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Development of modular wrist, hand and finger orthesis by additive manufacturing

Desenvolvimento de órtese modular para punho, mão e dedos por manufatura aditiva

Desarrollo de una órtesis mudelar de muñeca, mano y dedos por manufatura aditiva

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Abstract

Additive Manufacturing (AM) has been considered an innovative technology for the development of orthoses. Even so, the use of AM, utilizing low cost rigid and flexible material which can be used in different ways by the same user, to produce a modular orthosis has yet to be explored. Purpose: Develop a modular wrist, hand and finger orthosis that can be utilized as a functional or static orthosis, depending on the therapeutic objective. This being produced by low cost Additive Manufacturing, through a single anatomy acquisition process. Approach: Firstly, requirements for modularization and development were defined in a team with occupational therapists and mechanical engineers, After indirect anatomy acquisition of a volunteer, without disabilities, two parts of the same orthosis were modeled, one flexible (functional) and the other rigid (static). These were printed on PLA (rigid part) and flexible TPU (functional part) with an Open Source printer. In addition, fastening strips were also made in flexible TPU. Findings: Three parts of which make up the modular orthosis were produced. This can be used in two different ways; one being to maintain the static posture of the wrist, hand and fingers and the other to provide functionality of the hands, but with the correct positioning of the wrist and thumb. Originality: Even with low-cost material and an open source machine, it was possible to generate an innovative proposal with the use of AM as the orthosis manufacturing process.

Keywords: Orthosis; Additive manufacturing; Flexible material; Modular; Low-cost.

Resumo

A Manufatura Aditiva (AM) tem sido considerada uma tecnologia inovadora para desenvolvimento de órteses. Entretanto ainda não foi explorado o uso da AM para produzir uma órtese modular, utilizando material rígido e flexível de baixo custo, que possa ser utilizada de diferentes formas pelo mesmo usuário. Objetivo: Desenvolver uma órtese de unho, mão e dedos modular que possa ser utilizada como órtese funcional, ou estática a depender do objetivo terapêutico. Sendo esta produzida por Manufatura Aditiva de baixo custo, através de um único processo de aquisição da anatomia. Método: Inicialmente, em equipe com terapeutas ocupacionais e engenheiros mecânicos, foram definidos requisitos para a modularização e desenvolvimento. A partir da aquisição indireta da anatomia de um voluntário sem deficiência foram modeladas duas partes da mesma órtese, sendo uma flexível (funcional) e a outra rígida (estática). Estas foram impressas em PLA (parte rígida) e TPU flexível (parte funcional) com uma impressora Open Source. Adicionalmente foram confeccionadas tiras de fixação também em TPU flexivel. Resultado: Foram produzidas três partes que compõem a órtese modular. Esta pode ser utilizada de duas diferentes sendo uma para manter a postura estática da região de punho, mão e dedos e outra para propiciar funcionalidade das mãos, porém com o posicionamento correto do punho e polegar. Conclusão: Mesmo com material de baixo custo e maquina open source foi possível gerar uma proposta inovadora com o uso da AM como processo de fabricação de órteses.

Palavras-chave: Órtese; Manufatura aditiva; Material flexível; Modular; Baixo custo.

Resumen

La Manufactura Aditiva (AM) se ha considerado una tecnología innovadora para el desarrollo de órtesis. Aun así, todavía no se ha explorado en la AM el uso combinado de materiales rígidos y flexibles de bajo costo que podrían ser utilizados conjuntamente, de diferentes maneras, por un mismo usuario en la forma de una órtesis modularizada. Objetivo: desarrollar una órtesis modular de muñeca, mano y dedos que pueda ser utilizada simultáneamente como una órtesis funcional o estática, en función del objetivo terapéutico. La órtesis se produce mediante la Manufactura Aditiva de bajo costo, por medio de un único proceso de adquisición de anatomía. Enfoque: primero, se definieron los requisitos para la modularización y el desarrollo en un equipo con terapeutas ocupacionales e ingenieros mecánicos. Después de la adquisición de la anatomía indirecta de un voluntario sin discapacidades se modelaron dos partes de la misma órtesis, siendo una flexible (funcional) y otra rígida (estática). Estas fueron impresas en PLA (unidad estática) y en TPU flexible (unidad funcional) con una impresora 3D común de código abierto. Además, se fabricaron tiras de sujeción en TPU flexible. Resultados: fueron fabricadas tres partes que componen la órtesis modular. Esta puede utilizarse de dos maneras diferentes; una para mantener la postura estática de la muñeca, de la mano y de los dedos, y la otra para proporcionar funcionalidad a las manos, pero manteniendo la posición correcta de la muñeca y del pulgar. Originalidad: incluso con un material de bajo costo y una máquina de código abierto, fue posible generar una propuesta innovadora utilizándose la AM como proceso de fabricación de la órtesis.

Palabras clave: Órtesis; Manufactura Aditiva; Material flexible; Modular; Bajo costo.

1. Introduction

Additive manufacturing (AM) has been recognized as a modern process for the manufacture of customized assistive technology devices, such as orthoses for upper limbs (Chen, Jin, Wensman, & Shih, 2016; Fernandez-Vicente, Chust, & Conejero, 2017; Palousek, Rosicky, Koutny, Stoklásek, & Navrat, 2013; Paterson, Bibb, Campbell, & Bingham, 2015). The use of AM for making orthoses is justified as it is an automated fabrication method and less artisanal than conventional orthoses (Blaya et al., 2018; De Souza, Schmitz, Pinhel, Setti, & Nohama, 2017; Koutny et al., 2012). In addition, the fabrication process allows for the use of different materials and substantial changes in originally developed projects (Paterson et al., 2014; Poier et al., 2021).

In general, the upper limb orthoses made by AM, as reported in the literature, are of the static type, for limb immobilization, constructed with rigid materials such as ABS (Palousek et al., 2014; Kim and Jeong, 2015) or PLA (Rosenmann et al., 2018; Blaya et al., 2018). However, in some cases, it is desirable that the orthoses allow for a certain degree of movement, guaranteeing the functionality of the upper limb (Trujillo & Amini, 2013).

In clinical practice rehabilitation services, it is common to prescribe two types of orthoses for the same individual: rigid and flexible. The devices are used alternately, according to a rehabilitation protocol (Arakaki, Cardoso, Thinen, Imamura, & Battistella, 2012). In individuals with Cerebral Palsy (CP), for example, rigid orthoses are used to prevent the advance of deformities (Morris, Bowers, Ross, Stevens, & Phillips, 2011), however, concomitantly, flexible orthoses made with fabric (neoprene) can also be used to maintain joint stability while allowing the movement and functionality of the member (Schwartz, 2020). Each orthosis is made separately, with different processes, at different times.

In this context, the purpose of this study was to develop, with the aid of additive manufacturing, a modular orthosis model that could be used as a static and functional orthosis. Secondary objectives for the development of this new orthosis were the use of low-cost materials and methods and the elimination of materials traditionally used for finishing and fastening.

2. Methodology

This article is presented as an exploratory research conducted through a case study (Santos, 2018). We conduct the development of a modular orthosis, in order to structure a development process and validate ow-cost additive manufacturing technologies in the manufacture of this product. For the development of the proposal, a volunteer with no disability was recruited. This research was approved by the Human Research Ethics Committee (1.859.901). Using the analysis of static wrist, hand and finger orthoses and the functional orthoses used by people with upper limb deformities as a starting point, possibilities of modularization and modification through AM were explored. The study was then divided into five stages that consisted of defining requirements for orthoses, anatomy acquisition, 3D scanning, 3D CAD modeling, and 3D printing. Each phase will be described below.

Definition of requirements: From the analysis of the literature and clinical experience of two occupational therapists, the requirements were defined. The orthosis was designed to be composed of a rigid part, another flexible part and fastening fasteners. The requirements of the different parts can be seen in Table 1.

Table 1. Manufacturing and clinical requirements.

Rigid orthosis	Functional / flexible orthosis	Fasteners
Comfortable; Easy to sanitize; Resistant; Easy and suitable fastening and detaching on the flexible part; Able to keep the wrist, hand and fingers in the correct position. Intuitive use; Low cost.	Comfortable; Easy to sanitize; Resistant; Easy and suitable fastening and detaching on the static part; Able to keep the wrist and thumb in the correct position. Intuitive use; Low cost; Absence of pressure points; Do not have points or corners; Low cost; Flexible.	Comfortable, Firm; With different adjustment levels; Easy and suitable fastening and detaching in both forms of use; Easy to sanitize; Flexible. Low cost.

Source: Authors.

In addition to these requirements for each part of the orthosis, it was also defined to use only elements produced by AM and that the use of velcro, elastics or additional comfort materials such as foams were not necessary.

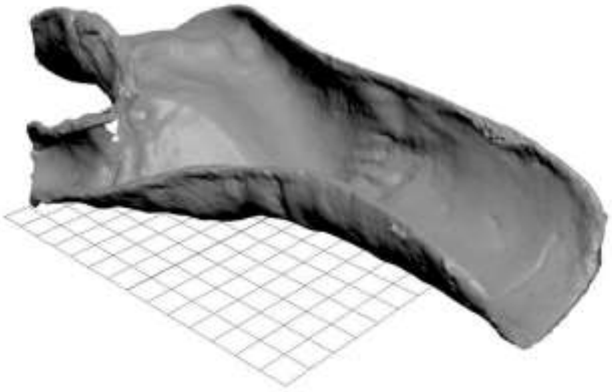
Anatomy acquisition: In this stage, a static orthosis for positioning the wrist, hand and fingers was made by an occupational therapist (OT) with a plaster cast (Figure 1). This technique allows for the correct positioning of the individual's wrist, hands and fingers, as the OT manages to avoid undesirable movements, and thus reduces errors that may occur due to the difficulty of scanning, directly, the upper limb in the correct position.

Figure 1. Making the plaster cast model.

Source: Authors.

Figure 1 shows the plaster orthosis model made with the hand posture determined by the Occupational Therapist. This was submitted to 3D scanning, whose 3D mesh can be seen in Figure 2.

Figure 2. Mesh obtained in the 3D scanning stage of the plastered cast model.

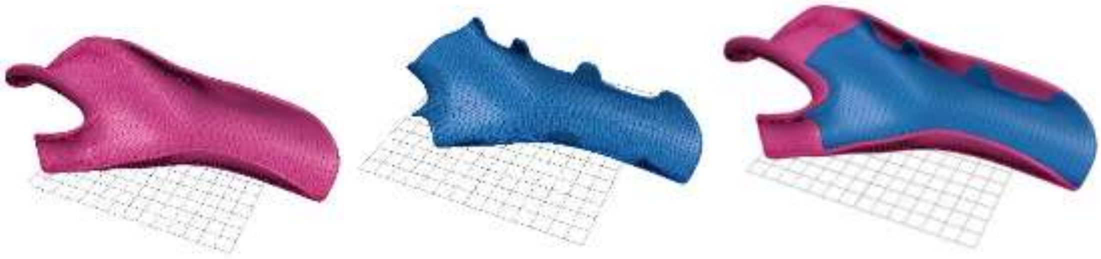


Source: Authors.

3D scanning: The present step consisted of 3D scanning the orthosis made with plaster cast. For this, a Desktop 3D® 2020i laser scanner from NextEngine was used. At the end of this step, a scanned mesh was obtained (Figure 2), exported in IGES (Initial Graphics Exchange Specification) format, to start 3D CAD modeling.

3D CAD Modeling: 3D CAD modeling was performed in two different softwares. The first one used was 3ds Max® 2018, from Autodesk Inc. Based on the scanned model, the two parts were modeled – the static (Figure 3a) and the flexible (Figure 3b), which can be used individually, or overlapped (Figure 3c).

Figure 3. Digital models of the modular orthosis (a) Rigid part model obtained from the scanned mesh; b. Flexible orthosis model obtained from the scanned mesh; c. Flexible orthosis superimposed on the rigid orthosis.



Source: Authors.

The other step of the modeling was performed using the SolidWorks® 2018 software, from Dassault Systèmes. In this second modeling phase, handles and openings were inserted to fit the parts and for passage the fastening strips (Figure 4). In the flexible part, a reinforcement in the wrist region was designed to maintain the hand posture determined by the therapist, even with the removal of the rigid part.

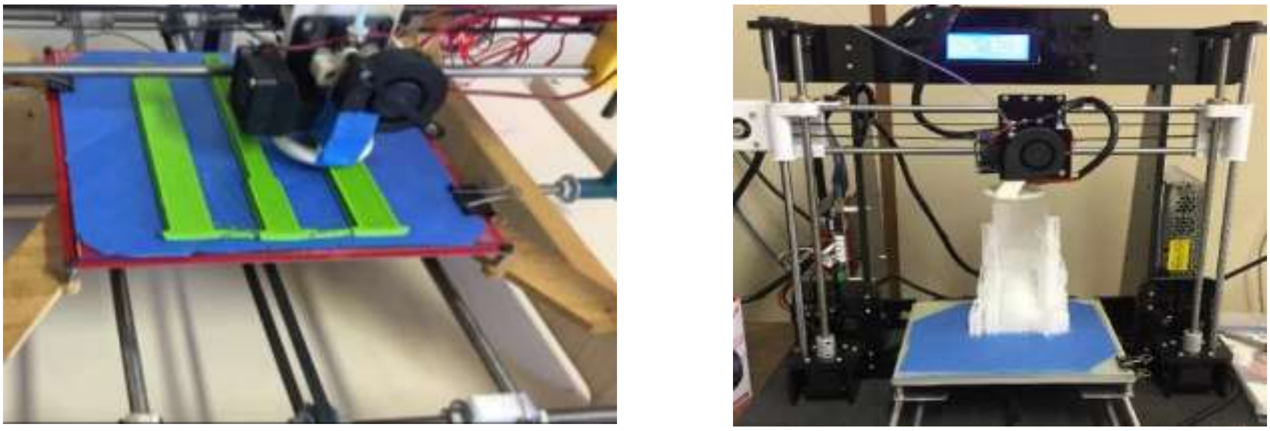
Figure 4. Assembled modular orthosis, without fastening fasteners. (a) top view; (b) bottom view.

(a) (b)

Source: Authors.

3D printing: The last step was to print the parts of the orthosis. To make both parts, an inexpensive open source machine ANET® A8 DIY (Figure 5) was used. The flexible part and the fastening strips were produced with thermoplastic polyurethane (TPU). The rigid part was made using PLA (polylactic acid) material. The temperature for the extrusion of the TPU was 215°C with the printing table temperature of 80°C. The extrusion temperature for the PLA was 230º C without the need to heat the printing table.

Figure 5. Open source machine ANET® A8 DIY printing the flexible part of the orthose.



(a) (b)

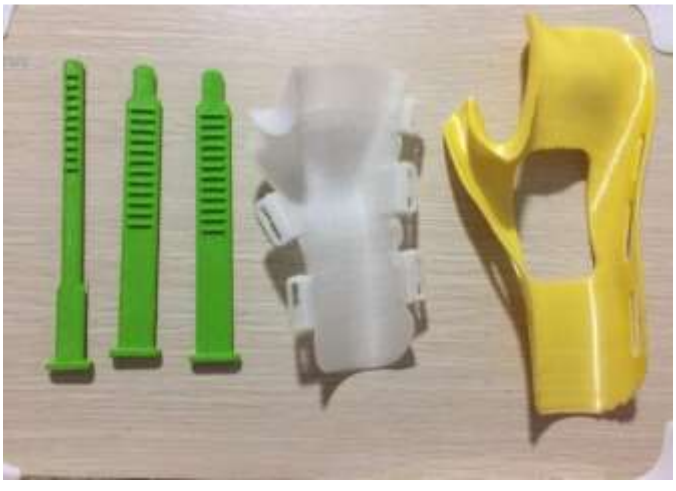
Source: Authors.

Figure 5a shows the printing process of the strips for fixing the modular orthosis. In Figure 5b the flexible orthosis is printed. After printing, the orthosis was analyzed in relation to the defined requirements. The time to produce each part of the orthosis, the mass (Kg) and the cost (dollar) in material used for making the orthosis were also recorded.

3. Results

Figure 6 shows the result of the printed parts of the orthosis, being a rigid part (static orthosis), another flexible part (functional orthosis) and removable fasteners. In the case of the rigid part, printed in PLA, support removal was easily performed. Whereas the flexible part required a thorough post-processing to remove the support material, requiring the use of pliers. The TPU showed a high adherence between the layers making this removal difficult. The fixing strips, also printed in TPU, had the same characteristic.

Figure 6. Modular orthosis parts. Fixed fastening (green material), flexible orthosis (translucent material) and rigid orthosis (yellow material).

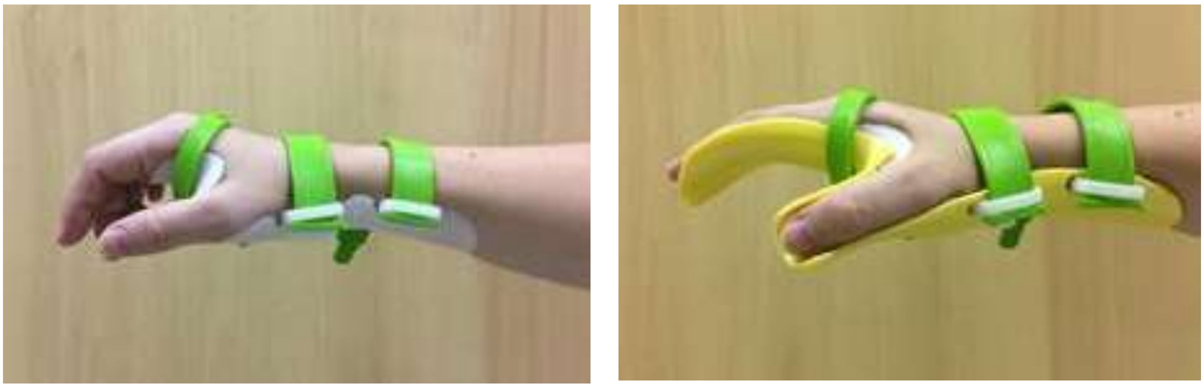


Source: Authors.

Regarding fulfillment of the requirements, the result of the printed physical models showed ease for fitting and detaching the parts. Using only the functional part made of flexible material, correct thumb positioning and extended wrist stabilization were observed (Figure xa) The inclusion of material reinforcement in the region of the wrist joint (under the flexible orthosis) was sufficient to limit the flexion movement. The coupling of the rigid part positioned the wrist, hands and fingers in the posture defined in the acquisition of anatomy.

The flexible material proved to be a potential comfortable and hygienic coating for the rigid orthosis, being able to replace EVA (splint cushions). The flexible straps allowed for the necessary fastening and adjustment, in addition to the ease of placement and removal, and the possibility of various levels of adjustment. These can be used both to fix the functional orthosis individually, as well as for the assembled set (Figure 7).

Figure 7. Modular orthosis placed on a person without disabilities: (a) flexible orthosis and (b) rigid orthosis covered by the flexible orthosis.



(a) (b)

Source: Authors.

Figure 7 shows the two ways of using the developed orthosis on the volunteer without disabilities. In figure 7a, the user uses the flexible part of the modular orthosis, which allows the movement of the fingers and thumb. Figure 7b shows the use of the set with the inclusion of the rigid part, providing the static positioning of the wrist, hand and fingers.

Table 2 shows the time required to perform each of the steps previously described for each component of the modular orthosis (fasteners, rigid and flexible orthosis). The times related to the anatomy acquisition and scanning steps are the same, as they were performed only once.

Table 2. Times demanded in the development stages.

STAGES	Components of the modular orthosis.		
	Fasteners	Rigid	Flexible
Anatomy acquisition	1h 30min		
3D scanning	1h 30min		
CAD modeling	1h 45min	1h 30min	1h 30min
3D printing and post-processing	1h 30min	1h 30min	1h 30min

Source: Authors.

Table 3 shows the mass of each of the three modular orthosis components, distinguishing when they are with and without support material. The total mass of the assembled set is also shown. Lastly, the costs inherent in making the modular orthosis are shown in Table 4. Also shown is the cost per machine hour for each component.

Table 3. Mass of each modular orthosis components.

MASS (g)	Fasteners	Rigid	Flexible
With support	39.67	154.95	90.90
Without support	24.56	71.59	45.50
TOTAL	64.23	226.54	136.40

Source: Authors.

Table 4. Cost of material and for manufacturing the components of the modular orthosis (values in dollars/2021).

INPUTS ($)	Fasteners	Rigid	Flexible
PLA	--	4.07	--
TPU	1.04	--	2.38

Source: Authors.

4. Discussion

The orthosis proposal, developed for a volunteer without disabilities, fulfilled the objectives of modularization and the proposed requirements guiding the research. It was possible to make two orthosis models in the same production process. In addition, the rigid and flexible parts fit together to create a unique product. The combination of properties of different materials in a single device can be considered positive for the rehabilitation process of individuals with upper limb dysfunction. Paterson *et al*. (2014) explored the combination of different materials for insertion, in rigid orthoses, regions with less rigidity, decrease in pressure points, facilitation of movement at certain angles and design of new forms of fastening, however utilizing expensive materials.

In relation to the flow for the development and manufacture of orthoses with low-cost materials and machines, these were effective. The process used for anatomy acquisition with the plaster cast has disadvantages due to the mess generated by the plaster. However, this proved to be a low cost and low complexity option. Therapists, in general, are familiar with handling this material. One possibility is that therapists utilize the plastered cast in order to materialize the orthosis models, in accordance to the specifications of the clients, and then send them to reference centers so that they can scan, model and print the orthoses using additive manufacturing. Paterson *et al.* (2010) evaluated, through literature review, different scanning methods, these being computed tomography (CT), magnetic resonance imaging (MRI), 3D laser scanning and anthropometry. In this regard, one approach considered successful was the use of molds and plaster to achieve the anatomy acquisition of the individuals. This technique reduces inaccuracies and noise caused by movements during acquisition (Paterson *et al*., 2010). Baronio *et al*., (2017) proposed the use of a support to enable direct scanning of the hand and wrist of people with spasticity, this being a future possibility for the making of this model of orthosis.

Regarding 3D CAD modeling, the use of different programs shows the complexity involved in correction and preparation for printing. The scanning of the plaster cast model facilitated modeling, however the mesh from the scanning process showed imperfections that were corrected, but required processing time with the risk of altering the original geometry

(Palousek *et al*., 2014). Paterson *et al*. (2014) proposed the development of an exclusive CAD program to provide therapists with the possibility of making modifications to an orthosis model for 3D printing. This would be an interesting option, since traditional CAD programs are difficult to operate and depend on the operator's experience. In the present study, the fact that the team is transdisciplinary made it possible to exchange information at all stages, especially in CAD modeling so that clinical objectives were respected in the final product.

Regarding costs, it is believed that this can be considered low cost. And, when considering that the total value refers to two orthosis models, this can be considered even more advantageous.

The utilization of open source printers proved to be a viable option for making orthoses with flexible and rigid components. The use of TPU for orthosis fastening fasteners can contribute to the replacement of velcro, which presents negative aspects (Kelly *et al*., 2015), such as being noisy, allowing for the concentration of dirt, harming of the skin and damage to clothes. In the case of the fastening fasteners developed in this project, in spite of being made with flexible material, does not have great elasticity, and are presumed to be sufficient in order to maintain the desired posture of the wrist, hand and fingers.

The next phase of the study will be the evaluation of comfort, intuitive use, ease of cleaning, presence of pressure points and resistance in the context of real use in a longitudinal study. This study focused only on the development of the proposal, emphasizing the modularization of the orthosis.

5. Conclusion

The modular orthosis developed presents innovative elements regarding the different options of use and the application of low cost flexible 3D printing. The results obtained with the use of the flexible material showed that the proposal, being used as a comfort material for the rigid static orthosis, is possible, and now depends on the realization of evaluations with real users. It is concluded that, even with low cost processes, AM favors the development of orthoses with the necessary qualities and requirements, and with the consideration of clinical aspects.

Evaluating the functionality of use of the flexible part for people with indication for this model of orthosis has also been suggested as future work. It is also suggested to evaluate the use of modular orthosis to measure the advantages of modularity compared to traditional models.

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