



Title:

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

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Introduction:

An orthosis is a medical device used in orthopaedic and traumatology for the treatment of certain pathologies. It has the main function of restraining articulation movements after a trauma, a surgery, a distortion or for arthrosis patients. The typical treatment for bones fractures foresees the use of a tailor-made plaster cast which 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 [1,8]. These issues can lead to serious medical complications such as compartment syndrome, ischemia, heat injury, pressure sores and skin breakdown [1,12]. 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 arm-wrist-hand pathologies [3,6,7,14]. The most common framework for the creation of these personalized casts starts with the acquisition of the arm geometry by means of 3D scanning technologies. The scanned data is processed to generate a CAD model of the custom-made orthosis that is finally fabricated thanks to AM techniques.

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 [9]; ii) a manual procedure performed within a CAD environment [4,5,8,10,11]. Most methodologies described in literature neither guarantee the achievement of a valid result from a medical perspective [4,8] 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 need 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 create 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. Taking into account 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.

Medical guidelines:

According to the common medical practice [1], 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 [1]. 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 [12], as shown in Figure 1a.

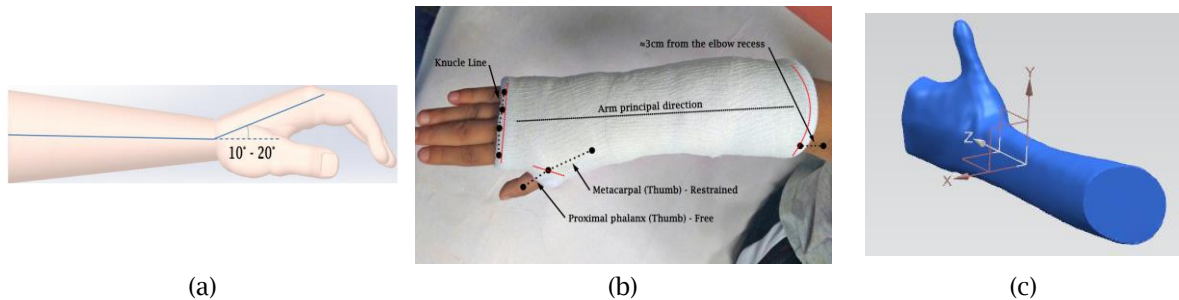


Fig. 1: a) Hand/arm angle in resting position; b) plaster cast with reference lines (black). Red lines represent the limits of the orthoses; c) example of arm-wrist-hand district pre-orientation.

Considering the principal direction of the arm (Figure 1b), the device must begin within ~ 3 cm from the elbow recess and end few millimeters below the knuckles, to ensure mobility of the fingers. The hole for the thumb must be positioned such to allow mobility to the proximal and digital phalanges and prevent discomfort (see Figure 2 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.

Method:

The systematic procedure proposed for designing 3D printable arm-wrist-hand cast consists of 5 phases as depicted in Figure 2.

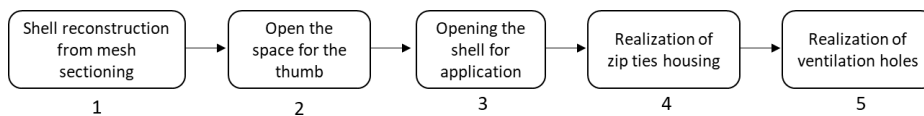


Fig. 2: Modeling macroblocks of the procedure for the generation of a personalized cast.

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 [2]. 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 Figure 1c). After the 3D reference data is properly aligned, 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 Figure 3a) and selecting (between the two resulting curves) the one corresponding to the external part of the arm.

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 reconstruct, following this strategy, is represented by the thumb area. In order to avoid the generation of irregular section profiles, which lead to reconstruction errors during the loft operation (see Figure 3b) 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 (Figure 3c). The edited surface is suitable for a reconstruction based on a single loft operation.

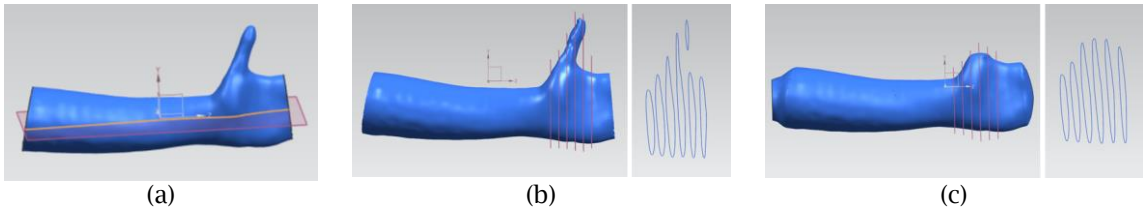
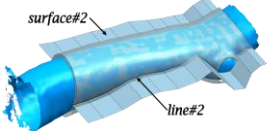
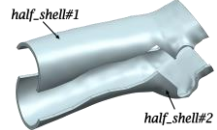
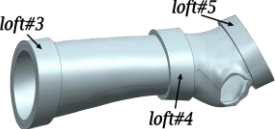
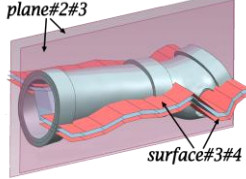

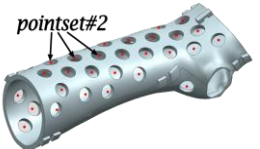


Fig. 3: a) Generation of the guide curve for section extraction; b) irregular sectional profiles of the original mesh; c) regular sectional profiles of the edited mesh.

The CAD modelling procedure is detailed in Tab. 1 where each task is numbered according to the steps of Figure 2. All the steps have been carried out within Siemens NX modelling environment [13].

	<p>1a. the mesh representing the arm geometry obtained from the acquisition system is imported (blue in the figure); 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>; 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>
	<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 <i>XZ-plane</i> 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 of the mesh characterized by the maximum Y value; 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; 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>
	<p>5a. a set of equally distributed points <i>pointset#2</i> is generated on the external surfaces of <i>halfshell#1</i> and <i>halfshell#2</i>. Such pattern is generated leaving a margin of 5mm from the surfaces edges and using a pitch distance of 20 mm. 5b. holes with a diameter of 12 mm are generated on each point of <i>pointset#2</i>, using local normal directions extracted from <i>halfshell#1</i> and <i>halfshell#2</i> as cutting directions.</p>

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

Results and Conclusions:

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. 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. In order 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. Figure 4 shows an example of the resulting orthosis manufactured using FDM technology.

Each subject tested their orthosis by wearing it for a limited amount of time in order to highlight possible major flaws and were asked to fill in an appositely devised questionnaire. Ergonomics, comfort and user satisfaction were investigated by the questionnaire; 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. Moreover, to assess the mechanical performance of the so-generated device, a Finite Elements Analysis has been performed to prove the effectiveness, in terms of strength, of the proposed random configuration of pre-determined diameter holes, proving the compliance of the orthoses w.r.t. the load conditions imposed with a safety factor approximately equal to 3.

Obtained results, therefore, prove the soundness of the whole procedure as well as its repeatability and general effectiveness. 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. 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.



Fig. 4: Custom-made orthosis manufactured with FDM technology.

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