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G-ear: a user-friendly tool for assisted autologous ear reconstruction

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Abstract— **The major breakthroughs in the fields of reverse engineering and additive manufacturing have dramatically changed medical practice in recent years, pushing for a modern clinical model in which each patient is considered unique. Among the wide spectrum of medical applications, reconstructive surgery is experiencing the most benefits from this new paradigm. In this scenario, the present paper focuses on the design and development of a tool able to support the surgeon in the reconstruction of the external ear in case of malformation or total absence of the anatomy. In particular, the paper describes an appositely devised software tool, named G-ear, which enables the semi-automatic modeling of intraoperative devices to guide the physician through ear reconstruction surgery. The devised system includes 3D image segmentation, semi-automated CAD modelling and 3D printing to manufacture a set of patient-specific surgical guides for ear reconstruction. Usability tests were carried out among the surgeons of the Meyer Children's Hospital to obtain an assessment of the software by the end user. The devised system proved to be fast and efficient in retrieving the optimal 3D geometry of the surgical guides and, at the same time, to be easy to use and intuitive, thus achieving high degrees of likability.**

I. Introduction

Several therapeutic and surgical methods have changed dramatically with the advent of reverse engineering (RE) and additive manufacturing (AM) techniques in the medical field, shifting towards a modern care viewpoint in which each patient is considered unique. The integration of RE e AM techniques in the clinical practice enables the modeling and realization of customized medical devices. In a nutshell, RE techniques allow to acquire and reconstruct the patient-specific anatomy and AM processes make possible to create complex geometrical shape, that could not be realized with conventional production techniques. Within this novel scenario, an increasing number of technologically advanced hospitals are creating in-house laboratories equipped with RE and AM technologies to offer personalized care.

A wide use of such techniques for the development of patient-specific implants and patient-specific surgical guides is observed in the field of reconstructive surgery. The use of custom medical devices which accurately fit the specific anatomy, has demonstrated to improve surgical outcomes in terms of aesthetic results, surgical time and safety for the patients.

In this context, the present work focuses on the design and development of tools able to support the surgeon in the reconstruction of the external ear. This procedure, namely Autologous Ear Reconstruction (AER), is performed in patients affected by malformation or absence of the external ear due to congenital reasons (microtia), as a result of trauma, burns or after tumor resections. In AER, the malformed or absent ear is restored using patient's costal cartilage, properly cut, carved and sutured together. The intervention is considered particularly complex by surgeons and the surgical outcomes are highly dependent on the clinicians' experience. In this perspective, within the T3Ddy Lab (personalized pediatrics by inTegrating 3D aDvanced technologY), a joint laboratory between the Department of Industrial Engineering of the University of Florence (IT) and the Meyer Children's Hospital of Florence (IT), the authors developed surgical aids to assist and guide physicians during the procedure, turning a completely manual reconstruction into a more straightforward, assisted procedure [1].

In [1] a systematic procedure was defined that, starting from the patient's anatomy, leads to 3D modelling of the devices. This procedure was evaluated in terms of robustness and repeatability of the results, giving excellent outcomes leading to consider the procedure reliable. Accordingly, in order to make the procedure usable by medical staff, a dedicated software, called G-ear (Geometrical ear acquisition and reconstruction), was developed in this work. Through an intuitive graphical user interface (GUI), the software enables 3D modeling of patient-specific surgical guides, requiring clinicians to select only a few anatomical landmarks. The software, detailed in Section 2, was evaluated in terms of usability by hospital staff in order to assess its actual potential to be use in common clinical practice, thus opening new frontiers for personalized medicine.

II. Materials and Methods

According to the surgical procedure proposed in [2], the auricular elements to be reconstructed during AER surgery are helix, antihelix, tragus-antitragus (Figure 1a), plus a support base. These elements, properly cut, carved and sutured together, constitute the ear framework that is positioned under the skin at the level of the missing ear (Figure 1, on the right).

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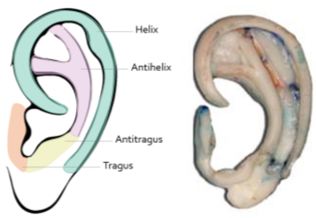


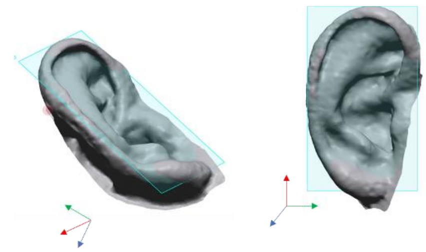
Figure 1. Anatomical elements of the ear.

As said in the introductory section, to assist the surgeons during the intervention, personalized guides were devised, as shown in Figure 2. The final design and technical requirements of the medical devices were the result of a process of successive approximations carried out in collaboration with surgeons. Please refer to [1] for in depth description of the design process.

Figure 2. Example of CAD models of the surgical guides.

The semi-automatic procedure, presented in the above-mentioned paper, is the result of the analysis of the CAD manual modelling process used to design these guides. In detail, after manually cropping the ear from the face scan, the operator defines the correct orientation of the input geometry, by searching for the plane that makes visible all the anatomical elements involved in the reconstruction (see Figure 3a). A 2D sketch is created on this plane, on which the profiles of the anatomical elements are drawn of them (Figure 3b). The 3D modelling of the surgical guides is finalized through consolidated CAD operations such as extrusions, cut extrusions, fillets and chamfers.

Based on the described manual process, the general scheme of the semi-automatic software was defined (see in Figure 4). The developed software consists of 1) ear isolation from the patient face, 2) segmentation of each ear element involved in the surgery, 3) extraction of few reference points used in 4) CAD modeling of the surgical guides. As can be seen in Figure 4, the procedure requires two inputs, i) the patient's face scan (on the side of the contralateral healthy ear), and ii) a second user input consisting of the insertion of few anatomical landmarks.



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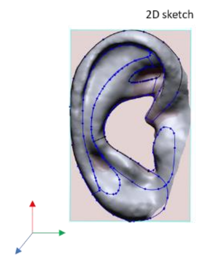


(b)

Figure 3. Example of surgical guide manual CAD modelling process.

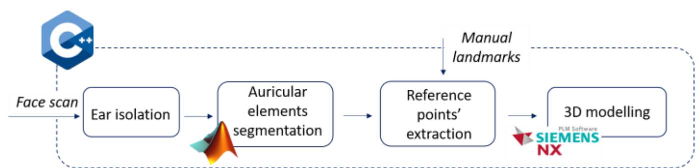


Figure 4. Macro steps devised for surgical guides modelling.

A. Development of the semi-automatic procedure

In the following subsections, the algorithms implemented to automate the macro steps, required for surgical guides modeling, are detailed.

1) Ear isolation

The production of personalized surgical guides starts from the mirrored model of the 3D scan of the healthy side of the patient's head. The acquisition of the healthy ear can be performed using different techniques [3] and, after an appropriate raw data processing, leads to a 3D model of the patient head like the one shown in Figure 5.

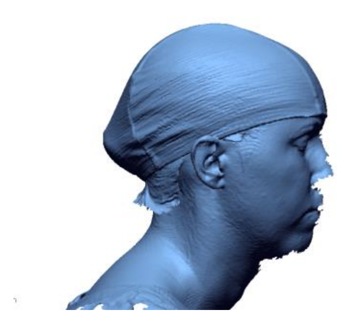


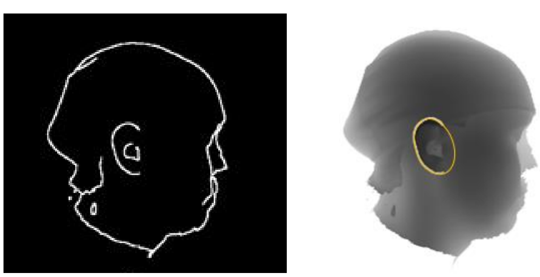
Figure 5. Example of head acquisition using the Artec Eva scanner [4].

The subsequent step consists of isolating the ear with respect to the patient's profile. There is an extensive literature dealing with this task [5]–[7], since the ear plays an increasingly important role in biometrics.

After a review of the literature concerning the ear isolation from photographs or 3D models, it was chosen to adopt a segmentation strategy based on the depth map, generated from the 3D model of the patient's profile. The literature confirmed that the use of the depth map can provide robust results [8]. As widely recognized, a depth map is an image that contains information about the distance of objects in a given scene from a given visual point of view. Since the most widely used edge detection algorithms are based on local sharp discontinuity, depth map images, where the grey levels depend on the object position, can be an optimal input for segmenting the scene. In this work the depth map is automatically created using a Z-buffer algorithm [9].

Although different orientations of the model result in different depth maps, a coarse orientation, with the ear being frontally positioned with respect to the point of view from which the depth map is generated, is sufficient at this stage to correctly isolate the ear from the patient's profile. Accordingly, the orientation of the model is performed by the user.

By using the Canny's algorithm [10], which is one of the most commonly used segmentation algorithms for ear isolation, the depth map, obtained by using the Z-buffer algorithm, is then segmented. The Canny edge detection algorithm involves the application of a Gaussian filter to smooth the image in order to remove noise, the calculation of image intensity gradients, an operation of non-maximum suppression (to consider only points corresponding to local maxima as belonging to a contour), and finally the contour extraction by hysteresis thresholding. Figure 6a shows the result obtained by applying the so defined algorithm. In order to select the ear edge, the program analyses the connected components of the image and, through geometric evaluations of scale and position, determines the correct edge (Figure 6b in white). Specifically, the first step in this phase involves the elimination of the connected component corresponding to the profile, statistically identified as the largest one. Moreover, with further empirical considerations, it was observed that, once the profile is removed, the largest connected component with centre of gravity closer to the image centre is that of the outer ear. The ear contour is then closed by fitting an ellipse on the contour of the ear (yellow in Figure 6b) using well-known ellipse fitting algorithms [11].



(a) (b)

Figure 6. Example of ear segmentation from face model: a) result of Canny's algorithm and b) ear contour selection (white) and ellipse fitting (yellow).

As stated above, the patient's healthy ear is used as a reference to reconstruct the malformed or absent ear.

It is clear that a mirroring procedure must be applied to the segmented ear anatomy for the design of the surgical guides, creating the ear model from which the modeling process continues in the steps listed below.

2) Auricular elements segmentation

The second step of the modelling procedure foresees the definition of the contours of the ear elements starting from the 3D model. The procedure is completely automatic and was presented in detail in [12]. In brief it consists of the following steps: 1) orientation of the ear in order to make all the ear elements to be detected as visible as possible, 2) creation of the depth map of the oriented model, 3) automatic segmentation through image processing operations. Figure 7 shows an example of the segmentation result. Orientation is determined by projecting the silhouette of the ear onto the faces of an icosphere positioned around the ear. The orientation plane is identified as the one corresponding to the projection with maximum area. The depth map is created with an implementation of the Z-buffering algorithm and segmentation is performed by applying successive thresholds to the depth image to identify individual elements, taking into account the anatomical characteristics of the auricular region defined by the Iannarelli system [13].

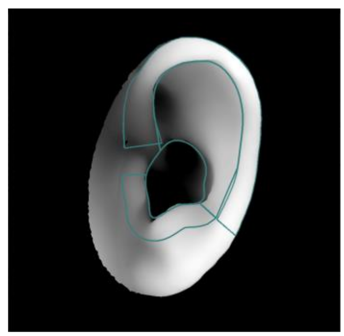
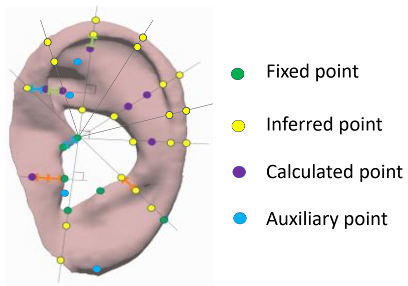


Figure 7. Result of the ear elements segmentation proposed in [12].

3) Reference points extraction

Although segmentation of the ear elements provides the exact contours of the elements to be reconstructed, these geometries cannot be strictly followed by modeling the surgical guides. In fact, due to the complexity of the geometries, the result would be guides that could not be used by the surgeon during surgery because they are too difficult to replicate on cartilage. For further clarity, please refer to [1]. For this reason the software entails a contour sampling phase to extract information constituting the input of the CAD modelling. The sampling strategy is based on ear biometrics and considerations regarding the modelling phase detailed in [1]. For the reader's understanding, Figure 8a shows the sampling scheme which is based on the green colored points (fixed points) used to compute all the others (with reference to Figure 8a: inferred points, calculated points and auxiliary points). In the present work a semi-automatic procedure of such a sampling process is provided. Starting from the manual input of the fixed points, the software automatically identifies all the others using the contours detected by the segmentation of the auricular elements. Figure 8b shows an example of the fixed points inserted by the user and Figure 8c shows the result of the automatic detection of the other points.



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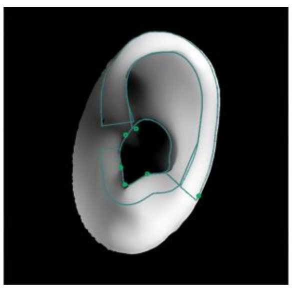

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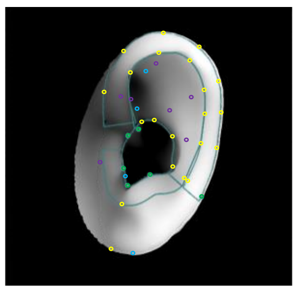

(c)

Figure 8. Extraction of key points: a) reference points position from [1]; b) manually inserted points; c) automatically derived points.

4) 3D modelling

The CAD modelling phase starts from the creation of the guides based on the points detected in the previous step. The sequence of CAD operations is carried out following the procedure systematized in [1], which is fully automated in the present work via a routine implemented for Siemens NX CAD modelling environment. The macro procedure was created by means of the API made available by the program [14] and takes approximately 5 seconds to generate new personalized surgical guides.

Figure 9 shows an example of the results of the automatic modelling process.

Figure 9. Example of the result of the surgical guide automatic CAD modelling.

B. Graphical User Interface

The entire automatic modelling procedure is made accessible to the user through a dedicated software named G-ear. The software exploits the C++ libraries Qt [15], for the graphical interface, OpenCV [16] for image processing and vtk [17] for mesh operations. The GUI provides a button for each step, as seen in Figure 10, which invokes the corresponding routine, so making the modeling method of surgical guides available to the medical staff.

The graphic interface was designed to be user-friendly, i.e. simple, clean, intuitive and reliable. The result is a straightforward tool that allows quick access to the commands, which is composed of three main areas, namely the navigation tab, the 3D navigator and a form to enter the patient's information.

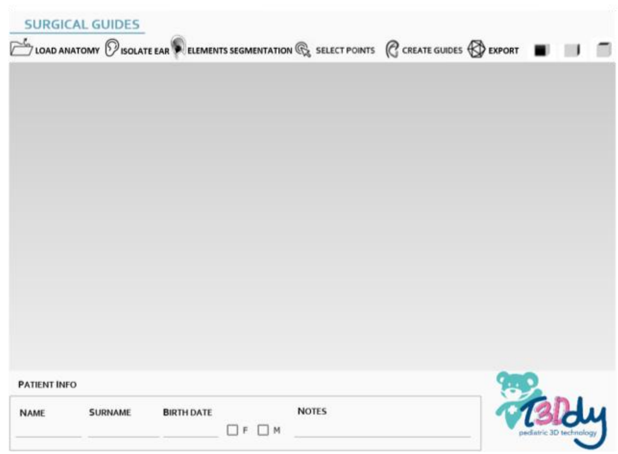

Figure 10. GUI for surgical guides modelling.

Inside the G-ear software, the modelling workflow begins with the upload of the head scan by using the “Load Anatomy button” Successively the user can exploit the 3D navigator to orient the model such that the ear is clearly visible.

Following the steps described in Figure 3, with the "Isolate Ear" button, the user launches the process of ear segmentation from the 3D model head. The second modelling phase, the segmentation of the auricular elements, is implemented in Matlab® environment [18], and, to facilitate the user in the exploitation of the program, the Matlab® routine is called in background by clicking the "Elements Segmentation" button of the GUI. To carry out the third step, the user clicks on the "Select Points" button, which enables the manual insertion of fixed points on the depth map shown on the screen; at the end of the insertion phase, by clicking again the button, the program starts the automatic extraction of the remaining points. Finally, the Siemens NX CAD modelling routine is invoked in background by the user by clicking the "Create Guides" button. The user can see the final result on the 3D navigator of the interface, as shown in Figure 11.

The extreme usefulness of surgical guides for autologous ear reconstruction, both in terms of increased confidence of the surgeon in performing the operation and in terms of aesthetic results and consequently patient satisfaction, has led to a growing demand for these devices. For this reason, it became important to develop software capable of creating surgical guides quickly and automatically. The program was designed to be used independently by the medical staff. Consequently, it was of crucial importance to assess the actual degree of acceptance and user-friendliness of the application by means of usability tests.

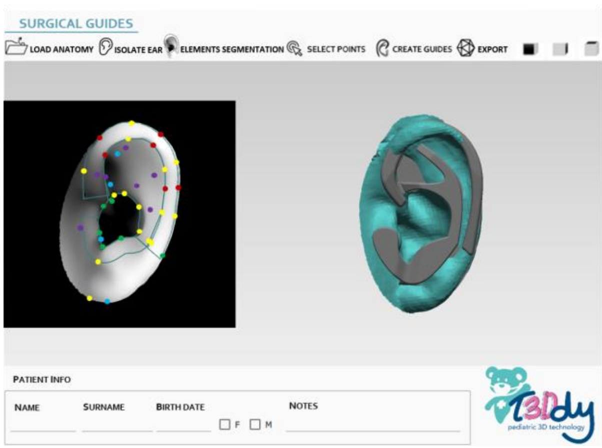

Figure 11. Final result of the surgical guides modelling.

According to the ISO 9126 series of standards (the most extensive software quality model developed to date [19]), 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". The evaluation of each metric was 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.

$$Effectiveness = \frac{number\ of\ tasks\ completed\ successfully}{total\ number\ of\ tasks\ undertaken} \quad (1)$$

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

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

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 the SUS (System Usability Scale) questionnaire [20], which has been found to give very accurate results. SUS consists of a 10 item questionnaire with five response options, from Strongly agree to Strongly disagree. To interpret the results of the questionnaire, the participant's scores for each question are added together and then multiplied by 2.5 to convert the original scores of 0-40 to 0-100. Though the scores are 0-100, they do not represent percentages and should be considered only in terms of their percentile ranking: value below 51 are to consider as strongly insufficient, 68 states the sufficiency threshold, and results above 80.3 are considered optimal.

The authors decided that, in order to assess the usability of the application, the entire procedure of making the surgical guides could be considered as a single task for the user.
Since it is common practice to test usability on five users [21], five pediatric surgeons from Meyer Children's Hospital were chosen for this study. A preliminary meeting has been held to explain to participants the GUI functionalities, 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.

Table 1 shows the results of the three metrics averaged over the five participants.

Table 1. Overall results for patient's usability test.

Effectiveness	Efficiency	SUS
100%	0.34 goal/min	91

The results show a 100% effectiveness in completing the task of creating the guides. The average time required for the execution of the whole process by the medical staff is about 3 minutes (0.34 goal/min), which is comparable with the time required by an experienced user which is about 2 minutes (0.5 goal/min). Finally, the tested software obtained an average SUS result of 91 stating a high level of satisfaction of the users.

III. Conclusions

The close collaboration, within the T3Ddy laboratory, with the surgeons of the Meyer Children's Hospital allowed the definition and realization of highly customized intraoperative instruments able to assist surgeons in AER surgery. In order to make physicians autonomous in the creation for each new patient of such devices, semi-automatic tools were developed in the present paper.

Based on the systematic modeling procedure of the personalized surgical guides presented in [1], and with a view to allow the hospital staff to create autonomously the surgical guides CAD models, a dedicated software, named G-ear, was implemented.

The tool requires minimal input from the user who is guided step by step through a succession of buttons in the execution of the procedure. In this work the software was tested in terms of usability through three important metrics, namely effectiveness, efficiency and satisfaction. The results showed a high degree of satisfaction and ease of use, proving that the software is a resource that can be easily exploited by medical staff.

In conclusion, the G-ear software allows medical staff to quickly and efficiently design patient-specific intraoperative guides that can significantly improve auricular reconstruction surgery.

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