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Comparison of a transtibial socket design obtained by additive manufacturing and reverse engineering and a traditional model

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Abstract. The purpose of this article is to present manufacturing methodologies through reverse engineering of socket design for a transtibial amputee, bearing in mind that it is a customized product. In addition, the traditional manufacturing process will be arrived at in comparison with the model proposed. In this sense, this document proposes a new practical approach to modeling the contact interface, i.e. the prosthetic socket and the skin, and thus making a more functional prosthesis by helping people to visibly improve their quality of life.

1. Introduction

Currently, the country's health system receives many patients with various conditions such as vascular diseases, trauma, cancer and congenital origin, which are the most important causes of lower limb amputation in the world. The OMS also state that almost 10% of the world's adult population suffers from diabetes, which is a tenfold increase in the likelihood that a lower limb will have to be amputated [1].

Every day the number of amputees increases, and many this population has few economic resources, so not everyone can buy a prosthesis and sometimes the measurements of the original socket change over time. In the case of children, prostheses must be replaced with the development of their limbs, since they are constantly growing, or in other cases a time of revision and change of prosthesis is planned when necessary, preventing diseases caused by prosthetic gait problems since the residual limb changes shape due to the thinning and deformation it suffers, due to the fact that, when the transmission of loads is not satisfactory, the person who uses it suffers discomfort (such as pain, blisters, etc.) and the change of socket becomes a necessity [2].

For several years, technology in the field of physical rehabilitation and physiotherapy has been implemented with a focus on assistance and product development used to increase, maintain or improve the functional abilities of people with disabilities. This is how aids for children and adults with physical disabilities are known. This is a common practice in current rehabilitation models. These studies help to visualize the improvements and advantages through new manufacturing methods, since the new prosthesis designs that will be addressed in this project are important for good product development, as well as for patient safety and confidence.

It should be added that the prosthetic socket has traditionally been made by hand, but with the new advanced manufacturing systems, the advantages are visibly noticeable and this not only in the medical area but also in its applications in modern production systems and with the manufacture through 3D printing it is easier to make new shapes and designs in which the patient sits in a more comfortable environment.

Additive manufacturing is a digitized production method that consists of manufacturing previously modeled objects, by deposition of layer by layer of material, until forming a three-dimensional object [3]. Additive manufacturing is transforming the practice of medicine; now it is possible to have a precise model of a bone before surgery and the possibility of creating a precise transplant, no matter how complex its shape. Similarly, it is possible to digitize amputated limbs and design by this process its extension adaptable to the patient's size [4].

Currently, Stereolithography (SL), Selective Laser Sintering (SLS), Fused Deposition Modelling (FDM), and 3D Printing represent the most important technologies for processing of plastics [5].

In the literature, was found a study about the development of surface textures with different geometries manufactured by additive manufacturing. The manufacturing of the different surfaces is done layer by layer, in a unique process, by means of the laser stereolithography technique (SLA), directly from the CAD files. The printed surface textures showed a reduction in the values of length, volume and mass measurements compared to the one defined in the design [6].

In another document consulted, the mechanical and tribological properties of steel matrix composite materials (316L stainless steel reinforced with Cr_3C_2 ceramic particles) processed by laser selective fusion (SLM) additive manufacturing technologies were determined. Demonstrating that additive manufacturing is a versatile and widely applied process [7].

Finally, this article presents the progress of the transtibial socket design project, in which part of its specific objectives are the selection of the clinical case for digitalization and subsequent 3D visualization of the model, using advanced manufacturing processes, within which are the techniques of Rapid Prototyping (3D Printing) and Reverse Engineering to obtain models from existing ones. To obtain the data, Reverse Engineering (RE) techniques were used, which allow digitizing, analyzing, modifying and manufacturing products based on existing objects; for the case study, the amputated limb will be used, and to obtain a design suitable for the patient's measurements.

2. Methodology

For the purposes of this study, it is important to bear in mind that transtibial amputations are those performed below the knee, these are the most recommended since it is always suggested that the knee be retained because it is a fundamental member in the performance of movements [8], therefore, this work focuses on this type of prosthesis, in addition to the fact that statistically they are the most frequent. These prostheses are commonly manufactured using traditional methods, which do not guarantee an ideal fit between the socket (part of the prosthesis that is in contact with the skin) and the residual limb. The socket is a fundamental component for this type of prosthesis, since a suitable socket is not one that fits exactly to the shape of the residual limb but one that meets the biomechanical parameters of the interface [9].

For this reason, socket must be completely customized, corresponding to the patient's anatomy, the other parts of the prosthesis are standardized, and therefore, this study will focus solely on this component. Having made the above considerations, a methodology will be proposed regarding the design and manufacture of Socket (transtibial prosthetic socket), to verify the variables that have a positive impact on the proposed design, through computer simulations using the Finite Element Method and manufacturing using Rapid Prototyping. In this sense, it will be necessary to make comparisons with the current reference, to show its advantages compared to the traditional manufacturing process.

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2.1. A subsection generation of de model

The generation of the model was done through the digitalization process, which depends largely on the model to be obtained, so it is important to understand the acquisition processes, knowing their advantages, limitations and conditions on which they can be useful, because for the selection of any method must be taken into account different factors depending on the characteristics of the object to be digitized, because these systems have particularities that make them different and adapt to some specific needs.

Considering the above mentioned in the digitization methods, the most recommended technologies for the present study are the active non-contact technologies, so that great care must be taken with the patient's amputated area. Consequently, the technique of digitization by Structured Light or active triangulation was chosen by using the 3D Scanner Spectra™.

The result of an individual scan of the patient provides a cloud of that view, which is processed through what is known as reconstruction, where those points that are not of interest for the study should be excluded, and the 3D model of the residual limb surface can be generated as shown in Figure 1, and converted to the STL format, which is a solid file for printing, to later execute the modeling of the 3D prosthesis, since the design of the prosthesis is subject to the anatomy of the amputated residual limb (Figure 2).

Figure 1. 3D surface model of the residual limb.

Figure 2. Transtibial Socket Design.

2.2. Application of the finite element method

With the accelerated development of today's technology, structural analysis is becoming more and more effective through computational methods, which is why finite element analysis has been used to study the effects of inertial loads and contact conditions at the interface between the prosthesis and the residual limb of an amputation, thus simulating the application of forces (Figure 3), being considered a tool for the study of optimal parameters and the evaluation of prosthetic components [10].

In recent years, the MEF has become the main tool to simulate various processes such as stress distribution, temperature changes in certain areas, deformations and other mechanical properties of the part, for the present case was used the technique of removal of material from the starting structure which was the traditional design, until it was no longer possible to continue, without deteriorating the static and dynamic properties of the object.

Slipping can accentuate skin abrasion and repetitive rubbing, causing blistering and unnecessary heat generation, triggering harmful and uncomfortable consequences. Due to the problems exposed, many people gave up the use of prostheses due to the discomfort and damage caused, so these studies were developed to ensure the reliability of the product and its response to possible eventualities, where the region that presents the greatest stress is the lower part of the prosthesis enclosed in a red circle, where a maximum tension of 551.8Mpa was observed, as can be seen in Figure 4.

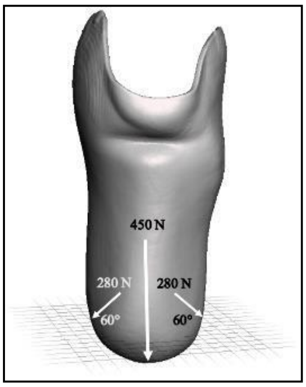

Figure 3. Application of FEM forces.

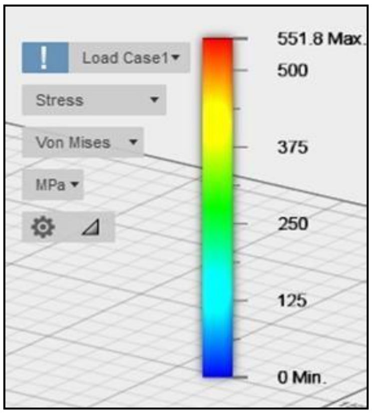

Figure 4. Von mises.

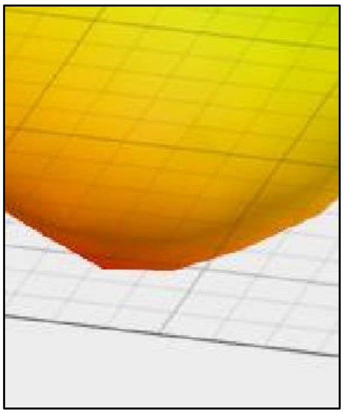

Figure 5. Stress analysis.

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2.3. Three-dimensional printing

PR is a very important technology for the development of prosthetics, since it is possible to create functional, customized products adapted to the specific needs and dimensions of the patient, and for this reason the manufacturing method was chosen.

A well-adapted technology for the manufacture of transtibial prosthesis socket is the SLS which has the ability to build outstanding regions that are inaccessible using other processes, allowing the construction of models with complex internal and external geometries[11], in addition to the fact that it does not require support structures, since unsintered powder provides support during construction, the process is carried out starting with 3D CAD design and transfer of the CAD data to the SLS machine to carry out the manufacture with the desired powders[12]. However, the prototype was printed on the 3DPrint machine as the method is similar to SLS printing in terms of the dimensional accuracy and geometry of the object, where the model was first processed in KISSlicer software (Figure 6). After model verification, the printing process was performed for the materialization of the prototype.

Figure 6. 3D printing process.

3. Result and discussion

As can be seen in Table 1, although the manufacturing time by the traditional method is shorter, it consists of multiple complex stages, which in many cases require the presence of the patient for its execution, which makes the process difficult for both the user and the manufacturer, bearing in mind that the adjustment process is totally personalized and in the event of any inconvenience or correction the tests performed should be repeated.

On the other hand, although the manufacturing process by the 3D Printing method is longer, it consists of basic stages and does not strictly require the presence of the patient since the data capture by means of digitalization is more precise, and the real measurements can be counted on at any stage of the process. However, this method must be performed by experts in the use of virtual tools, especially for 3D modeling of transtibial Socket. The data from the Table 1 were taken from the Associação Mineira de Reabilitação in Belo Horizonte, Brazil.

Table 1. Comparison of the times of the traditional method with the time proposed by 3D printing, the times are not continuous but spaced in intermediate stages.

Process	Time (min)	Patient present
Traditional method		
Taking measurements	40	X
Emptying the mould	30	
Mold polishing (Depending on the complexity of the die)	40	
Lamination	30	
Checking the proper contact of Socket	10	X
Corrections	30	X
Testing Socket	20	X
Total Time	200	
3D Printing		
Digitizing	20	X
Design modeling	270	
Printing	1200	
Socket test	20	
Total time	1510	

3.1. Traditional method

One of the main characteristics for the design of the handmade lace, is the need for knowledge and skill of a prosthetist, being also an experienced and observant person in the handmade manufacture of prosthesis since it is an extremely laborious process, from which excellent results must be obtained systematically. On the other hand, to make the modifications and adjustments, the process must be carried out in a different way each time, so that it is not sufficiently precise and accurate.

The traditional method lacks an objective assessment of the quality of the designed socket, and modifications of the socket shape are based on the knowledge and experience of the prosthetist, to achieve a satisfactory socket. In addition, evaluation using a trial-and-error approach continues to be used in this process, resulting in increased waste of both time and material, compromising patient well-being. In conclusion, the process may become longer if any corrections and adjustments must be repeated, and the patient may have to feel uncomfortable with each correction and check if they were correct.

3.2. Proposed method
As the latest technology is currently available for the digitalization of the amputated limb, it offers greater accuracy and precision in the manufacturing process and the production of comfortable prostheses according to the patient's measurements. In addition, the 3D data capture process of the amputated limb could be used as a parameter for the standardization of the design subprocess in terms of the rectifications that must be made considering the patient's pressure points.

Similarly, with the application of this method, in computer-aided design (CAD), the designer, instead of making a mold and making the respective corrections or adjustments in the pressure tolerant or pressure intolerant zones (which could be the cause of possible errors before an unqualified technician), can modify the digitally captured model, directly from the software and these corrections would avoid waste, because the final model would be reproduced until it was fully verified.

4. Conclusions
Manufacturing by means of 3D printing, gives the possibility of developing new designs, from new structures that allow a smaller dislocation of the piece and possibly a smaller wear and heat dissipation than the conventionally made one. In addition, with the application of this method, it could be implemented with training of the personnel regarding the computer tools used, since it requires intensive manpower in the image processing stage, presenting as an advantage the intervention of the prosthetist in the new phase that would be the supervision of the virtual process. Therefore, the great advantages that the 3D printing manufacturing method provides, present it as an attractive option or alternative to the methods traditionally used.

Finite Element Analysis allows a systematic evaluation of the socket's response to mechanical stress conditions, based on the patient's own parameters such as body weight. Similarly, the new designs obtained that facilitate this technique are more reliable due to the performance of computer simulations that ensure the reliability of the design and the desired final characteristics, in addition to being more comfortable and could become lighter depending on the type of material, avoiding costly and tedious experimental testing, without the need for the physical prototype.

The techniques of Rapid Prototyping (3D Printing) and Reverse Engineering for obtaining models from existing ones, is an important area that is advancing every day and facilitates the processes in all areas, in addition to the recognition of the importance of finite element analysis in which mechanical tests can be performed on any part and according to the material of the object of study.

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