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Computer-Aided Design AND APPLICATIONS

A Simple Interactive Tool for the CAD Modelling of Surgical Guides for Autologous Ear Reconstruction

Elisa Mussi[1], Michaela Servi[2], Yary Volpe[3] and Flavio Facchini[4]

[1] University of Florence, Italy, elisa.mussi@unifi.it
[2]University of Florence, Italy, michaela.servi@unifi.it
[3]University of Florence, Italy, yary.volpe@unifi.it
[4]Meyer Children's Hospital, Italy, flavio.facchini@meyer.it

Corresponding author: Yary Volpe, yary.volpe@unifi.it

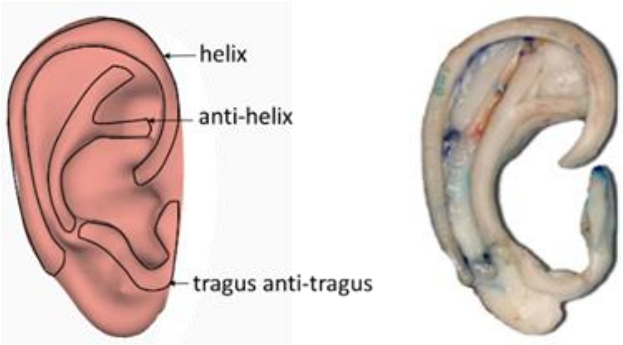
Abstract. The huge possibilities generated by the introduction of rapid prototyping techniques in the medical field has paved the way for collaborations between physicians and engineers to produce personalized medical devices, tailored to the specific anatomy of the patient. Specifically, in the field of autologous auricular reconstruction, i.e. the reconstruction of the external ear using the patient's costal cartilage, the authors worked towards the development of new patient-specific intraoperative devices, to support the surgeon during the procedure. The surgical guide design was then supported by the development of automated techniques for their modelling. In this work, a new hybrid technique for the CAD modelling of surgical guides is proposed. The idea is not to totally eliminate the intervention of the physician in defining the shape of the surgical guides, but rather to simplify their interaction with design tools. The proposed method is based on the straightforward adaption of a two-dimensional template developed by evaluating various auricular biometric parameters to approximate ear structure. The template is coupled to a parametric automatic procedure that generates the surgical guides' CAD model. The template was created outside of commercial CAD modeling software packages to make the procedure more accessible, and it is managed using a well-designed graphical user interface. With specialized questionnaires to evaluate the surgeon's satisfaction, the interface was put to the test, and the results were positive.

Keywords: CAD, Reverse Engineering, 3D Modelling, Microtia, Autologous Ear Reconstruction, Personalized Medicine
DOI: https://doi.org/10.14733/cadaps.2023.109-118

1 INTRODUCTION

The advent and consolidation of Reverse Engineering (RE) and Additive Manufacturing (AM) techniques in the medical field has significantly revolutionized the surgical approach, pushing

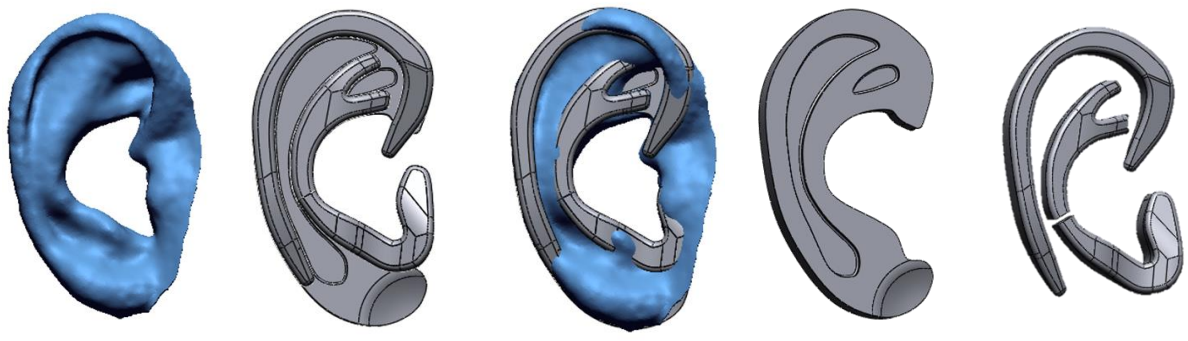
towards a new perspective of treatment based on the respect of interindividual anatomical variability [5,6,14,1]. These technologies have also been exploited for the surgical treatment of microtia [4,12], a congenital malformation characterized by partial or complete lack of the external ear architecture [11]. Surgery represents one of the treatment options for the anatomy restoration. The procedure, which generally takes 4/5 hours [8], involves 5 steps: 1) removal of a portion of costal cartilage from the patient, 2) opening of the surgical site at the level of the absent or malformed ear, 3) cutting, sculpting, shaping and suturing of the ear elements (helix, anti-helix, tragus-antitragus, base, shown in Figure 1(a)) into the auricular framework, that aims to resemble the contralateral healthy ear, shown in Figure 1(b), 4) insertion of the auricular framework into the subcutaneous pocket obtained in step 2, 5) suturing of the thoracic and auricular surgical sites [3,10].



(a) (b)

Figure 1: a) ear elements, b) example of ear framework.

Although this type of intervention has been a therapeutic solution for several years, it continues to remain a real challenge for plastic surgeons given the complexity of reconstructing a harmonious and physiological ear [7]. Scientific research through the introduction of intraoperative aid devices able to guide and support the physician in the realization of the framework has allowed to make progress in the direction of an improvement both in terms of surgical time and in terms of aesthetic results. Within this clinical scenario, a multidisciplinary research group of the T3ddy laboratory (a joint lab between the Department of Industrial Engineering and the Meyer Children's Hospital of Florence, which involves the authors of the present paper) has been working over the past four years to the development of solutions based on rapid prototyping techniques to assist pediatric surgeons during autologous ear reconstruction. Specifically, the designed aids are surgical guides for each ear element to be reconstructed; the design of the guides is the result of collaboration with surgeons and follows some general principles. In particular, the key features of three-dimensional surgical guides were defined, with the peculiarity of providing simultaneously information on the specific patient geometry and a substantial simplification; detailed information can be found in [2]. An example of this particular design can be observed in Figure 2. The modeling of the guides is done on the contralateral healthy ear to ensure compliance with patient characteristics. In [2], a systematic procedure to be applied in manual modeling by experienced CAD modelers was presented. Subsequently, with the goal of opening the door to in-house manufacturing of medical devices, a standard and simple process was created in [9] for the automatic CAD modeling of surgical guides by healthcare professionals using user-friendly software tools.



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

Figure 2: a) ear to be reconstructed, b) set of surgical guides, c) surgical guides superimposed on the ear reference, d) surgical guide of the base, e) surgical guides of helix, anti-helix, tragus-antitragus.

Although the process has proven to be repeatable and robust, thus satisfying initial expectations of physicians, the development of a fully automated procedure and its use have brought to light the limitations that arise when the user's control is completely eliminated. These limitations are primarily due to the fact that the physician does not have the ability to translate patient-specific clinical considerations into actual CAD model changes in the guides. In fact, in the context of personalized medicine distinctive factors of each patient should be considered such as, for instance, skin memory, presence of non-removable cartilage remnants and anatomies with features that deviate from the average. In light of these shortcomings, in this work a semi-automatic procedure for modeling ear surgical guide is developed in order to enable the surgeon to modify the CAD model according to purely clinical considerations without having knowledge of CAD modeling tools. As explained below, the proposed solution involves the design of a template that is adaptable to the anatomy of the ear, is easy to be managed and can provide immediate feedback of the final shape of the guides.

2 MATERIALS AND METHODS

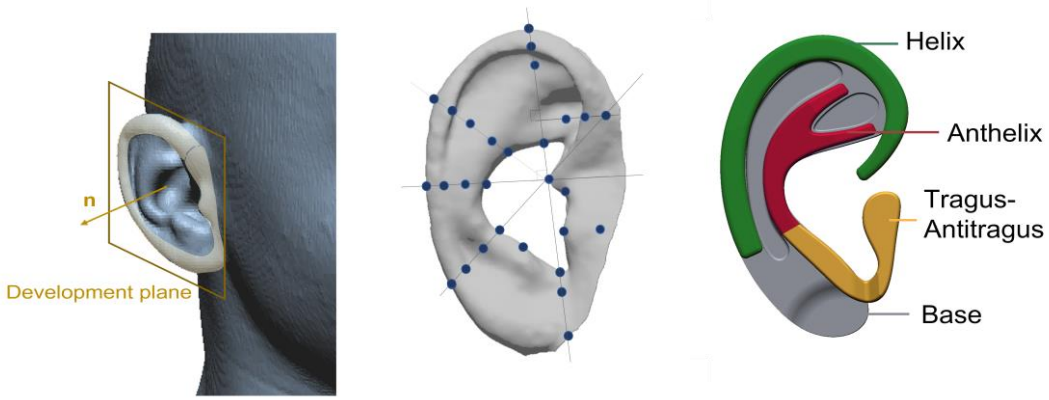
As mentioned before, the procedure devised in [9] does not allow the surgeon the freedom of changing the shape of the surgical guides based on possible clinical considerations. Therefore, in this work it was deemed necessary to make CAD modeling more accessible through the design of a template of surgical guides easily manageable through a semi-automatic modeling procedure, allowing the surgeon to dynamically change the shape of the surgical guide model.

From an operational point of view, the work envisaged two successive phases: 1) study and testing, within a CAD environment, of a procedure based on a 2D template adaptable to the patient's auricular anatomy; 2) implementation of the template and its handling in C++ environment in order to simplify the interface between the physician and the CAD modeling of the guides. The two phases are detailed below.

2.1 2D CAD Template

The development of the CAD procedure based on the 2D template was based on the modeling procedure of surgical guides proposed in [1]. In such work, starting from the geometry of the patient ear (Figure 3(a)), a set of points (see Figure 3(b)) are extracted on a predetermined reference plane, named "*development plane*", which represents the developmental plane of the ear

(see Figure 3(a)). Subsequently, through a systematic CAD-based procedure the surgical guides are modeled (as shown in Figure 3(c)).



(a) (b) (c)

Figure 3: a) Example of *development plane* of the ear; b) key points for CAD modeling of surgical guides; c) resulting CAD models of each auricular element surgical guide.

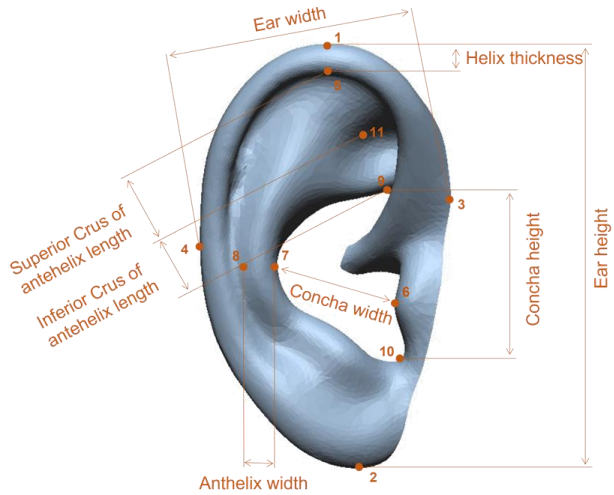
Exploiting this systematic procedure, the present work proposes a flexible solution based on an adaptable 2D template. The 2D template represents a simplified shape of an average ear, in which each element consists of splines and their corresponding guiding points. As in [2] the 2D sketch on which the splines lie must correspond in terms of orientation and position to the *development plane*, in order to model the surgical guides while respecting the auricular anatomy. The 2D template is linked to a parametric CAD procedure which automatically updates the final 3D shape of the surgical guides when the control points of the splines are moved by the user.

With the aim of creating a 2D template easily adaptable to any new anatomy a statistical study of the dimensions and characteristics of the auricular region is performed to obtain a template based on a middle ear. The study involved the use of two hundred 3D ears models (100 right ears and 100 left ears belonging to subjects of different sex and age), on which the following parameters were measured (see Figure 4): width and height of the ear, thickness of the helix, width of the anthelix, length of the upper and lower roots of the anthelix, height and width of the concha. Figure 4 shows the anatomical lengths averaged over the 200 cases in the dataset. These values were used to construct the aforementioned average model.

The parametric procedure was implemented in Geomagic Design X software and to use the 2D template, the user must execute the following steps: 1) import the patient's ear model and locate the *development plane.* As defined in [9], the plane is identified by extracting a best-fit plane on the perimeter triangles of the ear mesh as shown in Figure 5(a); 2) roto-translate the mesh to make the ear *development plane* coincide with the 2D template plane (Figure 5(b)); 3) manually edit the template points on the 2D sketch modifying the splines to better approximate the specific patient anatomy (Figure 5(c)). Once the points have been moved the 3D models of the surgical guides update automatically and can be exported. Figure 5 shows all the operations that need to be performed within Geomagic Design X to use the template and obtain the final model of the guides.

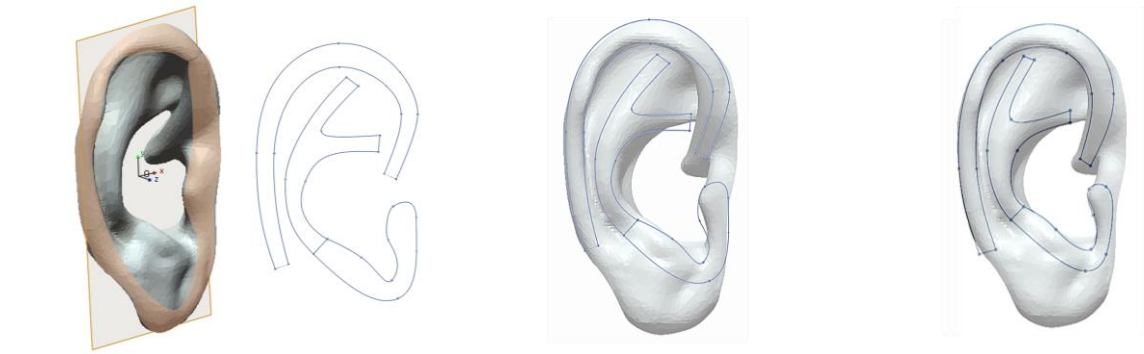
The parametric design employing the 2D template speeds up and simplifies the process of developing surgical guides. In fact, a CAD modeler takes about 40 minutes to complete the entire process of creating intraoperative devices, while using the proposed parametric model it takes only about 3 minutes. The template concept has the right characteristics and potential to be a tool that can be used within the clinical practice; in fact, the displacement of the points with the consequent updating of the geometry represents both a simplification of the procedure and a tool able to adapt to the patient-specific anatomy in perfect accordance with the medical requirements. It has to be

considered that the parametric modeling can be used by healthcare personnel after a dedicated training on how to move the relevant features (guiding points) on the average ear model and on how to determine the *development plane*.



Ear width	34.7 mm
Ear height	58.9 mm
Helix thickness	4.3 mm
Concha height	23.1 mm
Concha width	17.2 mm
Anthelix width	4.5 mm
Superior Crus of Anthelix lenght	8.8 mm
Inferior Crus of Anthelix lenght	9.2 mm

Figure 4: Definition of anatomical lengths and their value averaged on 200 models.



(a) (b) (c)

Figure 5: Example of the template adaptation procedure in a CAD environment: a) identification of the *development plane*; b) load of the 2D template; c) manual adjustment of points.

To ease these tasks, a software interface was developed, thus allowing the clinician to easily edit the template creating the surgical guides without the need of acquiring specific CAD modeling skills. The development of such interface is described in the next section.

2.2 C++ Environment Template

The application proposed in this work, that allows a simple interface with parametric modeling, was implemented in C++, using the VTK library for the management of 3D data.

The main objective was to minimize the intervention of the user, limiting it to the movement of the points of the template (avoiding all CAD operations necessary to perform the procedure described above). To this end, the ear mesh alignment with the template needs to be automated. The alignment procedure, developed in a C++ environment, automatically identifies the *development plane* of the ear using a method based on the identification of the plane on which the largest portion of the ear is projected, as in [9].

In detail, the routine that performs the alignment of the template with the mesh creates an icosphere centered in the mesh's barycenter, as shown in Figure 6(a). For each icosphere plane the ear mesh is projected, thus obtaining the silhouettes of the ear from each point of view (Figure 6(a)), and the area of each silhouette is calculated. The plane on which lies the silhouette with the maximum area is the chosen as the *development plane*.

The ear mesh is rotated so that the so found *development plane* is aligned with the template plane (by calculating the rotation matrix so that the normal of the *development plane* and the normal of the 2D template plane are aligned) and the center of mass of the mesh is brought to coincide with the center of mass of the template through translation operations. To complete the correct orientation of the anatomy with respect to the template plane, the max line of the ear, defined as in [13] and visible in Figure 6(a), is identified and aligned with the Y axis of the plane on which the template lies (Figure 6(b)).

The template was implemented by making the splines, defining the edges of each anatomical element, individually editable. To make the adaptation easier and more intuitive the spline points of each anatomical element are displayed using different colors; to ensure that a change of the position of each point results in an immediate change of the associated curve, so the user has immediate feedback of the resulting geometry of the guides, the program associates a listener event to each point so that the displacement determines the immediate recalculation and display of the spline.

To perform the CAD modeling which starts from the movable control points, a macro procedure was implemented that performs the CAD modeling in background, using Siemens NX API. The procedure follows the steps of the CAD modeling technique given in [2] though using the movable control points previously defined.

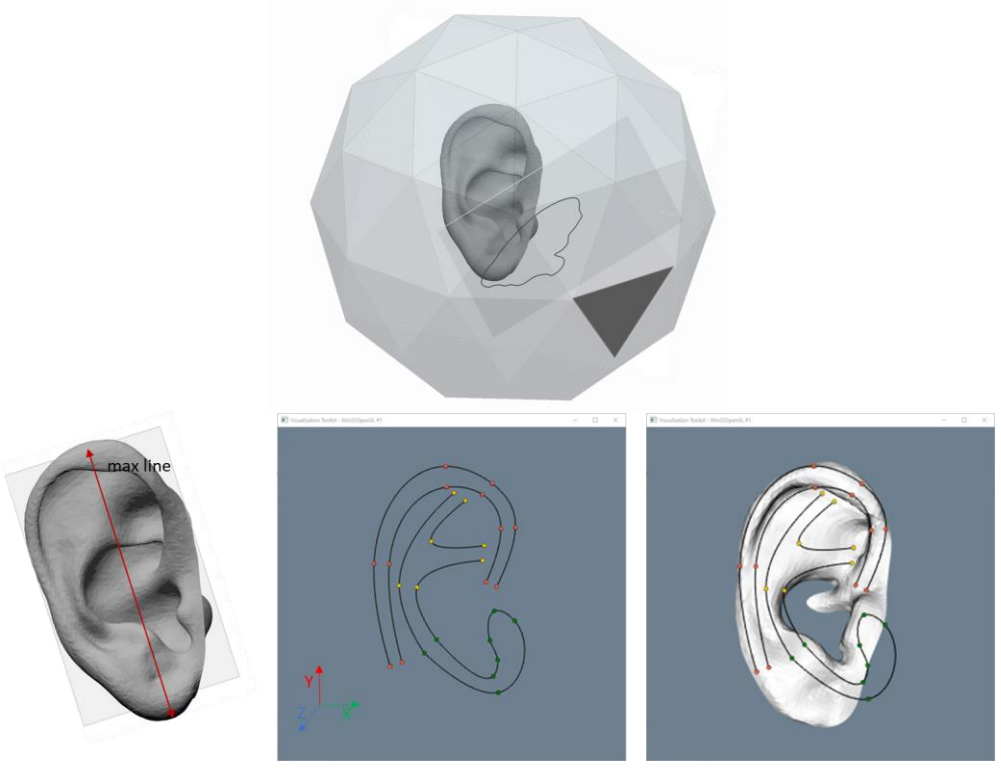


Figure 6: a) illustration of the procedure for the detection of the ear *development plane*; b) illustration of final alignment of the ear with the template.

The steps of the user's interaction with the program are (Figure 7): 1) the user starts the program and the ear mesh is loaded, the mesh appears on screen already aligned with the template (Figure 7(a)). 2) The template is edited, i.e., the template points are manually moved according to clinical consideration and ear geometry of the specific patient's anatomy (Figure 7(b)). 3) The guide is created, the user presses the "Enter" key and the macro procedure, which computes the 3D modeling of the surgical guide, is called in background on the automatically saved points Figure 7(c).

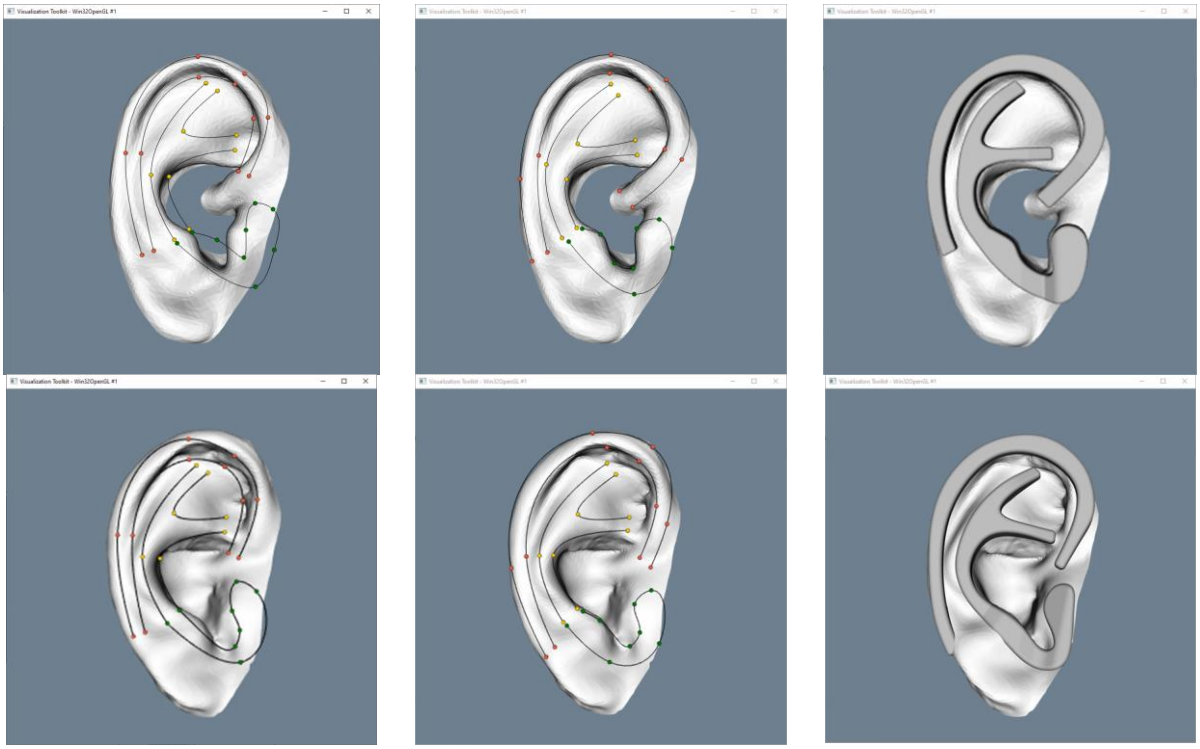


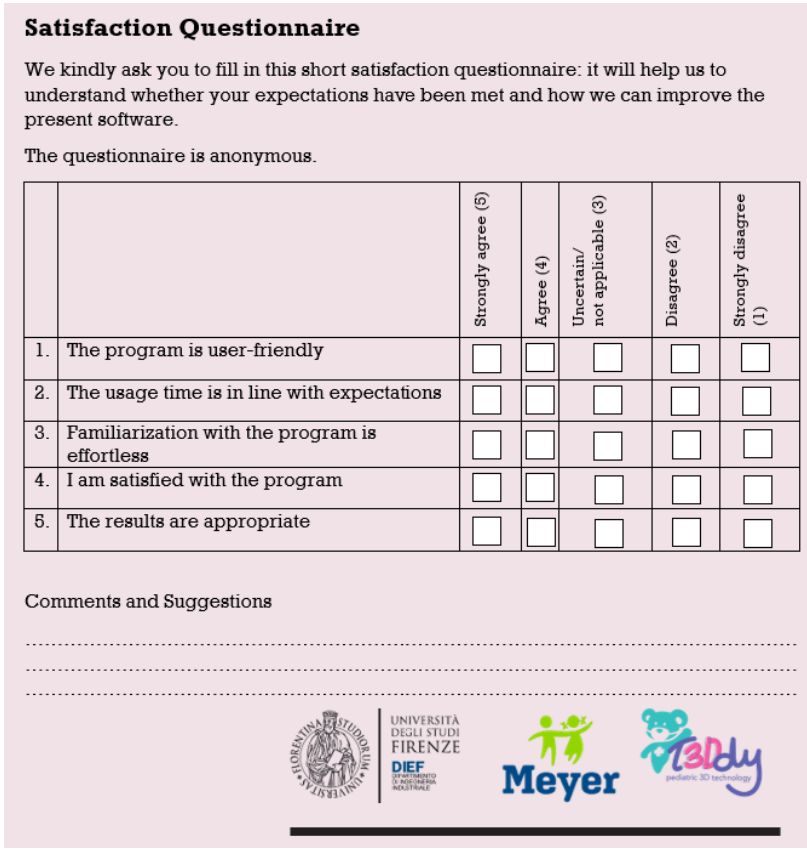
Figure 7: Example of usage of the C++ interface to adapt the template on a specific ear. a) the program starts showing the template superimposed on the anatomy; b) manual movement of the template by the user; c) result of the automatic modeling process.

3 RESULTS AND CONCLUSIONS

Given the specific field of application of the proposed software, which is aimed at the design of customized medical devices in accordance with the physician's requirements, it is not deemed possible to quantitatively evaluate the produced results. Referring to the CAD modeling procedure it was already evaluated in [2] by analyzing its intra- and inter-operator repeatability and robustness. Since the reconstruction process proposed in this work is analogous to the one defined in the previous work, such an assessment is not proposed here. Rather, in a first step the results of using the software on 50 models were evaluated and two examples are shown in Figure 7. Successively, it was decided to evaluate the proposed parametric design by submitting a specially prepared questionnaire to five specialized physicians (shown in Figure 8). The purpose of the questionnaire was to evaluate and collect feedback on user satisfaction with the software, assessing the following aspects: user-friendliness, time of use, familiarization time, general satisfaction, consistency of results. Each item was evaluated by assigning a score from 1 to 5.

The questions received an average score of 4.5, showing a high level of satisfaction by physicians, and the item with the lowest score was the one referring to familiarization time with the program. Two surgeons, in the comments and suggestions section, expressed comments regarding the possibility of inserting a measurement tool to better understand the anatomy, a need that could be traced back to the unfamiliarity of surgeons with 3D navigation tools and that, however, represents a useful tool in the context of 3D modeling. In addition to this, a second need which emerged from the questionnaires concerns the possibility of manually inserting additional points to the splines through a dedicated command to allow a greater adaptation of the template to the auricular anatomy. In conclusion, while in previous studies, the main focus of research was on the development of semi-automatic procedures to minimize operator input during the design process, the solution proposed in this study aims to provide the user/physician with a tool in which his or her clinical experience plays a crucial role in the final shape of the produced devices.

The implemented tool guarantees an easy management of the modelling process and, at the same time, allows to modify the shapes of the surgical guides according to purely clinical considerations through a simple user interface. The tool scored high appreciation values through satisfaction questionnaires filled by five surgeons, proving its clinical applicability. Future developments will aim at the implementation of the suggestions made by surgeons in the satisfaction questionnaires.



Satisfaction Questionnaire

We kindly ask you to fill in this short satisfaction questionnaire: it will help us to understand whether your expectations have been met and how we can improve the present software.

The questionnaire is anonymous.

		Strongly agree (5)	Agree (4)	Uncertain/ not applicable (3)	Disagree (2)	Strongly disagree (1)
1.	The program is user-friendly	☐	☐	☐	☐	☐
2.	The usage time is in line with expectations	☐	☐	☐	☐	☐
3.	Familiarization with the program is effortless	☐	☐	☐	☐	☐
4.	I am satisfied with the program	☐	☐	☐	☐	☐
5.	The results are appropriate	☐	☐	☐	☐	☐

Comments and Suggestions

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Figure 8: Satisfaction questionnaire.

	Surgeon 1	*Surgeon 2*	*Surgeon 3*	*Surgeon 4*	*Surgeon 5*
User-friendliness	4	5	5	4	5

Time of use	4	5	5	5	4
Familiarization time	3	4	5	4	5
General satisfaction	4	4	5	4	5
Consistency of results	4	5	4	5	5

Table 1: Results of the satisfaction questionnaire.

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