Artificial Cochlea Model Material Validation for Insertion Force Measurements

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Rationale

One of the standard procedures for developing and characterizing cochlear implant electrodes is the measurement of insertion forces, as they are assumed to be correlated with trauma.

Although human cadaveric cochlea specimens are the most realistic models of the patient's cochlear geometry and friction conditions, in order to produce a reproducible test setup an artificial cochlea model (ACM) is often used. Typically, these ACMs are made of an easy to process and smooth material, like polytetrafluoroethylene (PTFE), and combined with various lubricants in the insertion force measurements.

Until now the question has not been addressed of how well PTFE represents the conditions inside the real cochlea. As the friction conditions inside a living cochlea are currently not easily measurable this is a comparison study between temporal bones and ACMs. The use of fresh never frozen temporal bones is the best easily available approach. Porcine specimen are used, because the porcine cochlea is similarly proportioned to the human, provides straightforward surgical access and is readily available.

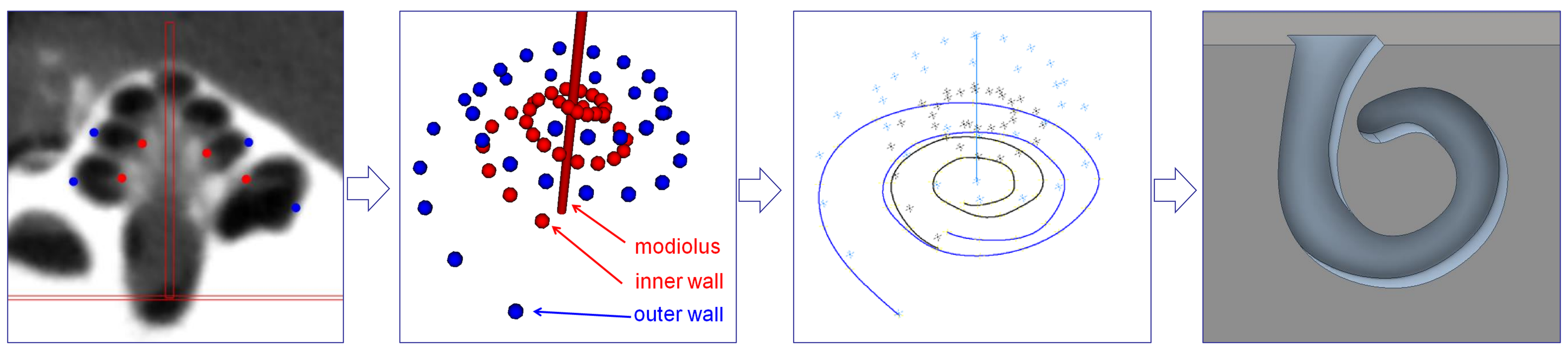
The insertion forces measured in fresh cochlea specimens and in PTFE ACMs of matching cochlear geometry are compared using different lubricants.

Methods

Fresh, never frozen porcine temporal bones were cut down to a small piece and fixed on a sample holder, the specimen were kept wet with saline solution during the whole process.

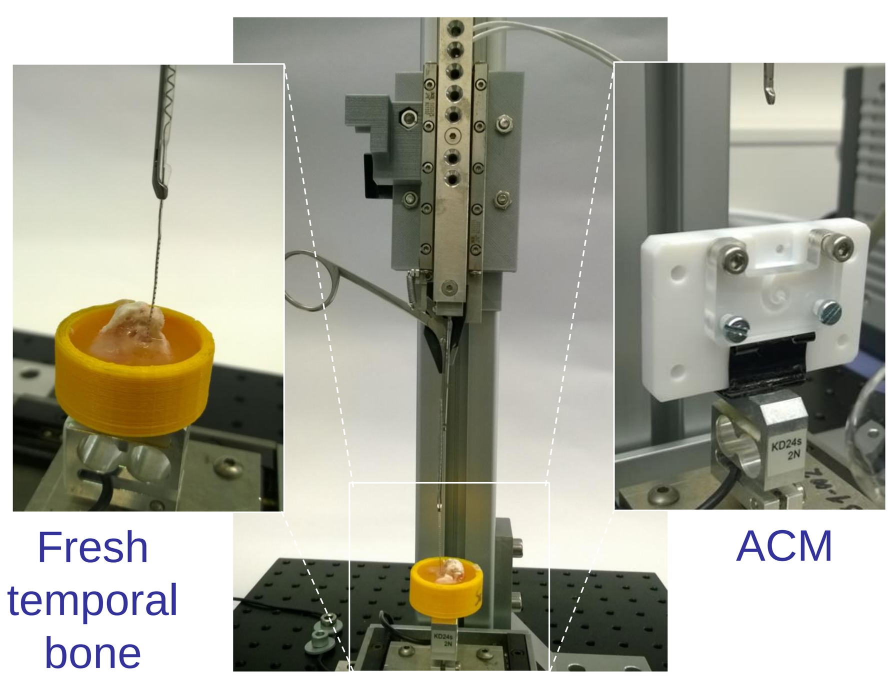
Two-dimensional ACMs matching the size and shape of the porcine cochlea were built based on CBCT scans, according to the following method:

- Cone-beam computed tomography (CBCT, Accuitomo, Morita, voxel size 0.08 mm) imaging was performed
- The shape of the inner and outer wall of scala tympani were segmented in steps of 22.5° around the modiolus using an in-house developed software, segmentation on the basal part was done with a smaller step size
- Inner and outer walls projected onto a plane perpendicular to the modiolar axis and 2D projected contours further processed using computer-aided design (CAD) software (Autodesk Inventor Professional 2017)
- The cochlea is modelled as a volume with 1.5 mm thickness and milled out of a PTFE plate using a computer numerically controlled (CNC) milling machine
- For use in the insertion force experiments the models are covered by a PTFE sheet supported by an acrylic glass disk and filled with the lubricant



Non-functional Cochlear Slim Straight electrodes were inserted to a depth of 15 to 17 mm into the porcine specimen and the ACMs:

- The insertion was done automated by a linear positioner with a speed of 0.5 mm/s (repeated up to 3 times in the porcine specimen and 6 times in the ACMs)
- Different lubricants were used in the PTFE model: (1) artificial perilymph, (2) saline solution, (3) saline solution and additional Healon on the electrode, (4) Healon on the electrode in air, and (5) soap solution (10% soap)

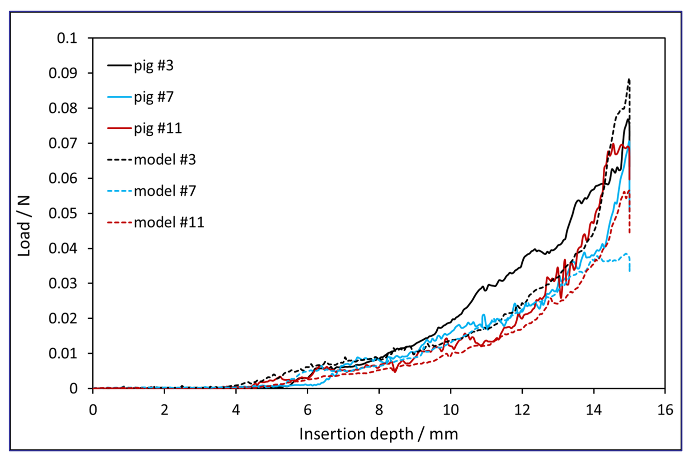


CBCT was done with the electrode still inserted for some of the porcine specimens.

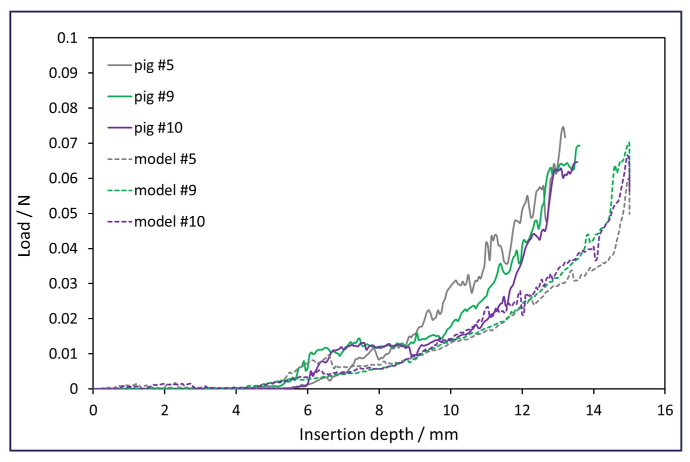
Results and Discussion

A good correlation a) was found between the insertion forces measured in porcine specimen and in the corresponding ACMs in one half of the sets when saline solution was used as a lubricant. However, in the other half a poorer correlation b) of the insertion forces in the porcine specimen and in the corresponding ACMs was found:

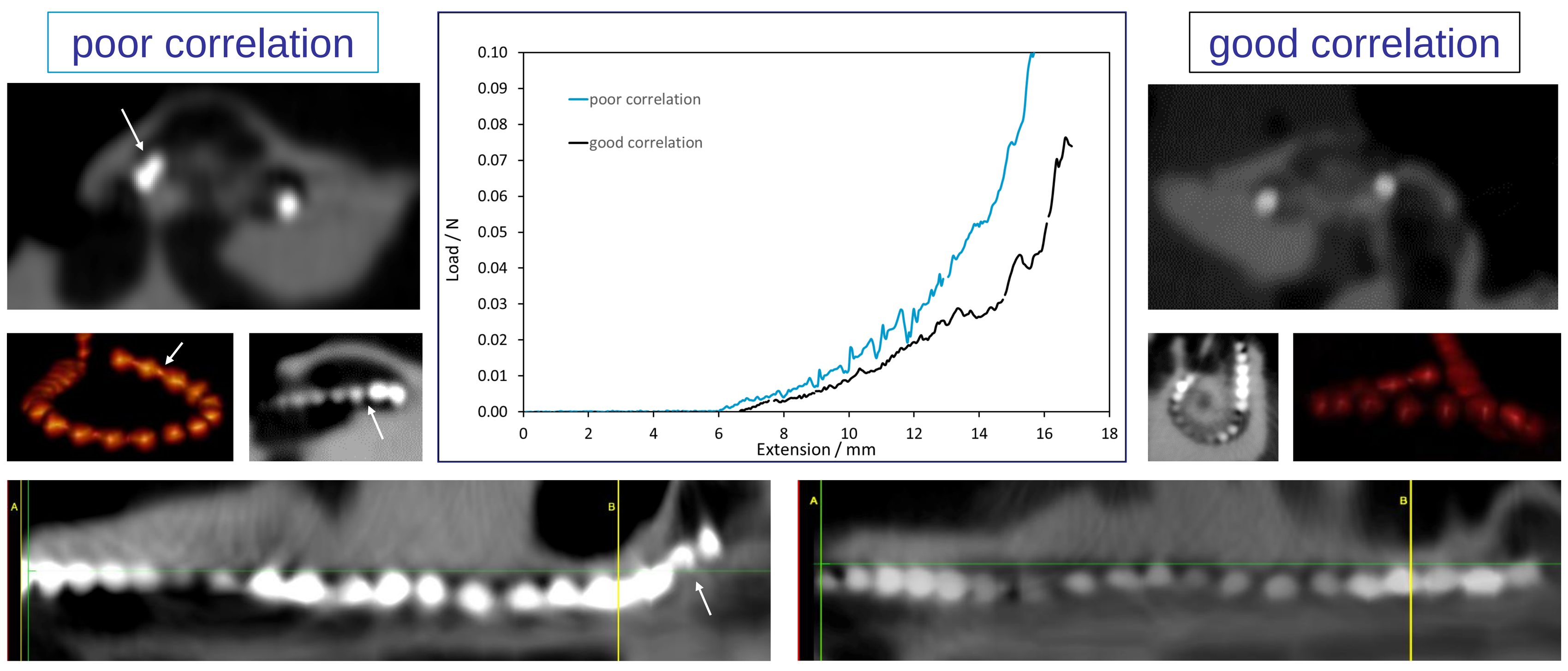
a)



b)

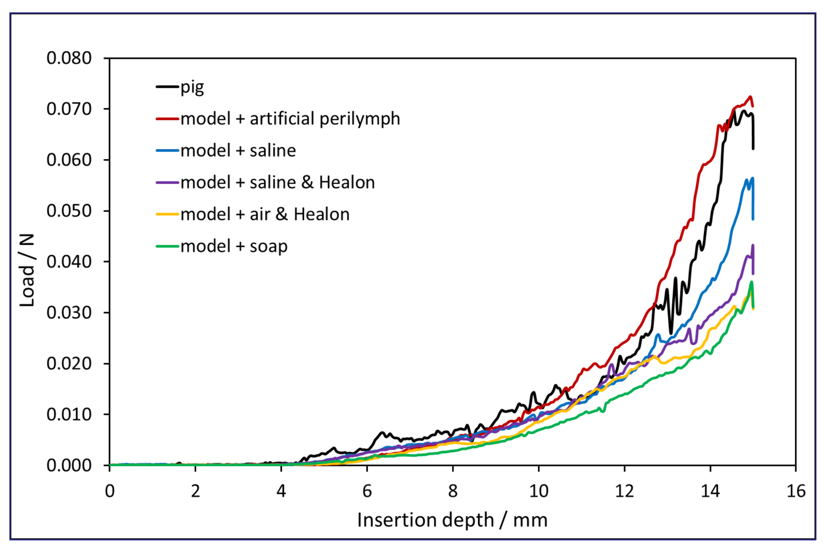


In case of the poor correlations, the force curves always have a steeper slope, resulting in the same forces as the good correlation ones and the PTFE model, but at shallower insertion depth. To explore whether dislocation or anatomical malformations in the porcine temporal bones could be the reason for this discrepancy, another set of insertions was conducted: single insertions with force measurements and following CBCT scans with the electrode inside were done in ten additional porcine specimens, two examples are shown below:



In the CBCT scan of the specimen showing the steeper slope (representing the poor correlation) on the left side a scala translocation in the end and some displacement in the basal part of the cochlea was observed (white arrows). In contrast in the specimen with the good correlation, right side, the electrode is placed nicely in the cochlea. This is an indication that the mismatch in the insertion force is induced by geometrical factors which led to misplacement and scala dislocations. A reason for these dislocations could be that the electrodes used in this study are made for humans and not for pigs.

Furthermore various lubricants were tested in the ACMs. The insertion forces measured with the artificial perilymph are matching the forces of the porcine best. Saline solution inside the model gives a similar, but a bit lower insertion force compared to the porcine specimen. With Healon added onto the electrode the insertion force is lower, independent of the presence of saline solution in the model. When using soap solution the force decrease even more.



Conclusion

In this work the combination of a two-dimensional artificial cochlea model made out of PTFE filled with artificial perilymph could be identified as a good representation for the friction conditions inside the real cochlea. For the most cases a biologically more realistic environment is not necessary and saline solution is a reasonably good match. This is of course not an exact reproduction of the real friction conditions, but similar enough to draw conclusions from insertion force measurements. With this combination, PTFE and saline solution, reproducible test setups for insertion force measurements can be made.

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