Diseño y manufactura de pie Protésico
Design and manufacturing of a prosthetic foot

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Resumen–*El término prótesis hace referencia al dispositivo que sustituye o compensa la pérdida de un miembro perdido, para el caso objeto de estudio, se da en una prótesis de miembro inferior, en el caso de una amputación de miembros inferiores a nivel transtibial, el pie es el elemento ausente más significativo ya que asume la estabilidad mínima del cuerpo del paciente, además de interferir en el balance intrínseco del cuerpo humano. Por lo anteriormente descrito uno de los pilares más importantes de la investigación consiste en el desarrollo y ensamble de un pie protésico que cumpla con las características morfológicas, físicas y mecánicas de pie a sustituir en las prótesis propias de nuestros pacientes caso de estudio.*

***Palabras Clave*–** *Pie, Amputación, Pie Protesico, Cosmesis.*

***Abstract*–** *The term prosthesis refers to the device which substitutes or compensates the loss of a limb; this case study addresses a prosthesis in a lower limb, for the case of transtibial amputation. The foot is the most meaningful absent element, since it assumes minimum stability of the patient's body and interferes in the intrinsic balance of human body. Because of this, one of the most meaningful pillars of this research consists on the development and manufacturing of a prosthetic foot, which complies with the physical, morphological and mechanic characteristics of the foot to be replaced in the prosthetics proper to the patients who are case of study.*

***Keywords*–** *Amputation, Cosmesis, Foot, Prosthetic foot.*

1. Introduction

Currently, there is a number of prosthetic feet in the market for individuals with transtibial amputation. All of these elements ultimately intend to increase the degree of wellbeing to be offered to the patient; this degree of wellbeing includes elements with a paramount importance, such as size, aesthetics and cost. These factors are rather relevant when implementing a prosthetic component [1]. There are substantial differences as to purpose, materials used in assembly and nominal cost of each of the feet available in the market.

Generally, we can describe the fundamental characteristics as follows: *conventional feet* refer to feet with zero energy storage potential, such as the Sach type. Another type of foot is *energy storing foot*, which intends, as pointed out by its name, storing some sort of energy and returning it in the function of walking. Finally, *bionic feet*, which at some point of walking generate autonomous type movement, which produce movement at some degrees of liberty, based on angular signals or electric potential; this movement is immediately transferred to some of the stages of walking [2] [3] [4]

Current research determines that results on the different types of feet are still not conclusive, meaning they do not display efficient results along walking cycle and even less over a prolonged period of around 30.000 use cycles. Feet with a more favorable result in walking cycle are the ones that store and somehow return energy to the general cycle of walking, since they are not made out of complex elements which depend on programming or patient adaption, but rather their natural founding lies in the use

of high-density compounds and geometrical design which mechanically compensate both dorsiflexion and plantarflexion at patient's walk. [5] [6] [7]. The fundamental purpose of this type of research in the field of orthopedic devices is being able to imitate the biomechanics of human ankle through components which display some sort of relevance when augmenting the levels of wellbeing for the patient, this is what our research seeks, "making a difference" [3].
Making proper analysis, it becomes necessary to have basic functionality, mechanic and esthetic characteristics to be born in mind for appropriate design of a component. Here, we will include the parameters used at the beginning of the design (they correspond to the first stage of the project).

- Patient's body mass: 80 kg
- Shoe size: 34
- Height: 1.70 m
- Activity level: 3
- Stump length: middle third
- State of the stump: Optimum conditions
- Articulation status: Preserved
- Muscular strength: 4
- Maximum foot length: 5 cm
- Dorsiflexion: 20°
- Plantarflexion: 50°
- Manufacturing material: Carbon fiber.

If we put these parameters to good use, it will be possible to fully restore vital elements of the foot, such as weight, cosmesis and durability, besides generating appropriate time to achieve balance between walk and accumulated energy immerse in the component [8] [9]; this type of balance is easily verifiable with a walk analysis through a walk behavior laboratory, where the different stages of prosthesis manufacturing are analyzed [10] [11] .
Walking pattern is a set of well-articulated movements, which make up a total that can become daily in a person's life. On the other hand, patient's movement can be affected by a great number of anomalies; the most worth noting ones are:

- Diabetes.
- Cerebrovascular accidents.
- Paralysis of lower limbs or other types of paralysis (cerebral).
- Dystrophy of some type.
- Accidents which lead to amputation (Victims of armed conflict)[12, 13] [14], among others.

These can lead to the presence of permanent limitations and conditions of disability [15].
An important reference, given that World Health Organization-OMS does not state that 15% of population suffer some type of disability and indicators in this study lead to believe that this figure is on the rise, and that population numbers with this condition is increasing. For Colombia, the 2005 census from the National Administrative Department of Statistics (Departamento Administrativo Nacional de Estadística en Colombia – DANE) [16], the analysis shows statistics by department on people's disabilities. Most relevant parameters indicate that the departments with the highest figures of disability are Cali (Valle del Cauca), Antioquia and Bogotá. According to this analysis, the official figure for this year suggests that in Colombia there are 2´624.898 disabled people. Off the record, by 2015 the WHO claimed the same indicator to be 3´051.217. For specifically physical disabilities, the figure corresponds to 29,3% of the population, according to the same statistics [17] [18].
This analysis generates the necessity of designing and implementing our own prototype, according to geographic, labor and socioeconomic considerations; which complies with morphological parameters of the patients who have suffered amputation due to the armed conflict, disabled soldiers, whose average weight ranges 80 Kg. These factors, along with proper alignment [19], and further walking analysis [20] [21], can provide a prototype capable of resisting high impact and functionally accommodating to the design parameters required [22].

2. General analysis of prosthesis

The analysis pf prosthesis begins with the parameters taken into account when designing the prosthetic component, which will not be discussed, as they have been thoroughly treated in previous papers [23].
The elaboration of the foot in carbon fiber is determined starting from the design and specifications, based on anthropometric and biomechanical measurements, specific to the patients object of study.
First, sketches are modeled by specialized staff of the school of orthopedic technology of the Centro de Diseño

y Metrología-SENA Center for Design and Metrology-SENA.

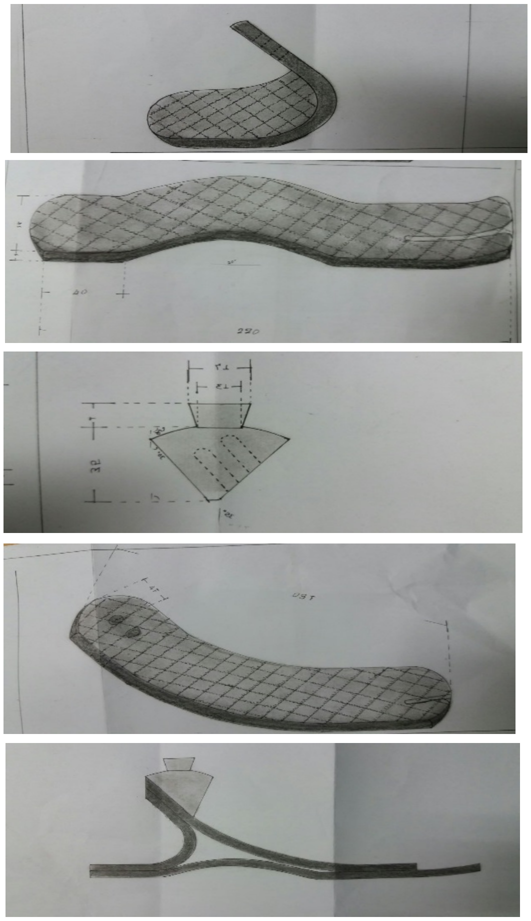

Figura 1. a) Ankle b) Sole c) Adapter d) Instep e) General.

Next, the design is elaborated using micro porous sheets.

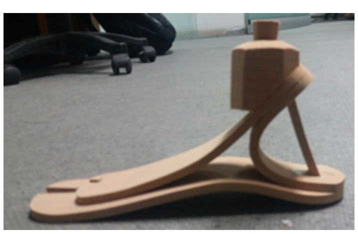

Figura 2. General assembly in micro porous sheets.

3. Full articulation assembly

In the general prosthesis assembly, the first step is making molds in plaster to make each of the components which compose the device, complying with required dimension (activity, weight, length, width, thickness, degrees, height).

Afterwards, the first tests were made with molds, using 100 grs of acrylic resin; 6 strips of carbon fiber were cut bidirectionally at 90°; the six layers of fiber were put in the mold, and the resin was poured inside. The mold was pressed until hardened for four (4) hours; then it was extracted from the mold and burr was removed from the pieces obtained. Uniformity and resistance of the piece were checked (Stencil, heel, instep, adapter) in anticipation for assembly. This process was repeated with each of the pieces forming the model.

Figura 3. a) Stencils b) Mold c) Assembly.

Once all the pieces have been obtained, and their quality has been checked, they are assembled, paying special attention to proper alignment and fitting.
Proper adaptation is checked when assembling the components, thus determining the alignment recommended and optimal for socket and prosthetic foot respectively.

4. Model analysis and results by finite elements

To begin the analysis, the prosthesis was defined in a model format *.igs for proper visualization and software adjustment during the use of the structural analysis module. In the first step, the prosthesis was visualized fully and all components were verified.

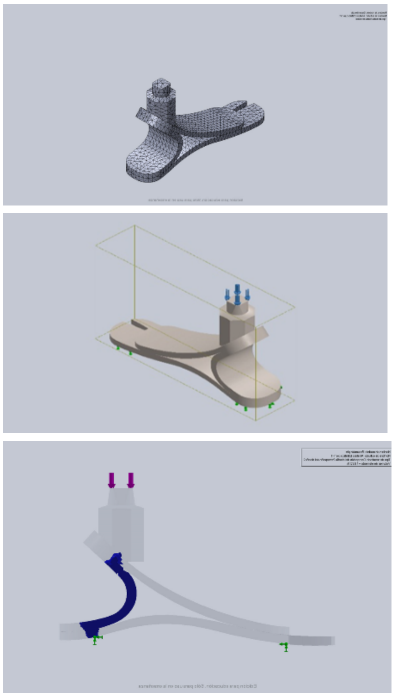

Figura 4. a) Tetragonal mesh b) Forces implementation c) Forces applied on critical elements.

When mesh visualization was finished, a single load vector was applied, corresponding to 100Kg, located in the zone where the previously analyzed socket or adapter will be placed. The load is studied as follows (figure 4) and it is verified to make sure it is not tilted.

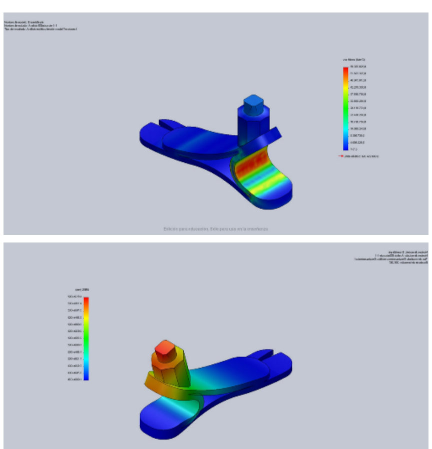

Figura 5. a) Von Mises tension force 100Kg. b) Implementation of forces focused on the adapter.

Tabla 1. Results of the static analysis for tension.

Name	Type	Min.	Max.
Tension	VON: von Mises tension	717.23 N/m^2 Node: 10111	5.63708e+007 N/m^2 Node: 12505
Static analysis feet- Tensions			

Tabla 2. Results of static analysis for displacement.

Name	Type	Min.	Max.
Displacements 1	URES: Resulting displacement	0 mm Node: 6919	0.045 1218 mm Node: 699
Static analysis foot- displacements			

Tabla 3. Results static analysis for deformations.

Name	Type	Min.	Max.
Unitary Deformation	ESTRN: Equivalent Unitary Deformation	3.82251e -009 Element: 5949	0.0001715 92 Element: 7141

Mostly, foot components display aggressive curve radiuses and fatigue failure possibility, due to the permanent load cycle it will endure. Therefore, breaking points, displacements and deformations, were revised, as seen in tables 1,2 and 3. In latter manufacturing, these issues will be corrected.

5. Conclusions

In the first test with molds, we could prove that it is not functional, due to the limited space of the piece for proper accommodation of carbon fibers.

Mostly, foot components display aggressive curve radiuses and fatigue failure possibility, due to the permanent load cycle it will endure.

For the case of the ankle, it is necessary to comply with active flection and extension movements in the load and balance phase, in order to resemble static and dynamic movements (cinematics) of physiological walk.

Foot must respond to mechanical functions of ankle component and assume functions proper to said component.

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