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DEVELOPMENT OF A TRANSFEMORAL TAKEN ACCESSIBLE FOR LOWER LIMB PROSTHESIS USING DISRUPTIVE TECHNOLOGIES

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Abstract: The high incidence of reports on lower extremity amputees who do not have access to a prosthesis and the use of disruptive technologies as an alternative to the problems associated with the traditional construction technique of these devices were the main motivations for this research. Its objective is to develop an anatomical socket or socket that will be used in a lower limb prosthesis for a transfemoral amputee patient, using digital fabrication (scanner, CAD-CAM software and FDM printer), and to study its feasibility as a low-cost method. For the purposes of the above, a bibliographic review was carried out and an experimental technological work methodology was determined, focused on a clinical case of a patient with transfemoral amputation. This way, a specific socket for the amputee was modeled and manufactured and three cases of critical load (heel strike, medium support and take-off) were simulated, as well as surface tests on the patient. Finally, an evaluation of the construction costs of a complete prosthesis was carried out and the final price was compared with the prices of similar prostheses in the current market, determining that it is possible to obtain anatomical transfemoral sockets for lower limb prostheses at low cost using disruptive technologies.
Keywords: Prosthesis, disruptive technologies, socket, ischial containment, 3D printing.

INTRODUCTION

According to a recent article (MCDONALD et al., 2005), it is estimated that there are 58 million people in the world who lack a limb due to the amputation of one or more of its members. According to the World Health Organization (WHO) (WORLD HEALTH ORGANIZATION, 2017) 0.5% of the world's population, that is, 35 to 40 million people, requires one of these devices.

Likewise, the WHO estimates that, currently, only one in ten people who need priority technical aids, including prostheses and orthoses, have access to them (WORLD HEALTH ORGANIZATION, 2017). The situation is even more unfavorable for low- and middle-income countries (LMICs), where an estimated 64% of people live with amputations (CLINTON ACCESS TO HEALTH INITIATIVE, 2020).

The majority of amputations performed each year are of lower limbs, representing more than 60% of the 1.5 million per year (CLINTON INITIATIVE FOR HEALTH ACCESS, 2020), therefore, the report focuses on lower limb prostheses.

The main barriers faced by amputees from LMIC countries are financial and logistical, since there are few prosthetic service units, and the majority of the population comes from rural areas, so they must include high indirect costs to access the service. (CLINTON INITIATIVE FOR ACCESS TO HEALTH, 2020). In addition, the traditional manufacture of this kind of devices requires different types of equipment and machinery, such as oven, vacuum suction and drills, therefore it is difficult to establish new units (CLINTON HEALTH ACCESS INITIATIVE, 2020).

From this perspective, the use of disruptive technologies is of great value as an alternative for the development of prototypes that imitate human movements and that can be attached to them, thus improving people's quality of life. In the field of prosthetics, these technologies focus on replacing heavy machinery with digital tools, such as a scanner, laptop or 3D printer, in order to reduce costs and use remote digital archiving to overcome logistical difficulties, especially in the manufacture of sockets adapted to the patient's residual limb.

In 1991, (ROGERS et al., 1991) began to investigate stereolithography printing (SLS), and shortly after, researchers such as Lee et al. (1998) explored fused deposition modeling (FDM), and in particular later the use of low-end 3D printing (FREEMAN; WONTORCIK, 1998).

Based on this information, authors such as Hervert et al. (2005) proposed very similar methodologies that would bring together all the digital techniques, that is, anatomical reconstruction by scanner, CAD/CAM modeling and simulation, and manufacturing by FDM or SL, however, they did not record the cost that their realization implied, and, therefore, the uncertainty arises as to whether the use of disruptive technologies to manufacture prostheses really manages to reduce costs, distancing itself from the current market.

Therefore, in order to study the feasibility of disruptive technologies as a solution to the problems mentioned above, in the present work a socket, basin or socket is developed for a lower limb prosthesis using digital manufacturing (scanner, CAD software). -CAM and FDM printer), and its cost and advantages compared to traditional construction are analyzed.

MATERIALS

The materials used in the research are the following:

- **Raw Materials.** Thermoplastic polyurethane (TPU) and polylactic acid (PLA).
- **Software.** Meshmixer, Ultimaker Cura and SolidWorks Simulation.
- **Machinery.** Portable 3D scanner, model 3D Scanner Pro, from XYZ printing; and an FDM printer for home use, Crealty CR10S model.

CASE STUDY

58-year-old male patient with transfemoral amputation and medium-length soft stump. The patient has been living with the amputation since 2018, uses crutches, and his lifestyle was classified within the K2 level described by GAILEY et al. (2002). According to its characteristics, an ischial containment socket was selected.

METHODS

The type of research carried out was experimental technology, based on a clinical case of a patient with a transfemoral amputation carried out in Venezuela in 2021. The methodology proposed in the project combines the sequential succession of actions and the iteration of certain phases that require feedback.

For the elaboration of the socket, the characterization of the patient and establishment of requirements were carried out first; followed by the modeling of the socket and an analysis of the mechanical behavior, and, finally, a prototype was manufactured and tests were carried out with the patient. After that, the selection of the rest of the components, the linking of all the pieces and their budget follow one another.

THREE-DIMENSIONAL RECONSTRUCTION

First, a three-dimensional image of the patient's residual limb was obtained using a portable 3D scanner, placing the subject in a soft prosthetic sock (Knit Rite A-Plus Prosthetic Sock) in order to homogenize the physical surface (Figure 1).

MODELING

Figure 2 shows the final design process, in which, first, a purification of the three-dimensional model was carried

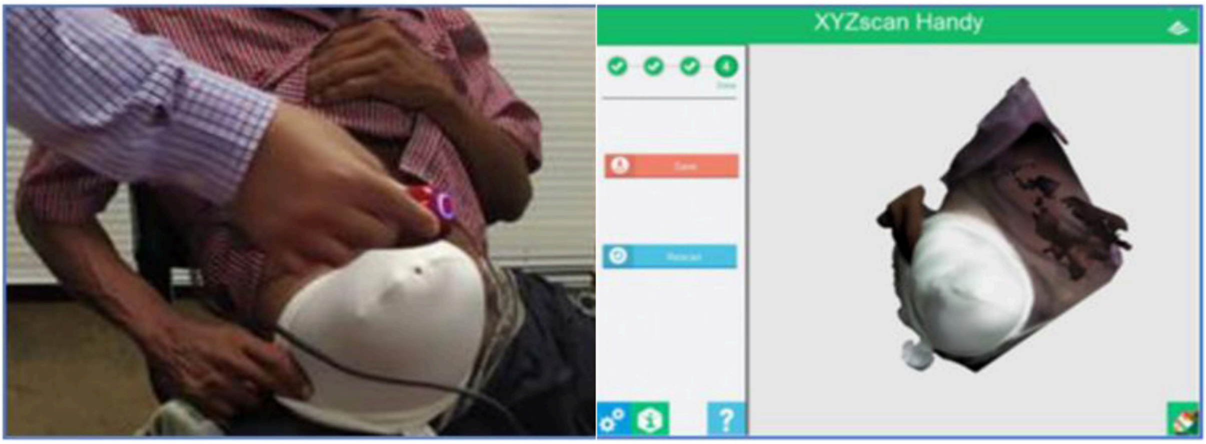

Figure 1. Digital scan of the patient's residual limb.

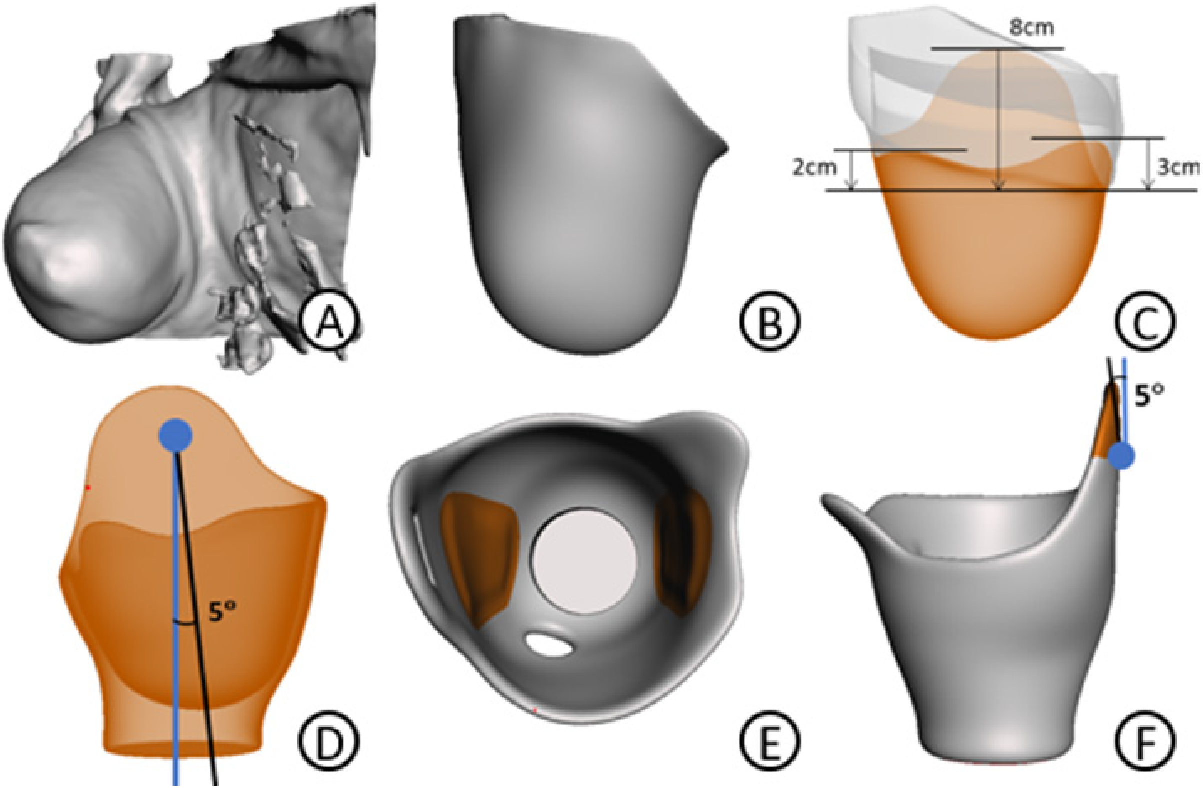

Figure 2. Modeling of the ischial containment socket.

out, eliminating the interferences and irregularities of the scan (A), those areas that did not correspond faithfully to reality were smoothed out and created the virtual mesh of the stump geometry that would serve as the reference model (B).

Next, following said reference, the socket was modeled (C). This was divided into two parts, a flexible frame capable of providing patient comfort and cushioning, and a rigid frame for weight transmission, similar to the Icelandic Swedish New York (ISNY) flexible socket system. In the design, the alignment with the rest of the prosthesis was taken into account considering 5º in the sagittal plane (D), and, in addition, an increase in material was made on the internal medial and lateral faces (E) with the purpose of generating a pretension in the muscles and channel the femur in the middle support (MURILLO et al., 2019). Its contour (C) was defined according to the parameters collected in (LÓPEZ GUALDRÓN et al., 2020), and the area between the head of the femur and the anterior superior iliac spine (ASIS) was rotated 5º in the frontal plane (F) to close the surface, thus adjusting it to the amputee's anatomy, and preventing it from separating with their weight and thus generating instability while walking.

SIMULATION

The gait cycle is a dynamic process, however, due to the complexity involved in carrying out this type of study, three static studies were chosen to bring together the most critical load situations produced during the march: heel strike phases, medium support and takeoff (GALLARDO RIQUELME, 2018). A simplified model of the rigid socket was used, in which the holes and grooves whose influence on the results were not relevant were eliminated.

Material

PLA was defined as a 3D printing material, with the properties obtained from (VILLAR, 2019), and it was assumed as a linear elastic isotropic material, since its plastic behavior was not of interest.

Boundary Conditions

A Fixed Geometry fixture was established on the lower distal face (Figure 3, green vectors) representing the adapter that would be placed on that face.

Loads

A contact pressure of 3.9 kPa was included in the distal, medial and lateral area and a

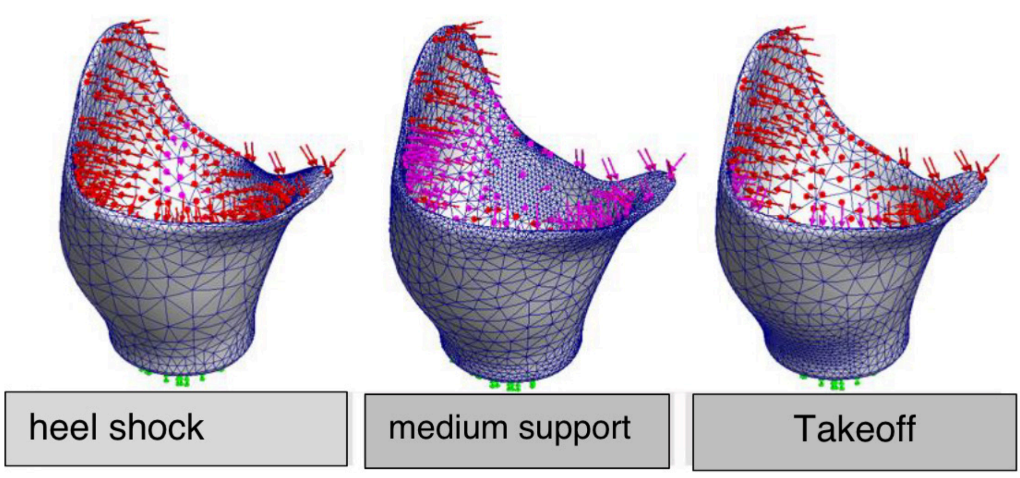

Figure 3. Study cases carried out for the simulation of the socket.

mean pressure of 0.9 kPa in the rest of the surface (Figure 3, red vectors), taking the study of Surapureddy as a guide (SURAPUREDDY et al., 2016).

On the other hand, the loads relative to the gait cycle were applied (Figure 3, pink vectors). In the half support phase, it was assumed that all the weight was supported by the amputated leg, and therefore the established force was 1000N (a weight of 100 kg was considered to go on the safety side). In addition, according to the theory, the load in this phase had to be assumed by the proximal part of the socket, so the force was distributed in the first third of it. In the heel strike and toe-off phase, half the patient's weight was considered, and therefore a force of 500N. In such situations, the difference occurred in the area of application, while in the heel strike phase the weight was concentrated on the posterior face, in the toe-off phase it was on the anterior face.

Meshed

A convergence analysis was performed with which maximum mesh sizes were defined as 15 mm in the mid-support phase, and 30 mm in the heel strike and toe-off phases. Likewise, in all phases a mesh control of 4.33 mm was applied in the areas that required greater precision.

ASSEMBLY

Once the socket was made, the rest of the prosthetic components were obtained, such as the knee, the adapters, pylons and the foot, and they were assembled to form the complete prosthesis. Their selection was based on previous bibliography (COLOMBO et al., 2013).

ECONOMIC VALUATION

The different costs assumed in the manufacture of the developed prosthesis were taken into account, contemplating both design and manufacturing costs, and also, the prices between which prostheses with similar characteristics oscillated on the market.

RESULTS

The results of displacements, Von Mises stresses and distribution of the factor of safety in each analyzed phase can be seen in Figure 4. In it, it can be seen how in the heel strike phase the displacements are maximum in the ischial region (U_{RES}=0.203mm), while the maximum stresses (σ_{VMmax}=2.67MPa) originate from the rear. Regarding the phase of medium support, the most relevant displacements are on the lateral face with a value of 1.678mm. Likewise, it can be seen that the base of the ring and the control area are the parts most affected by stresses, with a maximum of σ_{VM}=6.95MPa. On the other hand, regarding the detachment phase, the highest displacements were generated at the lateral end of the socket (U_{RES}=0.255mm), and relevant displacements were also distinguished on the anterior and medial face of the prosthetic component. In addition, the most significant stresses were on the anterior face of the socket, specifically in the distal area, with a value of 1.92MPa. Finally, the safety factor in all case studies is greater than 1.

Figure 5 shows the complete prosthesis and the surface tests performed on the patient, who commented that he felt comfortable with the anatomical adaptation of the rigid socket and the soft interface, expressing a high level of satisfaction with the developed product.

The final cost of the prosthesis was 265 euros, while the average cost of a prosthesis with similar characteristics on the market (basic socket adapted to the patient, monocentric knee and Sach -type foot) was 3,200 euros, therefore, the prototype

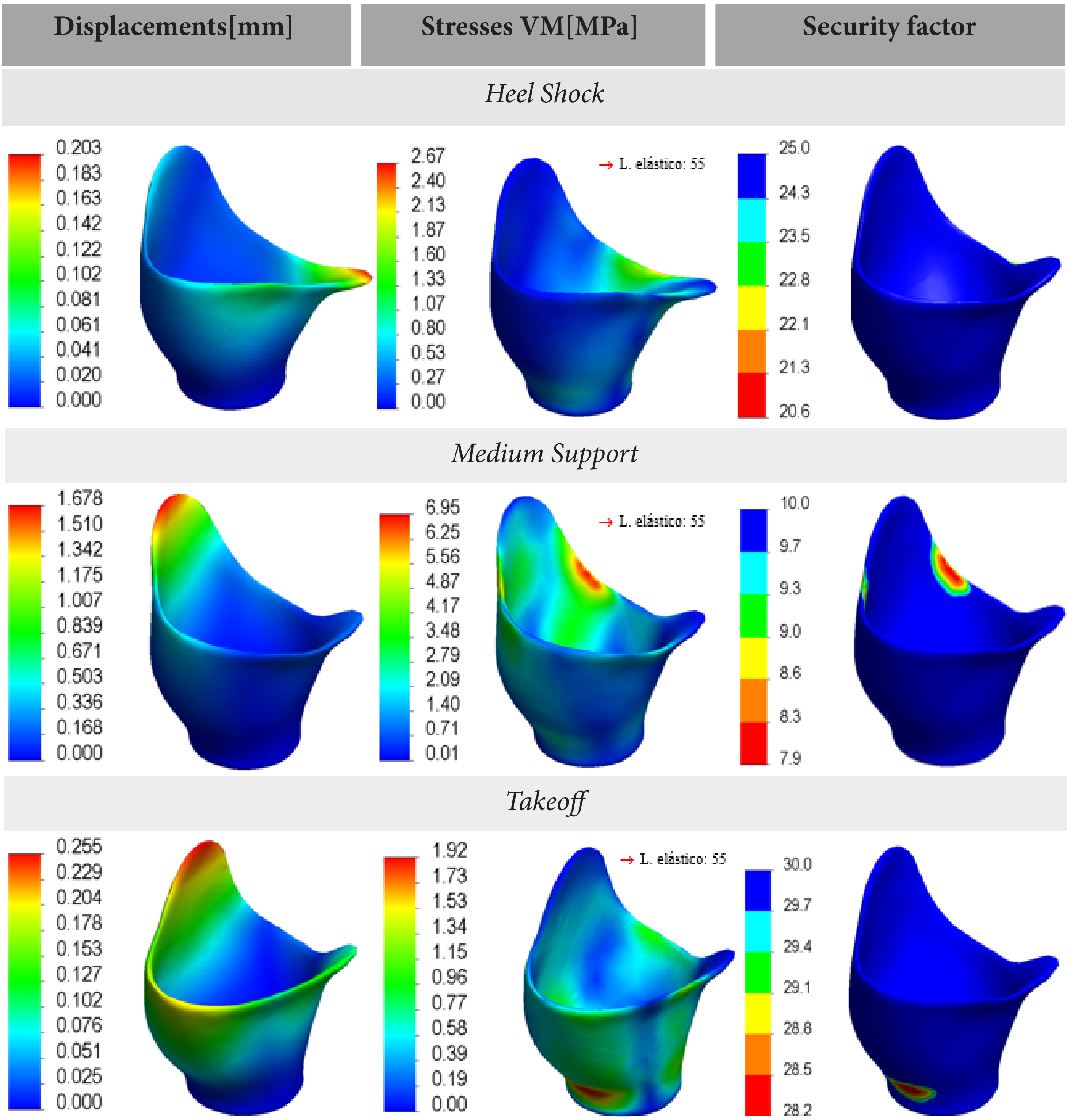

Figure 4. Results of Displacements [mm], Stress of VM [MPa] and FDS in the heel shock phase, medium support and takeoff.

Figure 5. Complete denture assembled (left) and adjusted to the patient (right).

represented an approximate cost of 92% below the price of a similar product on the market.

DISCUSSION

The objective of this project was to evaluate the feasibility of developing a prosthetic socket for a patient with a transfemoral amputation using disruptive technologies, with the final price of the prosthesis being more affordable than the rest of the prostheses available on the market.

Regarding the development of the prosthetic socket, the results showed that it was able to correctly satisfy its function. On the one hand, the three-dimensional characterization of the patient's residual limb was satisfactory for its subsequent modeling despite the fact that it required an initial debugging of interferences. On the other hand, the deformed that was observed in the assumed study cases corresponded to its prediction based on the location of the concentration of charges, and, therefore, the proposed simulation models were considered consistent with reality.

As it could be expected as it was the hypothesis with the greatest weight, the medium support phase was the one in which the greatest efforts and displacements originated, and as a consequence of supporting the force in the first third of the socket, the lateral part with less support is the one that had the highest displacement. In the heel strike and toe-off phases, the greatest stresses were generated according to the most susceptible geometric zones of the design for the established combination of loads, the ischial region and the distal anterior region, respectively. However, the greatest displacement in the takeoff phase, despite not receiving force, was caused in the lateral part due to the influence of the movement of the front face. Finally, the safety factor in all the cases studied guarantees the stability of the piece.

The behavior of the material agreed with the linearity assumptions that supported the analysis, so the error due to simplifications was treated as negligible. The stresses reached were well below their elastic limit, which was attributed to the force distribution throughout the selected surface. The PLA proved to provide sufficient rigidity to support the patient's weight and, therefore, it could be used in the final manufacture of the socket.

There are not many studies that evaluate the resistance capacity of the prosthetic socket, so it is difficult to compare it, although the orders of magnitude (0.003 to 6.95 MPa) are similar to the transtibial socket (0.44 to 5.068 MPa). analyzed in (ALVARADO SILVA et al., 2020).

Finally, the results obtained from the economic evaluation and the comparison with the market price confirmed that the prosthesis obtained met the requirement of low cost compared to the prices of other manufacturers. Likewise, the aspects related to the comfort and adaptation of the prototype to the residual limb consulted with the patient were satisfactory. However, more studies are needed to evaluate aspects such as durability or dynamic loads.

CONCLUSION

To consider the exposed results, it is possible to affirm the feasibility of developing an anatomical transfemoral socket for a lower limb prosthesis using innovative technologies, and, consequently, to reduce its price in relation to current available prostheses.

It was demonstrated that it is possible to develop this type of proposals through alternative procedures to conventional processes, managing to establish collaborative work digitally, establishing a precedent in which it was verified that disruptive technology in addition to contributing to the reduction of polluting waste and rework or inaccuracies due to the use of tools or manual work, it can also contribute to promoting multidisciplinary and decentralized work, the latter being demonstrated in a practical way in the fact that the place of characterization of the patient was different from the place of the stump scan, as well as modeling and 3D printing were carried out each in different locations, establishing an international work axis whose area of influence was Venezuela and Spain.

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