and not directly programmed. "*After **Revit** was acquired by AutoDesk, the rhetoric around parametric modelling ceased and they **coined the name Building Information Modelling (BIM)**. […] In doing so they distinguished BIM from parametric modelling by emphasizing the management of information (parameters), as opposed to the management of the parametric model itself.*"[12] Most 3D CAD softwares have their own Programming Environments containing standard methods, and allow the user to set just some predefined features, not to create mathematic algorithms. However parametric modelling developed as the same time in scripting interfaces too and the major softwares added a tool, or a plug-in dedicated to scripting interfaces of software packages. This tool gave a chance to designers not only to use but to program their tools: **AutoCAD scripting interface**, **Rhino Script or RhinoCommon, or MAX SCRIPT**, with Py thon language for 3DS Max, were market with this aim.

Grasshopper was released in 2007 with the name of *Explicit History* and then renamed by its author in Grasshopper, as a plug-in of Mc Nee's Rhinoceros. Despite the other softwares, it has the peculiarity of a visual scripting interface based around graphs that map the flow of relations from parameters. A much more intuitive visual interface, combined with the same huge potential of an advanced parametric design software lead to the adoption of this software for the design of the AFO.

MULLER-PROVE M., *Sketchpad*, in *Vision and Reality of Hypertext and Graphical User Interfaces*, Master Thesis at the Department of Informatics, University of Hamburg, February 2002 http://www.mprove.de/diplom/index.html (November 2014)

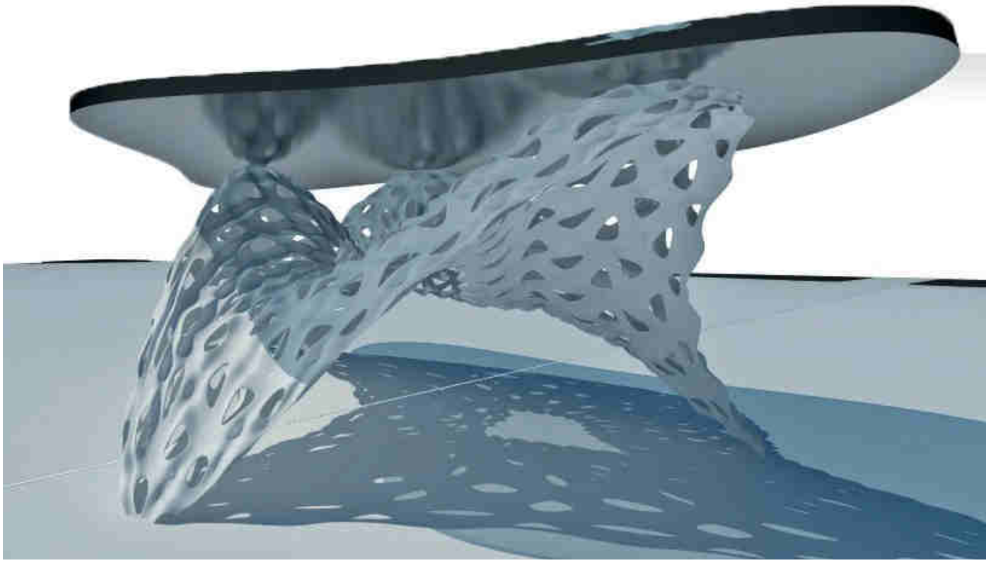
10 DAVIS D., *A History of Parametric*, www.danieldavis.com/a-history-of-parametric, 2013, (November 2014)

11 WOODBURY R., WILLIAMSON S., BEESLEY P., *Parametric Modelling as a Design representation in Architecture: A Process Account*, in *Third CDEN/RCCI International Conference on Education, Innovation, and Practice in Engineering Design*, Toronto, ON, Canada, Canadian Design Engineering Network, 24-26 July 2006, http://cumincad.architexturez.net/doc/oai-cumincadworks.id-047b

12 DAVIS D., *A History of Parametric*, op. cit.

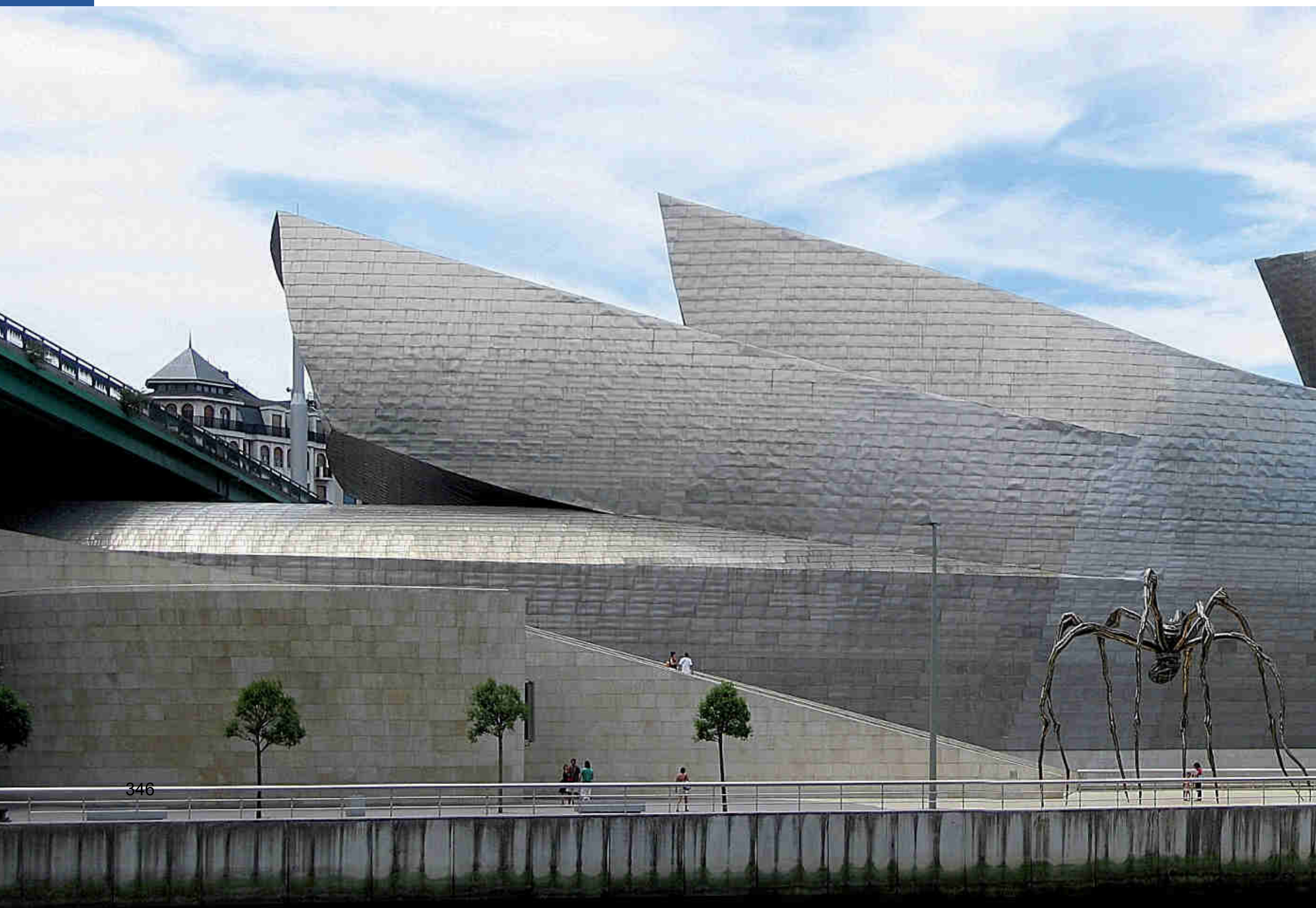
Simplexity, Conceptual Parametric Design for a Table that has a Sculptural Perforated Base.

@ Islam Salem



Frank Gehry was one of the first architets that experiment parametric design in architecture. Guggenheim Museum

@ Mr~Poussnik https://www.flickr.com/photos/alaind20sn/



Zaha Ahid is one of the most famous architects that explore the artistic potential of expresion of the application of parametric design to architecture.

@ Galaxy Soho / Zaha Hadid Architects, by Hufton + Crow

9.2.1 – Parametric Design with Grasshopper

Grasshopper is a parametric software, a graphical algorithm editor that works as plug-in of Rhinoceros' 3D modeling tools. Among others parametric software it is based on a nodal system. It is a system that comes in support of the numeric and mathematic digital representation.

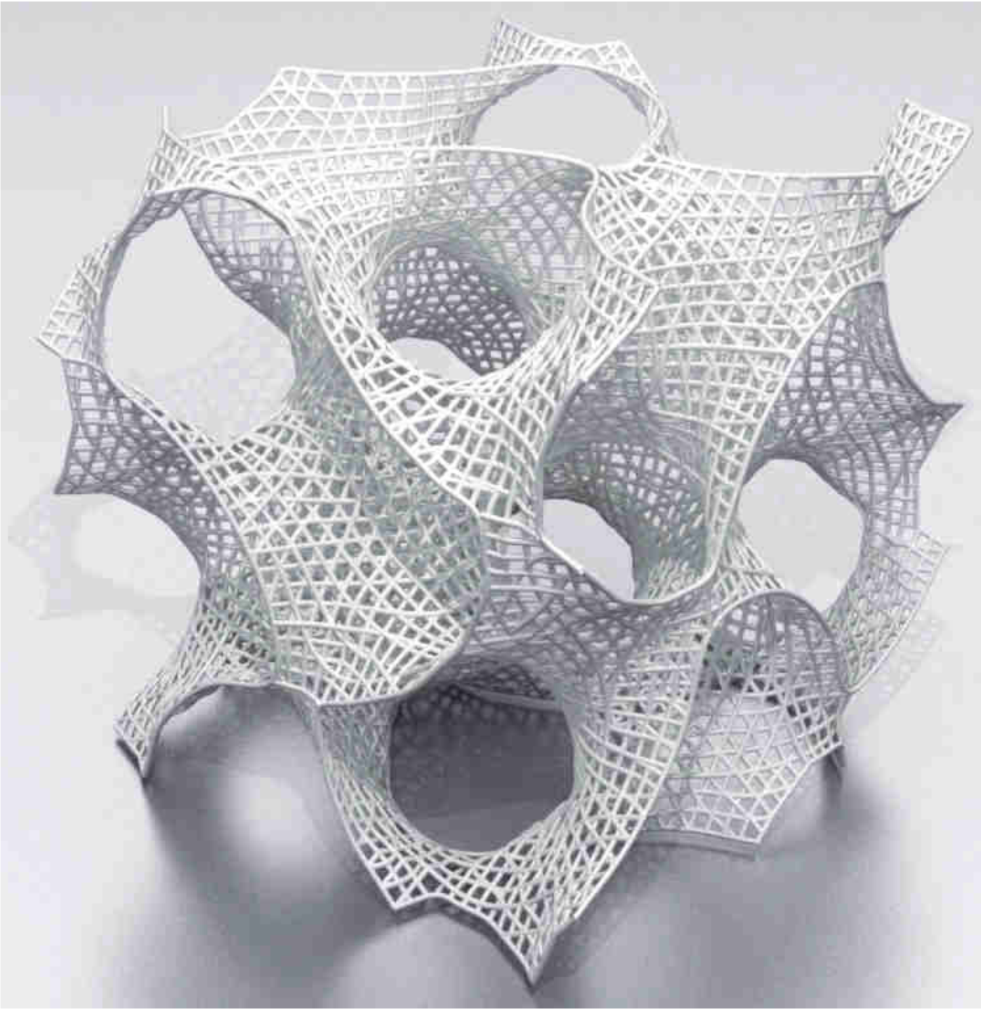
In a nodal system, as Grasshopper, the software works through nodes, considering some of them primary and other secondary. As a general framework we can classify these elements in:

- ***PARAMETERS***, *elements that define the function. As parameters, we have to consider not only numbers but even aesthetic and functional criteria or performance-based principles, as for example, "for instance structural load resistance and amount of light intensity at a given space."*[13]
  - *Inputs*, incoming data;
  - *Outputs,* out-coming data once the function has been processed;
  - *Numeric variables:*
    - *Integers,* used mainly for counting;
    - *Doubles,* that deal with decimal numbers*;*
  - *Booleans,* if we need to assert if a variable is true or false;

- ***COMPONENTS,*** nodes that put in relation parameters. Each component can become input of the following component or components. The characteristic of each component is that it fulfill an action. It is defined by an algorithm that put in relation data.
  - *Algorithm,* the set of rules that from inputs, through operations, produce outputs;
  - *Math operations;*
  - *Conditional executions,* check point where the tools verify certain conditions that, if satisfied, activate new processes;
  - *Repetition,* of some sequences of tools, usually changing some values or parameters;
  - *Strings,* to define variable by entering string of text;
  - *Functions,* sequence of statement that define a computation. It can be directly typed, stored and recalled when needed.

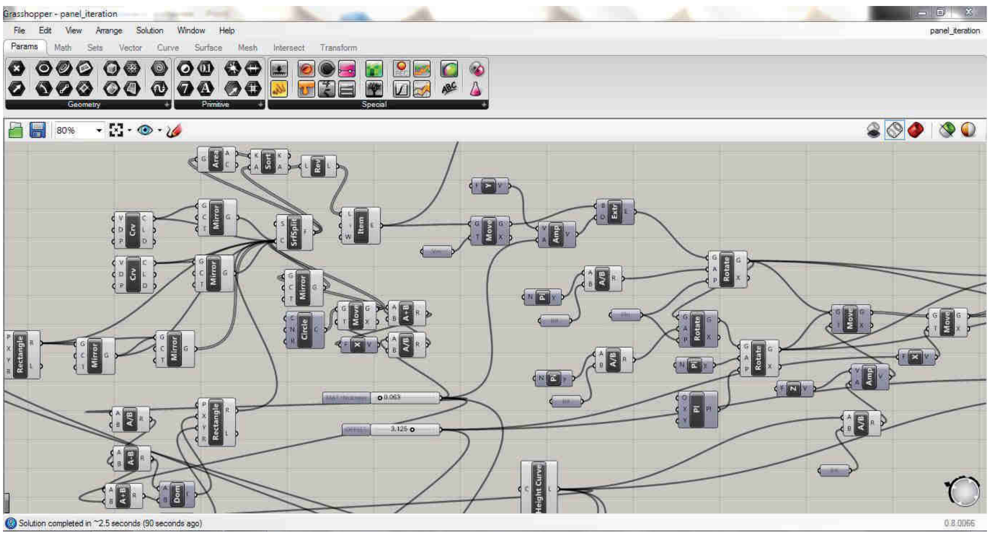
Therefore a designer, in a nodal system as Grasshopper, even without too skilled knowledge in computer programming is able to act not only to the parameters of pre-defined functions, but to build functions by himself. However it is at the same time the harder difficulty of this approach, since there is a vast range of geometric ideas that can be modeled and a number of different ways in which that result can be achieved.

13 BURRY, M., *Between Intuition and Process: Parametric Design and Rapid Prototyping*, in KOLAREVIC B., *Architecture in the Digital Age: Design and Manufacturing*, New York: Taylor & Francis group, ed. 2005: pp. 147-162



3D virtual model obtained trough a parametric design made with Grasshopper, plug in of Rhinoceros

@ http://adpcaad2011.altervista.org/Lessons/les09.html



Screenshot of an exstract of a Grasshopper's canvas

9.3 - IDEATION AND ORGANIZATION OF THE ALGORITHM

Applying a parametric model for the design of the orthosis means to define an algorithm that includes all the processes among which, from the 3D model of the user's lower limb, is possible to obtain a perfectly customized AFO. The ideation and set up of the algorithm went through a series of progressive steps of definition. However as for every design process, this sequence hasn't to be considered as a rigid procedure, since continuous iterations are integral part of the method.

1. Start from the current type of dorsal AFOs as a type that users recognize as comfortable;
2. Definition the force lines present in one shoe when fitted by a person affected by Duchenne Muscular Dystrophy that, with its plantarflection retractions presses on some areas that has to counteract this force applying a dorsiflexion stretching;
3. Localization of the more stressed areas, that have to oppose higher resistance . These parts needs higher resistance, or thickness of material, but, at the same time, even an higher attention in the positioning of the padding, since it has the crucial role of redistributing forces and limiting rubbing pains;
4. Definition of the minimum shape's profile required for the AFO to absolve its functional scope;
5. Definition of the profile of the AFO on the basis of the previous lines, trying to add harmonic and pleasant shape in its general features.
6. Extraction of the generative curves of the AFO
7. Individuation of the control points of these curves and attempt of reducing them to the minimum number as possible.

In particular this last point required particular attention since the algorithm has to start from this points and then, through an interpolation and elaboration of curves based on this parameters give form to the AFO. Fifteen points were identified and will be used, together with the 3D mesh as incoming data in the algorithm for the parametric modelling of the AFO. In the following paragraph the process of choosing these points will be illustrated.

9.3.1 - Identification of the control points on the leg related to the algorithm

The process of localization of the fifteen points on the lower limb that were at the basis of the algorithm was quite tough and demanding. It first started from an in-depth analysis aimed at the understanding of:

- ***basic terminology*** related to the anatomy of the foot, bones' structure, muscles, tendons and nervous system;
- ***functioning and motions*** of the lower limb, topic already discussed in occasion of the design of the pedal of the support of the child during the moments of the acquisition, in relation of the movements that it has to control,
- ***points in which tendons connect muscles to the bones***;
- ***mechanical function of dorsiflexion due to tendons' retractions*** in Duchenne children and the correct movement that it has to be stimulated to counteract this deformation and apply an effective stretching at the limb;
- the analysis of the ***points*** that, in case of an AFO's remote order with an indirect survey by measures, were ***considered crucial by others manufactures*** of AFOs for the design of the orthoses;
- the study of the logaritm composed to elaborate the AFO, from its first general structure, to the individuation of the generative curves required for its identification and further to control points of each curve;
- ***points that were automatically detectable by an hand scan*** with a specific software for the indirect survey of lower limbs.

The individuation of the control points able to define a solid model of the foot was then the following step. On this regard I considered as a reference one publication of the Faculty of Biomedical Engineering of Padova, in Italy, on the morphological configuration of the foot, related to different disease and, in particular, the chapter dedicated to the ***parameters that have to be evaluated to define the morphology of the foot***[14]. The merit of this text is not only the identification of the most important point that has to be surveyed to properly describe the 3D shape of a lower limb, but even relate these points with the survey techniques adopted for the acquisition of the spatial form.

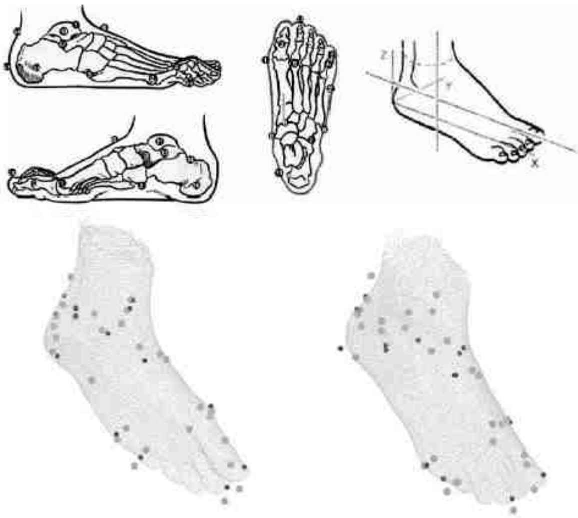
As an example, researches of the University of Valencia made a study on the possibility of recreating 3D shapes of the foot starting from few points located on it. The research was mainly aimed at shoes' e-commerce, in order to establish a parameter of fit and comfort of the shoes in a case when the user cannot directly try it. In this case 14 markers were located directly on the foot and it was scanned with an INFOOT laser scanner. Starting from these points it was possible to measure the length of the foot, the width of the forefoot, the width of the calcaneus, the high of the instep, the high of the first finger and of the lateral malleolus. Then the same test was replicated using an automatic recognition of the points made by the software associated with the scanner. In this case the 14 points where strictly depending from the recognition of the system of axis by the instrument and only 7 where in common with the manual method. The result of that research was the creation of a database of measures, called MORFO3D, useful to study the fit of the shoes and, at the same time, the shape of the foot[15].

14 CORAZZOL M., *Parametri considerati al fine di valutare la morfometria del piede*, in *Configurazione morfometrica del piede in relazione a condizioni patologiche*, Ingegneria Biomedica, Università degli studi di Padova, 2010: p. 22

15 Comparison of the acquired points by manual location of the markers or automatic recognition of

Manual location:

Automatic recognition:



Virtual acquisition of the shape of the foot by manual location of markets or by automatic recognition

@ MORFO3D University of Valencia

the points on the shape acquired by laser scanner.

Manual location::	Automatic recognition:
1. Tibial metatarsal	Tibial metatarsal
2. Fibular metatarsal	*15. Fibular metatarsal*
3. The highest point on the first finger in the interphalangeal joint	*(6) Instep point*
4. The highest point of the joint of the fifth finger at the distal interphalangeal joint;	*(10) The most lateral point of the lateral malleolus*
5. The head of the second metatarsal	*(11) The most medial point of the medial malleolus*
6. Instep point	*(12) Fibular sfirion*
7. Poiny of provisional junction	*(13) Sfirion*
8. Navicular	16. The most lateral point of the 5th finger
9. Tuberosity of the fifth metatarsal	17. The joint of Achilles'tendon at the heel
10. The most lateral point of the lateral malleolus	18. The most posterior point of the heel
11. The most medial point of the medial malleolus	19. The higher point of the first finger
12. Fibular sfirion	20. The most prominent point of the external calcaneus
13. Sfirion	21. The most prominent point of the internal calcaneus
14. Higher point of the medial heel	22. The most advanced point of the 2nd finger.

HERNÁNDEZ J. G., HERAS S., JUAN A., PAREDES R., NÁCHER B., ALEMANY S., ALCÁNTARA E., GONZÁLES J. C., *The MORFO3D Foot Database*, in J.S. MARQUES ET AL. (Eds.), I*bPRIA, Lecture Notes in Computer Science*, 3523, Springer-Verlag, Berlin Heidelberg, 2005

For my research their final result was my starting point for the evaluation of the points useful for my algorithm. Even if I contemplate the possibility of a virtual acquisition made by photo-modelling, I preferred to consider only the points that can be also recognized by an automatic software, in order to make the method applicable in any case, even if the medical staff prefers to directly apply physical markets on the skin.

In my case the individuation of these points was less lied by the responsibility of accurately describe all the shape of the foot, since each curve identified by this point was projected on the mesh. In my case the main concern was to reduce to the maximum the number of points to create a quick algorithm easy to be used and replicated for each user. The final points chosen for the algorithm that compute the design of the Ankle Foot Orthoses are useful to identify:

- the plane that detect the metatarsal width;
- the inclined plane that, under the most prominent points of the internal and external calcaneus connects the connection of Achille’s tendon at the heel;
- the points necessary to describe the axis of symmetry of the leg, from the instep point until the one at the joint of the patellar tendon below the kneecap.

The interpolations, offset, and vector operations among all these points together with the intersections of the planes with the shape of the foot and the extraction of junction curves, gives shape to the AFO.

Localization of the points on the leg required in the planned algorithm to define the shape of DMD’a AFO

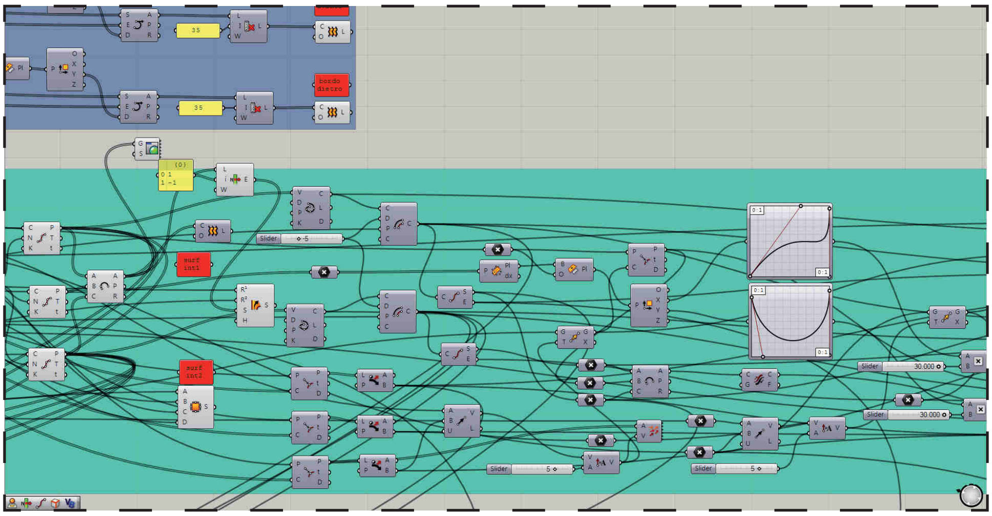
DESIGN

9.4 – PROCESSING OF A 3D MODEL OF A DMD'S AFO FROM A VIRTUAL RECONSTRUCTION OF USER'S LIMB

The 3D model of my DMD AFO was elaborated as a result of a Grasshopper's algorithm. The final shape is therefore the result of a parametric sequence of operations and not the outcome of a 3D modelling. In this algorithm, in order to obtain an AFO for one shoe for a single user, the input data were:

- ***Three dimensional mesh*** of the shape of the foot obtained as a result of the indirect survey of the lower limb of the final user;
- ***15 marker points*** located on the surface of the limb at pre-determinate places as we've just seen.

These points were recognized in the algorithm as variables of the function of the curves, that, step by step, composed the final shape. Three points on the surface of the foot define a plane, with a relative location and orientation to the foot. The plane is intersected with the 3D mesh and the obtained curve gives an accurate indication of the shape of the foot along that plane.



Extract of the Grasshopper algorithm for the design of the AFO

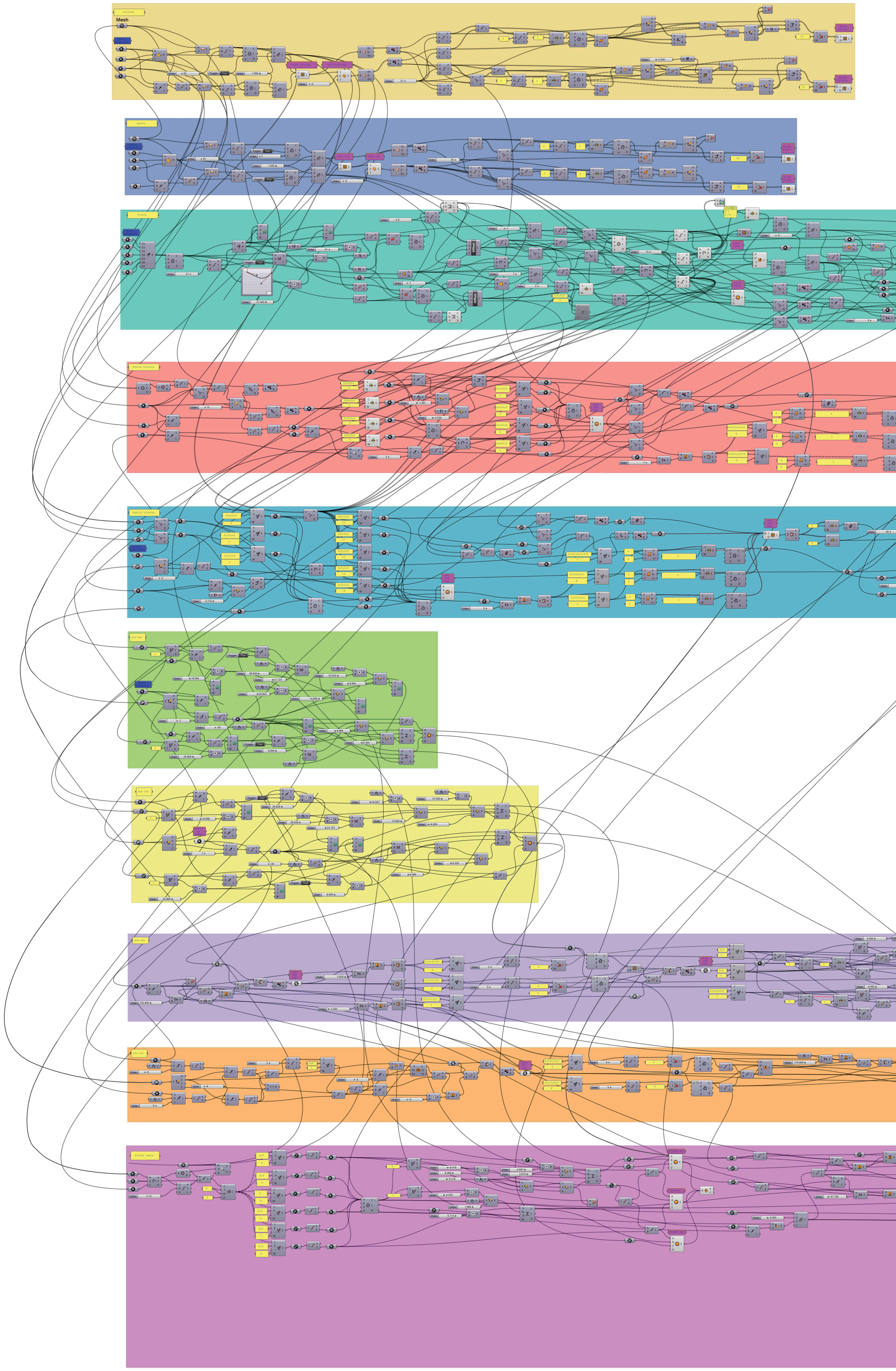
As a first step this curve is simplified in its control points, in order to have a more uniform result and because an excessive detail is not functional for the aim of the orthosis. Secondarily, it is offset of 6mm along the plane because we have to consider the 4mm of thickness of the padding and of the tissue for cladding. Moreover the structure of the AFO is extremely rigid in ABS because it has to counteracts the power of dorsiflexion and it has to cause a stretching movement on the tendons. However it can't be too close to the surveyed shape because we have to consider that the limb is a living body that changes continuously depending on the natural growth of the child, of its position, of the temperature, and of its health conditions. Furthermore even if this process of manufacturing an AFO is definitively simpler than the traditional one, we have to consider that the orthoses have to be worn for a considerable lapse of time of at least six months for younger children.
The process of obtaining generative curves from the mesh of the leg by offsetting the ones extracted from the 3D mesh of the foot was repeated for all the components, and at the end, step by step the final continuous inner surface of the AFO was calculated.
At this stage, for this first prototype, I fixed the ***thickness of the orthosis*** at 5mm, uniform along all the surface. However tests on field and further evaluations on the discharge lines of forces could easily vary this value in phase of experimentation,

adding more material in more stressed areas or thinning parts less strained. As a final stage all the curved connections among inner and outer surface are computed.

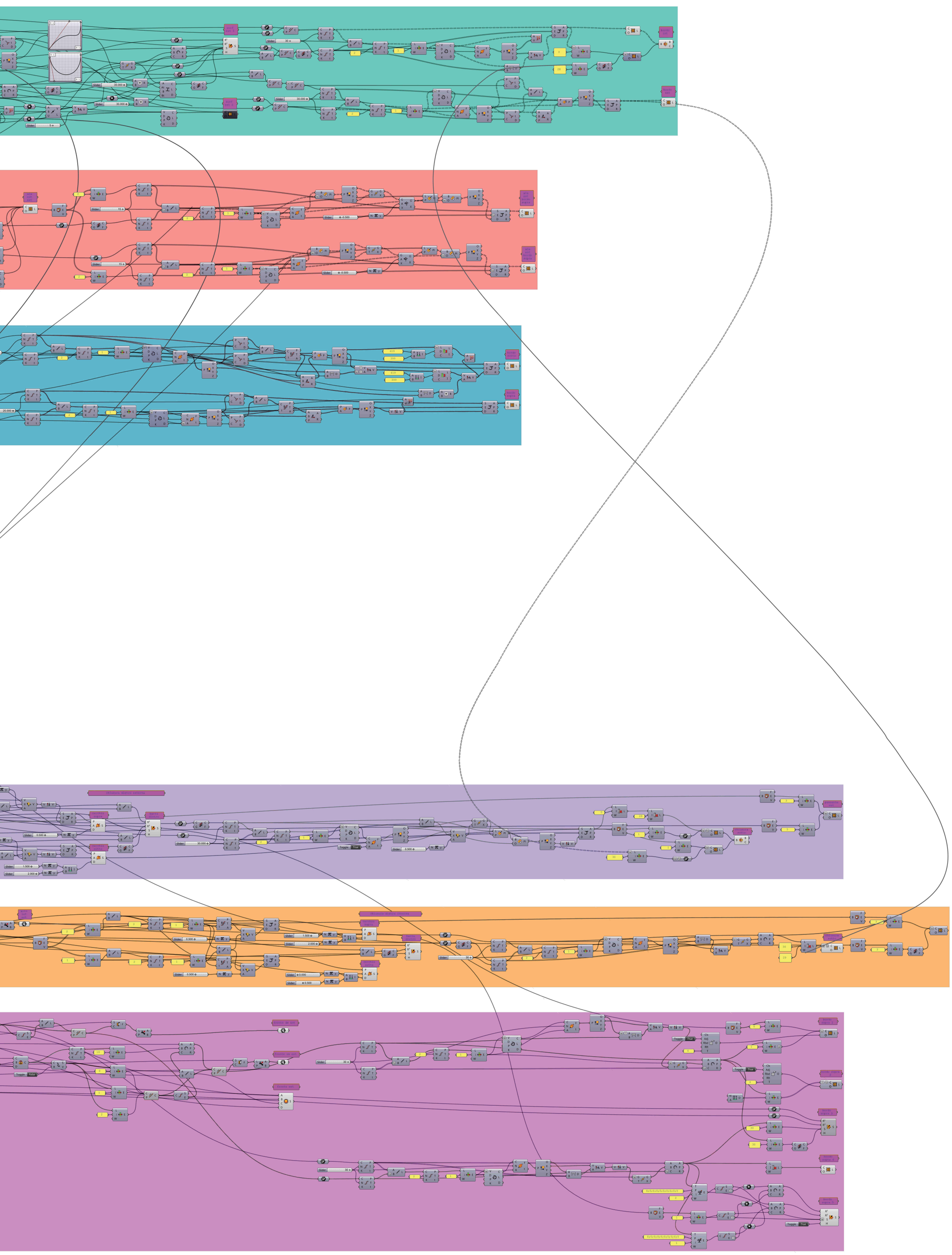
In the image below is possible to see a preview of this complex algorithm. In the following pages it is represented and it is illustrated how ***each coloured rectangle includes the sequence of steps required to obtain a different part of the AFO.***

Moreover, on the left, zooms of the algorithm evidence the 3D mesh and the 15 points used as inputs. If we need to adapt the AFO on a new shape, we have to simply re-associate these input data and the AFO will automatically find on the mesh its generative curves and eventually will adapt in real time on the new shape.

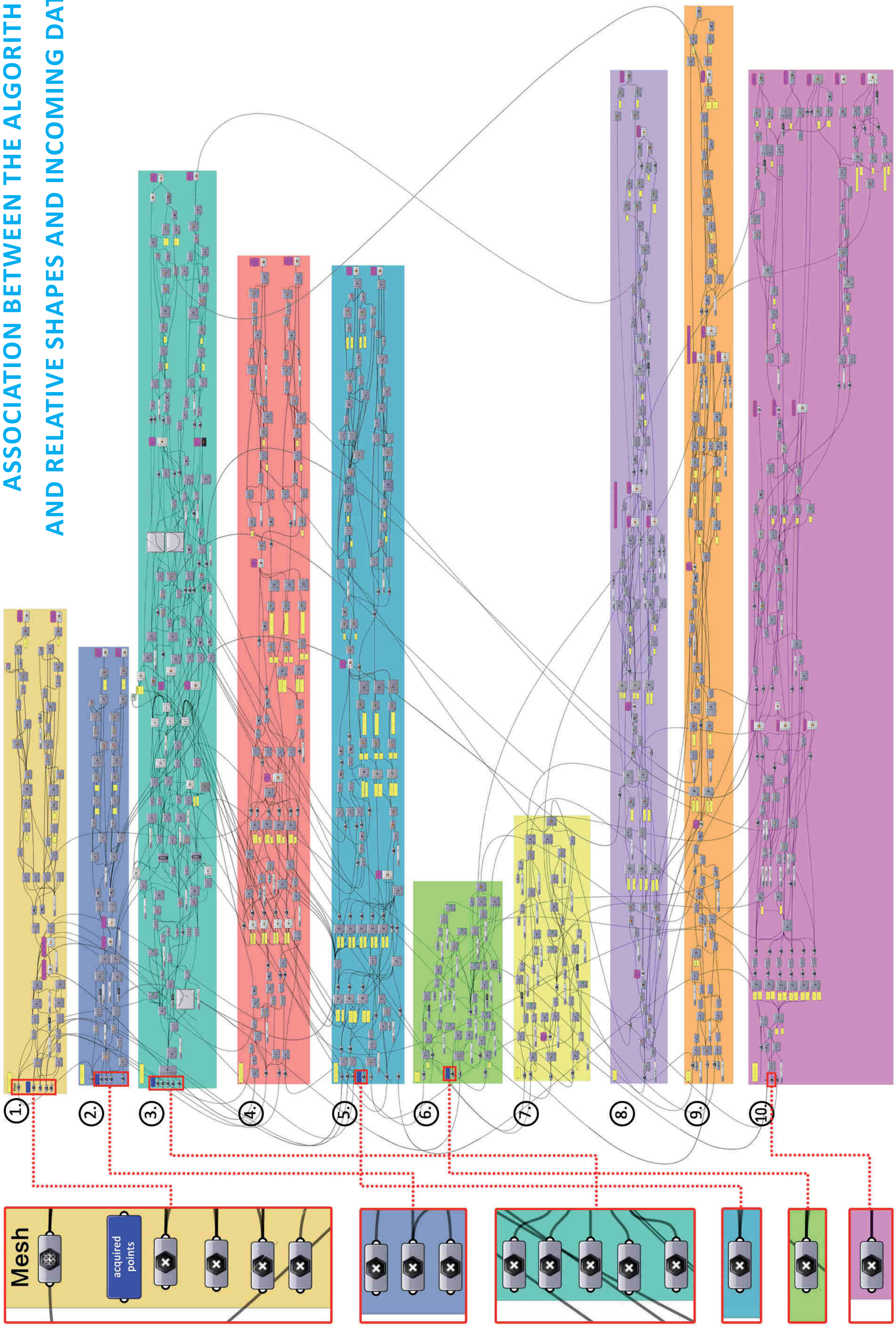
This is one of the most powerful effect of parametric design, but even one of its weakest points since, if the algorithm isn't properly set, a little change in one feature could completely affect the final result.

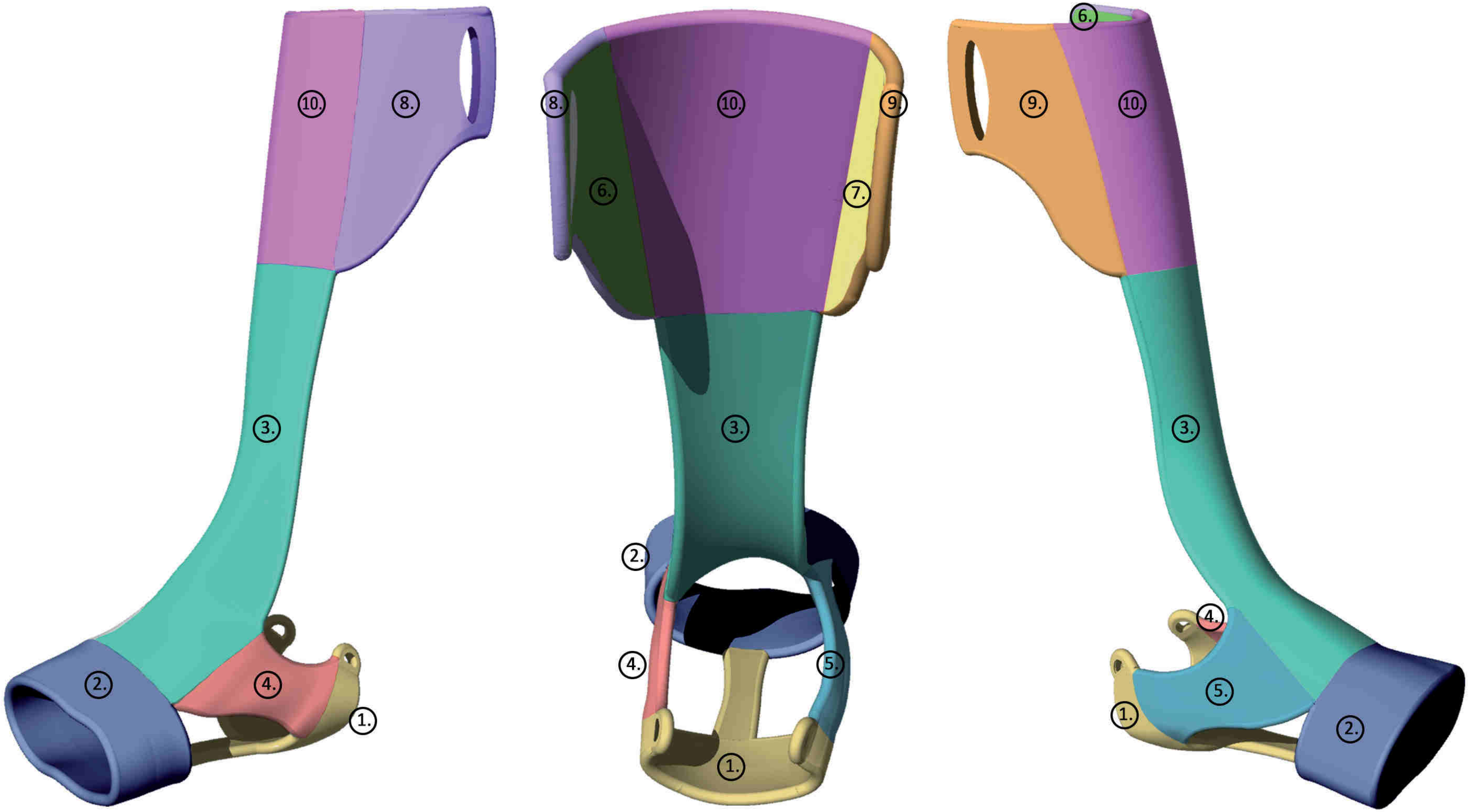


EXTRACT OF GRASSHOPPER ALGORITHM FOR THE DESIGN OF THE NIGHT AFO FOR DMD



ASSOCIATION BETWEEN THE ALGORITHM AND RELATIVE SHAPES AND INCOMING DATA





The algorithm to obtain a 3D model of the AFO was quite complex. In order to semplificate its visualization it was organized in ten boxes, where each one of them elaborates a single part of the AFO, indicated with the same colour and number. However, as can be seen these parts are not separate but there are several constraints that relate each curve or feature with the others. Once this surface was completed, all the final surfaces were merged, the central part was identified and a Voronoi pattern was applied on it.

9.4.1 - Aesthetic personalization, breathability and Generative Design

The application of parametric design doesn't involve only the morphology of the orthosis. Its potential includes all the features of customization of the AFO.
These personalizations can be made acting on various levels:

- **bi-dimensional drawings** applied on the model as textures of any type, as it is currently done with most of AFOs on the market;
- **singular modifications on each orthosis**, with infinite possibilities of acting on the shape, on the general aspect, colours, projecting or excavating letters, motives, textures with the only limit of manufacturability, clinical efficacy and strength resistance;
- ***application of three dimensional parametric textures*** that can scoop out the surface.

Simply changing few parameters of the algorithm, an infinite range of aesthetic solutions can be achieved. Architects, graphics and designer are becoming more and more interested in this new possibility offered by tools that aren't now anymore a prerogative of informatics and mathematics but have new interfaces accessible to them too. This new method is called **GENERATIVE DESIGN** and it is based on a set of rules defined by an algorithm. Despite evolutionary processes that proceed by continuous adaptation and optimization, in a generative process the result of a change of input data isn't certainly an improvement of the previous condition, but has to be evaluated case by case. *"Generative methods have their roots deep in the systems dynamics modelling and are by nature repetitive processes where the solution is developed during several iterations of design operations. In generative design process the production of complexity usually happens through aggregation."*[16]
If is a creative process since the designers transform rules of the algorithm to generate models, in this case 3D models in a subjective way, but in its application for the real world it is usually constrained but external factors too.
The application of this method to enlarge the possibilities of aesthetic personalization of AFOs could have interesting advantages:

- ***automatic adaptability of the desired weave on the shape of the orthosis***, its scalability, considering as the only constraints the structural resistance and manufacturability;
- ***breathability***. The generation of 3D patterns on the orthosis could be a crucial element to perforate the orthosis and improve the transpiration;
- ***reduction of time and cost of the final product***, since it allows to produce an high quality and good looking final product but applying automatic procedures and therefore optimizing the time spent in the modelling of personalized single orthoses.

In order to lighten and to make more breathable the orthosis a geometrical pattern that aesthetically characterizes the result was applied on the frontal part of the AFO. In this case I opted for a ***Voronoi parametric diagram***[17], since it allowed to be regulated in shape and size easily adapting to an irregular shape.

16 *What is Generative Design,* Diagramming machines. Writing on computational and generative design, http://www.reneepuusepp.com/what-is-generative-design/ (January 2015)

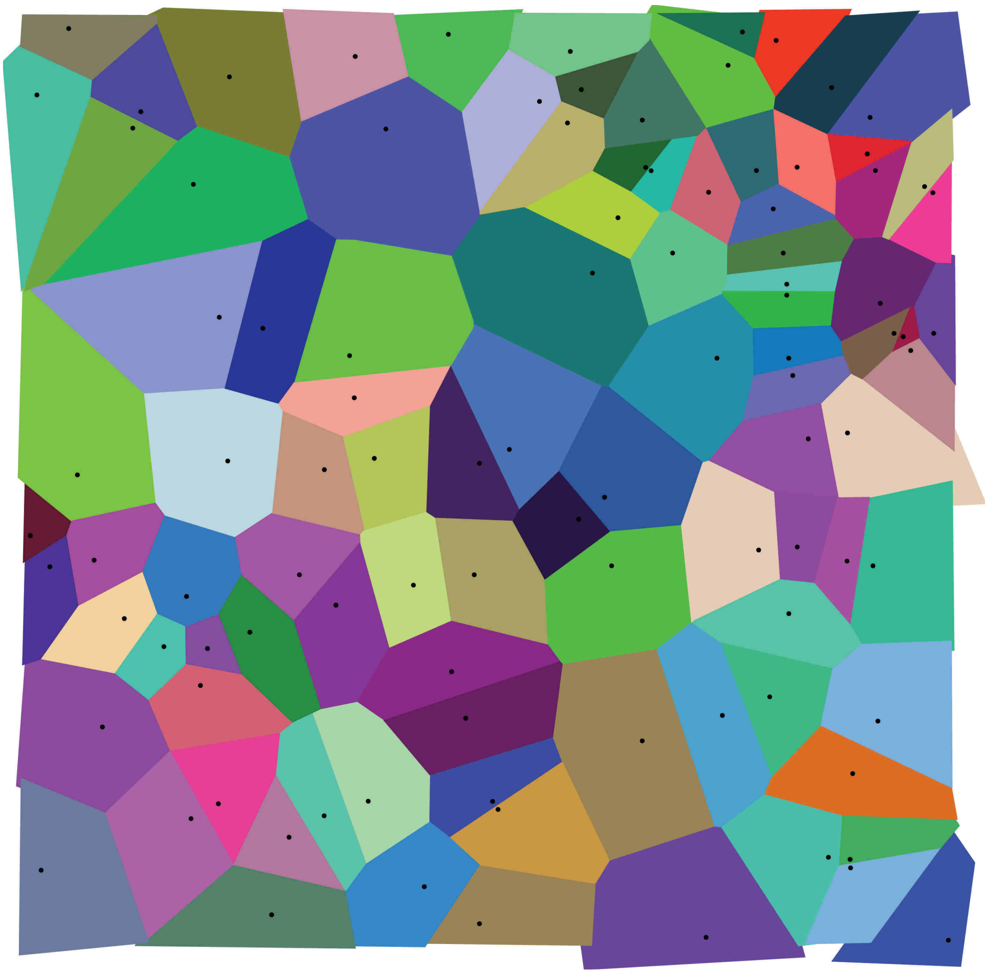
17 WEISSTEIN E., *Voronoi Diagram*, in *MathWorld* – A Wolfram Web Resource, http://mathworld.wolfram.com/VoronoiDiagram.html (November 2014)

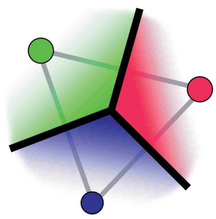
A Voronoi Diagram is a *"partitioning of a plane with "n" points into convex polygon such that each polygon contains exactly one generating point and every point in a given polygon is closer to its generating point than to any other."*
It is named after its definers, the mathematician Georgy Voronoy, and this diagram has practical and theoretical applications to a large numbers of fields, in science, technology, art, such as computer graphics, epidemiology, geophysics, meteorology, geometry, ecology, architecture, and others.
Grasshopper has this function already preset among its tools. Its input parameters are:

- Points for Voronoi diagram, randomly generated;
- Cell radius;
- Cointainment box for diagram;
- Base plane, or its best fit.

As an output this algorithm elaborates spatial curves that are applied on the desired surface. These curves are designed in order to leave always a septum between each all of at least 4 mm, to guarantee its manufacturability and strength resistance.

Nevertheless ***this is only one of the infinite possibilities of perforating the dorsal surface of the AFO*** and all the possibilities in changing shapes and colours will be discussed in the following paragraph.
Once the model was finished and the algorithm concluded, I baked the shape in order to have a solid model and no more a parametric one, I regulated and stitched the meshes generated in a single surface, and optimized it in order to be exported as an .stl file ready to be 3D printed.





Coloured 2D Voronoi diagram

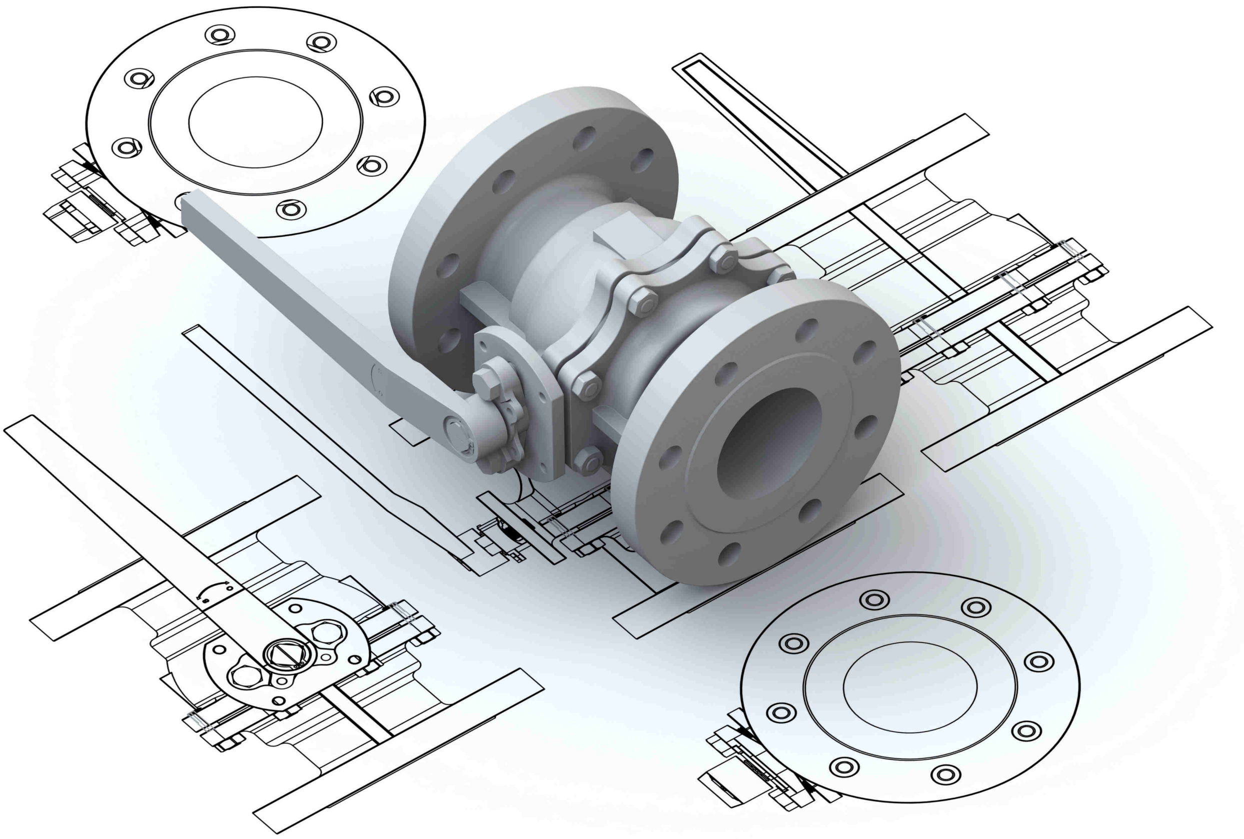
@ Maksim http://en.wikipedia.org/wiki/File:Coloured_Voronoi_2D.png#metadata

9.5 - Conclusion of the parametric design of the AFO

In this chapter we've seen how we arrived to the decision of a parametric design of the orthoses, how this idea was developed and all the advantages and disadvantage of this decision. However it must be noticed that ***the decision of the technique of design went in parallel with the choice of the technique of manufacturing***.

In a product design this is a common method of approaching issues, since anything has to be designed without interrogating on how it is possible to manufacture that element. However in this case the decision was, if possible, even more important since ***parametric design allows a freedom of design that could be lost if translated in a traditional manufacturing***, or it can be achieved but with an high cost of tooling for manufacturing and through sophisticated processes that makes it no more convenient or rational.

On the contrary the combination between parametric design and additive manufacturing with 3D printing techniques reciprocally enhance both the processes and enlarges the possibility of application and the potential of responding to users' needs. In the following chapter we'll examine more in detail which were the alternatives available for the manufactuer of the AFOs, which was the one choosen for the realization of a first prototype and which would be interesting new experimentation that could be conducted in future.



10 FROM 3D PARAMETRIC MODEL TO 3D PRINT

Potential of 3D printing in translating ideas and drawings
into prototypes, toolings and manufactures.

@ http://realpossibilities.pro/

10 – FROM 3D PARAMETRIC MODEL TO 3D PRINT

The phase of ***Manufacturing of the AFO*** is strictly related to its design process. The choice of the best technique to design the AFO and the one to manufacture it were conducted in parallel in order to reciprocally enhance the potentials of each technology.

In this chapter all the different alternatives available for the manufacture of the design of the orthosis will be illustrated and it will be motivated the choice of recurring to an ***additive manufacturing technique.*** 3D printing proves indeed to be the technology that makes all the potential of exploring an enlarged freedom in the determination of the shape and aesthetical features of the orthosis, available thanks to the adoption of a parametric design process, available at reasonable costs and time. The release from the necessity of creating complex formworks for the mold of the material has immediate relapses in the diminution of time and cost of production, beside a reduction in waste material and energy consumption. Moreover 3D printing technique is perfectly compatible with a production of unique pieces, since it is minimally affected by the logic of mass production and economies of scale.

In particular in this chapter the most common different techniques of manufacturing applying an additive technology will be analysed and compared. Even in this case we'll see how the final choice will not be the best technical solution possible at the moment but the best resulted from a User Centered Analysis that takes in consideration all the elements, the features and the consequences related to a technological choice.

10.1 – INTRODUCTION

Manufacturing is the ensemble off all the activities aimed at the transformation of row materials, energies or information in finished goods using labour, machines and tools.

The phase of choice of the best manufacturing technique to manufacture the orthosis took in consideration four issues:

- **USERS' NEEDS -** As for any decision afferent the design process, the first and main target is defined by users' needs and requirements. On this regard the issues emerged in the House of Quality of the Quality Function Deployment method regarding the choice of a manufacturing technique for the AFO were:
  - it has to improve customization;
  - it has to produce hypoallergenic products;
  - it has to produce high resistance products;
  - it has to be suitable with single pieces productions, it can't rely on economy of scale;
  - it has to be very flexible to meet aesthetic requirements of personalization;
  - it has to be quick;
  - it has to be cheap;
  - it has to perfectly respond to doctors' requirements;
  - it has to meet law standards with the support of the National Health System;

DESIGN

- **CURRENT PROCESSES OF MANUFACTURING OF AFO** - The most common processes applied on current Italian, European and North American market were in-deep analysed in chapter 3 and they were a solid basis of comparison, since every new hypothesis of solution was evaluated in terms of what tangible advantages could bring compared to eventual disadvantages.
- **CURRENT PROCESSES AVAILABLE OF PRODUCTS MANUFACTURING** - This analysis was conducted by general features, different possible approaches and filtered by users' requirements to individuate the processes applicable for the aim of the research.
- **COMPATIBILITY WITH THE DESIGN PROCESS** - This topic proved to be extremely relevant in the final decision of the technology to adopt in the manufacturing of the AFO. It implies the reflection that each decision, in each phase, has not to be done considering exclusively the inputs and outputs of that single step but has to include as crucial and determinants elements of evaluation all the process, its aim and final targets and expectations.

The analogical replication of a mold is nowadays the most common system of industrial production. The analysis of ***traditional techniques based on subtractive methods*** highlighted the limits of this technique, in particular in the production of AFO. Traditional manufactures requires long time of human labour, since it passes through many phases and in each of this phase, due to its handcraft nature, a little precision is lost and is introduced a percentage of human errors. Moreover it uses per each piece a lot of waste material that, since AFOs are unique pieces customized on users' shapes, aren't recyclable.

Nowadays is in course what many specialist are calling ***the Third Industrial Revolution: Digital Manufacturing***. It is a direct consequence of digital revolution that, especially in this last century, is starting to involve manufacturing applications and that it is aimed at rapidity, flexibility of application, customization. This new approach to production is growing fast since it follows the manufacture trend of substituting mass production with a customized production on demand, assisted by service strategy ad-hoc for the final user. These changes are not only due to the incoming of digital manufacturing technology but they have to be framed in a context of progressive saturation of the market, increment of the human labour cost, as well as of the costs of transportation.

"As mass production has migrated to developing countries, European and US companies are forced to rapidly switch towards low volume production of more innovative, customised and sustainable products with high added value"[1]

In this sense the highest innovation which came on the market is **3D printing**. It is one of the most common names to include a group of related technologies associated by the creation of objects through an ***additive manufacturing process*** starting directly from CAD data sources. It creates physical objects by the overlapping of thin layers of material from the bottom, up. Evidently this technology proves to be opposite to the traditional subtractive manufacturing processes, (as milling, drilling, grinding etc.), which produces objects by removing material from a compact shape.

The ***advantages of 3D printing compared with traditional processes*** are countless and can be reassumed in:

- *The possibility of turning concept ideas in physical products in a short time and efficiently*;
- *Easiness of communication and evaluation of concept ideas*. If the prototype is realized in a short time it leaves time to the staff to evaluate the project and

1 MELLOR et al., *IJPE,* 2013

DESIGN

to restart with another concept or with even drastic changes;

- *Fluency in the design process with the facilitated possibility of design iterations. By giving engineering, manufacturing, marketing and purchasing a look at the product early in the design process, mistakes can be corrected and changes can be made while they are still inexpensive*[2];
- *Enhanced control on the project and consequently better quality of the final product*;
- *Decreasing delivery time*, as if 3D printing is used as a prototyping tool as if it produces the final product too;
- *Almost unlimited complexity*. Huge enlargement of the freedom of generating geometric complexity or intricacy[3] since no mould are required in the manufacturing and, usually, no assembling is required if not for a dimension problem. Design complexity is not only extended, it is almost free of any additional cost or huge differences of time to be produced[4];
- *Reduction of time to market* since it is proved that the longer one product needs to be designed, realized and commercialized meaning less potential profit for the company[5];
- All these advantages lead to a *decrease in the general cost*. *"In 1994 Pratt & Whitney achieved an order of magnitude (cost) reduction and time saving of 70 to 90 percent by incorporating rapid prototyping into their investment casting process."*[6]

As it can be seen, almost all of the advantages in the application of a 3D printing technology are perfectly compatible with the aim of the manufacturing of Ankle Foot Orthoses. This technique perfectly responds to users' requirement of flexibility, customization, reduction in time of manufacturing, human labour and costs for low-volume products.
Moreover it is the natural consequence of the choice of a parametric design process, since it limits to the minimum the restrictions of manufacturability. Nowadays this technology is at the peak of its evolution cycle: everyone is talking about it, it is broadly present in each technological fair of trade show and many companyes are investing large capitals with great expectations relied on this technology. It is highly probably than in the next ten years this technology will have a down and a sort of disillusion of its apparently unlimited possibilities. However in a period of about 10 years it is highly probably that it will become a common process of many sectors of production. Biomedical applications, as the one object of this research, in particular, are among the highest probably ones that will continue to use more and more these technologies since their perfect correspondence with the characteristics and possibilities offered. For this reason in the following paragraphs of this chapter a brief overview of all the alternatives techniques of 3D printing is presented, in order to identify the best solutions applicable for the manufacturing of Ankle Foot Orthoses.

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2 EFUNDA, *Rapid Prototyping: an Overview*, http://www.efunda.com/processes/rapid_prototyping/intro.cfm (January 2015)

3 ADDITIVE3D, *What is Rapid Prototyping? A brief tutorial*, http://www.additive3d.com/rp_int.htm (January 2015)

4 CRUMP S., *Direct Digital Manufacturing. Part Two: Advantages and considerations*, Stratasys, http://www.stratasys.com/resources/~/media/A28A761279E845C29EC0AFD084C9E7C0.pdf (January 2015)

5 STRATASYS, *A new mindset in product design*, http://www.stratasys.com/resources/~/media/06F7C980480F4E90924548E0918539DF.pdf (January 2015)

6 PALM W., *Overview of Rapid Prototyping,* http://www.me.psu.edu/lamancusa/rapidpro/primer/chapter2.htm, 1998, in http://www.slideshare.net/IrHakimi/references2-13723321 (January 2015)

10.2 – Overview on 3D printing techniques

3D printing technology was initially applied to obtain small prototypes and for this reason its traditional name was ***rapid prototyping***. However nowadays the application of this technology and the materials that can be used are exponentially growing and for this reason the relation with the prototyping has been overtaken by other terms as ***3D printing***, ***additive fabrication***, ***solid freeform fabrication (SFF)***, ***layered manufacturing*** and others[7].

The first methods for rapid prototyping became available in the late 1980s. The stereolithography technology, a process that solidifies layers of ultraviolet light sensitive liquid polymer using laser technology, emerged in 1986 by 3D Systems of Valencia. Afterwards in few years all the other technologies appeared and in particular the industry's first 3D rapid prototyping system based on FDM technology was introduced in April 1992, by Stratasys company. The firsts 3D rapid prototyping systems based on PolyJet technology were introduced by Object in April, 2000[8].

Nowadays these techniques are used for a wide range of applications, from the realization of prototypes to final products, especially for "quality parts" and in small numbers.

ABS 3D printing filaments in different colors

@The Academy of Model Aeronautics https://www.flickr.com/photos/modelaircraft/9628382689/in/photostream/

In the previous paragraph we've already anticipated all the advantages that the introduction of an additive technique could bring in products' manufacturing compared with subtractive techniques. This scenario, in particular, proves to be particularly efficient if the machine is owned by the manufacture who can use it any time he desires without the necessity of researching for external services of 3D printing. Having an own 3D printer can transform the use of rapid prototyping as an iterative process, since it can be really quickly and with reasonable expenses avoiding delay for shipments and retires. Moreover it proves to be particularly necessary for fabrics since it guarantee the secrecy of data and of the design. The initial economic investment is quickly recovered (it is counted as at least two models per month on average), if the machine is frequently used, causing reduction of costs, of time to

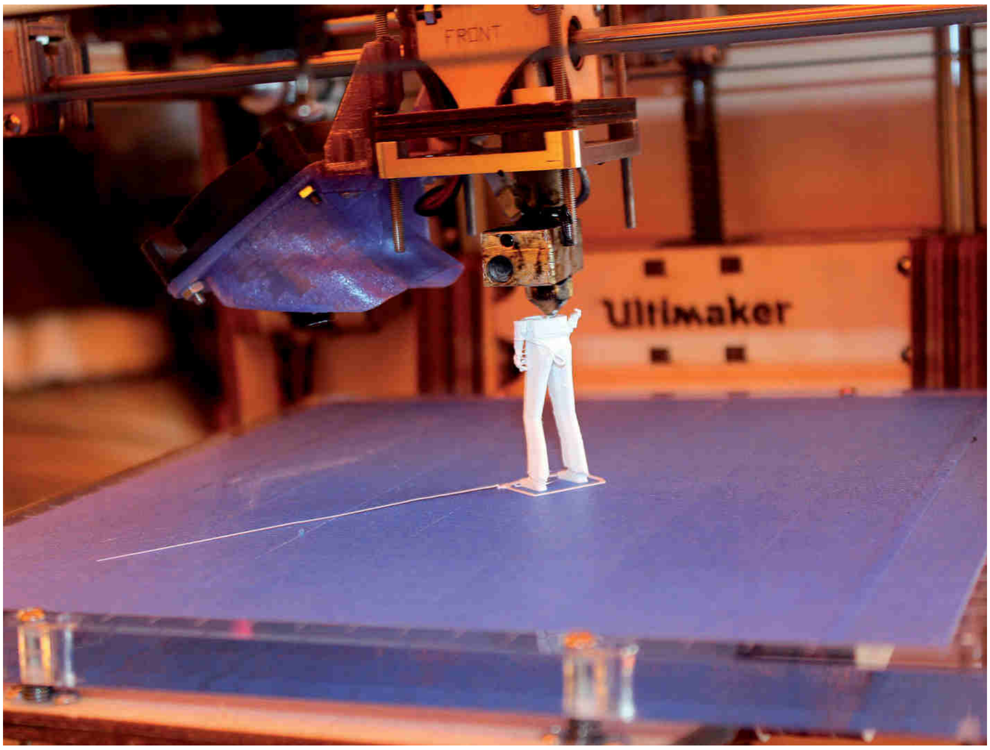
7 ADDITIVE3D, *What is Rapid Prototyping? A brief tutorial*, http://www.additive3d.com/rp_int.htm (January 2015)

8 STRATASYS, *What is Rapid Prototyping?*, http://www.stratasys.com/resources/rapid-prototyping (January 2015)

ANALYSIS

market and in the quality of the product, as said before[9]. Usually the outsourced prototyping requires a week or longer to get models back, and, for an economical and psychological effect, the design team will not order a model until it is almost finished, while having an own 3D printer can make this process more iterative and the time of the night or of the weekend can be used to prototype the object.

Of course this technology has some ***disadvantages*** but their analysis is quite difficult at the moment since it is changing so quickly and so many experimentation are in progress that better evaluations will be possible in future. We can state right now that it's main disadvantages are on the quantities of products need, since 3d printing is not a high volume manufacturing process[10] and on the volume of the product, at least for ordinary machines and on metal prototypes. In this case even if some tests are in progress at the moment, especially for large production runs or simple objects, conventional manufacturing techniques are usually more economical. Another issue could be the accuracy of 3D printed objects. However even since usually the accuracy of additive methods isn't good as subtractive methods made by Computer Numerical Control machines, for a wide range of application it is considered adequate[11].



Ultimaker open source 3D printing

@Elza van Swieten https://www.flickr.com/photos/confluencemedia/8888307124/in/photostream/

9 STRATASYS, *In-House or outsource?*, White Paper, Stratasys, http://www.stratasys.com/resources/~/media/1A1638080F244B8FBA71B7C4DE9091BC.pdf (January 2015)

10 *"If demands are for millions of units a year DDM (Direct Digital Manufacturing) will not be the right solution. Typically, DDM is used when production quantities range from one to 10.000 units per year. However the justifiable production quantity will vary with the size of the components. As part size decreases, the annual production quantity increases."*

CRUMP S., *Direct Digital Manufacturing. Part Two: Advantages and considerations*, op. cit.

11 *"Direct Digital Manufacturing is currently capable of holding accuracies that are approximately ± 0.001 to 0.002 inch tolerances across all features of a part."*

CRUMP S., *Direct Digital Manufacturing. Part Two: Advantages and considerations*, ibidem

10.2.1 Applications

The flexibility of the technology make it applicable in many fields that I reassumed briefly in three categories:

- **Rapid prototyping**. They can be concept models, as visual aids for communicating ideas with co-workers or customers, or functional prototypes as design testing. Designers have always used this strategy as a support of their conceptions, but rapid prototyping transformed it in a quicker and easier step. *Industrial designers mechanical engineers, packaging designers, graphic artists and marketing staff all use prototypes to understand a product's aesthetic and functional appeal*[12]. Aerospace engineering, for example, might place a model in a wind tunnel to measure lift and drag forces[13]. Medical and biomedical companies are investing in this technology, as we'll see in the following paragraph. Many applications are incoming in transportation, military and education. Furthermore with the incoming on the market of low-cost and open source systems, hobbyist and consumers are increasingly using this technology.
- **Rapid tooling**, to manufacture devices that aid in the production of the sellable products. They can be silicone rubber molds, investment casts, robot-arm ends, or others. Durable jigs and fixtures can be created in one night instead of weeks but 3D printing can also enable manufactures to skip it completely or to drastically simplify assembly processes.[14]
- **Rapid manufacturing**, or DDM, Direct Digital Manufacturing[15], if 3d printing technology is used to produce the final object. They can be components that go into sellable products, pieces of production machinery. Nowadays DDM is being applied in several types of industries, such as industrial designs, aerospace, automotive, consumer products, electronics, defence and medical and dental industries. At the moment this solution is proving to be particularly efficient for extremely low quantity applications and for customized solutions in an on-demand or just-in-time strategy. It mustn't be considered as a total replacement of traditional manufacturing process, but, on the contrary, as an alternative particularly effective especially when traditional methods prove to be ineffective in the manufacture of a product for technical, procedural or economic reasons. In particular the aerospace and medical industries in particular have developed advanced applications for 3D rapid manufacturing of final products. The undeniable advantage of this solution is the ***complete elimination of the phases of molding, machining, casting and forming with consequent elimination of extra time, cost or labor. It enlarge enormously***

12 STRATASYS, *Prototyping. Prototyping at a rapid pace*, http://www.stratasys.com/solutions-applications/prototyping (January 2015)

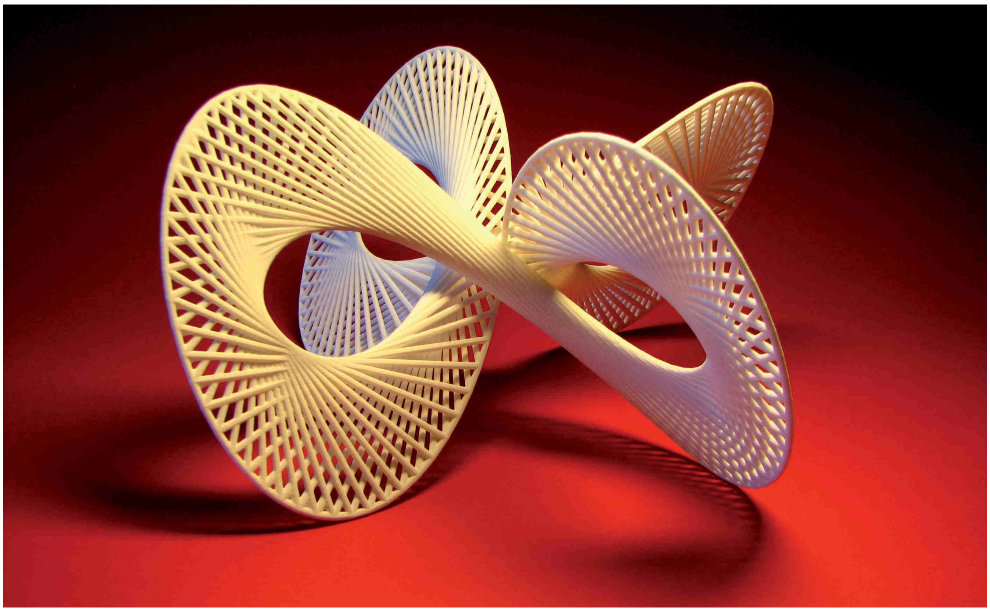
13 PALM W., *Overview of Rapid Prototyping*, op. cit.

14 STRATASYS, *Four ways 3D Printing is shaping product design and manufacturing*, White Paper, Stratasys, http://www.stratasys.com/~/media/Main/Secure/White%20Papers/SSYS-WP-FourWays-10-14.pdf (January 2015)

15 *"The shift away from the term rapid manufacturing is due to two factors. First, many conventional processes have begun using the term "rapid manufacturing" to describe the activity whether or not it incorporates additive fabrication technology. This has rendered the term somewhat meaningless. Second, and more importantly, DMD offers much more than an acceleration of the manufacturing process. An emphasis on "rapid" can lead to oversight of the numerous advantages delivered throughout the manufacturing process. DDM is not a simple revision of existing manufacturing methods that makes the process faster. It is a radical departure that fundamentally changes manufacturing."*

CRUMP S., *Direct Digital Manufacturing: Part One*, White Paper, Stratasys, http://www.stratasys.com/resources/~/media/32396FEC164E49FE93A710CED7097CFC.pdf (January 2015)

the design possibility of the draftsman since he is no more limited by the rules for Design for Manufacturability (DFM) or the rules for design for assembly (DFA)[16]. Moreover the elimination of tooling cost and of the wait for the first production, ***minimizes the start-up investment for a new product***. The complexity of the design of the object isn't for sure a requirement for DDM, but the benefits that can be derived, compared with a traditional realization of the product, usually increase proportionally to the component's design complexity[17]. Rapid manufacturing is a process not a technology and for this reason it can be performed with various solutions. The number of materials used in 3D manufacturing is rapidly increasing and among the others we can mention resins, plastics and, metals[18]. Finally another great advantage of rapid manufacturing is that it produces ***very little waste and consumes quite little energy*** and therefore it can be defined as a "green process". Even if support material is required, its elimination is very simple and it isn't dangerous for the environment.



Quadrifolium
3D Print

@ fdecomite
https://www.flickr.com/photos/fdecomite/8215690357

16 CRUMP S., *Direct Digital Manufacturing: Part One*, ibid.

17 CRUMP S., *Direct Digital Manufacturing: Part Three*, White Paper, Stratasys, http://www.stratasys.com/~/media/Main/Secure/White%20Papers/Rebranded/SSYS_WP_direct_digital_manufacturing_part_three_identify.pdf (January 2015)

18 STRATASYS, *A new mindset in product design*, http://www.stratasys.com/resources/~/media/06F7C980480F4E90924548E0918539DF.pdf (January 2015)

10.2.2 Operation

3D printing is a classification that includes several different technologies that will be discussed hereafter. However all these processes are associated by the same operation. Everything starts from elaborating a virtual model with a Computer Aided Design software. "*Besides CAD data, which is the overwhelming majority of data used, other types of data may be used to drive additive manufacturing machines. Among other it includes 3D scan data (for reverse engineering) and DICOM data (for making a physical representation of 3D medical imagery)*"[19].

3D printing uses as a standard data interface the STL file format, from ***Stereolithography***, to translate information from the CAD software to the 3D printing. The process of conversion from a CAD data to STL implies the approximation of the shape and its transformation in triangular facets[20]. It means that if we increase the number of triangles, we improve the approximation with the real curve but we proportionally increase the dimension of the file. It contains the coordinates of the vertices and the direction of the outward normal of each triangle[21].
The STL file is imported in a pre-processing program that prepares to the printing and orients the model. Orientation is extremely important for several reasons:

- *Structural properties:* prototypes are usually weaker and less accurate in the z (vertical) direction than in the X-Y plane.
- *Time required for the printing*: placing the shortest dimension in the z direction reduces the number of layers and therefore the build time.
- *Calculation of support material* (if the technology provide for it): auxiliary structure support the model during the construction especially in breakable points as overhangs, internal cavities and thin-walled sections[22].

Thickness of the slices, material and colours are then defined and, at this point, the 3D printing machine is ready to read the data from the .STL file and lays down and stitch successive layers of liquid, powder or sheet material, building up the physical model from a series of cross sections. These techniques are completely autonomous and don't require human intervention during the process if not at the beginning and at the end.

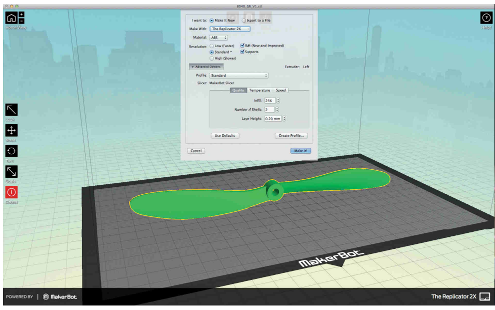
19 CRUMP S., *Is now the time to try direct digital manufacturing*, White Paper, Stratasys, http://www.stratasys.com/~/media/Main/Secure/White%20Papers/SSYS-WP-TimetoTryDDM-08-14.pdf (January 2015)

20 STRATASYS, *What is Rapid Prototyping?*, op. cit.

21 PALM W., *Overview of Rapid Prototyping*, op. cit.

22 PALM W., *Overview of Rapid Prototyping*, ibid.

a.



b.

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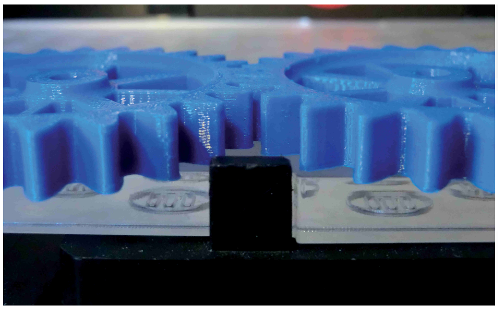
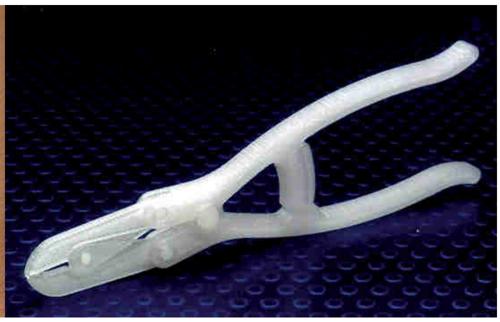


f.

g.

h.



a. and b.
3D-printed propeller for model airplane
@Creative Tools
https://www.flickr.com/photos/creative_tools/9155457179

c.
3D-printed pendant in pure brass plated in 22k gold and hand-polished to a fine sheen
@Shapeways
https://www.flickr.com/photos/51579195@N02/12092508423/in/photostream/

d.
3D-printed helmet in multicolor
@Stratasys
https://gigaom.com/2014/01/27/stratasys-reveals-a-full-color-multi-material-professional-3d-printer/

e.

3D-printed cogwheel
@Creative Tools
https://www.flickr.com/photos/creative_tools/9572541537

f.
Metal 3D rapid tooling
@ 3D Printer Store
https://www.flickr.com/photos/3dprintersonlinestore/14731032010/in/photostream/

g.
3D-printed gopro screws
@eok.gnah
https://www.flickr.com/photos/eokgnah/8491682562

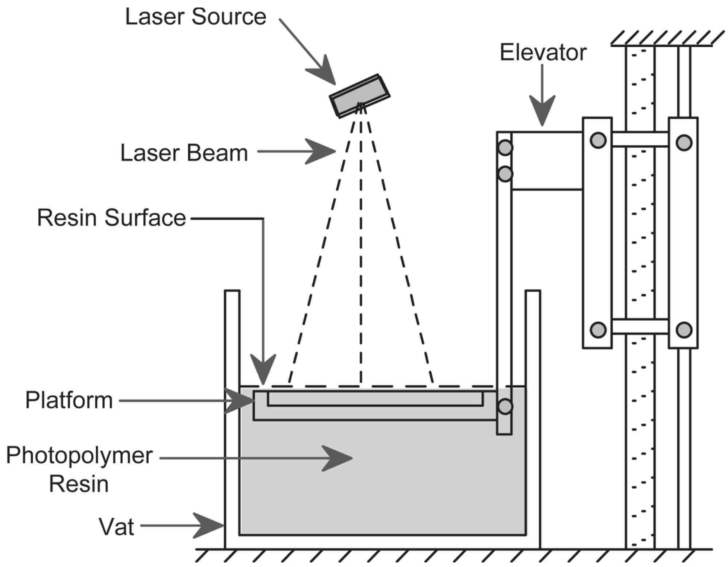
h.
3D rapid tooling
@ http://cfnewsads.thomasnet.com/images/large/031/31021.jpg

10.2.3 Technologies

As conceivable, it is impossible to define all the technologies diffuses nowadays under the label of 3D printing. Too many experimentations are in act, each brand is personalizing the machines trying to achieve the best results and we have still to wait some years to observe which of these technologies will have a real impact in the manufactory in the future. Among 3D printing technology, in this overview I selected only the additive manufacture systems that are currently commercially available and are extensively tested and applied.

10.2.3.1 - STEREOLITHOGRAPHY (SLA)

Stereolithography was the first Rapid Prototyping process used and it is still the most used and the most cheaper. It is composed by a vat full of photosensitive resin and that contains a vertically moving platform. A ultra-violet laser beam moves and project the light on the surface of the liquid hardening a thin layer (about 0.1 mm) of material. Then the platform moves downward of the same high and the beam traces out the superior shapes one by one. At the end the solid object will be completed, layer by layer, and completely immersed in the liquid. Then the platform rises out of the vat, the excess resin is drained and the support cut off[23]. However it needs a post-cure in an UV oven to fully solidify the resin, while a sanding process can remove the stair steps caused by the layers juxtaposition, for a better cosmetic finish. This technology provides for support materials in order to stabilize thin or weak areas.
Sthereolithography is generally considered to provide the greatest accuracy and best surface finish of any rapid prototyping technology[24]. It has some disadvantages since it requires curing but a long-term curing can cause warping, it hasn't milling step and this can cause little accuracy in z direction and final objects can be quite fragile[25]. Moreover even the long-term stability of materials can be a matter for concern that has to be taken in consideration depending on the aim of the object. Nevertheless modern machines are trying to solve these difficulties and guarantee more and more better results.



Analysis of the stereolithography process

@ SolidSmack http://www.solidsmack.com/fabrication/stereolithogrphy-110-micron-old-world-laboratories-nano-3d-printer/

23 QUICKPARTS, *Rapid Prototypes*, http://www.quickparts.com/LowVolumePrototypes.aspx (January 2015)

24 ADDITIVE3D, *What is Rapid Prototyping? A brief tutorial*, op. cit.

25 EFUNDA, *Rapid Prototyping: an Overview*, op. cit.

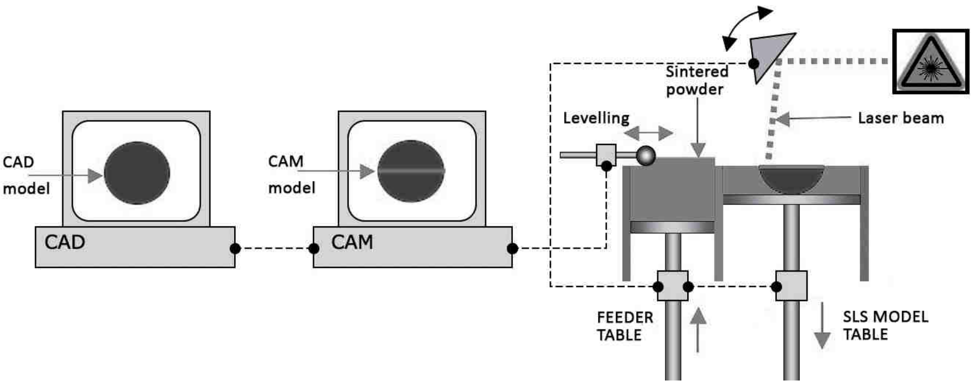
ANALYSIS

10.2.3.2 - SELECTIVE LASER SINTERING (SLS)

The main feature that differences SLS from SLA is that while Stereolithography process is limited to photosensitive resins, Selective Laser Sintering process can use polymer powders that, when sintered, approximate thermoplastics quite well[26], such as polycarbonate, nylon, or glass-filled nylon. This process was patented in 1989 by Carl Deckard, a Texas student and registered as trademark by DTM of Austin, Texas. The machine can be composed by two or three chambers, each one located on a piston. In the last case there are two powder magazines on either side of the work area. A levelling roller moves a thin layer of powder on the working area till the last chamber, a laser beam, through lenses sintered the powder and solidify the correspondence layer of the object. When one layer is finished the build chamber moves down for the high of one layer and simultaneously the lateral chambers (or chamber) moves up. Then the process restarts for the upper layer till the end. Once it is finished it is required a considerable time laps for cool-down before the part can be removed from the machine. *"Large parts with thin sections may require as much as two days of cooling time[27]".*

The process remains the same either for plastic or metal powders.

The final product has a powdery surface, compared with the smoother one made by Stereolithography but SLS technology offer more resistance and maintain higher quality by the time and in particular it is particularly indicated for high-heat and chemically resistant applications[28]. Moreover SLA technology requires support materials while in SLS's one is the same powder that amounts to support, even if this element can cause some cosmetic blemishes. This technology is usually chosen in all the cases when critical material properties are required, such as aerospace or medicine[29]. Indeed its highest quality is to create objects in their final high quality material but this involves a mechanical system further more complex than Stereolithography and compared with most of the other technologies.



Selective laser sintering process

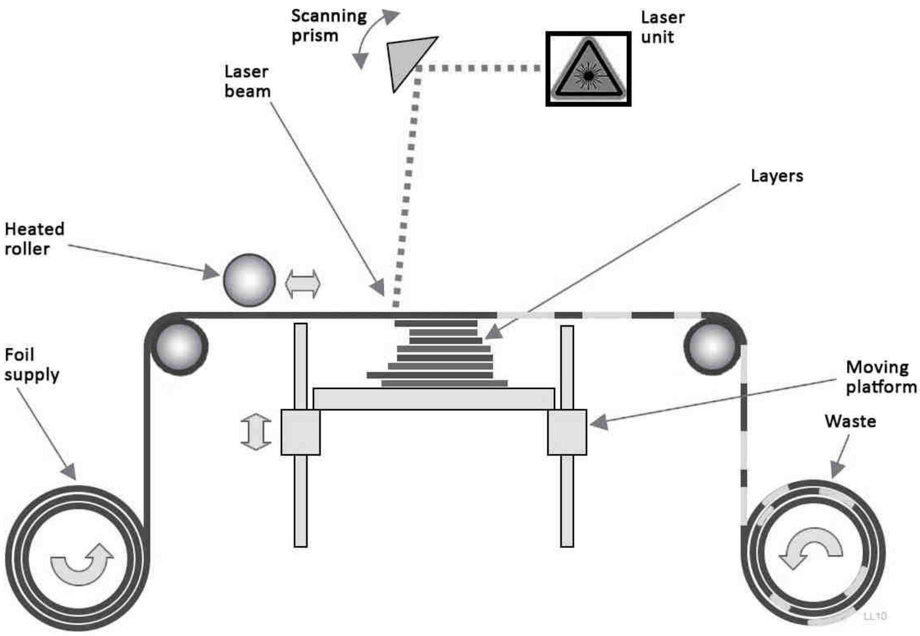
@ Laurens van Lieshout http://commons.wikimedia.org/wiki/File:Selective_laser_sintering_principle.png

10.2.3.3 - LAMINATED OBJECT MANUFACTURING (LOM™)

This technique was developed by Helisys of Torrance, CA[30], and it produces prototypes made by layers of adhesive-coated sheet material. A feeder roll and a supply roll make a paper or plastic laminated with heat-activated glue roll on the central platform. On this desk an optical head mirror directs a laser beam on the surface

26 EFUNDA, Rapid Prototyping: an Overview, op. cit.
27 ADDITIVE3D, *What is Rapid Prototyping? A brief tutorial*, op. cit.
28 QUICKPARTS, *Rapid Prototypes*, op. cit.
29 ADDITIVE3D, *What is Rapid Prototyping? A brief tutorial*, op. cit.
30 PALM W., *Overview of Rapid Prototyping*, op. cit.

and a roller applies pressure to bond the paper to the base. Then the focused laser activates the glue on the desired shape and cuts the area of the involved surface. Simultaneously the profile of the exact shape is heavily cross-hatched with the laser to facilitate the removal. The central area slightly moves down and another slice of paper is spread out on the model with the glue. During the build this excess of material proves to be extremely useful as a support for overhangs and thin-walled sections. At the end the prototype as a wood-like finish and for this reason it needs to be sealed and finished with paint or varnish to prevent moisture damage. This process doesn't guarantee the finish, accuracy and stability of others' techniques however the material is very cheap and if the final object must be in wood a prototype made with this technique offers the most similar aspect and it can be treated in the same way.



Laminated object manufacturing

@Laurens van Lieshout http://commons.wikimedia.org/wiki/File:Laminated_object_manufacturing.png

10.2.3.4 - FUSED DEPOSITION MODELLING (FDM)

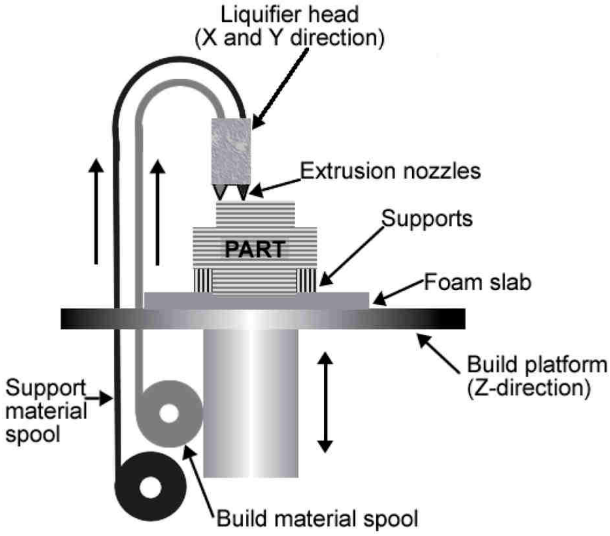
The Fused Deposition Modelling machine was developed by Scott Crump in 1988[31]. It is even called Plastic Jet Printing, thermoplastic extrusion or Melted Extrusion Modelling. A filament of thermoplastic polymer is heated and poured slowly from a moving nozzle to form each single layer one by one, while the platform slowly moves downward. The chamber that contains the platform is maintained at a cool temperature so that the thermoplastic soon returns solid. Its layer thickness ranges from 0,005 inch (0.127 mm), to 0,013 inch (0,330 mm), depending on the system. Several materials can be printed with this technology and so many others are in course of experimentation, but the most common ones include nowadays polyester, ABS and elastomers. Support structures are usually fabricated for overhanging geometries in a second, water soluble material that can be easily washed away with a slightly basic solution. The quality of the results is definitively improved in these years but it is still inferior compared with stereolithography.

An application similar to FDM is **Laser Powder Forming (LPF)** or similar ones that use high power laser to melt metal powder[32]. It can be stainless steel, Inconel, cop-

31 EFUNDA, Rapid Prototyping: an Overview, op. cit.

32 *"Metal poders are delivered and distributed around the circumference of the head either by*

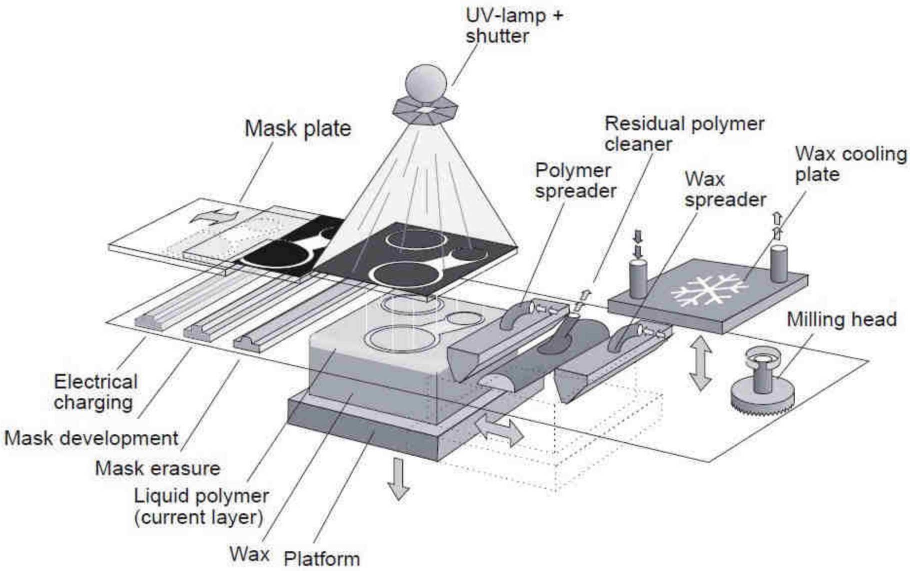
per, aluminium and titanium. The advantages of this technology is in the possibility of combining the advantages of a metal production of final goods with the advantages of 3D printing, even in most of the cases they require finish machining.



Fused deposition modelling schematic
1 - Support material spool
2 - Build material spool
3 - Liquifier head (X and Y direction)
4 - Extrusion nozzles
5 - Supports
6 - Foam slab
7 - Build platform (Z-direction)

10.2.3.5 - SOLID GROUND CURING (SGC)

Solid ground curing, or solider process is similar to Stereolithoghraphy but in this case each layer of photosensitive resin is harden at once. Moreover, despite SLA, in this case a milling step maintains vertical accuracy. Each layer of material is first sprayed on the platform, then a photomask is spread like a stencil and then a UV lamp hardens the exposed photosensitive resin. Afterwards the uncured resin is removed for recycling and the layer is cured again to fully solidify. Then wax replaces all the vacuuming left, it is hardened by cooling, then levelled and it becomes a support for the following layers of the model. Once it is finished, wax is easily removed and no post-cures are required if not finishing operations such as sanding, only if desired.



Solid Ground Couring Process

@Zay Yar Myint http://commons.wikimedia.org/wiki/File:Schematic_Diagram_of_Solid_Ground_Curing_Process.jpg

gravity, or by using a pressurized carrier gas. An inert shroud gas it is often used to shield the melt pool from atmospheric oxygen for better control of properties, and to promote layer to layer adhesion by providing better surface wetting."

ADDITIVE3D, *What is Rapid Prototyping? A brief tutorial*, op. cit.

ANALYSIS

10.2.3.6. - INK JET PRINTING TECHNIQUES

Inkjet technologies are associated by a shooting of liquid droplets in different materials that become solid and form the object.
Among Inkjet technologies, there's a large variety of different processes, like:

- **Thermal Phase Change Inkjets,** that squirts tiny droplets of plastic and wax material and guarantees fine resolution and surface finishes, almost equivalent to CNC, but the technique is very slow;

- **PolyJet** is a process based on photopolymers similar to laser-based stereolitography but with substantial inroads. It is particularly suited for fast-in office prototyping that requires good appearance and low operator effort;

- **Three dimensional printing (3DP)** is the most similar technique to FDM. It is a patent developed at MIT, in Boston, and it is used as for manufacturing processes as for concept modelling, like false teeth, filters and casting patterns[33]. The system is made by two chambers: the fabrication and the powder delivery. A moving piston supplies from the powder delivery chamber, the amount of material required for one layer to the fabrication chamber. Then, a moving head pose an adhesive liquid onto the layer, where required. Once one layer is finished, the piston moves down and the process is repeated till the end. After completion, extra powder is removed and no extra-cures are required. The advantages of this technology are in the speed of fabrication, low cost of materials and it is the only technology that provides full colour outputs. Its main disadvantages are low resolution and fragility, that can be partially compensated with adhesive infiltrations as a post cure[34].

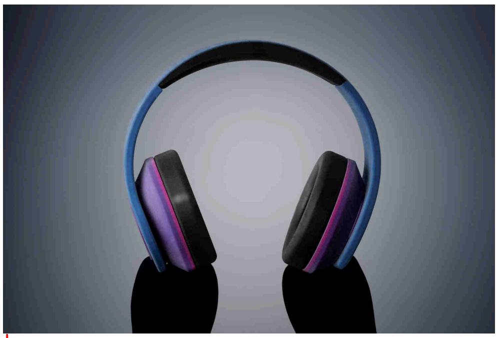
- **Multimaterial 3D printing** is a type of 4D printing that uses Inkjet printing technology but has the peculiarity of combining different 3D printing materials in one single object. These materials can *"range in properties, from rigid plastic to rubber-like, opaque to transparent and standard to engineering-grade ABS toughness."*[35] This technology seems to be the most forefront vanguard at the state of art for several reasons, among a range of over 120 3D printing materials composed by an acrylic based photopolymer resins among which it is possible to choose. Having an independent control of the two nozzles means that an object can be created made by the juxtaposition of this two different materials or that a new material can be created by the composition of the two resins. This possibility increases significantly the chance of improving mechanical and technical properties as tensile strength or flexural strength. At the same time the capability of printing an object made by different parts in different materials, opaque or transparent, and different colours in a single print, eliminates the need of studying them separately, to program their single manufactures and their assembly. All these conditions cause inevitably a drastic reduction of the time and costs of design. The applications of this technology are several and seems that they are going to grow exponentially in the very next future: object manufactures, building constructions, sport equipments, car and aircraft manufactures, as well as electronics, shoe sole, cellular phone and medical industries.

33 ADDITIVE3D, *What is Rapid Prototyping? A brief tutorial*, ibid.

34 ADDITIVE3D, *What is Rapid Prototyping? A brief tutorial*, ibid.

35 STRATASYS, Ten Reasons why Multi-Material 3D Printing is better for your Product Design & Development, Stratasys Ltd. http://www.stratasys.com/resources/~/media/D9D312E7FBA241E59FB612C70AE41756.pdf (January 2015)


a.


b.


c.


d.


e.


f.


g.

a. b. c. d. e.

Some objects made with Object500 Connex3 Multimaterial 3-D printer by Stratasys: a shower head, headphones, shavers, abs and rubber handspring, a translucent perfume bottle

f. g.

3D printed dress modeled on the body of the dancer Dita Von Teese. The dress is based on the Fibonacci sequence, it was assembled from 17 pieces and adorned with 13.000 Swarovski crystal

@ Schmidt M. and Bitonti F.,

ANALYSIS

10.2.4 Materials

An overview on nowadays available materials for 3D printers has to be necessary incomplete and lacking since every day new materials come on the market and many others are under experimentation. A simple e-bay research of different materials for 3D printers offers more than a thousand of solutions and they vary even depending on the additive technology chosen. For example Fused Deposition Modelling uses mostly thermoplastic materials such as PLA, ABS, PA, HIPS, PVA, PET, TPU, but even recently carbon fiber[36]. However most of them are variations of ABS, Acrylonitrile Butadiene Styrene, a thermoplastic polymer, or PLA PolyLactid Acid.

- ***ABS, Acrylonitrile Butadiene Styrene*** is the most used termpolymer for 3D printing. It is extremely flexible since a variety of modifications can be made to improve impact resistance, toughness and heat resistance. Even if its components are known to be carcinogen, the final product has few risks to health. However it isn't suitable for medical application if not specifically certified.
- ***PLA PolyLactid Acid*** is a biodegradable thermoplastic derived from renewable resources, such as corn starch (in United States), tapioca roots, chips or starch (mostly in Asia) or sugarcane (in the rest of the world)[37]. It can be used even with biomedical applications and it offers shiny and glossy colors even without extra finishes or varnishes' coating. However its mechanical properties are lower than ABS that is not as glossy as PLA but can be easily painted.
- ***PVA,*** polyvinyl alcohol is used as a dissolvable support material or for special applications.
- ***Nylon*** is a polyamide powder used for Selective Laser Synthering for a great variety of applications. It can be flexible or rigid depending on the thickness and it can be colored with a dye bath.
- ***Alumide*** is a mixture of nylon and aluminium powders. It is resistant but even slightly flexible, it has a coarse finish but it is preferred to print movable parts as joints or hinges.
- ***White resin*** is used mostly with SLA technology and for high detailed object since it can reach until 0,028 mm of resolution. It can be coated and painted and it resists until 48 °C.
- ***Fusion Wax*** used mainly in Multi Jet Modelling and it offers high resolution and extreme variety of applications.
- ***Glaze pottery***, available in different colors it is nowadays mainly used for alimentary applications or decorative objects. It has a smooth, brilliant finish and it is resistant to water and heat until 500 °C.
- ***Carbon fiber*** for 3D printers has a mechanical resistance even 20 times more than ABS, it has an excellent chemical and heat resistance but it has an high cost too.
- ***Peek*** is a polymer with great mechanical, chemical and heat performances too, similar to metals. For these reason it is applied in automotive and aerospace but even in prosthetics, since it is higly biocompatible. It requires High Temperature Laser Sintering machines and it is extremely costly.

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36 MAGNAGHI G., *Tutti I colori della Stampa 3D*, July 2014 http://soiel.it/res/news_dettaglio/id/848/p/tutti-i%20color-della-stampa-3d&print=1 (January 2014)

37 MATBASE, *PLA monomere (Polylactic Acid)*, http://www.matbase.com/material-categories/natural-and-synthetic-polymers/agro-based-polymers/material-properties-of-polylactic-acid-monomere-pla-m.html (January 2015)

- ***Metals' powders***are increasingly being used in additive technology applications. This technology, compared with traditional CNC process, reduces drastically the quantity of required material with a direct cost restraints. Steel, titanium, cobalt chromium, aluminium, silver, brass, Inconel (nickel alloy and chromium) and many others are all materials that can be used with an additive technology. They can vary depending on the material, for example for stainless steel SLS technology is preferred.
- ***Brass and silver*** are even used but in this case the 3D printer makes first a wax high defined prototype of the object. Then a liquid plaster is used to obtain the mold and it is used to drain brass and silver that will solidify before removing the mold.
- ***Full color Sandstone*** enables the production of 3d printed object of any colors, nuance, fine drawing. Predictably this is the preferred technology for any fancy goods that could take advantages from this possibility of printing even a human face with acceptable results.
- ***Glass powder*** spread layer by layer and bonded with adhesive spray.
- ***Bio Ink*** comprises stem cells and cells from a patient and laid them down layer by layer to form a tissue. *"Human organs such as blood vessels, bladders and kidney portions have been replicated using this technology."*[38]
- ***Skin***, similar to bio-ink could help in skin regeneration.
- ***Bone material*** comprising silicon, calcium phosphate and zinc.
- ***Food***, from chocolate to pasta or pizza, many food industries are experimenting the application of this technology in their production.
- ***Digital Materials*** are made by Object Multi-Material 3D printers of the Stratasys company. Their peculiarity is that digital materials are made right in the 3D printer, when two or three PolyJet base resins are combined in specific concentrations and structures to provide the desired properties, starting from the several hundreds of proven combinations[39].
- ***Rubber-like materials***, offered by Object Multi-Material 3D printers as *Tango Family*. Rubber-like material is useful for many modeling applications including: exhibition and communication models; rubber surrounds and over-molding; soft-touch coatings and nonslip surfaces for tooling or prototypes; knobs, grips, pulls, handles, gaskets, seals, hoses, footwear[40].

38 THOMAS G.P., *Materials Used in 3D Printing and Additive Manufacturing*, AZO Materials, February 2013, http://www.azom.com/article.aspx?ArticleID=8132#2 (January 2015)

39 STRATASYS, *3D Printing With Digital Materials,* http://www.stratasys.com/materials/polyjet/digital-materials (January 2015)

40 STRATASYS, *3D Printing With Rubber-like Material,* http://www.stratasys.com/materials/polyjet/rubber-like (January 2005)

ANALYSIS

	ABS (Acrylonitrite Butadine Styrene)	PC (PolyCarbonate)	ACETAL (POM-PolyOxyMethylene)	ACRYLIC (PMMA - PolyMethyMetaAcrylate)	NYLON (PA-Polyamides)	PP (PolyPropylene)	ALUMINIUM
Description	ABS is general purpose rigid Thermoplastic with a combination of properties that make it ideal for the widest range of applications.	Unfilled PolyCarbonate is a tough and durable, transparent engineering thermoplastic notable for its high impact resistance, temperature resistance and optical properties.	Acetal also known as POM is often used for precision components that require high stiffness, low friction and excellent dimensional stability. Generally two grades of Acetal available: Acetal Copolymer and Acetal Homopolymer which is made by the DuPont Company under the trade name Delrin	Acrylic also known as PMMA is an amorphous thermoplastic material with very good optical properties. Acrylic is often used as a glass substitute. Acrylic is hard and stiff but brittle and notch sensitive.	Nylon is a generic designation for a family of synthetic polymers known generically as PolyAmides. Nylons comprise the largest family of engineering plastics with a wide range of applications. Nylons are generally Strong, Tough and	PolyPropylene is semi-opaque thermoplastic widely used in variety of applications. Polypropylene has good resistance to fatigue. PP offers a combination of outstanding physical, chemical, mechanical, thermal and electrical	Aluminium is the most widely used non-ferrous metal. Aluminium is a soft, Durable, Lightweight, Ductile and Malleable metal with appearance ranging from Silvery to Dull Grey. Aluminium naturally generates a protective oxide coating and is highly corrosion resistant.
Characteristics	Easy machining, Smooth finish, High impact strength, Tough and strong, High Stiffness, Good Dimensional Stability.	High Impact resistance, Good Dimensional Stability, Excellent strength retention at elevated temperatures, Low coefficient of thermal expansion, Good Dimensional Stability. Good electrical insulator Heat resistant and Flame retardant	Excellent abrasion resistant Good working temperature, Glossy appearance, Excellent durability Self-lubricant Good stiffness, strength & Hardness. Wide range Chemical resistance (including many solvents). Good Electrical and Dielectric	Excellent optical clarity, Good Abrasion Resistance, Excellent environmental stability, Good Heat Resistance, Good Chemical Resistance. Flammable but low smoke emission.	Excellent abrasion resistance, High elongation, Good resistance to fuels, oils and solvents but is affected by acids and strong bases. Good Toughness, High Tensile Strength, High Impact Resistance, Good Dimensional Stability.	Excellent resistance to fatigue. Lightweight with good combination of toughness and flexibility. Resists most alkaline & Acids. Low moisture Absorption and Non-Toxic. Good Impact Resistance. Retains stiffness and flex. Food Contact acceptable. Excellent resistance to organic solvents, degreasing agents.	Aluminium is an Excellent Heat and Electricity conductor, Excellent Corrosion resistance, Non-Magnetic and Non-Sparking. Aluminium is 100% recyclable without any loss of its natural qualities. Aluminium is a good reflector of visible Light
Applications	General Household items, Toys, Automotive Parts, kitchen Appliances, Computer Parts, Laboratory Equipment, Phone/Fax machine parts, Electrical/Electronic enclosures, Aircraft and automotive interior trims	Automotive headlamp Lenses, Safety Shields, Medical apparatus, Auto parts, Construction Industry, Sporting Goods, Appliances, CD's, Casing and housings, Electrical Electronic parts, Connectors, Telecommunication Hardware.	Gears, Bearings, Screws, Pump parts, Electronic components, Insulators, Medical parts, Furniture hardware, Valve bodies, Zippers, Underwater applications.	Automotive light covers, Lighting fixtures, Clear Bottles and Container prototypes, Lenses, Shop-fittings, Aircraft glazing, Novelty display cases, Signs, Appliances, Modern furniture, Jewellery items, Medical and Healthcare Applications. PMMA has a good degree of compatibility with human tissues.	Ideal for wear applications such as Bearings and Gears, Sporting Goods, Fishing line, Automotive Parts, Tanks, Engineering Parts, Power Tools, Intake Manifolds.	Appliance housings, Food Packaging, Medical and Laboratory applications because it can withstand the heat in an autoclave, Pump Components, Casings with Living Hinges, Automotive parts, Food Containers, Industrial Applications, Loudspeaker drive units, Household Goods.	Large number of components for Automobiles, Aircraft, Trucks, Trains. Packaging application like beverage cans, foils. Construction industry, Wide range of household items, Consumer Electronics, Heat sinks for electronic appliances.
Finish Detail	Machine Finish, Smooth Finish, Polished Finish, Painted or Grey Primered, Electroplated, Vacuum Metalised.	Machine Finish, Smooth Finish, Highly Polished Finish to achieve transparency, Translucent finish (Foggy look like Lamp Shade), Painted or Grey Primered	Machine finish, Smooth Finish, Polished finish	Machine Finish, Smooth Finish, Translucent Finish, Highly Polished to get full Clarity. Painted or Tinted finish	Machine Finish, Smooth Finish.	Machine Finish, Smooth Finish	Machine finish, Polished finish, Mirror Polished finish, Bead Blast Finish (to give a Matt textured finish), Anodising, Painting, Powder Coating.
Remarks	Natural raw material is available in Cream White colour. Large and complex parts with undercuts can be easily made in sections and glued. Economical option for prototypes.	Typically parts have translucent look after machining but transparency can be achieved by polishing. It's strength, durability, impact resistance and transparency make it an ideal material for certain structural applications. Large parts or undercut features can be made in sections and glued.	Easy to machine but very difficult to bond. Good appearance with gloss finish. Acetals often compete with Nylons for many of the same applications but dimensionally stable than Nylon under wet and humid conditions.	PMMA is an economical alternative to Polycarbonate (PC) when extreme strength is not necessary. Common trade names of Acrylic include Plexiglas, Lucite and Perspex. Large and difficult parts can be easily glued.	Nylons are commonly used in textiles, automotive, carpet and sportswear due to their extreme durability and strength. Nylon has better wear-resistance than Acetal, but do not have good moisture resistance which makes it unsuitable to high-humidity.	Polypropylene is one of the lightest plastics available. Easy to machine and provide smooth finish. Since PP is resistant to fatigue, makes it suitable for most of plastic living hinged parts, such as flip-top bottle caps.	Aluminium is a very light metal with a specific weight of 2.7 g/cm3, about a third that of steel. We use Aluminium 6061 and Aluminium 5083 grades for machining.
Weaknesses	Not suitable for Petroleum-based oils, paints and solvents. Moderate heat, moisture and chemical, weathering resistance. Can easily scratch. Flammable with high smoke generation.	Subject to cracking due to stress, Moderate resistance to Chemicals, Low scratch-resistance.	Very difficult to bond, Poor resistance to acids, Flammable and High Specific Gravity. Difficult to paint. Large and thin parts with irregular wall section are prone to warpage.	Poor impact resistance, Subject to stress cracking, Not suitable for use with chlorinated or aromatic hydrocarbons. Brittle nature, PMMA swells and dissolves in many organic solvents.	High Moisture absorptivity degrades electrical and mechanical properties. Attacked by strong Acids, Bases, Oxidizing agents. High Notch sensitivity.	Hard to Glue. Degraded by UV radiation, Attacked by chlorinated solvents and aromatics. Large and thin wall sectioned parts are prone to deformation or warpage after machining.	Unlike steels, Aluminium alloys have no well-defined fatigue limit, meaning that fatigue failure eventually occurs, under even very small cyclic loadings. Subject to internal stresses following heating operations such as welding and casting due to low melting point.

Overview on materials that can be used for 3D printing

ARPTECH PTY LTD, *Overview of common materials we use for CNC Machining and Rapid Manufacturing*

10.3 – MEDICAL APPLICATIONS OF 3D PRINTING

The development of 3d printing technology is deeply involving Medical field. Most of medical applications are particularly advisable to be made with 3D printing technology since this process made drastically simpler the customization of the product and the manufacture of a single object where no economies of scale are programmable. Both FDM and InkJet techniques provide a dedicated set of biocompatible materials for medical devices but, in particular, PolyJet Technology is more used for medical device prototypes, while FDM technology works more on strong tooling, end-use parts and high-performance thermoplastics.
Several application of 3D printing are incoming in medical and biomedical firms:

- Highly accurate surgical guides, especially in order to direct surgeon's incisions;
- Simulation of organs and bodies for clinical surgery training[41], especially for the most complex or paediatric cases[42];
- Silicon organs[43];
- Reproduction of facial bones[44];
- 3D Printing of blood vessels around which are making human cells grow[45];
- Prosthetics covered with a synthetic silicone skin and filled with tissue;
- Exoskeletons;
- Replicas of cancerous body parts[46];
- True-to-life medical device prototypes used as a tool to study surgical operations as a device to help doctors to communicate with patients;
- Orthodontic applications[47];

41 DECKER B., *3D Printed Ribs Make Surgery Easier*, Bioprinting news, October 29th, 2014, http://bioprintingworld.com/3d-printed-ribs-make-surgery-easier-bioprinting-news/ (December 2014)

42 DECKER B., 3D *Printed Heart and Materialise's Efforts in Bioprinting*, Human Orgens, October 15th, 2014, http://bioprintingworld.com/3d-printed-heart-and-materialises-efforts-in-bioprinting/ (December 2014)

43 On this regard, Penn State Hershey Medical Center surgeon Randy Haluck, points out that the two biggest difficulties on organs' bioprinting is the size of a blood vessel, that has to be about 200 microns, while modern technologies are closer but not reached this result, and the integration in the chemical environment, that has to be perfectly controlled in order to avoid the necrosis of the surrounding tissues.

DECKER B., *Bioprinting in Orthopedics and 3D Printing in Organ Creation*, October 15th, 2014, http://bioprintingworld.com/bioprinting-in-orthopedics-and-3d-printing-in-organ-creation/ (December 2014)

44 In 2014 in Wales was successfully concluded a surgical operation of a twenty-nine years old man who fractured his left cheekbone, eye sockets, upper jaw and skull in a motorcycle accident. *"The medical team scanned man's skull and, based on the unbroken bones, determined what his full facial structure should be. They then 3D printed a replica in titanium and successfully implanted it."* GROOPMAN J., PRINT T., *How 3-D printing is revolutionizing medicine*, The New Yotker, Medical Dispatch November 24th, 2014 http://www.newyorker.com/magazine/2014/11/24/print-thyself (December 2014)

45 The University of Sydney, Harvard, Stanford and MIT are testing 3D printing of a skeleton of vessels around which growing human cells around them. Once the vessels are stable, they are able to dissolve the 3D printed material.

DECKER B., *Bioprinting and 3D Printing of Blood Vessels*, July 3rd, 2014 http://bioprintingworld.com/bioprinting-and-3d-printing-of-blood-vessels/ (December 2014)

46 The Institute of Cancer Research in London is using 3D printed replicas of cancerous body parts using CT scans and are using them to better target the tumors with more effective treatments.

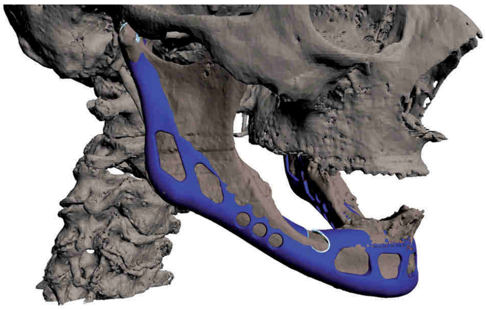
GRUNEWALD S. J., *Curing Cancer with 3D Printing*, in 3D printing, medical & Dental, December 19, 2014, http://3dprintingindustry.com/2014/12/19/curing-cancer-3d-printing/ (December 2014)

47 This sector was one of the firsts to develop an high sophisticated application of 3D printing thanks to its possibility of customization, accuracy and production of short or long-term use of dental

- Hearing Aids. *"The hearing aid industry boats perhaps the highest installed base of customized final consumer devices that were produced using 3D printers."*[48]

10.3.1 - Bio-compatible and certified materials

These applications were possible even thanks to the introduction on the market of **bio-compatible and certified materials** for these goals. Bio-compatibility is essential, since these objects are in direct contact with external or internal tissues for a variable lapse of time and the material has to be stable and to maintain its properties and don't release any noxious substance along all its scheduled time. In detail, regulations include standards such as **ISO 10993** and **USP Class VI**, which classify material as compatible.



World's first 3d printed Jaw implant.

@ Layerwise www.layerwise.com

ISO 10993-1:2009[49] is a standard of "***Biological evaluation of medical devices***",

prosthesis.

48 ENVISION TEC, *New Trends in 3D Printing – Customized Medical Devices*. EnvisionTEC, http://envisiontec.com/3d-printer-blog/trends-in-3d-printing-of-customized-medical-devices/ (December 2014)

49 ISO 10993 consists of the following parts, under the general title *Biological evaluation of medical devices*:

— *Part 1: Evaluation and testing within a risk management process*

— *Part 2: Animal welfare requirements*

— *Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

— *Part 4: Selection of tests for interactions with blood*

— *Part 5: Tests for* in vitro *cytotoxicity*

— *Part 6: Tests for local effects after implantation*

— *Part 7: Ethylene oxide sterilization residuals*

— *Part 9: Framework for identification and quantification of potential degradation products*

— *Part 10: Tests for irritation and skin sensitization*

— *Part 11: Tests for systemic toxicity*

— *Part 12: Sample preparation and reference materials*

— *Part 13: Identification and quantification of degradation products from polymeric medical devices*

— *Part 14: Identification and quantification of degradation products from ceramics*

— *Part 15: Identification and quantification of degradation products from metals and alloys*

— *Part 16: Toxicokinetic study design for degradation products and leachables*

— *Part 17: Establishment of allowable limits for leachable substances*

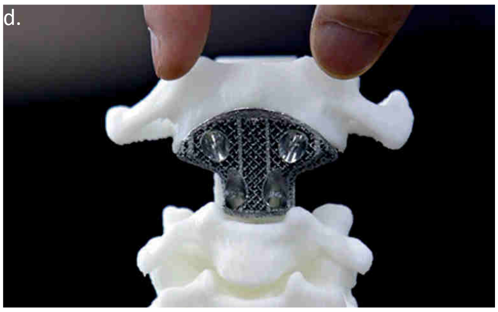
— *Part 18: Chemical characterization of materials*

— *Part 19: Physico-chemical, morphological and topographical characterization of materials* (Technical it is not specifically referred to 3D printing but defines all the characteristics that medical device should assure in order to protect humans from potential biological risks. A “medical device” could be considered as a complex instrument as a single material. One of the main concerns in this evaluation is tissue interaction, but even the design and the shape of the object perform a crucial role in this evaluation.

a.


b.


c.


d.


a.
Prototype of bionic ear

@ https://cosmosmagazine.com/life-sciences/make-your-own-spare-parts

b.
3d printing of organs is mainly used nowadays to plan surgeries in the most difficult cases

@http://makezine.com/magazine/guide-to-3d-printing-2014/life-changing-3d-prints/

c.
3d printing application to dental industry

@ http://galleryhip.com/3d-printing-dental.html

d.
Model of a spine with a 3D-printed artificial axis in Beijing, where doctors this year claimed they successfully implanted one into the spine of a bone cancer patient for the first time.

@Jason Lee/Reuters http://www.theguardian.com/business/2014/aug/24/medical-implants-drive-3d-printer-growth

USP Class IV is a certification offered by the United States Pharmacopeia (USP), *“a non-government organization that endorses public health by establishing up the minute standards to safeguard the quality of medicines and other health care technologies. This organization is concerned with the pharmaceutical and bio-technology industries. The USP sets standards for quality, purity, strength and consistency.”*[50]

USP protocols classify plastics in Classes from I to VI, based on end use, type and time of exposure of human tissue to plastics, when Class VI is the one that requires the most stringent testing of all the six classes[51].
Class IV, in particular determines biocompatibility in case of breached or compromised surfaces for a prolonged laps of time[52] and it is what would probably be required to DMD AFO too, since we have to consider that in some cases, if the skin is particularly sensible, or due to the strength of the stretching activity it could exceptionally cause rednesses or grazes and that even in the worst hypothesis, the shoes has to prove to be completely safe

Specification)

— *Part 20: Principles and methods for immunotoxicology testing of medical devices* (Technical Specification)

ISO 10993-1:2009, *Biological evaluation of medical devices* - https://www.iso.org/obp/ui/#iso:std:iso:10993:-1:ed-4:v1:en (December 2014)

50 HIGH PURITY SANITARY PROCESS APPLICATIONS, *What is USP Class VI Testing and Why is it Important*, Holland Applied Technologies, October 14th, 2013 http://hollandaptblog.com/2013/10/14/what-is-usp-class-vi-testing-and-why-is-it-important/ (December 2014)

51 U.S. PHARMACOPEIAL CONVENTION, *Reference Standards*, http://www.usp.org/reference-standards (December 2014)

52 UNITED STATES PHARMACOPOEIA PLASTIC DESIGNATIONS, *What is USP Class VI*, Distrupol, http://www.distrupol.com/images/USP_designations.pdf (December 2014)

ANALYSIS

and bio-compatible.

Faiz Bhora, chief of thoracic surgery at Mount Sinai Roosvelt says: *"I think within five years, we are going to see parts of 3D printed organs being implanted, as well as things like jawbones, tibia bones, things that are not very complicated and where failure is not usually catastrophic. The next step up perhaps is tubes and cylinders, the aiirway, perhaps, the ureters, arteries, veins. The third tier will be whole organs, heart valves, maybe parts of the kidneys, nerve cells. We're going to get to a point where if you have a defect in an organ, you'll just get a new one."*[53]

53 WINTER J., *How 3D Printing is Transforming Everything from Medicine to Manufacturing*, Parade magazine, October 11th, 2014, http://communitytable.com/345790/parade/how-3-d-printing-is-transforming-everything-from-medicine-to-manufacturing/ (January 2015)

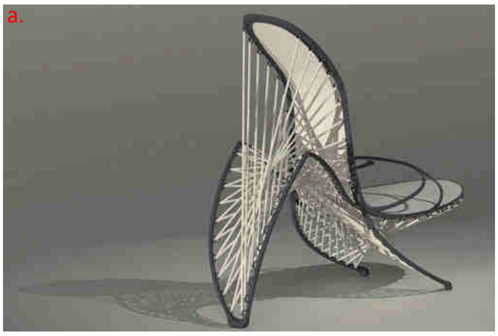
10.3.2 – 3D Printing for Lower Limbs

The technology of 3D printing is just starting to gain popularity and it is exponentially enlarging its potential of application. Therefore all the sectors of manufacturing are exploring with curiosity the possible prospectives of these processes. In this paragraph I'll examine in particular the ones in some way connected with lower limbs. This research proved to be useful to understand the state of art, to stimulate curiosity and creativity on what could be done and, most of all, to foresee possible interesting developments of the research. Among the numerous examples I found, I selected just one of two cases for each category, just to give a general overview.

10.3.2.1 FASHION AND ARTISTIC EXPRESSIONS

This brief summary has necessarily to start from the application of 3d printing for artistic expressions, luxury fashion and aesthetic experimentation related with the manufacturing of shoes. Art is always be looking for something new and new ways to express creativity. 3D printing, thanks to its way of production, without molds, makes possible almost all the fantasy you can imagine, without creations restrictions. In 2013 the London College of Fashion set up an exhibition at the Fashion Space Gallery with the title *"Layer by Layer"*. The title referred to the additive process of 3D printing that creates objects by the overlapping of thin layers of material and it demonstrated some of its most innovative uses in contemporary practice of design[54]. The most interesting aspect of this exhibition is that it illustrated how the use of a new final tool to produce a shoe can influence all the process already from the ideation of the product and that the adoption of this possibility requires a complete rethinking of all the design process with previously unimaginable creative outputs. This possibility is now becoming even wider thanks to the introduction in the 3D printing technology of several materials and finishes. This opportunity makes the technology go beyond the field of scholastic experimentation and to income in the industrial market that is more and more resorting to additive manufacturing to fulfil components, as sculpture heels or insoles, or directly for the entire shoe.

a.



b.

a. and b.
Layer by Layer
Exhibition at London College of Fashion.
Shoes made by:
- Naim Josefi and Souzan Youssouf;
- Marla Marchant

c.

d.

c.
Myth
Shoe collection

@Continuum Fashion

d.
Myth
Shoe collection

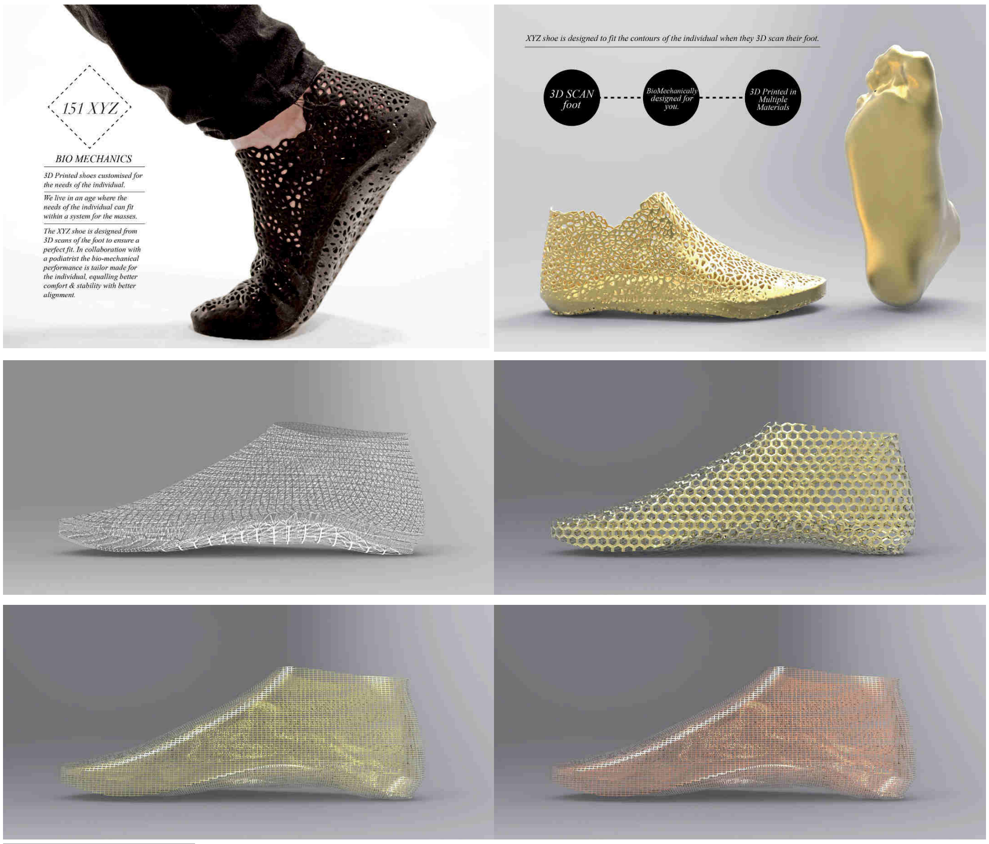
@Continuum Fashion

54 LONDON COLLEGE OF FASHION, *Layer by Layer*, exhibition from 10 April - 18 May 2013, Fashion Space Gallery, London http://www.fashionspacegallery.com/exhibition/layer-by-layer/ (January 2015)

ANALYSIS

10.3.2.2 COMFORT, CUSTOMIZATION AND SPORTS

One of the great advantages of a 3D manufacturing is its possibility to be combined with indirect survey in order to create customized, personalized and one by one produces without the necessity of a mass production to make the manufacture economically sustainable. Shoemakers have foreseen this possibility and started to explore and tests new products. So many new startups and fabrics are selling 3D printed shoes, even with the possibility of ordering them online, like **Feetz Company**[55], by uploading feet measures for the customization. **3D Shoes Company**[56], as another example, *"using 3D scanning methods such as the Footin3D universal orthopedic 3D foot scanner from Elinvision, Delcam Crispin Shoemaker CAD and visualization software and Right Shoes smart device, 3D scanner app, provides a service to allow customers to select from a portfolio of extant and original designs by leading 3D printed footwear fashioners."*[57]One of the product lines made by the company is the ***XYZ shoe***[58]. This project started as a Master thesis at Victoria University of Wellingyon, starts from an accurate 3D scan of the foot and applying parametric design principles generates 3D cellular matrix that gives shape to the shoe and evokes biological structure of a cellular growth. The sole is designed with the support of a podiatrist to ensure comfort, stability and alignment while the Multi Material 3D printer from Objects Connex allows to create flexibility and rigidity in a single form[59].



XYZ shoe, printed in multi-material and with different parametric textures

55 FEETZ, *Sizeme shoes. Your feet are unique. Why aren't your shoes?*, http://www.feetz.co/ (January 2014)

56 3D SHOES, http://3dshoes.com/ (January 2014)

57 TAYLOR S., *3D Shoes: Excellent Design Meets 3D Printed Personalisation*, 3D printing industry, 2014, http://3dprintingindustry.com/2014/10/14/3d-shoes-design-3d-printed/ (January 2015)

58 XYZ SHOE, http://cargocollective.com/earlstewart/XYZ-SHOE (January 2015)

59 The first prototypes were scanned with a Kinetect hand scanner, parametrized with Grasshopper software and manufactured in nylon with a selective laser sintering. Particular attention was dedicated to the Insole, elaborated with the traditional CAD CAM methods.

XYZ SHOE, http://cargocollective.com/earlstewart/151-XYZ (January 2015)

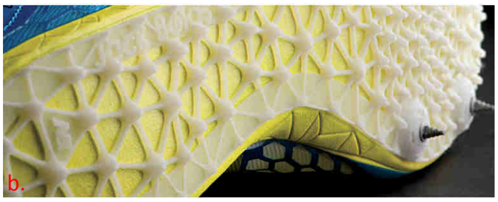
But, as we said for fashion, shoe's industries and multinational companies are testing as well additive manufacturing technology combined with users'customization like **United Nude**[60], that, starting from a quick survey of the feet prints the shoes directly in the store right before the customer's eyes.

In sportswear running shoes, for example, both New Balance and Nike have introduced on the market 3D printed shoes.
New Balance Sports Research Lab uses a proprietary process that collects, using a force plate, in-shoe sensors and a motion capture system. The acquired data are elaborated by advanced algorithms and software and then translated into custom 3D printed spike designs of the sole. The manufacturing is made with Selective Laser Sintering (SLS) technology and new prototypes are testing the prototipation of soft components too that mimic the cushioning properties of foam midsoles[61].

Even **Nike** footwear company is at its second shoe type made, adopting 3d printing technology. As Shane Kohatsu, Nike Director of Footwear Innovation says, *"3D printing allowed us to test, iterate and create shapes not possible with traditional manufacturing processes which in turn allowed us to push the limits of innovation faster"*[62]. Even Nike uses Selective Laser Sintering technology, traditionally used for prototyping but, through proprietary material selection, used for 3d manufacturing of the final product, allowing designers to make updates within hours, instead of months, truly accelerating the innovation process.

Moreover **Luc Fusaro**, a French engineering created a complete revolutionary 3D printed running shoe branded *"Design to Win"* that promise to shave 3.5 % off a runner's time. It is made in nylon polyammide powder with SLS technology and it's tailored on the shape of athlete's feet[63].


a.


b.


c.


d.

a. and b.
New Balance customized 3D printed spike plate

c.
Designed to Win Designed by Luc Fusaro and 3D printed by Selective Laser Sintering (SLS)

d.
Nike *Vapor HyperAgility Cleat*, with SLS plate contruction

60 UNITED NUDE, *United Nude launches a 3D printed shoe designed for the very compact 3D systems new Cibe 3D printer*, United Nude 3D printing, 2014, http://www.unitednude.com/news/2014/united-nude-3d-printing-52 (January 2015)

61 LAWTON M., *New Balance Pushes The Limits Of Innovation With 3D Printing*, Press Releases, March 7th, 2013, Boston, http://www.newbalance.com/press-releases/id/press_2013_New_Balance_Pushes_Limits_of_Innovation_with_3D_Printing.html (January 2015)

62 *Nike football accelerates innovation with 3D printed "concept cleat" for shuttle*, Nike press, February 2014, http://news.nike.com/news/nike-football-accelerates-innovation-with-3d-printed-concept-cleat-for-shuttle (January 2015)

63 LECHER C., *The total custom, absurdly light 3-D printed shoe that could win Olympic gold*, Popular Science, July 26th, 2012, http://www.popsci.com/technology/article/2012-07/3d-printed-shoe-could-help-save-sprinters-precious-seconds (January 2015)

10.3.2.3 PROSTHETICS AND ORTHOTICS FACILITIES

Of course we have already seen, since the 3rd chapter how 3D printing is not just for fashion-forward people seeking the latest trends in shoes but it has several therapeutic applications. The first ones that came in the market were Foot Orthoses and Insoles, manufactured starting from different techniques of direct or indirect survey. 3D printing is able to create an insole that is truly customized to support each foot[64]. *"They prove to be better in every way, stronger, yet dramatically lighter, more accurate, but remarkably less bulky, with a customizable surface that molds into a soft cover, with a 100% tailor-made shape."*[65]
For more difficult orthoses and prosthetics, the starting point is almost in any case a 3D scan, usually a foot hand scan used as a model for the orthopedic aid. It is demonstrated that this technology assures better accuracy and efficacy in the results leading to a better performing orthotic or prosthesis.
Furthermore 3D printing is used to create exoskeleton that helps disabled people with underdeveloped muscles in their arms or legs to provide artificial strength[66]. They are composed by a set of resistance bands, metal bars and customized pieces that can be resizable and reprintable at any time, following the growth of the user or the development of the disease and his physical conditions. The great challenge in this solution isn't a technical solution, since traditional ones can absolve equally to the same functions, but in terms of sustainability and usability. A standard limb prosthesis, for example, can cost about tens of thousands of euros and, in case of a child, it needs to be substituted every six to eight months, creating astronomical expenses. These types of exoskeletons, made in Polylactic Acid (PLA), on the contrary, cost just a fraction of that cost and can be easily substituted[67], they are maybe not aesthetically pleasant or sophisticated as many traditional prostheses, but these exoskeletons prove to be extremely cheap, usable, washable, lightweight and functional.

a.
WREX, Wilmington Robotic Exoskeleton is a 3D printed aid that provides artificial strenght to underdeveloped muscles of disabled people

b.
3D printed prosthetic legs for a dog printed in multimaterial, a stiff material for loops and spokes, a softer material for the cup at the attach onte dog0s legs.

@ http://i1.wp.com/blazepress.com/wp-content/uploads/2014/12/Screen-Shot-2014-12-18-at-00.33.58.3Dpng?resize=1358%2C904

c.
3D printed motorised exoskeleton helps paralysed users walk again

@ 3D Systems

64 *Supporting your every move*, RS Print, http://www.rsprint.be/ (January 2015)

65 *3D Printed Orthotics*, ACE Podiatry, http://www.acepodiatry.com.au/ace-podiatry/3d-printed-orthotics/ (January 2015)

66 GODDARD L., *WREX, a 3D-printed robotic exoskeleton for disabled children*, in *The Verge*, August 5th, 2012, http://www.theverge.com/2012/8/5/3219685/wrex-robotic-exoskeleton-arm-3d-printing (January 2015)

67 A beautiful story that tells how 3D printing helped a young girl to use her partially developed hand is narrated at: WINTER J., *How 3-D Printing is Transforming Everything from Medicine to Manufacturing*, in *Parade Magazine*, October 11th, http://communitytable.com/345790/parade/how-3-d-printing-is-transforming-everything-from-medicine-to-manufacturing/ (January 2015)

ANALYSIS

Moreover there are even some exoskeletons that, combined with motorized components can help even paralyzed patients to stand and walk. Even in this case everything starts from a full body scan on which the shapes of the flexible printed parts of the exoskeleton are based[68].

In chapter 3 I already mentioned the names of some manufactures that 3d print Ankle Foot Orthoses as the one that is object of my thesis. For this reason in this chapter I will name just one company that, thanks to additive manufacturing, invented a new job related to prosthetic manufacturing and a new object that didn't exist before. The **BeSpoke** company, based in San Francisco designs something called *"fairings"*. They don't build prosthetic limbs but covers for limbs. BeSpoke means custom made and *"Fairings invite an expression of personality and individuality that has never been possible before"*[69], and since they affordable cost, if desired, a user could buy more covers and change them depending of the of the day mood colours, the dress, the occasion, as a fashion accessory. Their shape, materials, colors, starting from some models as samples, are individually designed and it is printed and combined with leather, metal, chrome. Additive manufacturing allows customized, easy and cheap production of single pieces and this possibility is to create something that with traditional manufacturing would not have been economically and technically sustainable.

Fairings,
3D printed covers for prosthetic limbs

@ BeSpoke,
San Francisco

68 *3D-printed exoskeleton helps paralyzed users walk again*, De Zeen Magazine, March 5th, 2014, http://www.dezeen.com/2014/03/05/3d-printed-exoskeleton-helps-paralysed-users-walk/ (January 2015)

69 BESPOKE INNOVATION, *What is a fairing?*, Bespoke Innovations, San Francisco, 2015, http://www.bespokeinnovations.com/content/what-fairing (January 2015)

10.4 CONCLUSIONS ON 3D PRINTING TECHNIQUES

The exposed techniques are just a brief summary of some of the most common process nowadays used in 3D printing. Many of them were excluded and so many others are just in phase of incoming on the market. Even a comparison among these techniques could be risky since a complete technical and scientific literature is still missing. However, to synthesize and give a general idea on the state of art we can assume that generally InkJet Techniques are used for smaller objects and, together with FDM technology, they require the slower process. On the contrary InkJet technique usually offers the best accuracy and surface finish, laser sintering and Three Dimensional Printing are less detailed, while stereolithography is still the most used for large part size but FDM is fast growing even thanks to its good relationship between costs and results. In particular if we compare the two most promising technologies, FDM and InkJet, we can see that for FDM a smaller economic investment is required, A particular note must be done on the application and huge potential of multimaterial 3D printing, since it constitutes a complete new sector of production market while Three Dimensional Printing is more applied in the prototyping sector then in manufacturing.

In the following chapter we'll see how FDM 3D printing technology will be used in the production of the first prototypes of Ankle Foot Orthoses. This technology proved to be effective for this first phase of rapid tooling. However, focussing more on shoes and orthopaedic applications, we can see that the most used technology for these applications is SLS. This choice is probably due to the absence of support materials and to the possibility of a better surface finish. However for these first tests FDM technology with ABS material was an optimum solution, even because this technology was already available in the Laboratory of the Department of the Architecture of Ferrara, while SLS technology requires an higher initial investment. For this reason this choice has to be carefully evaluated in terms of its economic sustainability and fallouts on the whole project, without losing sight of the project's aim.

11 MANUFACTURING OF A NEW TYPE OF ANKLE FOOT ORTHOSIS FOR DMD

11 – MANUFACTURING OF A NEW TYPE OF ANKLE FOOT ORTHOSIS FOR DMD

This last topic of the third part is dedicated to the ***manufacturing of the AFO.*** The research on the available technology indicated 3D printing as the best solution to meet defined requirements. The aim of the research, at this level wasn't to produce a ready to use product but to verify the reliability of all the process, from its most theoretical premises to its material and morphological definition. For the realization of these first prototypes a Fused Deposition Modelling technique was tested until an acceptable result was reached.

The phase of padding of the inner surface of the orthosis is described in all its phases, from the unroll of the surface to have a model shape to reproduce, to the choice of the padding material and its cut. For a better cosmetics the pad is completely clad by elastic tissue and attached to the solid ABS skeleton of the AFO with five Velcros that make the padding removable and washable.

Concluding, brief notes on some of the almost infinite possibilities of an aesthetic customization are provided. This first prototypes evidence the huge potential of the project that reached a good level of definition but that can be said anything but concluded. Further researches and on field experimentations, as will be illustrated in the final consideration of the thesis, will be required to transform it in an usable orthosis.

Nevertheless this phase of manufacturing proved that we're on the right track.

11.1 Introduction

The last part of the design process is entirely dedicated to the manufacturing of the prototype of the orthosis and to its final finishing. This phase is strictly linked with the design process that has to carefully evaluate the manufacturability of the product to avoid bad feedbacks in this phase and the necessity of changing some features that could even severely impact the design concept. At this stage the input data for the manufacturing phase in the design process of this innovative type of dorsal night Ankle Foot Orthoses are:

- 3D model of an AFO made by indirect survey of user's lower limb;
- output of the research on different types of manufacturing and additive technology that suggested FDM 3D printing as the best solution for the phase of prototyping of the AFO.

The aim of this first manufacturing of a prototype was to test the general validity of the overall process, the applicability of the chosen method to gain desired results. In this optic the goal of the prototype wasn't to obtain a final product ready to be marketed and used. To obtain this result a further study and setup of the process will be required, with a broader experimentation on field of the technique. In this prototype neither the ABS used for the FDM printing of the skeleton, neither the padding and the tissue that coated it are certified materials that can be applied as a biomedical equipment. Moreover the prototypes were printed with different densities but this value has still carefully to be tested with a medical equip to understand if it oppose the required resistance to boy's strengths of retraction or if an higher value is necessary. Even an excessive density has to be avoided since it would uselessly aid weight on the final product, even if not in a relevant way, but what's the most high density influences drastically on the time of production and the final cost for the larger amount of material required. Furthermore the overview on the different techniques of 3D printing evidenced the possibility of recurring to alternative techniques to Fused Deposition Modeling, as Selective Laser Sintering, or InkJet Multimaterial 3D printer, that, simply relying on catalogue's information of the company that produces the machine, suggests the possibility of a unique print for the skeleton and the padding, but these ideas are just considered as a possible future experimentations.

The design process of the AFO ultimated with its parametric algorithm customized on the 3D model and 15 control points acquired thanks to an indirect survey. This process is completed with all the features that characterize the aesthetic of the AFO and that at the same time can improve their breathability. Once all this steps are concluded, when the final morphology of the orthosis is ready and no more changes on the shape are required, the model is transformed from a parametric model to a solid one. This process is necessary because the model needs to be further optimized in order to be exported to the 3D printer. In particular it has to be checked to control the regularity of the elaborated mesh, the absence of eventual holes or slots between different parts and the uniformity in the verse of the surfaces of the mesh. Then the file is ready to be exported in .stl format. This acronym stands for STereoLithography and it is the file format used by 3D printers to elaborate the 3D model. It describes only the surface geometry as a triangulated surface.

Hereinafter the most significant tests of 3D printing of the prototype are illustrated.

11.2 – 3D printing of the prototype of the orthosis divided in two pieces

AIM OF THE TEST

The first test of printing the prototype was aimed at testing the possibility of separating the AFO in two pieces, to facilitate its print, and check if this procedure was acceptable, evaluating pros and cons.

PREPARATION OF THE BUILD JOB

The total high of the elaborated AFO was of 32cm. Since this value is slightly longer than the maximum high available with the 3D printer already available at the Department of Architecture of Ferrara, it was necessary, in order to print it, or to slightly tilt the model or to divide it in two pieces. In this first test this last option was attempt. After the transformation of the parametric model in solid, it was divided with dove tail joints at about the half of its total length. In particular along the lines of division, it was applied an inner offset of 0,5mm, in order to leave a tolerance for the application of the glue and for the joint of the pieces.

The two .stl files were then uploaded in the CatalaystEX software and they were prepared for the printing, selecting model fill, support, and orientation. Then, pressing the “Add to pack” button, the software starts to calculate the required material for the model, for the support and an estimation of time

The first prototype of the AFO divided in two parts for the first test of 3D printing

3D PRINTER:

Dimension 1200es Series

MODEL MATERIAL:
ABS in ivory

SUPPORT MATERIAL:
Soluble Support Technology (SST)

BUILD SIZE:
254X254X305 mm

LAYER THICKNESS:
0.254 mm or 0.330 mm

SOFTWARE:

CatalistEX

DESIGN

PHASE OF BUILDING

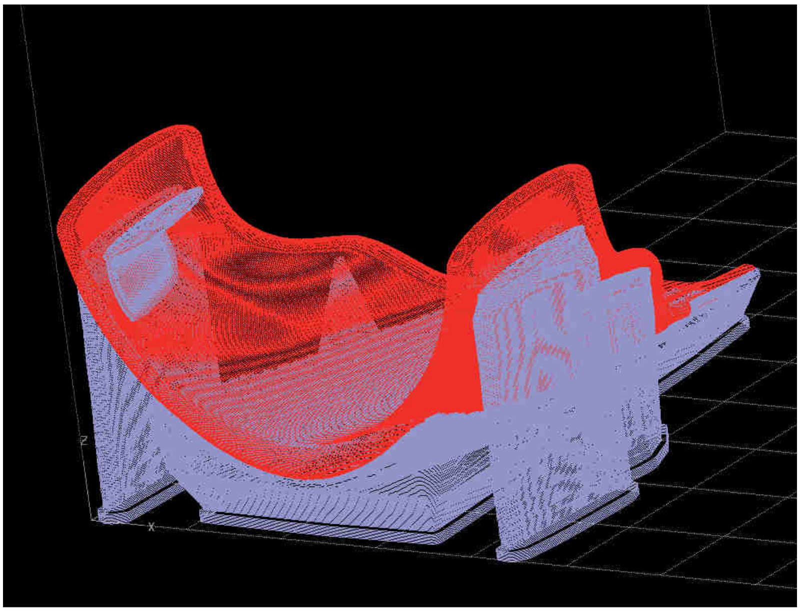
During the phase of building no technical support is required. The machine works autonomously and it starts first creating a layer for support material on the base, on which the model is anchored. Inside the 3D printer plastic filaments of model and support are cast slowly from the print head in a semi-liquid state.

PARTS REMOVAL AND POST PROCESSING

Once printing of both the pieces was done, the recyclable flexible plastic base was separated from the models and all the block of model and support was put in the support removal tank with a water-based solution for 6 hours.

FINAL CONSIDERATIONS

This test was extremely useful first of all in the evaluation of some morphological characteristics of the AFO that could be improved. The closed ring at the heel, for example, made the orthosis difficult to don and remove while probably another solution could be more indicated. In order to reduce as much as possible the amount of support material required, the model was oriented with the longer dimension of the high along the y axis on the basis. For this reason the bottom part was completely fulled on the inside with support material to build the other side of the shoe, while the top part was build with the surface that is in contact with the skin upward. However even if this was an economically convenient choice, aimed at reducing amount of support, time of building and costs, once it is stitched in a single piece, the diverse orientation remain visible and this should be something to be avoided. In a more general evaluation the division in two parts of the AFO could be aesthetically acceptable only if we consider to paint it, otherwise the cutting line remains visible.



The software analyze the shape and calculates the required support material

PRINT DATA:

Dimension 1200es Series

DATE: 21/10/2014

DIMENSION:
TOP:
109.4x152.7x76.9 mm

BOTTOM:
109.6X181.7X225.8 mm

MODEL INTERIOR:
Sparse - low density

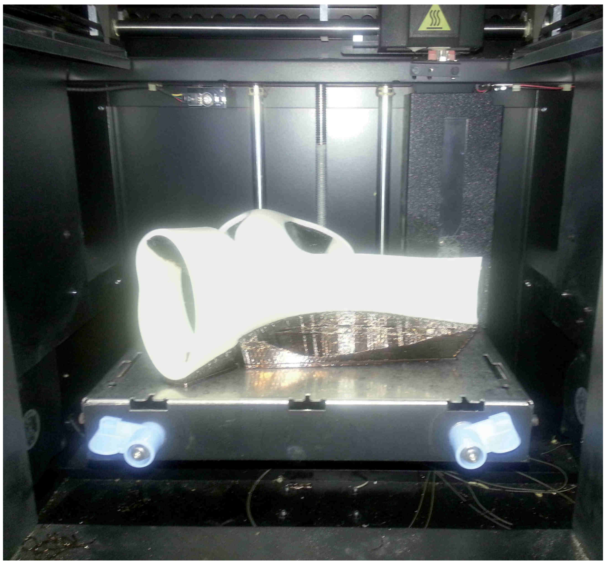
SUPPORT FILL:
Smart

LAYER RESOLUTION:
0.01 inches

TIME OF MANUFACTURING:
11 hours

On the contrary it isn't possible to state final judgments on regard of the loose of resistance of the AFO, if printed in two pieces and then jointed since no comparable value of strength are available and this orthosis was just a prototype that couldn't be dressed by a child to test its efficacy. However as a general evaluation a visual difference was noticed between this prototype and the one printed in a single piece on behalf of this last solution since the strength direction is the biomechanical function of an AFO dressed by a DMD user, is exactly perpendicular to the cut line and this facilitates its break up.

Phases of the 3D printing.
The upper and lower parts inside the 3D printer with their support material



(on the bottom)
The two pieces of the AFO after the removal of support material

(on the left) The AFO after the joint of the two parts

DESIGN

11.3 – 3D printing of the prototype of the orthosis in a single piece

AIM OF THE TEST

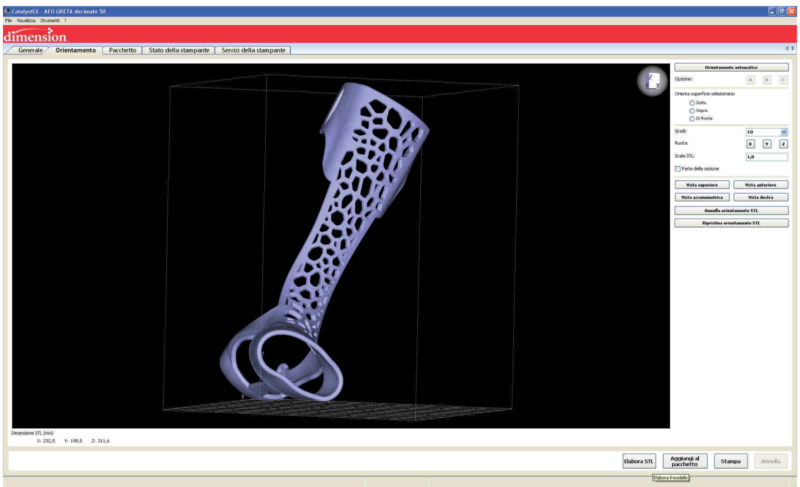
The second print was aimed at comparing the results of an AFO printed as a one piece with the ones of a double piece AFO previously illustrated, even if for doing so with the 3D printer available at the University it was necessary to slightly tilt the orientation of the orthosis. Moreover few changes were applied on the first prototype and this second one had to validate those improvements.

PREPARATION OF THE BUILD JOB

First of all the model was uploaded in CatalistEX software associated with the Dimension 1200es printer and it was orientated to fit in the printable box. On this regard it was necessary to slightly tilt the AFO of 30° of respect to its Y axis since it was too high to be printed vertically for this type of machine. Then, an High Density of the model's material and a Smart Mode of the Support Material was set. Once added to pack, the software calculated the amount of support material required.
The perforation of the frontal part of the AFO and, most of all, the tilt of the orthosis increased enormously the amount of support material required. All this support was necessary to hold up melted ABS until it didn't become solid but, once the print is finished, it dissolved away immersed in a tank with a water based solution. Once we checked the availability of the required material in the machine, we started the print.

PHASE OF BUILDING

The phase of building required 43 hours to finish but for all this time the machine worked autonomously without any intervention of the operator. The long time required was mainly due to its orientation, since it required a considerable amount of support material, even more since it was tilted. However unfortunately, after about 37 hours the most exterior column of support material, the tallest one, collapsed and the process, after causing a slight slip of the model, interrupted and left the model unfinished.



3D PRINTER:

Dimension 1200es Series

MODEL MATERIAL:
ABS in ivory

SUPPORT MATERIAL:
Soluble Support Technology (SST)

BUILD SIZE:
254X254X305 mm

LAYER THICKNESS:
0.254 mm or 0.330 mm

SOFTWARE:

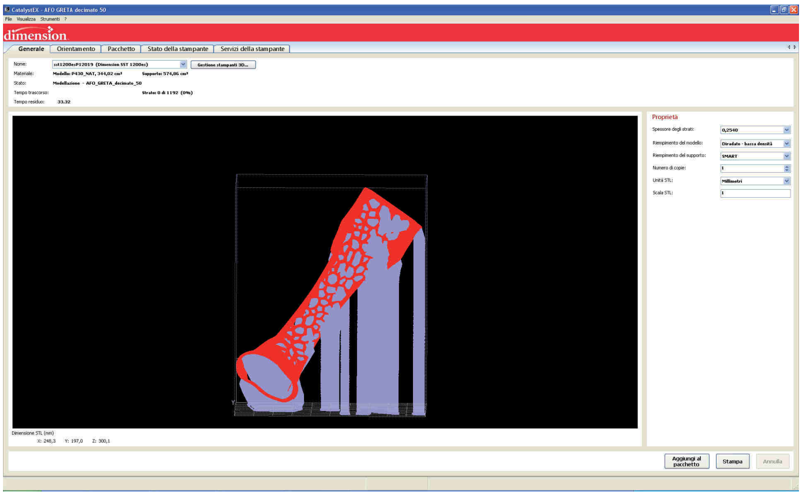
CatalistEX

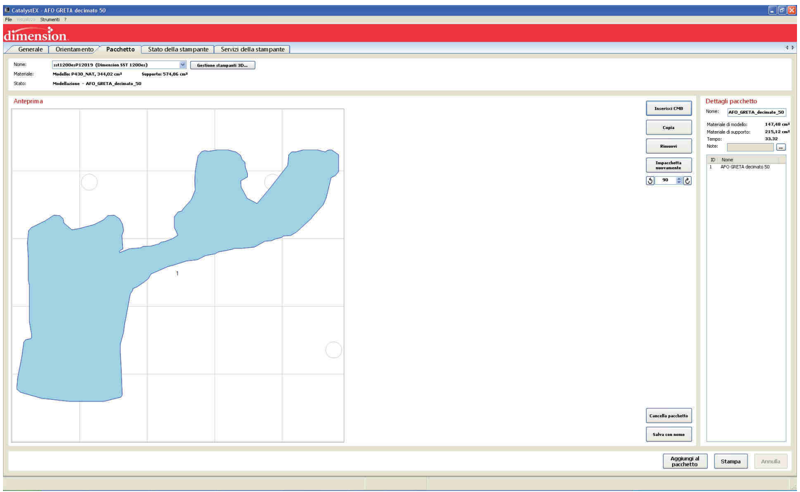
PARTS REMOVAL AND POST PROCESSING

Even if unfinished the model was as well separated from the basis and it was put for 12 hours in the tank with the basic solution to make the support dissolve. Just to give a smoother finish and to reduce the weave caused by the thin layers of material overlapped by the machine, the surface was sanded with a fine grit, but it isn't a necessary step.

FINAL CONSIDERATIONS

The breakdown of the test doesn't exclude the possibility of being able to do some evaluations. First of all this was the first test made with the frontal part of the AFO perforated by a Voronoi texture made to enhance the aesthetic quality of the product and, at the same time, to improve breathability. This test was successful but the quality of the print was slightly inferior in smallest holes, especially since the model was tilted. Each layer of ABS material added by the printer, in fact, wasn't orthogonal to the major axes of the AFO but, obviously slightly tilted and this worsen a little the overall aesthetic quality of the product and add some blemishes that will not be present if it would be printed vertically or, even best, with the major axis oriented on X or Y axis.





Screenshots of the phases of preparation of the building:
- orientation of the model (on the previous page)
- elaboration of the support
- calculation of the quantity of material and time required for the 3D printing

DESIGN

Failed test of 3D printing.
After the collapse of a support column the printer first losed its orientation, then stopped

The breakdown of the print suggested to increase the density and the quantity of the support. It was decided even to increase the density of the model to gain a better resistance to strengths.

Concluding the dimension and the shape of the eyelets where to pass the bands that tie the leg were judged ineffective and they changed in the final product printing.

PRINT DATA:

Dimension 1200es Series

DATE: 18/11/2014

DIMENSION:
Vertical position:
95.9x199.9x322,6 mm

Tilted position (Bounding Box):
232.5X199.9X311.6 mm

MODEL INTERIOR:
Sparse - low density

SUPPORT FILL:
Smart

LAYER RESOLUTION:
0.01 inches

MODEL'S MATERIAL:
147,48 cm^3

SUPPORT'S MATERIAL:
215,12 cm^3

TIME OF MANUFACTURING:
43 hours

11.4 – 3D printing of the final prototype of the orthosis

AIM OF THE TEST

The last test was aimed at solving the problems encountered in the previous test and at verifying the efficacy of this printing set with an higher density as of the support material as of the model material.

PREPARATION OF THE BUILD JOB

The model remained the same as the previous one, except for the top and bottom eyelets that were slightly changed. The file was load in CatalystEX software and all the properties were selected. In particular in this last print the density of the material was changed to “Sparse - high density”, and the support from Smart to Normal. The model was oriented with the same angle of tilt of 30° to make it fit with the printable box, even if we’ve already tested how this decision is counterproductive in terms of quality, time of building and cost. Then the model was added to the pack, the amount of required support was calculated and the print started.

PHASE OF BUILDING

A clean top was located inside the printer and the machine started to apply thin layers of support and model materials until it finished after 56 hours.

The model is slightly oriented to fit the maximum printing size of the printer

3D PRINTER:

Dimension 1200es Series

MODEL MATERIAL:
ABS in white

SUPPORT MATERIAL:
Soluble Support Technology (SST)

BUILD SIZE:
254X254X305 mm

LAYER THICKNESS:
0.254 mm or 0.330 mm

SOFTWARE:

CatalistEX

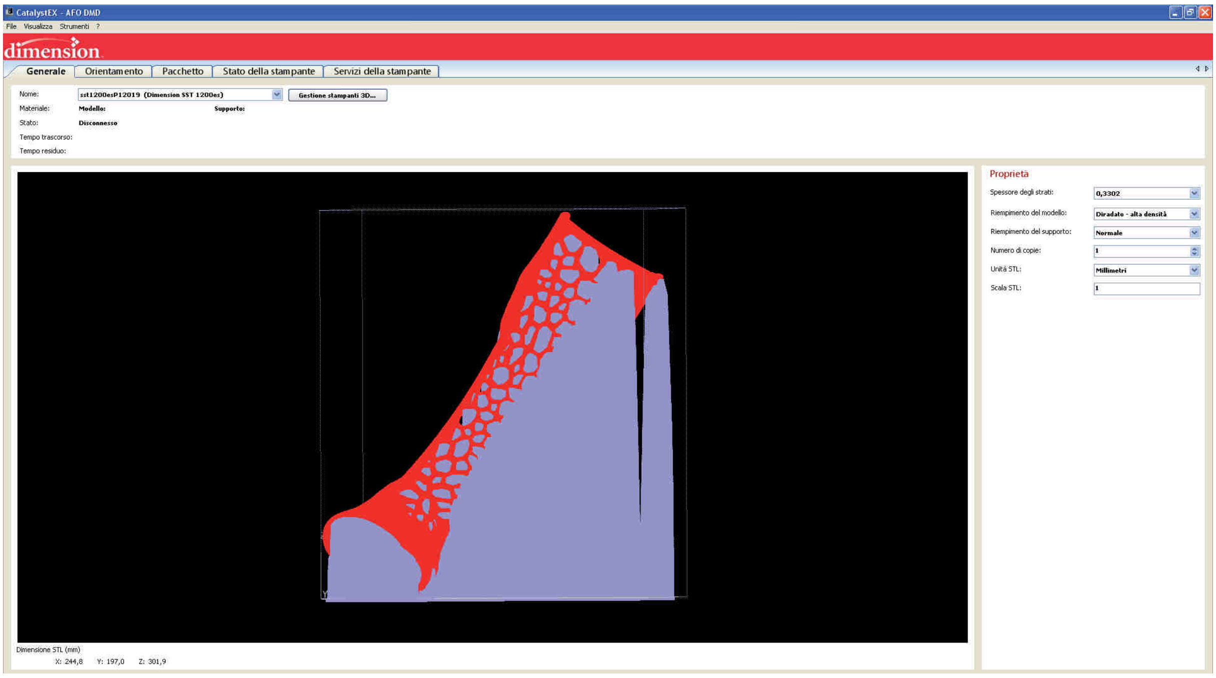
PARTS REMOVAL AND POST PROCESSING

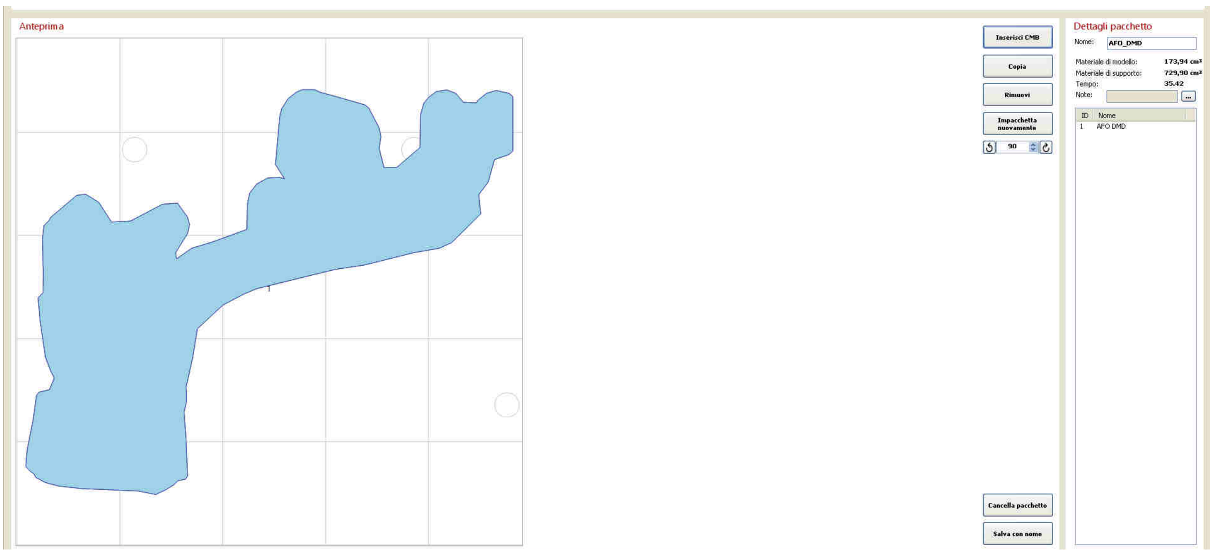
This time everything went well and when it finished the model and its support were removed from the basis and they stayed 18 hours in the container to make the support dissolve. Concluding, the model was washed and the surface was sanded with a fine grit to remove little imperfections.

FINAL CONSIDERATIONS

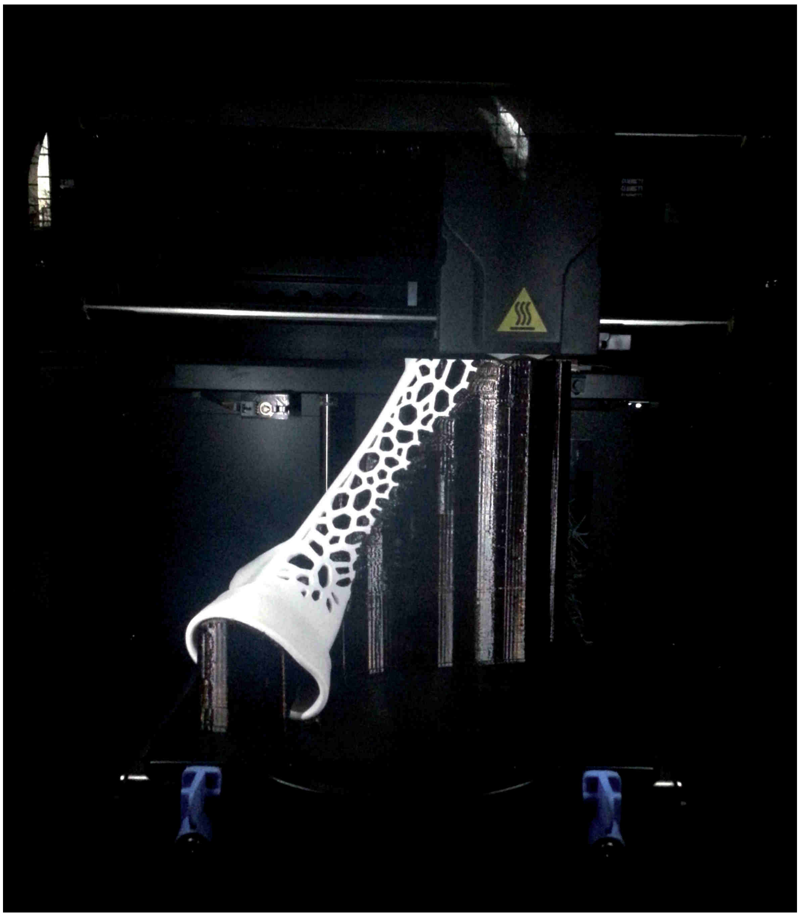
This last print was considered fully satisfactory for the aim of the test. Given the machine and the necessity of printing the orthosis with that orientation this was probably between the best result achievable and no possible improvement were individuated. Nevertheless in the conclusions we'll see how other different techniques or machines could be tested in future to analyse and compare the result in the attempt of a better optimization of the process and incrementation of the final result.

The elaboration of the support of this print is made in a Normal mode and, compared with the previous Smart one, it can be seen how it implies more support material





DESIGN



Phases of 3D printing.
The higher quantity of support material guaranteed a better stability of the model that was successfully printed

PRINT DATA:

Dimension 1200es Series

DATE: 14/01/2015

DIMENSION:
Vertical position:
95.9x199.9x322,6 mm

Tilted position (Bounding Box):
232.5X199.9X311.6 mm

MODEL INTERIOR:
Sparse - high density

SUPPORT FILL:
Normal

LAYER RESOLUTION:
0.01 inches

MODEL'S MATERIAL:
173,94 cm^3

SUPPORT'S MATERIAL:
729,90 cm^3

TIME OF MANUFACTURING:
35.42 hours

The final 3D printed AFO

11.5 Padding and closure systems

The process of padding of the internal side of the AFO was necessary since the ABS is an extreme rigid material and it requires a soft layer to distribute the strengths due to the stretching activity of the AFO, all over the surface.

Several companies were contacted and innumerous different materials for padding were selected. At the end of this demanding task, completed even thanks to the precious support of the technicians of the various manufactures, the material that, at the moment was chosen as one of the best for this scope was the ***Poron Xrd, Extreme Impact Protection***[1], micro-cellular polyurethane foam that has excellent compression-set resistance, high resilience, flexibility and shape memory that makes it return in the original shape as soon as the solicitation impressed on it stops. Moreover it has a cosmetic finish and biocompatible lines already used in orthopedic applications as shoes' padding. Together with an expert technician, retailer of the material, we chose the adequate density of the foam. It had not to be too soft, otherwise the pressure of the leg would completely crush the foam and push the skin against ABS walls. At the same time it had not to be too hard in order to meet its function of distributing the strains, avoiding pains.

From the parametric algorithm that generates the 3D model of the AFO, ***the inner surface***, before its perforation by Voronoi diagram, was isolated, transformed in a polysurface, no more parametric, and ***unrolled in order to obtain a bi-dimensional shape***. This process was quite difficult since the double curvatures of all the surfaces that compose the orthosis and it could be still improved. However the result can be considered acceptable and the silhouette of the Poron was cut.

Then, in order to enhance the breathability of the orthosis, as done with the frontal part in ABS, all ***the pad was riddle*** with small holes of about 2mm of diameter, regularly arranged in staggered lines. In this case, since its nature of a prototype,

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1 *Poron Xrd Extreme Impact Protection*, http://www.poronxrd.com/products/1/XRD-Extreme-Impact-Protection.aspx (January, 2015)

Extracted from the catalogue of the product:

The Best Repeated Impact Absorption Material

Soft and contouring against the body, yet instantly dissipates force upon impact

Absorbs more than 90% of energy* when impacted at high strain rates

Maintains performance beyond the life of the product

Consistent repeated impact absorption

Excellent compression-set resistance

Wearable Protection

Allows for ease of movement and range of motion

Low profile: available in variety of thickness (1mm - 19mm)

Light weight: as low as 9 pcf density

Drapable material with a "second skin" feeling

Soft and flexible to the touch

Contouring

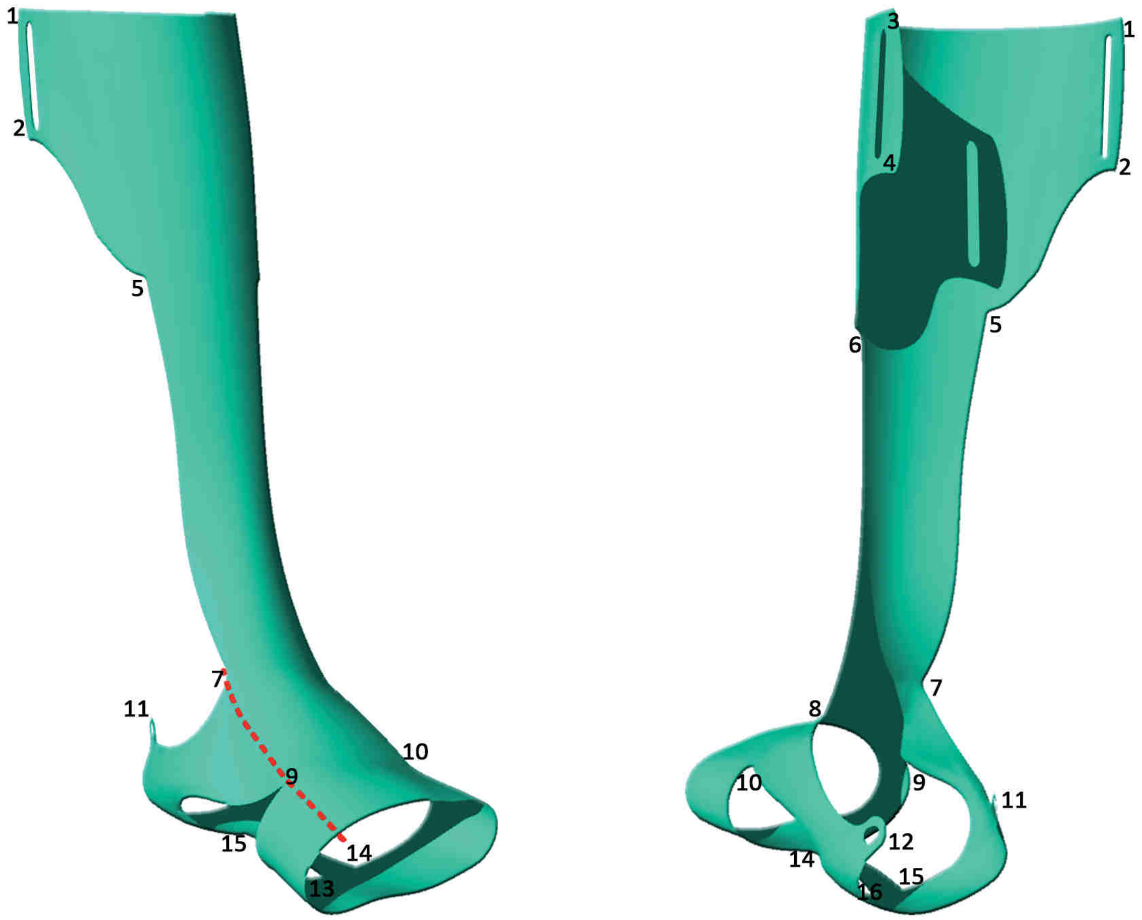
Breathable

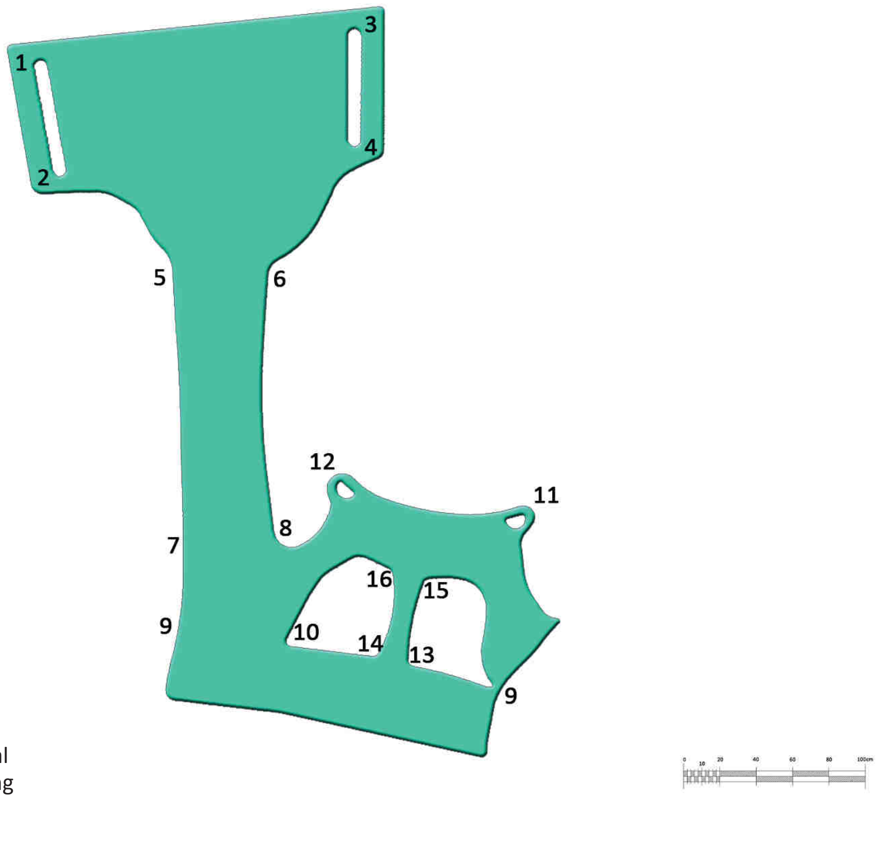
Microban® antimicrobial protection inhibits the growth of stain-and odor-causing bacteria

Easily fabricated to suit a variety of applications and placements

* % of Impact Absorbed

ASTM F1614-C Flat Surface Impact Test, Single Drop, 8.5 kg mass, 1.0 m/s Velocity





Unroll of the 3D inner shape
of the AFO in a bi-dimensional
profile used to cut the padding

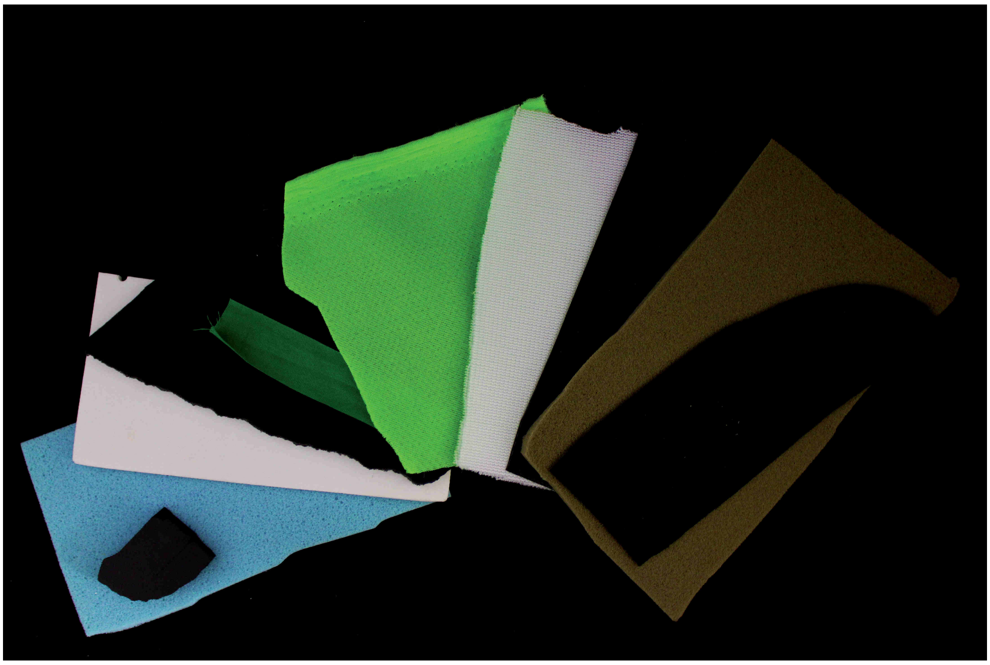
this process was done manually, but, if its experimentation will prove the efficacy of this solution, it can easily be done industrially or with apposite machines.

Then the padding was completely clad with an elastic Lycra tissue. The one chosen for this first prototype was simple and monocolor, but this element could be easily personalized by the user and used as a texture visible on the back of the holes of the frontal part, creating double levels effects.

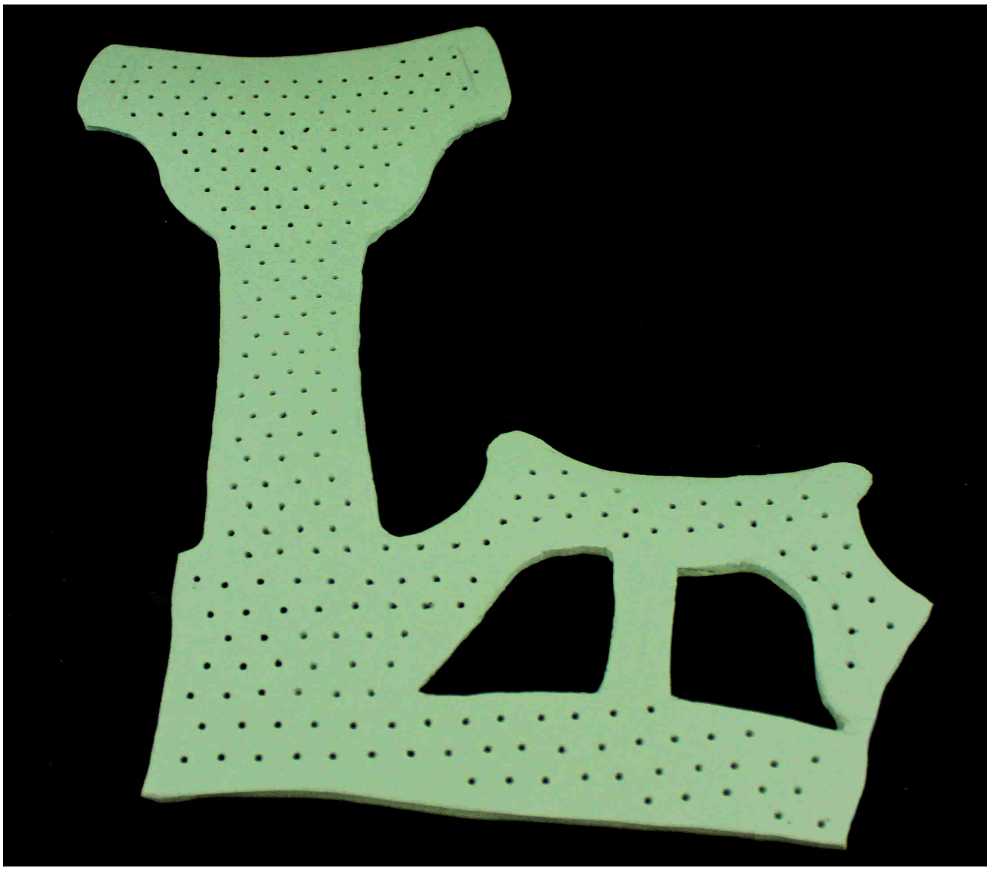
Concluding, **five Velcros** were stitched on the orthosis and sewn on the tissue. These Velcros allow to fix the padding to the orthosis but, at the same time, to remove, to change or wash the padding and the ABS separately. This element is extremely important to guarantee the hygiene of the orthosis and, at the same time, it can be useful even to add a simple element for personal aesthetic customization that can be easily substituted and changed meeting child's needs at a very low cost and effort.

Beside the inner padding ***two bands*** were prepared ***to lock the heel and the AFO behind the calf***. Both the strips were made by a more resistent strip that slips in the eyelets of the orthosis. These strips slides between small cushions, made by padding clued with tissue, that have the aim of dampen the pressure of the skin against the strips. These could be in fact the most breakable points of the skin and the efficacy of this solution in the long time has still to be evaluated.

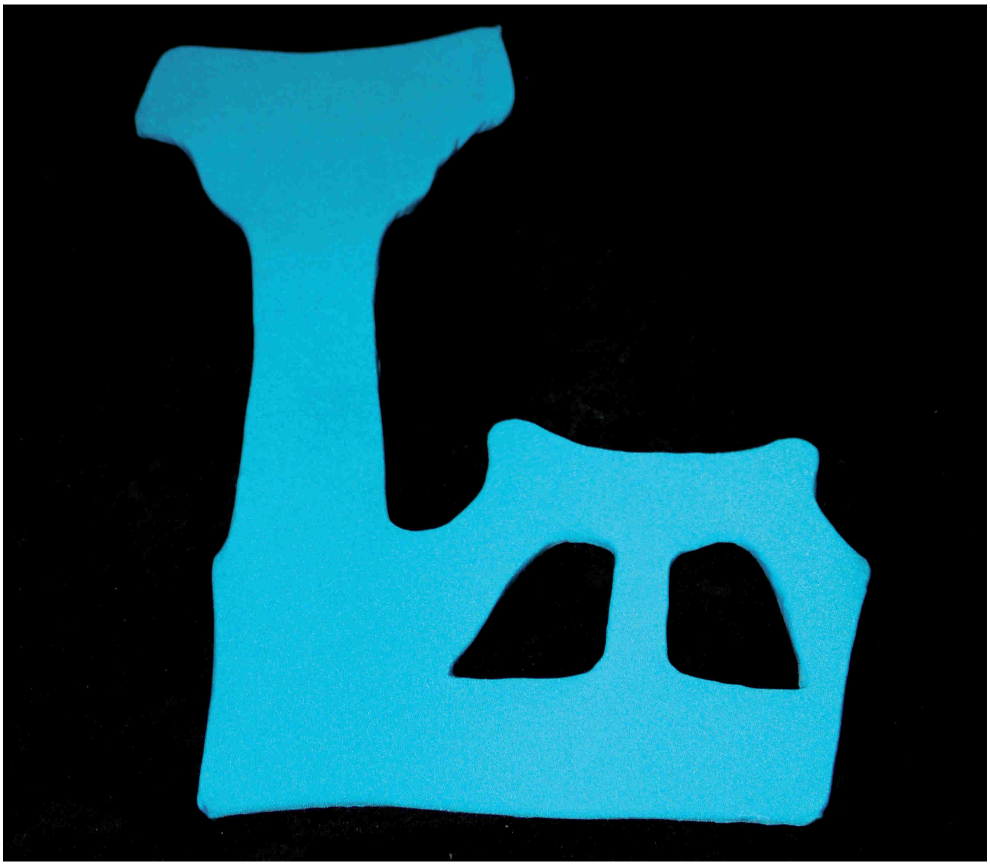
Just as a possible and interesting issue that could be explored in the continuation of the research we can even mention the possibility of 3D printining the padding too. The process just illustrated, indeed requires some hours of works and most of all it has to be done in a semi-handicraft way since, usually, the amount of the demands, and the customization on each patient, don't make economically convenient an automation of the process. A possible alternative offered by the technology could be the ***3D Multi-Material Printing, able in a single print to manufacture as the rigid ABS part as the soft biocompatible rubber part***. However this hypothesis has still to be tested and demonstrated and it could be referred only as a possible chance for the phase of experimentation of the research.



Samples of different materials evaluated as alternatives for the padding of the AFO



The foam padding was microperforated to improve breathability



Elastic lycra clothes the foam on which it is stitched on boths sides with spray glue for tissues

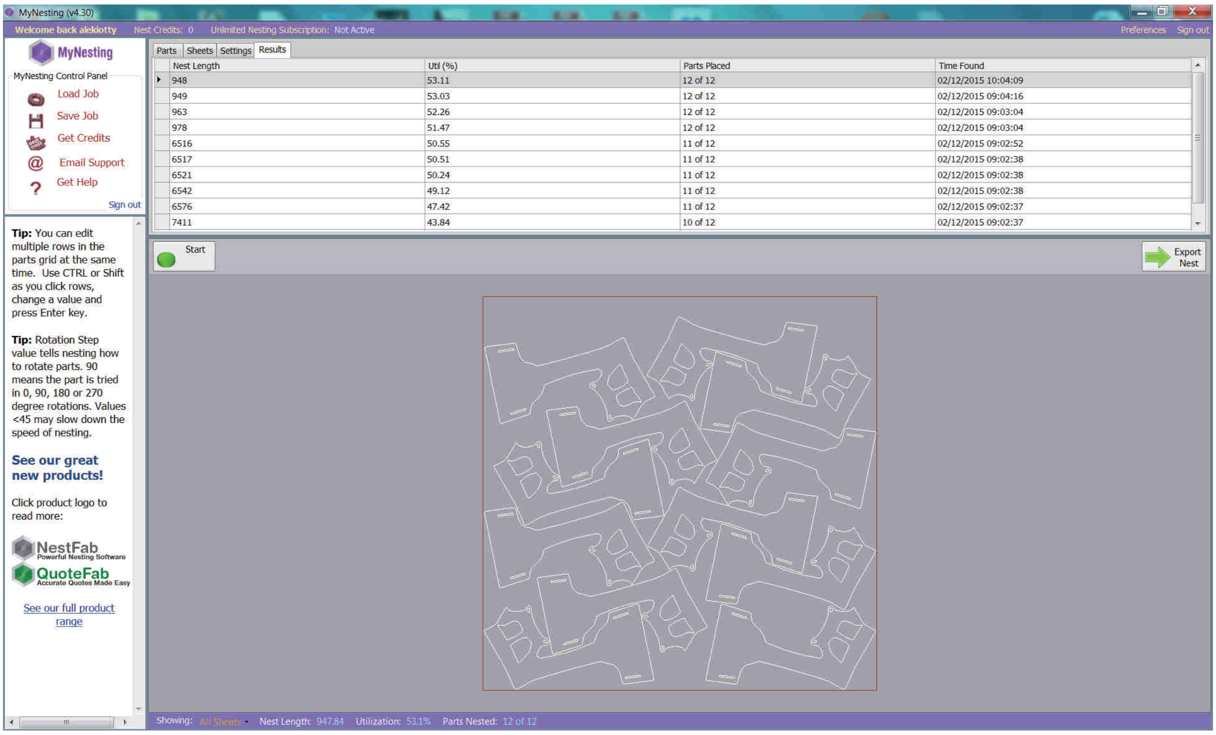
Five carvings accomodate Velcro to fix the padding to the AFO and to allow its removal when is necessary to wash it

11.5.1 Nesting of padding shapes

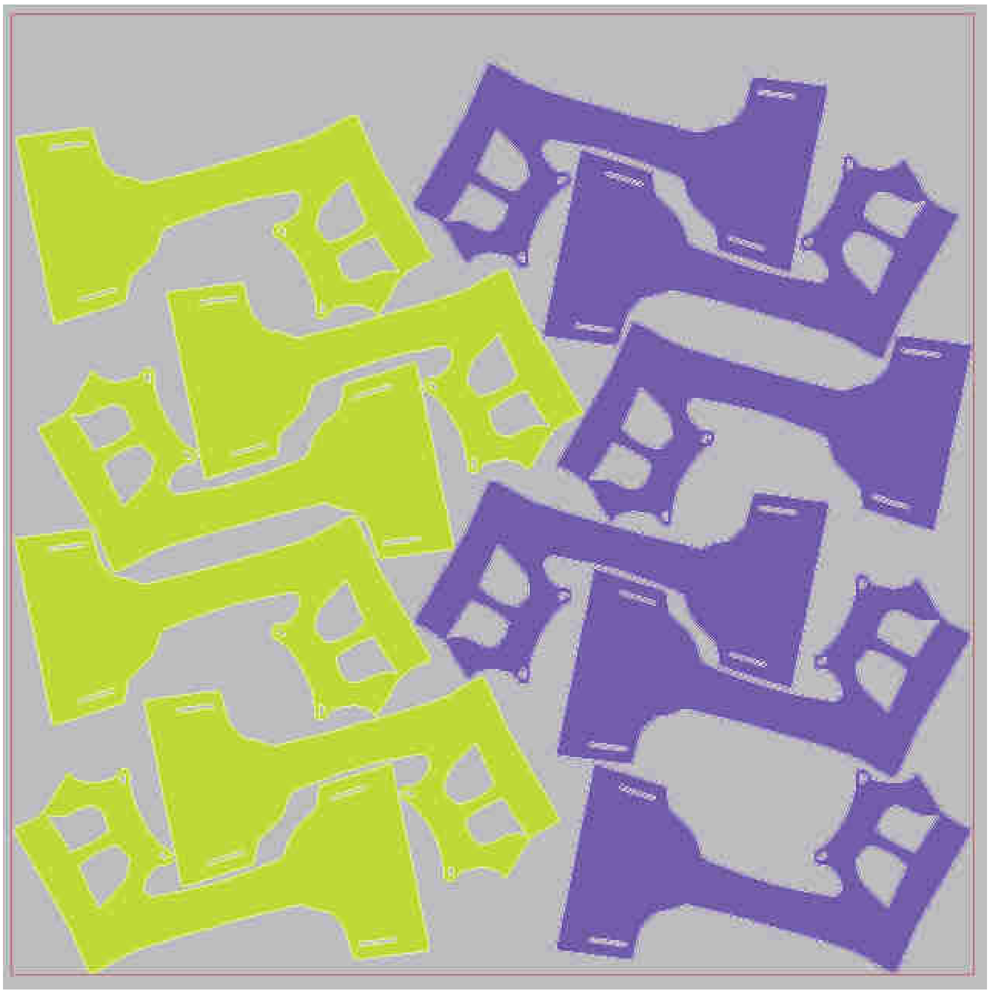
In the hypothesis of a paddings made as a separate piece, as the ones of the prototype, it was supposed the situation of producing more than a single pair of AFOs and to have to optimize the foam, reducing scraps as much as possible. A trial version of a professional software for “nesting”[2] was used to solve this problem. These programs are based on a mathematic algorithm that, given the pieces, the dimension of the sheet and the angles of rotation allowed by each piece, finds the best solution as possible. In the proposed simulation, the unroll of the padding of a left AFO was mirrored to have an hypothetical right one and then these shapes were considered three times as 3 pairs of orthoses. Obviously in a real case each one of these shapes will be slightly different, since they’re custom made, but this approximation was considered irrelevant for the aim of the test. In the first screen of the software all the details about the parts are inserted, their profile is uploaded in the software and the rotation step for nesting. Then, in the second screen, the information about the sheet are provided. In this case, as a sample, a 100cmx10cm sheet of foam was hypothesized and then some further details about the direction of nesting. Once the process started we can see in real time the figures that assembles and each time that a snap-fit is found, the solution is automatically saved, indicating the increasing percentage of use of the sheet.

The image illustrates the result and proves how it’s possible to integrate this process in the manufacturing of the AFO in order to optimize time and cost, eventually even with an automatic laser cut of the shapes.

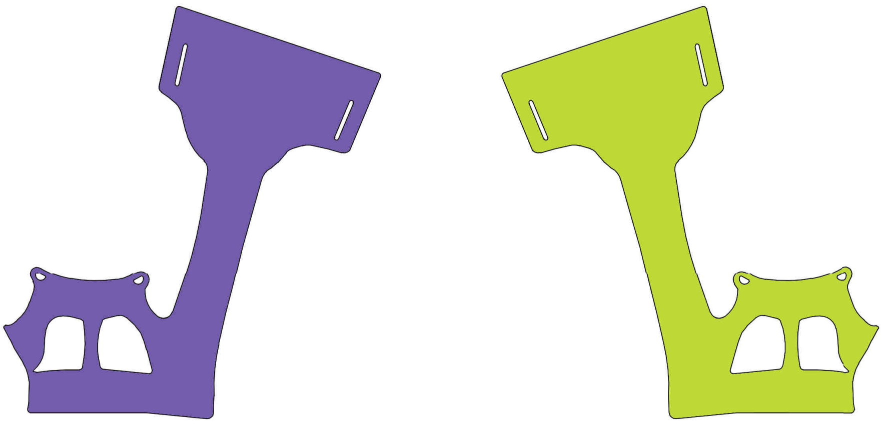
Nesting of six right and left paddings of three pairs of AFOs



2 *My Nesting*, http://www.mynesting.com/, (January 2015)



For this test the paddings were all equal and simply mirrored for right and left size but, evidently, they'll be all different



Right paddings in green and left paddings in violet

11.6 POSSIBILITIES OF AESTHETIC CUSTOMIZATION OF THE DMD'S NIGHT AFOS

In this research we've discussed several times the importance of guarantee a possibility of aesthetic customization of the AFO in order to improve the process of psychological acceptation of the orthosis. All the techniques selected, and in particular the choice of a parametric design for the AFO and the choice of a 3D printing technology for its manufacture were aimed, between other requirements, even to guarantee this important expectation. This huge enlargement of the possibilities of an aesthetic customization was just explored in a very little part at the moment and will definitively deserve higher space and attention in future. The process of affection of a boy, has difficulties of a different nature, but that passes through every age. As a general principle, valid for kids as for adults ***it is proved that the process of acceptation of an orthosis by a user is better stimulated if he can come in relation with the orthosis founding something in its aesthetic that can be connected to his personal life, his tastes, hobbies, his personality***.

In this perspective 3D printing technology is certainly the one that could best suits all these requirements. Its possibilities of personalization could vary from:

- ***Application of a coloured texture on the surface of the orthosis.*** This opportunity, offered by traditional current products is maintained even in the new type of night dorsal AFO for DMD, since every sticker can be glued on the surface, to give a more smoot, polish and coloured finishing to the orthosis. But that isn't all. Traditional FDM printers use single colours among a dozen of alternatives. Multi-Material printers on the contrary, offers the possibility of an integration of even 46 colours in a single prototype, chosen among a dozen of colours' palettes. These colours can have opaque or translucent finishes directly as the product is produced by the print, without even considering the numerous alternatives of extra finishes.
- ***Parallel drilling of a texture, even parametric, applied on the surface.*** This is what was done, for example, with the printed prototype. The texture of Voronoi diagram was applied on the surface and then empty parts are removed, filleting the edges. But as was done with the perforation of the frontal surface of the orthosis with a Voronoi pattern, it can be done with every conceivable pattern, motif, or decoration. An album with some graphic suggestions could be offered to the child just as an orientation of alternatives and customized products can be easily put in place. The perforation of the frontal part of the leg is functional to the enhancement of the transpiration and it makes the internal padding visible through the holes. This "double level" joke can be used to create graphic effects.
- ***Uniques personalization of the shape***, Clinical efficacy and 3D printability guaranteed, each shape of the AFO can be designed with every shape or idea complied with the final user. This is among the highest levels of aesthetic personalization conceivable. It is something possible even with traditional technique, but that becomes economically affordable thanks to 3D printing. The absence of a mold in additive technology, allows to build unique pieces one all different from the other without an additional cost. One of the main advantages in the application of 3D printing technology is indeed its possibility of an extreme customization in terms of measures and shapes. We've seen how the parametric algorithm allows to design the DMD's night AFO perfectly fit on the shape of the child's foot.

But that's just the functional aspect of the design. However this phase requires skilled designer professionals able to clearly understand desire and latent needs of the user and translate them in recognizable shapes and elegant morphologies. Hereinafter some examples of other different possibilities of aesthetic customization are illustrated. As it can be seen, at this level of in-deep in design possibilities, it was preferred to remain in applications that belongs to the second category, supposing the continuity of a single material. Multi-material printing promises to change rapidly this state of things and so many other experimentation with different materials are in course. They could certainly effect as the clinical efficacy, the hypoallergenicity in the contact of these plastics with the skin, even hypothesizing the use, now in phase of testing, of bio-compatible materials. All these possibilities will certainly effect even on the possibility of aesthetic customization, but improbably will affect the decision process that lead to the choice of this manufacture's technique.

The AFO can be printed in different colors or personalized with different textures











11.7 TEST OF TRY ON AFO ON THE CHILD

The validation of the process was the try on of the AFO on child's leg. As it can be seen in the following images the fitting was successful and this proves the validity of all the process. The AFO was don without particular effort autonomously by the child and fits with her measures.
However from the phase of acquisition 6 month passed, due to the illustrated technical problems in the 3D printing of the AFO. This cause a little growth of the child's foot that was compensated by the flaps on the back.
The pad in the short time period of the test seems to offers a good balance between resistance and softness but longer tests have to be carried to confirm this first impression. Moreover this test was made with a padding coated with elastic lycra sewn all around the foam. Next tests will try the solution of the tissue stuck on the pad with spray glue. This will probably further facilitate the try on of the AFO since the two materials will not slip with each other.
Concluding this object must be considered exclusively as a first prototype that validates the process and evidences its potentials but further experiments have to be carried out to test AFO's breaking strength with bio-compatible materials and different printing conditions.
Nevertheless the aim of the project can be considered successfully gained.

Try on of the customized AFO on the tester

Try on of the customized AFO on the tester

Try on of the
customized AFO
on the tester

11.8 CONCLUSIONS ON MANUFACTURABILITY

The end of the manufacture phase left more open questions than defined solutions.

It definitively validate the overall process, indicating 3D printing as the best technique to translate in a solid object the designed orthosis. But by which modalities and specificities is still an open question. In this occasion the aim of the project was to be able to produce a first prototypen and, after sveral trials, an acceptable result was reached but many features could still be improved.

For example, an FDM printer with a printing size that reaches 50cmx30cmx20cm could satisfy all needs and save a large amount of support material, with a direct advantage in terms of cost and time of production. In particular it would be better if the larger dimension corresponds to x or y axis since FDM technology has no milling steps on z axis and it causes less accurate results in the vertical than in the plane. If the orthosis is layed on horizontal plane the number of required layers would be drastically less, with a further reduction in terms of support material, time and cost and a direct advantage in terms of resistance.

Moreover we already mention another possible and interesting field of experimentation in the development of this project, offered by Objet Connex Multi-Materials 3D printers produced by Stratasys. This technology allows to print simultaneously an object composed by two different materials or by a mixture of the two. Many industrial objects are already in production made by a rigid and a soft rubber parts. Among the several materials offered by the company there are rigid ABS and rubber certified for biocompatible uses and it could be extremely interesting to test if this technology could be used to print the entire AFO, both skeleton and padding, in a single print.

Furthermore, the research on contemporary application of 3d printing to shoes' industry evidences that almost all of the products were made in nylon and applying an STL technology, due to its not necessity of support material, a better finish and with the advantages guaranteed by the elastic proprieties of nylon. It could be interesting to test the production of an AFO with this technology to have a direct comparison between FDM AFO and STL one.

Concluding, we can state that 3D printing technology is growing so fast in these last years that the alternatives and future developments and improvements in the production of the AFO are almost countless, from carbon fiber to natural materials with interesting mechanical properties and biocompatibility. Many others are probably just incoming in the market and will be known in the very next future. For this reason it is extremely important to have clear in mind the needs and user requirements as starting point and the aim of the design, in order to be in the conditions of choosing time by time the best possible solution.

The most vanguard projects and companies nevertheless are all investing towards an higher level of customization and personalization. At this moment the higher levels of products' design seems to involve more the word of prothesis than ortosis. This is reasonable due to the larger market of these products and the higher psychological and emotive impact that they have on users. Nowadays users are becoming more and more aware of their rights in every field, and their choices and manifested desires are the real engine that moves market trends. For this reason it is predictably that this renewall will certainly involve in the very next future even other sectors of medical devices, as this thesis attempts to do.

12 CONCLUSIONS AND FUTURE PERSPECTIVES

12 – CONCLUSIONS AND FUTURE PERSPECTIVES

"Are the designs of our children's orthoses the best we can offer them? Is it possible to do ***something better to improve the quality of their lives****?"*
On January 2012 this question motivated the PhD research on night Ankle Foot Orthoses for people affected by Duchenne Muscular Dystrophy. After three years of study many steps forwards were taken and the first results are here illustrated. The answer to the first question is negative but margins of improvement can be foreseen involving different approaches.

Networking of information.

The first relevant result of the study is the elaboration of an international database of the lower limb orthoses available on the Italian, European and North American market. This instrument could bring several advantages to users and professional specialists and, if properly implemented and diffused, develop a higher awareness on the available possibilities offered on the market. Parents could understand better the differences among the products and choose something that meets better the tastes of their child, but doctors, at the same time, would be more free of suggesting products that guarantee the desired clinical efficacy without being too much bonded by geographical restrictions. It could be even more relevant with the diffusion already started in America and United Kingdom, of the possibility of remote ordering, made even easier thanks to the application of indirect survey techniques.
However, what this market analysis highlighted was, first of all, a ***diffuse lack of information, in the phase of design of the product as well as in the marketing one***. No reliable information is at the moment available that statistically state, for example, the progressive strength's force that these orthoses have to counteract, the range of ages in which people affected by Duchenne Muscular Dystrophy are currently using these orthoses and their percentage of use expressed, for example, in numbers of nights, or hours per month. These data could become interesting material of further studies and could address more specific user needs. Moreover it must be noticed that this market analysis involved the first year of the PhD, it dates 2012-13 and in these last two years many new companies were born that are applying new technologies to the manufacturing of AFO or many others upgraded their traditional production. This trend isn't in detriment to the originality of the research. On the contrary it underlines a diffuse interest and confidence in the potential of these new technology that does nothing but strengthen the assurance in the applicability of the proposed process.
Nevertheless it is important to make this new information and progresses that are developing in our country available to users, trying to recover the surveyed delay of Italian manufacturing in communicating product details on the Internet. Considering this scenario, the proposed database could be an aid in this process of development and networking of information on Ankle Foot Orthosis.

A new approach in the design of an innovative type of night Ankle Foot Orthoses for people affected by Duchenne Muscular Dystrophy

The natural second response to the expressed request of improving Ankle Foot Orthoses was the proposal of a new type of orthosis. However it must be noticed that the answer that was attempted to be given, involved not only the product by itself. ***The shift of the orthoses' design from an exclusively biomedical production***

to the sphere of industrial design involves not only the features of the final product but a deeper theoretical and methodological approach to the issue. As worldwide a new approach to disability is diffusing, underlined by the efforts made by major international associations and schools of thoughts, a new approach to orthopedic aids has to follow. Universal Design, Inclusive Design, Design for All, Design for Disabilities, are all promoting an inclusive approach, stimulating disabled people in the process of awareness of their rights and encouraging governments and institutions in the process of legal recognition of these rights. At the same time the International Classification of Functioning, Disability and Health is promoting a new concept of disability that is no more related to the diagnosis of an illness but it is considered as the result of the relationships between body, functions, structures, activities, participation and environmental factors. In the same perspective the orthosis is evaluated in a new *User Centered Design* approach, considering it no more a label to disabled people who wear it, but as a chance of designing something appealing, comfortable, that combines clinical requirement with the aim of satisfying latent expectations.

This research started in fact from a deep survey of all users' needs, including in the category of users all the figures that in various roles interact with AFOs during their life cycle. Furthermore the application of the method of the House of Quality of the Quality Function Deployment allowed to put all these requirements in relation with market analysis results, in order to gain precise and innovative design suggestions.

Nevertheless this aim of improving existing products was pursued through a complete revision of the whole process of manufacturing, from the acquisition to its daily use and, step by step, the analysis of the current situation ran in parallel with the evaluation of all the possible meliorative contributions that the most vanguard technologies could bring in the process of manufacturing, actually conducted mostly in a really handcraft way.

New technologies for old needs

The analysis of the current process of manufacturing highlighted how new materials, as thermoplastics, were used in conjunction with old techniques, plasters and mold. A technological upgrade of all the manufacturing phases appeared soon as a possible solution to optimize the process with a direct improvement in terms of time and costs of manufacturing. The User Centered Design approach had indeed a crucial role in the choice of the best technology applicable in each situation. This vision made the difference, in particular, suggesting that in most of the cases, the best technical solution available on the market isn't the best if framed by all the process implications, evaluating effective benefits provided to final users. A high-tech solution, for example, that causes a minimum advantage to the user, but implies a considerable increment of the cost of the final product, or the need by the users to move far from their place to reach the specialized office, was considered ineffective for the aim of the research. The ***cost factor*** has to be carefully evaluated in the comparison between traditional handcraft techniques and indirect survey, especially in some fields as 3D body survey aimed at the production of prosthesis and orthosis. Once the cost of the instrument to scan the limb is amortized, indirect survey proves to be much cheaper than traditional plaster cast, because of the saving in terms of material, but most of all in time of work of the operators. The cost factor was in fact one of the key elements of each evaluation. Nowadays these orthoses have an exaggerated price compared to the quality of the product. This high cost is motivated mainly by working hours of the staff and it directly affects the possibility of a family to change the orthoses any time it is required, following children's growth and the progression of the disease. In this view, the ***accorded preference to low cost technologies*** was the best warranty of applicability and success of the final result. In details, these were the technologies suggested per each phase:

- ***Acquisition of the user's feet shapes for a customized orthosis*** – An Image-Based-Modelling, or a Hand Scanner, even best if with a Foot Scanner specific software are proposed as possible solutions. The first one is the cheapest but it requires a little bit more training of the therapist in the post-processing of data for the elaboration of a 3D model. The cost of an hand scanner is slightly higher but usually considered approachable by clinical centers and it requires a short time of training and the possibility of testing in real time a good result of the acquisition. However beside the specific technology the best indication given for this phase is the use of an ***indirect survey*** technique. This solution improves the accuracy of the final result, has a lower psychological impact on the child at the moment of the survey, compared with traditional plaster technique and introduces relevant elements of innovation in the process, starting from an enhanced possibility of ***remote ordering***. An indirect survey could in fact be made in the same clinical center where Duchenne boys have their regular physiotherapy, in a friendly environment and by a therapist that perfectly knows the ability of stretching of children's lower limbs. Furthermore it frees parents from the necessity of ordering an AFO from the closest manufacturers located in the same cities, since the file of the 3D model of the feet made with indirect acquisition could easily be mailed and the final product posted to the clinic that has to evaluate the clinical efficacy of the orthoses before delivering them to the final user. Moreover an indirect survey would be crucial in the constitution of a ***database of surveys***. In the previously highlighted lack of scientific information a complete database of 3D models of children feet could have a great role in the evaluation of the progression of the disease and even in the comparison among different cases, in order to advance in clinical studies on this issue.
- ***Parametric design of the orthosis*** – demonstrates to be the most effective linking point between an indirect survey and additive manufacturing technology, enlarging exponentially the possibilities of aesthetic customization, in the attempt to contextually improve comfort, breathability and clinical efficacy. The definition of an algorithm that automatically adapts the shape of the AFO to user's feet 3D model is a tool that could simplify the process, making it quicker and therefore cheaper.
- ***3D printing of the orthosis*** – is the last element of freedom introduced in the process. Freedom of aesthetic personalization, of shape, but even freedom from the necessity of human labor in its manufacturing since the final product, once its shape is elaborated on the computer, is autonomously produced by the printer even during the night with a further optimization of time and cost.

Nevertheless these technologies are continuously in evolution, new products and solutions are incoming daily on the market and for these reasons these indications have to be considered temporary and subject to possible changes. However the described process and the indicated family of technologies have to be considered as a reliable answer to the contemporary handcraft manufacture of orthoses and all the possible changes that could occur in the phase of defining the manufacture process during the phases of future experimentations will have to be considered as an improvement in the detail of a defined frame.

Ordering a new pair of orthoses could be fun

A relevant result gained with the application of indirect survey techniques is the release from the association between the order of a new pair of orthosis and a clinical practice, as the plaster of the lower limb. The survey tests conducted prove that this acquisition can be made in a playful and relaxed atmosphere, even outdoor.

Associating this first moment in the relation between the child and his orthoses with a pleasant experience could have a positive impact on the progress of the psychological acceptance of the AFOs. Nevertheless this change is not to detriment to clinical efficacy in the acquisition. On the contrary the design of an innovative support with the appearance of a rocking horse that puts the leg in a stretching position the leg has undeniable advantages in the acquisition and in the clinical efficacy of the orthoses. The therapist positions the foot on a pedal part of this support in the best position possible for the user in that moment, trying to recover as much as possible his dorsiflexion elasticity and correcting misalignments. In this way the orthoses will have the best effect, possible in applying a passive stretching during the night and the child will have only a playful memory of few minutes spent on a strange rocking horse.

Future perspectives

Concluding, this thesis proves that this innovative process is possible, it demonstrates it with a final case study and reveals its great potential of application, as recognized even by the Policlinico Gemelli in Rome, but it doesn't reach the production of final usable orthoses. This research proves that we're on the right track but to gain this result further studies and experimentations will be necessary.

All the developed research until this stage was made possible thanks first of all to the guide of my tutor, and to technical support in different branches provided by field experts. However, the multidisciplinary nature of this project, in order to be effectively put in practice, suggests the possible interaction of different professionals, in order to optimize all the processes and organically coordinate specific skills.

In particular for my opinion the specializations required to bring forward this project to its final step, in my opinion, should include:

- **Qualification in survey**, to set in detail all the process of acquisition in the simplest way possible and in collaboration with therapists who have in cure Duchenne boys;
- **Specialization in parametric modelling**, in order to optimize the algorithm on the basis of clinical observations provided by the medical staff in the phase of experimentations of the firsts orthoses, once the first prototypes will be ready to be given as a test to patients and it will be possible to directly observe their clinical efficacy compared with traditional products;
- **Skills in design**, to translate children and teenagers' tastes in modern, fashionable, attractive orthoses that could really impact the process leading to full psychological acceptance of AFOs;
- **Experience in 3D printing**, aimed at testing the best technical solution for the printing of the AFOs, and looking after the manufacturing of the orthoses;
- **General management**, to organize and coordinate different professionals and start all the procedures and requirements for the registration of the patent as a first step and then for the inclusion of the product in the list of the State Run Health Care.

Ankle Foot Orthoses are made to help children to walk independently for a longer period of their life.

Now we've designed our proposal of an innovative orthosis, but we also need to learn how to walk in order to go further in the research and reach the goal.

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- **Collaboration in the manufacturing of the first prototype of support for the child during the feet's indirect survey**

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CHAPTER 2 - Duchenne muscular distrophy

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CHAPTER 3 - Ankle Foot Orthoses

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CHAPTER 4 - Product Design Methods

CHAPTER 5 - DMD night AFO's design

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CHAPTER 6 - Overview on alternative techniques of lower limbs' survey

CHAPTER 7 - Survey techniques of DMD lower limbs

CHAPTER 8- Design of a support to survey lower limbs in stretching position

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CHAPTER 9 - Parametric design of a night DMD AFO

CHAPTER 10 - From 3D parametric model to 3D print

CHAPTER 11 - Manufacture of a new type of Ankle Foot Orthosis for DMD

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