A Preliminary Usability Assessment of a 3D Printable Orthosis Design System

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Abstract. The standard treatment for bones fractures entails 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 prevents ventilation of the treated area. Therefore, the application of traditional casts to orthopaedics patients does not represent, to date, the best option. To overcome the above-mentioned drawbacks, many strategies based on reverse engineering and additive manufacturing techniques have been proposed and proved to be a valid alternative for producing custom orthoses. Encouraged by the aforementioned results, the authors have developed a low-cost system (called *Oplà*), specifically dedicated to the hand-wrist-arm district of paediatric patients and capable of creating a 3D CAD model of the orthosis ready to be printed by using additive manufacturing techniques. Such a system comprises a 3D scanner, a control software and a semi-automatic CAD procedure to easily model the orthopaedic device on each patient, without the need of CAD modelling professionals. To evaluate if *Oplà* can be effectively used by the medical staff to design patient specific 3D printable orthoses in the clinical practice, a preliminary usability assessment has been performed. Five professional nurses from the Meyer Children's Hospital of Florence (Italy) have been selected and trained in the use of the system. Subsequently, each of them has been asked to perform the whole process for the same patient. Effectiveness, efficiency and satisfaction have been measured in accordance to ISO 9241-11. Results proved that the *Oplà* system is characterized by a good usability allowing the user to easily and intuitively perform all the tasks in a reasonable time.

Keywords: Usability · CAD · Reverse engineering · Cast modelling

1 Introduction

The present research has been carried out in the framework of a multidisciplinary collaboration between the Meyer's Children Hospital and the Department of Industrial Engineering in Florence (Italy) by relying on the basic idea that 3D technologies,

thanks to the possibility of delivering novel patient tailored solutions, enable more effective approaches in the medical scene. This study addresses the problem of building custom-sized plastic made arm orthoses for children with the aim of improving the traditional arm plaster cast performances by increasing the lightness and the ventilation of the device, while reducing most of the actual risks, such as compartment syndrome, ischemia, heat injury, pressure sores and skin breakdown [1]. Several solutions for personalized casts have been technically investigated, examples can be found in [2, 3]; nevertheless, the literature is still lacking a complete clinic-ready infrastructure which could be fully exploited by the medical staff not needing the presence of an expert CAD modeller. The proposed infrastructure (called *Oplà*) consists in both an ad hoc pae-diatric hand-wrist-arm 3D scanner and a control software to ease both the acquisition and the modelling process, that entirely eliminates the need of experts to construct the orthopaedic device. In fact, to convey a custom-made orthosis the two critical phases are the patient's anatomy acquisition and the device modelling, followed by a 3D printing process. The *Oplà* designing process is completely user-oriented and based on two principal objectives: (i) to hide from the medical staff the underlying technical schemes of both anatomy acquisition and orthosis modelling; (ii) to build a reliable instrument which could be used within a paediatric clinical facility. For these reasons, *Oplà* enables a rapid acquisition process, differently from state of the art scanners which are either very expensive or need to immobilize the patient for at least 30 s to reproduce the correct anatomy. The control software, instead, has been designed to be intuitive and user-friendly, and to facilitate the modelling process which is indeed a non-trivial procedure since it must be adapted to different paediatric anatomies varying in shape and size. In this work, the preliminary usability of the proposed software is tested with objective metrics on a sample of 5 professional nurses from the Meyer Children's Hospital of Florence (Italy). In Sect. 2 the proposed approach is presented; Sect. 3 describe the used metrics; finally, in Sect. 4, the obtained results are presented, and conclusions are drafted.

2   Proposed Framework

With the aim of designing a user oriented paediatric framework for patient specific plastic cast manufacturing, a fast, reconfigurable, robust and accurate 3D hand-wrist-arm scanner has been designed. The scanner is coupled with a compre-hensive user-friendly software conveying all the algorithms needed to build the 360° 3D model of the arm and to extract important features of the CAD model of the related orthosis. The realization of the final model will be performed in a different environment with a CAD procedure guided by the extracted features. This model, see Fig. 1, is composed of two halves, to ease the application, locked through a zip tie-based mechanism.
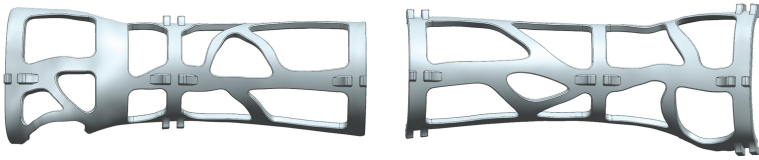
Fig. 1. Example of final orthosis model

2.1 Harm-Wrist-Hand 3D Scanner

The paediatric setting imposes compelling requirements to be used in the clinical practice [4]. With the aim of covering the full range of sizes variation of growing children, the arm scanner is composed of two rings hosting several close-range depth cameras [5] and a moving support for the elbow (Fig. 2).
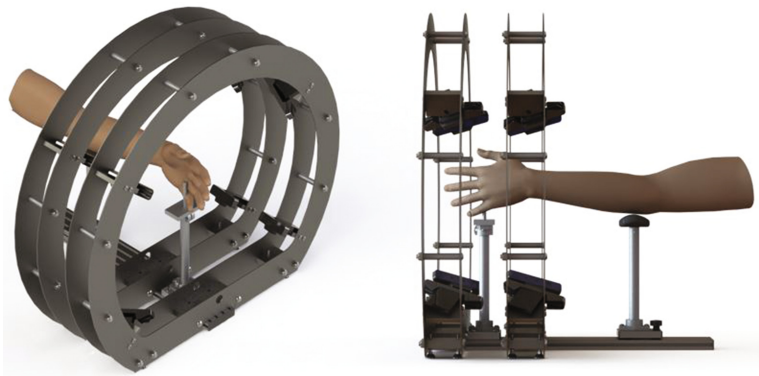

Fig. 2. The designed HWA 3D scanner

Each ring structure has a diameter of 720 mm, the support for the hand is positioned between the two rings and each camera is placed at approximately 245–255 mm from it. This allows to acquire anatomies with length varying from 200 mm up to 410 mm (covering in average the age size 3 yo–18 yo). The scanner is provided with a software developed to calculate the 360° model of the arm, envisage the alignment, cleaning and fusion of the depth camera images.

The control software has been designed to allow the medical staff to easily acquire the patient anatomy and define key features of the 3D printed orthosis (e.g. boundaries, length etc.). The possible operations are collected in a toolbar as shown in Fig. 3. The main steps to be performed by the users have been grouped in five tasks and are described in the following paragraphs.
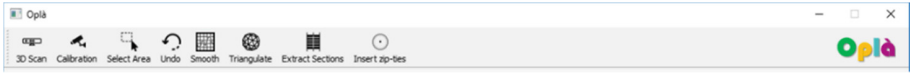
Fig. 3. Toolbar of the devised control software

Task 1: Patient Preparation and Arm Positioning

During this step the clinical professionals oversee the positioning of a white gauze on the patient's arm and the drawing of some visual references; specifically, they are asked to draw the knuckles line, the thumb finger base, the main orthosis boundaries, and the ulnar styloid process perimeter to next help the correct reconstruction of the orthosis model (Fig. 3 on the left). Once ready, the patient is asked to place the arm into the 3D scanner, to assume the resting configuration (with the hand defining an angle of 10°–20° with the arm, Fig. 4) [1] and keep it during the scanning phase.

Fig. 4. Example of landmarks drawn on the gauze (left); positioning of the arm into the acquisition system (right)

Task 2: 3D Scanning

Once the arm is positioned, the clinical specialist is ready to press the *3D Scan* button. The program launches a notification sound when the images are stored (within ∼2.5 s), after which the patient can remove the arm from the scanner. In background the software processes the acquired raw data to obtain the point cloud of the wrist-hand-arm district.

Task 3: 3D Data Selection and Cut

When the 360° 3D image of the arm is ready the user must press the button *Select Area* to select and cut all those portions of points which will not be part of the orthosis (see Fig. 5). During this phase and the following, the user will take advantage of the lines previously drawn on the gauze. At the end of this step, the user must press the *Smooth* button to let the software perform the smoothing step in background.

Fig. 5. Workflow of the third task

Task 4: Thumb Finger Opening

During this phase, the user must remove the thumb finger to create the correct opening to allow the patient to freely move such finger. To perform this task, the user must navigate the 3D model to identify the right point of view to cut, by using a rectangular selection, the thumb. Also, the user must select the area defining the opening space for the thumb finger. These operations are shown in Fig. 6.

Fig. 6. Workflow of the fourth task

Task 5: Zip Ties Positioning

The last task consists in pressing the *Triangulate* button to let the software perform, in background, the Poisson surface reconstruction which is a smooth and detailed mesh, and which automatically close the hole produced by removing the thumb finger.
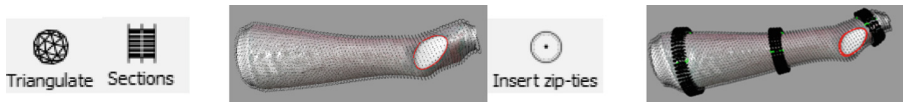

Fig. 7. Workflow of the fifth task

Once the mesh has been computed the user has to press the button *Sections*: the program will automatically extract and visualize sectional profile of the mesh necessary to generate the CAD model of the orthosis. Finally, pressing the button *Insert zip-ties* the user can define the zip-ties housing locations (see Fig. 7). This task is the final step of the user-guided procedure since the final CAD model of the orthosis, including optimized shape to reduce weight and to allow breathability, is automatically generated into a CAD environment (e.g. Siemens NX®).

3   Usability Analysis

According to the ISO 9126 series of standards, the most extensive software quality model developed to date [6], usability is interpreted as "the extent to which a product can be used by specified users to achieve specified goals with *effectiveness*, *efficiency* and *satisfaction* in a specified context of use". Usability can be expressed as the capability of the software product to be understood, learned, used and be attractive to the user, and is a combination of factors including: intuitive design, ease of learning, efficiency of use, memorability, error frequency and severity, subjective satisfaction. To evaluate the usability is a key step for User-Centered Design (UCD) framework for

software development, defined in the ISO-13407 standard [7]. Accordingly, usability evaluation must occur within the design life-cycle, with the results of the evaluation feeding back into modifications to the design.

3.1   Participants

Five participants have been chosen among the Meyer Children's Hospital orthopedic nurses; specifically, orthopedic nurses have been chosen over doctors since they oversee the typical casting procedure for bone fractures. Despite studies have demonstrated that the identification of flaws in the software remarkably increases with a higher number of participants, the common practice is to test the usability on five users [8, 9]. Accordingly, five participants are considered to be enough for this preliminary study. The usability sessions have been conducted in a quiet and private room reserved for this task accommodating the scanning system. Institutional Review Board approval has been obtained from the study organization to conduct this research.

3.2   Methods

A preliminary meeting has been held to explain to participants each single task, and to give the possibility to familiarize with the procedure. After this preliminary phase, participants' tests have been scheduled individually and the test has been performed by participants without any help by observers. Each participant has been asked to perform the whole process for the same patient. The evaluation of each metric has been carried out as follow:

Effectiveness is calculated measuring the completion rate, by assigning a binary value of '1' if the test participant manages to complete a task and '0' otherwise.

$$Effectiveness = \frac{number\ of\ tasks\ completed\ successfully}{total\ number\ of\ tasks\ undertaken} \tag{1}$$

Efficiency is measured in terms of task time, i.e. the time spent by the users to achieve the goals

$$Time\ Based\ Efficiency = \frac{\sum_{j=1}^{R} \sum_{i=1}^{N} \frac{n_{ij}}{t_{ij}}}{NR} \tag{2}$$

$$Overall\ Relative\ Efficiency = \frac{\sum_{j=1}^{R} \sum_{i=1}^{N} n_{ij} * t_{ij}}{\sum_{j=1}^{R} \sum_{i=1}^{N} t_{ij}} \tag{3}$$

Where: N = total number of tasks, R = number of users, n_{ij} = result of task i by user j, t_{ij} = time spent by user j to complete task i.

Satisfaction is measured through standardized satisfaction questionnaires: the SEQ (Single Ease Question) questionnaire, which is reliable, sensitive, valid and easy to respond [10], has been administered after each task; the SUS (System Usability Scale) questionnaire [11], which has been found to give very accurate results, has been administered after the usability test session.

4   Results and Conclusions

The tables below illustrate the results of the usability metrics described above. Generally speaking, the tests score is positive, highlighting both the general good impact of the software and some major flaws. As it can be noted from Table 1 all effectiveness scores exceed the 78% value, which is considered to be the average value for this metric [12].

Table 1. Effectiveness results scored by each user

	User #1	User #2	User #3	User #4	User #5
Effectiveness	80%	100%	80%	100%	100%

Efficiency, which is the speed of work with the product, is typically compared with the Expert Efficiency, the highest possible speed of work. As it is shown in Table 2, the efficiency obtained with non-trained users (i.e. the one measured immediately after the introductory presentation) is equal to ∼0.3 goal/min, and it is only twice as the reported expert efficiency. The Overall Relative Efficiency, i.e. the ratio of the time taken by the users who successfully completed all the tasks in relation to the total time taken by all users, is higher than 90%, thus proving a good efficiency of the system.

Table 2. Time-based and overall relative efficiency results

Time-based efficiency	Expert efficiency	Overall relative efficiency
0.309 goal/min	0.6 goal/min	91.3%

SEQ results are reported as the average SEQ value obtained by each user (see Table 3). Considering that satisfaction results typically range between 4.8 and 5.1 [13], results demonstrate a general high score of satisfaction by single users. The most challenging task for users with no 3D modelling expertise has been task 4 (Thumb finger opening). Future work will be oriented to the simplification of this step to be performed within a medical facility.

Table 3. SEQ score averaged over each user

	User #1	User #2	User #3	User #4	User #5
AVG SEQ score	5.6	6	3.6	5.4	5.2
Task with lower score	Task 4	Task 4	Task 4	Task 4	Task 4

Results of the SUS questionnaire are reported in Fig. 8, where values below the red dashed line are to be considered as strongly insufficient, the orange line states the sufficiency threshold, and results above the green line are to be considered optimal. The tested software obtained an average result of 85, and all scores are above the sufficiency line, stating a general high level of satisfaction of the users.
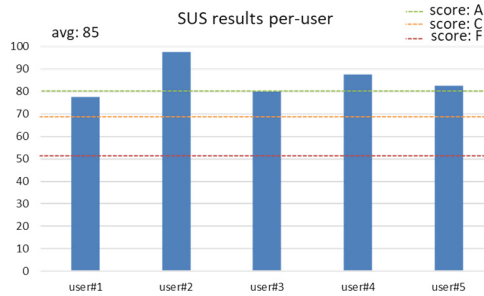
Fig. 8. SUS questionnaire results (in blue) and reference thresholds

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