Neuromonitoring during Robotic Cochlear Implantation: first clinical experience

J. Ansó[1], O. Scheidegger[2], C. Dür[3], W. Wimmer[1-3], K. Gavaghan[1], M. Caversaccio[3], S. Weber[1]

[1] ARTORG Center for Biomedical Engineering, University of Bern, Bern, Switzerland, juan.anso@artorg.unibe.ch

[2] Department of Neurology, Inselspital, University of Bern, Bern, Switzerland

[3]Department of ENT Surgery, Inselspital, University of Bern, Bern, Switzerland

Abstract

The aim of this study was to validate a neuromonitoring approach during a first robotic cochlear implantation clinical trial. It is hypothesized that multipolar neuromonitoring stimulus thresholds enable safe versus unsafe trajectory-to-nerve submillimeter distance assessment (95% confidence). In a total of n = 6 patients, after preoperative planning of a trajectory with sufficient distance to the facial nerve (> 0.4 mm), intraoperative robotic drilling was carried out following patient-to-preoperative image registration. Upon reaching the facial nerve (< 1.2 mm), a total of m = 5 neuromonitoring measurement points were assessed by direct stimulation using a multipolar probe inserted in drilled tunnel and recording elicited electromyogram signals. The neuromonitoring approach determined safe drilling distances (> 0.4 mm) in all cases based on a 0.3 mA stimulus threshold criteria (monophasic pulses, duration = 250 µs). Postoperative drill-to-facial nerve distance assessment confirmed final drilled-tunnel-to facial nerve distances above 0.5 mm in all cases. The proposed neuromonitoring approach aided the surgeon in determining intraoperative safety distance margins to the facial nerve during robotic cochlear implantation.

1. Introduction

Robotic cochlear implantation (RCI) consists of image-guided and robot-assisted drilling of an access tunnel to the entrance of the cochlea followed by electrode insertion [1]. Because the procedure is performed via stereotactic guidance (Figure 1) and the surgeon does not have direct visual control of the critical anatomy, structures such as the facial nerve are at risk (Figure 2). The approach requires the robot-guided drill to pass at distances below 1mm from the facial nerve and thus safety mechanisms for protecting this critical structure are required. Neuromonitoring is a commonly used tool to help surgeons locate the facial nerve during routine surgical procedures in the lateral skull base (e.g. mastoidectomy and cochlear implantation). During nerve monitoring, stimulation via a probe is used for localizing the course of the facial nerve in the mastoid region [2], [3]. The nerve monitoring system provides a functional signal (typically a stimulus threshold) that correlates with remaining bone thicknesses between the stimulating electrode and the nerve. Using available nerve monitoring systems, the variance in the estimation of facial nerve proximity ranges 0 to 3 mm, ten times higher than the required accuracy to enable robotic cochlear implantation (< 0.3 mm). Thus, conventional nerve monitoring systems are not sensitive and specific enough to enable reproducible facial nerve localization during stereotactic image-guided drilling in the mastoid.

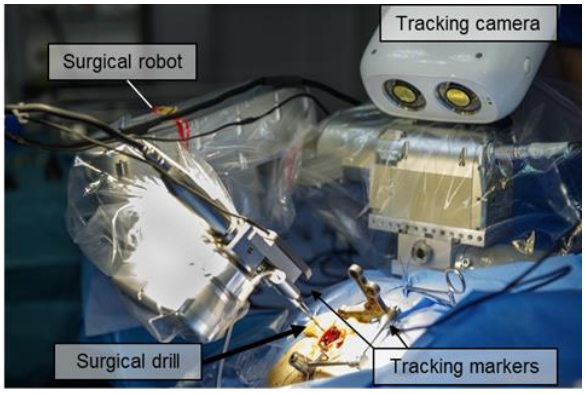

***Figure 1**. First-in-man robotic cochlear implantation trial.*

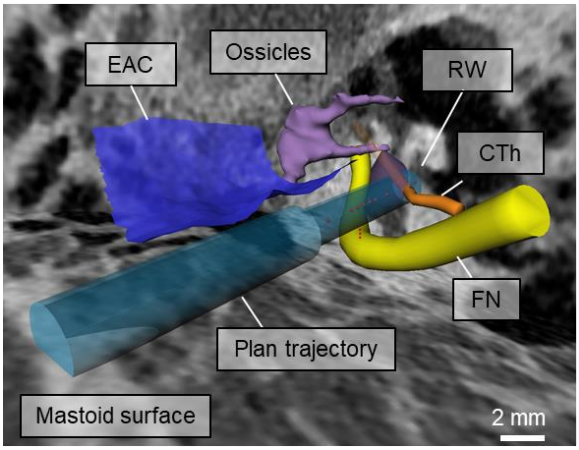

***Figure 2.** Preoperative planning to the entrance of the cochlea.*

Our aim is to develop a safety approach based on electrical nerve stimulation that can be used to warn of an impending collision with the facial nerve during robotic cochlear implantation. To this end, different nerve monitoring systems and protocols have been proposed and developed in the past. First, a monopolar nerve stimulating drill was integrated with an image-guided robotic system and sensitivity and specificity to localize the facial nerve verified in-vivo (sheep model) [4]. It was concluded that the system and approach were not sensitive and specific enough to localize the facial nerve at distances below 2 mm from the drill trajectory. This was primarily due to uncontrolled leakage current through the tunnel achieved by use of uninsulated drill bits as monopolar stimulating electrodes. Consequently, a multipolar image-guided stimulating probe and nerve monitoring approach were developed for use during robotic cochlear implantation, and the sensitivity and specificity to localize the facial

nerve were assessed during in-vivo experiments (n=5 sheep, 29 trajectories). The system enabled sufficient sensitivity (> 99 %) and specificity (> 95 %) to detect imminent collisions with the facial nerve at drill distances below 0.1 mm [5]. Discrimination of drill to facial nerve distances from 0.1 to 0.5 mm remained unspecific (< 95%). We argue that this is mainly due to patient-specific electrical properties of the mastoid, and hypothesize that electrical impedance models integrated in the image-guided nerve monitoring system may aid in reducing this uncertainty range.

Currently, a first-in-man clinical trial investigating robotic cochlear implantation is being carried out at the University Hospital of Bern [6]. Herein this work, the first clinical experiences using integrated neuromonitoring during RCI is presented. It is hypothesized that the NM system enables a sensitive and specific (> 95%) drill-to-FN proximity assessment at submillimeter distances (< 0.5 mm).

2. Materials and methods

By measuring electromyogram signals in the facial muscles induced by electrical stimulation of the facial nerve through a dedicated stimulating probe, the distance of the trajectory to the facial nerve can be estimated to allow the drill path to remain within safe limits. In the worst-case scenario, the procedure can be aborted on the basis of the neuromonitoring data alone, before iatrogenic damage to the facial nerve would be sustained. Independent of all previously described safety mechanisms [7], [8], this system is therefore to be considered the so-called last line of defense. The system is based on a commercial electrical nerve stimulation and monitoring system (ISIS, inomed) and was modified and customized with a multipolar stimulation probe/protocol and proprietary software control system. This resulted in a dedicated RCI EMG system with the following specific functionalities:

1) Sensitivity monitoring of the nerve (i.e., positive control [9]): established through a pair of surface stimulation electrodes located on the superficial branch of the facial nerve (Figure 3). The stimulus threshold values are expected to be in the range of 20 to 50 mA (monophasic pulses, duration = 250 ms) and are dependent on the electrode-electrolyte and skin contact impedance.
2) Functional nerve status is continuously monitored via non electrically triggered EMG (free-running EMG) responses to detect weak anesthesia conditions and potential nerve irritation due to, for example, excessive mechanical pressure or temperature rise [9].
3) During drilling proximal to the facial nerve, the robot automatically evacuates from the drill tunnel, followed by manual insertion of the multi-electrode stimulation probe. Each of the four electrode configurations in the stimulation probe (B1 = C-A1, B2 = C-A2, B3 = C-A3, and monopolar = C-far field needle) (Figure 4) is then subject to an automatic stimulus threshold search. Stimulus threshold values above 1 mA indicate that remaining bone thickness between the drill trajectory and the facial nerve, whereas values below 0.3 mA may indicate facial nerve dehiscence or absence of nerve bone covering. During electrical stimulation of the nerve, the amplitude of an electromyogram-elicited signal is expected to be above 100 µV and is composed of a complex polyphasic muscle action potential response. The stimulus threshold is the minimum intensity of the stimulating pulses that provides an EMG signal above 100 µV. Upon verification of electrode-tissue contact (Z < 20 kohm), a reference scale is consulted to estimate the proximity to the facial nerve and give the system a go/no go command by the surgeon. Given a positive margin, the next drilling segment is executed by Go, and the NM protocol is repeated with a final measurement as the facial nerve is cleared.

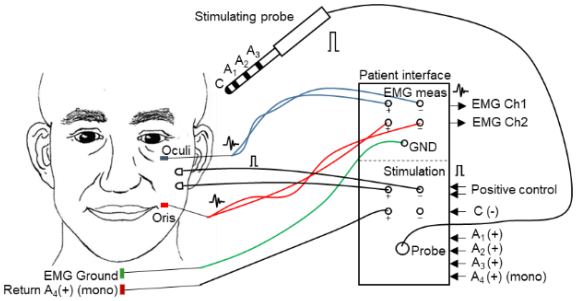

***Figure 3**. Electrode patient interface: EMG electrodes, stimulating probe, and positive control surface electrodes.*

Safe vs. unsafe assessment based on triggered-EMG

Drill-to-FN distance based on NM measurements is determined at five consecutive measurement points equally spaced ($AD = 0.5\ mm$) through the facial recess (Figure 5). The first NM point P_1 is defined 1.2 mm in front of the FN center, and the last NM point P_5 at 0.9 mm passed the FN center. At each point, monophasic stimulating pulses (0.2 to 2.5 mA, 250 µs) are applied per each of the stimulating channels of the probe. The minimum stimulating intensity that elicits an EMG response above threshold (> 100 µV) is defined as stimulus threshold (ST). From previous in-vivo experimental studies [5], the stimulus threshold capable of discriminating *safe* and *unsafe* drill-to-FN proximity ranges below 0.6 mm was 0.3 mA. Consequently, bipolar ($B_{1\text{-}2}$) stimulus thresholds equal or above 0.35 mA are used as indication of sufficient drill-to-FN distance greater than 0.4 mm (*safe passage)*. On the other hand, bipolar stimulus thresholds below 0.35 (B_1) indicate an *unsafe* (< 0.1 mm), or an uncertain ($B_{1\text{-}2}$) drill-to-FN distance margin (0.1- 0.4 mm) (as defined in [1]).

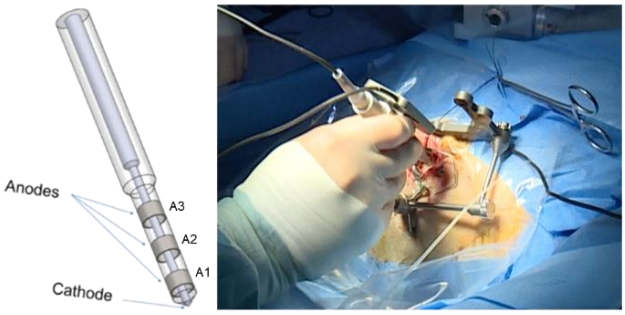

***Figure 4.** Stimulating-navigated probe as being inserted in the tunnel previous to start measurement of the next NM point.*

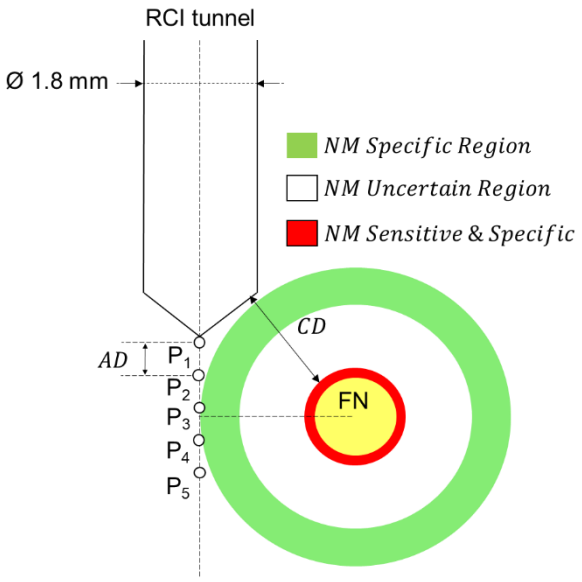

***Figure 5**. Discretized NM measuring points as defined along the trajectory at reaching the facial recess. Safe (green), unsafe (red) and uncertain (while) regions are depicted.*

3. First clinical RCI cases

After approval of the local ethics commission (IRB Bern, Switzerland, KEK-BE Nr.156/13) a first RCI clinical trial is undergoing at the university hospital of Bern [5]. The RCI procedure started with implantation of four fiducial screws (2.2mm × 5mm, M-5243.05, Medartis) in the mastoid of the patient. Thereafter a computer tomography scan was acquired (SOMATOM, Siemens) and a trajectory planned to the entrance of the cochlea. Then, via utilization of a non-invasive head-rest, the patient's head was fixed to the operation bed. The electromyogram (EMG) measuring electrodes were located in the facial muscles (orbicularis oris and oculi). The surface stimulating electrodes were positioned on the superficial branch of the FN (*positive control*). The positive control was executed and a minimum EMG amplitude level of 200 µV was verified. Confirmation of the positive control lead to draping of the patients' surgical site. Then, a reference marker (Figure 1) was fixed in the patient's mastoid to enable tracking of head movements during the robotic drilling operation. After physical registration of the mastoid to the preoperative plan via the implanted fiducial screws, RCI drilling was initiated up to 3 mm before the FN (1000 RPM, 0.5 mm/s, 2 mm pecking steps, Ø 1.8 mm). At this level, a radiologic safety confirmation of the drilled axis was achieved via intraoperative CT imagery (xCAT, Xoran). Thereafter, a temperature minimization drilling protocol (0.5 mm pecking steps) was initiated towards the critical drilling segment (drill-to-FN distances < 2mm) and *safe vs. unsafe* trajectories were determined based on the NM approach.

Data analysis

Drill-to-FN distance assessment was determined from postoperative CT images co-registered to the preoperatively determined (plan) facial nerves. For each measurement point, the Euclidian distance from the drill to the FN surface was defined as closest distance (CD). A sensitivity and specificity analysis was done assessing the stimulus thresholds and postoperative minimum distance from the drill tunnel to the facial nerve (CD_{min}).

4. Results

To date, a total of n = 6 patients have been operated using the developed robotic cochlear implantation system. The RCI-NM approach was successfully applied in all n = 6 patients. In one of the patients (subject 2), the RCI procedure had to be reverted to conventional CI. The reason of this event was a work-flow issue related to limited work-space of an intraoperative imaging system used to verify axis accuracy before reaching the FN.

In the n = 5 completed RCI cases, the NM approach suggested safe drill-to-FN distance margins in all cases (Table1). From the postoperative assessment, the minimum drill-to-FN distance margins were in agreement with the intraoperatively suggested margins (> 0.4 mm).

A representative facial recess neuromonitoring case is shown in Figure 6. It can be observed, a decrease in stimulus thresholds (monopolar) at the closest drill-to-FN distance plane. Subsequently, intensity increases again by passing the closest FN center plane (CD_{min} = 0.68 mm).

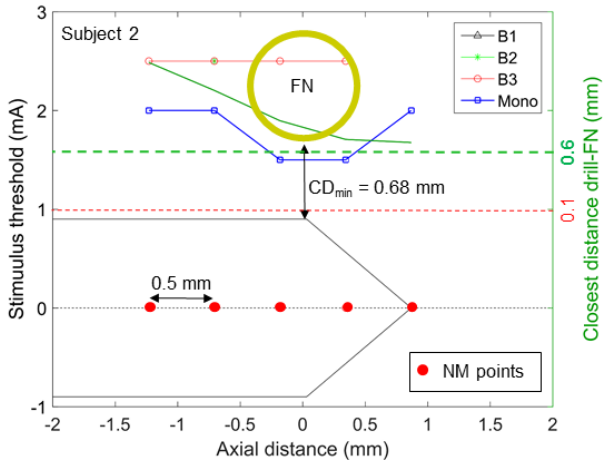

***Figure 6**. Postoperative co-registered stimulus thresholds (subject 2) relative to the axial NM measurement points.*

***Table 1.** Postop stimulus threshold to FN distances assessment.*

Subject	Min. stimulus threshold (mA)				FN-NM distance	CD_{min}
	B1	B2	B3	Mo.	(mm)	(mm)
1	NR	NR	-	2	> 0.7	0.82
2	NA	NA	NA	NA	NA	NA
3	NR	2.5	2.5	1.5	> 0.7	0.67
4	NR	NR	-	2	> 0.7	0.78
5	1.25	0.5	0.3	0.3	> 0.4	0.61
6	NR	1.25	1.25	1	> 0.7	0.58

NA: not applicable, patient converted to conventional CI
NR: no EMG response, stimulus threshold > 2.5 mA
- : anode channel presented high impedance (Z > 20 kohm)

5. Discussion

During these initial RCI cases, our proposed NM approach was able to confirm sufficient drill-to-FN distance margins (> 0.4 mm). Further validation of the nerve monitoring protocol during image-guide robotic cochlear implantation is necessary for verification of stimulus threshold values at the critical facial nerve distance range (< 0.3 mm). The results were consistent with in-vivo (sheep) experimental data at drill-to-facial nerve distance ranges above 0.4 mm, as reported in [5].

During the first RCI clinical trial trajectories are planned at drill-FN distances of at least 0.4 mm to minimize nerve risk in case of unexpected system error. Therefore acquisition of NM data at the critical distance range (< 0.3 mm) may not be possible, assuming system errors within 2 sigma (i.e. $< 0.15 \pm 0.08$, as suggested in [10], [11]).

To validate critical distance range stimulus threshold in human mastoid, we propose to use our navigated neuromonitoring stimulating system (modified approach) during middle ear surgeries. For instance, stimulus thresholds at a dehiscent facial nerve, i.e. no remaining bony cover, are expected to range 0.1 mA to 0.4 mA [2], whereas a bony covered facial nerve (intact fallopian canal), i.e. with at least a thin layer of bone cover, thresholds above 0.4 mA are to be expected [12]. Currently, to enable determination of the NM algorithm performance at critical distance range (< 0.3 mm), a prospective in-vivo validation is underway.

Acknowledgements

The authors acknowledge Prof. Thomas Nevian and Prof. Kai Rösler for guidance with electrophysiology aspects related to the neuromonitoring protocol. The authors also thank Prof. Frank Forterre, Dr. Christina Precht-Stahl and Dr. Helene Rohrbach for support during extensive in-vivo validation studies.

This work was supported by the Swiss National Science Foundation (project NCCR Co-Me), the Swiss Commission for Technology and Innovation (project MIRACI 17618.1), the European Commission (project HEAR-EU, 304857), the Swiss Nano-Tera initiative (project HearRestore), MED-EL GmbH (Innsbruck, Austria), and CAScination AG (Bern, Switzerland)

References

[1] S. Weber, K. Gavaghan, W. Wimmer, T. Williamson, N. Gerber, J. Anso, B. Bell, A. Feldmann, C. Rathgeb, M. Matulic, M. Stebinger, D. Schneider, G. Mantokoudis, O. Scheidegger, F. Wagner, M. Kompis, and M. Caversaccio, "Instrument flight to the inner ear," *Sci. Robot.*, vol. 2, no. 4, p. eaal4916, Mar. 2017.

[2] H. Silverstein, E. Smouha, and R. Jones, "Routine identification of the facial nerve using electrical stimulation during otological and neurotological surgery.," *Laryngoscope*, vol. 98, no. 7, pp. 726–30, Jul. 1988.

[3] D. Bernardeschi, N. Meskine, N. Al Otaibi, R. Ablonczy, M. Kalamarides, A. B. Grayeli, and O. Sterkers, "Continuous facial nerve stimulating burr for otologic surgeries.," *Otol. Neurotol.*, vol. 32, no. 8, pp. 1347–51, Oct. 2011.

[4] J. Ansó, C. Stahl, N. Gerber, T. Williamson, K. Gavaghan, K. M. Rösler, M.-D. Caversaccio, S. Weber, and B. Bell, "Feasibility of Using EMG for Early Detection of the Facial Nerve During Robotic Direct Cochlear Access.," *Otol. Neurotol.*, vol. 35, no. 3, pp. 545–54, Mar. 2014.

[5] J. Ansó, C. Dür, K. Gavaghan, H. Rohrbach, N. Gerber, T. Williamson, E. M. Calvo, T. W. Balmer, C. Precht, D. Ferrario, M. S. Dettmer, K. M. Rösler, M. D. Caversaccio, B. Bell, and S. Weber, "A Neuromonitoring Approach to Facial Nerve Preservation During Image-guided Robotic Cochlear Implantation," *Otol. Neurotol.*, vol. 37, no. 1, pp. 89–98, 2016.

[6] M. Caversaccio, K. Gavaghan, W. Wimmer, T. Williamson, J. Ansò, G. Mantokoudis, N. Gerber, C. Rathgeb, A. Feldmann, F. Wagner, O. Scheidegger, M. Kompis, C. Weisstanner, M. Zoka-Assadi, K. Roesler, L. Anschuetz, M. Huth, and S. Weber, "Robotic cochlear implantation: surgical procedure and first clinical experience.," *Acta Otolaryngol.*, vol. 137, no. 4, pp. 447–454, Apr. 2017.

[7] T. Williamson, B. Bell, N. Gerber, K. Gavaghan, J. Anso, L. Salas, M. D. Caversaccio, and S. Weber, "Multi - Level Safety Concept for Robot Assisted ENT Surgery," in *Annual Conference of the German Society for Computer and Robot assisted Surgery, CURAC*, 2012.

[8] T. M. Williamson, B. J. Bell, N. Gerber, L. Salas, P. Zysset, M. D. Caversaccio, and S. Weber, "Estimation of tool pose based on force-density correlation during robotic drilling.," *IEEE Trans. Biomed. Eng.*, vol. 60, no. 4, pp. 969–76, Apr. 2013.

[9] N. R. Holland, "Intraoperative electromyography.," *J. Clin. Neurophysiol.*, vol. 19, no. 5, pp. 444–453, 2002.

[10] B. Bell, N. Gerber, T. Williamson, K. Gavaghan, W. Wimmer, M. Caversaccio, and S. Weber, "In Vitro Accuracy Evaluation of Image-Guided Robot System for Direct Cochlear Access.," *Otol. Neurotol.*, vol. 34, pp. 1284–1290, Aug. 2013.

[11] T. Williamson, K. Gavaghan, N. Gerber, S. Weder, L. Anschuetz, F. Wagner, C. Weisstanner, G. Mantokoudis, M. Caversaccio, and S. Weber, "Population Statistics Approach for Safety Assessment in Robotic Cochlear Implantation.," *Otol. Neurotol.*, vol. 38, no. 5, pp. 759–764, Jun. 2017.

[12] Y. H. Choung, K. Park, M. J. Cho, P. H. Choung, Y. R. Shin, and H. Kahng, "Systematic facial nerve monitoring in middle ear and mastoid surgeries: 'Surgical dehiscence' and 'electrical dehiscence,'" *Otolaryngol. - Head Neck Surg.*, vol. 135, no. 6, pp. 872–876, 2006.