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### Fabrication of Human Anatomy-Based Scala Tympani Models with a Hydrophilic Coating for Cochlear Implant Insertion Experiments

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PII: S0378-5955(21)00039-3  
DOI: <https://doi.org/10.1016/j.heares.2021.108205>  
Reference: HEARES 108205



To appear in: *Hearing Research*

Received date: 20 November 2020  
Revised date: 7 January 2021  
Accepted date: 6 February 2021

Please cite this article as: Philipp Aebischer, Marco Caversaccio, Wilhelm Wimmer, Fabrication of Human Anatomy-Based Scala Tympani Models with a Hydrophilic Coating for Cochlear Implant Insertion Experiments, *Hearing Research* (2021), doi: <https://doi.org/10.1016/j.heares.2021.108205>

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## Highlights

- A fabrication process for patient-specific artificial scala tympani models is described.
- Intracochlear frictional properties are reproduced by an easily applied polymer brush coating.
- Measurements of insertion forces of cochlear implant electrode arrays show a very good agreement with measurements on cadaver specimens.
- The model enables large scale cochlear implant electrode array evaluation studies and insertion experiments.

# Fabrication of Patient-Specific Human Anatomy-Based Scala Tympani Models with a Hydrophilic Coating for Cochlear Implant Insertion Experiments

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November 2020

## Abstract

Electrode array insertion into the inner ear is a critical step in cochlear implantation, and artificial scala tympani models can be a valuable tool for studying the dynamics of this process.

This technical note describes the fabrication of electrode array dummies and patient-specific scala tympani models that address shortcomings of previously published cochlear models. In particular, we improve the reproduction of frictional properties with an easy-to-apply polymer brush coating that creates hydrophilic surfaces, and produce geometries with accurate macro-anatomy based on microtomographic scans. The presented methods rely only on commonly available materials and tools and are based on publicly available data.

Our validation shows very good agreement of insertion forces both in terms of linear insertion depth and insertion speed compared to previously published measurements of insertions in cadaveric temporal bones.

*Keywords:* cochlear implant, artificial scala tympani, electrode array dummy

impair both electrical and acoustic hearing and limit the qualification for future therapies [21, 6].

Although artificial scala tympani models represent a simplification of the complex anatomy of the inner ear, they can play an important role as a supplementary tool in addition to investigations on cadaver specimens [1, 24]. In contrast to the latter, they offer, for example, the possibility of performing a large number of insertions under repeatable conditions and direct visual observation of the movement of the electrode array.

Artificial models are usually made of a transparent plastic material to provide visibility of the inner lumen. Nguyen *et al.* used a resin cast of a coiled catheter to evaluate an electrode array insertion tool [18]. Leon *et al.* proposed a parametrically generated scala tympani model for insertion experiments [16], which was fabricated by a stereolithographic process and was later used by Kaufmann *et al.* to evaluate an electrode array insertion tool [8]. Hügl *et al.* used a planar polytetrafluoroethylene model to measure the dependence of insertion speeds on insertion forces [7].

## 1 Introduction

Since Lehnhardt's initial work in 1993 defining the soft surgery protocol for cochlear implantation [15], many studies have explored the effects of electrode array insertion into the cochlea. It is obvious that intracochlear trauma should be minimized, as it can

## 2 Rationale

Although high-resolution tomographic images of the inner ear are available, conventional models approximate average cochlear shapes and have a circular or rectangular cross-section along the lateral wall.

In addition, the frictional properties are often not explicitly controlled, but are a result of the

applied materials and the manufacturing process. As both contacting materials are usually hydrophobic, fluid squeeze-out between the interface leads to a coefficient of friction with a large speed-dependency [17]. This is very different from the contact between the electrode array and the endosteal lining and spiral ligament covering the lateral wall of the scala tympani and may explain the high insertion forces and shallow insertion depths observed in many artificial scala tympani models [19, 22, 12, 7].

In this technical note, we present a technique for creating patient-specific artificial scala tympani models. The models are based on open access data and. The Models can be produced with commonly available tools and materials. Furthermore, we describe the fabrication of dummy electrode arrays that can be used in insertion experiments. Our manufacturing method addresses shortcomings of previous models by creating geometries directly based on microtomographic scans of the scala tympani and by using an easy-to-apply polymer brush coating for an improved reproduction of intracochlear frictional properties.

### 3 Methods

In short, the artificial scala tympani models were produced by casting a 3D-printed acrylonitrile butadiene styrene (ABS) negative of a scala tympani in epoxy resin and subsequently dissolving the sacrificial blank in acetone. Photographs of the production process and final model are shown in Figure 2.

The electrode array dummies are based on the construction of dummy electrodes for research purposes proposed by Kobler *et al.* [10]. The dummies were produced by casting reinforcing steel wires into silicone rubber, which was colored black for visual purposes. Four snapshots of different steps inserting a dummy electrode array into a scala tympani model are shown in Figure 4 (left).

#### 3.1 Electrode Array Dummies

Electrode array dummies for testing purposes have been suggested previously by Kobler *et al.* [10] and

Hügl *et al.* [7]. The arrays presented herein are based on these suggestions. For a more refined control of the deformation under load, the design was adapted to contain a larger number of stiffening wires of gradual length. The arrays consist of 17 steel wires (grade 316L, diameter 40  $\mu\text{m}$ ) with gradual lengths embedded in silicone rubber (room-temperature-vulcanizing Elastosil Vario 40 (Shore A)).

The wire count and lengths were determined empirically. The dummy arrays were constructed to match the bending stiffness and plastic deformation in the basal and apical portion of a long free-fitting electrode array (Flex<sup>28</sup>, Med-El GmbH, Innsbruck, Austria). This specific lateral wall electrode array was chosen because it is the most implanted electrode array at our institution and is long enough to evaluate deep insertions. For this purpose, a series of dummies with varying count and length distribution of stiffening wires was fabricated. The flexural stiffness was compared by supporting the arrays at the base and measuring the deflection and curvature with weights attached to basal or apical locations, respectively. This process was iteratively repeated to determine a wire configuration matching the flexural stiffness of the clinical array. The deflection under apical load is shown in the bottom row of Figure 1.

Single-use molds were produced by embedding a steel blank with the target shape of the electrode array in hot-melt adhesive and withdrawing the blank. Ease Release 205 (Mann Release Technologies, Inc., Macungie, USA) was applied to the blank as release agent. The one-piece molds provide high surface fidelity, are quickly produced and assure dummies without flash caused by leakage at the seam of composite molds. The embedded steel wires were twisted and pre-coated with silicone rubber to prevent direct contact with the outer surface of the electrode array. After curing, the wires were inserted into the mold which was filled with the same silicone rubber. After complete curing, the mold was destructively opened to reveal the array dummy. An overview of all important production steps is provided in Figure 1.

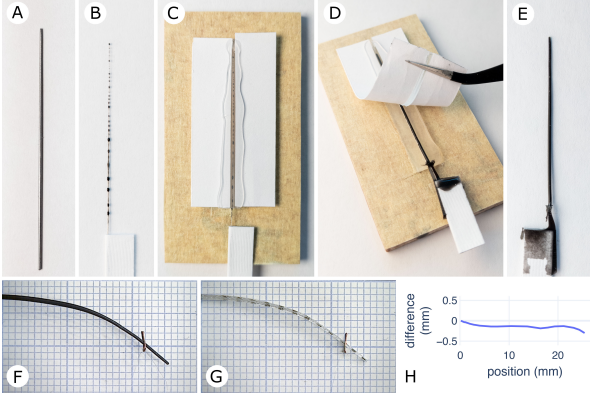


Figure 1: A: Steel blank with electrode dimensions for casting of the mold. B: Twisted stiffening wires, coated before insertion. Due to the surface tension of the silicone rubber, spherical nodes form along the wires, preventing direct contact of the wires with the mold surface. C: Single-use mold with inserted stiffening wires. A one-sided silicone release paper is embedded for easier opening of the mold. D: After curing, the mold can be opened to remove the array. E: Final array. F-G: Evaluation of the bending stiffness of the dummy and clinical array. H: Difference of the deflection as a function of the position along the electrode arrays.

### 3.2 Scala Tympani Geometries

As the cochlea is highly variable in shape and size [3], we produced six different models with different geometries. The geometries were taken from two publicly available data sets of cadaveric temporal bones [5, 20]<sup>1</sup>. These provide 3D meshes of the segmented scala tympani. The meshes were imported into a computer-aided design application (Fusion 360, Autodesk Inc., San Rafael, USA) and oriented according to the local cochlear coordinate system as proposed by Verbist *et al.* [23], with the modiolus defining the vertical z-axis and the x-axis passing through the round window. The models were trimmed to the first two full turns and extended with a 1 mm canal parallel to the modiolar axis for coupling a pressure

<sup>1</sup>SICAS repository, surface extracted from x-ray  $\mu$ CT [5], specimens *AS1-80591*, *AS1-80593* and *DS1-29503* and Open-Ear library, extracted from cone-beam computed tomography and micro-slicing [20], specimens *Gamma*, *Eta* and *Zeta*

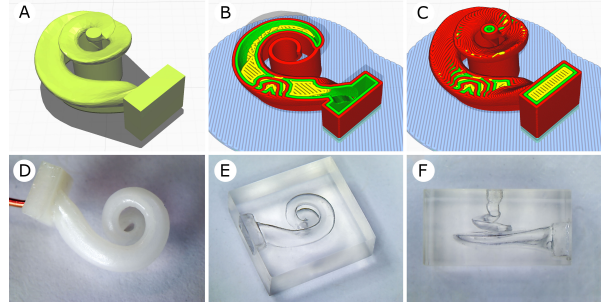


Figure 2: A: 3D model surface (left) and B-C: print path (center and right). The support structure for overhanging parts is implemented as a single coil-shaped wall. The model is printed without infill. D: Printed blank with support structure removed. E-F: Final model.

sensor. Basally, the models feature a cuboid extension at the location of the round window. This enables to attach an artificial promontorium or round window membrane to the final model.

The ABS negatives were printed on a fused deposit modelling printer (Ender 3 Pro, Creality 3D Technology Co. Ltd, Shenzhen, China), equipped with a 0.2 mm nozzle, at 40  $\mu$ m layer height.

Several steps were taken to optimize the resulting printing quality. The models were printed without infill material, avoiding reducing the need for travel moves of the print head. This also facilitates dissolving the material afterwards.

Due to the ascending shape of the cochlea, horizontal layers are crescent-shaped and support structures for printing overhangs are only needed at the uppermost point. For this purpose, a 0.2 mm spiral wall was integrated directly into the model, and automatically generated support structures were deactivated in the slicing program (Cura 4.4, Ultimaker B.V., Utrecht, Netherlands). This wall is obtained by projecting the lowest point (in z-direction) at each position along the scala tympani into the basal plane and extruding a spiral support structure along this line. The wall can be removed with a sharp knife after printing. The 3D-model and the generated print paths are shown in Figure 2 (upper row).

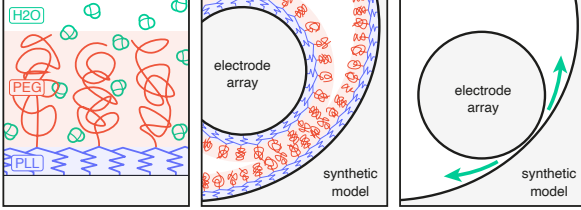


Figure 3: Left: Schematic of the polymer brush coating: PLL backbones (blue) act as anchoring units for hydrophilic PEG sidechains (red). Center: A thin fluid interface separates the hydrophobic surfaces of the electrode and scala tympani, mimicking the contact with the endosteum lining (not to scale). Right: Without a coating, the liquid is squeezed out, affecting frictional properties.

### 3.3 Epoxy Cast

After removing the support structure, the models were manually sanded to remove steps between the printing layers and smoothed by dipping in an acetone bath. To compensate for the thickness of a polyurethane clear coat on the final lumen, the blanks were coated with a sacrificial layer of the same varnish (RUCO Einkomponentenlack DD (Rupf & Co. AG, Glattbrugg, Switzerland) diluted with 15% RUCO Verzögerer V-23). To apply this layer, the blanks were dipped into the varnish, and excess liquid removed with compressed air. While curing, the blanks were regularly rotated to prevent varnish runs. ~~before embedding them~~ Afterwards, the blanks were embedded in clear epoxy resin (R&G Epoxyharz L with hardener GL-2). The outer walls of the model were polished and the ABS negative and the varnish coating was leached in acetone, revealing exposing the internal lumen. ~~which was subsequently coated with the polyurethane clear coat~~ Finally, the models were coated with the polyurethane clear coat by completely filling them, removing excess varnish again with compressed air and rotating the blanks while curing to ensure a uniform coating.

### 3.4 Polymer Brush Coating

The scala tympani model and electrode dummies were coated with a hydrophilic polymer brush, mimicking the interface between the electrode array and biological tissue inside the inner ear. A drawing illustrating the working principle of the coating is shown in Figure 3.

The coating is applied by submerging the material in a solution of 0.25 mg/mL poly(L-lysine)-graft-poly(ethylene glycol) (PLL(20)-g[3.5]-PEG(5), Nanosoft Polymers, Winston-Salem, USA) and 6 M potassium hydroxide (KOH) in deionized water. PLL-g-PEG adsorbs onto hydrophobic non-polar surfaces from aqueous solution, where lysine monomers on the PLL backbone play a role as an anchoring unit [14]. The PEG sidechains grafted onto the PLL backbone have high affinity for water and generate a brush-like conformation that prevents direct contact of the tribological pairs [13]. Before initial use, the scala tympani models and electrode dummies were submerged in the solution for 24 h, then rinsed with deionized water.

### 3.5 Friction coefficient

Kha and Chen determined the frictional conditions in cochlear implant electrode insertion by measuring the load difference between both ends of an array wrapped around a cylinder covered by a thin endosteum lining, at which sliding starts to occur. The case of the lateral side of the contour array (this side has no exposed contacts) without lubrication corresponds best to the electrodes used herein and suggest a coefficient of friction of  $\mu = 0.12$  [9]. The same experiment was repeated with an epoxy cylinder of the same construction and coating as the scala tympani models and with electrode dummies as described above. ~~In our case, a~~ A soap concentration of 10 % (Wetrol Gastronet, Wetrol AG in deionized water) reproduced ~~their~~ the targeted friction coefficient.

## 4 Results

Electrode array dummies were inserted using a motorized tool to validate the proposed models. The

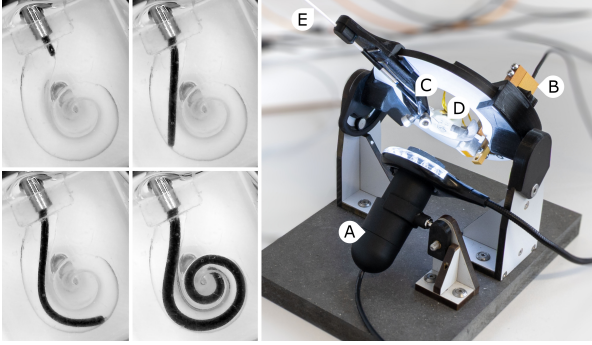


Figure 4: The setup for performing motorized insertions (right) and photomicrographs throughout the introduction process (left). The setup includes a microscope (A) and a load cell (B), which records the resulting forces in the direction of insertion. The electrode dummies are loaded into a guide tube (C) and pushed into the artificial model (D) with a bowden cable attached (E) to a linear actuator (not depicted).

tool includes a linear actuator that pushes the electrode dummies out of a guide tube. The scala tympani model is mounted on a load cell which records the forces along the insertion axis (accuracy 0.5 mN). The complete setup is shown in Figure 4.

A total of 138 insertions with 18 electrode array dummies showed good repeatability. The difference of maximal insertion forces to the average values for each of the six models have a standard deviation of 4.8 mN.

For a comparison to published data, the dummies were inserted into the model based on *AS1-80593* from the SICAS repository [5]. With a basal length of 9.2 mm, this cochlea corresponds to an average size [4] and also showed average insertion forces compared to the other produced models. Figure 5 (left) compares the measurements to forces recorded by Leon *et al.* in two cadaveric insertions. Our model shows good agreement with their data.

Figure 5 (right) shows the work done in the insertion, obtained from integration of the forces as a function of the linear insertion depth. Repeated insertions do not significantly affect the measurement results, confirming that no significant degradation of the applied surface coating occurs.

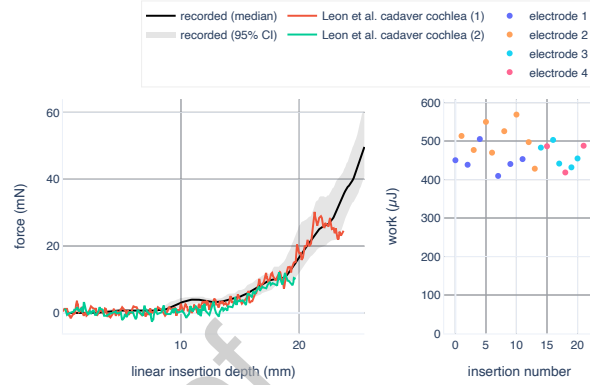


Figure 5: Force measurements as function of linear feed for 21 insertions (4 electrode dummies) at a feed rate of 0.33 mm/s. Left: Comparison shows very good agreement to force measurements into two cadaveric specimen published by Leon *et al.* [16]. Right: Insertion work of each insertion into the model indicates constant frictional conditions.

Several studies were conducted on the effect of insertion speed in artificial cochlear models, with inconsistent results [25, 11, 2, 7]. These studies did not verify whether the models reproduce the speed dependence of intracochlear frictional properties. Kaufmann *et al.* [8] investigated manual and motorized insertions into both a synthetic model and cadaver specimens. Increased forces were observed with very slow insertions into the 3D-printed model, while insertions into cadavers followed a reciprocal trend. We hypothesize that squeeze-out of the liquid between the electrode array and the hydrophobic model surface could be a contributing factor to these conflicting findings.

Figure 6 shows the maximum insertion forces for different insertion speeds into our model and compares them to the aforementioned measurements published by Kaufmann *et al.* [8]. Our model is consistent with these insertions into cadaver samples, indicating that the proposed surface coating reproduces intracochlear frictional properties. It should be noted that this source aggregates measurements from arrays from different manufacturers, and the flexible arrays used herein are expected to be at the lower limit end

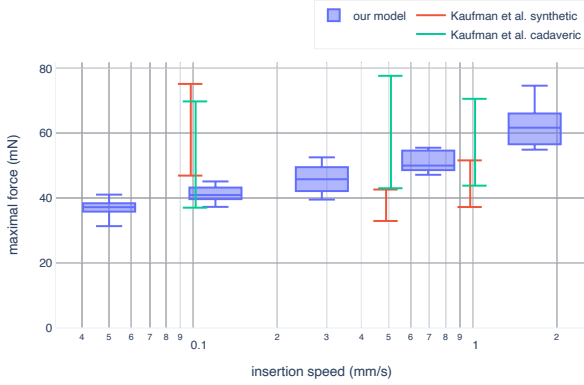


Figure 6: Maximal insertion forces for different constant insertion speeds compared to values published by Kaufmann *et al.* [8]. Speed dependency in our model shows very good agreement with the cadaveric samples. Note that [8] aggregates measurements of different electrode arrays and the flexible arrays used herein can be expected to be at the lower limit of these forces.

of the recorded forces. In contrast, the forces in the uncoated artificial model increase at very slow speeds, an effect that could be explained by s

A limitation of the presented verification is that a relatively low number of force measurements is available for insertions in cadaveric specimen, and that the geometries of the artificial models is not based on the specific temporal bones, as this data is not available.

## 5 Conclusion

We present a method for producing artificial scala tympani models with accurate macro-anatomy and an easy-to-use polymer brush coating to better mimic the frictional properties of intracochlear tissue. The models can be produced with commonly available tools and materials and are based on freely accessible data.

Furthermore, we present a process for the production of electrode array dummies. The described models are suitable for insertion tests of cochlear implant electrode arrays and allow deep insertion. They may

be used for the development of new electrode designs, the validation of surgical techniques and the evaluation of insertion tools.

Most importantly, our approach enables to create hydrophilic properties on synthetic cochlear models. Our tests show excellent good agreement with published measurements of insertion forces in cadaver specimens, both in terms of force development as a function of insertion depth and as a function of speed. We therefore believe that hydrophilic coatings and patient-specific human anatomy-based model geometries have the potential to become the standard protocol for future electrode array insertion experiments and electrode array evaluation studies.

## 6 Acknowledgment

Funding: This work was supported by the J&K Wonderland foundation and the Emperor foundation.

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