

Proposal of Custom Made Wrist Orthoses based on 3D Modelling and 3D Printing

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Abstract — Accessibility to three-dimensional (3D) technologies, such as 3D scanning systems and additive manufacturing (like 3D printers), allows a variety of 3D applications. For medical applications in particular, these modalities are gaining a lot of attention enabling several opportunities for healthcare applications. The literature brings several cases applying both technologies, but none of them focus on the spreading of how this technology could benefit the health segment. This paper proposes a new methodology, which employs both 3D modelling and 3D printing for building orthoses, which could better fit the demands of different patients. Additionally, there is an opportunity for sharing expertise, as it represents a trendy in terms of the maker-movement. Therefore, as a result of the proposed approach, we present a case study based on a volunteer who needs an immobilization orthosis, which was built for exemplification of the whole process. This proposal also employs freely available 3D models and software, having a strong social impact. As a result, it enables the implementation and effective usability for a variety of built to fit solutions, hitching useful and smarter technologies for the healthcare sector.

I. INTRODUCTION

According to the American Academy of Orthotics and Prosthetics, the number of people using orthoses is expected to increase by at least 31 percent. For instance, the number is estimated to reach 7.3 million by 2020 [1].

Regarding the manufacturing of orthoses, there is a variety of techniques already developed and still under development. Although the most promising techniques are related to additive manufacturing (AM) production, since the continuous evolution of newly materials are getting better, while the cost of the various AM technologies is decreasing [2, 3]. Therefore, all these benefits are leading to the standardization of orthoses and prostheses manufacture, which provides better treatments and improvements at the rehabilitation processes [3, 4].

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In general, orthoses are responsible for the application of strength at specific points, which may contribute for treating different dysfunctions and fractures. The efficiency of an orthosis depends on the force and place of application, which may also help at specific treatments [2]. It has been reported that users, who need to wear orthoses for long periods, mentioned that the ergonomics is one of the crucial factors for customers' satisfaction [2, 3]. Regarding immobilization orthoses, especially the ones worn after surgery, or due to fractured limbs, there are not many options available in the market. Most of the commercial models (available in large scale), consist in having both economic viability and being rentable for the manufacturer. But such models do not provide a satisfactory variability concerning size and ergonomics [2, 5]. In addition, since there is a huge variation in terms of human body's dimension, the task of providing a variety of ergonomic sizes for every patient, ended up being a very complicated job. So, at most cases, the orthoses are built based on pre-determined models, which is much easier.

Recently, there is a variety of different and innovative designs being proposed, based on 3D printing technologies. For example, The Jake Evill's cortex design [6, 7] is based on a 3D exoskeleton. The cortex's functionality is for substitution of plaster molds, as it is mainly due to fractures' immobilization. However, it is not re-usable, because of its socket's fitting, which once open it could be broken. Following similar styles, other designs are also gaining attention. For instance, the AmphibianSkin is a new high-tech medical device made by 3DMedScan [8, 9].

For specific cases, some orthoses can be built in a unique and personalized manner. For this situation, a specialized staff takes measurements directly from the patient's body, which will receive special manufacture, then building a unique orthosis. However, this process is very demanding, in addition to the high costs (which is mostly covered by the own patient) [2]. Additional complication arise when the patient is young (i.e. still under development). In such cases the orthosis requires periodical adjustments according to its growing, resulting to additional costs to the family.

Therefore, this paper proposes a new methodology for generating orthoses, which is adapted, built and fitted following specific application requirements. Additionally, it is also proposed better accessibility to the available technology for building orthoses and for sharing such knowledge. This is important in order to fit different patients, allowing to scale each owns measurements and creating it accordingly. This approach could be extend to developing, low and middle income countries, as a way to provide smarter technology for the healthcare sector.

II. 3D MODELLING FOR ASSISTIVE TECHNOLOGY

Before proceeding to the presentation of the methodology, it is worth to describe all the technologies being employed in this research, such as: 3D modelling and additive manufacturing for assistive technology purposes.

A. 3D Modelling

Accessibility to 3D technologies, such as 3D scanning systems and 3D printers, allows a variety of three-dimensional applications [10]. Specifically for medical applications, these modalities are gaining a lot of attention and present several opportunities for health related applications [11, 12].

The possibility of obtaining both digital and real 3D models makes possible a variety of projects that earlier were considered impossible [11], such as organs, vascular veins/arteries, body parts restoration (e.g. ears, noses, face, eyes and even skull, among others) [4, 13]. So, these innovations consist in motivation for additional developments, especially related to assistive technology.

The 3D modelling stage consists of generating a 3D digital model (obtained either from a CAD software or from a 3D digitizing system). Next, specialized software is able to read the 3D digital model and interpret as a set of layers.

B. Additive Manufacturing – 3D Printing

The previous step leads us to the additive manufacturing phase, which consists of adding successive layers of material (such as polymers, metals, and even organic materials) in order to form a three-dimensional real model [4]. The final part is the actual building process, which is adding materials, layer over layers.

Such manufacture has a potential for growing even more, involving a variety of applications. According to Schuber *et al.* [14], up to 2020, it is expected an increase of about US\$ 1.9 billion, regarding health applications within additive manufacture. There are a variety of areas contemplated by the additive manufacture, such as prostheses, orthoses, equipment and even biological tissues. The main innovation of this area is related to the availability of the digital files, enabling a system decentralization. This means that these files can be shared, exchanged, and easily interpreted through the web (worldwide). So, this leads to accessibility not only to the files but also to the available methodologies for fabrication, which can be shared as well [14].

C. Assistive Technology

This paper presents the application of the techniques described here (such as 3D modelling and 3D printing) with the purpose of creating orthoses. So, this consists of a specific application related to assistive technologies.

Assistive technologies involve the development of products and services aiming to help people with special needs [15]. These facilities might increase functionality, independence, and improve the quality of life for these people. Most of the products can be made employing 3D technologies, which results in personalized products with better fitting, as it also allows speed up of the fabrication process. If compared with the traditional methods, the use of

3D technologies helps in terms of creating comfortable, custom made and functional products [11].

Additionally, when planning the creation of a tool to be used for assistive technology purposes, it is necessary to know the final customers, such as their needs, challenges, tasks and expectations, and mainly their remaining and residual abilities, in order to supply orthoses for their personal and environmental barriers [5, 16].

III. METHODOLOGY

Since it is presented a case study, a brief profile of the volunteer is provided below. The patient is a 24 years-old male, who suffered a distal radius fracture at the left wrist. Due to this condition, he was submitted to an open reduction and internal fixation (ORIF) surgery, based on fracture's fixation with a plate. After the surgery, he had to wear an orthosis for immobilization while healing, for a period of about 45 days.

It is worth to mention that most of the orthoses available on the market are uncomfortable, do not fit properly, ending up being not very functional (which does not help in daily activities). Therefore, in order to overcome such disadvantages, we propose a new methodology for covering the orthosis' needs for this specific case study.

The orthoses or prostheses manufacture, which are custom made and with a low-cost development can be a solution, allowing accessibility for population in need. This approach allows the use of technology expertise, while reaching a large population worldwide. So, this paper presents such alternative for generating orthoses, which employ a light, clean, washable material, based on 3D modelling and additive manufacturing (3D printing). In addition, there is a possibility for training non-technical people in order to extend such technological inputs for solving healthcare related issues. So, this new proposed and differentiated methodology is detailed in the next four steps below:

A. 3D Modelling: Acquisition of the 3D wrist geometry

This step consisted of the acquisition of a virtual 3D geometry of the region under study. The main purpose of obtaining a 3D model is related to provide a best fitting for the orthosis. Although when cost is an issue, this stage could be discarded. Then, as alternative, some of the measurements could be provided directly by the volunteer.

For the geometry acquisition, there are two options: either to digitize the anatomic region directly, or to make a cast model (i.e. a negative impression, based on a plaster of Paris bandage). Nowadays, apart from the commercial 3D scanning systems available, there are a variety of options for obtaining 3D models from images. This means that with several photographs around the volunteer or the cast model, it is possible to obtain 3D models useful for medical applications. So, just to report alternatives of low-cost procedures, the software ARC3D (Automated Reconstruction Conduit) can be mentioned. This software or set of tools allows users to upload digital images into cloud servers, and it returns 3D models of the object/scene.

In this case study, since we have access to a commercial 3D scanning system, we chose to get the 3D virtual geometry directly from the volunteer's wrist (just for better guiding us during the process). We employed a hand held system, model REVScan, from Creaform Ametek [17] which is based on laser scanning. In order to illustrate the 3D geometry obtained for this volunteer's case study, it was acquired the 3D hand/wrist's model, as shown in Fig. 1. It is perceived from the 3D model that the hand/wrist's geometry was captured at his natural position, and the scanning of the fingers were not obtained in details, as this orthosis would fit only the region near to the wrist/carpal area.

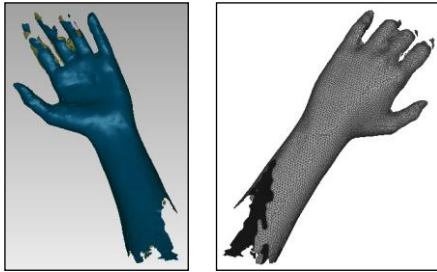


Figure 1. 3D hand/wrist's geometry obtained with a handscanner.

B. Volunteer's Measurements and Scaling

In this scenario, appropriate measurements can be taken either directly from the wrist, or from the 3D digital model. In our case, the measurements were taken from the digital model, using MeshLab freely available software [18]. This allows a best fitting for each volunteer. So, one of the measurements that provides better comparison was the broader region of the hand/wrist, which is in the carpal region. These measurements are necessary for enabling to scale the original pattern model (Fig. 2), based on the transformation of this original STL file for the generation of the new orthosis (Fig. 4).

C. Fabrication: Additive Manufacturing - 3D Printing

The literature reports different steps for the production of orthoses, which employ both additive manufacture and 3D scanning. For example, in Jin *et al.* [2], the main steps are: (1) 3D scanning of the member directly; (2) Measurements from the 3D model; (3) 3D Modelling using CAD software; (4) Production by additive manufacturing (3D printer). While the first steps may vary depending of the methodology, the common (final) step includes the manufacturing using a 3D printer.

In this paper, we also culminated with the 3D printing step; however our methodology differentiates by employing freely available 3D models (Fig. 2). Such standard models are available online at the STL format files. The advantage of this approach is that it allows sharing, alterations (such as in different scales) and can be easily reproduced.



Figure 2. Original pattern model of the orthosis (Source: <http://www.thingiverse.com/thing:403001>).

For the 3D printing step in this paper, a low-cost 3D printer - model Graber i3 was employed [19]. A PLA (polylactic acid) based material, was used mainly due to its cost (about US\$ 40 per kilogram). Also, this material is commercially available and it is biodegradable.

D. Volunteers' fitting

The final step consists of the fitting of the orthosis to the volunteer, based on his clinical conditions and own dimensions. This is done based on the thermo-molding properties of the material employed, which can be molded either in heated water bath or blowing air.

Since the purpose of this project is to provide a low-cost and widely accessible solution, it was chosen to employ the available pattern (Fig. 2) and then to fit accordingly to the patient's own measurements. Then, the proposed solution for this is to scale the STL file, based on a range difference from the original pattern model.

IV. RESULTS

Some measurements have to be taken for each patient, in order to provide best fitting for the orthosis. For the case study presented here, the measurements were taken and a scale was applied for both X and Y axes. At the Z axis there is no need for changing (since it relates to the thickness of the material, which is standard). This scale is performed at the program that is responsible for the interface with the rapid prototyping machine. The software employed in our case is the *Repetier* [20], which interface is shown at Fig. 3.

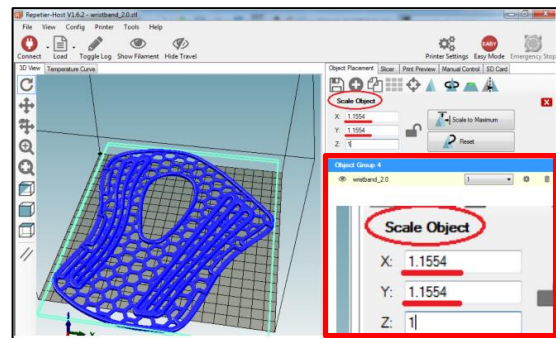


Figure 3. Representation of the software used for the 3D printer (Repetier) and the respective scale applied for the volunteer's fitting.

For this study, the manufactured orthosis's mass is 53 g, which means a material cost of only US\$ 2.40. Regarding the time for building, it took 45 min to be completed, using the basic 3D printer model Graber i3 [19]. However, this time could be even reduced, by changing the machine or fitting other parameters for fabrication.

In order to demonstrate the obtained results, Fig. 4 presents the orthosis being worn by the volunteer. This orthosis covers the basic requirements, such as: low-cost, accessible manufacturing process, light design, clean, allows easy cleaning (as it is washable and shower friendly), custom made (i.e. involving the volunteer's measurements), and finally optimized fitting.



Figure 4. Orthosis manufactured and worn by the volunteer of the proposed case study.

It is important to mention that the main purpose of this project consists in become available all the process, allowing that any hospital or clinic could provide accessible orthoses for immobilization purposes (especially for remote regions, low and middle-income countries). Additionally, we have been working on making this technology available and enabling non-trained staff to operate and go through the whole process. The idea is to be delivering a complete recipe/tutorial (step by step) allowing the process to be delivered and accessible worldwide.

V. DISCUSSION AND CONCLUSION

Three-dimensional (3D) technology has been used widely in the medical field. In most cases, the use of 3D modelling and AM can successfully improve the medical outcome. However Tack *et al.* [12] showed that only 14% of the investigated studies supported this statement by real numbers, while most of them are subjective. Despite this potential for increasing and sharing these technological advances, their impact is still small. For example, a recent survey concluded that from a total amount of US\$ 700 million, only about US\$ 11 million have been dedicated to healthcare applications (which represent about 2% only) [14].

Therefore, this research is being extended in order to provide enough details about evaluation, efficacy and durability analysis of the manufactured orthoses. Although, most of these evaluations are very subjective, which are mainly based on questionnaires. So we are performing more technical evaluations comparing different orthoses' styles within the same purpose.

It is worth to mention that a possible extension of this research is related to the implementation of a proper user interface. Such an interface will be accessible worldwide; therefore, this methodology will be shared, enabling to manage both the interface and the 3D models freely. Also, this will allow any non-trained staff to be able to deal with this orthosis fabrication process. Hence, that is the main reason for the creation and sharing of such interface.

One of the main advantages consists that this proposed orthosis' manufacture can be performed at any 3D printer available onsite, or even to forward the model to a nearest printer. So, this represents a global trendy towards the maker-movement and the open source community.

Overall, the proposed methodology presents a number of advantages, which are important points to be highlighted, such as: low-cost, freely accessible worldwide (mainly due

to the sharing concept), custom made (based on the volunteer's measurements), having a light design, functional, washable and biodegradable material.

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