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Preliminary evaluation of an additive manufacturing procedure for producing patient-specific upper-limb orthotic devices

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Abstract. In the orthopedic field, the need for patient-specific devices is crucial to ensure a rapid and successful care treatment. The traditional techniques for manufacturing customized orthopedic systems, specifically orthoses, are laborious and present multiple and time-consuming steps. The present research analyzed the possibility of optimizing the conventional process for manufacturing personalized orthoses by leveraging the principles of Reverse Engineering (RE) and Additive Manufacturing (AM). Digital orthotic models of different anatomical regions were obtained using 3D laser scanning and semi-automated CAD processing, whilst, the prototypes were produced using a Fused Deposition Modelling (FDM) printer and polymeric filaments suitable for the intended use. Furthermore, topological optimization was employed to improve the shape and the weight of the different medical devices. Potential advantages and drawbacks of the discussed procedure were evaluated through a preliminary indication of production times and costs.

Introduction

Additive Manufacturing (AM) techniques widely spread in the orthopedic sector [1,2]. Nowadays, the capability of AM technologies to fabricate articulated geometries with a variety of biocompatible materials represents a potential and valuable solution to the disadvantages related to the traditional manufacturing of patient-specific orthoses [3]. Indeed, it is common knowledge that the traditional practice of orthotics customization is not always effective: the skills and experience of the medical operator have a great impact over the quality of the final product [4] and, if the outcome is not good enough, the likelihood of the patient rejecting the rehabilitation therapy increases [5].

In the present article, an alternative methodology to the traditional fabrication of orthoses dedicated to the treatment of upper limb regions was studied in an effort to bring more comfortable and high-performance medical solutions. The approach involved three main steps: acquiring the anatomical region of interest as a 3D scanning, shaping the orthotic model on the basis of the individual diagnostic case and fabricating the final medical device. Three anatomical regions of different size and level of detail were used as test objects for the evaluation of the validity and repeatability of the manufacturing process under investigation. The anatomical regions involved the upper extremities of the limbs, particularly the wrist and finger joints.

Pathological conditions affecting the wrist joint may require the use of orthoses that immobilize the wrist joint, while enabling full mobility of the metacarpophalangeal (MP) joint and thumb. Clinicians might rely on a variety of wrist orthotic patterns depending on the anatomical region along which they extend: volar, dorsal, ulnar and circumferential. As the name suggests, circumferential devices completely envelop the wrist joint, bringing greater stability, and are especially indicated in fractures and complex regional pain syndrome.

On the basis of the medical consultation, pathological conditions affecting the fingers may need a medical device involving only the targeted finger or may necessitate a device involving the whole hand. Diagnoses such as, finger sprains, mallet finger, boutonniere and swan-neck deformities, may require finger-based orthoses to constrain only the movement of the proximal interphalangeal (PIP) and/or distal interphalangeal (DIP) joint under investigation, thus leaving the metacarpophalangeal (MP) joint unrestricted and allowing the mobility of the other digits. On the other side, other clinical conditions, like osteoarthritis and traumatic injuries of the thumb, may require more structured orthopedic devices, that, as opposed to finger-based splints, cross the entire palm and dorsum of the hand. This is the case of hand-based thumb orthoses, which constrain both interphalangeal (IP) and metacarpophalangeal (MP) thumb joints, allowing for wrist and other digits mobility.

Hence, from the present research, three medical devices, characterized by a different degree of complexity, were developed. At a later stage, different orthotics designs for each application were designed exploiting topologically optimization too. Their feasibility, along with the entire process validity, was assessed through a preliminary evaluation on 3D printing costs and times.

Methodology

Acquisition of the anatomical regions. The production of patient-specific orthoses started with the activity of acquiring the surface geometry information about the anatomical area to be healed. The acquisition was carried out by means of a handheld 3D scanner, in particular, the technology was Hexagon Absolute Arm 7-Axis equipped with an RS6 Laser Scanner. The instrumentation provides contactless, rapid (max 1.2 million points/s point acquisition rate, max. 300 Hz line rate) and detailed (0.026 mm precision) scans, in accordance with the current clinical requirements [6].

The three anatomical regions were acquired through a single scan in the form of a point cloud, directly exportable to stl-format. The scanning parameters remained unchanged for each application, while the acquisition set-up was in accordance with the dimension and level of detail of the specific anatomical region and, most importantly, the therapeutic goal. This implies that, in the presence of injuries that prevent active movement of the joint under consideration, it is essential for the physician to passively relocate the patient's joint in the correct alignment in order to scan a physiological joint and prevent the unsuccessful development of a pathological scan. This consideration safely applies to the pathologies outlined in the introductory chapter. Key information concerning the 3D scanning set-up of the different anatomical regions of the upper extremities is presented in Table 1.

Table 1. 3D scanning set-up of the three applications.

Upper limb region	Joints	Number of stabilizers	Position
Wrist	Radiocarpal, ulnocarpal and distal radioulnar joints	3	The arm is positioned horizontally and stabilized by three supports at: - radius head; - index, middle, and ring fingers middle phalanges; - thumb distal phalanx.
Thumb	Interphalangeal (IP) and/or metacarpophalangeal (MP) joints	3	The hand is positioned horizontally and stabilized by three supports at: - ulna head; - index, middle, and ring fingers middle phalanges; - thumb distal phalanx.

Materials Research Proceedings 35 (2023) 103-110 https://doi.org/10.21741/9781644902714-13

Finger (Index)	Proximal interphalangeal (PIP) and distal interphalangeal (DIP) joints	2	The (index) finger is positioned horizontally and stabilized by two supports at: - metacarpals; - (index) finger distal phalanx.

Elaboration of the customized anatomical regions into orthotic models. The 3D scans were imported into a software developed with the purpose of transforming the surface anatomical information into a solid model of the orthosis. The program was initially designed for a specified application, namely arm modelling [7], and partially automates its manual modelling in a series of simple steps (described in Table 2), based on the Python language. In the present research, the use of this software was extended to other atomic regions belonging to the upper-limb extremities (fingers) in an effort to test its adequacy.

Table 2. Operations of the modelling software.

Function	Description
Centering	Translation of the stl scan from its original reference system to a new reference system with (0;0;0) origin.
Fixing	Removal of duplicated/isolated vertices/faces, edge repair, hole closure, normal correction, mesh reconstruction and simplification.
Smoothing	Homogenization of the surface texture.
Expanding	Shift of the faces along their normal and towards the outside to arbitrarily expand the mesh.
Solid creation	Converting the surface into a solid through the generation of a thickness of arbitrary size.
Cutting	Removal of the element extremities through cuts perpendicular to Cartesian axes. Cuts in different directions are executed by orienting the orthotic element accordingly.
Lightening	Creation of holes (of arbitrary shape and dimension) along the solid structure to reduce the weight and volume of the orthotic element.
Dividing	Splitting the model into two halves.
Combining	Creation of connection points on the external surfaces of the two halves and implementation of elements that prevent slippage of the union surfaces during the assembly of the two halves.

From the software, two orthotic designs per anatomical application were retrieved: a full model and a lightened model. The latter design presented a pattern of rhomboid-shaped holes, realized through the lightening operation. An additional orthotic design was developed from the full model: simulations were performed using the optimization module of the finite-element analysis (FEA) software Abaqus in order to lighten the structure by considering reasonable forces acting on the orthotic element during the rehabilitation pathway.

Static simulations simplified the patient-device system by considering only the orthotic element. Load conditions were conceived to recreate the flexion of the joints considered in each application and, in the current optimization study, were represented as followed:

- Wrist – Application of a torque (with F = 200 N and d = 100 mm) on the distal perpendicular surface of the orthosis (in the proximity of the fingers), forcing the proximal perpendicular surface of the orthosis with an encastre constraint.
- Thumb – Application of a torque (with F = 30 N and d = 100 mm) on the perpendicular thumb surface of the orthosis, forcing with an encastre constraint the perpendicular surface of the orthosis near the wrist.
- Finger (Index) - Application of a torque (with F = 30 N and d = 60 mm) on the distal perpendicular surface of the index finger, forcing with an encastre constraint the proximal perpendicular surface of the index finger.

The optimization process determined a new material distribution based on the minimization of the strain energy, while satisfying a volume (below the 60% of the original volume) and geometric (preservation of the load and boundary condition areas) constraint.

Additive manufacturing of the orthotic models. The orthotic models were manufactured by Ultimaker S5 desktop Fused Deposition Modelling (FDM) machine, an additive manufacturing (AM) technology based on heating and extrusion of a thermoplastic filament from a nozzle to a building platform. The polymeric filament was polylactic acid (PLA) and, besides being one the most commonly used material in 3D printing, it combined the needs for cost-effectiveness [8]. The mechanical properties (Table 3) and printing settings (extra fast modality, Table 4) of Ultimaker PLA were retrieved from the technical data sheets. Besides, the use of the manufacturing material, the use of support material was kept to a minimum: only orthotic models characterized by large overhangs and hanging features necessitated the use of Ultimaker Breakaway support material (the minimum overhang value for which the support was printed was 65°).

Table 3. Mechanical properties of Ultimaker PLA.

	Density	Elastic modulus	Ultimate tensile strength	Poisson ratio
PLA	1.24 g/cm^3	2347 MPa	46 MPa	0.33

Table 4. Printing settings of Ultimaker PLA (extra fast modality).

	Layer height	Infill % , pattern	Printing temperature	Printing speed
PLA	0.6 mm	100%, line	210°C	70 mm/s

Results

Process evaluation. The process of manufacturing customized orthoses for upper limb rehabilitation progressed according to the three stages stated in the methodology.

Scans of the three anatomical regions under consideration were obtained in multiple attempts owing to the high resolution of the scanning medium (RS6 Laser Scanner), which inevitably detected the presence of unintentional muscle contractions inducing misalignment issues in the mesh. The resulting scans were of high quality and the meshes were extremely dense (i.e., the arm scan featured over 150,000 nodes).

Subsequently, the scans were entered into the modeling software. By subjecting the arm scan to the modeling commands, orthotic models (full and lightened designs) for wrist rehabilitation were obtained flawlessly. Also, the software responded positively to the generation of orthotic models of a different shape and geometry, indeed, orthotic models for rehabilitation of the thumb finger and index finger were successfully obtained. Nevertheless, two remarks concerning the development of the latter two orthotic models should be made; these scans were not subjected to the fixing command, as this algorithm (combined with the smoothing function) was prone to excessive shrink the original mesh in an attempt to optimize the number of nodes and triangles (as shown in Figure 1, representing the index finger application). One further remark concerned the orthotic model for the treatment of the index finger, dividing and combining operations were not necessary since the orthosis could be modeled as a single part.

Different designs for the three applications were developed (as presented in the following paragraph, in Table 5-7):

- Model 1 – full model.
- Model 2 – lightened model obtained with the lightening function.
- Model 3 – lightened model obtained with the optimization module of Abaqus.

Regarding model 3, at the completion of the topological optimization process, the resulting geometry was definitely rough such that extra edge refinements are necessary. Particularly, the finishes would be functional to facilitate the 3D printing process, besides providing practical wearability. Depending on the extension and medical function of the specific anatomical region, different orthotic thicknesses were made: the wrist and thumb orthoses were built with a thickness of 2 mm, whilst the index finger orthosis of 1 mm. The thicknesses conformed to medical indications and are slightly thinner than traditional devices.

The medical prototypes were printed in PLA using FDM technology (Ultimaker S5). In almost every instance the use of support material (Ultimaker Breakaway) was necessary, with the only exception of models 1 and 2 of the index finger orthosis. Models derived from topological optimization (model 3) maximized the use of support material.

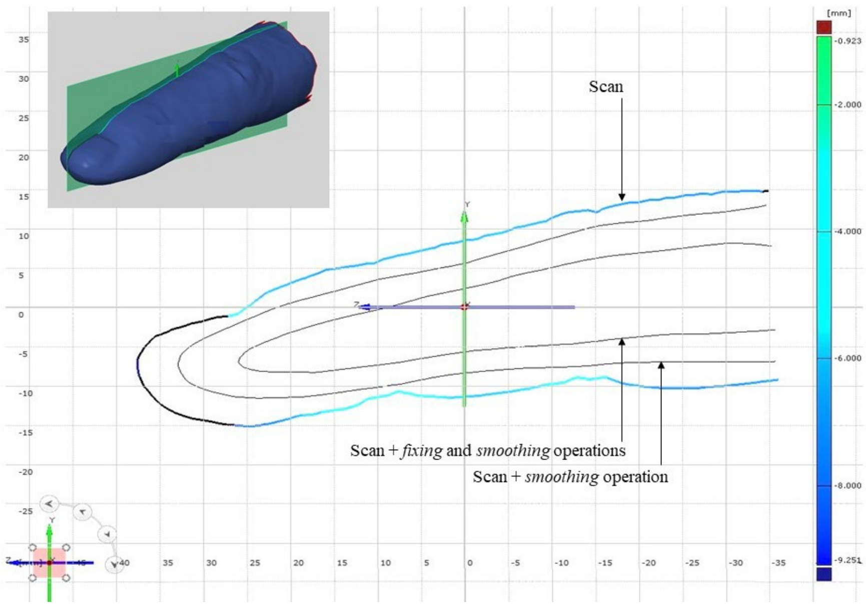


Figure 1. Graphication of the error (mm) between the finger original scan and the finger model which was developed using the fixing command. In the upper left quadrant measurement section was reported.

Product evaluation. The current procedure was complemented with a time-cost valuation of the medical devices. Time analysis comprised the estimation of the production time (material deposition time) through the use of the Ultimaker Cura slicing program. Cost analysis involved the cost of the materials used to produce the prototypes, thus the manufacturing material (PLA, about 0.57 €/m) and the support material (Breakaway, about 0.92 €/m). Cost analysis was based on the length of deposited filament, captured through the Ultimaker Cura slicing software. Also, the analysis was supplemented with the information on prototype weight and mechanical behavior under reasonable working condition to assess the feasibility of the two strategies of volume reduction. The mentioned information is discussed below and reported in Table 5-7.

In terms of time, in each medical application, the progressive lightening of the device showed an increase in printing time prompted by the need of employing support material for the manufacturing of geometries characterized by large overhangs and thin-walled structures. The effect was particularly emphasized in topologically optimized models (model 3), whose designs were characterized by printing times at least twice as long as the full models (model 1). In percentage terms, the worst-case scenario was the orthosis dedicated to the rehabilitation of the index finger conditions: the printing time of the orthotic model 3 was 2.6 times longer than the printing time of the orthotic model 1.

Materials Research Proceedings 35 (2023) 103-110 https://doi.org/10.21741/9781644902714-13

Table 5. Assessment of the wrist orthotic models.

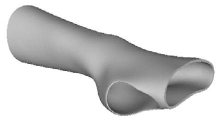
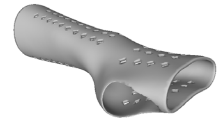
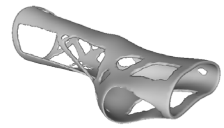
	Wrist – Model 1	Wrist – Model 2	Wrist - Model 3
			
Printing time	122 min	176 min	294 min
Material cost	7.07 €	8.27 €	11.66 €
Weight	95 g	92 g	64 g
Max. stress	30 MPa	31 MPa	32 MPa
Max. displacement	2.7 mm	3.2 mm	4.0 mm

Table 6. Assessment of the thumb orthotic models.

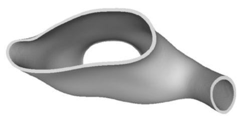
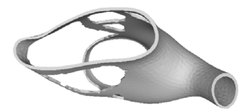
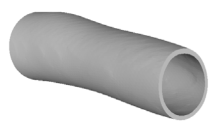
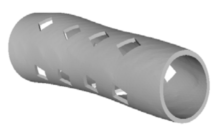
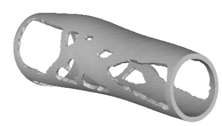
	Thumb – Model 1	Thumb – Model 2	Thumb - Model 3
			
Printing time	74 min	95 min	151 min
Material cost	4.95 €	5.43 €	6.71 €
Weight	64 g	62 g	42 g
Max. stress	11 MPa	11 MPa	11 MPa
Max. Displacement	0.5 mm	0.5 mm	0.5 mm

Table 7. Assessment of the (index) finger orthotic models.

	Finger – Model 1	Finger – Model 2	Finger - Model 3
			
Printing time	12 min	14 min	31 min
Material cost	0.40 €	0.35 €	0.80 €
Weight	6 g	5 g	3 g
Max. stress	14 MPa	24 MPa	25 MPa
Max. Displacement	0.5 mm	0.6 mm	0.5 mm

A similar trend is shown in the cost analysis too. Indeed, in each medical application, the progressive lightening of the device led to a rise in material cost. The implication of the above consideration was that the manufacturing material cost saved through the volume reduction strategy (particularly that referring to topological optimization) was totally recovered by the use of support material (which for the same quantity has a higher purchase price than PLA). The worst-case scenario was, once again, the orthosis dedicated to the treatment of the index finger: cost of model 3 was twice as much as model 1, however, in absolute terms, the cost was moving from € 0.40 to € 0.80.

From a mechanical behavioral perspective, during the conducted FEA simulations, all the medical applications and each different design of medical application were considered compliant in terms of tensile strength and deformation. Regarding the maximum stress values recorded, the stress was always found to be less than the UTS of the manufacturing material, thus preventing failure during service. In terms of deformations, the highest displacement values were recorded in the case of the orthosis dedicated to the wrist joint care: these values were slightly more than 3 mm, but were still considered acceptable as they occur near the distal end of the device, thus, leaving the wrist area almost unaffected; displacements of the wrist region varied from 0.5 mm to

Materials Research Proceedings 35 (2023) 103-110 https://doi.org/10.21741/9781644902714-13

1.1 mm. Regarding the thumb and the index finger orthoses, the registered maximum displacements were definitely contained, thus making the proposed solutions viable.

Considering all the factors mentioned above, some observations emerged. First, production time was a significant variable in the evaluation process of the analyzed methodology. Production times were meaningful (especially for large volume applications) and prolonged by additional time variables not taken into account in the current study (e.g. acquisition and modelling times). Given the circumstances, it is unlikely to guarantee ready-to-use devices and, therefore, it would be necessary to adopt some measures to streamline the overall process time. While no particular advantage emerged from the time analysis, sources of competitiveness did emerge from the cost evaluation. Indeed, the estimated material cost for 3D production was significantly lower than the cost of material used in the production of conventional orthoses (LTT materials).

The strategy of reducing the volume of orthotic models with the aim of optimizing the production process did not achieve the desired results in terms of time and cost (except for the finger index orthosis model 2, whose output might be a considerable alternative). Even more dubious was the role of volume reduction implemented through topological optimization. Indeed, there was also evidence of an even greater increase in material cost and production time: the irregular shapes derived from the topological optimization simulation required an immoderate amount of support material, which drastically affected the material deposition process. In contrast, from the mechanical performance perspective, satisfactory stress and displacement values were ensured for moderate volume (and weight) reduction in both the strategies of volume reduction. Of course, topological optimization, whose inherent purpose is to define the best material distribution while satisfying a peculiar operating condition, allowed for even lighter solutions.

Certainly, through the illustrated methodology, it was possible to make extremely customized and lightweight geometries able, at the same time, to ensure adequate mechanical strength, which up to date it is not possible with traditional splinting techniques.

Conclusions

The present research evaluated the process of customized splinting for the treatment of upper limb pathologies through the utilization of advanced techniques, specifically Reverse Engineering (RE) and Additive Manufacturing (AM).

The manufacturing process of patient-specific orthoses, analyzed in the current study, was considered functional and straightforward. Some general observations may be drawn. Regarding the acquisition activity, although the scanning laser under consideration was highly performant, it is advisable to evaluate technologies that facilitate the scanning operation for the medical worker, even in the face of a reduction of the image quality. Inherent to the modelling activity, the software developed with the purpose of transforming the arm surface into an arm orthosis successfully designed also medical devices of various kinds, demonstrating the possibility of using a single application for modelling diverse anatomical areas. Optimization of the software algorithms would allow even more agile handling of meshes of different sizes. On the 3D printing side, there was an emerging need to optimize printing time, for instance using higher-performance 3D printers. In addition, post-printing surface finishing treatments of the devices should be provided too.

Two volume-reduction approaches were investigated by developing lightened orthotic models. Nevertheless, from the current product evaluation, the most competitive design in terms of cost, time and mechanical behavior resulted to be the standard full prototype (model 1). Thus, the role of the two emptying strategies found to be still uncertain: the costs and production times associated with the deployment of these approaches must be justified by the value and specificity of the considered application. Surely, the use of the topological optimization technique is a powerful tool, able to greatly lighten medical devices while ensuring good mechanical performances. However, in some cases the role of topological optimization compared to the volume reduction performed with the lightening command was questionable (e.g., in the case of model 3 of the wrist and thumb orthoses improved lightness was achieved and mechanical performance simulations suggested that lighter structures can be further realized), in some others it was clearly the option to be discarded (e.g., in the case of model 3 of the index finger orthosis, whose efforts would not bring additional value compared to model 2).

To conclude, the present study consisted in a preliminary analysis, evaluating few factors (such as production cost, time and mechanical behavior); future research needs to be conducted to provide a more exhaustive assessment.

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