

# A 3D printed patient specific artificial outer ear model for use in auricle reconstruction surgery: A clinical feasibility study

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*Abstract: Auricle reconstruction is a routine surgery in the field of Otolaryngology but the design of the reconstruction is based on the clinicians guess of the correct previous anatomy. Using additive manufacturing processes to build a model the surgeon can refer to may be a good substitute for conventional surgery. The quality of the framework replicating the three-dimensional architecture of the ear and precise sculpting of the anatomical structures are necessary in order to reach a desired outcome. In this work we present the workflow to produce an individualized 3D outer ear model for use in auricle reconstruction surgery and report on the clinical application of this model in a particular patient reconstruction surgery.*

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## I. Introduction

A common congenital malformation is the so-called microtia, i.e., the presence of an underdeveloped external ear, which occurs approximately in 1:6,000 (~0.03%) births in the general population [1]. The malformation can affect size, orientation, shape, and position of the external ear [2] that can degenerate towards the total absence of the ear auricle. Total auricular reconstruction is the best treatment for congenital microtia till now [3] and autologous costal cartilage has proven to be the most reliable technique for establishing an ear framework [2].

But the creation of an anatomically accurate framework is a difficult process considering the complexity of the geometry to be reproduced [2]. To date the most common approach for microtia repair is by creating a two-dimensional (2D) tracing or image of the unaffected ear and using this as a model to approximate a three-dimensional (3D) construct from the 2D illustration; a process that is imprecise and difficult [4, 5].

3D printing has dramatically improved the fabrication of scaffolds for the ear in need of reconstruction. Some studies have already presented a 3D cartilage model by molding cartilage and pouring it [6] or 3D printing of a model using Fused Deposition Modelling [2]. But the literature about the ear reconstruction in a clinical setting using 3D printing is rare and above all none of the studies have described a method that can be applied one day prior to the surgery.

We propose the development and design of an ideal custom-made 3D ear model for use in auricular reconstruction surgery and describe the 3D printing method used in our institution.

## II. Material and methods

### II.I. Creation of a 3D outer ear model

One day prior to the auricular reconstruction surgery a magnetic resonance imaging (MRI) was performed to capture the anatomy of the region of interest (ROI), i.e. the unaffected ear (Fig. 1a+b). The acquired data were saved as images slices in the DICOM (digital imaging and communications in medicine) format and the ROI was segmented manually using 3D Slicer™ version 4.11 (<http://www.slicer.org>) to build a 3D reconstruction of the unaffected ear. The segmentation resulted in the isolation of the ROI through a semi-automatic process based on region thresholding, hole filling and edge smoothing (Fig. 1c). Subsequently, the digital model was mirrored to create a model of the affected side and exported as STL (standard tessellation language) file (Fig. 1d) prior to being 3D printed.

### II.II. 3D printing of the 3D outer ear model

The STL file was loaded into the Perfactory RP software (EnvisionTEC GmbH) and was sliced into 320 µm slices (80% of the needle diameter, detailed below). The resulting file was transferred to the main software of the 3D-Bioplotter, VisualMachines, where the model was assigned an infill comprising 1 mm fiber spacing and a 90° layer-to-layer rotation, and a single contour outline. The patient-specific auricle model was 3D printed using a 3D-Bioplotter® Manufacturers Series (EnvisionTEC, GmbH, Gladbeck, Germany), equipped with a low temperature printing head operated by pneumatic pressures of 5 bar and an UV Curing Head (365 nm) (Fig. 1e). Medical grade EnvisionTEC UV silicone 60A MG was loaded into the low temperature head attached with a 400 µm dispensing needle

tip (Nordson Australia Pty Ltd) and printed at 27°C at a movement speed of 2 mm/s.

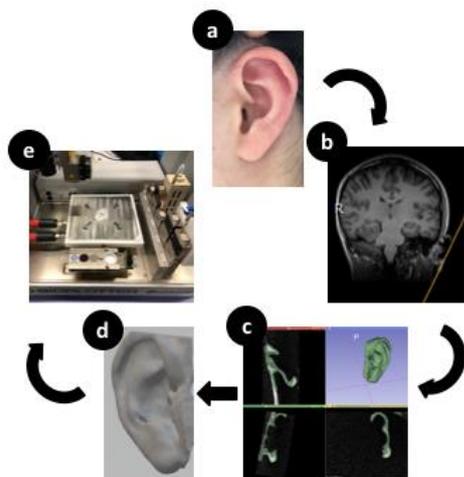


Figure 1: Workflow to produce three-dimensional ear model: (a) image of the unaffected left ear (b) magnetic resonance imaging of the unaffected ear; (c) 3D reconstruction; (d) mirroring of the ear; (e) 3D printing of the model

### II.III. Sterilization of the 3D outer ear model

The 3D printed ear model was irradiated using UV-light ( $1800 \times 100 \mu\text{J}/\text{cm}^2$ ) from both sides for 30 minutes in an UV-Crosslinker (SpectroLinker XL-1000; Spectroline, Westbury, USA) for sterilization and subsequently transferred in autoclaved/sterile pouches (Self Seal Sterilization Pouch, 134 x 280 mm, Henry Schein Inc., Melville, USA).

### III. Results

On the day of surgery, the sterilized, patient-specific 3D model was brought to the operating room to be utilized for the ear sculpting. The sterilized model was used to harvest the costochondral graft (Fig. 2) and subsequently placed alongside costal cartilage grafts where it could be held, turned and studied by the surgeon as a reference for cutting and modelling and allowed for more accurate anatomic measurements (Fig 3a+b).

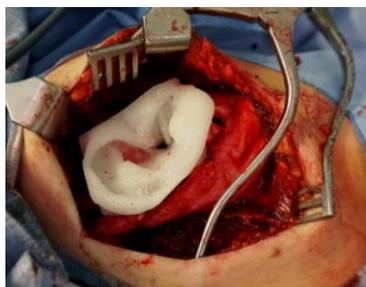


Figure 2: placement of the 3D ear model (white) on the costal cartilage to inform the surgeon on the needed size and shape of the costochondral graft

### IV. Conclusions

The here presented workflow of imaging – reconstruction – printing – sterilization – and clinical application proves the feasibility of the patient-specific 3D auricular model to be used in a clinical set up. 3D printing technology can overcome the limitations of previous auricular reconstruc-

tion methods [7] thanks to the ability to obtain the complex patient-specific ear shapes for the use as models.



Figure 3: a) 3D ear model used by the surgeon as a reference (right) for cutting and modelling of the costal cartilage graft (left)

We defined a workflow process for 3D printing of a customized auricular model which can be applied on the day before the planned surgery and we are convinced that this technique of 3D printing customized models for use as intraoperative references is very promising for future reconstruction surgeries.

Future directions to current ear reconstructions are scaffold fabrication, tissue engineered auricles of autologous chondrogenic cells, and 3D bioprinting of complex patient-specific auricles by depositing biomaterials layer-by-layer in a controllable manner [2, 8]. However all these techniques are at this stage far from being used in common clinical implementations.

#### AUTHOR'S STATEMENT

Authors state no conflict of interest. Informed consent has been obtained from the patient included in this study. The research related to human use complies with all the relevant national regulations, was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional ethical committee.

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