Towards Customized Medicine with Open-source Applications in Developing Countries: Foot Drop and Transtibial Prosthesis

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Abstract: Alterations in the normal gait can be enhanced to improve patients' quality of life. Although several devices improve these conditions, the technology to diagnose and create solutions is expensive. The present work focuses on developing a methodology to use free software and hardware to create solutions. The process starts gathering and analyzing the patient's clinical data; then analyze the human motion kinematics of the patient, so it is possible to customize and manufacture either an orthotic or prosthetic device. With the aim of implementing the methodology, two cases of study are presented in this work. The patient with foot drop presented an angular difference between the ankle and the toe of 10.10° ± 4.76°, which was corrected throughout the spring-like behavior of the material used for the 3D printing process. Further, the prosthetic device was a design with an ankle joint that allows the plantarflexion and dorsiflexion angles of 30° and 25°, respectively. Therefore, this methodology allows the diagnosing of the angular difference between joints during the normal gait and how to create either orthotic or prosthetic devices to reduce them. Hence, the present work aims to open doors towards the customization of medicine and rehabilitation, especially in developing countries.

1 INTRODUCTION

The foot drop is a gait abnormality commonly associated with several causes such as weakness of the plantar flexors or the dorsiflexor muscles, lesion of the peroneal nerve, spinal cord trauma, abnormal anatomy, and neurological dysfunction (Stewart, 2008). A patient uses an orthosis or prosthesis as an extension of their body to help to improve the gait. This interaction and its complexity can be seen as a biomechanical system that needs to be attended by physical therapists and engineers during the rehabilitation process. Hence, it is necessary to develop methodologies for the rehabilitation process that consider the entire biomechanical interaction and the orthosis or prosthesis (Bedotto, 2006; Stewart, 2008).

Among the alternatives to improve this condition, the use of the "L" shaped foot-up ankle support (ankle-foot orthosis AFO) has proved to be a non-surgical resourceful option (Lenhart and Sumariva, 2008; Bedotto, 2006; Stewart, 2008). Another method uses a cuff placed around the ankle, a topside spring, and hook installed under the shoelaces. The hook connects to the ankle cuff and lifts the shoe when the patient walks. We can also find complex mechanical solutions using a passive actuator composed mainly of a gas spring and a cam to lift the foot (Rodriguez et al., 2018), or using superelastic springs based on nickel-titanium alloys (Amerinatanzi et al., 2017; Rodriguez et al., 2018).

On the other hand, another lower limb disability condition is transtibial amputation. This procedure is performed to fully remove the lower limb (below the knee) damaged due to trauma, congenital disease, or diseases like diabetes. Most commercialized transtibial prostheses are energetically passive, whose main disadvantages are nonsymmetrical gait patterns and walking at lower speeds. Additionally, the metal ankle joints provide a characteristic weight to the prosthesis, which produces around 20% to 30% more metabolic energy consumption for the amputees (Au et al., 2009). In this line, some solutions based

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on powered transtibial prostheses are actually gaining popularity. However, its main disadvantages are the high price and the requirement of an additional source of energy. Other little-explored alternatives for the fabrication of transtibial prostheses are those based on additive manufacturing. In this line, the development of new materials and the feasibility to elaborate complex forms makes them a promising technology.

Healthcare is moving towards the philosophy of being predictive, preventive, personalized, and participatory, which is commonly known as P4 medicine (Hood, 2008). This is achieved by digitalizing medical information and processing this information in real-time (Flores et al., 2013; Morley and Vellas, 2017; Pulciani et al., 2017). Thus, it may be possible to improve patients with lower limb disabilities by implementing patient-centered methodologies (Creylman et al., 2013; Salles and Gyi, 2012; Salles and Gyi, 2013). For the design and manufacturing of prosthesis and orthosis, the computer-aided design (CAD) and modern manufacturing techniques appeal to a particular interest like the 3D printing techniques, due to their versatility to create complex geometries that may not be feasible with other manufacturing techniques (Telfer et al., 2012; Dombroski et al., 2014; Jin et al., 2015; Baronio et al., 2016). Although the cost of these technologies can be a considerable restriction, especially in developing countries, it may be possible to overcome these difficulties with open source technologies (de Souza et al., 2017; Loayza et al., 2018; Tack et al., 2016).

This work aims to develop a methodology to customize the design and manufacture of orthotic and prosthetic devices for patients with foot drop and transtibial amputation. Besides, the entire methodology is developed with free software and hardware. The present study was carried out in collaboration between the ESPOL Polytechnic University and the Teodoro Maldonado Carbo Hospital (hTMC), from Guayaquil, Ecuador.

2 MATERIALS AND METHODS

The methodology implemented in this work considers the next steps: 1.) Patients clinical data, 2.) Human motion kinematics, 3.) Data analysis, 4.) Customized design, and 5) Implementation and Validation.

2.1 Patients Clinical Data

The first patient was a 45-year-old man with a height of 1.65 m and 88.6 kg of weight. The patient presents a foot drop at his right foot, which was diagnosed as an alteration in the nervous systems by an expert traumatologist (GS). Besides, we recruited a control subject to obtain the motion kinematics data: a 24- year-old male volunteer with a height and weight of 1.64 m and 73 Kg, respectively. The second patient, a 60-year-old man, 72kg. of weight and 1.68 m. height, presents a transtibial amputation of 15 cm. below the right knee, this due to complications produced by diabetes type II. Patients and control subjects signed the informed consent approved by the university review board.

2.2 Human Motion Kinematics

The analysis of the human motion kinematics plays an important role in characterizing the normal gait of the patient. This analysis was performed only for the patient with foot drop. We used motion capture technology to obtain the motion parameters of the subject. Human motion measures were assessed during multiple trials of treadmill walking of the foot drop patient and the control subject. Walking speeds were initially determined by the patient at speeds that he felt comfortable walking with running shoes at 0.5 m/s, with increments and decrements from 1.0 m/s to 2.0 m/s. Normal speed was 1.0 m/s because, for speeds of 1.5 m/s and 2.0 m/s, the patient had to hold on the treadmill to be able to walk.

Previous to the AFO customized design, we assess the patient motion kinematics to obtain the angle and force required for the design and the conventional shoe measurements. To assess the influence of the AFO on the behavior of the lower limb joint angle, the patient performed two walking trials with four markers placed along each leg: at the hip, the kneecap, the heel, and at the toe. These markers were placed carefully at each joint as a reference for further calculus and analysis. During the first trial, used as a control, the subject walked without the AFO and using his conventional shoes. For the second trial, the patient wore the AFO on the left foot. The data acquisition was performed using an iPhone 8 camera of 1080 pixels located over a tripod at a 2 m distance from the treadmill. The camera was recording at 60 frames per second (FPS) for both legs. The recordings were made on both sides of the subject to get a better perspective of the movements of both legs. Each recording of the elapsed time for each leg was of 20 seconds, equivalent to approximately ten gait cycles.

2.3 Data Analysis

For the data analysis, we used the software Tracker® (Tracker video analysis and modeling tool) and

Python®. The software tracker® let us analyze the regular gait video, display the markers, and discretize the positions within the recording time. Python was used for the corresponding analysis and plotting results. For each recording (6 previous and 6 wearing the AFO), we measured each angular position of the joint, frame by frame. The measured data was plotted to select a time window of 10 gait cycles after reviewing it for a constant period (Figure 1). Further, each gait cycle was split out, and then we obtained the average and standard deviation for each angular data point of each joint, previously checking for its normal distribution. Finally, the average of the angular position and its corresponding standard deviation of the data points were plotted by using Python® as is shown in Figure 2. to obtain the average values of the angles and standard deviation and calculate the necessary angular compensation of the foot drop in reference to the healthy foot.

2.4 Customized Design of the Orthosis

With the dimensions of the leg and the food, it is possible to adapt an orthotic device to the anthropomorphic characteristics of the patient. The orthotic device dimensions were defined with the CAD software, which allows parametrizing and easily making changes. The manufacture of the design was executed with a 3D printer (Creality®, model CR-3040s). The orthosis was divided into six parts, where five of them work as rigid components printed with PLA at 40% of triangles infill, at 200°C, 0.2 mm resolution, 1.2 mm wall thickness and 8 hours of print time. The flexible component, which works as spring-like behavior, was 3D printed with TPU at 50% infill at 235ºC, 0.2 mm resolution, 0.8 mm wall thickness, and 10 hours of print time. All components were designed using FreeCad and then exported as STL format.

2.5 Orthosis Implementation and Validation

Once the device was implemented, the gait of the gait was recorded to process the information in the tracker® analysis software and plot the data obtained in Python® to compare the three cases: foot drop without orthosis, foot drop with the orthosis, and the healthy subject.

2.6 Prosthesis Design

king anthropometric measures of the left leg. This lets us design the prosthesis according to their anthropometric measurements.

The prosthesis was divided into two elements: the foot and the shank joined via a bolted joint at the ankle. According to the requirements, the complete shank, including the socket, was designed to be printed as a rigid component with PLA or ABS. The foot, instead, including the ankle, was designed to be printed as a flexible component. The idea was to take advantage of the flexibility of the material to provide an adequate rotation at the joints, of both the toes and the ankle, as well as vertical cushioning.

To design both components, we used Blender software version 2.8. The shank was designed as a solid element down to the socket base, as shown in figure 5A. The prosthetic right foot was designed base on the anatomy of the left foot. To give it flexibility and rotation in the ankle and toe joints, like a flexible hinge, some groves were made in both sides of the instantaneous center of rotation, as shown in figure 5B. These flexible hinges were tested in the first design under the working condition with the weight of the patient. After several tests, we found that the flexible hinges deteriorated only at the ankle joint, due to the vertical load. After two additional iterations and tests, the final design of the flexible joint at the ankle was the incorporation of two S-like springs that can work as tendons and ligaments attached to the shank, as shown in figure 5B-2.

Before printing the final foot, we estimated the printing parameters according to (Mutlu et al., 2016). Additionally, we performed two experiments to estimate the percent of infill. For that, we created a foot part that includes only the flexible knee joint. Then, this part was printed twice with two different infill settings: 50% and 20%. Further, those parts were subjected to rotational deformation with the application of different torsion loads.

The manufacture of the components of the prosthesis was performed with the 3D printer (Creality®, model CR-3040s) with the following parameters: the shank was printed in one piece with PLA, and 30% of triangles infill at 200ºC, 0.4 mm resolution, 1.2 mm wall thickness and 53 hours of print time. The foot was printed with TPU with 25% of triangles infill at 235ºC, 0.2mm resolution, 0.8 mm wall thickness, and 55 hours of print time.

3 RESULTS

This section describes the results for the two patients, the foot drop and the amputee patient.

3.1 Foot Drop Patient

The normal gait of the patient was recorded at 1 km/h, where the curve represents the angle of the ankle dorsiflexion/plantar flexion. Three different cases are plotted in figure 1 and 2 for this study; healthy foot, drop foot without orthosis, and drop foot with an orthosis. Additionally, the orthosis 3D model is presented in figure 3 and 4 shows the patient wearing the AFO on the treadmill.

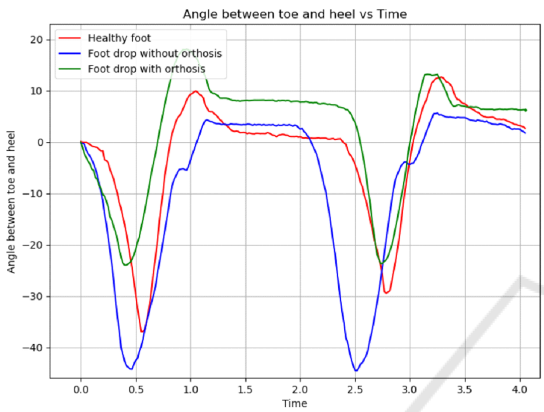

Figure 1: The curve of the angle between toe and heel vs. time. The red line corresponds to a healthy foot. The blue line corresponds to the foot drop patient without orthosis. The green line corresponds to the foot drop with an orthosis.

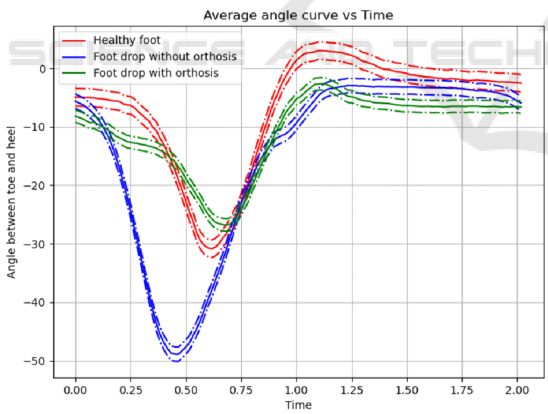

Figure 2: The average curve of the angle between toe and heel vs. time. The red line corresponds to a healthy foot. The blue line corresponds to the foot drop patient without orthosis. The green line corresponds to the foot drop with an orthosis.

The measurements of the normal gait were recorded at 1 Km/h to feel comfortable during the recording process. The peak values of the angles of each curve were chosen to calculate the average and its standard deviation, and both angles were subtracted to obtain the necessary compensation of the foot drop. The difference between the patient's healthy foot compared to his dropped foot is in the value of the angle that the toe presented with respect to the heel, causing a difference of 10.1 degrees between both cases. This occurs because the dropped foot causes a person to drag their foot while walking, which increases the angle between the toe and the heel.

It was necessary to correct the angular difference because continuing to drag the foot during walking may cause the thigh to rise at the moment of the march as if one were climbing stairs. This causes the foot to hit the floor with every step. As in most patients, the upper skin part on the foot and toes is sensitive to the impact created by the movement.

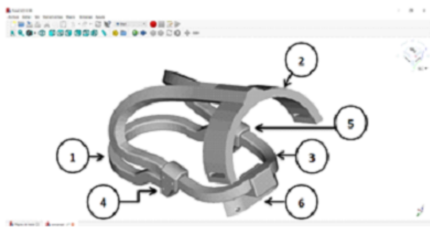

Figure 3: Shows the design of the prosthetic device performed in FreeCad. This model was then exported in STL format, which was 3D printed in a flexible material (TPU).

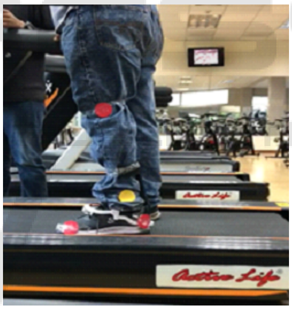

Figure 4: Depicts the tracking measures performed with the foot drop patient using the treadmill.

The angular difference between both feet was related to the deformation that flexible material can have so that the angles of the toes of both feet will be similar. To achieve this, it was necessary to consider the force required to maintain the foot in the natural position during the normal gait; thus, the drop foot moves approximately like the healthy foot.

3.2 Amputee Patient

After removing the support material in both 3D printed elements, the following table summarizes the results. Besides, the prototype is shown in figure 5.

The plantarflexion and dorsiflexion angles obtained for the ankle joint were 30º and 25º, respec-

Table 1: main settings of the printed elements.

Element	Foot	Shank
Print time (h)	55	53
Print temperature (ºC)	235	200
Material	TPU	PLA
Resolution (mm)	0.2	0.4
% infill	25	30
Infill type	triangle	triangle
Weight (g)	490	220

tively as is shown in figure 6. For the toe joint, the angular rotation for this flexible hinge was 36º in both directions. The total cost of printing both items was USD 80.00, including the material and the printing itself.

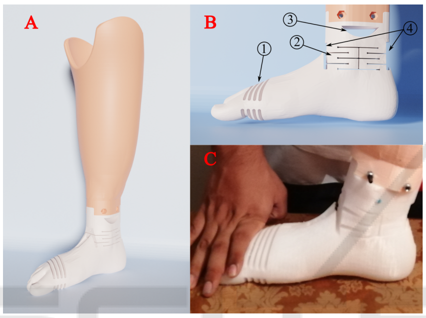

Figure 5: Panel A depicts the assembling of both elements. Panel B shows the foot printed with flexible material where 1 is the flexible hinge for the toe, 2 the flexible hinge for the ankle, 3 the cushioning element, and 4 two slots are shown with their respective holes that allow an elastic band to be added by screws on each side to complement the elasticity of the ankle joint if necessary. Panel C shows the printed foot.

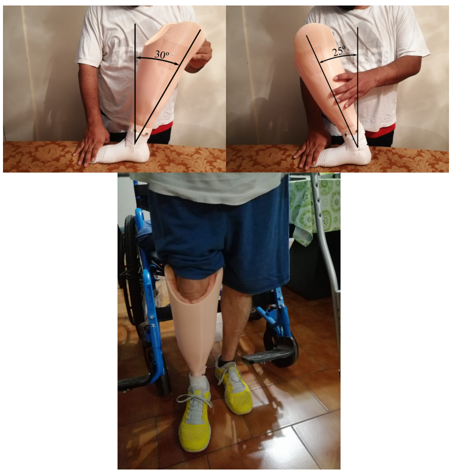

Figure 6: Upper left, it is shown the plantarflexion angle and, on the right, the dorsiflexion angle. The bottom picture shows the patient wearing the prosthesis.

4 DISCUSSION AND CONCLUSIONS

In this work, two customized solutions 3D printed are presented. The first solution was an orthotic device for a patient with a foot drop, and the second solution consists of a transtibial prosthetic device for an amputee patient. In both cases, we used a combination of flexible and rigid material printed with the FDM technique.

Currently, there are several designs and methods to manufacture lower limb orthosis. Nevertheless, not all of them represent viable options due to the cost of software and manufacturing equipment. Thus, the choice of using free software and hardware is appealing for these types of applications, especially in developing countries. For example, the manufacturing cost of this case study was USD 55. In the same line, the majority of commercial transtibial prostheses are manufactured using expensive techniques and materials that, in many cases, are unaffordable for low-income patients.

Even though the free software helps achieve the objectives of this project, it always is possible to improve the designs. Current applications in this area use active parts, which represent a significant advantage towards rehabilitation. Nevertheless, the cost increments, and the more components are used, the higher is the probability of failure during operation. Therefore, the present work considers the use of simple components and designs. Additionally, as the manufacturing price has dropped considerably, it is possible to create different designs with the purpose of rehabilitation and testing. Although, it is necessary to make a trade-off between potential environmental effects of the manufacturing and the designs before moving forward in this direction.

It is important to mention that only the case of the patient with foot drop was validated through a human motion kinematics analysis. The case of the transtibial amputation was not possible to evaluate the human motion kinematics because the patient was within the phase of physical rehabilitation and was still getting used to the prosthetic device.

For future work, the methodology presented in this work needs to be applied to a larger number of cases, of each type of medical condition, either foot drop or transtibial amputation. Thus, it may be possible to make a clinical analysis.

4.1 Conclusion

With the proposed methodology in this work, it is possible to fabricate orthotic and prosthetic devices through 3D printing techniques, taking advantage of the characteristics of different materials available in the market. Further, devices that can improve the foot drop and amputee problems using free software and hardware are suitable for developing countries.

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