



A CAD-based Procedure for Designing 3D Printable Arm-Wrist-Hand Cast

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ABSTRACT

Wrist injuries are one of the most common fractures, specifically around 25% of fractures among the pediatric population and up to 18% in the elderly age group are distal radius fractures. To date, the standard treatment entails the use of a tailor-made plaster of Paris cast. Although it is a simple and reliable treatment, it presents several disadvantages: its weight generally causes discomfort, it cannot be taken off without breaking it, it can cause skin rashes and prevents ventilation of the treated area. To overcome the limitations of the above mentioned treatment, 3D printed orthopaedic casts based on reverse engineering (RE) and additive manufacturing (AM) techniques have been proposed in literature. Despite these solutions prove to be a valid alternative to the standard treatment, the clinical use of AM-based devices is not trivial due to the need of expert CAD modelers to design the 3D model of the orthosis starting from the patient's anatomy 3D acquisition. In this work, the authors identify a systematic procedure to create an orthosis model, compliant with medical guidelines, using common CAD tools. The systematic procedure, even still manually performed, envisages a set of tasks, grouped into five main blocks, that will be easy to be automatized in the future, thus eliminating the necessity of designing expertise to model the orthosis. The proposed procedure allows to design a device composed of two halves, to ease the application, locked through a zip tie-based mechanism. A preliminary ventilation pattern is proposed and tested with a FEM analysis to ensure structural resistance. The procedure has been tested on six case studies: all the orthoses models were correctly generated without major complications and positive user feedbacks were generally obtained throughout the tests.

Keywords: CAD, Reverse Engineering, Orthosis Modelling, Cast Modeling, Personalized Medicine.

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1 INTRODUCTION

An orthosis is a medical device, used in orthopedic and traumatology, which has the main function of restraining articulation movements after a trauma, a surgery, a distortion or for arthrosis patients. Moreover, an orthosis can be used to reduce the articulation load and to prevent bones faults [20]. The typical treatment for bones fractures foresees the use of a tailor-made plaster cast; the established procedure is quite simple, inexpensive and reliable. Nevertheless, a plaster cast has several disadvantages: its weight generally causes discomfort, it cannot be taken off without breaking it, it can cause skin rashes, and it cannot ventilate the treated area [4,16,18]. These issues can lead to serious medical complications such as compartment syndrome, ischemia, heat injury, pressure sores and skin breakdown [4,7,9,12]. Therefore, the application of traditional casts to orthopaedics patients might not represent, to date, the best option. To overcome the above-mentioned drawbacks, a number of strategies based on reverse engineering (RE) and additive manufacturing (AM) techniques have been carried out and proved to be a valid alternative for the treatment of hand-wrist-arm (HWA) pathologies [7,13,17,30], which are among the most common fractures [22]. Starting from the arm-wrist-hand district anatomy acquisition, by using these techniques it is possible to manufacture a custom-made orthosis having similar mechanical properties (e.g. stiffness) of traditional casts. At the same time, besides being much more comfortable, additive manufactured orthoses can be designed in order to have useful advantages such as lightweight and removability. Moreover, when a reticulated structure is used to design the orthosis, a beneficial access of water and air to the treated arm can be assured. These benefits are particularly important for children, who could gain a better range of motion and portability, not to mention the advantages from waterproof nature of the device.

The most common framework for the creation of 3D printed personalized casts starts with the acquisition of the arm geometry by means of 3D scanning technologies. As widely known, such technologies can be classified into professional 3D scanners (e.g. Romer Absolute Arm, Konica Minolta Range7, Aicon 3D System StereoScan), and low-cost devices (such as RGB-D cameras, e.g. Kinect, Intel RealSense, Occipital Structure and time-of-flight (ToF) cameras, e.g. Kinect v2). Due to the high cost of professional technologies several applications at the state of the art for 3D cast modeling makes use of low-cost devices [14,29]. Unfortunately, to date, HWA district dedicated scanners (integrating either professional or low-cost technologies) require the patient to stay still for an extended period (at least 30 seconds). The speed of the acquisition process is nonetheless a fundamental characteristic to minimize artefacts due to subject movement; in this work the dedicated scanner proposed in [6], which is characterized by a high accuracy and a high speed of acquisition (approximately 2 seconds), has been used to obtain the 3D reconstruction of the HWA anatomy. The scanner makes use of four Intel RealSense SR300 depth cameras, which prove to be well-suited for close-range applications [5].

The scanned data is processed to generate a CAD model of the custom-made orthosis that is finally fabricated using AM.

Two principal strategies can be identified at the state of the art to create the CAD model: i) the adaptation of a pre-defined template to the scanned geometry [11,19,23]; ii) a manual procedure performed within a CAD environment [8,10,16,18,24,25]. Most methodologies described in literature neither guarantee the achievement of a valid result from a medical perspective [8,18] nor allow an easily usable and scalable framework for the application in clinical practice. Specifically, these last goals would be reached by implementing a fully automatized procedure that: i) does not require CAD technical skills to the user; ii) does not needs significant time for the generation of the CAD model; iii) are validated against a set of clinical trials. To reach such an ambitious and challenging result, a first important step consists of creating a systematic procedure, which would allow to produce a consistent orthosis model using common CAD tools. To this aim, the present work focuses on defining a procedure to design an arm-wrist-hand cast for the treatment of wrist fractures, starting from 3D scanned data, by using CAD tools, hence following a RE paradigm. Considering medical guidelines, the procedure is conceived to be easily automatized, thus reducing as much as possible the human interaction. Moreover, in order to prove the soundness as well as the scalability and possible automatization, the devised procedure underwent a validation campaign on six case studies. Section 2 summarizes the medical requirements for an effective treatment. In section 3 the proposed framework is presented. Results of the application of the procedure are described in section 4 and, finally, conclusions are drafted in section 5.

2 MEDICAL GUIDELINES

According to the common medical practice [4], the effective treatment of a wrist fracture requires the application of a restrictive device, which, regardless of its production technology, assures the compliance with the fundamental requirements described below. The arm-wrist-hand district needs to be rigidly constrained during the entire treatment, which usually requires four to eight weeks for healing [4]. During this period, the arm position

needs to be in a resting configuration, with the hand defining an angle of 10° - 20° with the arm [26], as shown in Fig. 1(a).

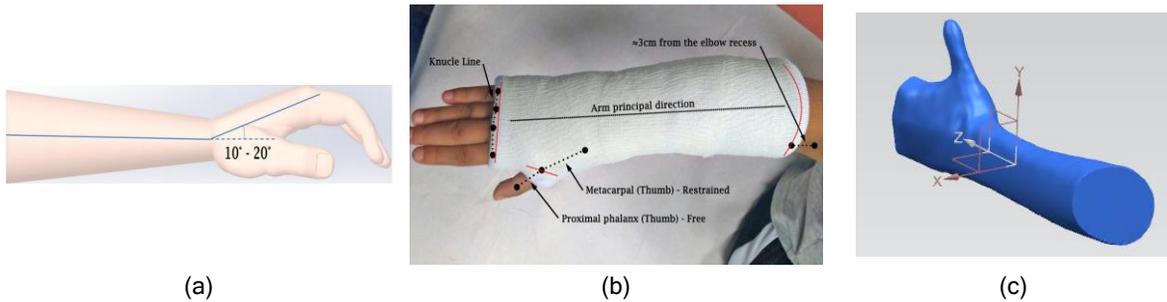


Figure 1: a) Hand/arm angle in resting position; b) plaster cast with reference lines (black). Red lines represent the limits of the orthoses; c) example of arm-wrist-hand district pre-orientation.

Considering the principal direction of the arm (Fig. 1(b)), the device must begin within ~ 3 cm from the elbow recess and must end few millimeters below the knuckles, to ensure mobility of the fingers. The hole for the thumb must be positioned to allow mobility to the proximal and digital phalanges and to prevent discomfort (see Fig. 1(b) as an example). Moreover, the device must have a good adhesion to the arm surface in order to hinder articulation movements as well as rigid movements between the arm and the device itself.

3 METHOD

A valid and reliable orthosis reconstruction procedure needs to satisfy two principal aspects:

- It must be sound - i.e. a correct model reconstruction should be obtained independently from the acquired arm geometry. This means that it should allow the reconstruction of all possible arm anatomies (e.g. adults/children, male/female, etc.).
- It should be well suited for automatization in order to reduce the user intervention so as to maximize the usefulness of the technology.

In order to assure the wearability of the AM-produced device, the orthosis is designed as composed by two separate shells: one rests on the back of the hand, and one on the internal side. The two halves are joined together by means of a closing system based on zip-ties; the connectors are kept in place thanks to a specifically designed housing system.

According to these aspects, the systematic procedure proposed for designing 3D printable arm-wrist-hand cast consists of 5 phases as depicted in Fig. 2.

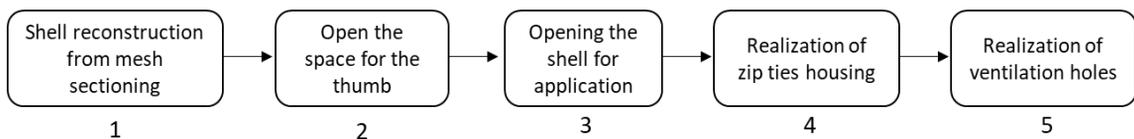


Figure 2: Modeling macroblocks of the procedure for the generation of a personalized cast.

The starting point of the procedure is the 3D reference data of the arm that is acquired by means of the 3D scanner based on RGB-D cameras described in [6] that proves, according to [5], to be sufficiently accurate for such an application. Despite authors' choice to use commercial devices to obtain the anatomy of the patient, the procedure is not strictly linked to the acquisition mode. In this case, the output data produced by the scanner is pre-oriented so that the *z-axis* is aligned with the arm principal direction; the origin corresponds to the barycenter of the obtained mesh, the *y-axis* is oriented towards the upper side of the hand and the *x-axis* is consequently oriented (see Fig. 1(c)). If a different acquisition mode is chosen the 3D reference data must be properly aligned, thereafter a solid shell is built upon the arm anatomy (Step 1). In Step 2, the solid shell is perforated to create an

opening for the thumb finger. Subsequently, the shell is cut in half to create two wearable parts (Step 3) and zip-ties housing features are built on the external surface of the orthosis (Step 4). Finally, in Step 5, ventilation holes are generated on the two halves of the orthosis. The result of the procedure consists of the CAD model of the cast, ready to be manufactured using AM.

The reconstruction approach makes use of a number of 2D sections obtained by intersecting the 3D scan data with properly chosen planes. Two issues related to the generation of such mesh sections have to be confronted with: i) the position and the orientation of cutting planes with respect to the reference system; ii) the number of sectional planes and their reciprocal distance to assure a good resolution during the loft operation. Cutting planes are generated as locally orthogonal to a guide curve obtained by intersecting the mesh with the *XZ-plane* (see Fig. 3(a)) and selecting (between the two resulting curves) the one corresponding to the external part of the arm. This choice has been tested as preferable to obtain a smooth yet detailed model of the arm geometry (i.e. well-distributed sections); moreover, the use of the external curve minimizes the risks of obtaining intersecting or incomplete sections.

Referring to the number and spacing of cutting planes, convenient values are identified for both the arm and the hand regions; searching for a compromise value between required accuracy and the weight of the procedure as well as the smoothness of the generated surface, such values are set at 10mm for the arm and 5mm for the hand. This choice was confirmed during a series of preliminary tests, as it well adapts to the reconstruction of arms characterized by significant differences in shape and proportion (e.g. children vs. adults).

The polylines obtained by intersecting the 3D scan data with the sectional planes are used to generate 2D sketches (i.e. closed spline curves) of sectional profiles of the arm district so as to reconstruct the arm model by using a single loft operation. The most challenging geometric feature to model, following this strategy, is represented by the thumb area. In order to avoid the generation of irregular section profiles, which leads to reconstruction errors during the loft operation (see Fig. 3(b)) and to provide the bases for the generation of a suitable hole for the thumb, the original mesh must be edited. Specifically, the thumb area is “segmented” in the original mesh and deleted, leaving a hole which is subsequently filled with a curvature-based automatic patch (Fig. 3(c)). The identification of the area to be segmented can be guided by the user, who would select the points of the thumb to be removed.

Even non-expert users can perform this rather simple task. The need for a manual intervention does not compromise the automatization of the entire procedure as this task could be integrated in a series of semi-automatic steps (i.e. the automatic process could stop when required to ask for user input).

The edited surface is suitable for a reconstruction based on a single loft operation.

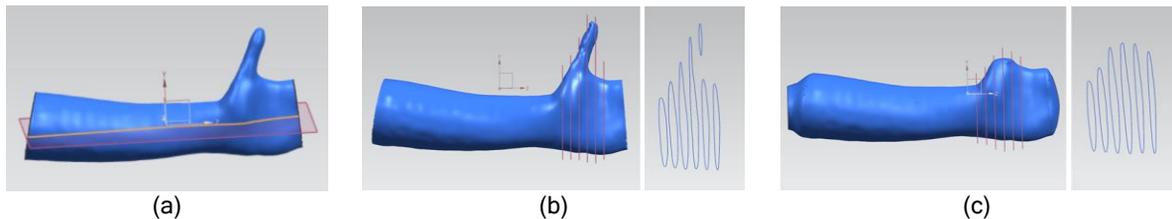


Figure 3: a) Generation of the guide curve for section extraction; b) irregular sectional profiles of the original mesh; c) regular sectional profiles of the edited mesh.

The CAD modelling procedure is detailed in Tab. 1 where each task is numbered according to the steps of Fig. 2. All the steps have been carried out within Siemens NX modelling environment [27].

	<p>1a. the mesh representing the arm geometry obtained from the acquisition system is imported (blue in the figure);</p> <p>1b. the guide curve (<i>line#1</i>) representing the back profile of the arm-wrist-hand district is extracted by intersecting the mesh with the <i>XZ-plane</i>;</p> <p>1c. consecutive sections (<i>sectionset#1</i>) of the mesh are extracted with a sheaf of plane locally orthogonal to <i>line#1</i>;</p>
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	<p>1d. from each section of <i>sectionset#1</i> a set of 20 points uniformly distributed (<i>pointset#1</i>) is extracted and a spline is built (<i>splineset#1</i>); the number of points has been empirically determined as sufficient to describe the arm geometry. 1e. a solid loft (<i>solid#1</i>) is performed on <i>splineset#1</i>;</p>
	<p>1f. each spline of <i>splineset#1</i> is offset of 4mm (<i>splineset#2</i>) and a second external solid loft (<i>solid#2</i>) is performed on <i>splineset#2</i>. The thickness value is chosen as a compromise to allow orthoses strength and reasonable time for the AM process. 1g. a Boolean subtraction operation between <i>solid#2</i> and <i>solid#1</i> is performed to obtain the principal shell of the orthosis (<i>shell#1</i>);</p>
	<p>2a. a plane parallel to the XZ-plane intersecting the mesh in the thumb area is created (<i>plane#1</i>). The position of <i>plane#1</i> is determined by a distance of 4mm from the vertex characterized by the maximum Y value within the reference mesh; 2b. a spline curve (<i>spline#1</i>) is fitted on the polyline resulting from the intersection of <i>plane#1</i> and the mesh; 2c. from <i>spline#1</i> is created an extruded surface in the Y direction (<i>surface#1</i>) which is used to delimitate <i>shell#1</i> and create the hole for the thumb;</p>
	<p>3a. <i>line#2</i> is defined as the broken line which interpolates for each curve of <i>splineset#1</i> the point characterized by the maximum value in the Y coordinate among the 20 points extracted in step 1d; 3b. <i>line#2</i> is extruded in the Y direction to create <i>surface#2</i></p>
	<p>3c. <i>shell#1</i> is trimmed with <i>surface#2</i> to generate <i>half_shell#1</i> and <i>half_shell#2</i></p>
	<p>4a. three section pairs within <i>splineset#2</i> (placed in elbow, wrist and hand areas) are offset of 3mm; the wrist section is identified using the hole for the thumb as reference element (25 mm from the end of the thumb curve in the Z direction). 4b. three lofts are generated from each section pair to create the housing space for zip ties (<i>loft#3#4#5</i>);</p>
	<p>4c. <i>surface#2</i> is offset of 4mm and -4mm (<i>surface#3#4</i>) in the X direction to delimitate <i>loft#3#4#5</i>, discarding the areas of <i>loft#3#4#5</i> that are not contained between <i>surface#3</i> and <i>surface#4</i>; 4d. the XZ-plane is offset of 4mm and -4mm (<i>plane#2#3</i>) in the Y direction to delimitate <i>loft#3#4#5</i>, discarding the areas of <i>loft#3#4#5</i> that are not contained between <i>plane#2</i> and <i>plane#3</i>;</p>
	<p>4e. rectangular openings (4 mm width) are generated in the centre of <i>loft#3#4#5</i> following the curvature of <i>shell#1</i> to create the guides for the zip ties.</p>

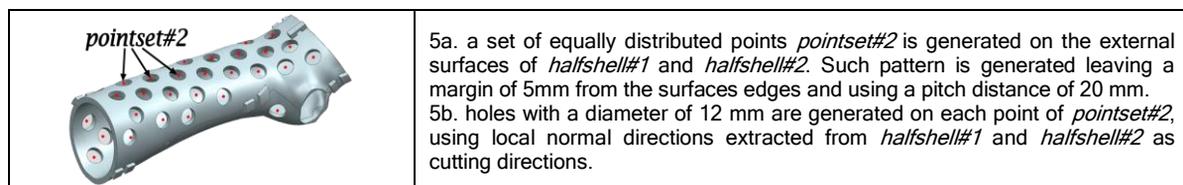


Table 1: Evolution phases of an applying example of the devised procedure.

The last step, i.e. the realization of ventilation holes, is fundamental to reduce weight and to allow both inspection and ventilation of the treated area. The proposed solution is based on a hole pattern obtained starting from a set of randomly generated points equally distributed on the entire surface, except for the perimeter of the two halves and the zip ties housing locations. At the end of stage 5b the digital model can be exported into two distinct STL files (one for each part of the device), ready to be built thanks to additive manufacturing processes.

4 RESULTS

The devised procedure has been tested in the generation of orthoses for six people, three children (1 male and 2 female) and three adults (2 male and 1 female). The composition of the panel group has allowed the validation of the modelling process on significantly different arm-wrist-hand anatomies (Tab. 2). For each case, the procedure has been applied following the framework described in the previous section. All the orthoses models were correctly generated without major complications, enabling the generation of six valid medical devices ready to be manufactured.

	<i>Patient information</i>				
	<i>Gender</i>	<i>Age</i>	<i>Weight</i>	<i>Arm Length</i> (elbow to knuckles line)	<i>Arm Diameter</i> (elbow)
Patient #1	<i>M</i>	<i>11</i>	<i>40kg</i>	<i>31cm</i>	<i>7</i>
Patient #2	<i>M</i>	<i>50</i>	<i>73kg</i>	<i>38cm</i>	<i>8</i>
Patient #3	<i>M</i>	<i>45</i>	<i>87kg</i>	<i>40cm</i>	<i>9</i>
Patient #4	<i>F</i>	<i>6</i>	<i>25kg</i>	<i>19cm</i>	<i>4.5</i>
Patient #5	<i>F</i>	<i>7</i>	<i>26kg</i>	<i>22cm</i>	<i>5.5</i>
Patient #6	<i>F</i>	<i>30</i>	<i>48kg</i>	<i>31cm</i>	<i>6</i>

Table 2: Composition of the panel group.

In order to have the result analysed by orthopaedics, and to evaluate the effectiveness of the produced results in terms of practical usability such as the reliability of the closing system, the adherence to the scanned arm, and their restraining properties compared with traditional plaster casts, all the generated models were manufactured. All devices were FDM-produced, specifically using the Stratasys F370 machine [28]. ABS-M30 material [1], a z-resolution of 0.178 mm and a horizontal orientation of the device on the build plate were chosen to maximize the orthosis strength. All the remaining settings are automatically handled by the software provided with the F370. The machine of choice is capable of printing soluble support material; as a result, minimal post processing efforts are required to clean the produced parts. Fig. 5 shows an example of the resulting orthosis manufactured. Most important factors that brought to the choice of FDM are: i) it is a “clean” process - no dust is generated - and, therefore, it can be used also in medical environments; ii) the mechanical performances of the printed parts are generally compliant with the application requirements; iii) FDM-printed orthoses (in ABS) have already been proposed and approved for medical applications [2].

Each subject tested his/her orthosis by wearing it for a limited amount of time (~1 hour) in order to highlight possible major flaws. Even in this limited timespan, comfort/discomfort related issues can be highlighted. More advanced tests will be performed once the procedure will be implemented in its final form and will eventually consider also a clinical trial of the orthoses (i.e. the devices will be used for the actual treatment of wrist fractures). Subjects were asked to fill an appositely devised questionnaire, designed, based on published studies [7,15], to

investigate ergonomics, comfort and user satisfaction; the questionnaire is presented in Tab. 3. For each question, each subject assigned a score from 1 (very unsatisfying) to 5 (highly satisfying).



Figure 5: Custom-made orthosis manufactured with FDM technology.

Question	Scores				
	1	2	3	4	5
Q1. Is the cast comfortable?	Want it removed	Irritating	Fairly comfortable, occasional irritation	Comfortable	Very comfortable
Q2. Would you prefer the new cast over traditional one?	Non-willing	Accepted reluctantly	Minor doubt	Positively	Strong willingness to try new cast
Q3. How do you consider the cast weight?	Heavy cast. Difficult to use arm	Moderately heavy. Limited multiple activities	Mildly heavy. Limited several activities	Fairly light	Light cast. Won't interfere with activities
Q4. Is the restricting effect stable?	Non-satisfying reduction requiring further procedure	Reinforced same cast	Slight shift	Marginal shift but no need for re-manipulation	No loss of reduction

Table 3: Satisfaction questionnaire.

Results of the questionnaire for the six patients are in Tab. 4.

	Scores				
	Q1	Q2	Q3	Q4	Total Score
Patient #1	3	4	5	4	16
Patient #2	2	3	4	5	14
Patient #3	4	4	5	5	18
Patient #4	3	4	5	4	16
Patient #5	3	4	5	4	16
Patient #6	3	3	4	5	15
Average	3.0	3.7	4.7	4.5	

Table 4: Results of the questionnaire.

Three subjects out of six scored 16 out of 20, one subject scored 18 and no subject scored fewer than 14. With an average score of 3, the comfort of the device (Q1) represents the lowest score. From a further verbal investigation this discomfort resulted mainly caused by the contact of the 3D printed cast on the ulnar styloid process. Consequently, for a future development of AM-based casts, an appositely shaped hole in the correspondent region of the cast needs to be created. Accordingly, this aspect will affect the strategy adopted for generating ventilation holes.

On the other hand, the overall assessments of both HWA district restricting effect and weigh of the device were assigned high marks (4 to 5) thus proving that the new device is highly effective in these terms.

Moreover, in order to assess the mechanical performance of the so-generated device, a Finite Elements Analysis (FEA) has been performed on a simulated worst-case scenario representing the orthosis for a 95th percentile 14 y.o. male arm [2]. Accordingly, an orthosis of length ~400 mm and maximum diameter of ~90 mm,

has been used for this analysis; five alternative design solutions have been 3D modelled, changing the random configuration of scattered points on the surface, and analysed. A cantilever load case has been simulated.

Load has been imposed as a vertical concentrated force (100N) applied on the side of the hand, while the opposite side has been modelled as fixed geometry. This load condition is perfect to test the resistance of the most critical section of the arm (i.e. wrist section); moreover, it simulates a possible load condition typically characterizing the HWA district.

In the absence of specific strength requirements for immobilization devices, the entity of the vertical load has been estimated referring to similar studies in literature [21]. The resulting stress distribution is similar in all analysed cases, as reported in Tab. 5. In particular, the maximum value of the Von Mises stress is around 13MPa, with a maximum total displacement of around 2,5 mm. Fig. 4 reports two of the tested configurations.

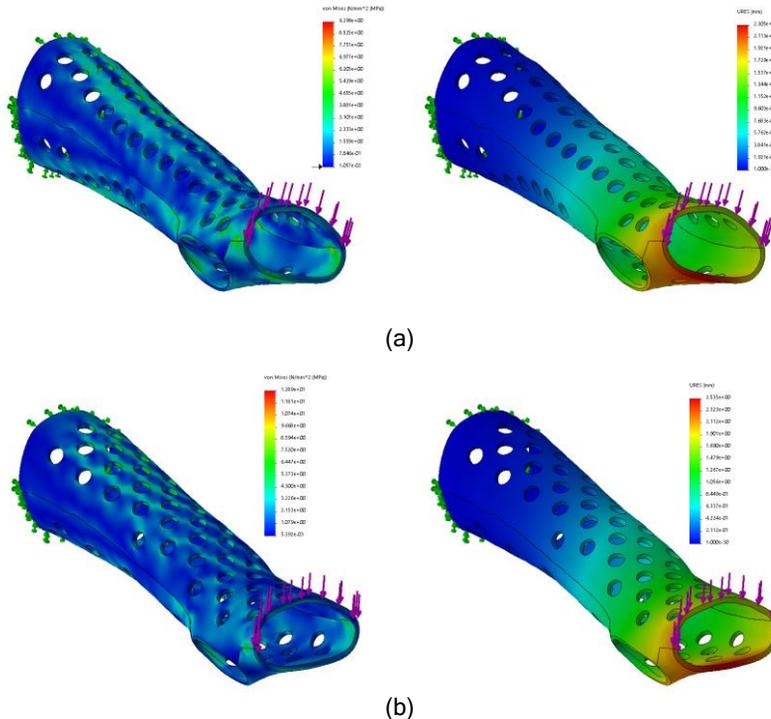


Figure 4: Results of the FEM analysis for two random configurations of ventilation holes, on the left the Von Mises stress distribution, on the right the corresponding total displacement.

#simulation	Maximum Von Mises Stress (MPa)	Max Total Displacement (mm)
1	9.60	2.34
2	9.29	2.31
3	10.33	2.42
4	11.19	2.49
5	12.89	2.54
mean	10.66	2.42
std.dev.	1.45	0.097

Table 5: Results of the FEM analysis conducted on five different models, reporting five different configurations of the ventilation pattern.

Since, as mentioned above, the standard deviation value characterizing the maximum stress observed in all the simulations is negligible for the considered application, the adoption of a random procedure to generate the pattern of ventilation holes is not prone to introduce an unexpected stress peak or an atypical tension distribution

that could compromise the safety of the device (i.e. all generated models are topologically equivalent). In fact, the material used to produce the orthoses is the Stratasys ABS M-30 which has a tensile yield strength equal to at least 26 MPa (along Z axis of the 3D printer, as reported in [1]); this value is two times higher than the maximum stress condition observed in the simulations (12.89 MPa). In other words, the compliance of the orthoses w.r.t. the load conditions imposed is assured with a safety factor equal to about 2.

5 CONCLUSIONS

The aim of the present work was to devise a systematic approach to the CAD modelling process for the reconstruction of patient-specific orthosis envisaging a future automatization of the whole process within a CAD environment. Starting from the 3D geometry of the hand-wrist-arm anatomy, the proposed procedure is presented as a framework consisting of five blocks, which generates an orthopaedic device composed of two halves, one laying on the back of the hand, and the other on the internal side, joined together by means of a closing system based on zip-ties.

The generation of the ventilation pattern is based on a set of equally distributed random points and represents a first attempt strategy that will be refined in the future, considering a proper structural analysis of the orthosis and ventilation/lightness considerations. Nevertheless, a FEA has been performed to prove the effectiveness, in terms of strength, of the proposed random configuration of pre-determined diameter holes. Future work, in this direction, will be oriented towards the simulation of different load-case scenarios (e.g. compression). It is the authors' opinion, however, that more reliable results can be achieved only performing physical tests on the printed orthoses. Multiple aspects, in fact, cannot be easily simulated using FEA techniques (e.g. anisotropy of the FDM process, manufacturing defects, contacts between arm/orthosis).

Validation tests showed that the proposed steps, depicted in Fig. 2, can be strictly followed without the need of any additional manual intervention from the user. Obtained results, therefore, prove the soundness of the whole procedure as well as its repeatability and general effectiveness. Positive user feedbacks were generally obtained throughout the tests. Occasionally, localised discomfort in the wrist area was reported; this aspect will be addressed in future work.

The study suggests the feasibility of an automatic implementation of the entire procedure. A future automatization could allow a significant reduction in terms of time required to produce the final model. Accordingly, future work will be oriented towards the development of an automatic tool for the modelling of personalized casts. The tool will be supplied with an intuitive GUI in order to allow the medical staff to autonomously control the orthoses generation. Moreover, a strategy based on optimization algorithms (such as Topological Optimization) for generating ventilation holes, will be investigated in order to further increase lightness, to reduce fabrication costs and times while preserving the strength of the orthosis.

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