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Research Article

A Critical Analysis of a Hand Orthosis Reverse Engineering and 3D Printing Process

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The possibility to realize highly customized orthoses is receiving boost thanks to the widespread diffusion of low-cost 3D printing technologies. However, rapid prototyping (RP) with 3D printers is only the final stage of patient personalized orthotics processes. A reverse engineering (RE) process is in fact essential before RP, to digitize the 3D anatomy of interest and to process the obtained surface with suitable modeling software, in order to produce the virtual solid model of the orthosis to be printed. In this paper, we focus on the specific and demanding case of the customized production of hand orthosis. We design and test the essential steps of the entire production process with particular emphasis on the accurate acquisition of the forearm geometry and on the subsequent production of a printable model of the orthosis. The choice of the various hardware and software tools (3D scanner, modeling software, and FDM printer) is aimed at the mitigation of the design and production costs while guaranteeing suitable levels of data accuracy, process efficiency, and design versatility. Eventually, the proposed method is critically analyzed so that the residual issues and critical aspects are highlighted in order to discuss possible alternative approaches and to derive insightful observations that could guide future research activities.

1. Introduction

In the orthopedics and rehabilitation fields the personalization of the patient care is increasingly influenced by the development of new additive manufacturing (AM) technologies and, in particular, by the diffusion of 3D printers. As evidenced in Negi et al. [1] and in Hieu et al. [2], various rapid prototyping (RP) techniques are workable in the medical field. In particular, the use of 3D printers is spreading in the orthotics field and their diffusion is expected to rapidly increase in the near future, given the continuous evolution of available materials and the lowering of the device and production costs of the various AM technologies.

If it is true that the use of AM processes allows attaining high level of customization, this requires that a geometric model of the orthosis to be realized (3D printed) has to be generated first. It is therefore necessary that a reverse engineering (RE) process precedes the implementation phase. The three main phases of an RE/RP of an orthosis by 3D printing technologies can be outlined as follows:

(1) Acquisition of the 3D geometry of the interested anatomy using an optical 3D scanner.

(2) Processing of the acquired data through dedicated software (including CAD 3D modelers).

(3) Realization of the orthosis using a 3D printer.

While for the third phase suitable (possibly low-cost) hardware can be chosen according to specific needs and among the available and well identifiable AM technologies, the first two phases are instead far from being self-evident. In fact, for the first phase there are a variety of possible acquisition technologies (i.e., structure form motion and dense stereo imaging, time-of-flight range imaging, laser scanners, and structured-light scanners) and modalities (e.g., static multiview or real-time incremental acquisitions) that can correspond to very different feature combinations in terms of metric accuracy, hardware and software costs, and ease of use.

Likewise, the choice of the most suitable 3D processing and modeling tools strictly depends on a rich set of parameters including the acquisition equipment and the produced data features and the clinical or design requirements and constraints. By the analysis of the literature there are basically two alternative approaches that one can follow:

(1) As discussed by Paolusek et al. [3], a traditional industrial RE methodology can be followed: this involves the modeling of the details of the orthosis using a generalist 3D CAD modeling software (that can be relatively complex to use and/or expensive to acquire).

(2) As discussed by Paterson et al. [4] one can instead develop dedicated CAD software for specific orthotic applications (this can be of more immediate use but is extremely targeted and therefore of limited usage, other than likely being more expensive).

Focusing on the orthoses of the upper limbs (forearm, wrist, or hand), we acknowledge the existence of comparative studies regarding the suitability of various 3D printing technologies for the RP of customized orthoses (as described by Paterson et al. [5] and Negi et al. [1]). Less attention, however, is devoted to the development of new acquisition methods of the morphology of the forearm and to the definition of new subsequent data processing and 3D modeling solutions. In fact, a biased interest toward the evolution of 3D printing techniques in the biomedical field is probably justified from its closeness to the final product (e.g., orthoses), while the importance of the development of appropriate technologies for the acquisition and processing of 3D data can be more difficult to perceive, with a natural inclination to simply borrow the knowledge from the RE processes typical of the manufacturing industry.

Forearm, wrist, and hand orthoses are corrective and therapeutic devices that find indications of use for several pathologies and temporal or permanent disability conditions (as described by Jacobs and Austin [6]). With respect to a well assessed variety of prefabricated orthoses, which can be selected simply with respect to their available sizes, a high level of design and manufacturing personalization can be seen as supporting the solution of the problematic aspects related to the level of compliance and tolerability of long-term use of these devices. In fact, a major requirement is the comfort (as described by Andringa et al. [7]), and the high level of orthosis customization, made possible by an accurate anatomical acquisition, is aimed precisely at an optimized adaptation to the anatomy and can be directed to the avoidance of pressure points and other pain and discomfort factors. Moreover, the possibility to include a highly personalized and possibly independent management of the fingers increases the patient care possibilities, for example, in the handling of paraplegic/hemiplegic subjects (antispasticity corrections, poststroke rehabilitation), and can enable solutions not yet considered or experimented, at least on a large scale.

In this work, we implement and critically review the production phases of a hand orthosis (including fingers) within a RE/RP process of industrial type. We use the new optical 3D scanner *Scan-in-a-Box*, some recently developed rigid and deformable scan alignment solutions, the *Rhinoceros* CAD software and a *Stratasys Dimension BST 1200es* 3D printer. These elements were chosen because they can be all considered and located in a low-cost range with respect to the spectrum of available technologies while, taken both singularly and together, they ensure a high level of accuracy and good versatility of the target RE/RP processes. Building on this framework, a further objective of this paper is to highlight the critical issues of traditional RE processes (meant and developed for industrial uses) once applied to the targeted medical application. The recommendations coming from this work are intended to promote and guide further research and experimentations efforts. Particular attention will be given to the 3D data processing phases.

2. Materials and Methods

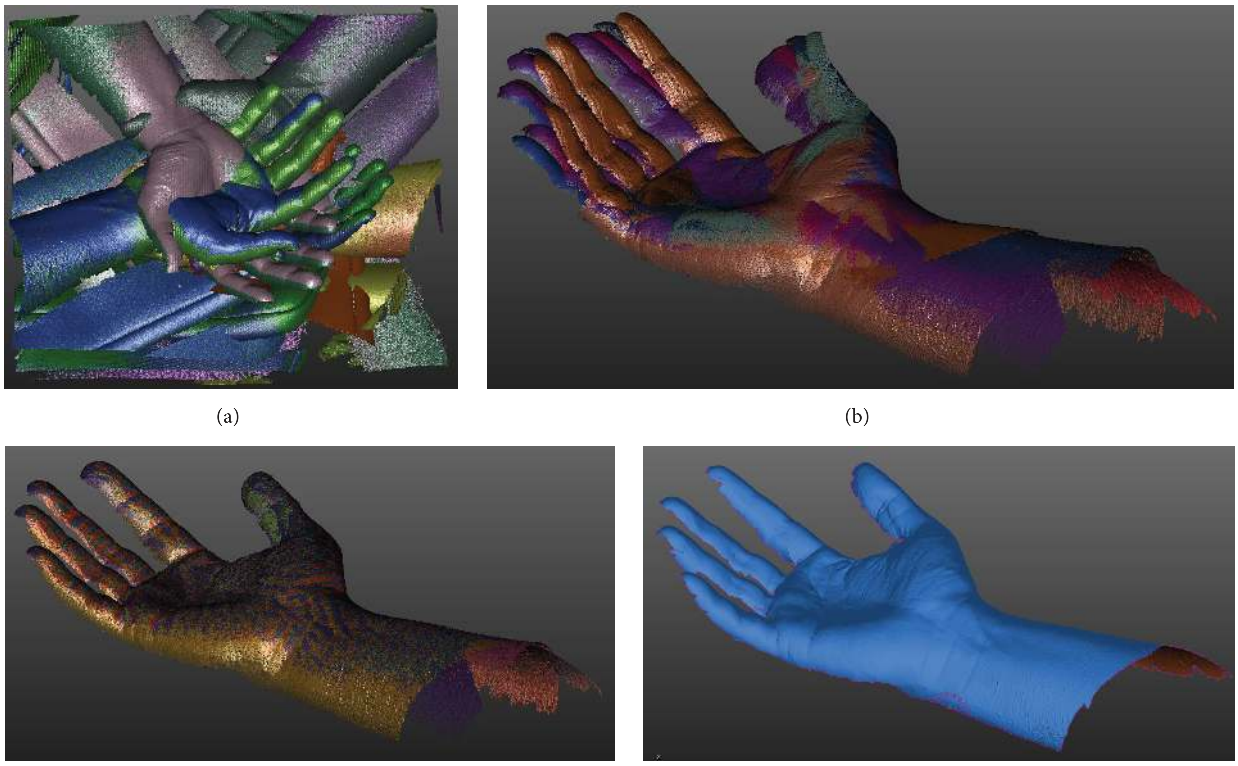
In this section we go through the production process of a personalized hand orthoses starting from the reverse engineering of the patient anatomy and according to the three steps listed above.

2.1. 3D Anatomy Acquisition. The purpose of this phase is to produce a faithful anatomical digitization of the hand/wrist complex using an optical scanner that offers an interesting cost-accuracy combination. The scanning takes place with respect to a free standing or partially sustained arm (we neither block the arm nor the hand). Therefore, it is necessary that the acquisition would not be invalidated by the presence of slight involuntary movements, with respect to a reference position, that unavoidably occur during the scanning session.

We operated with the new low-cost structured-light optical 3D scanner *Scan-in-a-Box* (by OpenTechnologies srl, Italy (http://www.scaninabox.com/)) to acquire the range images that contribute to the creation of the triangular mesh of the lower part of the limb. This lightweight reconfigurable scanner performs high-resolution structured-light scans in about 4 seconds, guaranteeing a metric accuracy till 0.1% with respect to the object size (in our case this means about 0.2 mm). The scanner comes with interactive software that handles the measuring process and processes the acquired data, including range image cleaning, alignment, mesh generation, basic mesh repair tools, and various data exporting formats.

The 3D mesh (usually in STL format) is required by the subsequent design and printing stages of the orthosis. Before that, a cumulative point cloud is created by the alignment of the different range scans acquired from various viewpoints to guarantee the complete coverage of the anatomic region of interest. In more detail, we report an example where the following steps have been realized:

(i) Whole anatomy coverage is obtained with 8 acquisitions of the forearm positioned on a chair armrest from 4 vantage points. The scanner is repositioned



(a) (b) (c) (d)

Figure 1: The 3D acquisition phase.

around the limb, according to the next needed vantage point, for a total scanning time of approximately 2 minutes. This is compatible with many clinical situations. However, since each single range image is referenced with its own coordinate system, the various scans need to be aligned (Figure 1(a)).

(ii) After cleaning each scan from the unwanted background (using the scanner software), a completely automated coarse alignment of the range images was obtained by the technique described in Bonarrigo et al. [8] which guarantees reliable and robust alignments, based on the automatic detection of correspondences between local geometric features, which are robust to viewpoint changes and partial deformations. Given the low number of needed scans this step can be possibly substituted by facilitated manual alignment provided by the scanner software at an additional time cost of about 10 min.

The resulting aligned image set is shown in Figure 1(b).

(iii) The impossibility to maintain a perfectly fixed position during the scanning time determines a difference between the positions of the fingers of different range images. This is clearly visible in Figure 1(b). We solved this problem by applying the patch-wise as-rigid-as-possible deformable alignment technique described in Bonarrigo et al. [9] that allows the deformable alignment of various scans with respect to a reference one. This method is able to compensate for various kinds of motion and deformation that the acquired data can exhibit, which is achieved by a nonlinear, physics-inspired deformation regularization. The surface is discretized into a hierarchy of partially overlapping patches, for each of which a distinct rigid transformation is found by minimizing a global objective function that takes into account both the need for accurate alignment and for the regularity of the deformation field. The resulting rigid transformations are then extended to all sample points in a rigid manner using dual quaternion interpolation. As a result of this as-rigid-as-possible deformation this dynamic registration avoids unnecessary distortion and faithfully preserves geometric features. As it can be seen in Figure 1(c), this allows proper motion-compensated alignment without any detrimental effect on the geometric accuracy.

(iv) The scanner software allows the direct conversion of the aligned scans (i.e., the cumulative point cloud) in a 3D triangular mesh (Figure 1(d)). Such a mesh is required for the subsequent modeling of the customized hand orthosis by a 3D CAD software.

(v) The final mesh has been optimized (border regularization) and repaired from its defects by the automatic fixing tool RameshCleaner (as described by Centin and Signoroni [10]). This is a structured set of effective

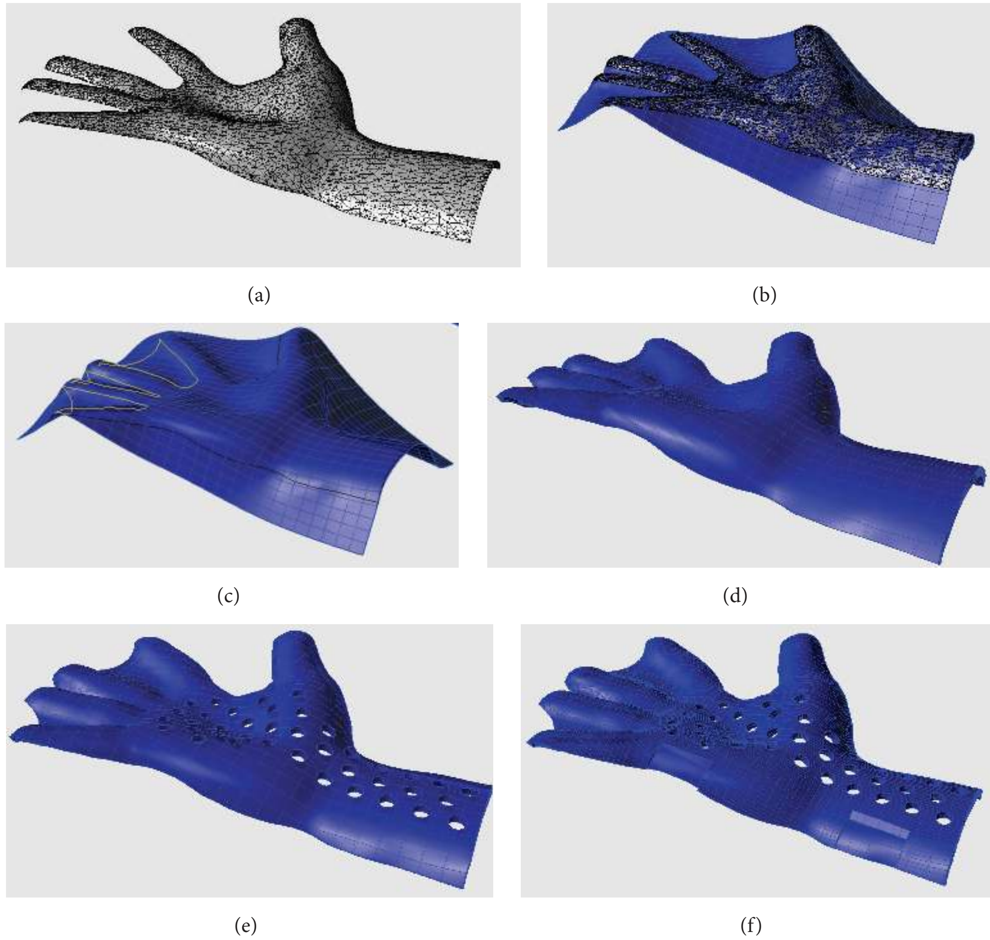


Figure 2: The 3D modeling phase.

fixing strategies that maximally preserve the original data while effectively solving several important and typical mesh weakness (possible holes, degenerate triangles, foldovers, or spikes).

Other optimization operations were not necessary. The total time to accomplish all the above operations is about 1 h 30 min, subdivided as follows: 15 min for multipose hand acquisition with data cleaning and rigid alignment, 15 min for fine deformable alignment, and about 1 h for mesh creation, regularization, and repair.

2.2. 3D CAD Modeling of the Hand Orthosis. The *Rhinoceros* CAD software was used to import the triangular mesh (STL) previously obtained and, using its dedicated tools, to derive the NURBS representation of the surface. Then, by modeling the reconstructed surface, the solid geometry of the orthosis to be printed was obtained. In particular, the operations that have been carried out are as follows:

(i) An offset of 2-3 mm is applied to the imported mesh. This is necessary to create an adaptation space between the hand and the inner surface of the orthosis, in order to avoid discomfort and to prevent/tolerate the physiological swelling (Figure 2(a)).

(ii) The so processed triangular mesh is automatically converted in a mathematical NURBS surface by the dedicated tool (*RhinoResurf*) integrated in the CAD software (Figure 2(b)).

For the NURBS conversion of the previously optimized mesh we used the following parameters of the *RhinoResurf* plug-in: max tolerance 0.5 mm, smooth "medium." With these coefficients the average (max) mesh to surface point deviation is 0.076 mm (0.497 mm).

The parameters of the NURBS surface obtained by the reconstruction are

"U": degree = 3 num. CV = 31 ($0 \leq U \leq 203.085$),

"V": degree = 3 num. CV = 31 ($0 \leq V \leq 296.855$).

(iii) Extraction of the projection curve of the mesh border on the CAD surface (shape of the hand) and design of closing curves projected on the CAD surface over the finger area (Figure 2(c)). These curves are needed to create a connecting surface between the various fingers in order to stiffen the orthosis.

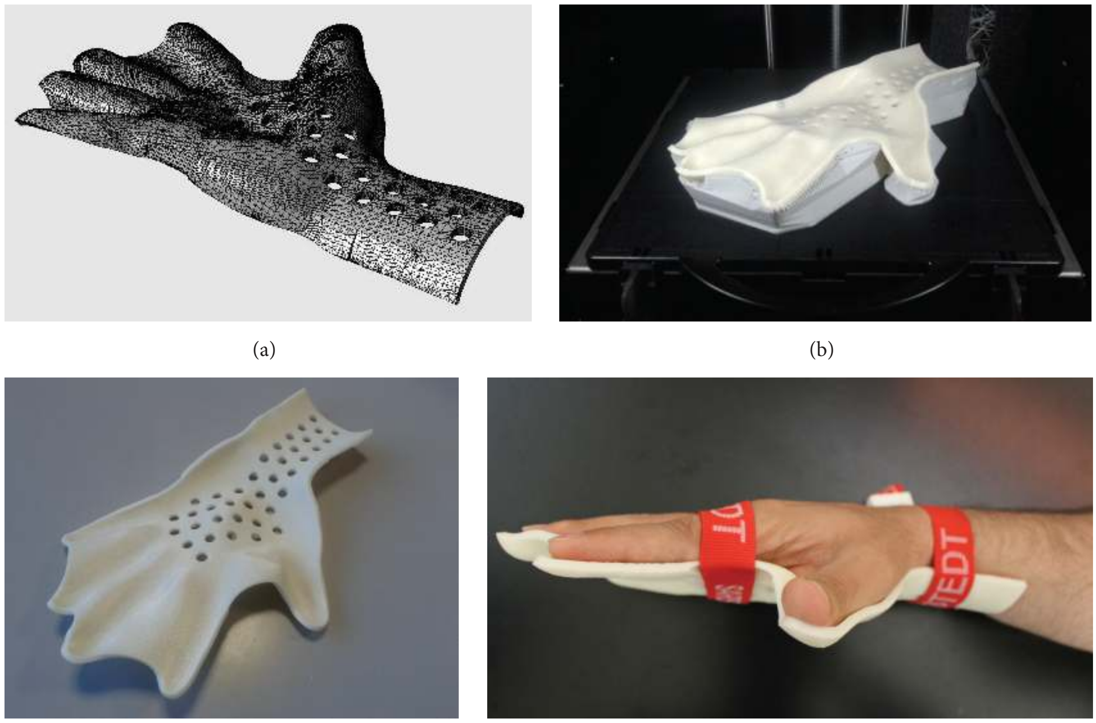


Figure 3: The 3D printing phase.

(iv) Shaped cut of the CAD surface and its thickening of 4 mm (solid offset operation) to obtain the solid volume of the orthosis (Figure 2(d)).

(v) In order to realize lightening and skin breathing holes on the orthosis, in the forearm and palm areas, a repeated volume subtraction operation (e.g., cylinder intersections) has been performed (Figure 2(e)).

(vi) In order to realize the housing grooves for the fastening bands, another volume subtraction operation was performed on the orthosis where CAD model, at this point, is completed (Figure 2(f)).

The total time to accomplish all the above operations is about 2 hours (this can vary depending on the skillfulness of the operator).

2.3. Back-Conversion of the CAD Orthosis Model in a Triangular Mesh for 3D Printing. In the last phase of the orthosis realization process, we must convert back and export the optimized 3D CAD model in a triangular mesh (Figure 3(a)) format (STL) which is required for 3D printing, as depicted in Figures 3(b), 3(c), and 3(d). In our case, a FDM printer (Stratasys "Dimension BST 1200es") employing ABS material (ABSplus, tensile strength: 37 MPa) was used with a layer thickness of 0.254 mm and build size 254 × 254 × 305 mm.

The forearm accommodation of the printed prototype does not have an optimal length (Figure 3(d)); this was only due to the limited available printing area of the used printer (Figure 3(b)).

The total printing time was about 11 hours. Summing up all the acquisition, modeling, and printing phases, we obtained lead times of about 1 working day (dominated by the printing time). This can be considered tolerable and compatible with the clinical and patient needs. Possible finishing phases are not considered here, but the reader can refer to Palousek et al. [3].

3. Discussion

On one hand, we can look at the methodology described above as geometrically satisfactory and as an inspiring way for the production of hand orthoses that must lead to a favorable trade-off between high-accuracy (in the reproduction of the patient anatomy) and low-cost (of both hardware and software tools throughout the production chain) requirements.

An acquisition of the hand and fingers anatomy with submillimeter accuracy, as the one allowed by the selected acquisition and processing pipeline, is undeniably a good starting point for the design and production of orthoses with a high degree of comfort and tolerability and to give the opportunity for clinicians to indicate pressure zones and to create orthoses fully responsive to the therapeutic needs, other than enabling the faithful translation of therapeutic indications also for the fingers.

However, our work is significant also because it allows highlighting some critical aspects of the process that we want to examine in the following discussion. We believe that the production of highly personalized orthoses is still very challenging and presents open issues that can be addressed and solved only through a serious and deeply interdisciplinary work between different expertise in the fields of orthopedics and rehabilitation, mechanical RE and material science, computer vision, and geometry processing.

3.1. Scanning of the Forearm and Scan Alignment. The morphological complexity of the hand requires the acquisition of more range images from different vantage points. It is therefore necessary that the subjects keep the limb and the hand steady for a certain amount of time (one to two minutes). If the hand is not firmly constrained, involuntary movements generate scan misalignments especially in the finger area. The use of an innovative deformable alignment technique (as described by Bonarrigo et al. [9]) allowed us to overcome what is usually considered a major problem in the use of static optical scanners for body scans (as described by Paterson et al. [11], Bibb et al. [12], and Tzou et al. [13]). The scanner used in this work has also the additional feature of being lightweight and therefore easily repositionable around the limb.

Possible alternative scanning techniques are those operating by stereophotogrammetric principles. They usually are specific devices able to shoot, in a split-second (so that motion problems are inherently solved), simultaneous multiview images which estimate and generate a 3D surface (as described by Paterson et al. [11] and Tzou et al. [13]). However, these dedicated systems can be very expensive and may even suffer from some versatility and surface coverage issues, especially for the reconstruction of complex geometries, as in the case of the hand fingers and even limiting to single-side acquisitions.

Another more recent alternative consists in the so-called real-time scanning technologies (examples of devices on the market are: *Health Care Partner 3D* from Creaform (http://www.creaform3d.com/), *Artec Eva* from Artec3D (https://www.artec3d.com/), and *Insight3* from OpenTechnologies (http://www.scanner3d.it/)) which are usually portable and handy optical scanner devices operating with fixed light patterns, where the acquired views are continuously accumulated (similarly to what described in Izadi et al. [14]) while the scanner is smoothly moved around the object of interest. Although the accumulation process does not allow too rapid movements, the scanning can be faster compared to what is obtained using static devices, but not such as to avoid body motion issues. In this case, the nominal scanner accuracy can be compromised because, depending on the entity of the motion, the compensation mechanisms within the view accumulation process can introduce nonnegligible deviations from the true geometry. This can generate an orthosis that causes discomfort or even unwanted compressions on some body parts. In addition, these systems can still be widely more expensive with respect the one selected in this work.

3.2. 3D CAD Modeling of the Orthosis. The use of a 3D CAD modeling software is typical in a RE environment. However, its use requires specific skills that are not that diffuse among clinicians and orthopedic/orthotics technicians. Thus, the rehabilitation facility (either a clinical structure or an external service), even if it is equipped with appropriate hardware (3D scanner and 3D printer), could not be self-sufficient (unless investing in skilled CAD technicians) in reaching a cost-efficient production of customized orthosis using AM processes.

Conversely, the potential of traditional CAD systems is only marginally exploited in the considered processes: the modeling procedures only needed basic commands (offset, Figure 2(a), thickening, Figure 2(d), cut, Figure 2(e), etc.) or the execution of very specific tasks (reinforcement of the finger area, Figure 2(c)). Interestingly, the most complex phase remains the conversion of the triangular mesh into a mathematical surface representation (Figure 2(b)). This operation is usually left to a specific plug-in, whose quality is a main guiding factor for the choice of the CAD system.

It is evident that there is a 3D domain transition (STL-CAD-STL) which is not strictly required from the 3D printing point of view, but that is necessary for the type of software (3D CAD) used to process the data within the typical RE approach. However, this can be seen as an extra burden, both procedural and economical, for the orthoses design and production chain. The ability to perform basic modeling operations directly on the 3D mesh seems then to emerge as a particularly interesting and desirable opportunity.

The possibility to directly operate on the mesh produced by the scanner through an appropriate and handy interface would also make these editing tools usable even by nontechnical CAD staff. As a matter of fact, systems that directly work on meshes already exist but either they are general purpose creative mesh sculpting tools (e.g., Autodesk Meshmixer, http://www.meshmixer.com/), not specifically conceived for the clinical use, or they are clinically oriented tools, but in this case they are usually very specific and verticalized on single applications. This is why there is still room for the development of mesh editing systems that might be easily exploited, through appropriate interfaces, by practitioners and technicians in the clinical field for the design and production of printable STL models of orthoses.

3.3. 3D Printing. The use of a low-cost 3D printer (FDM technology) can lead to restrictions in the geometric definition of some details. For example, the size of the lightening and aeration holes on the orthosis could be optimized (smaller or different textures) according to the quality, resolution and materials of the selected printer (see Paterson et al. [4]). Alternative but currently more expensive 3D printing technologies can yield orthosis with higher resolutions and made of materials with better performance than ABS.

3.4. Further Considerations. In rehabilitation, when, for example, spasticity symptoms (either caused by cerebral palsy or stroke outcomes) must be treated, it is not always possible to acquire the scan of a freestanding hand in the desired working position of the orthosis. In these cases, the clinicians make use of tapes and provisional supporting systems to acquire the forearm and the hand anatomy in the desired position.

This, however, may not always be done in a simple and accurate way, so that the availability of suitable mesh deformation tools (similar to those already seen or specifically informed by an articulated deformation model) could become a great opportunity for the practitioners. For example, this would enable the possibility to implement angular adjustment of the position of the fingers according to, possibly progressive, corrective criteria. Such adjustments could also be directed to the reduction of comfort issues affecting the patient compliance (as described by Andringa et al. [7]).

4. Conclusions

The analysis and the experimental considerations we made about the proposed hand orthosis RE/RP process lead us to the following main conclusions and insights:

(i) For the digitization of the forearm anatomy we have identified low-cost optical 3D scanning solution able to guarantee a high degree of accuracy of the single scans.

(ii) A feature based multiview automatic coarse registration approach followed by a deformation alignment software can be both used to recover a faithful and accurate alignment of the scans, including the complex finger area, in a resilient way with respect to unavoidable slight movements of the limb and fingers. It is therefore not strictly necessary (unless specifically required by the clinician for correction purposes) to fix the limb and fingers with tape or special retainer systems during the acquisition.

(iii) The use of a 3D CAD modeler to import and process the triangular mesh obtained as a product of the anatomy digitization would not be necessary if there was a software able to perform the needed modeling operations directly on the triangular mesh (STL).

(iv) This software might also include the possibility to correct, working on the acquired anatomy, the angular position of the fingers according to the rehabilitative needs identified by the clinicians. Most of the works in the literature consider processes oriented to the production of customized wrist immobilization splints, where the fingers are deliberately left free to move. However, due to the population aging, it is becoming increasingly important to also treat people with stroke outcomes. For these subjects the orthotic rehabilitation is directed to the treatment of the spasticity of the entire wrist-hand complex and thus also of the fingers.

These considerations reveal several open issues and suggest the need to continue with research studies directed to develop new data processing software and cost-efficient RE/RP methodologies to give better answers to the specific clinical requirements and to the usability needs coming from the orthotics technicians.

Competing Interests

The authors declare that they have no competing interests.

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