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Design of Ankle Foot Orthoses using Subject Specific Biomechanical Data and Optimization Tools

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“O valor de uma ideia está na sua utilização.”,

por Thomas Edison – Inventor – Co-fundador General Electric

“Ideias são fáceis de ter. Executá-las não.”,

por Michael Dell – Fundador Dell

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RESUMO

O primordial objetivo deste trabalho é a apresentação de uma metodologia computacional para análise e dimensionamento estrutural de uma ortótese do tornozelo-pé (AFO) e consequente produção de um protótipo funcional com características especificas para um determinado utilizador com a patologia de espinha bífida (EB), nomeadamente mielomeningocele, de forma a apoiá-lo na locomoção.

A metodologia proposta assenta na premissa da otimização da área mínima necessária de uma ortótese para suportar as cargas à flexão a que esta será submetida. O dimensionamento da ortótese é realizado através de uma ferramenta de otimização, que tendo em consideração um conjunto de parâmetros geométricos da secção em cálculo, os momentos articulares máximos obtidos na análise dinâmica experimental realizada ao indivíduo, as características de resistência mecânica do material a utilizar no seu fabrico e o módulo de resistência à flexão do respetivo patamar, obtém a geometria e área ótima de cada secção ao longo dos vários patamares que compõem a ortótese no seu todo.

De seguida, foi escolhido um dos resultados obtidos pela ferramenta computacional, tendo em consideração a patologia, os desvios ortopédicos e o tipo de marcha apresentada pelo indivíduo, de forma a que fosse construída uma ortótese que permitisse auxiliá-lo na locomoção.

Foi possível verificar a viabilidade da metodologia computacional desenvolvida através do período dilatado de utilização da ortótese, que se estende por cerca de 5 meses. Assim como a possibilidade de obtenção de diferentes resultados mediante o indivíduo em análise e o material utilizado para construção da ortótese.

PALAVRAS CHAVE: Ortótese Tornozelo-Pé, Otimização, Dimensionamento Estrutural, Protótipo Funcional, Espinha Bífida.

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ABSTRACT

The main objective of this study is to present a computational methodology for structural analysis and design of an ankle-foot orthoses (AFO) and consequent production of a functional prototype with specific characteristics, for a particular user with the pathology of spina bifida (SB), in particular mielomeningocele, in order to support him in locomotion.

The proposed methodology is based on the premise of optimizing the minimum area required for an orthoses to support the loads to bending that it will be submitted. The dimensioning of the orthoses is performed by an optimization tool that taking into account a set of geometric parameters of the calculated section, the maximum joint moments from experimental dynamics analysis of the subject, the mechanical resistance characteristics of the material used in its manufacture and the resistance to bending module of the respective level, obtains the optimal geometry and area of each section along the various levels that constitute the orthoses in its all.

Then was chosen one of the results obtained by computational tool, taking into account the disorder, orthopedic deviations and the type of gait presented by the subject so that an orthoses enabling assist in locomotion was built.

It was possible to verify the feasibility of computational methodology developed through the long period of use of the orthoses, which extends for about 5 months. As well as the possibility of obtaining different results by individual analysis and the material used for construction of the orthoses.

KEYWORDS: Ankle-Foot Orthoses, Optimization, Structural Dimensioning, Functional Prototype, Spina Bifida.

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List of Symbols

σ – tension

A – area

P - axial load

$\boldsymbol{\sigma_{adm}}$ **-** allowable stress

q – vector of generalized coordinates

ϕ– kinematic constraints expressions

$\dot{q}$ **-** vector of generalized velocities

$\ddot{q}$ **-** vector of generalized accelerations

ϕ q - jaciobian matrix of in order to q

Ʋ – velocity

γ – acceleration

f – vector of all forces that produce virtual power (external and inertial forces)

g - is the vector of generalized applied forces

λ **-** is the column vector of Lagrange multipliers

M - is the global mass matrix

M$\ddot{q}$ - representing the vector of inertial forces

Є – normal strain

δ – deformation

L - length

E – elasticity

Ρ – arc radius

Θ – angle

$\in_m$ - maximum absolute value of the deformation

W – work

I – Inertia

GLOSSARY

AFO - ankle-foot orthoses

SB - spina bifida

QTM – *Qualisys Track Manager*

CTEV - congenital talipes equinovarus

FEM - finite element models

CAD-CAM - Computer Aided Design - Computer Aided Manufacture

AF - additive fabrication

IRAM - (pag 13)

COM –

GRF - ground reaction forces

RBC –

DOF – pag 22

MRN - Newton-Raphson Method

EOM - equations of motion

LBL - Lisbon Biomechanics Laboratory

IR - infrared reflective

AIM - Automatic Identification of Markers

C – Centroid

CS - case study

CHAPTER I

1. INTRODUCTION

1.1. MOTIVATION

There are many orthopaedic and neurological pathologies which present consequences as the impairment of the locomotor system. Since this system is what provides the support and balance in standing position, allowing us to walk, when compromised it affects the quality of life of the individual in question. Depending on the degree of impairment, there are some less severe cases in which a minimum mobility reduction occurs, and others where there's a complete inability (Lenhart et al., 2008).

In the case of congenital defects such as spina bifida, depending on the level and type, they may or may not show clinical manifestations (Pina, 1999). Muscular deficits and bone deformities are some common consequences of this condition, which causes stabilization problems both in affected and in adjacent joints, as well as problems in postural control and difficulty in walking. Therefore, it is essential to prescribe support products to assist the gait, in order to overcome these problems and prevent their evolution (Patar, et al., 2012).

Orthoses are devices that are included in the rehabilitation of a wide variety of pathologies. Their designation is related to the body segment covered and the function provided. To the correct development of an orthosis, the existence of a clinical diagnosis and a prescription by a physician, usually an orthopaedist or physiatrist is necessary. However, the determination of which type of orthosis applied should be discussed by an interdisciplinary team in order to conclude which segments should be involved and what are the functions that are intended to improve, and in the case of multiple needs, what are the design priorities (Edelstein et al., 2006).

In parallel with the increasing technological development, in the last century it has been observed a growing concern in studying the field of orthoses, including: obtaining resources for analyzing and diagnosing gait to quantitatively determine normal gait patterns in different population groups; checking the effectiveness of orthoses on the gait of an individual; studying of various materials to be used in the production of orthoses; and developing the technology to improve the accuracy and reduce the time confection of orthoses (Carvalho, 2006).

However, until the current date it has not been observed studies for the development of a computational tool to assist the determination of the geometry of an orthoses, taking into account the individual characteristics and the characteristics of the materials to be used. The results of this present study allows an improvement in the production of orthoses, since it enables the orthoses to be performed specifically for a particular individual, taking into account the loads which it has to bear and the mechanical characteristics of the selected materials, which confers particular importance since these aspects are directly related with the performance of the functional orthotics and the quality of life of the user.

1.2. OBJECTIVES

The main objective of this work is the development of an optimization tool for the design of a functional prototype of a new model of ankle-foot orthoses (AFO), taking into account the maximum bending efforts at the ankle joint of a specific subject with a condition that affects locomotion, and the characteristics of the material being used.

To achieve this objective a case study was selected and used to obtain a number of individual parameters such as: inherent pathology, gait performed, types of forces exerted, moment performed at the affected joints and weight. To acquire this data it was necessary to perform kinematics and kinetics analyses in the laboratory, and subsequently the results obtained were treated with the acquisition software Qualisys - QTM™ (Qualysis, 2010), and used as inputs to the academic software Apollo (Silva, 2003) in order to calculate subject specific ankle moment needs. Additionally, the material to be used was selected, considering its yield stress, weight and easy to wear. As so the appropriate safety coefficient was defined, regarding the type of loads the orthoses will endure.

It is the purpose of this work to develop a computational methodology for the design of a passive non-articulated AFO, considering among other design specifications, the specific efforts that they will be submitted, and the type of material that they will be fabricated.

Once obtained the optimized configuration of the orthoses through the data submitted to the developed tool, these were built using traditional process. The functional prototype that was constructed using the proposed methodology.

1.3. LITERATURE REVIEW

The term Orthosis derives from the greak and its the result of the combination of the words orthos (correction) and titheme (placement). Thus, we have an external device placed in a given body segment that aims functional improvement, support, protection and correction is called orthotics (Carvalho, 2006).

The oldest archaeological findings that represent the use of orthoses are dated back to 2750-2625 b.C. and these are paintings of the fifth Egyptian dynasty. Is also possible to find references to column orthoses for treatment of fractures, dislocations and scoliosis in the writings of Hippocrates 460-375 b.C., and Claudius Galen in the second century b.C. Caelius Aurelianus (400 a.C.), Paul of Aegina (625 -690 a.C.) and Guy de Chauliac (1330-1368 a.C.) published books in which they referred to treatments that contemplated the use of orthoses. It was in 1575 that Ambroise Paré published the first work that spoke of the treatment of clubfoot with the aid of an external device. However, it was the publication of the book De Humani Corpus Fabrica of Andreas Vesalius, 1514-1564, which became a reference for the scientific community that defined the concepts, classifications and application of orthoses in medicine. Between the sixteenth and nineteenth centuries, other authors have emerged, primarily in the area of the spine, for the treatment of scoliosis, and in foot area for the treatment of club foot also called congenital talipes equinovarus (CTEV), e.g.: Guilelmus Fabricius Hildanus Nicolas Andry, Hugh Owen Thomas, James Knight, Rochard Von Volkmann, Bradford and Brackett (Carvalho, 2006; Edelstein et al., 2006).

Early descriptive studies of gait were made by Leonardo da Vinci, Galileo and Newton, in the period of the renaissance. In the following centuries, there were several names that worked in the study of gait and the development of techniques to facilitate the acquisition and processing of data (Whittle, 2007).

It was after the first and second world wars and after the polio epidemic in the 50s that there was a great clinical progress and scientific development in medicine. Parallel with these three important factors, there was a remarkable development in materials engineering which allowed the use of other materials in the manufacture of orthoses (Lusardi, et al., 2013). In the 60s and 70s with the emergence of the first light-weigth metals such as aluminium, and then of polymeric materials such as polypropylene and polyethylene, which have as main characteristics the high fatigue resistance, light weight, high strength, easiness of manufacture and cosmetically more attractive. The early 80s was marked by the creation of new topologies for foot and ankle orthoses (AFOs) (Chu, 2001) and with the use of gait analysis in clinical practice (Whittle, 2007), thus allowing researchers and clinicians to began to examine different gait patterns and the existing deflection depending on the AFO used (Chu, 2001).

The next decade was a major technological and scientific development in various areas of engineering such as the study and development of finite element models (FEM), which aims to identify the distribution of stresses in orthotics and therefore providing the information on the location of weak points, and CAD-CAM (Computer Aided Design - Computer Aided Manufacture) which in a system that allows scanning the limb, design the geometry of the orthotics and its automated production, which reduces the steps and increases the accuracy in the fabrication of orthoses, making this process more efficient (Chu, 2001).

Subsequently, many studies have been conducted in different target populations, such as children with cerebral palsy (Radtka, et al., 1997), myelomeningocele (Gutierrez , et al., 2005), Stroke (Routson, et al., 2013), hemiplegic patients (Chen, et al., 1999); and the comparison of different types of orthoses (Bregman, et al. al , 2009); in CAD- CAM systems (T. T. Chu, 2001); and the 3D study using finite element models (Chu, et al., 1995).

Since early 2000 there has been developments in manufacturing techniques and rapid prototyping in order to solve some of the problems of the CAD-CAM system. Pallari et al. (2010) studied the additive fabrication (AF) whose main advantages with respect to CAD-CAM are the ability to support the import files of finite element models; the output file is compatible with other machines, in addition to milling machines; on the other hand CAD system allows only the manipulation performed on the positive cast to the client (Pallari, et al., 2010).

In 2011, Baptista made the first work on the distribution of contact forces that the interface body/orthosis segment develop, to try to settle any relation with the comfort felt by the user.

However, until the present time and to the knowledge of this author there are no studies in which orthoses are dimensioned taking into account the forces to which they will be subjected, and the specific characteristics of each user, i.e., the weight and the moment of force of the affected joint. These studies are of considerable importance since when these characteristics are not taken into account, what happens regularly at AFOs, especially with active users, is the rapid wear, sometimes leading to their premature rupture in zones of high stress as such as near the tibial-tarsal and/or metatarsophalangeal joints.

1.4. CONTRIBUTIONS

The primary objective of this thesis is to contribute with a compressive methodology that resorting to concepts of mechanics of materials and optimization tools calculates the minimum area required for the construction of an AFO so that it supports the efforts to which it is submitted, taking into account the factor of safety to keep structural stresses below the ultimate stresses of the material.

The methodology proposed in this work provides to orthotics/prosthetics technicians, developing orthoses, a precise definition of its topology. It also provides decision support regarding the type of orthoses prescribed by medical staff, as it takes into account the condition of the user and its characteristics. In what refers the user, this methodology will increase the level of confidence in the product in use and consequently increase the quality of life of people with disabilities.

1.5. THESIS ORGANIZATION

This thesis consists of eight chapters, which are outlined below:

Chapter I - makes reference to the main objectives proposed in this paper and what led to their achievement. Then a brief historical background of orthoses is performed and what the contributions that this work intends to make to progress in the field of orthoses.

Chapter II - This chapter makes a brief presentation of the anatomy and physiology of the skeletal system and the types of movements performed by the lower limbs. It also contextualizes the spina bifida condition and the existing type of foot and ankle orthoses that by the degree of severity of the injury can aid in locomotion.

Chapter III - This section explains the normal gait cycle as well as the pathological gait inherent in spina bifida. What are the analyzes that can be made to analyze the individual's gait, as well as how are obtained and treated their specific data.

Chapter IV - This section makes a brief statement of biomechanical concepts and structural mechanics underlying to this work, that is to the confection and use of orthoses.

Chapter V – Presents the way the computational methodology inherent in this work was developed.

Chapter VI - Gives the results obtained through the tool developed for a case-study. As also discussed the results and which the selected solution for manufacturing, as well as the reason for their choice.

Chapter VII - This chapter presents the procedures used for the manufacturing of the working prototype previously selected.

Chapter VIII - The conclusions are described and how this work can contribute to future developments in this area, custom manufactured orthoses.

CHAPTER II

2. HUMAN MOVEMENT AND SPINA BIFIDA

2.1. ANATOMY AND PHISIOLOGY OF THE SKELETAL SYSTEM

The human body is a complex biological machine that adapts to various environments. The skeletal system is what allows the support, protection and body movements. However, it has other functions such as ensuring the production of blood cells and store minerals. Bones, cartilage, ligaments and joints are the elements that make up this system (Seeley, et al., 2006). This chapter makes a brief and concise description of the physiology and anatomy of the spine and lower limb necessary for a better understanding of the theoretical framework that will be addressed in this work.

The structure of the spine is usually composed of 26 vertebrae, separated by intervertebral discs, and plays a major role in the support of the head and trunk, protecting the spinal cord, it allows spinal nerves to exit the spinal cord, provides sites where the muscles can attach, and allow movement of the head and trunk. The spinal cord is located in the spinal canal and is protected by the vertebral body and arcs.

Providing body support and allowing body movements (standing, walking or running) are the fundamental functions of the lower limbs, so their structure presents characteristics and appropriate settings for fulfilling these duties. The leg is the segment between the knee and the ankle and is composed of the fibula and the tibia, the latter being the bone that supports most of the weight of the leg. The ankle joint, is formed by the leg and the foot: the medial and distal part of the tibia, which forms the medial malleolus; the distal and lateral fibula that forms the lateral malleolus; and the talus of the foot which corresponds to the most proximal bone. This type of joint allows movement of dorsiflexion, plantar-flexion, eversion and inversion. The calcaneus is the bone that supports the talus, and is the site of insertion of the calf muscles.

The normal weight distribution on the foot is 40% in the forefoot and 60% in the rear foot in load situations, whereas both during the gait as in static position this weight is transferred through the three arches: the internal, the external and the transverse (Tortora et al., 2008). There are pathologies that affect the configuration of bones, muscles and ligament insertion altering the structure of these arches and consequently the weight distribution and the flexibility to adapt the foot to irregular surfaces.

The musculoskeletal system has a complementary function which is: the production of body movements, mostly through skeletal muscle function; the maintenance of posture, through the conservation of the tone of the skeletal muscles; the production of body heat among others. Given the functions of this system, it is understandable the high specialization of muscle tissue to contract, or shorten, forcefully. Skeletal muscle has 4 functional properties: *contractility* is the ability of producing a given force through the muscle shortening; *excitability* which is the responsiveness to a stimulus, usually derived from a nerve; *Extensibility* which is the amount which a muscle lengthens beyond its resting length; *elasticity which is* the capacity of returning to their original size after stretching (Seeley, et al., 2006).

Most body movements are generated by muscle contraction. Energy is generated when a muscle contracts concentrically and is dissipated if it contracts eccentrically. In the case of isometric contraction, muscle transfers force and moment through the joint without generating or absorbing mechanical power. To be possible to walk it is essential to have energy absorption, when we have a pathological gait due to problems in the lower limb(s) there is the need to absorb energy through other segments or through an assisted-gait device (Whittle, 1996).

2.2. Lower Limb Movements

One of the common functions to the muscular and skeletal systems is the production of movement in the various segments. Assessing the state of the range of motion of these segments, it is possible to verify if both systems present a problem. It should be mention that we have two different types of movements; these correspond to the active movement performed by the person, and those that are passive movements that are performed by third parties. For a correct evaluation, a three-dimensional framework is primary defined as well as the plans contained in this framework (sagittal, frontal and transverse) and then movements and amplitudes occurring in each plan are checked-up. The relative movement between segments is highly dependent on the type of joint and muscle contraction.

2.2.1. Leg Movements

The above thigh muscles are sartorius and quadiceps, that groups the rectus femoris, vastus lateralis, vastus medialis, vastus intermedius. This muscle group has a common insertion on the anterior tuberosity of the tibia and has the function of knee extension. The sartorius muscle is in contraction when the knee flexes, however, also allows hip flexion and lateral rotation of the thigh. The knee flexors are the posterior tight muscules: the hamstrings which consist in biceps femoris, the semimembranosus and the semitendinosus. However, these muscles also have the function of knee rotators depending on their insertion point in the leg, i.e. those that fall on the side are the external rotators and those which fall into the medial region are the internal rotators (Pina 1999; Kapandji, 2000).

2.2.2.Ankle, Foot, and Toe Movements

Since the foot is the only part of the body acting on an outer surface, the ground, to have a normal gait cycle it is essential that the ankle can perform the normal range of motion to provide the required support and stability and to support the normal joint mobility.

The ankle and foot are moved by the leg muscles. The movements of dorsiflexion, eversion and inversion of the foot and toe extension are performed by contracting the muscles of the leg (Pina, 1999).

The gastrocnemius and soleus correspond to superficial and posterior muscles of the leg and are involved in plantar flexion of the foot. While the posterior deep muscles besides having the function of plantar flexors, these muscles also inversion of the foot and flexion of the fingers. The lateral muscles have as main function the eversion of the foot, however, also aid in plantar flexion (Fig. 1). The muscles located in the foot are responsible for the movements of the fingers, i.e. flexion, extension, abduction and adduction (Pina, 1999).

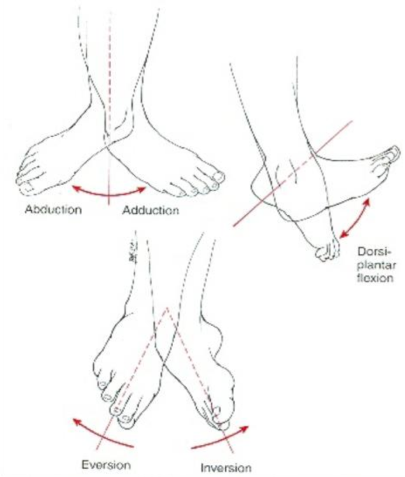

Fig. 1 - Movements of foot (14Nov)

2.3. SPINA BIFIDA

During fetal development, in the first month of embryonic development, sometimes occurs a defect in the neural tube or in the spinal column formation (the vertebral laminae are not formed or a partial or complete failure occurs in their fusion) or in both, designated as Spine Bifida (Fig. 2). When this malformation involves the spinal cord is considered to be severe and may interfere with the normal function of the nerves located below the place where the abnormality occurs (Seeley, et al., 2006).

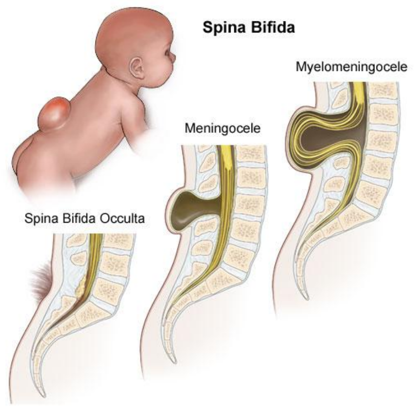

Fig. 2 - Different levels of Spina Bifida (14Nov)

This disease is the most common of all diseases involving the neural tube defects (National Spinal Cord Injury Association, 2011). It is estimated that worldwide for every 2,500 births there is one case of spina bifida. The prevalence is dependent on geographic regions and ethnic groups (Genetics Home Reference, 2014). In 2002 a study was conducted in 10 regions of the United States to ascertain the prevalence of cases of Spine Bifida in children and adolescents of 0-19 years of age. This study showed that the results prevalence of the disease is of 3.1 cases per 10 000 inhabitants(Shin, et al.., 2010). In Portugal, until the given time, there are no epidemiological data for our population.

These malformations can be simple situations where there are no clinical manifestations, which include the absence or bifurcation of one or two apophyses spinous, to more serious situations, where upon the location, can cause paralysis of the limbs, intestines or bladder (Seeley, et al., 2006).

Therefore, there are different types of spina bifida, the most simple situation is referenced as occult spina bifida and the most severe as myelomeningocele. The latter type is when there is exposure of spinal cord at birth, due to incomplete closure of the spinal column. In this case, given the high susceptibility to contract an infection it is necessary to proceed to the closure of the spinal column and recreate the shape of the spinal cord as well as the adjacent tissue, as soon as possible after birth (Neurological Surgery, 2014).

Different nerves correspond to different nerve roots whose function affects certain muscles, so depending of the level of malformation, the degree of paralysis varies. For example, if the injury occurs at the lumbar level only the lower limbs are affected, however, if the thoracic level is also involved the chest muscles, abdomen and part of the upper limbs can be affected. For this reason, there are many individuals who are capable of walking, although this this hability is usually affected (Whittle, 2007).

Thus, it becomes important the monitoring of the patient by a multidisciplinary team, to provide the best treatment and thus increase the quality of life of patients (National Spinal Cord Injury Association, 2011).

Usually this malformation occurs in the lumbar area (Seeley, et al. 2006) and the most common consequences are muscular deficits and bone deformities, which cause stabilization problems in adjacent joints, muscle weakness and decreased postural control, triggering a pathological march, which differs with the affected muscles. It is therefore essential to use orthotics to address these problems, reduce energy costs and prevent its development (Pattar, et al., 2012).

2.4. ORTHOSES

Defined by orthoses to an external device applied to a body part that has as main objective functional improvement in that segment. Can therefore be used in both small segments (finger) as in large (trunk); Also common is the use of orthoses that operate in more than one segment, as occurs with AFOs (Carvalho, 2006).

These devices when used by individuals with neuromusculoskeletal impairments (temporary or permanent) contribute to a more secure, fast and effective recovery, thus presenting a major role in rehabilitation. For this reason it can be used as an additional method of treatment (Bruckner & Edelstein, 2006). However, a suitable prescription is needed for the orthoses effective contribution. This prescription implies a customization of the orthosis by identifying which or which segments should be involved, the topology for the most suitable orthosis, selecting the best material for each situation, and the biomechanical and psychosocial characteristics. Given the complexity of this process, because in patients with multiple needs is sometimes inevitable prioritization, it is essential that the selection, implementation and adaptation of orthosis is performed by a multidisciplinary team. So the challenge is to select the appropriate equipment through the various solutions presented. (Edelstein & Bruckner, 2006).

The method of classification of orthoses can be made as to its functionality, the segments and include materials used. Thus, for functionality we have static / passive and dynamic / functional, and the latter can be further divided into reactive or active. The former provides support, immobilization, correction, protection, stabilization and rest of one or more body segments. While the latter are shown to help limit or direct certain movements and range of motion, so if we are speaking of reactive its activity is mechanical, and are manufactured with flexible material and joints, in the case of the active they are motorized, ie, have mechanisms for external power production such as hydraulic, pneumatic or electromechanical motors (Fernandes, et al., 2007). Briefly, in the first category we have rest orthoses, precluding a segment of unwanted conduct joint movements; and detention, which do not allow any type of joint motion. The second category consists in proprioceptive flexible orthoses and allows joint movements so as to maintain or correct postural alignment; and correction Orthoses which aims to reverse structured deviations. There is also the protection Orthoses which can be either passive as functional as it aim is to limit unwanted movements (Carvalho, 2006).

2.4.1. AFO Models

The foot and ankle orthosis are used to maintain the tibiotarsal and subtalar joints in functional position and thereby keep the adjacent joints in functional position, since it is common to have muscle, bone and / or joint compensation. Since the beginning of human movement analyzes, there are studies aiming to verify the ability to march, static and dynamic balance with and without orthoses (Carvalho, 2006). Depending on functional characteristics, there are several types of AFOs, being the most widely used models listed below:

• The submaleoloares (Fig. 3a) That promote medial-lateral stability of the retro and medial-foot (ex .: pronated feet);

• The supramaleolares (Fig. 3b), stabilize the movements in the frontal plane, ie, inversion and eversion;

• Thermoplastic dynamic AFOs (Fig. 3c), the upper limit of the posterior contour of the malleoli, that is, the configuration of the orthosis on the rear face of the legits a stem with small width, and this topology allows the rod to be slightly dynamic during phases of gait. It is possible to perform a slight plantarflexion when transfering the weight to the support leg during the response to load, then, during the support phase, as the leg moves beyond the foot the rod permits a slight dorsiflexion. The plantar part of the orthosis must present the effect of a spring, so it should not be thick, so as to avoid the drag of the fingers in the final phase of support and oscillatory phase. This orthosis however does not prevent rotational movement;

• Semi-rigid thermoplastic AFOs (Fig. 3d), as they have contours at the level of the malleoli, it is possible to perform some degree of passive dorsiflexion but limits the total plantar flexion and keep ankle joint and the knee neutral and is therefore ideal for cases of high rotational deviations;

• Thermoplastic articulated AFOs (Fig. 3e), these orthoses can allow free movement in the dorsal and plantar flexion or one of the two can be controlled. This control can be provided upon the type of joint used either putting a later stop (prevents plantar flexion) or earlier to avoid dorsiflexion. The joints must be aligned with the malleolus and the frontal plan so that during weight transfer there is no unwanted movement. The major disadvantages of the use of joints is that the movement of the ankle in certain patients can cause or increase the clonus, the AFOs become heavier, less durable and more difficult to put the shoe;

• Rigid thermoplastic AFOs (Fig. 3f) present their anterior contours to the malleolus, preventing the movement of the ankle and the back-foot, while maintaining forefoot flexibility to ensure natural gait. Doesn’t allow ankle plantar flexion and inversion of the foot and protects against sudden dorsiflexion, otherwise it could trigger clonus. That is, during the response to load phase, the foot usually suffers a plantar flexion to allow all the foot to contact the ground without the knee flex, however, this orthosis maintains a rigid alignment of the foot and ankle and is therefore there is not a gradual full support. From the phase of full support tor the pre-swing, as the body weight forwards the foot, as the AFO restricts the dorsiflexion movement, the knee and the quadriceps are supporting the whole flexor strain. The proximal portion of the stem also offers resistance to knee hyperextension. This orthosis is indicated in cases of established deformities, however, given the characteristics and functions indicated there should be a careful assessment of the benefits and contraindications;

• The AFO for reducing tone (Fig. 3g) show in their base a posterior support for the metatarsal heads (metatarsal pad) to assist the extension of the fingers, static immobilization in retro-foot design with full contact and involvement in the dorsal mid zone of the foot to stimulate the dorsal flexor muscles (during the boost phase and swing). These orthoses are effective in patients who present neurological lesions with hypertonia;

• The ground reaction (Fig. 3h) are prescribed in cases of excessive knee flexion, ankle dorsiflexion, calcaneal valgus and flat foot. Its setting has a previous support that produces a posteriorly directed force that stabilizes the knee at the beginning of the stance phase, preventing the vector of the ground reaction force passes well after the knee joint. During the stance phase, the support of the previous orthoses to stabilize the knee continues, while the side rods provide the medial-lateral and rotational control of the leg and ankle. This configuration despite controlling the knee during the final phase of support and during oscillation, allows flexion;

• The AFO for adduct metatarsal (Fig. 3i) have the medial side the boundary wall of this higher to keep the foot in a neutral position;

• The metal AFO (Fig. 3j) is usually prescribed for patients with a high body weight or who have intolerance to contact with polymers;

• The dynamic movement orthosis (BMD Medical ® - Fig. 3k) which are dynamic with a combination of lycra that assist in neurological rehabilitation of cases and musculoskeletal conditions and posture orthoses, since they provide an increase in sensory perception, an improvement in gait patterns, pain relief, increased range of motion and dorsiflexion;

•The spiral (Fig. 3l) consists in an insole and a narrow strip that is shaped proximally forming a spiral of 360 degrees. This spiral starts at the medial surface of the insole contours the leg and ends near the medial tibial condyle. During the initial period of the stance phase, as the member receives load, the orthosis allows a discreet ankle plantar flexion. From the pre-acceleration, the support member stops receiving the ankle loading and returns to its neutral position, allowing the spiral to return to its original shape to support the forefoot, thus avoiding drag of the fingers. These lightweight, aerodynamic, and without closures AFOs, makes it simple to place. Are indicated for cases of valgus the tibio-tarsal and may also be present in semi- spiral, and in this case is indicated in cases of varus, however, both types are contraindicated in severe spasticity conditions and in the presence of Significant edema, since its configuration must be perfectly adjusted to the user;

Therefore, it is possible to verify that AFOs manufactured with the same plastic and equal thickness, it is possible to obtain different features and rigidities through the cutting line drawn. Since the cut lines passing anterior to the malleolus AFO provide greater rigidity than in the case of the cut lines posterior to the malleolus.

Fig. 3 - AFO (a) submalleolar, (b) supramalleolar, (c) dynamic thermoplastic (OttoBock), (d) thermoplastic semi-rigid, (e) hinged (Costa), (f) thermoplastic rigid, (g) to reduce tone, (h) ground reaction, (i) for metatarsus adductus, (j) steel (14No), (k) dynamic movement orthosis and (l) spiral (14No1)

2.4.2. Materials

The orthoses may be made of one material or may be composed of various materials depending on the strength and configuration that is intended to give the orthoses. The elasticity, yield strength, weight and the manufacturing process are some of the materials have characteristics which inevitably affect the IRAM durability, aesthetic acceptance by the customer and the cost. Therefore, the properties of each material should be considered when prescribing or confection of orthoses upon the type of user (e.g. whether it is an AFO with further support for a 5 year old or an adult 30 years both active).

For the manufacture of orthotics is crucial to know whether that safely supports the load that will be subject, ie if exists and what is the likelihood of this break. In engineering, the development of a project this factor is found by knowing the resultant force to the machine or structure shall be subject to its total area and the material that will be built.

Is referred to as the tension(σ) the force per unit area, or intensity of distributed forces on a certain section, then we have an expression of the tension in a given cross-section area(A) and subjected to an axial load(P) is:

$$\sigma = \frac{P}{A} \tag{1}$$

The tension can be compressive, tensile or shear, the first case in situations where the force is pressing the material and is expressed with a negative sign; in the second case when there's elongation of a material, which in this case expressed with a positive sign; and the third consists of a sliding force in the horizontal plane of the material over another, however, this will not be developed here.

As the allowable stress(σ_{adm}) of a material is the maximum rated tension this material endures without breaking, this value must be higher than the stress value supported.

The deformation consists in changing the shape of a material by applying a stress. The amount of stress required to deform the material it's designated as stiffness. This property is very important when choosing the material to manufacture the orthoses, since orthoses as shown in Fig. 1c, the deformity is use as part of the design of the AFO, since in response to ground reaction forces, the rear blade of the orthoses curves and returns to the initial position when the force ceases, thus acting mechanically aiding the dorsal flexion without the need for mechanical joints. This issue will be addressed in detail in chapter IV.

Therefore, it is so important to know the allowable stress of the material used, as whether the deformations produced by the load are acceptable.

Materials can fail for different reasons: excessive torsion; constant and prolonged stretching; in case of brittle materials simply applying a small force can break them; the temperature can make a material more brittle (as in the case of metals).

The ability of a material to withstand continuous use is called fatigue resistance. For example, an active child who uses orthotics with metal joints is common for the orthoses to present problems and need frequent repairs.

In addition to these there are other properties, also essential to know and understand for a conscious choice of the most suitable material, such as elasticity, which is the ability of a material to recover its original form after being applied to it a tension; plasticity, which corresponds to a material change its form without breaking, as is notorious in polyethylene insoles that change their shape when subjected to compression; corrosion resistance is when a material is in contact with certain chemical agents and is has propensity to corrosion, such as occurs in metal or fabric orthoses that may be in contact with urine; among other properties.

We conclude that since each user is different, the orthoses their bear support different loads, so it would then be essential before producing them, to make a detailed study of the selection of the material indicated to perform the function for which it was prescribed.

There is a wide variety of materials, but as already mentioned, the most widely used are plastics, and plastics are in numerous, but the most frequently used in orthopaedics are composed of complex chemical units, polymers. This group of plastic becomes the first choice of most Orthotics/Prosthetics Technicians given they are relatively lightweight, easily molded with considerable resistance, easy cleaning, corrosion resistance and are available in several colours.

CHAPTER III

3. HUMAN GAIT

The biomechanics of movement could be used in different areas of knowledge. It has been observed over time and with the technological developments, that for professionals in engineering, medicine, biomechanics and orthotics/prosthetics technicians, analysis of human movement has become crucial since it provides detailed quantitative data.

Given the complexity of human locomotion it is essential to standardize the language used between the teams of different areas to describe what is observed in the analysis of human movement (Ed Ayyappa, 1997).

The analysis of human motion is accomplished through complex theoretical and computational methodologies that provide detailed information of the kinematics and dynamics of human movement.

The main objective of this type of analysis is the calculation of quantitative biomechanical data, such as the time-distance parameters (stride length and stride, cadence); positions, velocities and accelerations; forces (internal, external); moments of force (joint); power and energy. These parameters can be correlated in various ways, in order to fundamentally understand abnormal gait, as occurs in pathological gait. However, it should be noted that during the gait all body segments are coordinated (that is, when the foot reaches the ground, the soleus acts directly on the foot and shin, and in the thigh and trunk indirectly, to maintain balance during movement) causing difficulty in establishing the relationship between the variables measured at the output and those measured in the input (Zajac, et al., 2002) .

Saunders et al. (1953), Perry (1992) and Sutherland (1997), were some of the names that have contributed to a better understanding of normal and pathological human gait through several studies covering the identification of phases, sub-phases and events that occur in a gait cycle; determinants that enable a qualitative analysis of gait; as well as studies of kinematic and dynamic analyzes.

3.1. NORMAL GAIT CYCLE

The time period between two identical events on a walking moment, is designated by gait cycle. As described before, the gait cycle was studied by various researchers, and there is a consensus that there are two phases in this cycle: the stance phase corresponding to the time when the member is in contact with the ground; and the swing phase which is when the same member is not in contact with the ground. At each stage various events occur, however, there are differing opinions regarding nomenclature and number of sub-phases. This thesis will consider the sub-phases described by Perry Whittle in 1992 and in 2001, for considering it the classification system that best defines normal and pathological gait (Fig. 4) (Baptista, 2011).

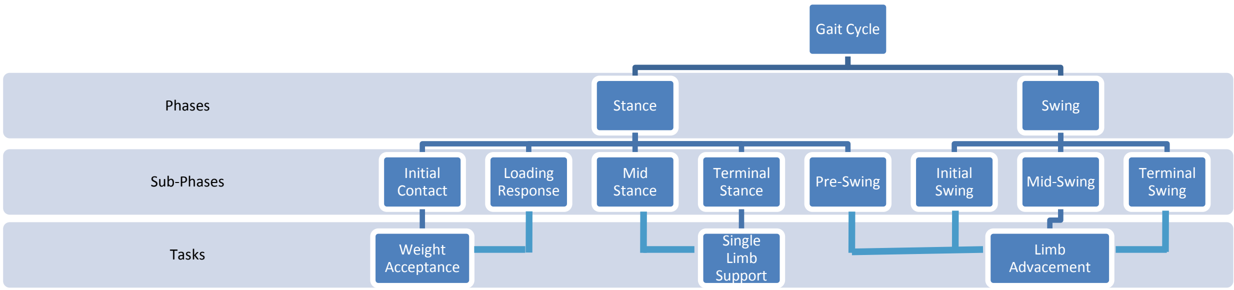

Fig. 4 - Classification of gait analysis by Perry Whittle (1992 and 2011)

The events defined for a normal gait cycle are generically presented below. We will assume that the first foot to get in contact with the ground is the right one:

• The first contact of the foot (right) with the ground is done with the heel through the action of the ankle dorsiflexor muscles that control the plantarflexion of the foot; After the initial contact the tibia and fibula first transfer the weight to the talus and calcaneus, then the soleus muscle controls the advancement of the tibia in relation to the foot dorsiflexion that decreases during this period;

• The load is distributed laterally along the arcs of the foot to the metatarsal heads, while the contralateral limb plantar flexors (left) raise the heel, and provide power to move the member;

• The right heel rises, and the weight is transferred to the medial side, why the hallux is the last segment of that same foot to stop touching the ground;

• The member is now performing the swing motion after the hallux leaves the contact with the ground;

• Finally the oscillatory motion ends when the ipsislateral heel enters again in contact with the ground.

At the moment the heel rises, the foot of the contralateral limb contacts the ground and are triggered, that side, the same events mentioned above (Seeley, et al., 2006). It should be noted that in addition, the above referenced muscles of the hip extensors are very important in the initial contact and loading response, since they resist the flexion moment of the ground force reaction, and accelerate the trunk over the femur, while the hip abductor muscles, during loading response stabilize the pelvis. In late swing, to control knee extension and the pre-positioning for loading the leg, the knee flexors are active (Gutierrez, et al., 2003)

The gait is said to be normal when the movements of the segments involved in each event of the gait cycle are within the limits considered normal for individuals of the same sex and age (Whittle, 2007). When this is not the case, there is an excessive energy expenditure, Saunders et al. (1953) reported that during locomotion the centre of gravity moves in order to have the lowest energy expenditure and higher mechanical efficiency possible. So if any displacement of the center of mass in superior to the normal limits (or in cases that despite not exceeding these limits there is a sudden or irregular movement) there is an increase of the energy expenditure. This analysis is easy to be performed by checking the six major determinants of gait:

- 1st Pelvic Rotation (Fig. 5a) occurs anterior pelvic rotation in the horizontal plane (range of 4 ° to - 4 °). This rotation allows, without significantly altering the displacement of the COM, give longer distance.

- 2nd Pelvic Tilt (Fig. 5b) there is a 5º pelvic decay, in the swing member, decreasing the horizontal displacement of the COM.

- 3rd Knee Flexion at midstance (fig. 5c), it reduces the vertical displacement of the COM. The knee flexes about 15º through the quadriceps control (eccentric contraction), during mid-stance, remaining until the contralateral foot contact on the ground.

- 4th and 5th Foot, Ankle and Knee Motion (Fig. 5d and 5e), during the first part of the stance phase, occurs an eccentric control of the dorsiflexor muscles of the knee-ankle-foot chain, thus avoiding sudden changes of COM.

- 6th Lateral Pelvic Displacement (Fig. 5e) improves the position of the center of mass over the support limb. This defines the motion of the COM in the horizontal plan.

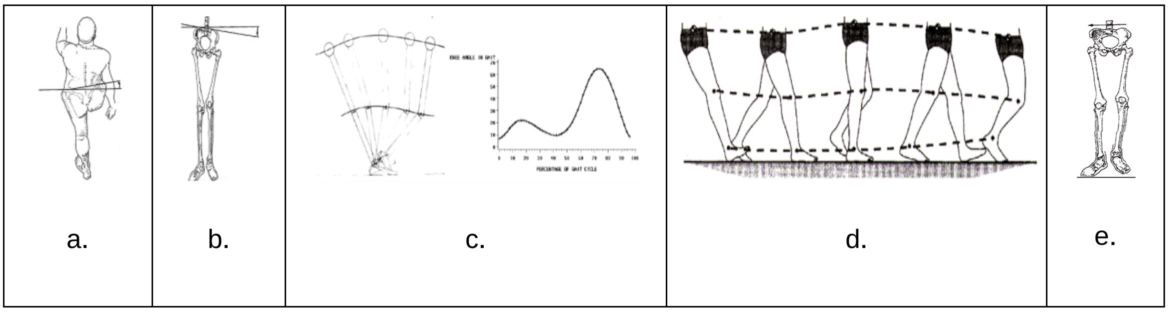

Fig. 5 - (a) pelvic rotation, (b) pelvic tilt, (c) knee flexion at midstance (Saunders et al., 1953), (d, e) foot, ankle and knee motion, (e) lateral pelvic displacement (Ed Ayyappa, 1997)

Gait analysis data provides an additional tool for the design of support solutions and is very important for support clinical evaluation too. It consists in basically three types of information: kinematics, kinetics and electromyography. The latter type is outside the scope of this work and it will not be addressed any further.

Kinematics Data and Kinematic Analysis

Kinematics is the study and determination of the trajectories of the system components (the positions as a function of time) and its associated differential properties (velocity and acceleration), taking into account the input provided by the system's drivers.

Therefore, the study of the motion of the system is referred to without considering the forces that gave rise to it (Zajac, et al., 2003).

The kinematic analysis aims to identify and describe the following data for each of the segments and the whole body mass:

1. Joint Motion

2. Linear and angular displacements

3. Linear and angular velocities and accelerations.

These data can be measured through direct techniques using instruments such as accelerometers and goniometers or by imaging techniques. This technique came up with the technological development of recent decades, which is to use reflector markers placed on body segments and video cameras that allow one to capture the movement and record it in 3D. To carry out this recording there is the need to use multiple cameras to more effectively capture the displacement of each reflector marker. This capture of the marker position is performed in 2D by each camera and later through an algorithm is estimated the respective positioning in 3D. After obtaining this result the calculation of the joints angle and velocites recorded during the movement, is possible. (O'Malley, 1993, Whittle, 1996)

3.2. KINETIC DATA AND DYNAMIC ANALYSIS

Due the dependence of kinematics and muscle activity on the kinetic parameters, Raja et al. (2012) claims to be crucial information about these last parameters for a better understanding of the changes in gait patterns.

Dynamic analysis, is the study of motion in the multibody system taking into account the external forces (eg, joint moments, powers, and ground reaction forces - GRFs) acting on this and its inertial characteristics (mass, inertia and COM position). Some of these external forces need to be acquired experimental (the kinetic data) others are calculated from the solution of the equations of motion of the system.

There are two types of dynamic problems, the most common being the inverse dynamics or forward dynamic. It should be noted that for the inverse problem, it is first necessary to obtain the problem data kinematic (velocity and acceleration of body segments) and of the ground reaction forces (GRF). The inverse problem consists in determining the dynamic moments and powers, which produce a specific motion as well as the reactions that occur in each of the joints. The forward dynamic analysis, through implementation of the applied forces and the initial conditions given, simulates the motion of the multibody system during a given time interval (Jalon).

3.3. BIOMECHANICAL MODELS - MULTIBODY

To solve these problems of inverse/ forward dynamics, it is essential to have a biomechanical model, which is a mathematical approximation of the real biological system by means of anthropometric parameters, external data (such as forces) and the equations of motion of the system. These models can be in the form of whole body or only a few body segments, and consist of a kinematic structure that includes the definition of the rigid anatomical segments; of joints and degrees of freedom; the system topology; and anthropometry, through the length of the body segments. They have as well mass and inertia characteristics of each body segment, the location of the center of mass of each segment; as well as the joint and muscle resistance characteristics data (origin insertion path points, maximum length, isometric force among others).

Briefly, to simulate the kinematic and dynamic environment of the system we use the multibody system approach, which consists of two or more rigid bodies interconnected by kinematic joints that allow their movement and that are acted upon by external forces. The configuration of the kinematic joint allows a certain number of degrees of freedom, and the number influences the type of movement performed, that is, the kinematic joints introduce restrictions on the relative movement between the rigid bodies.

3.3.1. *Fully Cartesian Coordinates*

For modeling the motion of a system in three dimensional space, it is first necessary to determine the most suitable type of coordinates, since different types can be used to model multibody system. In this work fully cartesian coordinates were selected and they will be briefly described therafterafter.

Fully cartesian coordinates are described by a set of points located on the extremities or at the joints of the model, and by unit vectors that define the axis rotation of the joints, which are presented in the form of a column vector $\boldsymbol{q}$.

$$\boldsymbol{q} = \{\mathrm{x_{P1}}\ \mathrm{y_{P1}} \mathrm{z_{P1}} \dots\ \mathrm{x_{Pn}}\ \mathrm{y_{Pn}} \mathrm{z_{Pn}}\ \ \mathrm{x_{V1}}\ \mathrm{y_{V1}} \mathrm{z_{V1}}\ \dots\ \mathrm{x_{Vm}}\ \mathrm{y_{Vm}} \mathrm{z_{Vm}}\}^{\mathrm{T}} \tag{2}$$

Where *P* stands for points, *V* for vectors, *n* and *m* are respectively the number of points and vectors used to model the system.

Therefore, for a generic system, the vector $\boldsymbol{q}$, a vector consisting of generalized coordinates is used. The total number of coordinates corresponds to the number of entries of the vector and is given by $nc = 3(n + m)$.

To describe a body in space is required at least 6 generalized coordinates, which correspond to three position coordinates and three orientation coordinates relative to a fixed frame. The coordinates can be independent or dependent. The independent coordinates, in number, are defined by the number of degrees of freedom of the system. One have dependent coordinates when their number is higher than the degrees-of-freedom of the system and in the circumstance the system has associated constraints, i.e. the system has several interconnected bodies, whose coordinates are related by algebraic constraint equations that are generally non-linear. Kinematic constraints are described by the following column vector:

$$\mathbf{\Phi}(\mathbf{q},\mathrm{t}) = \begin{cases} \Phi^{RBC}(\boldsymbol{q}) \\ \Phi^{JC}(\boldsymbol{q}) \\ \Phi^{DC}(\boldsymbol{q},t) \end{cases} = \mathbf{0} \tag{3}$$

in which Φ_i represents the i^{th} kinematic constraint equation, *RBCs* the rigid body characteristics, *JCs* the joint kinematics and *DCs* the kinematic drivers of the system.

A rigid body without restrictions in space has 6 degrees of freedom (three translational and three rotational), however, each joint decreases the system DOF as it introduces algebraic constraint equations that are used to restraint the relative body motion. The number of degrees of freedom of the mechanical system is therefore equal to the total number of generalized coordinates used to describe the system minus the number of constraints introduced by kinematic joints.

3.3.2. Kinematic Analysis

As previously mentioned, this analysis is the study of motion without regarding to the forces that originate it, with the result being the kinematics of the system.

Sometimes called initial position problem because it corresponds to the determination of all the bodies that make up the system position, taking into account the input provided by the driving constraints. Mathematically, it's the determination of the generalized coordinates corresponding to the elements of the generalized vector of dependent coordinates that $\boldsymbol{q}$ satisfy the set of kinematic constraint equations at the system for each time step of the analysis:

$$\mathbf{\Phi}(\boldsymbol{q},t) = \mathbf{0} \tag{4}$$

For solving the equation (1.3) one uses the Newton-Raphson Method (MRN) that has a quadratic convergence near the solution and it is based on linearisation of the system, for each time t, for the first two terms of its Taylor series, evaluated at the initial guess vector $\boldsymbol{q}_i$:

$$\mathbf{\Phi}(\boldsymbol{q},t) \cong \mathbf{\Phi}(\boldsymbol{q}_i) + \mathbf{\Phi}_{\mathbf{q}}(\boldsymbol{q}_i)(\boldsymbol{q}-\boldsymbol{q}_i) = \mathbf{0} \tag{5}$$

The Jacobian matrix of constrains $\mathbf{\Phi}_{\mathbf{q}}(\boldsymbol{q}_i)$expressed in (6), evaluates the solution the partial derivatives of each kinematic constraints in relation to the vector of generalized coordinates.

$$\mathbf{\Phi}_{\boldsymbol{q}}(\boldsymbol{q}_i) = \begin{bmatrix} \frac{\partial\Phi_1}{\partial \mathrm{q}_{\mathrm{n}1}} & \cdots & \frac{\partial\Phi_1}{\partial \mathrm{q}_{\mathrm{nc}}} \\ \vdots & \ddots & \vdots \\ \frac{\partial\Phi_{\mathrm{nh}}}{\partial \mathrm{q}_{\mathrm{n}1}} & \cdots & \frac{\partial\Phi_{\mathrm{nh}}}{\partial \mathrm{q}_{\mathrm{nc}}} \end{bmatrix} \tag{6}$$

where nh is the number of constrained equations, and nc is the number of dependent coordinates.

The solution of equation (1.4) gives the vector $\boldsymbol{q}$ representing an approximation to the correct system position. Considering the next approach as $\boldsymbol{q}_{\boldsymbol{i}+\mathbf{1}}$ an iterative equation is formulated:

$$\mathbf{\Phi}(\boldsymbol{q}_i) + \mathbf{\Phi}_{\boldsymbol{q}}(\boldsymbol{q}_i)(\boldsymbol{q}_{\boldsymbol{i}+\mathbf{1}}-\boldsymbol{q}_i) = \mathbf{0} \tag{7}$$

To obtain the velocity of the system, it is only necessary to differentiate the kinematic constraint equation (1.4) with respect to time, yielding:

$$\mathbf{\Phi}(\boldsymbol{q},\dot{\boldsymbol{q}},\mathrm{t}) = \frac{\mathrm{d}\Phi(\boldsymbol{q},\mathrm{t})}{\mathrm{dt}} = \frac{\partial \boldsymbol{q}}{\partial \mathrm{t}}\frac{\partial \Phi(\boldsymbol{q},\mathrm{t})}{\partial \mathrm{t}} + \frac{\partial \Phi(\boldsymbol{q},\mathrm{t})}{\partial \boldsymbol{q}} = \mathbf{0} \quad (8)$$

where $-\frac{\partial \Phi(\boldsymbol{q},\mathrm{t})}{\partial \mathrm{t}}$ is the vector $v(t)$ with the partial of $\mathbf{\Phi}$ derivatives in respect to time, $\frac{\partial \Phi(\boldsymbol{q},\mathrm{t})}{\partial \boldsymbol{q}}$ is the Jacobian matrix and $\frac{\partial \boldsymbol{q}}{\partial \mathrm{t}}$ is the vector of generalized velocities $\dot{\boldsymbol{q}}$. Thus we have the velocity equation expressed by:

$$\boldsymbol{\Phi}_{\boldsymbol{q}}\dot{\boldsymbol{q}} = v(t) \quad (9)$$

From the differentiation of the constraint velocites equations (8), with respect to time, the vector of constraint accelerations is obtained as:

$$\ddot{\mathbf{\Phi}}(\boldsymbol{q},\dot{\boldsymbol{q}},\ddot{\boldsymbol{q}},t) = \frac{d\dot{\mathbf{\Phi}}(\boldsymbol{q},\dot{\boldsymbol{q}},t)}{dt} = \mathbf{\Phi}_{\boldsymbol{q}}\ddot{\boldsymbol{q}} + (\mathbf{\Phi}_{\boldsymbol{q}}\dot{\boldsymbol{q}})_{\boldsymbol{q}}\dot{\boldsymbol{q}} + \boldsymbol{v}_t = \mathbf{0} \quad (10)$$

Since the vector $\gamma(q,\dot{q},t)$ is defined as:

$$\boldsymbol{\gamma}(\boldsymbol{q},\dot{\boldsymbol{q}},t) = \boldsymbol{v}_t - (\mathbf{\Phi}_{\boldsymbol{q}}\dot{\boldsymbol{q}})_{\boldsymbol{q}}\dot{\boldsymbol{q}} \quad (11)$$

Then, the acceleration equation results in:

$$\boldsymbol{\phi}_{\boldsymbol{q}}\ddot{\boldsymbol{q}} = \boldsymbol{\gamma} \quad (12)$$

3.3.3. *Dynamic Analysis*

To solve the dynamic analysis problem it is essential to know the external forces and inertia of each rigid body comprising the multibody system.

There are several approaches to derive the equations of motion (EOM), such as the one that will be shown below - the principal of virtual power - in which at each instant, the sum of the virtual power produced by the external forces is equal to zero :

$$P^* = \sum_{i=1}^{nc} \boldsymbol{f}_i \dot{\boldsymbol{q}}_i^* \equiv \dot{\boldsymbol{q}}_i^{*T} \boldsymbol{f} = \mathbf{0} \quad (13)$$

where $\boldsymbol{f}$ is the vector of all the forces that produce virtual power, being expressed by:

$$\boldsymbol{f} = \boldsymbol{M}\ddot{\boldsymbol{q}} - \boldsymbol{g} \quad (14)$$

knowing that $\boldsymbol{M}$ is the global mass matrix, $\ddot{\boldsymbol{q}}$ is the vector of generalized accelerations, one have $\boldsymbol{M}\ddot{\boldsymbol{q}}$ representing the vector of inertial forces; $\boldsymbol{g}$ is the vector of generalized applied forces, including centrifugal forces and Coriolis forces, and other velocity-dependent inertial forces.

Since the internal forces are associated in action reaction pairs, they do not produce virtual power and therefore are not represented in equation (13), however, through the method of Lagranges multiplier it is possible to calculate them:

$$\boldsymbol{g}^{\Phi} = \mathbf{\Phi}_{\mathbf{q}}^{\mathrm{T}}\boldsymbol{\lambda} \quad (15)$$

where $\boldsymbol{g}^{\Phi}$ is the generalized forces vector containing the internal forces associated with the kinematic constraints, and $\boldsymbol{\lambda}$ is the column vector of Lagrange multipliers. Through these multipliers we obtain the magnitude of the internal constraint forces, while the lines of the Jacobian matrix gives us the direction of these forces. The equation of the virtual power is obtained from the combination of equations 13 to 15:

$$P^{*} = \dot{\boldsymbol{q}}^{*T}(\boldsymbol{M}\ddot{\boldsymbol{q}} - \boldsymbol{g} + \boldsymbol{\Phi}_{q}^{T}\boldsymbol{\lambda}) = \boldsymbol{0} \tag{16}$$

The complete equation of motion is shown bellow and is solved so as to obtain the unknows of the system:

$$\begin{cases} \boldsymbol{M}\ddot{\boldsymbol{q}} + \boldsymbol{\Phi}_{q}^{T}\boldsymbol{\lambda} = \boldsymbol{g} \\ \boldsymbol{\Phi}_{q}\ddot{\boldsymbol{q}} = \boldsymbol{\gamma} \end{cases} \tag{17}$$

This methodology assembles and solves the equations of motion (17) of the biomechanical system. Through the different ways of getting the solutions of (17) one will then have Inverse Dynamic Analysis (Analysis) or Forward Dynamic Analysis (Simulation).

The problem of inverse dynamic analysis, the one done on this paper, can then be used todetermine the external forces that produce the observed motion, and the results obtained are the external and internal forces previously unknown.

3.4. Pathological Gait in the Presence of Spina Bifida

The events that occur in the gait cycle of an individual with the Spina Bifina condition differ from those occurring in the normal cycle, and the causes to these differences come upon any of the body systems, most commonly the nervous, skeletal and muscular system (Whittle, 2007). It is preponderant to do this type of analysis to identify major differences between pathological and normal gait, so that later, in clinical terms it is possible to establish the best treatment for rehabilitation and thereby enhance the quality of life of the wearer (Vankoski, Sawark, Moore, & Dias, 1995). However, various pathological conditions can lead to the same abnormal gait patterns, since those patterns correspond to incorrect movements of body segments (Whittle, 2007). That said, a certain pathological gait can have one or more abnormal gait patterns. Whittle (2007) relates to the importance of distinguishing and understanding what causes an abnormal movement, since this may be caused by spasticity, muscle weakness, deformity or otherwise can be a compensatory motion. Whereas when there is a compensatory movement, it is important to identify the cause.

This work will focus only on abnormal movements and patterns of usual gait in individuals with spina bifida at the lumbosacral level.

Vankoski et al., in 1995, identified and described kinematic patterns in children with myelomeningocele, and concluded that children adopted compensatory gait patterns in order to bridge the muscle weakness that had, thus enabling some function and independence. One of the results that was observed with the common plantar flexors muscle weakness is the usual prescription of

AFOs, however, these orthoses restrict the advancement of the tibia in an increase in the anteversion of the pelvis and / or trunk (an anterior tilt of the pelvis and / or trunk). Besides this muscle group, the extensors and flexors of the thigh are the main generators of energy during walking, so a decrease in muscle strength of any of these muscles also originates compensatory pelvic moments.

Gutierrez et al., in 2003, published two articles that analyzed the same type of population group. Firstly, thus examined the movement of the CoM, since these data is important for evaluating the efficiency and gait symmetry and thus describe the pathological gait. Then thus analyzed the parameters of the body segments and the main characteristics of the kinematic compensation patterns resulting from the weakening of some muscle groups. In the same paper they also concluded that joint stabilization through orthoses can benefit patients, as these decreases the compensatory mechanisms which are sometimes harmful to other segments, muscles and joints of the body.

In 2005 the same group of researchers conducted a dynamic analysis in order to understand the compensatory mechanisms of children with the same condition, during gait. The power, work and moments at the joints of the knee and hip (in all planes), and ankle (in the sagital plane) were analyzed. Due to the restriction of motion of the ankle caused by the use of AFOs and the weakness of the plantar flexor muscles, the joint moment capacity is lost at the ankle, however, other joints, such as the hip are loaded in order to compensate this weakness (Gutierrez, Bartonek, Haglund-Akerlond, & Saraste, 2005).

3.5. Human Movement Aquisition and Data Treatment

For this work it was conducted a case study, of an subject with spina bifida condition, more precisely myelomeningocele, and several analyses were conducted. First a kinematic assessment was made based on the positioning of relevant bone structures and the angles produced by the major joints. Then, taking into account the results previously obtained a dynamic evaluation was performed throughout inverse dynamics analysis, to obtain the joint moments. It has also acquired the morphology of the foot-ankle segments, of the left and right side, by performing the traditional methodologies, which consisted of a negative cast with resins bandages.

3.5.1. *Kinematic Data Aquisition*

Bellow it will be referenced all the systems that were used synchronously, for this analysis and data acquisition in Lisbon Biomechanics Laboratory (LBL) at Instituto Superior Técnico. It were used fourteen infrared reflective (IR) cameras - Qualisys ProReflex MCU 1000 and two video cameras, with the sampling frequency of 100Hz and 25Hz cameras, respectively. For the acquisition of external forces there were used three AMTI-OR6-7 force platforms (508mm x 464mm), with sampling frequency of 1000Hz. The plantar pressures were acquired with pressure plataform footscan® 3D Gait (1m x 0.4mx 0.008m).

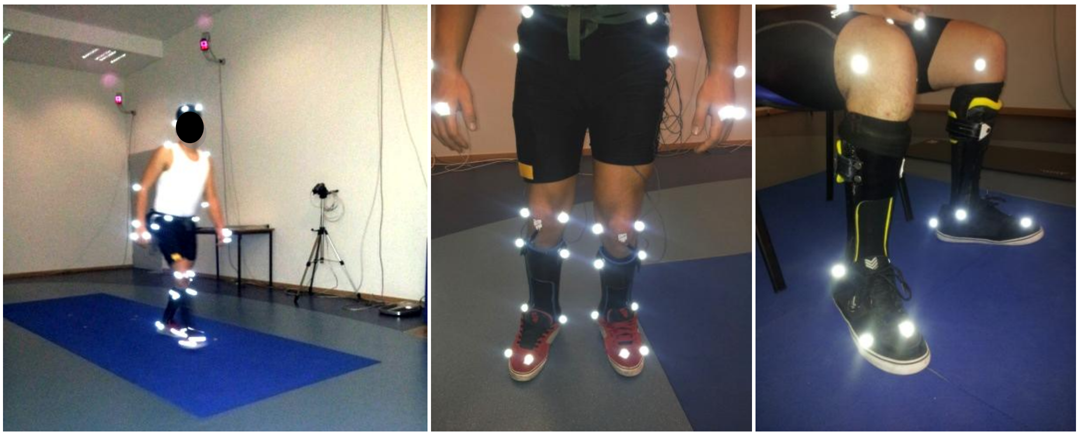

Fig. 6 - Data Aquisition in LBL

To obtain these data, the marker set protocol used was based on *Helen Hayes Marker Set* and on *Milwakee Foot Model*, and consists of 43 markers positioned in the major joints and bony prominences, 16 markers placed in a clusters on each leg and thigh (with 4 markers in each cluster) and 9 markers on each feet (see Appendix A). The markers used are spherical (with a flat base) and have 19mm and 12mm diameter respectively.

The *Qualisys Track Manager (QTM)* software was used for the acquisition and treatment of the markers trajectories. Having used the Automatic Identification of Markers (AIM) the trajectories were efficiently defined. Each acquisition was treated was divided by gait cycles, from first contact of the first foot platform forces to the next one from the same tools. Certain trajectories had gaps so interpolation was needed and also performed by the QTM software. Then, after this treatment of the data, they were exported to a *.tsv file, to be later analyzed directly by a routine developed in Matlab software (Gonçalves, 2009).

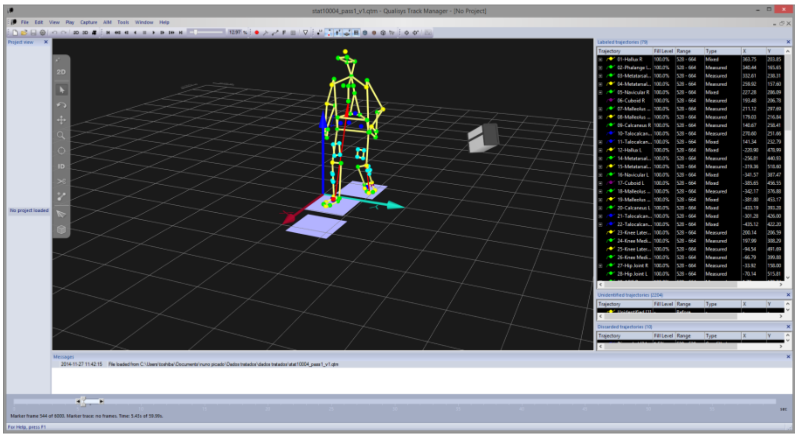

Fig. 7 - Data Treatment in QTM

Finally the *Apollo* software was used to obtain the values at the moment at the tibio-tarsal joint. This software carries out the inverse dynamics analysis of the multibody system using a who biomechanical model of the human body (Silva, 2003).

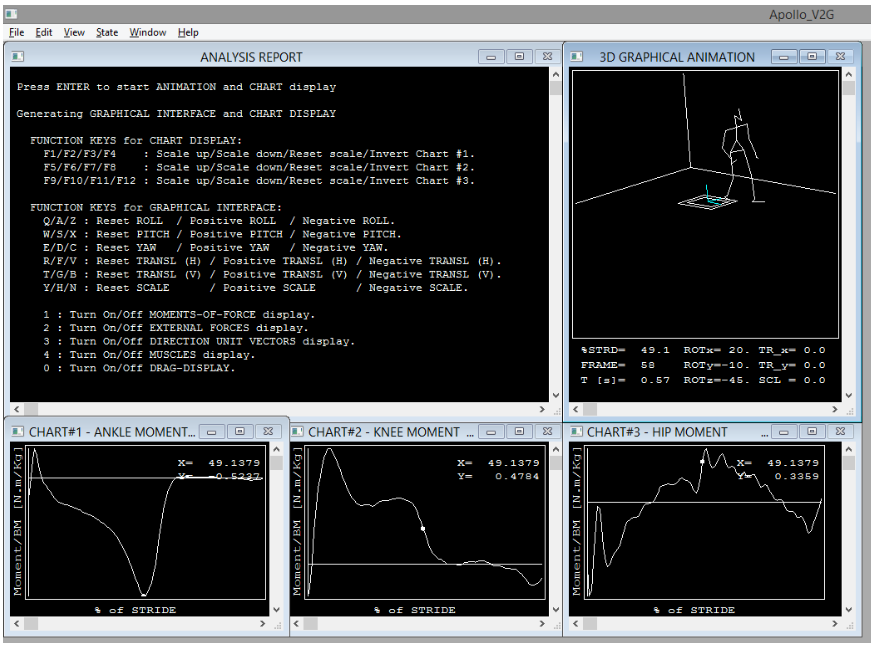

Fig. (8) - Moment acquisition in *Apollo*

CHAPTER IV

4. BIOMECANICAL PRINCIPLES AND STRUCTURAL MECHANICS

For the analysis and design of load-bearing structures, it is essential to understand the mechanics of materials. The two basic concepts inherent in this study are stress and the strain, which will be briefly presented below. However, beyond this it is important to review some basic concepts of biomechanics related to the use and comfort of orthoses.

Many are the components of machines and structures that are subjected to bending. Similarly, many anatomical structures are also subject to bending loads as well as it is possible to observe that all our body segments perform flexion movements. The lower limb, specifically the leg and the foot through the ankle joint performs the movements of dorsiflexion and plantar flexion. These movements are of utmost importance for efficient running, however, when they are done in an impaired gait or moment such as crouch gait, thus can cause high stresses in the involved joints or in other joints and body segments. Therefore, when we are dealing with an individual with a pathological gait which requires the use of the orthoses to compensate for the deviations performed, the type of the primary load that the AFO undergo is flexion. This type of orthoses suffer high wear due to the distribution of stresses and repetitive loads, so in some cases their life cycle is very short and there is a relatively early breakage.

4.1. PRESSION SYSTEMS OF AFOS

As already mentioned, the whole area of the orthosis in contact with the wearer generates forces that are applied in certain areas of the body segment. The amount of force and the contact area that the subject is submitted to has a direct influence on the comfort and effectiveness of the orthosis. Therefore, the comfort of the orthosis in the direction of use is closely related to the forces applied to a particular area of the body (Bruckneret et al., 2006), as can be demonstrated in the following expression:

$$\sigma = \frac{p}{A} \tag{18}$$

In that A corresponds to the orthoses contact area with the body segment and σ the applied contact force (Nm^2).

The therapeutic benefits underlying the application of these forces can be as resistance or assistance to certain movements, transfer of forces or the protection of certain body parts (Edelstein et al., 2006). So it is essential to control and adjust these forces (static and dynamic) that are applied in the segment so that they perform the desired function and at the same time to be comfortable, otherwise it is likely that the patient won't use it (Carvalho, 2006). As can be seen in the above expression, one way to ensure the comfort of the use of orthoses is to minimize the pressure felt by maximizing the body area involved by the orthoses. Another way to increase comfort is to provide a greater leverage, i.e., the greater the longitudinal length of the orthoses, lower is the pressure at each end of the segments to occur the same functional benefits (Bruckner & Edelstein, 2006).

A pressure system is a support system that involves the use a number of forces to balance an opposition force. The most widely used system is the force with 3 points of application, which consists of balancing a vector of a main force with a particular way and direction, with two opposing forces in the same direction but opposite way. There are also a four points forces system where is applied interchangeably two anterior and two posterior forces. The other system is when the orthosis is wrapped around the body segment, a circumferential pressure applies full contact, as DMO® for example (Fig. 3k) (Carvalho, 2006).

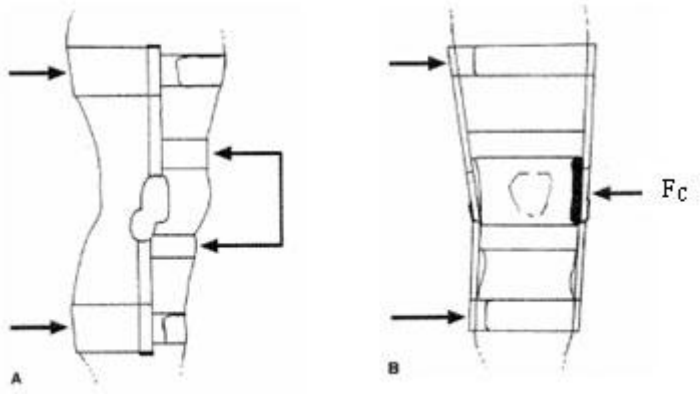

Fig. 8 - Force systems (a) four points and (b) three points (Lusardi, 2000)

Because the forces are parallel to each other, the closer they are to the joint center support, higher is the pressure generated, so using a larger lever arm, the distribution area is also increased which leads to increased comfort. In the case of forces not being parallel, however, it is necessary to satisfy the condition of the resultant force is zero, to obtain the desired result (Bruckner & Edelstein, 2006).

4.2. GROUND REACTION FORCE

Ground reaction force is the force exerted by the ground on the body in response to the force exerted by the subject in the ground. It is equal in amount and opposite in direction to the force applied by the patient. During motion, this force is the resultant of the vertical force, which represents the interaction between gravity and acceleration; the horizontal force, which is the tendency of the foot to slide forward; and rotational force, which prevents twisting motion of the leg. Upon heel contact, the ground force reaction usually goes behind the ankle causing plantar flexion produced by the moment. The ankle dorsiflexors have the function of controlling plantar flexion of the ankle in response to this external force.

All body parts are affected, in the three plans, by the location of the centre of mass and the vector of ground reaction. Therefore, when using an orthosis these aspects are essential in stabilization and assistance of joint motion, both in gait as in the static position. The reaction force to the ground is generally higher than the actual body weight and generates moments at the joints. Given this function, when there is realignment of that force due to the use of an orthosisthe value of these moments is considerably changed (Carvalho, 2006).

Since the external and internal forces acting on a given body part should be in equilibrium when there is a deficit in the internal forces (for muscle deficits, ligament injuries, among others) the orthoses must compensate in order to reach the lost equilibrium. That is, the joints develop axial loads, which are composed by the sum of body mass and gravity and opposite reaction force to the ground. When there are structural failures, such as a pathology fractures and cartilage degeneration, the forces which are transmitted to these structures can lead to pain and damage to the mobility. On these occasions, the orthoses may reduce these forces (Edelstein & Bruckner, 2006).

4.3. Stress and Strain in an Element Subjected to an Axial Load

Recalling equation (18) which indicates the normal stress on an element under axial load, one can only check whether a structure can safely support a certain load, knowing its internal force and cross-sectional area, as well as the material it was built with. The tensile stress is represented by the positive sign and the compressive stress by the negative sign.

The analysis of a structure should consist in determining the stresses applied, compare this tension with the allowable stress of the material and verify it the first are smaller than the last as well as that the strain produced by the load is acceptable is bellow a given limit.

The tension obtained from equation (18) is an average value, as the actual distribution of stresses in a certain section is statically indeterminate. It is therefore assumed that in the case of a bar submitted to an axial load that normal stresses are uniformly distributed, except in the region of the point of load application, and for this to occur the line of action of the load passes the centroid *C* of the section.

While one could construct a diagram that includes the strain of a material as it increases the applied load value, this way is not suitable for studying the deformation of a material, since it cannot be used to predict strain in the same material but with different dimensions.

However, as mentioned in the previous chapter, from the stress-strain diagram a characteristic curve of important properties of materials is obtained that does not depend on its rise or applied load.. For this, to occur tests were done to a tensile specimen, from which one get the tension values by expression (18), and the normal strain (ϵ) that is the deformation δ that occurs per unit of length(L), that is:

$$\epsilon = \frac{\delta}{L} \tag{19}$$

From the curve obtained we can divide the materials into two major groups: the ductile and fragile materials.

It is noted that a material has an elastic behavior in case when the load is removed and the strain totally disappears from the body, that is, the ability of a material to recover its original dimensions after a tension being applied to it.

The structures are designed to undergo relatively small strains, which in the case of ductile materials, involve only the linear part of the stress-strain curve. At this moment, we have for a given material, the coefficient(E) called modulus of elasticity or Young's modulus, which is proportional to ϵ, and therefore Hooke's Law applies:

$$\sigma = E\epsilon \tag{20}$$

We refer to the proportional limit, the highest amount of tension to which we can apply Hooke's Law, in which the ductile materials coincides with the yield stress value.

Hence one can say that a material has an elastic behavior for tension values below the yield stress value. In cases where a force is applied and the body undergoes permanent strain after the removal of that load, without the occurrence of breakage, it is said that a permanent or plastic deformation.

When we have a structure in which loads were applied repeatedly, after a cycle (for long times) rupture occurs at a much lower tension than the tensile rupture strength, this phenomenon we call fatigue. So the fatigue failure is one of the most common failures to occur in orthoses, given the continuous and systematic use that users give to it. Therefore, even orthoses made of ductile materials are fragile when this failure occurs. Given the danger that may arise from a failure of this type, this is one of the features that one has to take into consideration when designing an orthosis.

When one has a structure in which an axial force is applied on the centroid of the section and in which the obtained tension does not exceed the proportional limit, then one can apply Hooke's Law, replacing the tension by the expression (18):

$$\epsilon = \frac{P}{AE} \tag{21}$$

From expression 19 δ is obtained:

$$\delta = \frac{PL}{AE} \tag{22}$$

This expression can be used only to structures having uniform cross-section and the force applied at the end.

4.4. PURE BENDING

This section is based in Johnston (2005). The next elements studied are subjected to bending moments M and M 'equal and with opposite directions in the same longitudinal plane, i.e. elements that are in pure bending. Hence, if the structure under study is cuted at an arbitrary point it is require that the internal forces in the section are equivalent to the conjugate M.

When M is greater than zero then bending occurs, and the plane that contains that point sees its section changed, i.e., the lines that were flat become curved, while the axis sections to the axle remain unchanged. Because the initial arc length, now deformed, is equal to the initial length L of the undeformed beam (Fig.9) :

$$L = \rho\theta \tag{25}$$

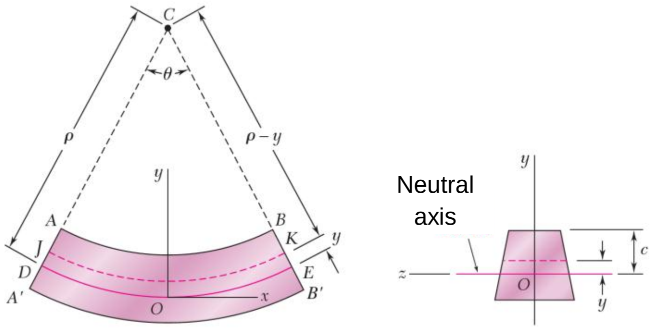

Fig. 9 - Prismatic member (a) plane of symmetry, vertical section, and (b) transverse section (Johnston, 2005)

Where ρ corresponds to the arc radius and θ to the angle. Considering now an arc located at a distance y above the neutral surface, it becomes:

$$L^{'} = (\rho - y)\theta \tag{26}$$

Thus, from the difference of the final length to the original arc length, one have the value of deformation:

$$\delta = -y\theta \tag{27}$$

Replacing the δ from previous equation in the expression 19 one get the longitudinal strain(ϵ_x):

$$\epsilon_x = -\frac{y}{\rho} \tag{28}$$

The negative sign of the above expression means that the bending moment is positive and so that the beam has an upward concavity. Still, from expression 28 is possible to see that ϵ_x varies linearly with the distance y relative to the neutral surface therefore ϵ_x reaches its maximum absolute value when y is in its maximum. Thus, calling c the further distance from the neutral surface, and ϵ_m the maximum absolute value of the deformation, one have:

$$\epsilon_m = \frac{c}{\rho} \tag{29}$$

Solving eq. 28 by replacing ρ one obtain:

$$\epsilon_x = -\frac{y}{c}\epsilon_m \tag{30}$$

As mentioned earlier, when we are dealing with deformities that occur in the elastic range, Hooke's Law is applied. Therefore, for a given material with a modulus of elasticity$E$, by solving the expression above by multiplying all the members for E, we have:

$$\sigma_x = -\frac{y}{c}\sigma_m \quad (31)$$

It follows that, in the elastic range, the normal stress varies linearly with distance from the neutral surface. However, the location of the neutral surface and the maximum stress is obtained from the equations that relate the static bending moment M with the axes of the planes that contain the axis and perpendicular to its plane, that result the section static equilibrium. Assuming that the bending moment occurs in the xy plane, then the plane containing the z axis is perpendicular to its plane, through the sums of the components and of the moments of the elementary forces, one can then write the equivalence of the elementary internal forces:

x component: $\int \sigma_x dA = 0$ (32)

Momentum around y axis: $\int z\sigma_x dA = 0$ (33)

Momentum around z axis: $\int -y\sigma_x dA = M$ (34)

therefore, substituting σ_x from the expression 32 for expression 31 it turns out that:

$$\int y dA = 0 \quad (35)$$

From the above expression, it is concluded that in the elastic range, the neutral line passes through the section centroid. Likewise, by solving the expression 34, one has:

$$\frac{\sigma_m}{c}\int y^2 dA = M \quad (36)$$

As in pure bending, the neutral axis passes through the centroid one notes that the integral term corresponds to the inertia I or second order moment, of the cross-section relative to the axis passing through the centroid and perpendicular to the plane of bending moment M. Hence:

$$\sigma_m = \frac{Mc}{I} \quad (37)$$

Thus replacing σ_m from the previous expression in 1:31, one has:

$$\sigma_x = -\frac{My}{I} \quad (38)$$

This way we can determine at any distance from neutral axis the normal tension. The two previously deduced formulas are called formulas of bending in the elastic range, and the normal stress by bending stress.

Yet, analyzing equation 37, it is found that the relation I/c, which is referred to as elastic section modulus (W) depends only on the geometry of the cross section:

$$W = \frac{I}{c} \quad (39)$$

So from the expression 37, and substituting for 39, one can write:

$$\sigma_m = \frac{M}{W} \quad (40)$$

This expression will be the one used in the designing process presented in the next chapter.

4.5. ANALISYS AND DESIGN OF BEAMS TO BENDING

Beams are defined as the structural elements that support forces applied at various points along its length and are usually present as straight and long prismatic elements. The structural study and development of an ankle-foot orthosis is based on the premise that its function and geometry can be approximated by a beam, i.e., the frame is located at the base of the foot and the straight beam is understanding bending loads along its entire lenght. Generally, these forces are applied perpendicular to the beam axis (transverse loads) thereby causing bending and shearing of the material. However, when these forces are not applied perpendicularly but with some angle relative to the axis of the structure, the axial forces may be produced. For the present work only bending forces one considered and axial and transversal forces are discarded

For the design of a structure, it is very important to determine the location and intensity of higher bending moment, as seen in the expression 40 the maximum value of normal stress is directly proportional to the bending moment.

It follows from the above analysis that in order to have a safe design is necessary that the maximum stress is less than or equal to the allowable stress of the material used. So we should replace x in the equation 40 for σ_{adm}. Designing the structure to the allowable tension, then the resistance of the module associated bending is the minimum acceptable.

When designing more than one solution, it proceeds to choose the most economic, so for a structure of the same type of material and characteristics, we select the one having less cross-sectional area, so being the one with the lower weight per unit length.

When we are dealing with the design of a beam there are four important considerations, it was also necessary to fulfil for success in achieving the desired result:

Determination of the yield strength of a material, i.e. how the selected material will behave in a particular type of load. Specific tests are performed on specimens, to check the behaviour of the material, as if there are changes in the length and diameter or what the maximum amount of power (we call load limit) until it breaks or support a lower load

The permissible load, the allowable stress and the safety factor. The maximum load that the orthoses support should be, in normal use conditions, considerably less than the value of the load limit. At this lower load is called the admissible load. So when the permissible load, only a fraction of the load capacity threshold is used, which ensures a safe performance is applied. One can then set the safety coefficient:

$$Safety\ coeficient = S.C. = \frac{limit\ load}{admissible\ load} \tag{41}$$

or having as a base the use of stress, we have:

$$S.C. = \frac{limit\ tension}{admissible\ tension} \tag{42}$$

or it's possible choose the factor of safety based on the yield strength (see Appendix B)

Having regard to the previous point, it is then necessary to select the appropriate safety coefficient. This choice is very important to ensure the safety of the equipment, since the case study of this work is an AFO to be used by subject, any failure to break in the orthoses, will jeopardize the physical integrity of the individual. Therefore, the selection may not be a very small safety factor, since the probability of failure may be large, however, if the choice falls in a very high coefficient, the solution obtained may not be functional. Thus to make the choice of an acceptable safety cofficient for the production of a AFO, one will be obliged to take into consideration the following aspects: the variations in composition, size and resistance, which can occur in the material during the thermoforming; material fatigue, i.e. the number of loads that can be expected during the life of the orthoses; the type of loads that will be applied to the AFO, for example if these are cyclic, impulsive or dynamic; what kind of failures may occur, if they are sudden or if there is a prior to failure state (as in the case of AFOs); and the deterioration that the material will suffer, either by natural factors such as lack of maintenance.

Determine the maximum absolute value of the bending moment of the beam, so this way to find the minimum permissible value of the bending moment of the beam. This value was obtained for the ankle joint from the inverse dynamics analysis performed in the previous chapter.

CHAPTER V

5. DESIGN METHODOLOGY USING A COMPUTATIONAL OPTIMIZATION

The development of the computational methodology was based in the first instance in the study and determination of the initial project data. These data corresponds to the characterization of the material used (Appendix F)

Choose the material to be used (polypropylene) and obtain its yield stress. This value was taken from the data sheet of the material provided by the supplier to which the material was purchased.

Determine the appropriate safety coefficient. In this case, given the specific nature and type of use to which the structure will be subjected, the coefficient is composed of two terms: a static term with the value of 2 and dynamic term with the value of 2 as well. In total we have:

$$S.C. = S.C._{static} \times S.C._{dynamic} = 2 \times 2 = 4. \qquad (43)$$

Through the values obtained in the previous points it is possible to calculate the allowable stress value. Hence:

$$\sigma_{adm} = \frac{30}{4} = 7{,}5\ (MPa) \qquad (44)$$

The height of the orthoses was defined on the individual's gait analysis, taking into account the distance from the ground to the head of the fibula and subtracting, approximately, 2 or 3 cm. Thus the initial height is considered to be $x = 0$ and the maximum height of orthoses, for this case, is given as $x = l = 39\text{cm}$.

A maximum bending moment of ankle joint was obtained from the inverse dynamic analysis of the individual and after the processing of data in Qualisys QTM software, Matlab and Apollo. The design methodology considers the orthosis as a cantilever beam with a force P applied at its tip. Accordingly, it is considered the evolution of the bending moment along the beam to be linear with its height, with the value 0 at the end $x = L$, and the maximum value at the fixed support for $x = 0$, as presented in fig 8. The value of the moment at each section along the length of the orthosis is given by:

$$M_x = M_{max} \frac{(L-x)}{L} \qquad (44)$$

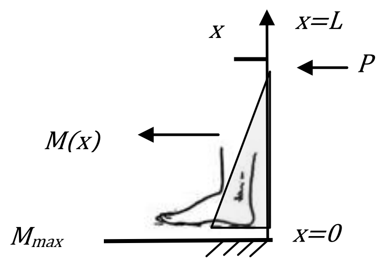

Fig. 10 - Evolution of bending moment along the linear beam

The initial geometry of the cross section of the orthosis is given as a parametric surface defined by 10 design variables, representing 4 lengths, 4 thicknesses and two radius (equation 46 and Fig. 9).

$$y_0 = [y_1\ y_2\ y_3\ y_4\ b_1\ b_2\ b_3\ b_4\ r_1\ r_3] \tag{45}$$

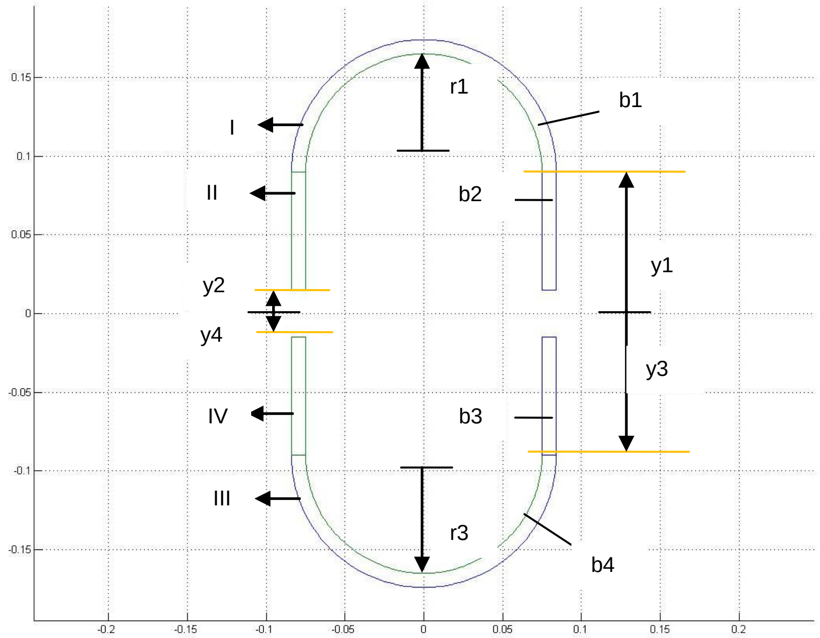

Fig. 11 - Initial geometry of the Cross Section

A negative cast to the wearer with resins bandages was taken, so that an evaluation could then be made of the upper and lower limits of the design variables (yu and yl), that must be taken into consideration when perform the design of the structure. In next figure it's possible to see, how it changing the variables it's possible obtain different solutions, as with or without anterior support.

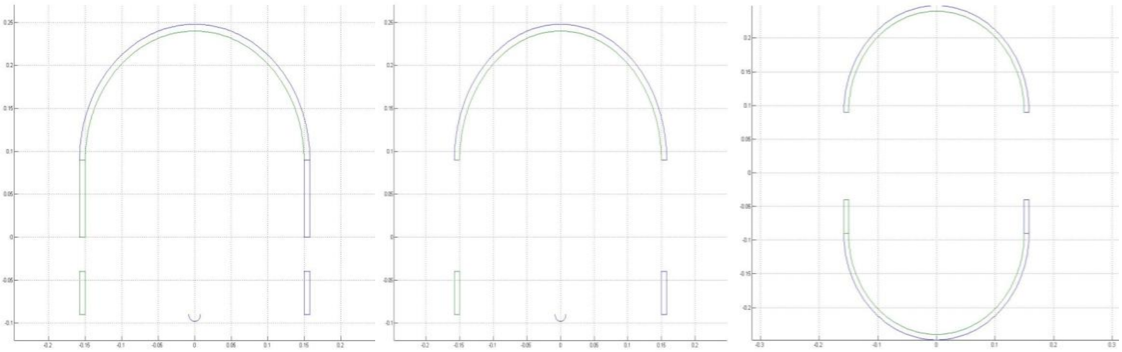

Fig. 12 - Cross section with changing different variables (a) y4, (b) y2 and y4, (c) y2, y4 and r3

With the project data obtained above one can provide the initial guess of the parameterized cross-section.

Since the ultimate goal of this computational approach is to determine the minimum area that each cross section needs to have to withstand the stresses to which the structure is submitted, an optimization function was used, i.e. a function that optimizes each section to ensure that the minimum area, is obtained in such a way that the elastic section modulus (W=I/Y) is able to withstand the loads exerted in the section.

In the present case, minimizing the area corresponds to minimizing the weight of the orthosis. Hence, the following constraint optimization problem is proposed:

for minimum A, s.t.:

$$\frac{M(x)}{W(x)} \leq \sigma_{adm}$$

and

$$y_i^{lower} \leq y_i \leq y_i^{upper} \tag{46}$$

where A is the total area of the parametric cross section and y_i^{lower} and y_i^{upper} are the lower and upper bound of the design variables, respectively.

This optimization type is called nonlinear constrained optimization. The correspondent function in Matlab is *fmincon* that attempts to find from an initial estimate, a minimum of a scalar function of several variables. Starts at x0 and tries to find the minimum for each x described in the function. To make it possible for the solution, we define a set of upper and lower limits on the design variables that are included as bound constraints to the optimizer as represented above.

So in order to proceed with the optimization of each section, the calculation of the section area and elastic section modulus is needed, assuring the structure endures the stress. To obtain this, it is necessary to perform some calculations that are shown below:

The total area of the section. As the total area accounts to 2 geometric figures (the semi-circle and the rectangle), the calculation of each area is carried out and then the total area is obtained So have:

$$A_{circle} = \pi r^2$$

$$r_{ext.} = r + b_1,$$

$$r_{ext.}^2 = (r + b_1)^2 = r^2 + b_1^2 + 2rb_1^2$$

$$A_1 = \frac{\pi}{2}(r_{ext.}^2 - r_{1int.}^2)$$

$$A_1 = \frac{\pi}{2}(2r_1 b_1 + b_1^2)$$

$$A_2 = 2\big(b_2(y_1 - y_2)\big) \tag{47}$$

The above calculations are corresponding to figures located in the positive part of the frame, while the following are for the negative.

$$A_3 = \frac{\pi}{2}(2r_3 b_3 + b_3^2)$$

$$A_4 = 2\big(b_4(y_3 - y_4)\big)$$

The total area of the parametric section is then given by:

$$A = A_1 + A_2 + A_3 + A_4 \tag{48}$$

Evaluate the geometric characteristics of the section. For that first purpose the total area is checked then the centroid of the parameterized section is calculated and the farthest point from the centroid is determined:[1]:

Yc – calculate the centroid of the parameterized section

$$Y_C = \frac{\sum_{i=1}^{n} A_i Y_i}{\sum_{i=1}^{n} A_i}$$

$$Y_{c1} = y_1 + \frac{4}{3\pi} \times \frac{3r_1^2 b_1 + 3r_1 b_1^2 + b_1^3}{2r_1 b_1 + b_1^2}$$

$$Y_{c2} = \frac{(y1+y2)}{2} \tag{49}$$

Analogously, as considered previously in the calculation of the total area, considering Y_{c3} e Y_{c4} negative, one have:

$$Y_{c3} = -\left(y_3 + \frac{4}{3\pi} \times \frac{3r_3^2 b_3 + 3r_3 b_3^2 + b_3^3}{2r_3 b_3 + b_3^2}\right)$$

[1] It´s possible see auxiliary calculus in Appendix C (page 60)

$$Y_{c4} = -\left(\frac{(y_3+y_4)}{2}\right) \quad (50)$$

Ymáx - determining the furthest point from the centroid

$$y_{max1} = y_1 + r_1 + b_1 - Y_c$$

$$y_{max2} = y_3 + r_3 + b_3 - Y_c \quad (51)$$

From the above results (eq. 51) the one that has the highest value is selected to be used to calculate the resistance module of the section.

Then proceed to the calculation of inertia of each part that makes up the section, so it is possible to calculate the elastic section modulus. The expressions for the calculation of each inertia are then given by[1]:

$$I_1 = i_1 + A_1 d_1^2 \quad (52)$$

the same way we obtain I_2, I_3 e I_4, , in wich:

$$i_1 = \frac{\pi}{8}(4r_1^3 b_1 + 6r_1^2 b_1^2 + 4r_1 b_1^3 + b_1^4)$$

$$i_2 = \frac{b_2(y_1 - y_2)^3}{6}$$

$$i_3 = \frac{\pi}{8}(4r_3^3 b_3 + 6r_3^2 b_3^2 + 4r_3 b_3^3 + b_3^4)$$

$$i = \frac{b_4(y_3 - y_4)^3}{6} \quad (53)$$

For the calculation the transport term given by the parallel axes theorem, the distance d_1 are calculated as follows:

$$d_1 = Y_{c1} - Y_c \quad (54)$$

Analogously we have d_2, d_3 e d_4.

It is therefore possible to calculate the total inertia I of the section:

$$I = I_1 + I_2 + I_3 + I_4 \quad (55)$$

At this moment it is now possible to calculate the elastic section modulus. However, if $y_{max} \cong 0$, then $W = 0$, otherwise

$$W = \frac{I}{|y_{max}|} \quad (56)$$

There are optimization some constrains associated with this design methodology, such as operating stress must be smaller or equal to the allowable stress, i.e.:

$$c_1 = \frac{C.S.\times M_x}{\sigma_{ced}\times W} \leq 0 \tag{57}$$

As well as the design variables,

$$y_1 \geq y_2 \tag{58}$$

$$y_3 \geq y_4 \tag{59}$$

And the equality constraint: $b_3 = b_1 \rightarrow Ce_1 = b_3 - b_1 = 0$ (60)

The structural design is therefore conditioned by the existing value of the bending moment at a given level x, the resistance to bending of the elastic section modulus and the characteristics of the material that comprises it:

$$\sigma_x = \frac{M_x\, Y}{I} = \frac{M(x)}{W(x)} \leq \sigma_{adm} = \frac{\sigma_{ced}}{C.S.} \tag{61}$$

All these optimization steps will be repeated from x=0 until$x = L$ (eq. 44). However, according to the initial approximation and boundary limits, the function at any given time may not find a solution, ie the function verifies that the design variables produce a section that does not provide the conditions necessary to withstand the efforts undergone and the optimization process is halted.

Chapter VI

6. Case Study

A gait analysis of an individual, we will call CS (case study) was performed. This analysis consisted of a kinematic analysis, an inverse dynamic analysis and functional assessment.

Through these analyzes was possible to obtain the value of the maximum bending moment and its location, the analysis of plantar pressure through the pressure platform and pedigraphies (fig. 27a), body weight, volumetric measures(fig. 10b), the length of both lower limbs and the negative mold of the foot-leg segments was taken.

Fig. 13 - Left side, sagittal plane (a) detailed pedigraphy and (b) measuring the volumetric leg and foot

The above data were essential to be able to proceed with the development of the project under study, both at the time of the optimization calculation by computational tool, as at the time of rectification of the positive mold and implementation of the orthoses.

During the gait analysis, it was found that the wearer had a gait of the type crouch gait, i.e., excessive dorsiflexion, knee flexion and flexion of the hip joint, resulting in pronation of the feet and pelvic anteversion.

Functionally, it was found that actively C.S. could not reduce the flexion of the knee and ankle, however, it was possible to passively reduce knee flexion side 87 on the left and 83 on the right side ankle and could reached the 90 if reduce pronation of the feet and the tibio-tarsal valgus manually (fig. 10).

Fig. 14 - Alignment of the feet frontal plane rear view

The feet were analyzed in detail in order to subsequently be able to carry out the alignments and corrections were allowed.

As regards the optimization provided by the software tool, this allows it to be dynamic, that is, allows the user limits the design variables, in order to create the solution or solutions seem to be the most suitable for the case . Therefore, the tool is divided by levels of transverse sections: plantar up to below the malleolus; distance from the distal end of the malleolus to the proximal portion; to the bulkier leg part (approximately half of the gastrocnemius); the last portion previously mentioned until 2 or 3 cm below the head of the fibula. This way, gives freedom to the tool to find the optimal solution of each level, with certain limits. For example, if we want only posterior support its necessary to limit to zero the rays relating to the anterior of the leg, since it is not necessary that area of the orthoses.

6.1. Results

The main results of this work are those obtained by the developed computational tool, however other results were obtained alongside, they fundamental to be able to achieve the ultimate goal of producing a functional prototype of an AFO. So at this point these results will also be presented: plantar pressures obtained in pedigraphy and pressure plate; positive cast of body segments, rectification of the positive cast in view of the performed analyzes; fabrication of the orthoses; implementation of cutting lines and respective cut through the solution obtained by computational methodology; and trial of orthoses to C. S.

The first results were obtained regarding the dynamic analysis performed for obtaining the maximum bending moment at the ankle. The analysis consisted of 10 trials viable, the natural cadence of the individual with its old orthoses that were broken in relative short time. It was possible to use them as C.S. got them arranged so as to be able to walk for a little while. This analysis was performed without orthoses. The maximum moment value was obtained without orthoses, having 118Nm (Fig. 11 and 12), a value used for all solutions which are presented below.

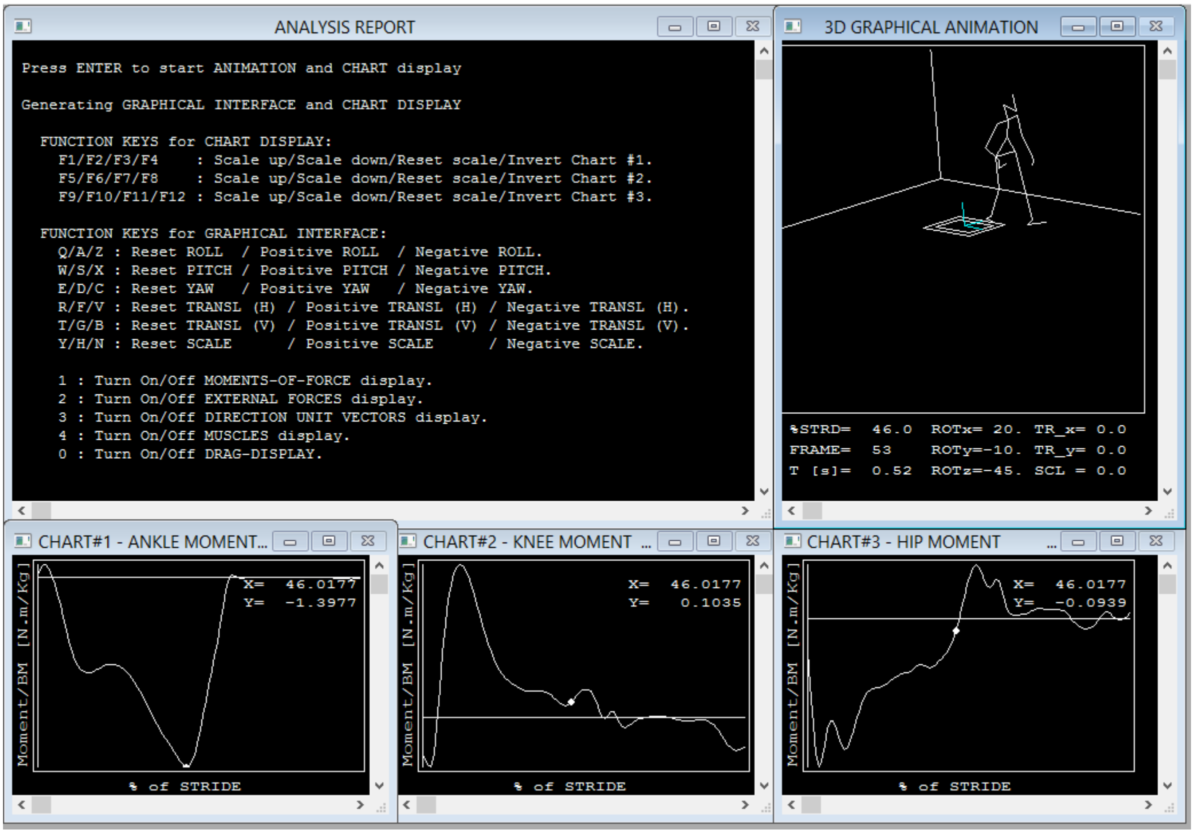

Fig. 15 - Moments of ankle, knee and hip obtained in Apollo software

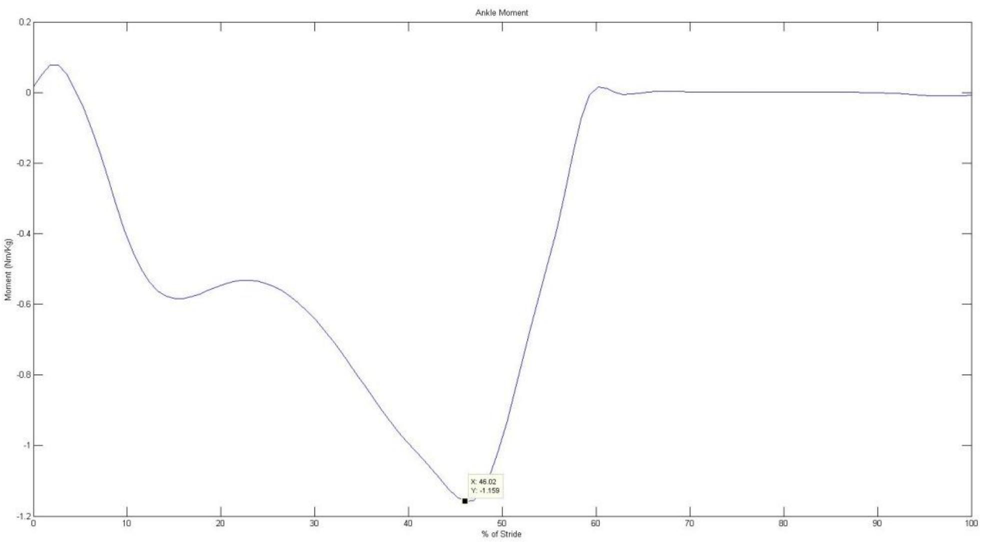

Fig. 16 - Moments of ankle obtained in Matlab software

Next are some of the results achievable for the production of orthoses, except the first result was one of the tests performed to the computational methodology to determine its viability. It is noted that for any of the solutions the initial design data has not been altered.

6.1.1. Trial Version

To obtain this result, the upper and lower limits were placed only for the variables that represent the material thickness of 1 mm and 4 mm respectively, since they are commonly used thicknesses. For the variables [y_1 y_2 b_1 b_2 r_1] were not imposed limits, thus allowing the computer tool to optimize the sections without any restriction, in positive part. The variables [y_3 y_4 b_3 b_4 r_3] were imposed values of 0.

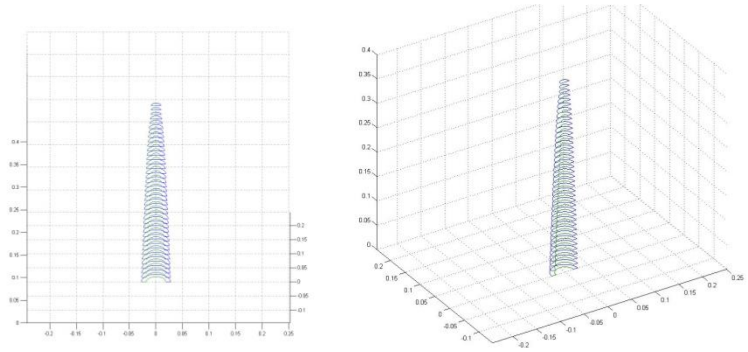

Fig. 17 - Cantilever beam (a) frontal plan anterior view and (b) in the three plans anterior view

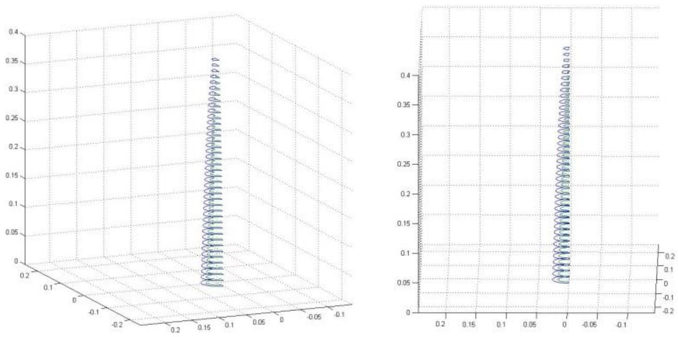

Fig. 18 - Cantilever beam (a) three plans frontal view and lateral view and (b) no sagital plan

6.1.2. Anterior Support Version

Once the material purchased to manufacture the orthoses has a thickness of 4 mm, this was the value imposed on the computational tool.

There were imposed different lower and upper limits for the different levels to make it possible to design a orthoses with anterior support. That is to just above the malleolus the variable corresponding to the posterior edge was defined, whereas in the proximal area of the orthoses is being imposed the anterior contour of the leg. Between these two zones have established a range of values for the length of the lateral stems, so as to don't interfere with the shoes and clothing, however, the tool does not optimized them.

The result thus obtained did not find solution for the optimization of sections situated 18 and 25cm above the ground, as can be seen in Fig. 11 and Fig. 12, in which space cross sections are not drawn.

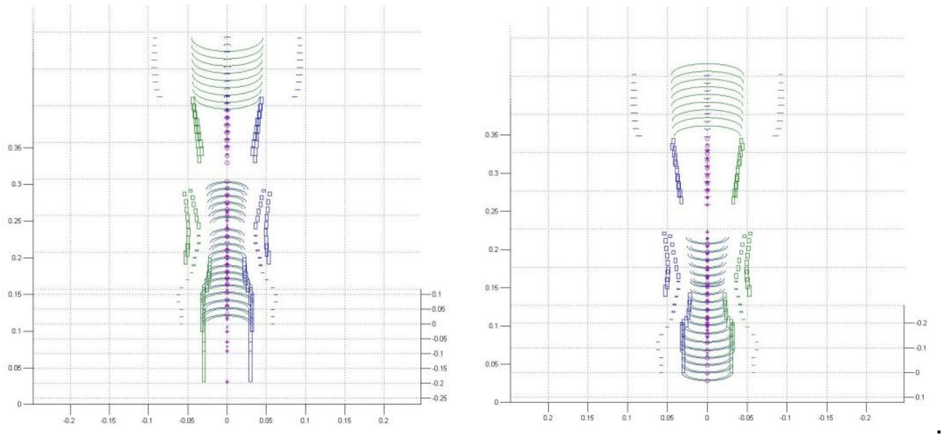

Fig. 19 - AFO with anterior support with 4mm thick (a) frontal plan anterior view (b) frontal plan posterior view

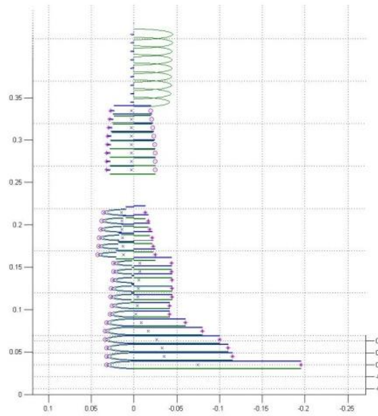

Fig. 20 - AFO with anterior support 4mm thick, sagital plan, lateral view

After that, the variables of thickness of material corresponding to this plane were changed, so they vary between 4 and 6 mm. Since this improvement, a solution was found to a structure with this topology.

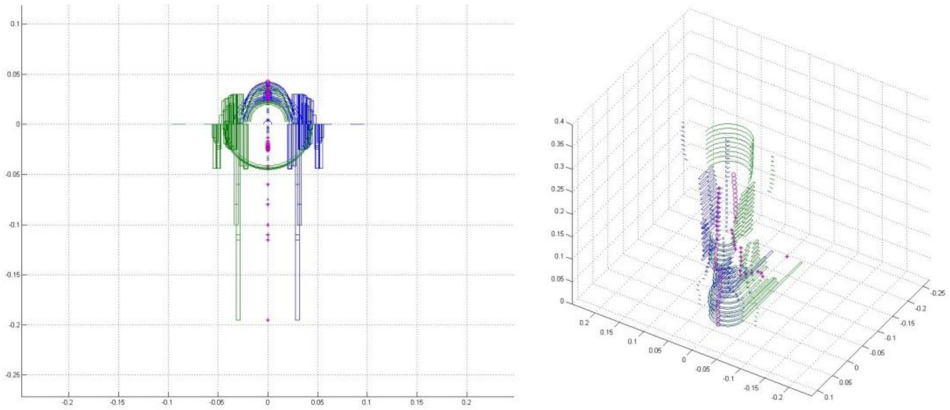

Fig. 21 - AFO with previous support with thickness of 4 to 6mm (a) cross top view plan and (b) in the three planes view later

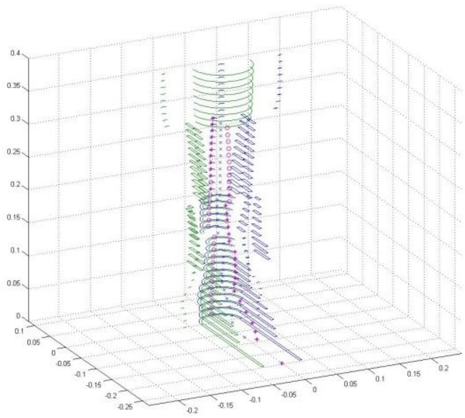

Fig. 22 - AFO with anterior support with 4 e 6mm thick three plans anterior view

6.1.3. New Posterior Support Version

Then, limits were placed in order to obtain a solution with posterior support, however, with relatively large intervals of values for the tool to have freedom to set the structure, this is merely only the value of posterior radius of the leg for real values was imposed, thus they can't change, but no lower limits on the length of the side walls of the orthoses were defined, having just given as values for the upper limit the lengths of the leg and foot for the orthoses not to exceed the length of the segments.

In this case, a 3mm material thickness across the orthoses was also imposed.

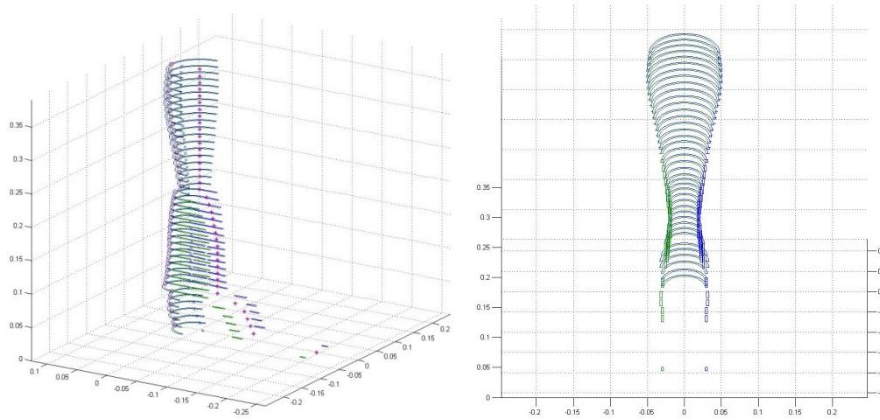

Fig. 23 - AFO with back support with a thickness of 3mm (a) in the three planes previous view and (b) above view frontal plane

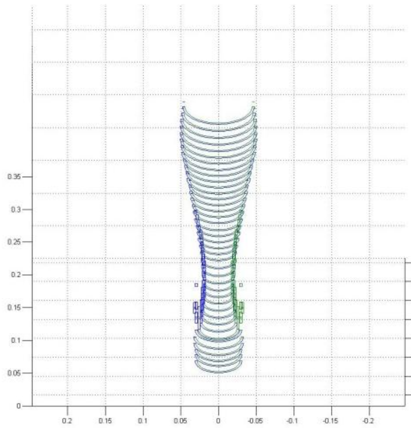

Fig. 24 - AFO with back support with a thickness of 4mm (a) front view rear view

6.1.4. Posterior Version Support

In this case, further search to find a posterior solution was undertaken, with a more rigid configuration, ie with greater medial-lateral support, given the problems presented by the user. The upper and lower limits of levels above the malleoli are the same as the anterior selection. However, the variables were limited not to permit open spaces on the sides of the orthoses. However, it allowed the optimization of the length of the side supports.

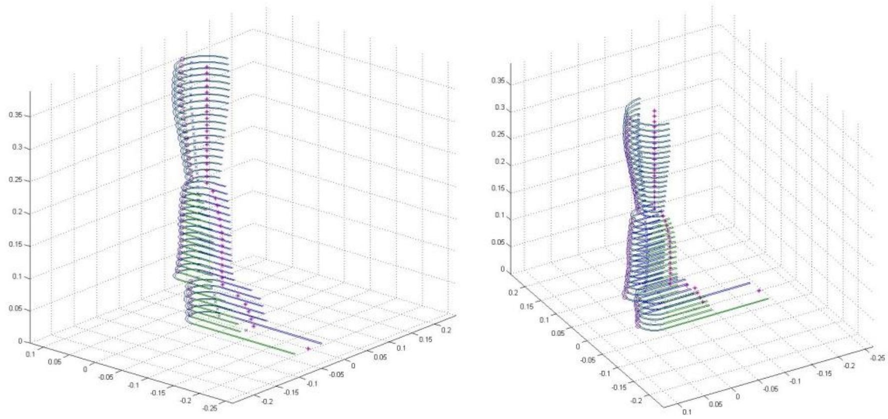

Fig. 25 - AFO with posterior support with a thickness of 4mm (a) in the three planes front view and (b) in the three planes lateral view

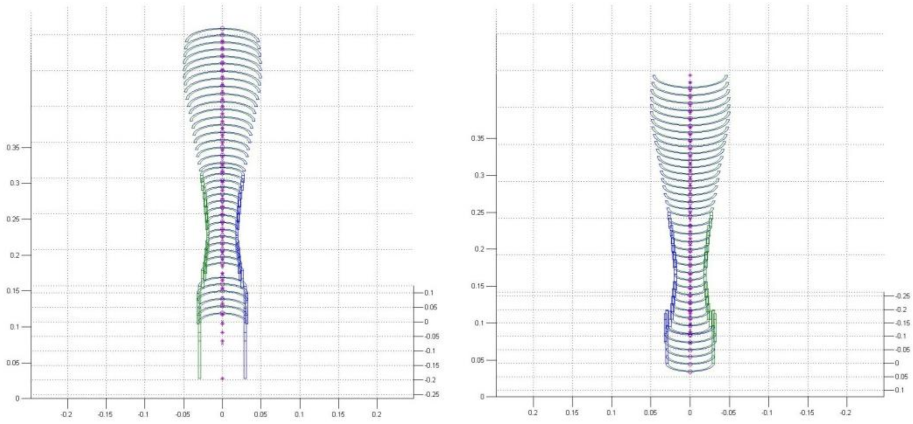

Fig. 26 - AFO with posterior support with a thickness of 4mm (a) frontal plan anterior view and (b) frontal plan posterior view

6.2. DISCUSSION

6.2.1. Trial Version

The first solution obtained is similar to initial problem proposed (Fig. 10). This solution shows that the computational methodology developed is working properly, since the maximum bending moment is located in the area of the joint, then the area of the sections in this zone is maximal in order to withstand the loads to which the structure is subjected. Whilst moments decrease along the height , the area of the sections will also reduce, reaching its minimum value at the top.

6.2.2. Anterior Support Version

The user has a pair of orthoses with posterior support made of carbon with side stems and mechanical joints in aluminum, but broke up in a month in the distal portion of the stems in the area of malleolus (see Appendix E). Usually users with the type of gait that the C.S. has, are indicated to/ prescribed the use of orthoses with anterior support to avoid excessive bending of the knee. Therefore we analyzed the chance to make orthoses with this topology, but possessing a resistance module that supports the loadings that are subject.

However, the first result is not found the solution to the optimization of the sections between 18 and 25 cm in height from the ground, since the bending moment in this zone is high, it is concluded that the limits do not allow the resistance module section to be sufficient to support the loads.

The variables representing the thickness of the material were changed, corresponding to this point, so these may vary between 4 and 6 mm. With this change, the tool optimized lateral rods with a structure having a thickness ranging from 4.3mm, in the proximal part of the anterior support, and at most 6 mm at the distal region of the posterior support.

6.2.3. New Posterior Support Version

Since one of the main complaints of customers is the thickness of the material and the appearance of orthoses, there was the possibility of performing a more elegant orthoses and 3mm thick, which would have a slightly lighter structure.

Data from previous results, limits are placed so as to obtain a solution with posterior support (Fig. 23 and 24).

It was possible to optimize a solution of 4 mm polypropylene and the obtained result has characteristics in its topology which is not usual in AFOs. At the foot segment to tolerate stresses to which it will be subjected, it will only be necessary material to evolve the rear portion of the heel and a wall with a length of 2,5cm with a curved topology which subsequently initiates at the metatarsal heads to below the malleoli or situated above the inner and outer longitudinal arches of the foot. The place where it is most required cross-sectional area is in the ankle joint, and the height of 13cm from this area is reduced by decreasing the length of the side walls, and above 20 cm height is only necessary posterior support.

Through this configuration it is clear that the critical area which suffers the largest stress is the ankle joint and the distal part of the leg.

This topology, in fact, makes the most elegant and lightweight orthoses.

6.2.4.Posterior Support Version

In order to avoid that CS uses anterior support orthoses that allows him to rest in knee flexion, a posterior support solution of 3mm thickness was studied. The solution obtained by optimization tool, similar to the version presented above, however with lateral and medial support in the foot segment subsequently located at the metatarsal heads. Once again, the portion with the largest area is the ankle joint, and from the proximal region of the malleoli sidewalls reduce its length by 19 cm. From this point to the most proximal part of the orthoses is only necessary posterior support of the leg.

This topology as the former is more elegant and lighter than usual.

6.2.5. Selecting the prototype version

After analyzing the three versions shown above for the case of CS, the solution chosen to be produced and tested was the last with posterior support.

The first solution, the anterior support, was the first to be withdrawn by the type of configuration that was obtained, since it would be very difficult to dress it. The distance between the posterior support and the anterior support is very low for an individual who has difficulty achieving foot flexion movements, to position the foot in order to enter that space. The fact that this solution is feasible with only about 6 mm thick in the side rods hampers the production thereof. It would be complicated in the production process to add material to the area in order to make up the required value, and even if it could be a risk in an individual with locomotive difficulties, since there was no guarantee that the material 4mm thick would fuse properly with another 2mm. Other possibility would be to produce the entire orthoses 6mm thick, however, this solution is also impractical since the orthoses would be too thick which greatly complicate the placement of the same into a shoe.

The second solution, despite being easily manufactured, is not indicated for SC in that it has a high degree of pronation in both feet, so the lack of support would not limit this movement which would continue to alter the march.

The latest version was chosen because it allows the control of excessive pronation, the ankle alignment in the frontal plane (decreasing valgus associated with pronation) and allow placement of the segments foot-leg to just 90 in the sagital plan. This latter fact helps in reducing excessive bending of the knees.

In addition to the above, there was the added concern to align the foot and offset the cavus feet. Thus the area of the plantar orthoses is configured and shaped as a corrective insole. The internal longitudinal arch acceptable to the user, with discharge into the tuberosity of the scaphoid was performed; one metatarsal pad of average height (about 6 mm) was performed; subsequent discharge of the tuberosity of the cuboid bone; and 90 ° heel alignment in the sagittal plane and 0 ° in the frontal plane.

After molding and implementation of orthoses cuts, was added a Velcro strip in the foot input line and an elastic band with velcro at the proximal portion of the leg in order to be able to perform normal flexion during gait, yet with an element that makes it impossible to perform excessive bending.

The CS was observed again after 4 months and the orthoses remains intact with no signs of fatigue, it is therefore evident that the computational methodology developed is suitable for the problem posed initially. It was only necessary to slightly enlarge the external malleolus space on the left side, as it was becoming sore.

The possibility of being able to perform minor changes after the orthoses is completed is an added advantage that is not present in other materials.

CHAPTER VII

7. FABRICATION PROCESS OF FUNCTIONAL PROTOTYPE

The methodology and time of confection of orthoses is diverse. The prefabricated are built in series and may suffer mild adjustments made by the technician. Another type of orthoses can be customized directly on the body segment, which also shortens the time between preparation and delivery to the customer. However, there are other, more complex, elaborated and time-consuming methodologies. Despite the advances of technology evolving in order to circumvent these negative aspects, the realization of these processes with technologically advanced methods implies a high financial outlay for the company (which is not currently bearable).

The traditional process that was developed in this work for thermoplastic molded at high temperatures (i.e.: polypropylene). The following steps and images correspond to the manufacturing process of the working prototype runs from the developed computational methods. It was decided to present the manufacturing process for this case study in this point, since this process is the result of the analysis previously prepared, including negative casts. Therefore, any of the steps presented were prepared taking into account all the analyzes conducted à priori and are therefore considered case study results.

a) Completion of the negative cast of the leg-foot, with resin bandages (Fig. 27 and 29), and plantar pressures obtained for pressure platform and pedigraphys.

Fig. 27 - (a) Negative cast and (b) cut of negative cart

Fig. 28 - (a) Extending negative cast to (b) take out the lower limb

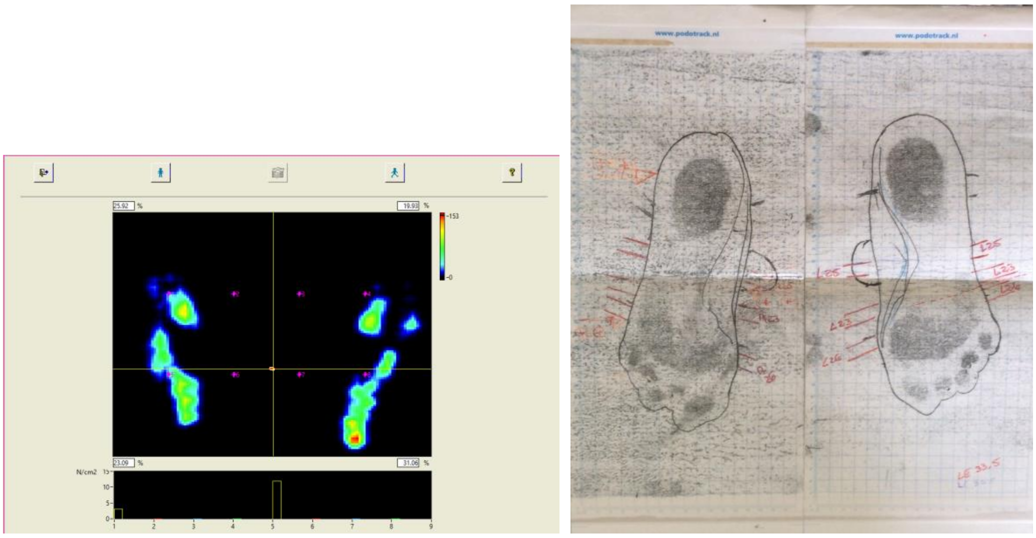

Fig. 29 - (a) Computerized plantar pressures, and (b) plantar pressure with pedigraphy by volumetric measurements of the foot

It appears in both plantar pressures (Fig. 29), both acquired pressures in the platform, as well as the pedigraphy, the individual has cavus and consequently performs much of the support on the rear foot and forefoot.

b) Completion of the positive cast by filling the negative cast with liquid plaster;

c) Rectification of the positive cast: relief of bone regions, applying pressure zones intended for support and alignment of the foot and leg in the frontal and sagittal planes (Fig. 30 - 33);

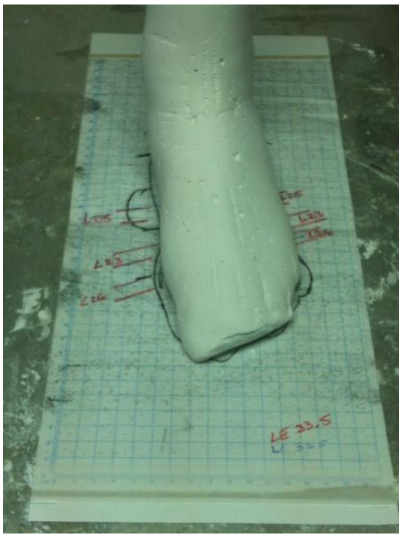

Fig. 30 - checking size of the positive cast with pedigraphy

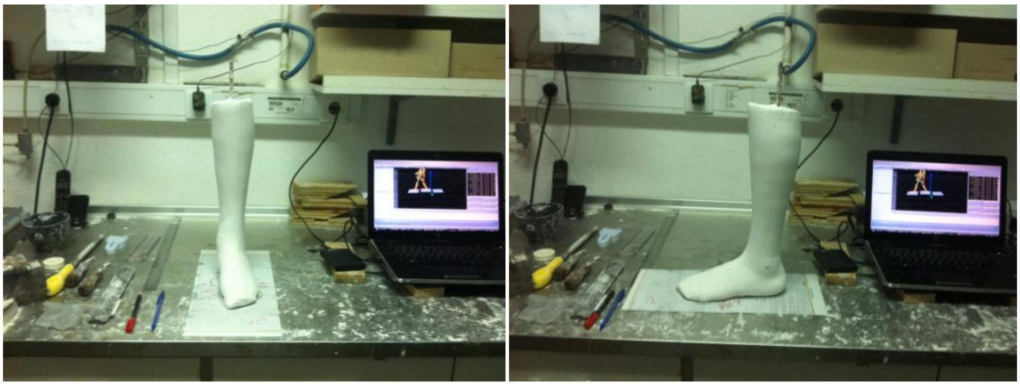

Fig. 31 - Positive cast correction (a) frontal plan anterior view and (b) sagital plan anterior view

Fig. 32 - Positive cast corrections (a) sagital plan anterior view, (b) frontal plane anterior view and (c) frontal plane posterior view

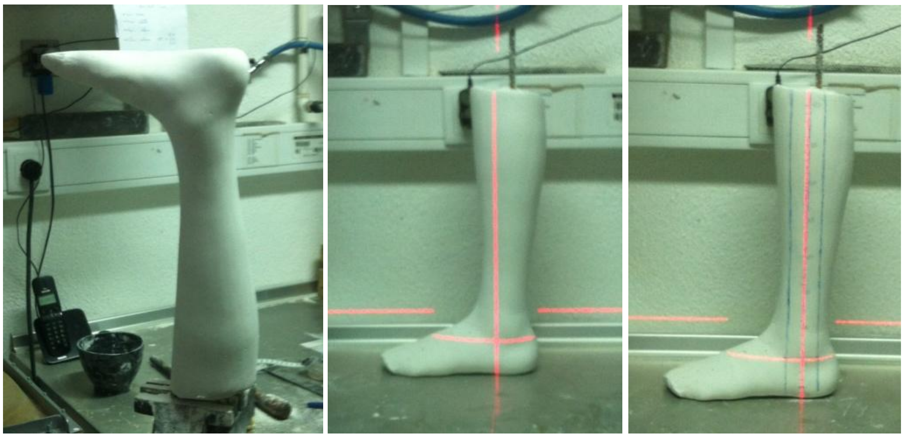

Fig. 33 - (a) Positive cast corrections sagital plane front view, (b) design of the sagital and transverse lines in the positive cast and (c) verification measures of the corrected cast

When taking up the resin bands the negative cast was obtained, which was adjusted taking into account the observed plantar pressures and the day on which C.S. was functionally evaluated. Then the corrections and re-alignment of the positive mold, the volumetric measures were conferred.

d) Casting at high temperatures the material used for the lining of the AFO (ethylene vinyl acetate) and the material that composes the AFO (polypropylene) through a *vaccum-formed* technique (Fig. 34);

Fig. 34 - (a) placement the polypropylene in positive cast, (b) molding of material and (c) cut off excess material

e) Then drew on plastic molded, the topology provided by the computational tool developed in this work, and proceeded to the respective cuts and finishes to trial (Fig. 35 - 36);

Fig. 35 - (a) Material molded on the plaster cast, (b, c) drawing of the sagital line on the molded material

Fig. 36 - (a) Measurements verification on the molded material (b) drawing and cutting lines

f) Cut the orthoses by the boundaries drawn in the previous step;

g) Polishing and finishing of the orthoses (Fig. 37 - 39);

Fig. 37 - (a) Left side AFO sagital plan, (b) AFOs pair frontal plan(c) AFOs pair sagital plan

Fig. 38 - AFOs ready for trial (a) frontal plan, (b) frontal plan right side and sagital plan left side

Fig. 39 - AFOs pair ready for trial (a) transversal plan superior view, (b) frontal plan posterior view right side and sagital plan posterior view left side

h) Fit to patient and modify as needed (Fig. 40 - 41).

Fig. 40 - Trial of the AFO (a) right side e (b) and left side a 18/07/2014

Fig. 41 - Reassessment of the AFO (a) right side and (b) left side a 22/11/2014

Briefly, the polypropylene (material used in this study) when heated becomes soft and is molded vacuum. After cooling, the material keeps the form as shaped. Subsequently, if there is need for a simple adjustment, it can be reheated and molded again indefinitely, which gives a great advantage to the technician.

As can be compared in Table 1, the modern techniques have great advantages as a decrease in lower stages and therefore the total process time, high dimensional accuracy, the possibility of fabrication of the orthoses in a location far from the scanner was held member, ease of storage and retrieval of detailed information about the contours of the client and finally an excellent finish of the final orthoses. In this case, the chosen was the traditional process to manufacture the orthoses for to be much more cheaper.

However, there are two common to both cases the assessment steps and the choice of the most appropriate topology for each user. Thus, before proceeding to manufacture the orthoses is imperative to evaluate the coordination, sensitivity, reflexes and skin conditions. This is because even if we are before unhealed wounds or scar tissue is possible to perform orthotics, however with specific characteristics, such as the addition of liner material, decompression of a certain area, among others (Bruckner & Edelstein, 2006).

Traditional Process	Additive Fabrication Process
Patient Visit	Patient Visit
Plaster Casting	Scan body part
Make the negative	Design orthotic device
Close the negative	Production (automatic)
Make the positive	Clean-up
Correct and finish positive	Add strap etc
Laminate positive	Fit to patient and modify as needed
Cut from positive	
Cut trimlines	
Finish edges	
Fit to patient and modify as needed	

Table 1 - Comparison between a traditional process and an additive fabrication process (s.d., Pallari et al.)

CHAPTER VIII

8. CONCLUSIONS AND FUTURE DEVELOPMENTS

The problem that gave rise to this work, was the fact that both the prefabricated orthoses as the made to measure, for young and active adults that are broken in a short time, which can endanger users. Having been thought to carry out a computational tool that could predict whether the structure would support the forces which it would be subjected.

This study aimed to develop a computational methodology to undertake the structural design of an orthoses through a non-linear optimization function, in which the section of the module of resistance calculated is greater than or equal to the project module. Thus, the solutions calculated by the optimization tool to converge structures with minimal area admissible to support the loads submitted to it. The final goal was based on building a functional prototype that is used for a case study.

Once this methodology works dynamically, i.e., allows the orthotics technician to change the wanted variables, possible solutions are endless. One could, for example, change the type of material to be used by modifying the value of same yield stress. This tool is extremely useful for selection and orthoses decision as it indicates the solution designed for a given individual has an acceptable safety factor. It also allows, find new answers to certain cases. However, the technician that uses this tool must have a cross knowledge in the area of orthoses, pathology, orthopaedic and gait deviations, to allow him to understand that the solution is feasible for the patient and meets the functional requirements.

After the kinematic and dynamic analysis, it was possible to obtain the maximum value of the bending moment, which is fundamental and crucial to achieve the expected result. Therefore, associated with this tool is always required this type of gait analysis. Then, to add the initial design data, and by varying the upper and lower section variables parameterized different solutions were obtained. Of all the results, only one complied with all needs of the CS, having been the accomplished through the traditional process. In July this year was delivered to the CS a pair of orthotics with the topology obtained in the tool, and he continues to use them and it was not shown any sign of weakness or fatigue. It was also observed an improvement in his standing position and decreased the triple-bending, both the static level and dynamic that was common. The user said he felt more balanced and has greater ease of locomotion, to feel that the plantar basis of the orthoses was as expected to function as a spring. Additionally, showed no peeling or blisters of inadequate pressure, only a mark in the left external malleolus, which was readily resolved slightly widening the zone and adding further a cushioning material.

It follows that the computational methodology developed and functional prototype is functioning properly. As this new orthoses production approach contributes to future enhancements and developments of software that has this functionality integrated. In fact, there has been a technological level a large development in the area of orthopaedics particularly in the manufacturing process, through rapid prototyping, to obtain the segment configuration through scanners and imported into digital format, for CAD systems. However, this software does not include the functionality discussed in this work, which implies the existence of a risk factor for the patient.

In addition to the above, though possibly one way to go, the actual computational method does not consider certain major characteristics such as the ability to determine joint or solutions composed of more than one material. The rotation and torsion associated with various orthopaedic deviations are also not considered in this tool. Therefore, it is expected that this view is the starting point for the study and development of this tool in order to be able to guarantee some security to the patient.

Note that this study reinforces the author's opinion that it is essential the work of an interdisciplinary team in the development of orthoses. Since this team as well as being composed by health professionals, it is fundamental to work with engineers, since these are professionals who can provide the technological tools necessary for the acquisition of more efficient, reliable and accurate results. Each professional has their role and competence and only the synergistic work of all may enable an improvement in the quality of life of patients.

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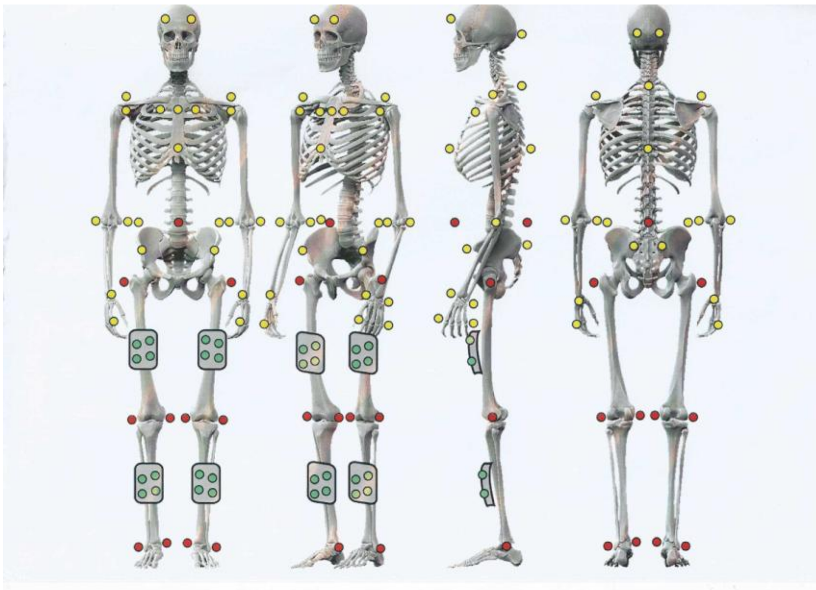
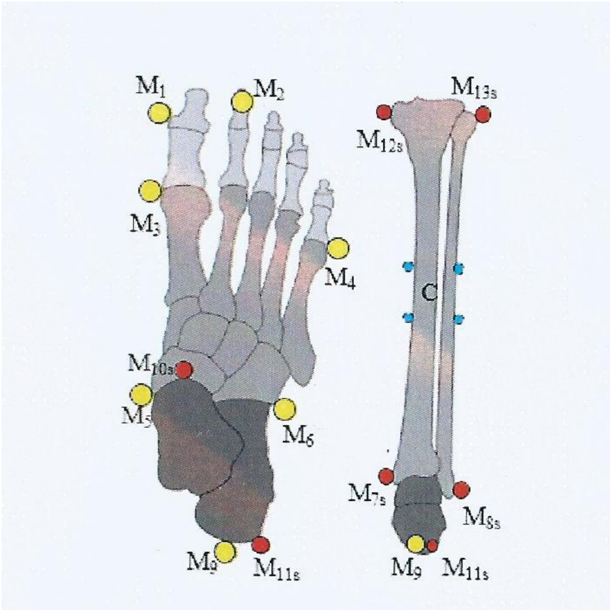
Appendix A - Marker Set Protocol

Based on *Helen Hayes Marker Set*



Maker Nº	Location	Anatomic Landmark
0	Anterior Left Skull	Temporal line of frontal bone
1	Anterior Right Skull	Temporal line of frontal bone
2	Posterior Left Skull	Occipital protuberance (left)
3	Posterior Right Skull	Occipital protuberance (right)
4	neck	Spinous Process of C7
5	Left Shoulder	Clavicle – Acromion
6	Right Shoulder	Clavicle – Acromion
7	Left Distal Elbow	Lateral epicondyle of humerus
8	Left Medial Elbow	Medial epicondyle of humerus
9	Left Wrist	Styloid process of radius
10	Left Wrist	Styloid process of ulna
11	Left Hand	Distal head of II Metacarpus
12	Left Hand	Distal head of V Metacarpus
13	Right Distal Elbow	Most prominent point of lateral epicondyle of humerus
14	Right Medial Elbow	Most prominent point of medial epicondyle of humerus
15	Right Wrist	Styloid process of radius
16	Right Wrist	Styloid process of ulna
17	Right Hand	Distal head of II Metacarpus
18	Right Hand	Distal head of V Metacarpus
19	Pelvis	Left iliac crest (LIC)
20	Pelvis	Right iliac crest (RIC)
21	Pelvis	Left ASIS
22	Pelvis	Right ASIS
23	Pelvis	Left PSIS
24	Pelvis	Right PSIS
25	Left Hip Joint	Center of acetabulum
26	Right Hip Joint	Center of acetabulum
27-30	Left Thigh	Cluster
31-34	Left Leg	Cluster
35-38	Right Thigh	Cluster
39-42	Left Leg	Cluster

Based on *Milwakee Foot Model*



M1	Medial aspect of the hallux
M2	Top head of the phalange II
M3	Medial aspect of the head of metatarsal I
M4	Medial aspect of the head of metatarsal V
M5	Medial apex of the tuberosity of the navicular
M6	Lateral apex of the tuberosity of the cuboid
M7S	Apex of the medial malleolus
M8S	Apex of the medial malleolus
M9	Posterior aspect of the calcaneus
M10S	Super – medial aspect of the talus
M11S	Posterior – lateral “corner” of the heel
M12S	Medial apex of the head of the tibia
M13S	Lateral apex of the head of the fibula
C1-4	Front shank Cluster (4markers)

Appendix B - Factor of Safety

Disclaimer: The information on this page has not been checked by an independent person. Use this information at your own risk.

ROYMECH

Safety Factors..

Basic Notes on Factor of Safety

The factor of safety also known as Safety Factor, is used to provide a design margin over the theoretical design capacity to allow for uncertainty in the design process. The uncertainty could be any one of a number of the components of the design process including calculations, material strengths, duty, manufacture quality. The value of the safety factor is related to the lack of confidence in the design process. The simplest interpretation of the Factor of Safety is

FoS = Strength of Component / Load on component

If a component needs to withstand a load of 100 Newtons and a FoS of 4 is selected then it is designed with strength to support 400 Newtons...

The selection of the appropriate factor of safety to be used in design of components is essentially a compromise between the associated additional cost and weight and the benefit of increased safety and/ or reliability. Generally an increased factor of safety results from a heavier component or a component made from a more exotic material or / and improved component design

The factors of safety listed below are based on the yield strength..

Factor of Safety	Application
1.25 - 1.5	Material properties known in detail. Operating conditions known in detail Loads and resultant stresses and strains known with with high degree of certainty. Material test certificates, proof loading, regular inspection and maintenance. Low weight is important to design.
1.5 - 2	Known materials with certification under reasonably constant environmental conditions, subjected to loads and stresses that can be determined using qualified design procedures. Proof tests, regular inspection and maintenance required
2 - 2.5	Materials obtained for reputable suppliers to relevant standards operated in normal environments and subjected to loads and stresses that can be determined using checked calculations.
2.5 - 3	For less tried materials or for brittle materials under average conditions of environment, load and stress.
3 - 4	For untried materials used under average conditions of environment, load and stress.
3 - 4	Should also be used with better-known materials that are to be used in uncertain environments or subject to uncertain stresses.

Repeated Cyclic loads :
The factors established above must be based on the endurance limit (fatigue strength) rather than to the yield strength of the material. The strength calculations should also include for stress concentration factors.

Impact Shock forces :
The factors given in items 3 to 6 are acceptable, but an impact factor (the above dynamic magnification factor) should be included.

Brittle materials :
The ultimate strength is used as the theoretical maximum, the factors presented in items 1 to 6 should be approximately doubled.

Impact Shock forces :
The higher factors of safety given above (2.5 to 4) may be used but based on stress levels calculated based on the resulting dissipated energy at impact.

Where higher factors might appear desirable, a more thorough analysis of the problem should be undertaken before deciding on their use.

Extreme care must be used in dealing with vibration loads, more so if the vibrations approach resonant frequencies. The vibrations resulting from seismic disturbances are often important and need to be considered in detail.

Use of Standards and Codes

A convenient method of ensuring safe confident design is to use design codes; A good standard used by mechanical engineer is

BS 2573-Pt 1:1983 Rules For Design of Cranes. Specification for Classification, stress, Calculations and design criteria for structures.

This standard (together with BS 2573 part 2) includes rules for completing calculations and applying factors and the relevant allowable stresses to be used for the different grades of materials. This standard is primarily used for design of cranes and associated equipment but it is used widely for design of similar mechanical systems. When designing systems based using the rules from this standard it is not generally necessary to include additional margins of safety.

.

When design engineering structures using structural steel section a useful standard is..

BS 5950-1:2000-Structural use of steelwork in building. Code of practice for design. Rolled and welded sections.

This standard together with BS 5950-Part 2,3-1,4,5,6,7,8 & 9 provide service factors and design stresses relevant to structural design.

In designing many equipment items including vessels, pumps, valves, piping systems there are equivalent standards and codes which should be followed. These documents generally identify the necessary design procedures and the safety margins to be included.

Use of Proprietary Items

A mechanical design often includes rolling element bearings, gearbox units, shaft couplings, belt / chain drives etc. When using these items it is necessary to strictly follow the design rules provided in the suppliers technical documents. The operating duties and service factors to be used are generally clearly specified. It not correct to simply use oversized equipment for convenience. It is also recommended that the supplier is consulted on the duty.

Links on Safety Factors

1. STRESS, STRENGTH AND SAFETY ... DANotes - Very useful notes of safety ...

This Page is being developed

Home

Reliability / Safety Index Page

Please Send Comments to Roy Beardmore

Last Updated 10/04/2008

Appendix C - Auxiliary Calculus Protocol

Centroid:

$$Ay_c = A_e\, y_{ce} - Ay_c$$

$$(A_e - A)y_c = A_e y_{ce} - Ay_c$$

$$Y_c = \frac{A_e Y_{ce} - Ay_c}{A_e - A} = \frac{\frac{\pi r_e^2}{2}\frac{4}{3}\frac{r_e}{\pi} - \pi\frac{r^2}{2}\frac{4r}{3\pi}}{\frac{\pi}{2}r_e^2 - \frac{\pi}{2}r^2} = \frac{\frac{2r_e^3}{3} - \frac{2r^3}{3}}{\frac{\pi}{2}(r_e^{2-}r^2)} = \frac{4}{3\pi}\frac{r_e^3 - r^3}{r_e^2 - r^2}$$

$$= \frac{4}{3\pi}\frac{r^3 + 3r^2 b + 3rb^2 + b^3 - r^3}{r^2 + 2rb + b^2 - r^2}$$

$$Y_c = \frac{4}{3\pi}\,\frac{3r^2 b + 3rb^2 + b^3}{2rb + b^2}$$

Inertia:

$$I_c = \frac{\pi}{8}\,(r_e^4 - r^4) = \frac{\pi}{8}\,(r^4 + 4r^3 b + 6r^2 b^2 + 4rb^3 + b^4 - r^4)$$

$$I_c = \frac{\pi}{8}\,(4r^3 b + 6r^2 b^2 + 4rb^3 + b^4)$$

Appendix D- Lower Limb Assessment

Lower Limb Assessment

Identification

Technician: Maria Martins Costa
Assessment Date: 04/06/2014 **Delivery Date:**____/____/20___
Name: C.S.
Data of Birth: ----------
E-mail: ----------------
Address: ---------------
Mobile: ----------------
Medical Prescription: Ankle foot-orthoses for alignment

Clinical History/ Clinical Assessment:

Pathology - mielomeningocele L3-L4.

Characteristics of foot and limb:

Pés pronados, valgismo da tibio-társica, flexão dorsal excessiva em posição ortostática, flexão excessiva dos joelhos e anca; anteversão pélvica.

Gait Pattern:
Crouch gait

Height (cm): **Weight (Kg):** 77.9

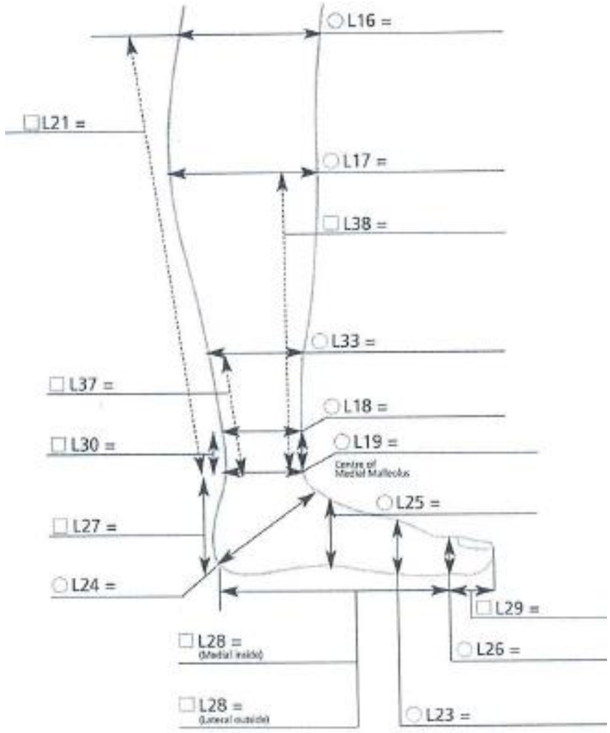
Others: Calçado tamanho 42; elevar arco longitudinal interno; barra metatársica; tuberosidade do astrágalo e cuboide proeminentes, necessidade de descompressão. Colocar forro em todo o pé e maléolos para proteção. Não consegue realizar 0º de flexão dorsal em ambos os lados

Goniometry: em posição de sentado, passivamente.

Movements	Measurement		Degrees
	Right	Left	
	Quadríceps		
Flexion			0 - 125º
Extension			0 - 10º
Internal Rot.			0 - 45º
External Rot.			0 - 45º
	Knee		
Flexion			0 - 140º
	Ankle		
Dorsiflexion	5º(minimum)	2º (minimum)	0 - 20º
Plantarflexion			0 - 45º
Inversion			0 - 20º
Eversion			0 - 40º

Measurements (mm):

R28 (LS) – □ L28 –
R28 (MS) –□ L28 –
R23 (LS) – ○ 229 L23 – 228
R26 (LS) – ○ 235 L26 – 231
R29 (LS) – □ L29 –
R25 (LS) – ○ 246 L25 – 232
R24 (LS) – ○ 333 L24 – 335
R27 (LS) – □ 75 L27 – 75
R19 (LS) – ○ 258 L19 – 252
R18 (LS) – ○ 225 L18 – 215
R30 (LS) – □ 25 L30 – 27
R37 (LS) – □ 131 L37 – 91
R33 (LS) – ○ 240 L33 – 215
R38 (LS) – ○ 253 L38 – 253
R17 (LS) – ○ 320 L17 – 315
R16 (LS) – ○ 313 L16 – 310
R21 (LS) – □ 318 L21 – 313



MS - Medial Side; LS - Lateral Side.

Appendix E- Orthoses of the Case Study




Appendix F- Sheet of Product

FICHA TÉCNICA
FECHA EDICIÓN FEBRERO 2008

POLIPROPILENO REF. OI-6420

NORMA MOLDEADA EXTRUSIONADA DIN EN ISO 1873, Teil 1

NORMA MASA MOLDEADA PRENSADA: DIN EN ISO 1873, Teil 1

MASA MOLDEADA EXTRUSIONADA: PP, EHN, 16-09-003

MASA MOLDEADA PRENSADA : PP-H, QHN,16-09-003
DENSIDAD, G/CM : 0,905
ISO 1183

TENSION DE ESTIRADO, Mpa: 30
DIN EN ISO 527

DILATACION BAJO LA TENSION DE ESTIRADO,%: 8
DIN EN ISO 527

DILATACION DE DESGARRE,%: 70
DIN EN ISO 527

MÓDULO E TENSIÓN, Mpa: 1400
DIN EN ISO 527

RESISTENCIA AL IMPACTO, KJ/M2: sin rotura
DIN EN ISO 179

RESISTENCIA, KJ/M2: 07
DIN EN ISO 179

DUREZA BRINELL, Mpa: 70
DIN EN ISO 2039-1

DUREZA SHORE (D): 70
ISO 868

COEFICIENTE MEDIO DE DILATACIÓN TÉRMICA, K E-1: 1,6 X 10-4
DIN 53752

CONDUCTIBILIDAD TERMICA W/m*K: 0,22
DIN 52612

COMPORTAMIENTO ANTE EL FUEGO: inflamabilidad normal
DIN 4102

ORTOIBERICA S.L – Parque Tecnológico de Asturias parcela 1
33427 Llanera (Principado de Asturias)
Tfno.: 34 985794800 Fax: 34 985794810
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