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HearRestore RTD 2013

FNSNF

Clinical Integration of Nerve-monitoring for Robotic Cochlear Implantation

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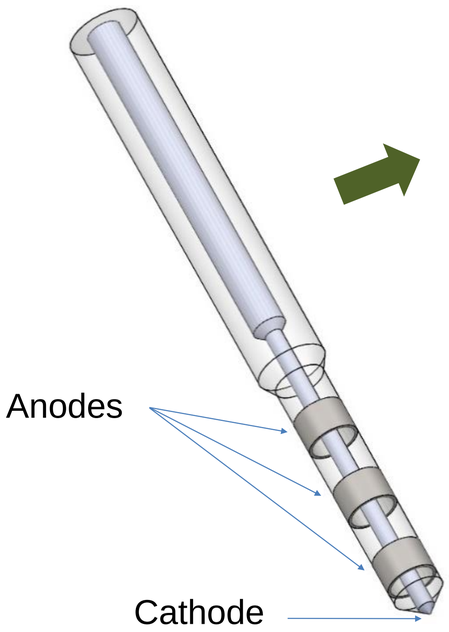
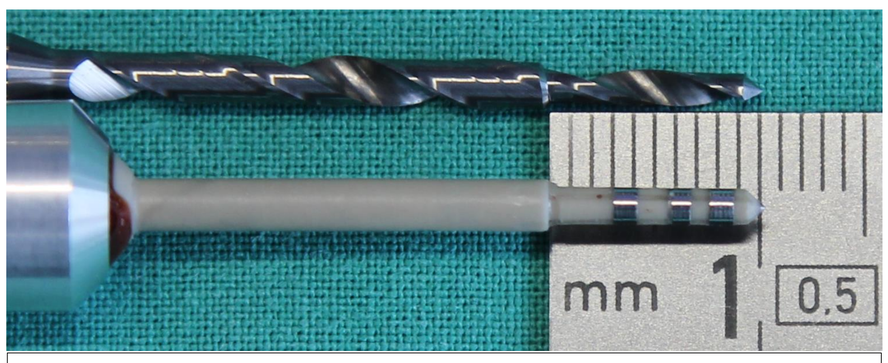
Introduction

In robotic cochlear implantation (CI) an access tunnel to the inner ear (cochlea) at a distance below 1 mm from the facial nerve (FN) is drilled [1]. This approach requires safety mechanisms to prevent injury of the facial nerve in case of system malfunction. Available electromyography (EMG) based neuromonitoring (NM) was reported to lack the necessary sensitivity and specificity of FN detection to be used during robotic CI. Recently, a NM approach for facial nerve preservation was proposed and verified in an in-vivo animal study [2]. Herein, clinical integration of the new NM method for validation during a 1st in man robotic CI study is presented.

Electrode design for highly specific facial nerve monitoring

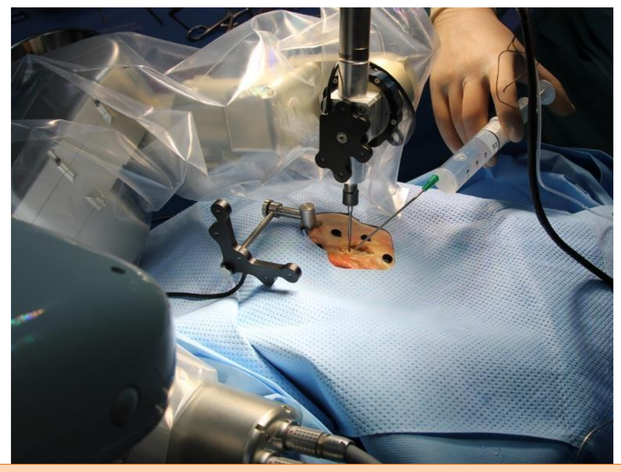




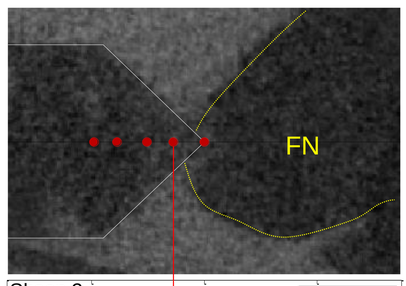
Stimulating probe

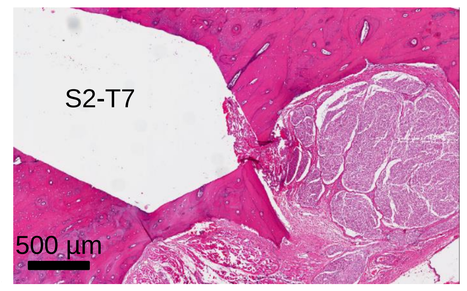
- Same geometry as cochlear implantation drill
- Shorter cathode-anode distance → higher specificity

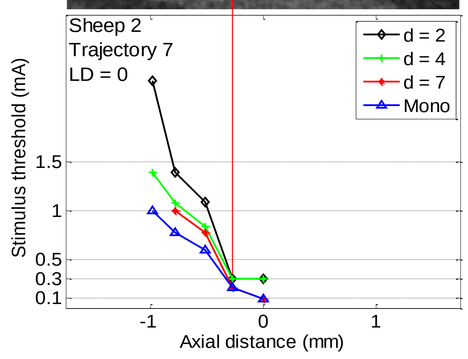
- Cathode at the tip
- 3 anodes at distances d= 2, 4 and 7 mm (from tip)
- Larger anode distance → greater field penetration depth

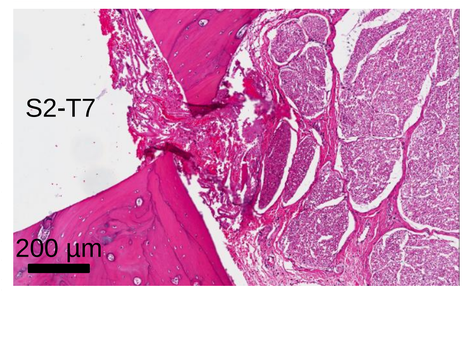


Research in-vivo animal study

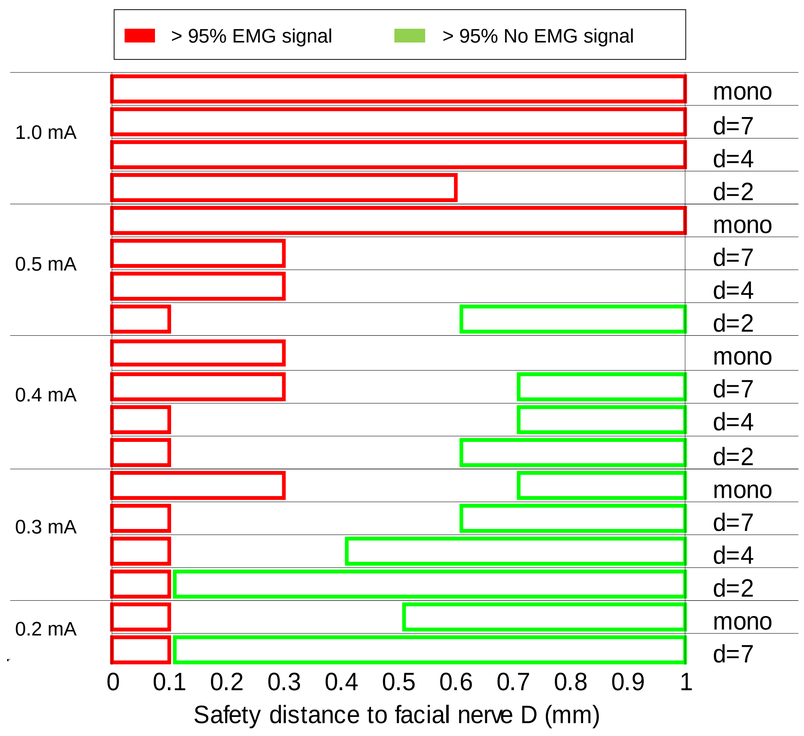








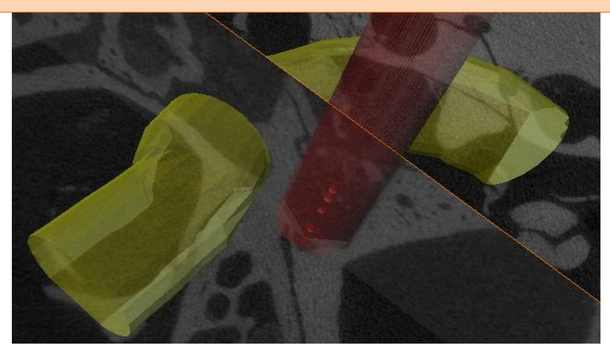
- Micrometer EMG to facial nerve distance analysis
- Histopathological evaluation of FN damage
- Development of a binary safety system

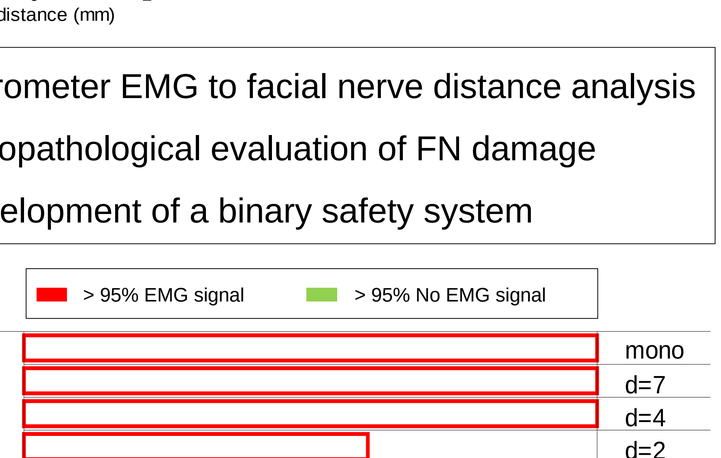


Clinical validation

Problem statement

- Robotic cochlear implantation
- Facial nerve at 0.2 to 1 mm distance from drill
- Robotic system enables high accuracy (<0.2 mm)
- Facial nerve safety required to enable clinical use





On going clinical validation

- OR testing of robotic and NM systems
- Optimization of NM probe design and App
- Patient recruiting for 1st robotic CI has started

Technology transfer

- Industrial partners (CAScination & Inomed)
- Integration of probe into clinical grade hardware
- Development of software App for 1st in man study

Conclusion & outlook

- The NM probe and approach has been successfully integrated into a medical grade NM system and will be validated during a 1st in man robotic CI study
- An investigation is underway for integration of stimulating electrodes in the drill
- Tissue impedance sensing is being investigated for redundant drilling safety

References

[1] B. Bell, N. Gerber, T. Williamson, et al. 2013, “In Vitro Accuracy Evaluation of Image-Guided Robot System for Direct Cochlear Access.” *Otology & Neurotology*, vol. *34*

[2] J. Ansó, C. Dür, K. Gavaghan, etal. 2016, “A Neuromonitoring Approach to Facial Nerve Preservation During Image-guided Robotic Cochlear Implantation,” Otol. Neurotol., vol. 37