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

Maria Natália Figueiredo Martins dos Anjos Costa
Master of Science Degree in Biomedical Technologies
Instituto Superior Técnico, Universidade de Lisboa
December 2014

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 for an user with spina bifida (SB), to support him in locomotion.

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 of the subject, the mechanical resistance characteristics of the material used in its manufacture and the resistance to bending module of the respective level. The solution obtained corresponds to the optimum geometry and area of each section along the various levels that constitute the orthoses in its all.

Then was chosen one of the results taking into account the disorder, orthopedic deviations and the gait presented by the subject.

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.

1. Introduction

There are many orthopedic and neurological pathologies which present consequences as the impairment of the locomotor system. In the case of congenital defects such as spina bifida, depending on the level and type, they may or may not show clinical manifestations [1]. Muscular deficits and bone deformities are some common consequences, which causes stabilization problems, as well as problems in postural control and difficulty in walking. Therefore, it is essential to prescribe support products, as orthoses, to assist the gait, in order to overcome these problems and prevent their evolution [2].

The oldest archaeological findings that represent the use of orthoses are dated back to 2750-2625 b.C. The first writings are dated to 460-365 b.C. and were performed by Hippocrates. Caelius Aurelianus was the first to publish a book a.C. (400 a.C.). Later, there are some scientific references that defined the classification and the application of orthoses in medicine. From the end of World War II, there was a great developments in orthotics, especially in the materials used for its confection. In the Renaissance period there were the first descriptive studies of gait made by Leonardo da Vinci, Galileo and Newton. In the following centuries, a number of names who worked on the study of gait and techniques to facilitate the acquisition and processing of the data. 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, such as CAD-CAM system [3].

However, until the current date 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.

Therefore, the main 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 design of a functional prototype, of a new model of 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 and the characteristics of the material being used. Once obtained and chosen the optimized configuration of the orthoses, these were built using traditional process.

The methodology proposed in this work provides orthotics technician a precise definition of the orthoses 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 confidence in the product in used and consequently increase the quality of life of people with disabilities.

2. Data Acquisition

For this work it was conducted a case study (C.S.), 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.

The kinematic data acquisition was performed in Lisbon Biomechanics Laboratory (LBL) at Instituto Superior Técnico. It was 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 platform footscan® 3D Gait (1m x 0.4mx 0.008m).

To obtain these data, the marker set protocol used was based on Helen Hayes Marker Set and on Milwaukee 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 (4 markers in each cluster) and 9 markers on each feet) [4].
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 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 [4].

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 [4].

To obtain the positive cast of lower limb, its need to made a negative cast with resin bandages.

3. 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. One of these data corresponds to the characterization of the material used.

First it’s need choose the material to be used and obtain its yield stress. This value was taken from the data sheet of the material provided by the supplier. Then, 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. In total we have:

\[
S.C. = S.C_{\text{static}} \times S.C_{\text{dyn.}} = 2 \times 2 = 4 \quad (1)
\]

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 is given as \( x = l = 39 \text{cm} \).

A maximum bending moment of ankle joint was obtained from the inverse dynamic analysis of the C.S. and after the processing of data in Qualisys QTM, Matlab and Apollo software. 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:

\[
M_x = M_{\text{max}} \frac{(L-x)}{L} \tag{2}
\]

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 (eq. 3 and Fig. 9).

\[
y_0 = [y_1, y_2, y_3, y_4, b_1, b_2, b_3, b_4, r_1, r_3] \tag{3}
\]

Through the negative cast, it was possible make an evaluation about upper and lower limits of the design variables \((y_u \text{ and } y_l)\), that must be taken into consideration when perform the design of the structure. 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:

\[
\text{for minimum } A, \text{ s.t.:}
\]

\[
\frac{M(x)}{W(x)} \leq \sigma_{\text{adm}} \tag{4}
\]

and

\[
y_i^{\text{lower}} \leq y_i \leq y_i^{\text{upper}} \tag{5}
\]

where \( A \) is the total area of the parametric cross section and \( y_i^{\text{lower}} \text{ and } y_i^{\text{upper}} \) 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 \textit{fmincon} that attempts to find from an initial estimate, a minimum of a scalar function of several variables. Starts at \( x_0 \) 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:

\[
r_{\text{ext.}} = r + b_1,
\]

\[
A_1 = \frac{\pi}{2}(r_{\text{ext.}}^2 - r_{\text{int.}}^2)
\]

\[
A_2 = 2(b_2(y_1 - y_2)) \tag{6}
\]

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

\[
A_3 = \frac{\pi}{2}(2r_3b_3 + b_3^2)
\]

\[
A_4 = 2(b_4(y_3 - y_4)) \tag{7}
\]

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

\[ Y_c = \text{centroid of the parametrized section} \]

\[ Y_c = Y_1 + \frac{4}{3\pi} \times \frac{3r_{11}^2 b_1 + 3r_{12} b_1^2 + b_1^3}{2r_1 b_1 + b_1^2} \]

Analogously, as considered previously in the calculation of the total area, considering \( Y_{c3} \) and \( Y_{c4} \) negative, so have:

\[ Y_{c3} = -\left( y_3 + \frac{4}{3\pi} \times \frac{3r_{22}^2 b_3 + 3r_{23} b_3^2 + b_3^3}{2r_2 b_3 + b_3^2} \right) \]

\[ Y_{c4} = -\left( \frac{y_4 + y_4}{2} \right) \]

\( Y_{\text{max}} \) - determining the furthest point from the centroid

\[ Y_{\text{max}1} = y_1 + r_1 + b_1 - Y_c \]

\[ Y_{\text{max}2} = y_2 + r_3 + b_3 - Y_c \]

From the above results 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:

\[ I_1 = i_1 + A_1 d_1^2 \]

the same way we obtain \( I_2 \), \( I_3 \) and \( I_4 \), in wich:

\[ i_1 = \frac{\pi}{8} (4r_{11}^3 b_1 + 6r_{12}^2 b_1^2 + 4r_{13} b_1^3 + b_1^4) \]

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

\[ i_3 = \frac{\pi}{8} (4r_{22}^3 b_2 + 6r_{23}^2 b_2^2 + 4r_{24} b_2^3 + b_2^4) \]

\[ i = \frac{b_a(y_2 - y_4)^3}{6} \]

For the calculation the transport term given by the parallel axes theorem, the distance \( d_i \) are calculated as follows:

\[ d_1 = Y_{c1} - Y_c \]

Analogously we have \( d_2 \), \( d_3 \) e \( d_4 \).

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

\[ I = I_1 + I_2 + I_3 + I_4 \]

At this moment it is now possible to calculate the elastic section modulus. However, if \( Y_{\text{max}} \equiv 0 \), then \( W = 0 \), otherwise:

\[ W = \frac{I}{Y_{\text{max}}} \]

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.:

\[ c_1 = \frac{c_s \times M_x}{\sigma_{ced}} \leq 0 \]

As well as the design variables,

\[ y_1 \geq y_2 \]

\[ y_3 \geq y_4 \]

And the equality constraint:

\[ b_3 = b_1 \rightarrow c e_1 = b_3 - b_1 = 0 \]

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:

\[ \sigma_x = \frac{M_x}{I} = \frac{M(x)}{W(x)} \leq \sigma_{\text{adm}} = \frac{\sigma_{ced}}{c.s.} \]

All these optimization steps will be repeated from \( x=0 \) until \( x= \). However, according to the initial approximation and boundary limits, the function at any given time may not find a solution, i.e 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.

4. Results and Discussion

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. 4), a value used for all solutions which are presented below.

a. **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.

The solution obtained is Cantilever beam at zero. 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.

b. **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 that the tool does not optimized them so as to interfere with the shoes and clothing.

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., in which space cross sections are not drawn.

![Fig. 7 - AFO with anterior support with 4mm thick frontal plan anterior view](image)

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.
The user has a pair of orthoses with posterior support made of carbon with side rods and mechanical joints in aluminum, but broke up in a month in the distal portion of the stems in the area of malleolus. Usually users with the type of gait that the CS 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 efforts.

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.

c. New Posterior Support Version

Next, 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.

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. It was possible to optimize a solution of 3 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 transversal 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.
d. **Posterior Version Support**

In this case, further search to find a posterior solution was undertaken, with a more rigid configuration, i.e., 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. 10 - AFO with posterior support with a thickness of 4mm in the three planes lateral view](image)

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.

e. **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 wearer it. 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.

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 gait.

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 sagittal 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.

5. **Fabrication Process of Functional Prototype**

The traditional process that was developed in this work for thermoplastic molded at high temperatures (i.e.: polypropylene), presupposes the following steps:

a) Completion of the negative cast of the leg-foot, with resin bandages

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;
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 vacuum-formed technique;

e) Drawing the borders of the AFO provided by the computational tool developed in this work;

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

g) Polishing and finishing of the orthoses (Fig. 11).

Fig. 11 - AFOs ready for trial frontal plan right side and sagittal plan left side

Fig. 12 - Trial of the AFO left side a 18/07/2014

Fig. 13 - Reassessment of the AFO (a) right side and (b) left side a 22/11/2014

6. Conclusions

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.

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.

The CS was observed again after 5 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.

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.

7. References


