On the development of electrode arrays that change their intracochlear position: Does the incorporation of nitinol shape memory wires hamper a slow insertion speed?

M. Geraldine Zuniga, Tim Ehmann, Thomas Lenarz, Thomas S. Rau

Department of Otolaryngology, and Cluster of Excellence EXC 2177/1 “Hearing4all”, Hannover Medical School, Hannover, Germany.

Objective

To perform insertions of experimental shape memory electrode arrays (SMEA) into a cochlea model placed in a temperature-controlled medium.

Introduction

The idea of developing an electrode array (EA) that is initially straight in its configuration and that later adopts an intracochlear perimodiolar position has been previously explored using a thin wire made of Nitinol, a shape memory alloy. This material allows for temperature-induced shape changes. Provided recent work has described a method to temporary cool down the cochlea [1, 2] to facilitate temperature shifts, the future transfer of the shape memory effect in the field of cochlear implants (CI) appears more feasible.

Previously, our research group ruled out the possibility of increased trauma that could result from the stiffness added by the incorporation of such a Nitinol wire to a standard EA [3].

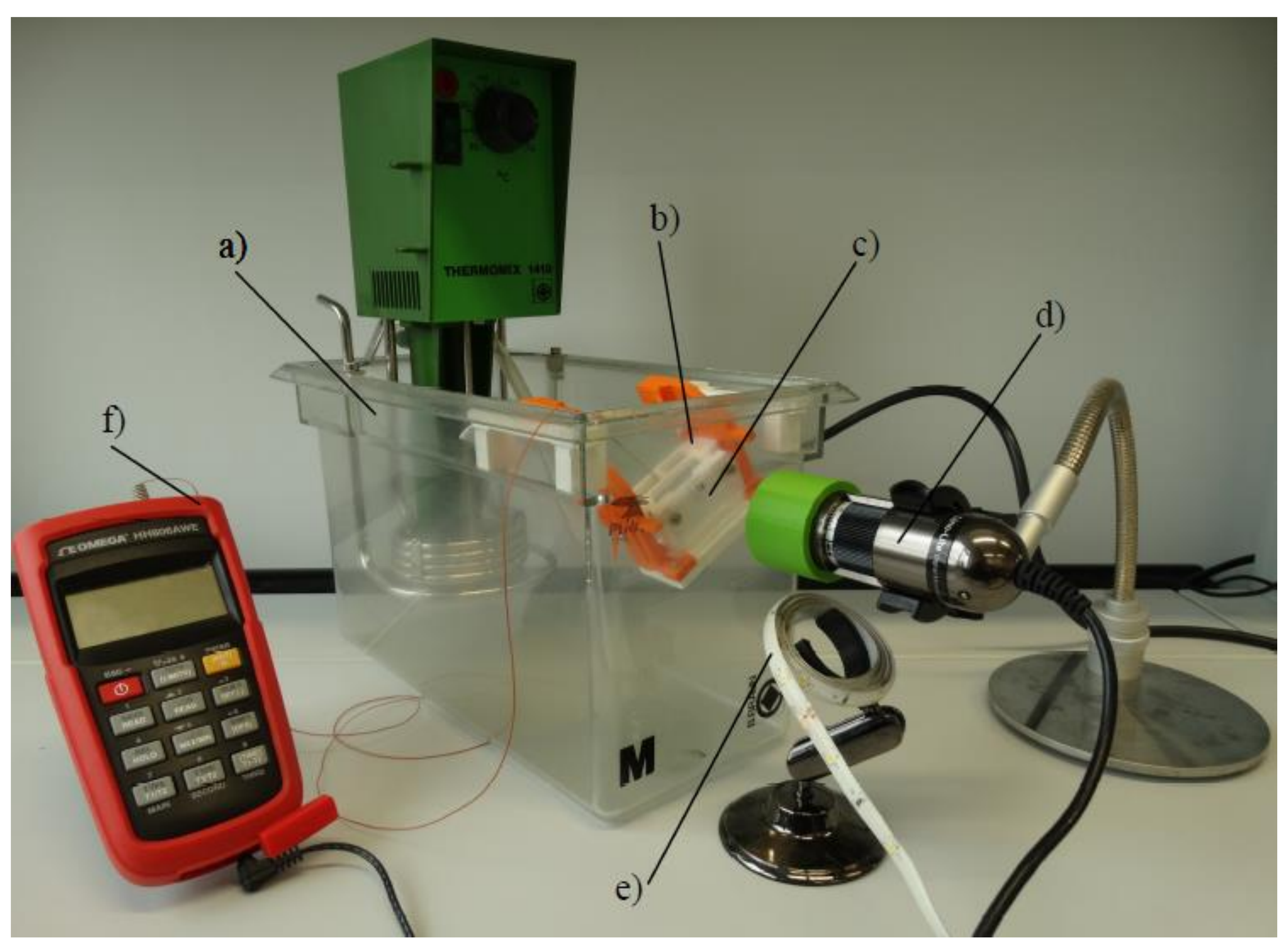

Figure 1: Test setup. a) water container with adjustable temperature, b) model holder, c) artificial scala tympani model, d) video camera, e) light source, f) multimeter

However, it remains to be better elucidated how stable the initial straight configuration is once such an experimental shape memory electrode array (SMEA) enters an environment cooled down from body temperature. This study sought to perform insertions of SMEAs into a cochlea model placed in a temperature-controlled medium.

Methods

SMEA samples (n = 2) were constructed using a shape-memory alloy wire made of Nitinol placed into a silicon sheath that has comparable stiffness properties to other EAs. The SMEA samples were used for insertions into an artificial scala tympani model (Figure 1, c).

The artificial scala tympani model was submerged into water at 31°C, which represents the initial temporary cold scenario. A CI surgeon aimed to insert the SMEA slow- and gently, as in a hearing preservation surgery. The insertion was video recorded and the average insertion speed was then calculated for each trial (Figure 2). Once an insertion was completed the water was heated up to 37°C in order to simulate the restoration or recovery of body temperature.

The shift in final position of the SMEA (from lateral/outer wall to inner wall of the model) was observed 15 minutes after the insertion.

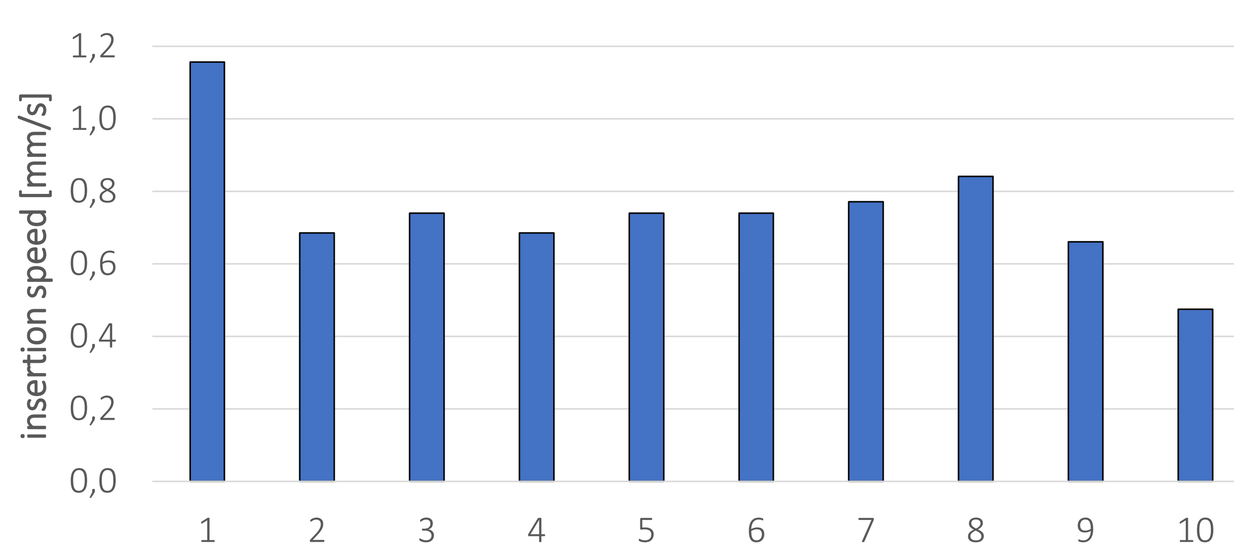

Figure 2: Average insertion speeds of the 10 SMEA insertion trails.

Results

A total of 10 SMEA insertion trials were successfully completed at an average insertion speed of 0.75 mm/s (SD 0.16 mm/s). The used temperature-control provided enough stability of the material that prevented premature shape changes in the SMEA.

All 10 insertions revealed a position shift from lateral to inner wall of the artificial scala tympani model 15 minutes after the insertion, as a response to the temperature shift (Figure 4).

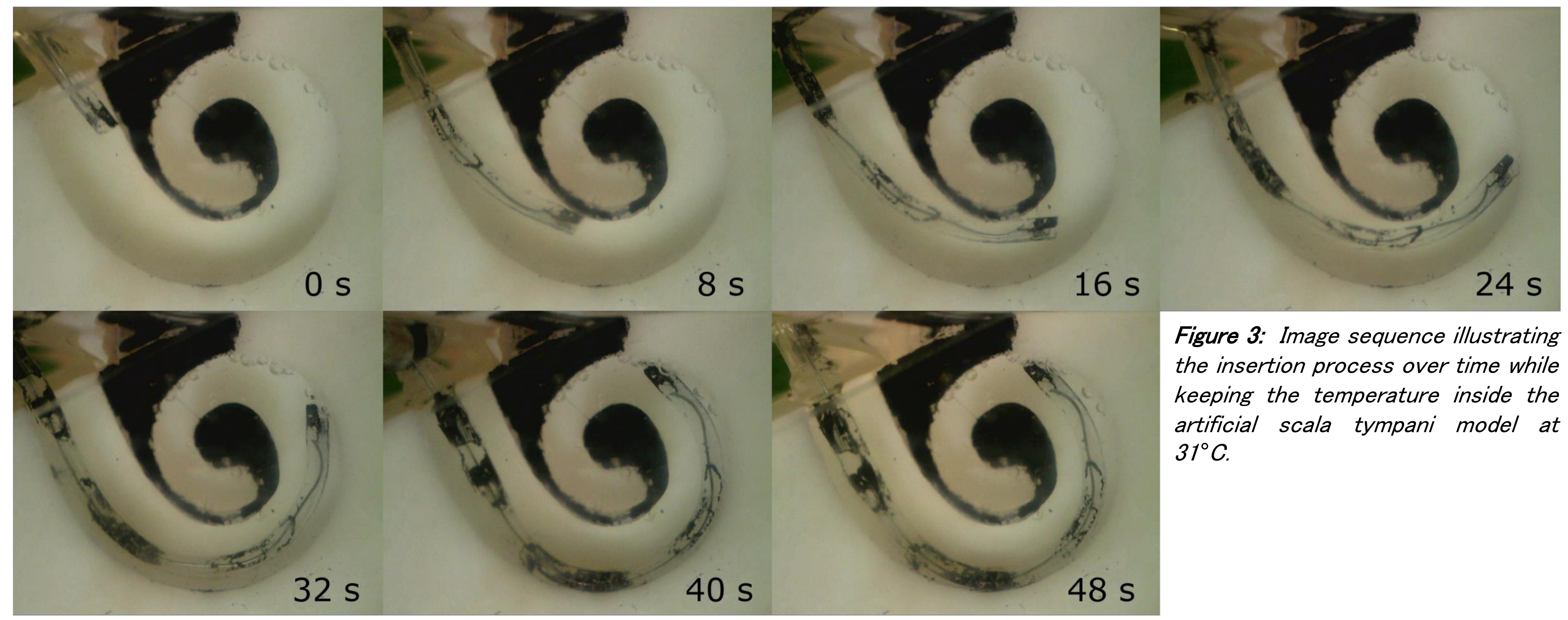

Figure 3: Image sequence illustrating the insertion process over time while keeping the temperature inside the artificial scala tympani model at 31°C.

Figure 4: Position changes by the shape memory effect following completion of the insertion (left) up to a temperature of 37°C (right).

Conclusion

In a 31°C water medium the experimental SMEA allowed insertions at a speed of 0.75 mm/s. This is comparable to EA insertion speeds reported in the literature in the context hearing preservation CI surgery. Our results indicate that in this initial *cold scenario* with the used temperature-control method the potential change in shape of the SMEA does not rush the surgeon during the insertion process. Further experiments exploring different *cold scenarios (i.e. not so cold temperatures)* are needed.

Contact

Rau.Thomas@mh-hannover.de

www.vianna.de/ags/cas

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References

[1] Perez et al. 2019 Otol. Neurotol., 40 (9), 1167–1177. [2] Tamames et al. 2018 Ear Hear., 39 (4), 712–719. [3] Rau et al. 2016 Eur. Arch. Oto-Rhino-Laryngology, 273 (11), 3573–3585.

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