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Temporal bone phantom for decoupled cochlear implant electrode insertion force measurement

https://doi.org/10.1515/cdbme-2023-1033

Abstract:

In research on cochlear implants, preclinical testing of newly developed electrode arrays and surgical tools is an essential procedure, which requires the availability of a suitable testing environment. For this purpose, human temporal bone specimens are most realistic, but their availability is limited and additional parameters such as insertion forces are hardly measurable. Therefore, the aim of this study was to develop a temporal bone phantom with realistic anatomical structures for intracochlear force measurement.

The temporal bone was segmented from CBCT data of a human cadaver head. The segmented model was 3D printed with an additional artificial skin layer to enable the simulated use of surgical instruments such as a self-retaining retractor. A mechanically decoupled artificial cochlear model was realistically positioned within the temporal bone and was furthermore attached to a force sensor. The usability of the phantom was evaluated by performing automated EA insertions using an automated hydraulic insertion device.

The experiments showed that the insertion forces within the cochlea could be measured without interferences from surrounding structures. Moreover, the artificial skin provided a rigid interface for the insertion tool. The new phantom is a realistic testing and training platform for cochlear implant electrode insertions with the advantage of measureable insertion forces.

Keywords: artificial cochlear model, temporal bone, surgical training, automated electrode insertion, 3D printing

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1 Introduction

Over the last decade, research on cochlear implants (CI) enabled numerous new technologies such as robotic tools for the automated insertion of the electrode array (EA) into the cochlea or minimally invasive surgical approaches [1]. Moreover, parts of the cochlear implant itself are constantly advanced, e.g. EA design parameters [1, 2]. However, prior to transfer to clinical application, extensive testing of new developments is essential to ensure a safe usage for patients and surgeons. In this context, it is important that a realistic test environment is available in order to obtain meaningful preclinical results.

The most realistic test environments are human cadaver heads or temporal bone specimens, which are limited in availability and require extensive regulatory procedures. Therefore, several studies have proposed artificial, 3D printed temporal bones for surgical CI training, mostly focussing on training surgeons to manually drill the access to the cochlea [3–7].

Apart from surgical training, other test setups are needed to objectively determine evaluation parameters. One common safety parameter for new technical developments in CI surgery is the force exerted by the EA onto the cochlea during the insertion process. It has been shown that higher insertion forces increase the likelihood of intracochlear trauma and thus the probability of residual hearing loss [8, 9]. In order to determine and validate these forces, several studies suggested different kinds of insertion force test setups [8, 10–13]. Typically, these setups include an artificial cochlear model (ACM) or a cochlea specimen, which is attached to a force sensor to measure the insertion forces. In most cases, however, these test setups neglect the anatomical structures around the cochlea, e.g. the posterior tympanotomy and the mastoid cavity, resulting in incomplete testing conditions.
Therefore, the aim of this study was the development of a new temporal bone phantom, which allows for the measurement of intracochlear insertion forces while also providing an

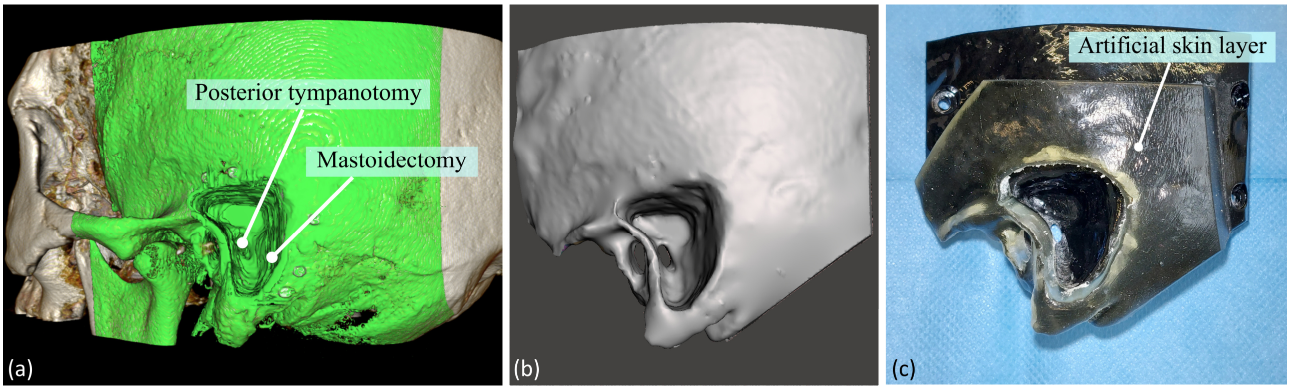

Figure 1: From CBCT temporal bone data to 3D printed model: **(a)** Segmentation in InVesalius; **(b)** Post-processing in Meshmixer; **(c)** 3D printed temporal bone including artificial skin layer.

anatomically realistic structure. Unlike other 3D printed temporal bones, the new phantom was designed to include an artificial skin layer to attach surgical instruments such as self-retaining retractors.

2 Material and Methods

The development of the new temporal bone phantom was structured in three parts. First, realistic anatomical structures were segmented and post-processed from a human temporal bone data set. Afterwards, a test setup including an artificial cochlear model (ACM) and a force sensor was designed around the temporal bone and subsequently manufactured. The finalized phantom was evaluated by performing automated EA insertions using an automated insertion device.

2.1 Temporal bone segmentation, post processing and manufacturing

The basis of the segmentation was a cone beam computed tomography (CBCT) dataset of the left side of a human cadaver head, which was previously used for surgical training of cochlear implant surgery. Therefore, it provided a mastoidectomy and a posterior tympanotomy. An initial automated segmentation of the bone structure was conducted in *InVesalius* [14] (Fig. 1a), an open source software featuring 3D rendering and segmentation of medical data sets. Due to the pneumatized bone structure, the area of the mastoidectomy required further manual segmentation for a clearer definition of the bony border areas. After segmentation, a 3D model of the segmented bone was exported as an STL-file. Post-processing of the 3D model was performed in *Meshmixer* (*Autodesk, San Rafael, USA*) and included smoothing of the bony surfaces, filling of cavities and removal of unnecessary bone structures, e.g. parts of the jawbone (Fig. 1b). Further post-processing was necessary in order to create an artificial skin layer for the phantom. For this reason, the outer bone surface surrounding the mastoidectomy was extracted from the 3D file and subsequently extruded. The artificial skin layer thus created was re-attached to the 3D structure of the bony surface using a computer aided design (CAD) software (*Autodesk Inventor Professional 2023, Autodesk, San Rafael, USA*). We chose an artificial skin thickness of 15 mm to provide a sufficient contact surface between the skin and the surgical instrument and to avoid tearing of the skin due to the clamping force. The temporal bone with the skin layer was 3D printed using a PolyJet 3D printer (*Objet 350 Connex3, Stratasys, Eden Prairie, USA*), which enables the printing of a single object from different materials (Fig. 1c). The bony structure was printed from hard, solid material (*Vero Black, Stratasys*) while the skin layer was printed from a soft silicone-like substance (*Agilus30, Stratasys*).

To assure realistic positioning of the cochlear model within the temporal bone structure, the CBCT data was used to plan a straight trajectory passing through the posterior tympanotomy and the round window while being as tangential as possible towards the centreline of the scala tympani within the basal turn of the cochlea (Fig. 2). In addition to the orientation of the trajectory, two points were defined, one as the entrance into the cochlea at the round window and the other to define the curling direction of the cochlea.

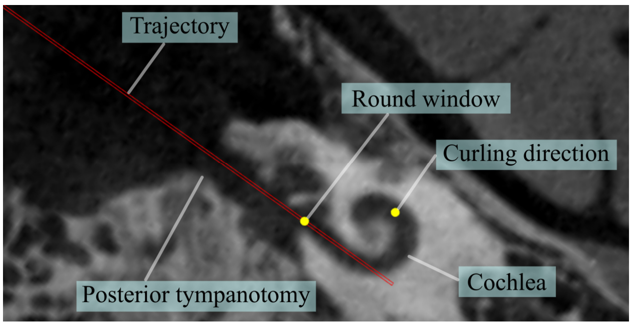

Figure 2: Planned trajectory with planning points to enable precise alignment of the temporal bone towards an artificial cochlea model within the phantom.

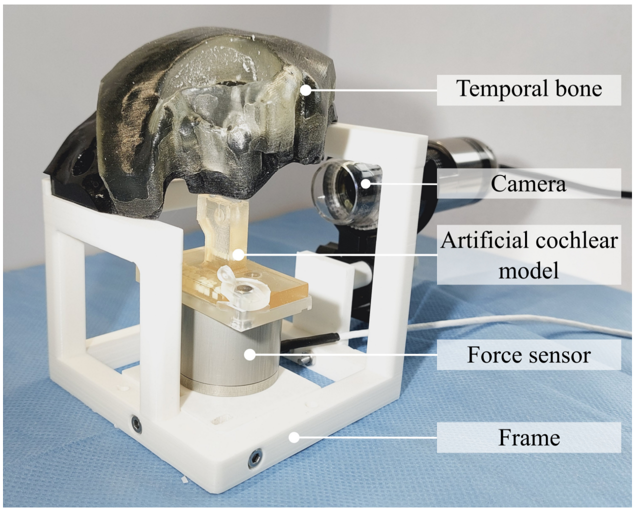

Figure 3: Assembled temporal bone phantom with its components.

2.2 Phantom design

The remaining phantom was designed using CAD software. First, a 3D printed artificial cochlear model (ACM) representing the scala tympani lumen was registered towards the temporal bone. This was done using the previously planned trajectory and planning points from the CBCT-scan which were also defined in the data of the ACM. The components were separated by a small gap that ensures mechanical decoupling of the ACM and the temporal bone to allow the measurement of intracochlear forces without measuring contact forces from the surrounding structures. The ACM was attached to a 3D force sensor (*K3D35, ME Messsysteme GmbH, Hennigsdorf, Germany*) using an interface, which enables the exchange of the ACM and therefore the use of different cochlea geometries within the setup. A frame structure connects the force sensor and the temporal bone to assure the correct positioning of the ACM along the trajectory. Furthermore, the frame includes an additional interface for a microscope camera (*Dino-Lite, AnMo Electronics Corp, Sanchung City, Taiwan*), which is oriented orthogonally towards the cochlear model to allow video documentation of the EA insertion process. The frame was manufactured using a fuse deposit modelling 3D printer (*Ultimaker S3, Ultimaker, Utrecht, Netherlands*). The whole phantom setup is shown in Figure 3.

2.3 Experimental evaluation

For a proof of concept study we performed three automated EA insertions with a hydraulic insertion tool – the Cochlea Hydrodrive (CHD) [15]. The CHD was attached to the phantom in the same way it would be fixed to a real patient using a surgical self-retaining retractor and a flexible arm. A FLEX28 electrode array (*MED-EL, Innsbruck, Austria*) was inserted into the ACM with a velocity of 0.1 mm/s. For better friction properties, the ACM was lubricated using 10% soap solution. The whole setup is shown in Figure 4a.

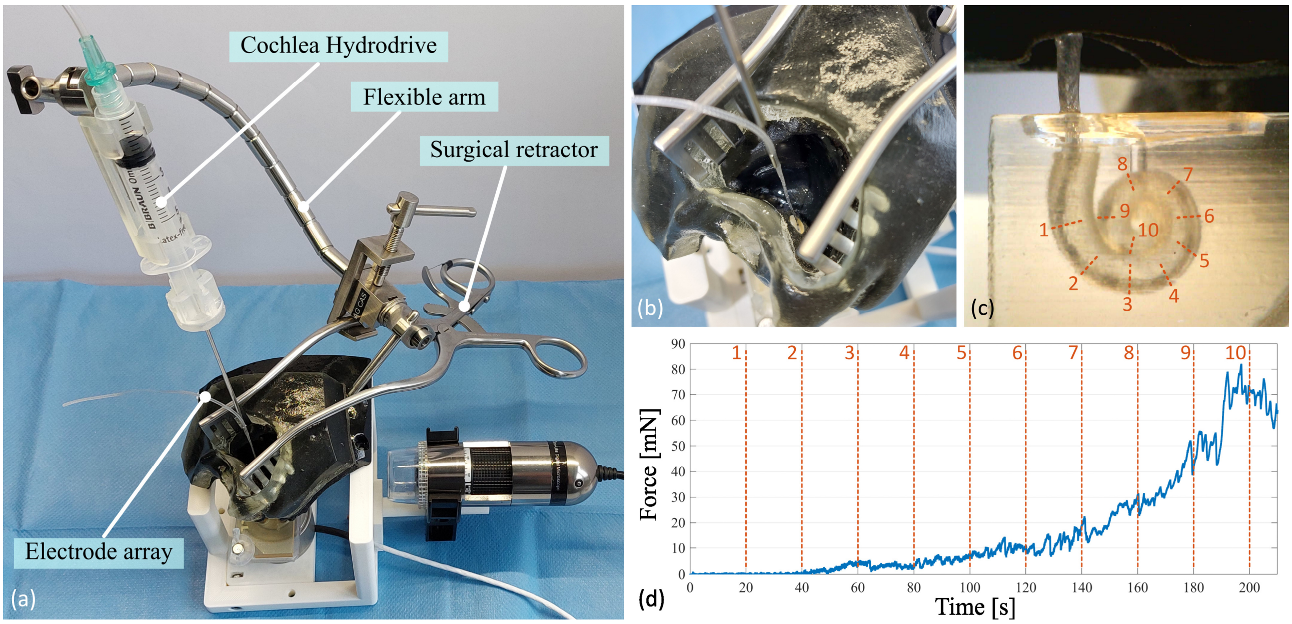

Figure 4: Experimental evaluation: **(a)** Attachment of the Cochlea Hydrodrive to the phantom using a surgical retractor; **(b)** Close up of the aligned insertion tool; **(c)** Picture taken from the microscope camera showing the inserted electrode array; The marked positions show the location of the electrode tip every 20 seconds during the insertion process **(d)** Representative force profile of an electrode insertion into the cochlear model of the phantom using the Cochlea Hydrodrive with corresponding markers of the electrode tip.

3 Results

The assembly of the individual components could be completed as planned, ensuring a gap between the ACM and the temporal bone. The 3D printed phantom showed good adhesion between the bony structure and the artificial skin. Therefore, a firm attachment of the surgical retractor to the skin was possible providing stable fixation of the CHD with respect to the round window (Fig. 4b). A complete insertion of the EA into the ACM was achieved in all trials. Besides the force profiles, the insertion process could be tracked and recorded in real-time due to the additional camera (Fig. 4c). The measured forces showed the typical exponential course of insertion tests in ACMs [10] (Fig. 5d).

4 Discussion

The proposed temporal bone phantom is an anatomically realistic testing platform that allows decoupled insertion force measurement. The setup is characterized by high flexibility, as different force sensors and ACMs, i.e. cochlear geometries, can be used due to the modular design. In contrast to a comparable approach described in [13] our phantom features the surgically relevant skin for tool attachment as well as intracochlear insertion process recording. Evaluation of the insertion forces showed typical profiles indicating that the mechanical decoupling serves its purpose and reduces the amount of force interferences to a negligibly small value. This allows future investigations of how external factors, such as EA fixation, EA lead management or different insertion techniques, affect the intracochlear forces or EA location and thus influence the risk of intracochlear trauma.

Further improvements of the phantom could be considered e.g. an integrated implant bed for the cochlear implant processor. Additionally, the phantom could be advanced by adding another force sensor to specifically measure the external forces at the temporal bone structure. This would enable a more detailed investigation of the relation between intracochlear and extracochlear forces measured in a typical insertion. In summary, the newly developed phantom poses an important step towards a deeper understanding of the impact of external factors on the intracochlear forces and can be used to answer a variety of current research questions.

Author Statement

Acknowledgements: We would like to thank Max Fröhlich from MED-EL for providing the electrode array used in this study. *Research funding:* The presented work was funded in part by the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) under Germany's Excellence Strategy – EXC 2177/1 – Project ID 390895286 and in part by MED-EL. *Conflict of interest:* Authors state no conflict of interest. *Informed consent:* Informed consent is not applicable. *Ethical approval:* Ethical committee approval was not required.

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