Title:
Automatic CAD Modeling of Ventilation Holes for 3D Printed Wrist Orthoses

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Introduction:
Personalized medicine was revolutionized by the recent advent of Additive Manufacturing (AM) and Reverse Engineering (RE): these techniques can be effectively applied to the medical field to i) acquire information on patient anatomy; ii) design CAD models based on specific anatomical reference; iii) manufacture parts with sufficient accuracy for several medical applications.

In this framework, one of the most studied thread of research is the development of 3D printed casts, as an alternative to the traditional plaster of Paris, to be used to immobilize injured body regions. Specifically, most of the literature deals with the development of algorithms and CAD procedures to design forearm casts to treat wrist fractures [5,3,6], which are among the most common injuries.

Lightness, good ventilation to skin and muscles, an improved thermal comfort, and water resistance are the advantages that stand out comparing plastic casts to traditional ones. Indeed, a well-designed pattern of holes allows for a well-distributed water and airflow to the arm, hence contributing to the wettability of the device. Moreover, a significant weight reduction is possible only removing all the nonessential material. Obviously, the integrity and safety of the device must not be prejudiced in any way. As a result, the development of a reliable procedure to generate a pattern that respects both medical and structural constraints is essential to pursue the general goal of designing an effective 3D printed arm cast.

Different techniques to generate the openings have been proposed in the literature [2]:

- Random or regular repetition of a seed feature; several features can be used as template to be repeated - e.g. cylindrical holes or spheres [5].
- Surface mapping tools can be used to compute patterns defined by the original surface's geometrical properties. In this case, the general shape of the pattern is influenced by the considered surface. Other aspects of interest can occasionally integrate geometric ones to produce more effective patterns. As an example, Zhang et al. present in [6] a method based on a Hollowed Voronoi Tessellation to compute a pattern that optimizes the thermal flow to the injured arm.
- Topology Optimization (TO) approaches deal with the problem from a purely structural perspective: various algorithms can be used to determine the pattern that offer the best static or dynamic response to the loads faced by the orthosis. As a result, material is removed from the areas that less contribute to the mechanical performance of the orthosis (e.g. [1]).

While the generation of a pattern of regular shapes can arguably be considered as the most straightforward approach (several CAD systems offer dedicated tools to obtain a pattern of features), the generation of a tailored pattern, optimized to consider functional aspects, can guarantee more benefits to the patient. TO approaches, however, entail severe difficulties to be carried out effectively. Firstly, each case should be analyzed and simulated individually by means of finite element (FE) analyses that are time-consuming and difficult to automatize. Secondly, some medical constraints cannot be considered using TO. Finally, several aspects make the general problem difficult to be faithfully replicated in a simulation: interaction between arm and orthoses, possible collisions, definition of volumes where to apply constraints and loads that are different in each case. As a result, the effectiveness of the patient-specific TO approach would be weakened by a series of conservative hypotheses that must be imposed to assure the resistance of the orthosis.

To overcome the above-mentioned drawbacks, this paper proposes the design of a new reference pattern, obtained by integrating various aspects (mechanical strength, medical guidelines, ventilation optimization, comfort and replicability) and on its adaptation to each specific anatomy. A customized automatic algorithm to adapt the reference pattern on the surface of each cast is also proposed. The starting point of the developed procedure consists of additive manufactured orthoses designed following the procedure by the authors in [2]. However, the method has general validity for all orthoses consisting of two halves, lying on the back and frontal part of the hand-wrist-arm district, on which reference points can be extracted as described below in the adaptation phase.

Definition of the reference pattern

The reference pattern has been determined through a process of synthesis of various aspects, discussed in the following. The pattern should be clinically sound: it should maximize the quality of the treatment, patient's comfort and reduce typical cast-related problems – e.g. rashes and compartment syndrome. Moreover, areas sensitive to rubbing and compression should be left uncovered. Regions that require particular attention (see Fig. 1a) are: i) the internal wrist area – this is the area that, in case of wrist fractures, needs to be protected the most; ii) styloid process of the ulna – area that should be left open to allow the arm pronation/supination; iii) center line of both internal and external halves, this area should be left intact to preserve a continuous ribbing structure where is possible to apply padding if required.

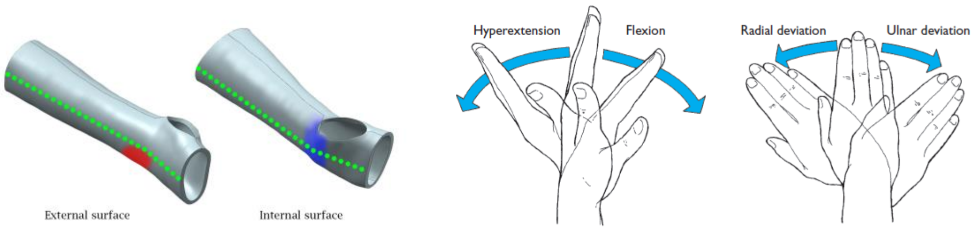


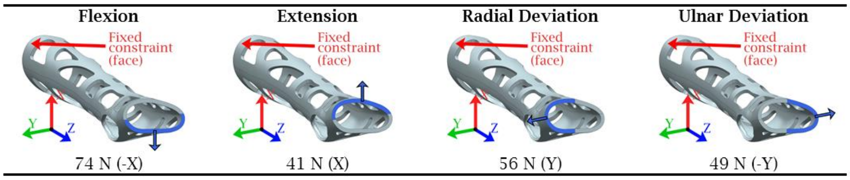
Fig. 1: a) Important areas of the arm. Red – styloid process of the ulna. Blue – Internal wrist area. Green – center line. b) Wrist joint movements [4].

Considering ventilation needs, the holes should evenly cover the surface of the cast; a minimum area of ~1cm^2 should be kept in order to assure a good water and airflow. The pattern should guarantee the integrity of the device and its compliance w.r.t. the loads caused by regular use. Other structural aspects are the preservation of a minimum thickness of 4 *mm* in every direction and the removal of stress concentrations points, which results in the generation of a smooth set of curves for the generation of holes, characterized by large fillet radiuses. Finally, an additional functional aspect needs to be considered in case the orthoses are generated using the approach provided in [2]. In fact, three zip ties are applied near the knuckles, the elbow, and in a medium region, to keep the two halves of the orthosis together. Such areas need to be left untouched by the hole pattern in order to avoid possible complications. Future work could also consider the integration of thermal comfort analyses as a parameter in the definition of the reference pattern; such aspect, has not been included in the present paper. The final pattern has been obtained relying on the results provided by a TO software (Inspire Solidthinking), using the load conditions listed in Tab. 1. The TO is performed with the two halves of the orthoses joined in the area where the zip ties are applied to reproduce the closing system; face-to-face contacts are considered on the other surfaces. The material used is ABS plastic. The analysis was carried out maximizing the stiffness/mass ratio of the object. The obtained pattern, although valid from a structural point of view, has been subsequently manually edited to meet the requirements discussed in this section. The final result is visible in Fig 2.

FE analyses

The reference pattern depicted in Fig. 2 has been applied to two orthoses (*Large* and *Small*), representative of the entire size spectrum of anatomies considered in this study. The *Large* orthosis is characterized by a length of ~400*mm* and a maximum diameter at the elbow region of ~90*mm*. The *Small* orthosis is ~195*mm* long and has a maximum diameter of ~65*mm*. The pattern has been applied to both orthoses, following the considerations previously described. FE simulations have been performed to test the mechanical validity of the generated geometries.

Due to the unpredictability of possible external and accidental loads, this study takes into consideration only the loads that can be traced back to the patient itself. Considering the wrist joint, four movements can be identified (see Fig. 1b): *flexion-extension* and *radial-ulnar deviations*. Following the approach proposed in [3], literature values have been used to estimate maximum torques that healthy people usually produce. Four different load conditions, one for each wrist movement, have been considered (Tab. 1).



Tab. 1: Loads configuration used in the study.

Wrist torques have been expressed as forces applied on the front face of the orthosis (different areas depending on the direction – see Tab. 1 where a value of 0.1m has been used as distance). In all cases, the orthosis is constrained at the elbow with a fixed constraint essentially reproducing a clamped beam condition. All the choices have been made trying to use a conservative approach: both the absence of the arm and the chosen constraints set contribute to the definition of a condition that is more severe than the real one. The simulations are performed with the two halves of the orthoses that are joined in the area where the zip ties are applied to reproduce the closing system; face-to-face contacts are considered on the other surfaces. The material used is ABS plastic. The results obtained are summarized in Tab. 2; the worst condition (*Flexion* load – *Small* orthosis) is depicted in Fig. 2: a maximum stress value of 25.3 MPa is observed. Such value is compatible with the yield stress of 3D printed ABS (26 MPa along ZX axis of the FDM printer [7]). Displacement values are tolerable even in worst cases (especially considering that the simulated configuration is far from the real one on this specific aspect).

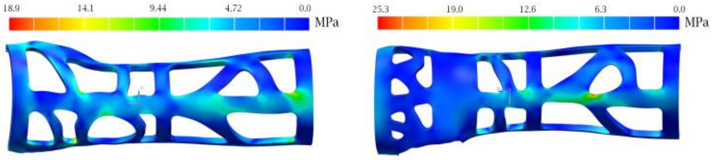


Fig. 2: FE analysis results for the *Small* orthosis, under the *Flexion* load (internal and external surface).

Load Configuration	*Large Orthosis*		*Small Orthosis*	
	Stress (Von Mises) [MPa]	*Displacement [mm]*	*Stress (Von Mises) [MPa]*	*Displacement [mm]*
Flexion	20.2	4.4	25.3	4.3
Radial Deviation	11.7	2.0	13.9	2.2
Ulnar Deviation	8.8	2.1	13.9	2.2
Extensions	7.5	1.6	11.6	1.8

Tab. 2: Validation of the pattern - FE analyses results.

Adaptation Strategy:
The adaptation procedure consists of two phases, which have been incorporated into the overall modeling process defined in [2]: a) definition of the key points that contour the holes, extracted from the scanning of the patient's arm; b) the perforation of the CAD model using curves generated from the obtained key points. The holes generation is completely automatic.

a) Key points extraction
The development of an automatic procedure is supported by the availability of a number of repeatable references in the designed orthosis. In particular, the position of the scanned arm and the geometric features created are required to be kept constant. Due to the conceived architecture, the main direction of the arm has to be approximately aligned with the Z axis, while the Y axis is required to be oriented with the upper side of the hand (see Fig. 3).

In this work the above mentioned references are known since the extracted feature are automatically computed through the software presented in [2]. In detail such features are the position of the three zip-tie housings and the position of the wrist. Both areas must be preserved. It has to be noticed that, as already mentioned, the medical device is applied to the patient's arm with zip-ties; therefore, the perforating procedure will leave the corresponding areas unaffected by the holes.

Specifically, the wrist is identified with two planes, placed at a distance of +/-15mm from the point of the thumb aperture with minimum Z value (Fig. 3a). Accordingly, twelve zones (six palmar and six dorsal – yellow in Fig. 3b) to apply the ventilation pattern are identified. Such zones are defined as 3D polygonal objects and are mapped on the orthosis, avoiding the center line and the wrist area. A different approach could be used to identify the zones to apply the pattern; hence, the specific procedure used to identify reference points and the zones does not prejudice the general validity of the proposed reference pattern. Within each zone, a set of ventilation holes are automatically defined as polygons, moving along the main lines that define the zone and following the shape of the reference template. In other words, starting from the reference pattern proposed in Fig. 2, a simplified polygon-based pattern has been defined by reducing the complexity of the original geometry. As an example, the template of the holes of zones 1 and 2 is shown in Fig. 3c. Incidentally, because of the way they are defined, the vertices may not lay on the arm surface; to solve this issue, the patterns will be projected subsequently on the target surface, as discussed in the following paragraph.

Fig. 3: a) Extraction of the two planes defining the wrist area; b) the six zones of the dorsal pattern; c) template of the holes to be adapted for zone 1 and 2.

The proportions of the holes within each zone are guaranteed by dividing the long side of each zone of each orthosis always by the same number of segments, for example the side AB of zone 2 is divided into 9 segments (Fig. 3c). The points obtained are finally saved in a text file.

b) Holes opening in the CAD model
The second phase is carried out within Siemens NX and has been integrated in the automatic cast generation procedure described in [2]. Specifically, the points defining the patterns computed in the first phase are used to generate first-degree splines. The splines are then projected onto the external surface of the orthosis and filled to create a set of 3D surfaces. Each surface is extruded in both directions to create solids, which are then subtracted from the two solid halves of the orthosis. Fillets are then added to all the edges of each so-generated hole; a radial value of 5mm is used to ensure patient comfort and reduce stress concentration. The entire procedure is depicted in Fig. 4; a total time of ~1min is required to perform all the described phases.

Fig. 4: Phases of the CAD holes adaptation.

Validation:
The pattern has been applied, using the described automatic procedure, to five orthoses that differ significantly in size and local geometry. The resulting pattern was approved from a medical perspective. Mechanical performances of the orthoses have been tested in a series of FE analyses, performed following the indications of Tab. 1. The most severe configuration was, as expected, the flexion one which, in the worst case, caused an acceptable maximum stress of 25 MPa. The proposed procedure has been applied on a previously defined design of orthosis but its applicability can be guaranteed also on different cast design under the condition of retrieving the necessary reference features.

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