Orthotic prototype for upper limb printed in 3D: A efficient solution

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Abstract. Traditionally a limb that has suffered a fracture, rupture or dislocation is immobilized with plaster, a procedure that generates discomfort in the patient to take a shower, besides producing excessive itching and sweating, stimulating the growth of the bacteria and leading to an odorous form, unhygienic and difficult to keep clean of treatment. On the other hand, if the plaster remains for a long period, it can cause injuries in joints and ligaments. This project describes a methodology of manufacturing a prototype of orthosis for upper limb printed in 3D, through additive manufacturing and reverse engineering, technology that is presented as an excellent alternative to solve the problems of traditional plaster molds. The model of the orthosis is obtained through the Meshmixer software and the structural viability of the design is studied using methods of finite element analysis and biomimetics, to guarantee the best possible mechanical properties. The realization of this work provides a custom-made prototype orthosis, a more comfortable, hygienic and aesthetically pleasing solution, which in turn allows the reduction of the time of use of the plaster molds.

1. Introduction
The orthoses are medical devices used to support weak or ineffective joints or muscles. As for the upper limb and particularly the pulse joint, this is a complex and delicate structure that is subject to various types of injuries, and where the use of orthoses is commonly indicated as a complement to therapy. Traditional methods for custom orthoses consume time and resources, and depend on the skill of the technician, not always guaranteeing the best possible fit. In this way, factors such as discomfort, hygiene and aesthetics influence the acceptance and correct use of the orthosis, which normally fails [1].

Custom orthoses offer superior fit and comfort and, in many circumstances, can be less bulky than over-the-counter items. In addition, they retain their shape at all times, while standard items must be adjusted every time they are put on, and it is not always possible to replicate the precise fit every time. The use of additive manufacturing (AM) technologies in orthopaedics is becoming a viable option because it meets the function, aesthetics and user-fit requirements for orthopaedic devices [2].

AM technologies enable the direct fabrication of new objects from three-dimensional (3D) model data, layer by layer, eliminating the need for auxiliary resources and allowing greater complexity of shapes that cannot be obtained through subtractive fabrication processes [3].

New technology for manufacturing using reverse engineering (II) and 3D printing has been gradually introduced into orthopaedic treatment. These new technologies allow the construction of three-dimensional models of human body structures based on virtual anatomical information. Today, physical
objects with complex geometry can be manufactured in a wide range of materials and sizes, from plastics and metals to biocompatible, and from large models to microstructures [4].

Finally, through this research, the possibility of designing an orthosis was evaluated, performing structural simulation based on finite element analysis (FEA), and making use of biomimetics to guarantee a structurally viable product; in addition to comparing the methods of the current orthosis production process with the traditional ones, in factors such as time and manufacturing costs, in order to obtain the design of a prototype of a lighter, removable orthosis with the possibility of ventilation for the upper limb.

2. Methodology
The AM is a technology that allows to reach a high level of customization, requiring a geometric process. The model of the orthosis to be performed requires a reverse engineering (RE) process that precedes the implementation phase. The three main phases of an RE, for orthosis using 3D printing technologies are the acquisition of the 3D geometry of the anatomy concerned using the scanning method, in this case, by structured light; followed by the processing of the data acquired through software; and finally, the realization of the orthosis using a 3D printer [5].

2.1. Acquisition of three-dimensional geometry
The member's model was obtained by means of the structured light scanning system, which emits light lines of different patterns from a fixed source, obtaining the coordinates corresponding to each point of the scanned models, as well as their colors and textures. All this through the spectra 3D handheld optical scanner, which allows you to electronically capture a high-resolution 3D model in seconds, without any patient contact or the complication and discomfort of the plaster. This, in turn, is supported by the Canfit software that allows scaling, rotating and bending with precision and anatomical accuracy, and which then transforms the scanned data into a point cloud, which digitally represents the real anatomy, and which in turn becomes a polygon mesh that is exported as an standard triangle language (STL) file for further processing [6].

In this case, the 3D scan of the member was performed at the Oh Lab Laboratory belonging to the AMR mining rehabilitation association, Belo Horizonte-Brasil. The 3D exploration (Figure 1) was performed in 10-15 minutes, due to the complex shape of the limb and its involuntary movements. Figure 2 illustrates how the results were visible in real time through the software.

![Figure 1. Member scan using 3D Scanner Spectra™.](image1.png)

![Figure 2. Member scanned in STL format.](image2.png)

2.2. New design
For the execution of the model proposed in the objectives of the project, a structural simulation based on FEA was carried out in the projected model; in addition it was considered to apply the concept of
biomimetics for the orthosis. FEA, a powerful technique to support modern engineering, is now a common practice in daily product development. It is a digital way of testing projects, being useful when making design decisions. [7]. From the virtual orthosis presented, a two-part orthosis is created, one upper and one lower, which represents an adequate solution without compromising its functionality and structural viability (Figure 3).

Model surface segmentation was developed for FEA testing. The results of the stress and temperature simulations are shown below. In Figure 4, it is possible to observe that the area presenting the greatest stress is the distal end of the lower part of the orthosis, marked with a red circle, supporting a maximum pressure of 972.7 MPa. Once the areas of greatest stress concentration are identified, it is possible to know the area of the orthosis with the highest temperature (40 °C), in this case it is the palmar center of the lower orthosis, as illustrated in Figure 5.

The results obtained by the FEA in this study are conditioned by the design of the orthosis developed and the physical characteristics represented for this work. A new FEA is shown below; this was performed due to a change in the dimensions of the orthosis, for which it was necessary to evaluate the stress and temperature concentrations according to the new study conditions.

Figure 6 shows that the areas of greatest stress concentration in the orthosis are the distal end, and to a greater extent, the proximal end, withstanding a maximum pressure of 10.93 MPa. In Figure 7, it is
observed that unlike the previous study, the area of greatest stress concentration are the distal edges and the proximal part of the orthosis, instead of the union between the thumb and ring finger, reaching a maximum pressure of 31.75 MPa. All of these significant changes occur due not only to the increase in the dimensions of the orthosis, but also in this last study flexion forces are considered instead of shear forces, and in terms of temperature analysis, in this last analysis, contact and friction between the skin and the orthosis are considered. For the orthosis joints, the bending force considered was 60 N. Now, the temperature considered for skin contact was 40 °C and 41 °C; however, the estimated temperature, without skin contact, was 38 °C.

The use of cellular structures in the project is suggested through additive manufacturing, motivated by the desire to deposit material only where it is needed [8]. The Voronoi diagrams are presented as an alternative for the modeling of cellular structures. These consist of geometries typically found in nature, related, in several cases, to light and strong structures. The main advantage offered by these structures is that of high mechanical strength, even for a geometric shape that has a relatively low mass [9].

The biomimetics implemented in the orthosis was developed from the cellular structure of Voronoi, in accordance with the benefits described above. The meshmixer tool was used because it is capable of creating network-like shapes or Voronoi patterns. The result of the application of this tool is visible in Figure 8.

2.3. Three-dimensional printing
Rapid prototype (RP) is a very important technology for the development of prostheses and orthoses, since it is possible to create functional and customized products adapted to the specific needs and dimensions of the patient [10], for the project was applied the manufacturing method by selective laser sintering (SLS).
In this last stage of the process, the 3D computer-aided design (CAD) model is converted and exported into a triangular mesh STL format, which is required for 3D printing. A ProX SLS 500 printer was used, using DuraForm ProX PA material, as shown in Figure 9. The final dimensions of the orthosis prototype are 91.93 x 92.37 x 181.62 mm, with a thickness of 2.5 mm and an approximate weight of 45 grams. The final result can be seen in Figure 10.

![Figure 9. Printing process.](image)

![Figure 10. Orthosis prototype printed in 3D.](image)

3. Result and discussion

It is evident that the methodology described above is geometrically satisfactory, that it complies with and respects the anatomical structures of the study member, in order to guarantee the best possible result. Table 1 shows a comparative table between the production costs and processing times required to perform an antebraquiopalmar immobilization by the traditional method with plaster, and the current method of AM through 3D printing. The data presented in Table 1 were taken from the associação mineira de reabilitação in Belo Horizonte, Brazil.

| Process                                         | Time (min) | Patient Present |
|-------------------------------------------------|------------|-----------------|
| Traditional Method                              |            |                 |
| Analysis of the affected area (correction of the trauma) | 15         | X               |
| Preparation of the personnel and necessary materials | 5          |                 |
| Moistening and placement of the wadding bandage  | 10         | X               |
| Moistening and application of the plaster bandage | 8          | X               |
| Modeling and setting of the plaster             | 12         | X               |
| Total Time                                      | 50         |                 |
| 3D Printing                                     |            |                 |
| Analysis of the affected area                   | 5          | X               |
| Member scan                                     | 15         | X               |
| 3D CAD design modelling                         | 180        |                 |
| Print                                           | 240        |                 |
| Total time                                      | 440        |                 |

In relation to production costs, the traditional method demanded a total of $16 US dollars and the current AM method required a total of $10 US dollars. This shows that the 3D printing method being a slower process, is cheaper and offers some possibilities of developing new designs that offers the traditional method, in addition to providing a comfortable design, printed on a material such as Nylon with better mechanical properties and in turn, thanks to biomimetics, dissipates heat in a better way.
3.1. Traditional method
Most fractures in the forearm area are treated with closed reduction maneuvers and the placement of a brachiopalmar plaster. The best treatment for these specific lesions is a cast device to achieve immobilization that neutralizes the biomechanical forces acting on the fracture that would cause its displacement or angulation [11]. The treatment is done through immobilization with a plaster cast or orthosis or through surgeries according to the characteristics of the individual and the fracture [12].
On the other hand, it is necessary to monitor the cast, exploring the color, temperature, degree of swelling, mobility and sensitivity in the fingers [13]. Furthermore, when the cast is removed, muscle weakness and atrophy are common due to immobilization of the limb.

3.2. Proposed method
The use of 3D CAD modeling software is typical in an RE environment. However, its use requires specific skills that are not as diffuse among clinicians and orthopedic technicians. Therefore, the rehabilitation center, even if equipped with the appropriate hardware (3D scanner and 3D printer), cannot be self-sufficient (unless it invests in specialized CAD technicians) to achieve an efficient production cost of custom orthoses using AM processes [5].
In addition, details such as the size of the illumination and ventilation in the orthosis (smaller or different textures) may vary according to the quality, resolution and materials of the selected printer [14].

4. Conclusions
The orthoses are commonly used as a complement to therapy and for various purposes, not only for the upper limb but for almost all parts of the body. The morphological complexity of the hand requires the acquisition of more range images from different points of view. Three-dimensional scanning proved to be an effective method for obtaining the patient's anatomy; during this process supports can be used to increase the comfort and stabilization of the individual during digitalization. The result is a 3D model that accurately describes the anatomy and is easy to share and store for later use.
The Meshmixer software facilitated the creation of an efficient and structurally viable model design. In addition, the FEA proved to be not only a useful tool for evaluating this structural feasibility but a digital alternative for testing projects against predictable forces and determining if and when they will fail, and if so, how and when the material will deform or collapse. The results of these analyses are useful in making design decisions, shortening the process, requiring the construction of fewer prototypes prior to product launch.
The biomimetics implemented from the Voronoi structure, created through Meshmixer, met the objective of material reduction, enabling the creation of a lighter orthosis. According to the resulting mechanical properties, the feasibility of producing orthopedic medicine devices from 3D printing was verified.
The AM process stands out as a viable option for the production of custom orthoses, along with other digital methods such as CAD and CAE. Finally, the orthosis prototype meets certain therapeutic objectives, such as immobilizing and stabilizing an affected limb, through an ergonomic, lightweight, removable and waterproof external appliance that provides greater comfort, mobility, hygiene and aesthetics.

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