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

Authors:
Elisa Mussi, elisa.mussi@unifi.it, University of Florence
Michaela Servi, michaela.servi@unifi.it, University of Florence
Yary Volpe, yary.volpe@unifi.it, University of Florence
Flavio Facchini, flavio.facchini@meyer.it, Meyer Children's Hospital

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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 [3]. These technologies have also been exploited in the surgical treatment of microtia, a congenital malformation characterized by partial or complete lack of the external ear architecture. [5]. Such a surgical procedure involves the removal of a portion of the patient's costal cartilage, the manual modeling of the cartilage tissue in order to obtain a geometry that resembles the healthy auricular anatomy and the insertion of the cartilage framework thus obtained in a subcutaneous pocket in the malformed area [2].

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. 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 its simplification; detailed information can be found in [1].

The 3D modelling of the custom devices was initially performed by experienced CAD modelers. Subsequently, software tools to easily interface physicians with CAD modeling were defined and implemented to create a standard and straightforward process for their manufacture with the aim of introducing them into common clinical practice. The idea behind this line of research was to pave the way for the new frontier of in-house production of medical devices by increasingly advanced hospitals.

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 creation 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.

Materials and Methods:

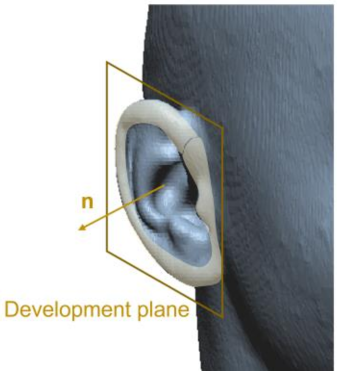
As mentioned before, the procedure devised in [1] does not allow the surgeon the freedom of changing the shape of the surgical guides based on possible clinical considerations. Therefore, in this work it was deemed necessary to make CAD modeling more accessible through the creation of a template of surgical 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.

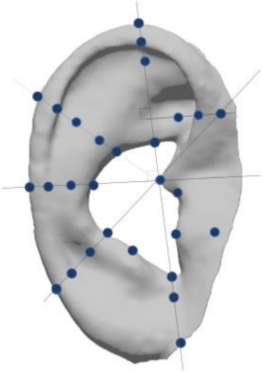
The two phases are detailed below.

2D CAD template

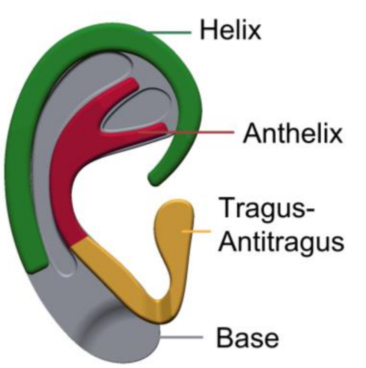
The realization of the 2D template is based on the modeling of surgical guides proposed in [1]. In such a work, starting from the geometry of the patient ear (Fig. 1a), a set of points (see Fig. 1b) are extracted on a given reference plane, named “development plane” (see Fig. 1a). Subsequently, through a systematic CAD-based procedure the surgical guide of Fig. 1c is modeled.



(a)



(b)



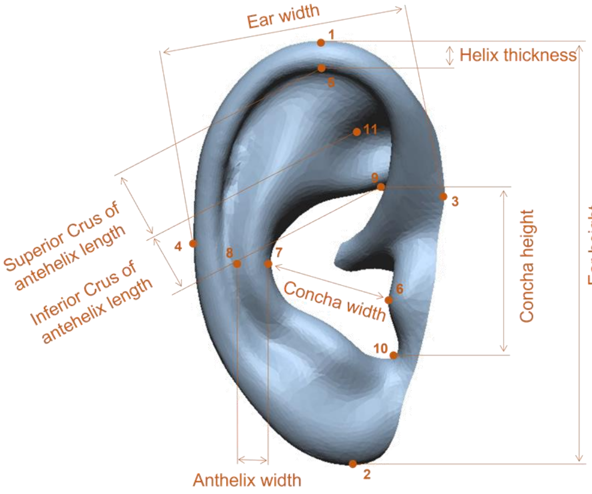
(c)

Fig. 1: a) Example of development plane of the ear; b) key points for CAD modelling 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 [1] 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. he 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 200 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 Fig. 2): 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.

Fig. 2 shows the anatomical lengths averaged over the 200 cases in the dataset. These values were used to construct the aforementioned average model.



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

Fig. 2: Definition of anatomical lengths and their value averaged on 200 models.

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 Fig. 3a; 2) roto-translate the mesh to make the ear development plane coincide with the 2D template plane (Fig. 3b); 3) manually edit the template points on the 2D sketch modifying the splines to better approximate the specific patient anatomy (Fig. 3c). Once the points have been moved the 3D models of the surgical guides update automatically and can be exported. Fig. 3 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.

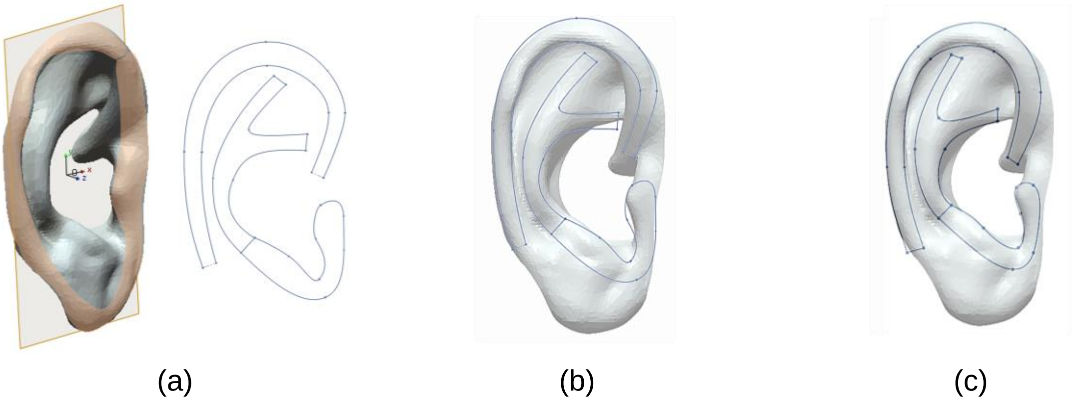


Fig. 3: Example of the template adaptation procedure in a CAD environment.

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 constitutes 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.

To ease these tasks, a software interface is 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.

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 [4]. After identifying this plane, it 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.

For the implementation of the template, the measurements identified on the average ear model were used. The template was implemented by making the splines individually editable and displaying each anatomical element in a different color to make the adaptation easier and more intuitive; in addition, 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.

To perform the CAD modeling which starts from the control points and the connecting splines, a macro procedure was implemented that performs the CAD modeling in background, using Siemens NX API.

Fig. 4 shows the steps of the user's interaction with the program.

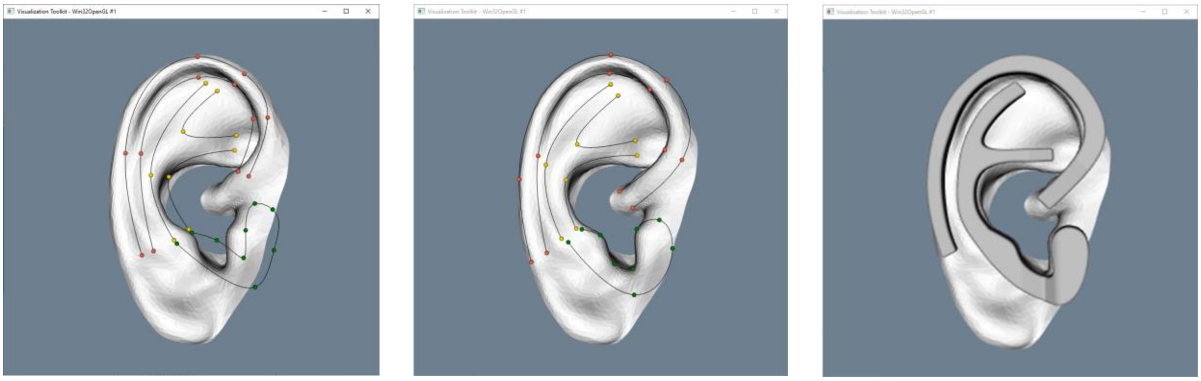
The user starts the program and the ear mesh is loaded: the mesh appears on screen already aligned with the template (Fig. 4a). 2) The template is edited: the template points are manually moved (Fig. 4b). 3) The guide is created: the user presses the “Enter” key and the macro procedure, which compute the 3D modeling of the surgical guide, is called in background on the automatically saved points Fig. 4c.

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 [1] 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 this work it was decided to evaluate the proposed parametric design by submitting a specially prepared questionnaire to five specialized physicians. 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.

In conclusion, 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, while maintaining the automation of the modelling process. Thus, 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.



(a) (b) (c)

Fig. 4: 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 modelling process.

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