Title:
Autologous Ear Reconstruction: Towards a Semiautomatic CAD-Based Procedure for 3D Printable Surgical Guides

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Keywords:
CAD modelling, Reverse Engineering, 3D Ear Templates, Autologous Ear Reconstruction, Personalized Medicine

DOI: 10.14733/cadconfP.2020.1-5

Introduction:
External ear reconstruction with autologous costal cartilage is a demanding surgery to restore the deformed or missing ear anatomy following a trauma, tumor intervention, or due to a congenital malformation (microtia) [7]. The surgical intervention consists of the following surgical phases: i) the harvesting of a portion of costal cartilage from the patient, ii) the manual cut and carve from costal cartilages of the principal ear anatomical elements and the suture of these components to create the ear "framework" (described in detail below) and, iii) the positioning of the framework inside a skin pocket located in the auricular region. The so generated cartilage framework aims to replicate the anatomy of the healthy mirrored ear, herein addressed as reference ear. Assuming a complete reconstruction of the ear (in case the patient present a total absence, i.e. anotia), the framework consists of segments replicating ear anatomical elements and a base that functions as a support [3]. The creation of a suitable framework is a tricky surgical procedure due to the complex and extremely unique geometry to be reproduced [2], and requires practice and a long experience [6]. The common practice involves the adoption of a 2D template which assists the surgeon in the ear "framework creation". The 2D template is delivered by placing a 2D X-ray film over the contralateral healthy ear and tracing the contours.

Since the 2D template does not provide the relevant information on the 3D morphology of the ear, i.e. height, thickness, depth characteristics of the anatomical elements of the ear structure, the 3D replica of the healthy ear has also been exploited in literature as a reference during the reconstruction surgery [5]. Nevertheless, according to this technique, the 3D model is only a visual aid for the plastic surgeon rather than an actual surgical guide that can be used to identify and cut from the cartilage the individual elements involved in the reconstruction process. Therefore, the result is still strongly dependent on the surgeon artistic and technical skills and on the visual capacity to draw out from the full model each anatomical elements to be replicated. To overcome these limitations, this work focuses on devising a novel approach to create simplified (therefore more effectively helpful) patient-specific surgical guides that can help the surgeon both in simulating the procedure before entering the surgical room and in performing a guided surgery. More specifically, effective and efficient surgical guides were defined and a systematic procedure that, starting from the 3D model of the reference ear enables the 3D modelling of personalized guides, was developed. The procedure to date has not been

automated, however this work, by defining a modelling method which can be applied systematically to any new case study, lays the foundations for a future automation of the process. The devised procedure was validated on ten case studies, to test its robustness and repeatability.

Design of surgical guides:

The first step taken to overcome the limits of the surgical methodologies present in the literature, as mentioned in the introductory section, was the definition of the technical and clinical requirements of the surgical guides to be designed. The delineation of these requirements was the result of a close multidisciplinary collaboration between clinicians and engineers; the latter have the role, inter alia, to identify the system requirements that can be the operational response to clinical needs.

The correct shape and functionality of the ear surgical guides (referenced also as “fragments” in the following) was identified through an iterative process of design and physical simulation during which the clinician tested the devised models in the realization of the ear framework. The testing and simulation phases involved the manufacturing of costal cartilages physical replicas using silicone rubbers mixed with additives to make the cut as realistic as possible. Initially, according to clinician's suggestions and state-of-the-art techniques, the guides of each anatomical element (helix, anti-helix, tragus-antitragus, depicted in Fig. 1) were created following faithfully the original anatomy, i.e. extracting them directly from the 3D-scanned model of the reference ear. Details on acquisition modalities of the 3D geometry of the healthy ear with reverse engineering technologies are available in [4] and are not subject of interest of this work.

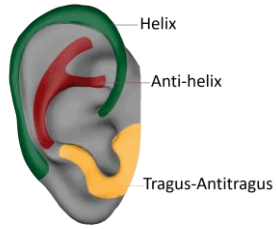


Fig. 1: Description of ear anatomy.

Simulations showed that the use of guides resembling faithfully the ear anatomical elements implies a few drawbacks: an excessive difficulty in the framework creation due to the complexity of the geometries that prevents an easy, precise and fast surgery. In addition, the reference 3D model acquired by means of optical scanning includes a layer of skin covering the auricular cartilage; for this reason, the actual auricular cartilage geometry is slightly modified (e.g. smoothed by the skin) when extrapolated from the model.

In light of these considerations, the CAD models of the guides have undergone a simplification process such as to maintain the characterizing properties of the patient-specific anatomy and, at the same time, to eliminate unnecessary features that could hinder the simplicity of the procedure.

Fig. 2: Example of: (a) the full framework, (b) helix, anti-helix tragus-antitragus CAD models, (c) base CAD model, (d) CAD models superimposed to ear reference mesh.

As motivated above, specific ear features are emphasized in order to create templates that can facilitate the extraction of the geometries from the cartilage tissue and thus simplify the manual cutting of the fragment and to deal with the socket skin layer. Specifically, the definition of the characteristics, that each anatomical template must have, is obtained as a trade-off between the feasibility of the carving procedure, an aesthetically pleasant outcome and finally, as shown in Fig. 2(d), should match the overall sizes, volumes and primary shapes of the patient-specific anatomy.

Method:

To lay the foundations for implementing a semiautomatic procedure capable of creating the 3D models described above, this paper focuses on the identification of *key reference points* detectable on any auricular geometry. The procedure requires a pre-oriented input mesh, on which the fragments are modelled. Specifically, the orientation should maximize the visible portion of each anatomical element involved in the ear reconstruction surgery, see Fig. 3. The identification of this point of view can be achieved by looking for the plane on which the maximum area of the ear silhouette is projected. The definition of this orientation plane is a key step as the fragments are extracted from the 2D projection of the ear on this plane (in other words, the CAD modelling and therefore the identification of the *key reference points* is carried out entirely on this plane).

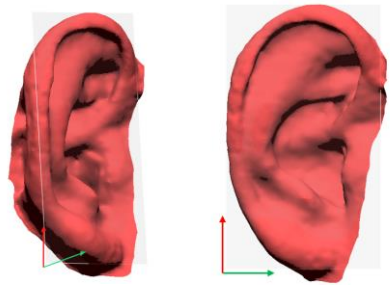


Fig. 3: Example of an (a) incorrect and (b) correct orientation of the reference ear.

The *key points*, shown in Fig. 4(b)(c), are divided into *fixed* (manual input), *inferred* and *calculated points*. Three *fixed points* (1,2,3 in Fig. 4(c)) are placed on the helix in correspondence of the extremities of the element; other three *fixed points* (4,5,6 in Fig. 4(c)) are located on the tragus-antitragus element. *Point* 5 is located on the anatomical area of separation between tragus and antitragus; *points* 4 and 6 are located in correspondence of the change of curvature of antitragus and tragus. By using *fixed points* it is possible to define four lines (Fig. 4(b)): two lines, **a** and **c**, are identified as passing through respectively points 1-5 and 1-3; line **b** is perpendicular to line **a**, while line **d** is bisector of the angle defined between line **a** and line **b**. The *inferred points* are defined as belonging to these lines in correspondence with the boundaries of the anatomical elements. By way of example, *key points* 7 and 8 are located at the intersection points of line **a** and the boundaries of the helix (see Fig. 4(c)), analogously, *key point* 9 on line **c**. Finally, *calculated points* derive from both *fixed* and *inferred points* according to anthropometric considerations and clinical requirements indicated by the physician. For example, *point* 10 is positioned at a distance from *point* 9 equal to the distance between *points* 1 and 2, along the direction defined by line **b**. *Point* 12 is defined as belonging to line **a** at a distance from *point* 8 equal to 20% of the segment defined by *point* 1 and 8. The same shift (parallel to line **b**) is applied to *point* 10 to obtain *point* 11.

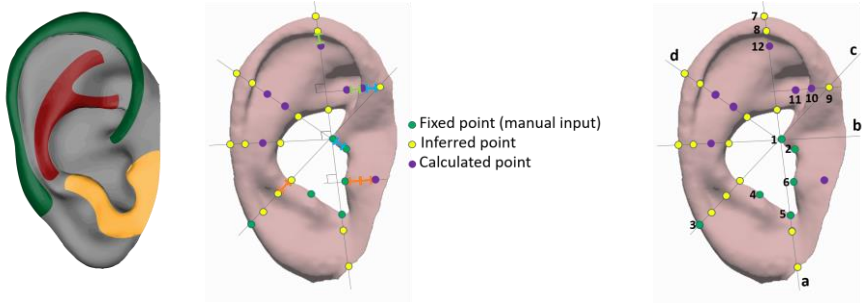
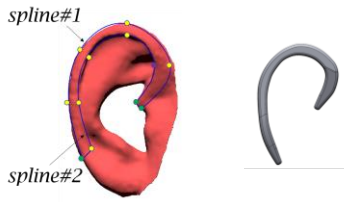
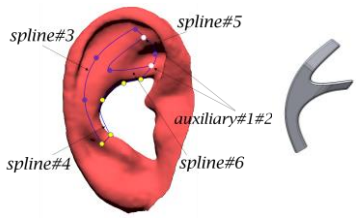
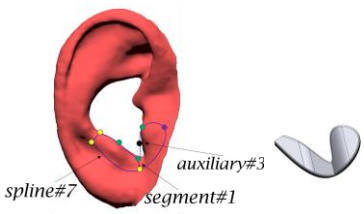
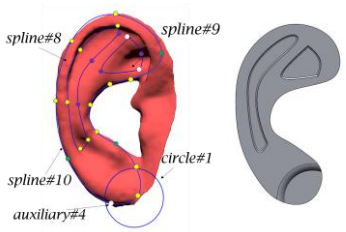


Fig. 4: Example of: (a) ear anatomical elements, (b) the extraction of the *key points* used for the CAD procedure (the concha was removed to facilitate the visualization of *key points*), (c) labelled *key points* and lines.

In Tab. 1 the reconstruction steps to obtain the CAD models realized with Geomagic Design X are shown [8].

	To create fragment#1 two spline, *spline#1* and *spline#2,* are created and their extremities are joined together with a segment. s*pline#1* is obtained connecting the points of Fig. 4(b) placed on the external perimeter of the helix. In the same way, *spline#2* derivers from the points defining the internal profile of the helix. The so generated profile is extruded of a fixed value (5 mm) defined with the clinician according to a morphological study. A chamfer operation is then exectued from the second-to-last to the last points of the two extremities with a final thickness of 2 mm. All edges are blended of 1 mm; the blending value, as well as the chamfer, were chosen experimentally to avoid the occurrence of errors.
	Fragment#2 is created from *spline#3#4#5#6.* Specifically, *spline#3* is created with the *key points* on the outer perimeter of the anti-helix and s*pline#4* on the inner perimeter. These two splines are connected at the inferior side with a segment; s*pline#5* connects the superior side. To create *spline#6,* two points (*auxiliary#1#2*) are extracted on *spline#5* at fixed distance from the two extreme points. This distance was set to 25% of the total length to ensure the Y-shape. The so generated profile is extruded with a fixed value (3 mm) again defined according to morphological studies. The two upper extremities are chamfered from the minimum point of the Y-shape to the final thickness of 2 mm and the element's edges are seccessively blended of 1 mm. Again, the fillet and chamfer values were chosen experimentally to avoid the occurrence of errors.
	Fragment#3 is created from *spline#7* which is obtained from the points delimiting the tragus-antitragus region and closed with a segment at the antitragus extremity. The so generated profile is extruded with a fixed value (3 mm) defined according to morphological studies. The solid is then divided along *segment#1,* using the two *key points* on line **a**, in order to apply a chamfer operation to obtain a saddle point which characterises this auricular region. It is important to note that it is necessary to use the midpoint (*auxiliary#3*) between the two green points of the tragus to define the chamfer of this element. Again, the fillet and chamfer values were chosen experimentally, respectively of 1 mm and 2 mm, to avoid the occurrence of errors.

	Fragment#4 is created from *spline#10* which is obtained from the points on the outer perimeter removing the region between helix and tragus delimeted by the *key points* in this area. To create *spline#10* an auxiliary point (minimum point along Y-axis) was used to maintain the original curve of the lobe. *spline#8* is created from internal *key points* of the helix and outer *key points* of anti-helix. *spline#9* is created combining *spline#6* and *spline#5.* Two sockets are created through a cut extrusion of a value equal to 2 mm of the so generated profiles. A circular cut of 2 mm is made in the area of the lobe, as shown on the left circle*#1* is calculated as the circumference passing through *inferred* and *auxiliary points* in that area. The value of the cut extrusion was defined with the surgeon. The edge is then blended of 1 mm, again to avoid the occurrence of errors.

Tab. 1: Evolution phases of an applying example of the devised procedure.

Discussion and Conclusions:

The devised procedure was tested in the generation of ear surgical guides for ten subjects, five females and five males. The panel group structure has allowed the modeling method to be validated on significantly different ear geometries. The procedure was applied in each case according to the steps mentioned in the previous section. In each case the ear fragments were correctly generated without major complications. CAD models were printed in ABS (acrylonitrile-butadiene-styrene) through FDM 3D printing technology (MakerBot Replicator 2 [1]) and then evaluated and validated by the surgeon. The repeatability and robustness of the method were tested by evaluating the result according to three main parameters: fitting of the patient-specific ear, usability during surgery and caricatures of ear features. The tests showed that while the method proved to be robust to significant input variations, repeatability issues may arise. Specifically, the method is repeatable when used by the same surgeon, but with small variations in the manually inserted points, given the surgeons' personal view of the anatomy, the procedure can lead to significantly different results yet still hold its validity on all three criteria. As a consequence, although intraobserver repeatability is not achievable, using the proposed method, different users have the possibility to obtain effective surgical guides although slightly different according to the vision of each surgeon. Future developments foresee the automation of the modelling process starting from the proposed method and the realization of a user interface able to simplify the identification of fixed points.

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