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A New Automatic Process Based on Generative Design for CAD Modeling and Manufacturing of Customized Orthosis

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Abstract: As is widely recognized, advancements in new design and rapid prototyping techniques such as CAD modeling and 3D printing are pioneering individualized medicine, facilitating the implementation of new methodologies for creating customized orthoses. The aim of this paper is to develop a new automatic technique for producing personalized orthoses in a straightforward manner, eliminating the necessity for doctors to collaborate directly with technicians. A novel design method for creating customized wrist orthoses has been implemented, notably featuring a generative algorithm for the parametric modeling of the orthosis. To assess the efficacy of the developed algorithm, a case study was conducted involving the design and rapid prototyping of a wrist orthosis using Fused Deposition Modeling (FDM) technology. Subsequently, the developed algorithm was tested by clinicians and patients. The results obtained indicate that the implemented algorithm is user-friendly and could potentially enable non-expert users to design customized orthoses. These results introduce innovative elements of originality within the CAD modeling, offering promising solutions to the challenges associated with the design and production of customized orthoses. Future developments could consist of a better investigation regarding the parameters that influence the accuracy of the scanning and of the printing processes.

Keywords: wrist orthosis; reverse engineering; generative design; additive manufacturing; CAD

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1. Introduction

Personalized medicine represents an increasingly pivotal paradigm in patient care. In contrast to the conventional approaches [1], personalized medicine integrates different patient needs, leveraging advanced reverse engineering (RE) and additive manufacturing (AM) techniques [2–5] to pioneer innovative solutions. This methodology finds several applications in rehabilitation medicine wherein each patient needs to receive tailored treatments [1,6]. Since rehabilitation medicine is a multidisciplinary field, orthopedists should be specialized in the manufacture and adjustment of orthoses, which includes determining patients' needs and assessing the anatomy, musculoskeletal structure, and extent of the injury in order to determine the best type of orthosis, as well as continuously monitoring the patient's condition and adaptation to the device.

Orthoses, external medical devices primarily restricting joint movements following trauma, surgery, or distortion [7], support and modify the structural and functional characteristics of the human musculoskeletal system and have an important role during the rehabilitation phase.

They can be prefabricated or customized. Prefabricated orthoses are readily available and less expensive than custom products; however, customized products that take individual characteristics into consideration have a better fit to the patient's body, which is the most important factor in user satisfaction.

Despite a shift away from prefabricated orthoses in rehabilitation medicine, which sometimes compromised therapy success and patient acceptance, custom orthoses have conventionally relied on plaster molding techniques [8]. This method is time-consuming, laborious, wasteful, and often falls short of accurate personalization [1].

Thanks to AM, it is possible to realize complex structures while saving time and labor costs. AM has flexibility that permits customization for special applications or the consideration of individual characteristics. It provides new opportunities for freedom of design, avoidance of material surplus and waste, and cost efficiency in one-of-a-kind manufacturing.

This study concentrates on personalized wrist orthoses designed to yield distinct treatment outcomes by immobilizing the wrist while permitting finger mobility [9,10].

Wrist orthoses are commonly used for injury rehabilitation and can accelerate the recovery from a wrist fracture or other wrist pathologies. In addition to providing immobilization, a good fit of the orthosis in the affected area is efficacious in allowing the wrist to heal. The immobilization of the wrist using a traditional plaster cast is effective in fracture rehabilitation, but internal pressure can cause some problems, such as dermatitis, nerve paralysis, and compartment syndrome. Due to a plaster cast's inability to be removed or adjusted easily, the weeks-long recovery may cause ankylosis in the immobilized area [11]. The commercially available materials for wrist braces were innovated from traditional plaster to thermoplastic casts or splints, and the materials were reshaped as fiberglass resin tape or splints. However, these materials have similar issues after application: stuffiness, being uncomfortable, not being ventilated, and being difficult to negotiate for dressing. Furthermore, most splints and casts using these materials can only be removed and replaced by professionals.

In addition, a considerable number of materials are needed for casting the plaster, which includes a shirt, cotton padding, a roll or sheets of plaster or fiberglass, elastic bandages with clips or adhesive tape, heavy scissors, and a bucket of water. With AM technology, it has been possible to solve these problems by creating orthoses made of biocompatible material and composed of a single component. Furthermore, the patient-specific wrist orthoses fabricated by AM technologies may perfectly fit the individual's wrist, unlike commercial orthoses. AM permits precise replications of existing products and makes it possible to increase the functional performance with less weight [12–15]. Furthermore, the integration of the functions in AM can reduce the need for assembly procedures. Additionally, the 3D printing of thermoplastic products with satisfying values of accuracy and strength is difficult as the process parameters significantly influence the properties of the obtained parts. This always requires other specific engineering knowledge [16].

However, one problem in the AM fabrication of customized orthoses is the requirement for specialized engineering knowledge to acquire and post-process the patient's wrist and to correctly model the obtained shape by the CAD systems [17]. In fact, the acquired patient's arm must be gathered and processed, usually manually, and this could generate many inaccuracies if the technician does not have specialized engineering knowledge. Also, there are many RE technologies with different features in terms of accuracy, cost, and ease of use, so it is fundamental to have accurate knowledge of this technology.

For all these reasons, nowadays, the lack of dedicated and easy-to-use design software significantly limits the possibility of the widespread use of additively manufactured orthoses and can generate many inaccuracies. Furthermore, no design methods focus on orthosis design, which may lead to inefficient devices. Studies on how to make data gathering, processing, and manufacturing easier and more available in general medical practice have been carried out [18]. Different authors have proposed different solutions to improve and speed up the design process of personalized devices regarding the 3D acquisition or CAD modeling phases of orthoses or prostheses. The approaches proposed in the past, although interesting, are not ready to be used directly in clinical practice since the design of these devices requires significant interaction among medical staff and technical experts.

Presently, there are a dearth of design methods specifically fitted to orthosis design, potentially resulting in suboptimal devices. Since the patient's medical condition, the body segment to be treated, and the kinematics of the orthosis represent unique characteristics, they deserve to be taken into consideration during the conceptual design phase of the orthosis itself [19]. Various efforts to enhance the design process of personalized devices have emerged. Palousek et al. [20] advocated for a simplified design and manufacturing process involving scanning one arm side for generating a splint, offering advantages like ventilation, cleanability, and lightness, albeit with limited patient protection. Huhn Kim et al. [21] proposed a hybrid model with a patient-fitted inner structure and a standardized outer cover. Górski et al. [22] explored automation to streamline the procedure. Other authors focused on the 3D acquisition or CAD modeling phases [23–25], yet these approaches, while intriguing, lack immediate clinical applicability, necessitating significant collaboration between medical and technical experts. Furthermore, this work delves into the use of additive manufacturing for orthosis realization, an ideal technology for mass customization. AM reduces the labor requirements compared to the traditional methods and excels in rapidly and cost-effectively fabricating intricate shapes [26–30], resulting in a polished surface finish dependent on the process parameters. The orthopedic field has witnessed an expansive integration of AM, offering flexible solutions for customized implants to specific shapes and sizes [31,32].

This study proposes a novel approach to expeditiously design and fabricate personalized orthoses. The CAD modeling process is tailored for non-expert users, employing an automatic process rooted in generative design (GD). The GD approach was developed to overcome the problems that it is possible to encounter during the CAD modeling with the conventional software for AM [19].

2. Materials and Methods

2.1. 3D Acquisition by Photogrammetry

For 3D acquisition, there are many technologies with different features in terms of accuracy, cost, and ease of use [33,34]. To scan the patient's wrist without the use of complex and expensive 3D scanners, a smartphone camera was used as photogrammetry tool. This technology enables the generation of CAD model of any object from hundreds of photos, taken from different points of view (Figure 1). Compared to other reverse engineering techniques, photogrammetry is a more user-friendly technique for non-expert users.

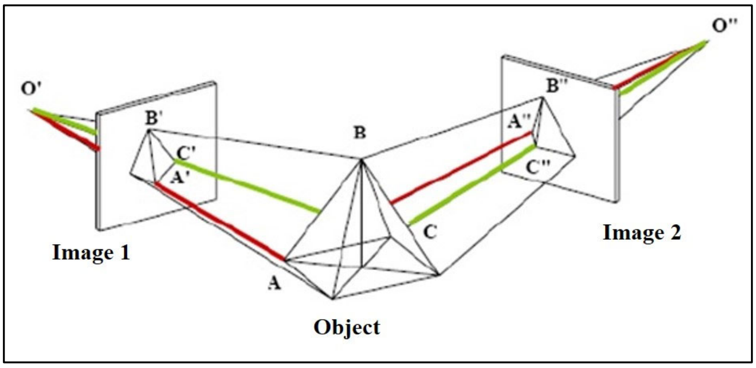

Figure 1. Photogrammetry technique.

For the case study examined in this paper, approximately 130 photos of the patient's wrist were obtained from various angles (Figure 2a). This process was efficient and did not necessitate the use of an external device to immobilize the wrist and fingers. However, depending on the pathology of each patient, a support system could prove beneficial for positioning and ensuring patient comfort. The reconstruction of the 3D model of the patient's wrist was created by means of Agisoft LLC Metashape 2.1.2 (St. Petersburg, Russia). The final reconstructed mesh is shown in Figure 2b.

Figure 2. Wrist and hand (**a**) and reconstructed mesh (**b**).

2.2. CAD Modeling of the Orthosis by Generative Algorithms

A new approach based on generative algorithms was proposed to model wrist orthosis using an automatic process. New algorithm was developed using Grasshopper, a graphical algorithm editor that can be used as a plug-in inside 5.0 Rhinoceros nurbs modeling software (McNeel & Associates, Seattle, WA, USA). The overall workflow of the orthosis design is shown in Figure 3.

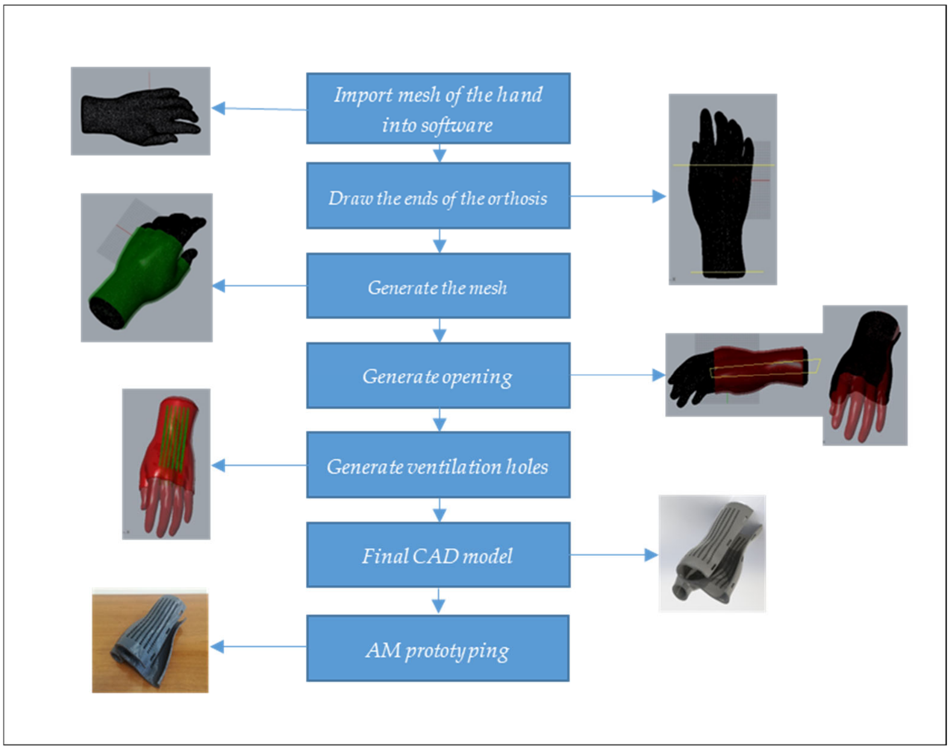

Figure 3. Operation workflow of orthosis design.

After importing the mesh of the patient's wrist/hand into the software, the user simply needs to define the upper and lower boundaries of the orthosis by sketching two lines directly on the 3D model (see Figure 4).

Then, the algorithm automatically generates orthosis as a mesh perfectly adapted to the reconstructed geometry of the patient's wrist. At the end, the orthosis mesh was extracted (Figure 5). Preliminarily, to ensure the suitable stiffness of the orthosis but at the same time not add too much weight to the entire device, a thickness of 4 mm of the structure was set through an offset function. This value of thickness is usually adopted in commercial orthoses and could be modified by the user.

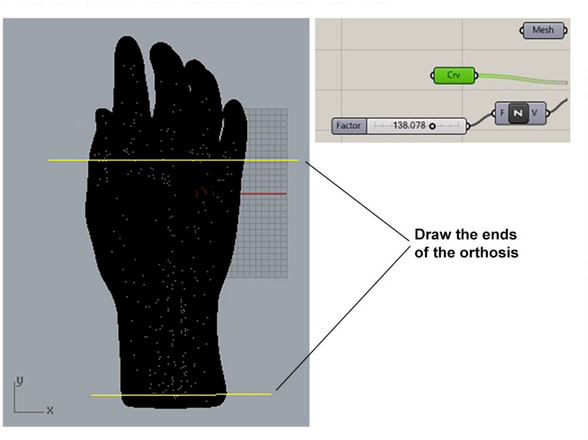

Figure 4. Indication of the ends of the orthosis.

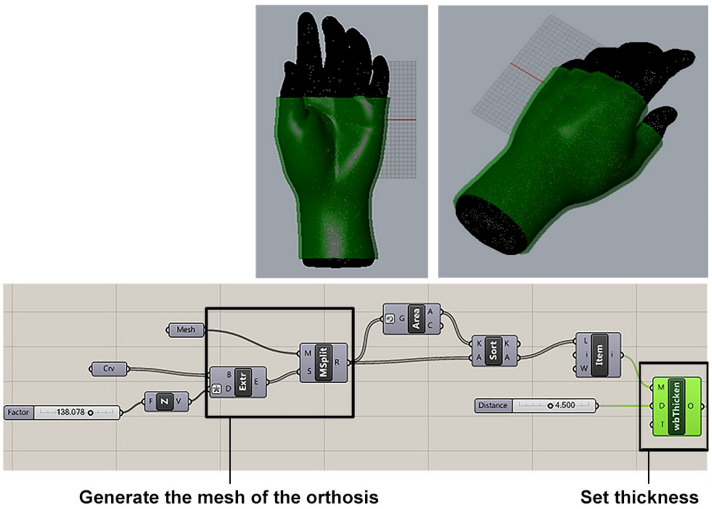

Figure 5. Mesh of wrist orthosis.

To meet the wearability requirements, always according to medical recommendations, a longitudinal gap was created to allow both to wear the orthosis without problems and to increase the adaptability. The aforementioned gap was created by means of a user-dependent cutting plane that indicates the cut position (Figure 6). Subsequently, the proposed algorithm automatically creates the gap, maintaining device functionality by an extrusion function, and then through mesh split function creates the final mesh (Figure 7).

Finally, after performing smoothing operation to eliminate sharp edges, the mesh of the orthosis was created including the opening.

The smoothing operation was performed by a particular function wbLaplace that is based on Laplacian smoothing algorithm. In particular, Laplacian smoothing is an algorithm to smooth a polygonal mesh. For each vertex in a mesh, a new position is chosen based on local information (such as the position of neighbors) and the vertex is moved there.

More formally, the smoothing operation may be described per vertex as

$$\overline{x}_i = \frac{1}{N}\sum_{j=1}^{N}\overline{x}_j \quad (1)$$

where

- ✓ N is the number of adjacent vertices to node i;
- ✓ $\overline{x}_j$ is the position of the j-th adjacent vertex; and
- ✓ $\overline{x}_i$ is the new position for node i.

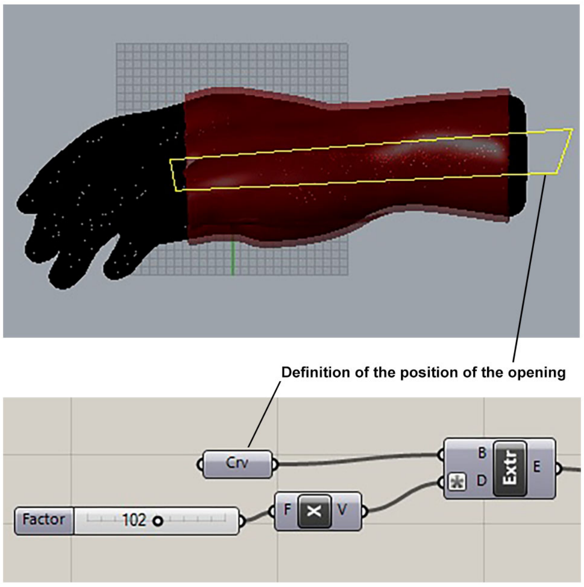

Figure 6. Definition of the position of the opening.

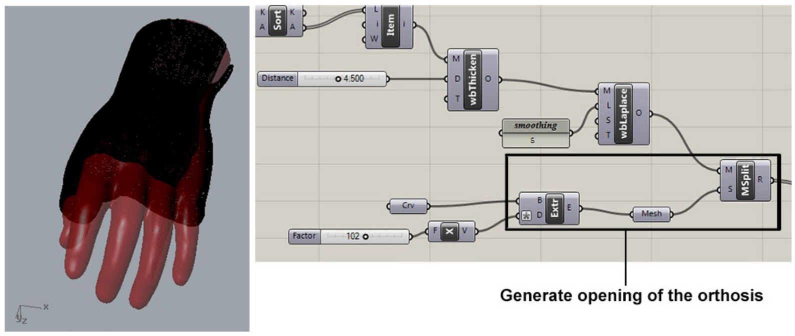

Figure 7. Opening of wrist orthosis.

Another important aspect that can be achieved by 3D-printed orthosis is transpiration and the possibility of a regular inspection of the injury site. Compared to the traditional plaster casts, additive manufactured casts can be perforated to increase ventilation of the treated area to promote breathability, reducing skin inflammation and sweating and to reduce overall device weight without affecting required stiffness.

Thanks to a specific block of the algorithm being implemented to generate the ventilation holes in an automatic way, in particular, it is possible to define the shape and array for ventilation holes (Figure 8).

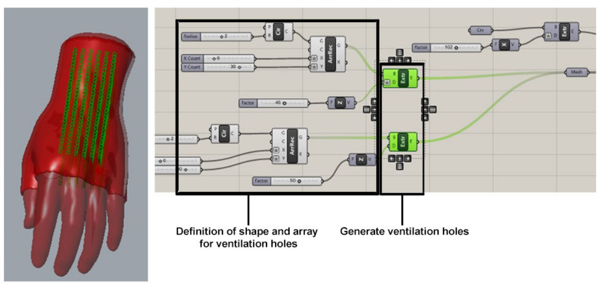

Figure 8. Orthosis with ventilation holes.

3. Orthosis Additive 3D Rapid Prototyping

The investigated orthotic model was manufactured and has been submitted to the judgment of orthopedic physicians to evaluate its actual usability in terms of reliability, adherence, and comfort regarding the patient's arm. The prototype was produced in ABS using an FDM (Fused Deposition Modeling) 3D printer. This technology was chosen for three important reasons:

- ✓ the printing process avoids the presence of potentially dangerous residuals in medical environments;
- ✓ the mechanical performances of the printed parts are generally compliant with the application requirements;
- ✓ FDM printing by using ABS material has already been used for orthoses manufacturing and approved for medical applications [7].

4. Results

Figure 9 shows the final CAD model of the orthosis that could be directly used for manufacturing purposes by AM technology.

Figure 9. Final CAD model.

The orthosis can also be customized with different patterns depending on the patient's liking (Figure 10).

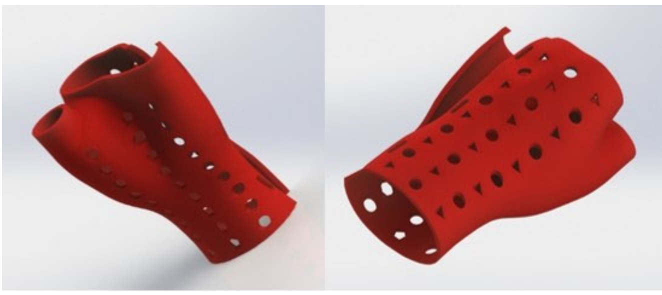

Figure 10. Final CAD model with different patterns.

After the CAD model of the designed orthosis was completed, a prototype of the device was produced in ABS using an FDM printer (Figure 11).

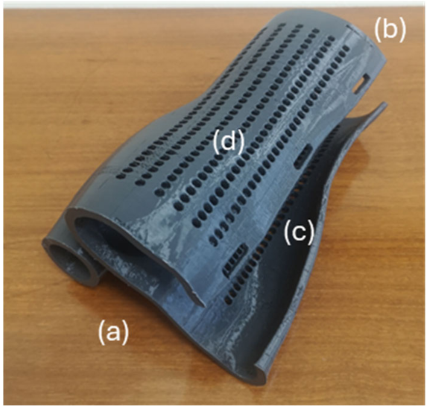

Figure 11. Final prototype. In the figure, the prototype shows the different phases reported in the method: operator-dependent cuttings, hand (a) and elbow side (b); lateral orthosis opening (c); patient-specific shape design; and holes for ventilation (d).

The prototype was tested by the patients; they wore it for a short period to highlight possible major defects. Even in this limited time frame, problems related to comfort/discomfort could be highlighted. Figure 12 shows the final prototype worn by the patients.

Figure 12. Final prototype worn by the patient.

5. Discussion

In this study, a new automatic process based on the GD for the CAD modeling and manufacturing of customized orthoses was developed, providing a useful instrument for clinicians with no experience with CAD systems. This novel approach has been specifically applied to the design of a customized wrist orthosis, enabling medical staff to conduct 3D acquisition without the need for a specialist throughout the entire procedure [23]. For the 3D acquisition phase, photogrammetry was utilized, leveraging the camera of a smartphone to capture approximately 130 photos of the patient's wrist from various angles [35]. This method proved efficient as it did not require external devices to stabilize the patient's limb, although a support system for positioning and securing the wrist can be provided depending on the specific pathology of each patient.

A key feature of this work is the modeling process simplification of the orthosis, which could be accomplished by merely delineating the immobilization area with two lines. The algorithm then automatically generates the orthosis model, complete with ventilation holes. The prototype orthosis, fabricated from ABS using a 3D FDM printer, was evaluated by an orthopedist to assess its practical usability, including the reliability of the closure system and the fit to the scanned arm [4,36].

The methodological approach employed in this study has significant potential for future research and application [19,30]. It could facilitate the development of an automated workflow capable of easily identifying the optimal shape for each individual patient. Parameters such as wrist width, finger length and width, and palm size, along with the required degree of immobilization, could be easily obtained and replicated, further simplifying the customization process. The integration of recent innovative technologies, such as artificial intelligence, could enhance the user-friendliness and accuracy of the proposed approach, making it even more accessible and precise [37].

Moreover, this approach offers substantial benefits in terms of time and cost efficiency [24]. By reducing the dependency on highly skilled technicians and minimizing the need for specialized equipment, the overall process becomes more streamlined and accessible. This can lead to broader adoption in clinical settings, particularly in regions where access to specialized CAD modeling expertise is limited.

However, the developed method could present some actual limitations, such as the use of commercial closed scanning software that cannot provide the accuracy parameter, the reduced clinical tests performed, and the choice of the cutting planes that have operator dependence.

Future studies could expand on this foundation by exploring the integration of advanced AI algorithms to optimize the design process further. Machine learning techniques could analyze a larger dataset of wrist orthosis designs and patient outcomes to identify patterns and predict the best design parameters for new patients. Additionally, incorporating feedback from a wider range of clinicians and patients can provide valuable insights to refine the system, ensuring that it meets diverse clinical needs effectively.

The development of this automated process for the CAD modeling and manufacturing of customized orthoses represents a significant advancement in personalized medical care. By harnessing the power of generative design and user-friendly 3D acquisition methods, this approach holds the promise of improving patient outcomes, enhancing clinician efficiency, and democratizing access to high-quality custom orthotic solutions.

6. Conclusions

In this work, a new approach that can enable medical staff to easily carry out the 3D acquisition and modeling of the orthosis has been developed. The newly developed approach has been effectively tested by designing a customized wrist orthosis.

The first phase of this approach is the 3D reconstruction of the wrist of the patient, which can be easily performed with a smartphone, using a classic reverse engineering process based on photogrammetry. Then, a new algorithm based on generative algorithms was implemented to allow the users to model the wrist orthosis using a highly automated process. The CAD model of the orthosis created with the new tool has been subsequently used to produce a functional prototype of the wrist orthosis using the FDM technology.

The developed algorithm was tested by clinicians and patients. The future step will be to perform a trial with clinicians to better understand the time needed for designing the orthosis and achieving the ease of use of the tool, creating an interface that is more user-friendly for all users, as well as to study the influence of the parameters of the processes.

The results obtained are promising to contribute to making the design process of customized orthoses accessible even to non-expert users, reducing the time needed to design and manufacture these medical devices.

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