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OTOLOGY

Robotic cochlear implantation: feasibility of a multiport approach in an ex vivo model

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Abstract

Purpose A recent clinical trial has shown the feasibility of robotic cochlear implantation. The electrode was inserted through the robotically drilled tunnel and an additional access through the external auditory canal was created to provide for means of visualization and manipulation. To obviate the need for this additional access, the utilization of multiple robotically drilled tunnels targeting the round window has been proposed. The objective of this study was to assess the feasibility of electrode insertion through a robotic multiport approach.

Methods In four ex vivo human head specimens (left side), four trajectories through the facial recess (2x) and the retrofacial and suprameatal region were planned and robotically drilled. Optimal three-port configurations were determined for each specimen by analyzing combinations of three of the four trajectories, where the three trajectories were used for the electrode, endoscopic visualization and manipulative assistance. Finally, electrode insertions were conducted through the optimal configurations.

Results The electrodes could successfully be inserted, and the procedure sufficiently visualized through the facial recess drill tunnels in all specimens. Effective manipulative assistance for sealing the round window could be provided through the retrofacial tunnel.

Conclusions Electrode insertion through a robotic three-port approach is feasible. Drill tunnels through the facial recess for the electrode and endoscope allow for optimized insertion angles and sufficient visualization. Through a retrofacial tunnel effective manipulation for sealing is possible.

Keywords Cochlear implantation · Robotic surgery · Multiport surgery · Electrode insertion

Introduction

Conventional cochlear implantation surgery requires access to the middle ear via a mastoidectomy and posterior tympanotomy approach to create visibility of middle ear structures and contours of inner ear structures. This allows the otologist to navigate and create access to the cochlea using visual confirmation of anatomical landmarks including the promontory, the stapes and the round window. Robotic cochlear implantation (RCI) is a robot-assisted surgical procedure designed to be performed without any direct visual access to the anatomical structures subject to the surgery [1]. The intervention relies on accurate surgical planning based on preoperative imaging to determine the optimal trajectory for cochlear access, middle ear access drilling using a sensor- and image-guided robotic drill supported by EMG

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neuromonitoring safety protocols, followed by inner ear access milling and electrode insertion [2]. The latter two steps are carried out manually in a current clinical trial of RCI [3], in which microscopic visual monitoring of cochlear opening and electrode insertion is ensured through a tympanomeatal flap created through the external auditory canal [2, 4]. The tympanomeatal flap involves the manipulation of the ear drum, which can cause complications (perforation of the tympanic membrane, trauma to the ossicular chain, inflammation causing stenosis of the external auditory canal) and takes away from the inherent advantages of a fully sensor driven technology. Nonetheless, this work-around is necessary in the clinical trial because the robotic system developed in our group, so far only has the clinically validated functionality to plan and create a robotically drilled tunnel access to the middle ear, targeting the cochlea.

Work has been underway to design and integrate cochlear access and electrode insertion capabilities to permit the robotic platform to perform the complete end-to-end RCI procedure. This would allow the procedure to take place beyond the human sensory and manual limitations, which is generally considered the basis of any technology that could deliver atraumatic CI surgery and herewith potentially more hearing preservation cochlear implantation.

To resolve the limitations to simultaneous visualization and manipulation assistance requirements that are imposed by a single drill tunnel to the cochlea, a multiport approach was investigated for its suitability and feasibility for the RCI approach. It has previously been shown that planning multiple trajectories with adequate safety clearance despite anatomical variations was feasible [5–7]; as was the drilling of trajectories with the adequate accuracy [8].

We therefore hypothesized that through a trajectory matrix designed to optimize the meeting point of endoscopic, micromanipulation and electrode insertion feeder tunnel, successful round window placement of the electrode via minimally invasive access would be possible, therefore obviate the use of the tympanomeatal flap and lead the way to the full integration of all stages of the RCI procedure into the robotic platform.

Materials and methods

With the approval of the local ethical committee (KEK-BE 2016-00887) electrode insertion through a multiport approach was investigated using Thiel-embalmed human cadaveric head specimens. In this study, a robotic multiport approach was defined as a configuration of robotically drilled trajectories, one each for electrode insertion, endoscopic visualization and manipulation. Multiple trajectories to the round window were planned and drilled in each specimen. Experimentally, the optimal configuration of trajectories was to be determined for each specimen. Subsequently, an electrode was inserted in each specimen through the specimen-specific optimal configuration. Postoperative imaging was used to analyze the insertions.

Specimen preparation, preoperative imaging and planning

After performing a c-shaped retro-auricular incision, the left sides of four human cadaveric head specimens were implanted with four bone fiducial screws (CAScination, Switzerland). Cone beam computed tomography (CBCT) images were acquired (XCat, Xoran Technologies, USA) and reconstructed with an isotropic resolution of 0.1 mm^3. Temporal bone, facial nerve, chorda tympani, external auditory canal and ossicles were annotated, and cochlear dimensions were assessed using an otologic planning software (OTOPLAN®, CAScination, Switzerland). Cochlear duct length was found to be 32.4 ± 0.8 mm and FLEX28 electrodes (Synchrony, Med-El, Austria) were selected for all subsequent experiments. Per subject, four trajectories of diameter 1.8 mm from the mastoid surface to the round window were aimed to be planned inferiorly and superiorly through the facial recess, suprameatal and retrofacial with a minimum clearance of 0.2 mm to all surrounding anatomical structures (Fig. 1a) [9]. In specimen 1 and 3, retrofacial trajectories with sufficient clearance could not be defined due to inevitable collision with the sigmoid sinus and the facial nerve resulting in 14 planned trajectories (Fig. 2).

The optimal insertion trajectory was chosen on the basis of the insertion angle. Out of the available two facial recess trajectories, the one with the smallest in-plane and out-of-plane insertion angles [10] was selected for electrode insertion. Selection of the insertion trajectory was limited to trajectories through the facial recess since it is the most established port to bring a cochlear implant electrode to the round window. In addition, robotic milling of the bony overhang covering the round window membrane through the predefined insertion trajectory was planned using the previously mentioned otologic planning software. Additionally, relative angles of each trajectory relative to the superior facial recess trajectory were measured in the *xy*- and *xz*-planes of the cochlear coordinate system [11] to estimate angular values for potentially automated planning of additional trajectories (Fig. 3).

Robotic drilling

Per specimen, an optical patient reference was rigidly attached to the skull. Available preoperative image data were co-registered using the implanted fiducial screws and a screw-specific registration tool. Subsequently, all trajectories were drilled using a task-specific surgical robotic

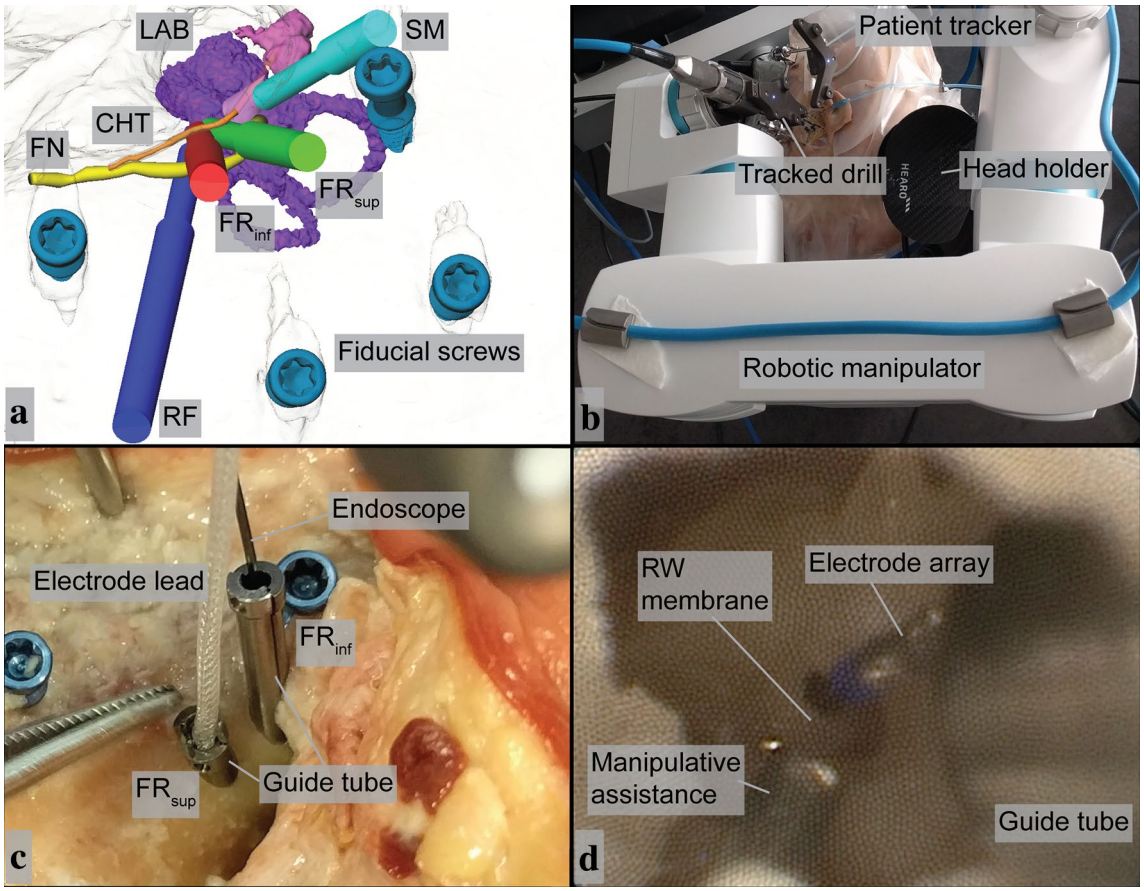

Fig. 1 **a** Planning of the robotic trajectories; **b** tunnel drilling; **c** electrode insertion using a removable guide tube and endoscope; **d** manipulative assistance is provided through a third tunnel

system (HEARO®, CAScination, Switzerland, Fig. 1b). Image-guided robotic milling of the bony overhang through the insertion tunnel was endoscopically visualized (Miniature-Straight Forward Telescope, angle 0°, diameter 1 mm, length 6 cm, Karl Storz, Germany) through the other facial recess tunnel.

Evaluation of the optimal multiport configuration

By selecting three of four trajectories and using the previously determined insertion trajectory, six multiport configurations were assessed for each specimen (for the two specimens with three trajectories, two multiport configurations were assessed). For each configuration, the endoscope and a straight pick were placed in the respective tunnels and the tip of the electrode manually guided to the level of the round window through the insertion tunnel using a removable two-piece guide tube [12] (Fig. 1c, d). The configuration enabling optimal visualization and manipulation was assessed using the following criteria: (1) round window membrane endoscopic visibility, (2) round window membrane accessibility, (3) relative alignment of manipulation and insertion axis within 45°, and (4) visibility of anatomical structures in proximity to the manipulation instrument. If no configuration fulfilled all criteria, a minimal access through the external auditory canal was created by mobilizing the skin on the posterior wall down to the annulus creating a 1–2 mm diameter access to the middle ear without the need for any incision in the skin of the external auditory canal or the tympanic membrane.

Insertion through optimal multiport configuration

Finally, the electrode was inserted through the optimal multiport configurations in each specimen. After cleaning of the round window region under endoscopic vision through the drill tunnels, the round window membrane was opened. A removable two-piece guide tube was placed in the insertion tunnel and its correct alignment with the round window and contact with the promontory was verified using the endoscope. The electrode was manually inserted under endoscopic visualization. If needed, manipulative assistance was available through the manipulation tunnel in case of difficulties during the insertion (e.g., tip of electrode deviating into

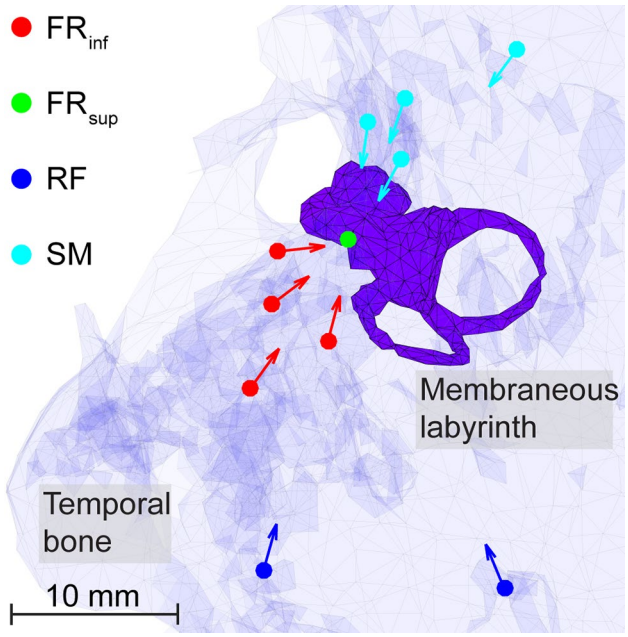

Fig. 2 Overview of planned trajectories. Superiorly (FR_{sup}) and inferiorly (FR_{inf}) through the facial recess, retrofacial (RF) and suprameatal (SM), with all superior facial recess trajectories aligned. For reference, the temporal bone and labyrinth of specimen 1 are augmented

the middle ear or bending of the electrode). Subsequently, the guide tube was removed. Sealing of the round window with soft tissue harvested from the temporal subcutaneous tissue was performed through the manipulation tunnel. A straight pick was used to transport the fat to the round window and place it around the electrode. The period starting with the placement of the guide tube until the round window was sealed after insertion was measured as insertion time. The endoscopic video feed during insertion was recorded (supplementary material).

Postoperative validation

Titanium rods were inserted into the drilled tunnels and postoperative CT scans were acquired ($0.15\ mm^2 \times 0.2$ mm, Somatom Definition Edge, Siemens, Germany). Those scans were co-registered to the preoperative image data and the planned trajectory. The rods were threshold segmented and the relative displacement to the plan was measured as the drilling error. In addition, insertion depth angles, the number of inserted electrodes and potential complications of the insertion (e.g., intracochlear tip fold-over, scalar dislocation) were assessed using the previously mentioned otologic planning software.

Results

Planning and robotic drilling

All 14 planned trajectories were successfully drilled with the robotic system. Milling of the inner ear access allowed direct access to the round window in all four specimens. No damage to the membrane due to milling was observed. The effective drilling accuracy was 0.13 ± 0.09 mm and 0.26 ± 0.16 mm at the level of the facial nerve and round window, respectively.

Retrofacial trajectories with sufficient clearance could not be defined due to inevitable collision with the sigmoid sinus and the facial nerve in specimen 1 and 3. Definition of the other 14 trajectories was possible with a clearance of 0.2 mm to the facial nerve. Three planned trajectories resulted in a distance to chorda tympani smaller than 0.2 mm. All other trajectories were clear of potential collision (clearance < 0.2 mm) with all anatomical structures of interest. In specimens 1, 2 and 4, the in-plane angles of the inferior facial recess trajectory were more negative compared to the

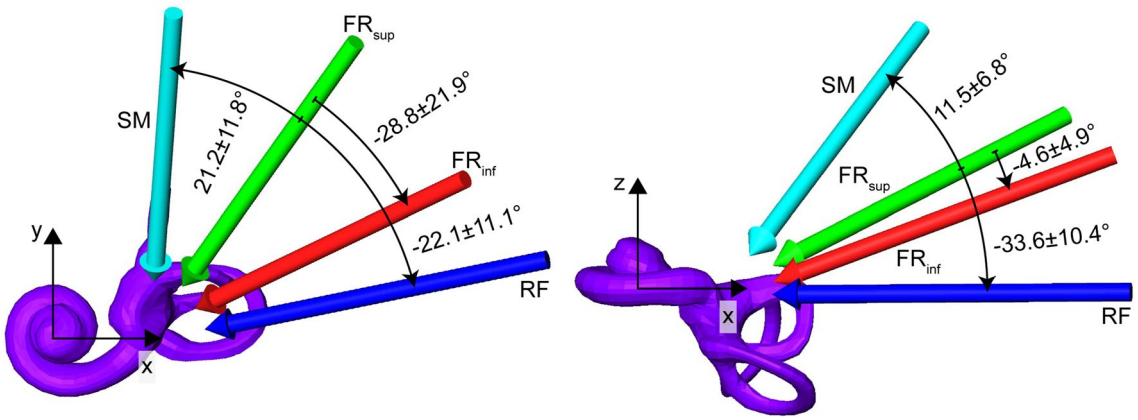

Fig. 3 Angles of the inferior facial recess (FR_{inf}), retrofacial (RF) and suprameatal (SM) trajectory to the primary insertion trajectory (superior facial recess, FR_{sup}) measured in the (left) *xy*-plane and (right) *xz*-plane of the cochlear coordinate system

superior facial recess trajectory. Hence, insertion through the superior facial recess trajectory was chosen (Table 1). In specimen 3, the inferior facial recess trajectory resulted in insertion angles closer to zero than the superior facial recess trajectory and was accordingly chosen as insertion trajectory (Table 1).

Angles between the primary insertion trajectory (superior facial recess) and the other trajectories are depicted in Fig. 3.

Insertion

Electrode insertion procedures through a robotically created three-port approach were successfully conducted in all four specimens. Full insertion of the implant could be achieved without manipulative assistance in all specimens. The time required for the insertion procedures was < 16 min. The insertion depth, the number of inserted electrodes and the time required for the insertion are shown in Table 1. The round window could adequately be sealed after the insertion in three of four specimens. In specimen 3, the ossicles were touched during sealing through the suprameatal tunnel and the sealing remained incomplete. No other complications such as intracochlear tip fold-overs or scalar dislocation were observed (Fig. 4). A video of the full insertion procedure was generated and is available as part of the supplemental data.

The optimal tunnels for insertion and visualization were through the superior inferior facial recess, respectively (or vice versa in case of superior insertion angles of the inferior facial recess tunnel). After robotic milling of the bony overhang, the round window niche and membrane were visible through the facial recess tunnel in all four specimens and the whole insertion procedure could be visualized sufficiently. The retrofacial tunnel was effective for sealing of the round window, hence declared optimal for manipulative assistance, however, not practicable in every patient anatomy. The suprameatal tunnel was determined optimal for manipulative assistance in specimen 3. Due to the long process of the incus and the stapes limiting the accessibility of the round window through the suprameatal tunnel in specimen 1, a minimal access through the external auditory canal was used for manipulative assistance.

Discussion

We recently reported the successful clinical introduction of a robotic platform technology dedicated to robotic cochlear implantation [2, 3]. In the trial, we showed an intermediate solution to the end-to-end robotic cochlear implantation and demonstrated robotic middle ear access. The stages of robotic inner ear access and robotic electrode insertion that would complete robotic cochlear implantation were not included as they are still subject of active research. A key next step would be to obviate a tympanomeatal flap for visualization and manipulation as used in the clinical trial, which led us to investigate a robotic multiport approach for electrode insertion.

We have shown that a three-port trajectory configuration is feasible for a successful electrode insertion ($n = 4$ specimens, time for the insertion procedure < 16 min). From the described and numerous previous studies, the time of the whole procedure from installing the system until completion of sealing of the round window is known to be 60–90 min [2, 3] (system setup: 5–10 min, screw placement: 4–6 min, imaging and planning: 25–35 min, robotic drilling and milling: 3–5 min per trajectory, insertion 8–15 min). Electrode insertion and visualization through the superior and inferior facial recess (or vice versa), respectively, was optimal in terms of insertion angles and sufficient to (1) see the round window, promontory and stapes, (2) control exact placement of the guide tube, (3) monitor and stop the insertion procedure, and (4) guide sealing. Manipulation through a retrofacial tunnel was effective for sealing of the round window,

Table 1 Optimal configuration (I: insertion, V: visualization, M: manipulation, FR_{sup}: superior facial recess, FR_{inf}: inferior facial recess, SM: suprameatal, RF: retrofacial), insertion angles, insertion depth, time required for and complications occurred during the electrode insertion procedure

Specimen	1	2	3	4	$\mu \pm \sigma$
Optimal configuration	I: FR_{sup} V: FR_{inf} M: EAC	I: FR_{sup} V: FR_{inf} M: RF	I: FR_{inf} V: FR_{sup} M: SM	I: FR_{sup} V: FR_{inf} M: RF	–
Insertion trajectory out-of-plane angle (°)	13.3	15.1	14.9	15.4	14.7 ± 0.9
Insertion trajectory in-plane angle (°)	−20.7	7.3	2.5	10	-0.2 ± 14
Insertion depth (°)	486	640	623	587	584 ± 69
# Inserted electrodes	12	12	12	12	–
Insertion[a] time (min)	7.8	8.7	10.3	15.2	10.5 ± 3.3
Complications	–	–	Manipulation of ossicles Sealing incomplete	–	–

[a]Time period starting with the placement of the guide tube until completion of the round window sealing

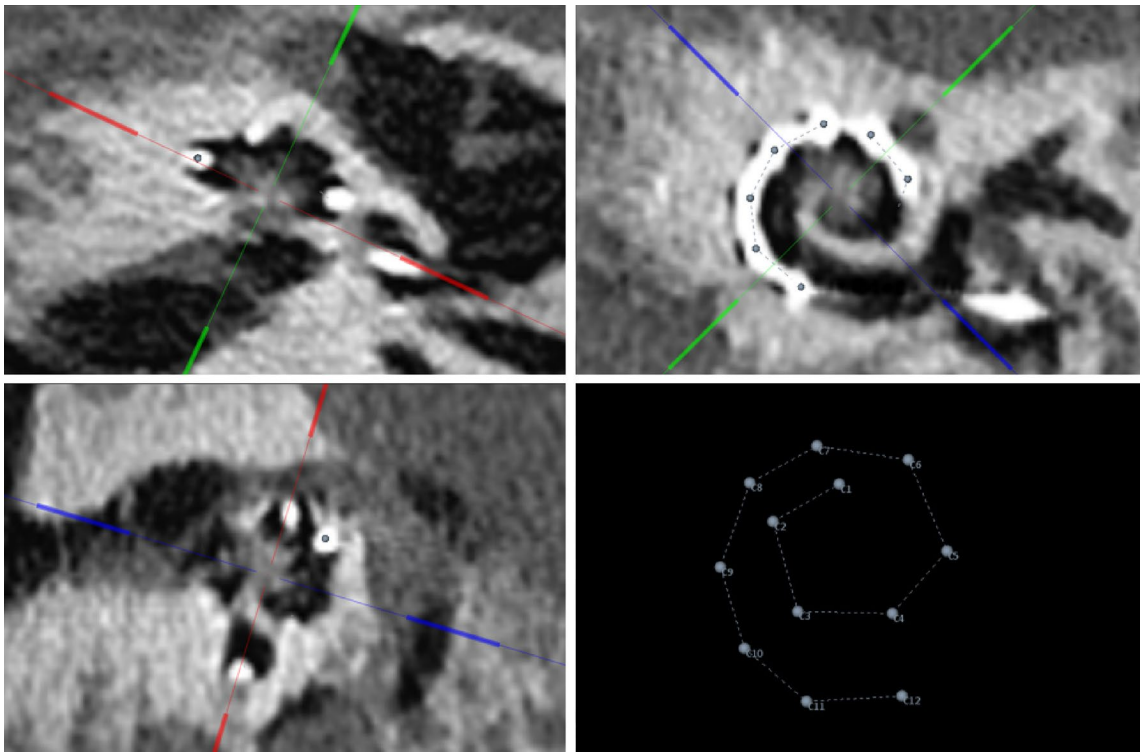

Fig. 4 Postoperative analysis of insertion depth and intracochlear complications in specimen 3. All electrodes are within the scala tympani and the angular insertion depth is 623°. No intracochlear complications such as tip fold-overs or scalar dislocations could be observed

however, not practicable in all patients due to limited space between the sigmoid sinus and the facial nerve. While a suprameatal tunnel can alternatively be used for manipulative assistance, care must be taken not to damage the chorda tympani or the ossicles. If manipulative assistance cannot be provided through the retrofacial or the suprameatal tunnel, a two-port approach for insertion and visualization through the facial recess plus a minimal access through the external auditory canal for sealing is feasible. While one in four cases required a minimal access through the external auditory canal, a larger sample size is required for a valid statistical statement. Nonetheless, the creation of the tympanomeatal flap imposes the same risk for complications as they are for current robotic cochlear implantation and does not increase the risk of the multiport procedure. In any event, the emergency creation of a tympanomeatal flap can be the mitigating action in a rescue scenario, without any inherent detrimental effect.

Anatomical variations among patients affect the feasibility of the multiport approach. Williamson et al. [13] have shown that roughly 50% of the population can be treated safely using a 1.8-mm-diameter drill bit and considering the available drilling accuracy and the population facial recess size of 2.5 ± 0.5 mm. The proportion of the treatable population can be significantly increased by decreasing the drill bit diameter [13]. While a small facial recess may prevent the realization of two distinct trajectories through the facial recess, the trajectories can be planned to partially merge at the level of the facial recess, thus creating an enlarged posterior tympanotomy with two access ports. Furthermore, anatomical variations such as a low middle fossa dura or a high jugular bulb affect the practicability of a suprameatal or retrofacial trajectory, respectively. While we have observed insufficient space between the sigmoid sinus and the facial nerve in two out of four specimens, a larger sample size is required for a valid statistical statement. Nevertheless, computer-assisted surgical planning enables accurate and intuitive inspection of the patient-specific anatomy and anomalies and according proactive actions such as customized planning of trajectories. Furthermore, the current robotic system is not intended to be used for revision surgery. Future version may include elements that allow robotic support also during revision cases. Revision surgery of a robotically performed cochlear implant has been done [14].

While full electrode insertion using a robotic three-port approach and two-port approach plus minimal access through the external auditory canal approach seems feasible, individual surgeon practice will determine the approach chosen—whether one drill tunnel plus a tympanomeatal flap or multiple drill tunnels—and is subject to personal preferences, patient anatomy and the capabilities of commercial endoscope technology.

Further, the form factor of the robotic trajectory forestalls the use of conventional instrumentation. Task-specific tools must be developed to facilitate insertion but moreover prevent and manage adverse events such as electrode kinking or bending, bleeding and obliteration of the scala tympani. Submillimeter high definition endoscopes will facilitate visual monitoring of the insertion procedure.

Overall, a robotic multiport approach with any number of trajectories has the same final safety configuration as the RCI subject to a clinical trial [2, 3], in which conversion to a conventional mastoidectomy and posterior tympanotomy approach is possible at all times to ensure the patient can receive a CI through conventional surgery.

Conclusion

A robotic three-port approach is feasible for successful cochlear implant electrode insertion. Tunnels through the facial recess for the electrode and endoscope enable optimization of insertion angles and sufficient visualization of the insertion procedure. Manipulative assistance through a retrofacial tunnels allows for effective sealing of the round window. Since a retrofacial tunnel is not practicable in all patient anatomies, sufficient manipulative assistance can alternatively be provided through a suprameatal tunnel.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Research involving human participants and/or animals All procedures performed in studies involving human participants (ex vivo) were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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