Next-generation Robotics in Otology: The HEARO Procedure

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Background: In a world that is globalizing and centered on rapid communication, hearing impairment is one of the most common disabilities. The most effective and successful neural prosthesis in humans for treating the dysfunction of a sensory organ is cochlear implantation. The minimally invasive placement of the array in the cochlea should warrant the rehabilitation of profound hearing loss over all frequencies. Some key factors for structure and hearing preservation consist of minimal invasive drilling in the temporal bone and tailored inner ear access. Next-generation Robotically Assisted Cochlear Implantation Surgery (RACIS) focuses on robotic inner ear access. The purpose of this cadaveric preclinical study was to assess the viability and precision of a novel technology (the HEARO method) for RACIS, or more particularly, personalized robotic inner ear access.

Methods: The external auditory canal, chorda tympani, ossicles, facial nerve, and other pertinent anatomical components were all 3-dimensional (3D)-reconstructed by the surgeon. The mean intended distance and drilling trajectory to the chorda tympani and facial nerve were, respectively, 0.44 ± 0.13 and 0.35 ± 0.27 mm.

Results: With a mean insertion percentage of 94%, the surgeon was able to complete the HEARO method in 9 out of 10 procedures. There was no evidence of a collision or damage to vital structures.

Conclusion: Future iterations of RACIS will prioritize haptic feedback, automated segmentation and trajectory, robotic insertion with adjustable speed, and imaging mobile cone beam computed tomography.

Key Words: Cochlear implantation, image-guided surgery, inner ear, robot assistance, robotically assisted cochlear implantation surgery

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In a world that is globalizing and centered on rapid communication, hearing impairment is one of the most common disabilities.[1] It is almost incomprehensible that hearing aids remain stigmatized. A subset of the hearing-impaired population with severe to profound hearing loss that could benefit from Cochlear Implantation (CI) is even more undertreated, possibly as a result of it requiring a low-risk surgical procedure.[2,3] Nevertheless, the most effective and successful neural prosthesis in humans for treating the dysfunction of a sensory organ is cochlear implantation.[3] It consists of an external processor that records sounds and converts it into an electrical signal to conduct them safely to an internal part that needs to be implanted in the correct part of the inner ear.

The main goal of CI surgery is to insert an electrode array in the cochlea's scala tympani (ST). Classically, the surgeon finds the facial nerve (FN) and the chorda tympani (ChT) as landmarks in the temporal bone so as to safely pass between them (through the facial recess) to reach inside the middle ear cavity. Then, access of the inner ear is obtained to insert the electrode. Nowadays, surgeons' main priorities include preserving residual hearing thresholds (rHTs) and minimizing damage to inner ear components. When an array can be implanted in the cochlea without damaging the function of the apical part of the cochlea responsible for rHT, combined electro-acoustic stimulation (EAS) can restore hearing capacities more completely due to brain plasticity. Not only will this improve speech understanding, but the (acoustically amplified) rHT will also allow for the appreciation of music and natural sounds.[4] Some key factors for structure and hearing preservation consist of minimally invasive drilling in the temporal bone and tailored inner ear access. The anatomic variation requires the optimization of many factors within micro scales for each individual patient.[5] However, surgeons have realized that controlling all mechanical factors for hearing preservation is beyond human dexterity and potentially leads to inconsistent surgical outcomes.[6,7] Therefore, the development of Robotically Assisted Cochlear Implantation Surgery (RACIS) has been evaluated in preclinical studies in the last decade, and Labadie and colleagues succeeded in a clinical study for the first time.[8–10] The following-generation RACIS—the OtoBot robotic system—was also developed to achieve

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tunnel-based direct robotic middle ear access, but it had more automated steps.[11] Preclinical studies and, subsequently, the clinical feasibility of the OtoBot system were successfully demonstrated in six patient systems.[12] These pioneering studies aimed to overcome the burden of the size of the facial recess in entering the middle ear. This facial recess approach has become the golden standard for middle ear access and, for inner access, there is consensus for the Round Window (RW) approach in CI surgery.[13] The FN has major motoric functions in facial mimics and functional mouth and eye movement. The ChT contributes to the sense of taste on the ipsilateral side of the tongue. In this era, RACIS mainly focused on a safe opening towards the middle ear. After this step, the surgeon took over to create inner ear access through the ear canal. Manually lifting the eardrum, the surgeon drills the canopy-shaped bone over the RW membrane and manually inserts the array into the cochlea through the tunnel.

The next-generation RACIS focuses on robotic inner ear access. Inner ear access irrevocably demands much more of a robotic system. The RW is situated deeper in the temporal bone, and its size (1.31 ± 0.31 mm diameter on average) is smaller than the facial recess (2.5 mm on average).[14] The system needs more robustness because the accuracy and precision are easier to obtain for closer targets. In addition, the anatomy and a close relation of the RW to critical intracochlear structures determine the importance of the target and angle used to enter the inner ear when preserving the inner ear structure and possibly residual hearing.[14–16] RACIS aims to reduce mechanical and noise-induced trauma,[17,18] not only by acquiring middle ear access in the mastoid but also by acquiring inner ear access using a force-controlled milling process.[19] In fact, one of the first developments in the field of robotic inner ear access was a robotic micro-drill.[20–22] The force and torque transients were used to effectively predict the drill breakthrough of the cochlear bone-targeted at the lateral wall of the cochlea (cochleostomy) and automatically stop the drilling process.[23] Today, the RW targets entering the inner ear because current insights in manual hearing-preserving CI surgery are based on maximum exposure of the RW.[13] In contrast to its name, "round window" (Latin: fenestrae cochleae), it is not easily entered because a canopy of bone (canonus fossulae fenestrae cochleae) often almost completely hides the RW.[24] Fully drilling this Canonus (C) away (canonectomy) is more damaging than making a small hole in it (canonostomy) that is just large enough to pass the CI array. A thin diamond-coated 1.0 mm tungsten-carbide diamond burr is mounted correctly, and the canonostomy is performed by milling the bony overhang of the RW. Moreover, the next-generation RACIS—HEARO—uses preoperative information of the patient's anatomy to plan tailored inner ear access. Topsakal et al performed inner ear access by controlling the angles in the cochlear approach,[16] applied RACIS with the HEARO procedure in a case with an inner ear anomaly (incomplete partition type III) for the first time in the literature,[25] and could complete the HEARO procedure with a full insertion in 21 cases.[26] Robotic approaches can guard pre-calculated ideal trajectories better than human dexterity and only remove bone that is blocking this direct access. The hypothetical inner ear mechanical trauma and noise damage are mitigated to a minimum, and a preset optimal angle for insertion is warranted. Although RACIS seems highly experimental at the moment, this study among others tries to achieve minimal invasive access to the inner ear. Although conventional CI surgery can be performed under local anesthesia, today it still involves a wide mastoidectomy to identify the third portion of the FN for safety. For the moment, the fastest time for the HEARO procedure is 3.5 hours including the postoperative imaging as a check in the protocol. Conventional surgery in experienced hands can be within 1 hour. Nevertheless, inner ear access with HEARO can be reached within 8 minutes if we leave all current safety protocols aside. If RACIS is completely fine-tuned and proven safe and effective to be performed in 8 minutes CI will probably become an outpatient procedure under local anesthesia as the golden standard. The impact of these applications will not only reduce costs for society and health care significantly but will also positively influence the burden of general anesthesia for the patient.

This preclinical cadaveric study aimed to evaluate the feasibility and accuracy of a new device (the HEARO procedure) for RACIS, or, more specifically, the tailored robotic inner ear access. The main objective is the ratio of successfully to non-successfully completed HEARO procedures, in which robotic inner access is created, and an electrode array is manually inserted through the drilled keyhole channel.

METHODS

Five formalin-conserved human cephalic specimens (Sciencecare) were used for RACIS with permission of the Bernese cantonal ethical commission, Switzerland (KEK BE 2018-00770). The same otologist, trained for the HEARO procedure, and including at least 10 full procedures on the human specimen, performed all of the HEARO procedures for this study. The specimen cases were not screened for HEARO procedure eligibility in terms of facial recess size. Today, the current HEARO procedure is CE-marked for clinical use in adults and requires a minimal planned distance of 0.4 mm to F.[27] However, this in vitro study tolerated trajectory planning at closer distances, and embedded safety algorithms of the system had to be overruled. Furthermore, the inbuilt facial nerve monitoring of the system was turned off because it requires an intact nervous system. In preoperative analyses of patients, it is possible to estimate the Cochlear Duct Lengths (CDL) for tailored and complete cochlear coverage to obtain an optimal audiological outcome.[5] In this study, all specimens were inserted with a 28 mm electrode array regardless of the preoperative CDL estimations (SYNCHRONY FLEX28, MED-EL). Audiological examinations are again impossible, and this length of array was chosen because it covered 95% of the human cochlea lengths.[28] A commercially available mobile cone beam CT (CBCT) with 0.1 mm spatial resolution (XCAT XL, Xoran Ltd) acquired radiological images for preoperative planning, checking the partially drilled trajectory, and postoperatively checking the array placement in the cochlear. Empowered visual inspection was assured by the arriscope (ARRI Medical GmbH & Co), which is a commercially available, high-definition, fully digital microscope for stereoscopic viewing through the ear canal that allows the surgeon to work with both hands. In addition, a custom-made endoscope with a diameter of 1 mm (Schoelly GmbH) allowed the surgeon to visually inspect through the drill trajectory, occupying one hand for controlling it.

HEARO Procedure

The HEARO robotic system (CASCINATION AG) is an assistive otological next-generation surgical robot based on the Otobot system (Fig. 1). It integrates a set of sensors, actuators, and core functionalities to allow the surgeon to perform image-guided surgery with a robotic arm. The HEARO procedure for CI surgery is described below and comprises 3 main stages followed by postoperative analyses (Fig. 2).

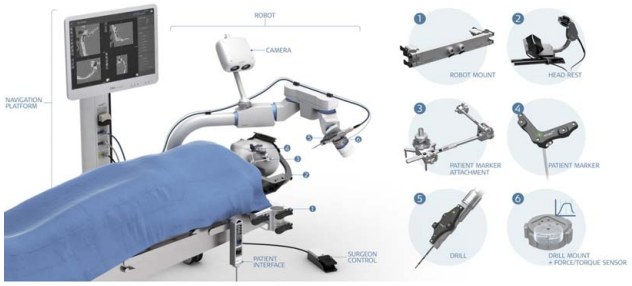

FIGURE 1. HEARO robotic system: (1) robot mount; (2) headrest; (3) patient marker attachment; (4) patient marker; (5) drill; (6) drill mount with force/torque sensor.

Preparations and Planning

After the skin incision, the pinna often had to be removed because folding it away was not possible due to rigor mortis or formalin fixation. Then, 5 fiducial screws (4 for registration and 1 for patient marker attachment) were placed on the mastoid cortex as artificial landmarks on preoperative imaging and later for navigation. Next, a CBCT image was scanned and imported to the dedicated planning software (OTOPLAN, CASCINATION AG). The surgeon reconstructed all of the relevant anatomic structures, such as the FN, the ChT, the ossicles, and the external auditory canal, in 3D. The surgeon then manually set the target point at the level of the RW membrane and adjusted the ideal trajectory line based on the patient's specific anatomy and in-plane and out-plane angles as previously described by Wimmer et al[29] Sufficient safety distances and individualized inner ear access were optimized. At the final stage, the surgeon manually identified the lateral and medial points of the canonus along the trajectory and its thickness was estimated. The surgical plan was exported from OTOPLAN to HEARO with a common USB stick. The HEARO software automatically rendered if the planned trajectory was executable within the safety margins of the FN. As mentioned before, this part of the software was modified to allow for unsafe drillings. The surgeon performed a patient-to-image registration to enable the navigation of the robot. Possible planning out of the reach of the robot arm or possible collision with fiducials was signaled to the surgeon by the system.

Performing Robotic Drilling

In this stage, the robotic arm executed the surgical plan. The surgeon exchanged the registration tool with a custom-made helical step drill (1.8 mm diameter HEARO Step Drill, CASCINATION AG) and assured that it was mounted correctly in a sterile surgical manner. The first access was drilled into the middle ear, which comprises three phases:

(i) Drilling from the cortex of mastoid bone until 3 mm before the level of the FN;
(ii) Drilling through the facial recess;

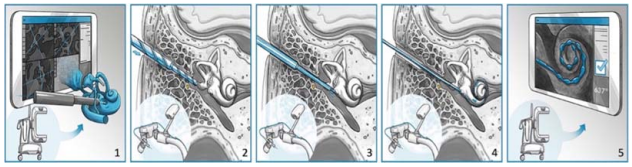

FIGURE 2. The HEARO procedure for cochlear implantation surgery: (1) scanning and planning; (2) performing middle ear access with cutting bur; (3) performing inner ear access with diamond bur; (4) placement of array through a removable insertion tube; (5) postoperative.

(iii) Drilling mastoid cells further than FN to complete the middle ear access.

After phase (i), intraoperative imaging was required. A titanium rod (HEARO Trajectory Imaging Reference, CASCINATION AG) was placed in the partially drilled tunnel by the surgeon. This device enhanced the contrast of the drilling tunnel in the image. The image was loaded into the planning software, allowing the surgeon to assess the safety margins between the drilling trajectory and the anatomy, as well as to measure the drilling accuracy (Supplementary Table 1, Supplemental Digital Content 1, http://links.lww.com/SCS/H74). Upon confirmation of the safe trajectory (not compromising FN), phase (ii)—the drilling through the facial recess—was performed. In a study by Hudson et al,[30] the facial recess angle between the ChT and FN was reported as 23.5 ± 24.0 degrees. Here, multipolar FN stimulation would have been performed 5 times at 0.5 mm intervals, providing diverse and navigation-independent means to verify the safe distances to the FN.[27] However, it was not possible in this in vitro setting as mentioned before. Phase (iii) is usually swiftly performed because it is neither near FN nor middle ear structures. Throughout cortical drilling towards the middle ear, the robotic drilling was performed in pecking cycles. The drill bit needed to come out of the trajectory for automatic irrigation to clean the helix of the drill bit. This also allowed the surgeon to clean the drilled tunnel and check for possible bleeding tendencies. The cleanness of the drill bit is necessary to avoid extensive heat to FN during drilling.[27] This pecking is not necessary for the next phase of drilling and inner ear access.

Inner Ear Access

After completion of the middle ear access, a 1.0 mm tungsten-carbide diamond burr (HEARO Diamond Burr, CASCINATION AG) with fine diamond coating needed to be correctly mounted to mill a canonostomy. The inner ear access was achieved by combining preoperative and intraoperative parameters. Preoperatively, the canonus thickness was already predicted, and intra-operatively, milling forces from the 6-axis force–torque sensor of the arm (Mini-40, SI-20-1 calibration, ATI) and intraoperative depth of the drill in the trajectory were determined from the navigation of the system. As the milling began, the surgeon observed and followed the force graph on the robot interface to determine the relative position of the diamond burr with regard to the bony overhang. The tunnel approach for millimetric keyhole surgery limits the visual feedback for the surgeon during the drilling of the canonus. In particular, the depth of the burr tip cannot be continuously assessed by vision. Therefore, the surgeon had to mainly rely on the information provided by the system. This situation without a surgical view was out of the surgeon's comfort zone. It is important to note that the surgeon could stop the milling at any point and visually inspect the access, either through the drilled keyhole exposition with an endoscope or through the ear canal with a microscope, by lifting the eardrum. Regardless, this maneuver of lifting the eardrum is necessary for electrode insertion later on and is a rather standardized procedure for a trained otologist. After a stop, the system was allowed to continue according to the surgical plan or for the further milling of a selectable distance. To avoid damage to the inner structures of the cochlea, drilling cannot be further than the target point. If a surgeon suspects that the target point was set wrongly, it is even possible to abort from RACIS and continue manually.

Canonostomy can be divided into four phases depending on the location of the diamond burr (Fig. 3).

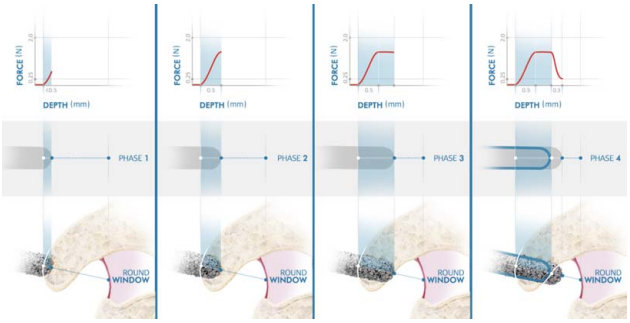

FIGURE 3. Illustration of the inner ear access algorithm of HEARO. The distance between the lateral wall and medial wall points represents the bone thickness of the inner ear access point. The red rectangle under the graph also represents this thickness.

Phase I: The diamond burr reaches the Lateral Wall (LW) of the C and the force profile starts increasing with a steep gradient: the touchdown phase. The depth of the latneral LW of C predicted in the preoperative planning is used as an estimation depth at which the contact should occur. In an ideal case, phase I starts exactly at the estimated LW point in the preoperative planning. However, the surgeon needs to verify this so that the inner ear algorithm does not start prematurely. If the force profile rises before or after the estimated LW point, the surgeon can shift the preset LW line. This automatically shifts the Medial Wall (MW) line to maintain the predicted bone thickness of C.

Phase II: The diamond burr is fully in the C: the plateau phase. If the C is sufficiently thick and approached rather perpendicularly, as simulated in Figure 3, the force profile stabilizes. Perpendicular angles on C are likely to have a plateau phase, whereas more tangential angles may not. The latter represents a grazing shot on C. There is automated feedback between the milling speed and feed-forward rate. When a force threshold of 2.0 N is applied by the system, and if this force is reached, the system automatically adjusts the feed rate to reduce the milling force.

Phase III: The diamond burr has just reached the MW of C: the breakthrough phase. As the bone in front of the drill becomes very thin, it begins to deform locally, resulting in a drop in force. The MW selected in the preoperative planning is used as an estimation at which the breakthrough occurs, but again, the surgeon is observing the force graph and must confirm this moment.

Phase IV: The diamond burr is in the RW niche: the enlarging phase. The diameter of the CI array used here was 0.8 mm. For a frictionless passage, the minimum required size of the canonostomy is 0.9 mm. As the diameter of the drill burr was 1 mm, a further 0.3 mm milling after the MW was required to achieve this. The system automatically stops the milling process at the predicted target depth. The surgeon needs to verify if this predicted target is correct and if insertion is possible. When a larger canonostomy is desired, the surgeon also needs to verify that there is enough distance between MW of C and RW membrane in the RW niche for that specific trajectory.

Placing the Array

The next step in the clinical workflow was to incise the RW membrane. As the surgeon now had to take over from the robotic system, visual exposure became indispensable. An insertion tube, consisting of 2 half-pipes, was placed in the drilled trajectory to avoid a false route of the array into aerated mastoid cells in the temporal bone. The insertion tube (HEARO Protective Barrier, CASCINATION AG) consisted of 2 pieces to allow for its removal from the drilled tunnel alongside the array after insertion, leaving the array in place. The insertion tube was also designed with a step to avoid over-insertion. By selecting a target, the surgeon also decided how far it may be inserted. The 2 composing pieces were of different lengths, allowing the surgeon to see how the array slides through towards the inner ear. The shorter piece was oriented towards the visualizing modality, either endoscope or microscope, through the ear canal. Before insertion, the surgeon performed classical steps of CI surgery according to local or personal habits, such as making an implant bed or using other fixation methods necessary for the PIN implants, which required a tight periosteal pocket and two pin holes drilled into the cortex of the temporal bone. The surgeon needs to position their hands to manually open the RW membrane, insert the array, and take the insertion tube out of the keyhole trajectory in 2 pieces without manipulating the array. Some standard surgical steps have to be performed as well, such as suturing the skin, potentially sealing the RW area depending on the surgeon's preferences, and sinking the complete array into a cortical bone channel to protect against trauma. All of these steps require some training for the surgeon to become acquainted with the view and handlings.

Postoperative Analyses

A postoperative radiological image was taken after the final stage of the procedure to analyze the electrode's insertion status into the inner ear. In addition, the planning software has postoperative analysis features that can even provide a processing strategy for the implant. In addition, an electrophysiological test can usually confirm correct placement by registering the impedance and currents of the implant to verify its functioning. The ultimate proof of a good placement is obtained by testing the hearing function and asymmetric smile on the patient, indicating that no harm was done to the FN. As this was an in vitro cadaver study we assessed the FN function and correct inner ear placement more thoroughly with microscopic x-ray computed tomography (microCT) technology. Laboratory-based microCT provides high-resolution isotropic imaging of the soft tissues of the inner ear. It is possible to visualize the membranous labyrinth, sensory epithelia, and their innervation nerves together with the FN and middle ear with different contrast enhancement techniques.[31]

RESULTS

The rate of successfully completed HEARO procedures was 90%. The first case of 10 RACIS on cadaver heads failed because of a mistake by the surgeon. After taking out the cutting burr, the diamond burr, it was not correctly connected to the drill. Because the diamond burr was further out than the software expected, the first contact point was incorrect. In addition, the burr was not turning and was therefore not cutting, resulting in a high force profile. The system was enhanced to automatically detect and stop the process in such a situation. However, the issue could not be reversed, and the resulting outlier data obliged this case to be excluded from all analyses.

Imaging and Planning Robotic Drilling Surgical Insertion of Array Through the Trajectory

The preoperative CBCT rendered a sufficient image quality to enable the surgeon to segment the crucial anatomic structures and set targets for inner ear access on the dedicated software. The ideal trajectories were subsequently defined. All predicted CDLs were larger than 28 mm and would theoretically allow for

the full insertion of the chosen electrode (Supplementary Table 2, Supplemental Digital Content 2, http://links.lww.com/SCS/H75). However, a prediction depth of 841 degrees in case 2AS may be unrealistic. The mean planned distance and drilling trajectory to FN and ChT were 0.44 mm (SD = 0.13 mm) and 0.35 mm (SD = 0.27 mm), respectively. The mean in-plane angle was 15.5 degrees (SD = 7.7 deg) and the mean planned out-plane angle was 16.8 degrees (SD = 2.9 deg). The mean thickness of C was 1.00 mm (SD = 0.20 mm). The mean depth of C was 24.8 mm (SD 2.1), and the target was set deeper, with an average depth of 26.9 mm (SD 2.0 mm). The parameters of the planned trajectory for each case are presented in Supplementary Table 2, Supplemental Digital Content 2, http://links.lww.com/SCS/H75. The facial recess was too narrow in 4 cases. In three cases, a trajectory was planned closer to the FN—"2AD", "4AD", "5AD"—and one case was planned closer to the ChT: "3AS". The system had to be overruled to be able to drill these trajectories. In case "4AD", the surgeon was unable to segment ChT with certainty and depicted chordal eminence (eminentia chordae tympani or chordiculus). Choosing this reference point for the chorda subsequently pushed the trajectory closer toward the FN.

Robotic Drilling

In 9 cases, it was possible to execute both robotic inner ear drilling from the cortex of the mastoid through the middle ear cavity with the cutting drill according to the surgical plan and a canonostomy with the diamond drill. The system accuracy is presented in Supplementary Table 1, Supplemental Digital Content 1, http://links.lww.com/SCS/H74. The mean absolute drilling accuracy to the FN and the ChT was measured as 0.117 mm (SD = 0.043 mm) and 0.084 mm (SD = 0.067 mm), respectively (Fig. 4). The measured drilling accuracy to the depth of C was 0.11 mm on average (SD 0.07), allowing the inner ear algorithm to start the force profile registration. With a mean depth of C at 24.8 mm (SD 2.1 mm) and a mean depth of target at 26.9 mm (SD 2.0 mm), there seemed to be enough space in every case to advance, and an extra 0.3 mm to perform a canonostomy of a diameter of at least 0.9 mm. Even when the system accuracy at C (0.11 mm SD 0.07 mm) and at target (0.181 mm SD 0.07) was accounted for, the surgeon seemingly had enough space in the RW niche. However, the target might be misplaced during segmentation. The drilling on C was interrupted by the surgeon in three of the nine cases for the intermediate inspection of the access and RW niche. An example of an endoscopic view over the partial canonostomy is shown in Figure 5. The system stopped as planned in all cases at a set target point and at a predefined stopping force of 0.25 N. All cases were visually inspected before continuing to the insertion phase. In 4 cases, the visual inspections clearly revealed that the RW membrane was intact and the surgeon felt comfortable enough with the canonostomy size to continue with insertion. In 5 of the 9 cases, the RW was difficult to visualize because of the angle of approach and small size of the canonostomy. In addition, the imaging quality of the used endoscope and angle of the microscope view through the ear canal were both poor.

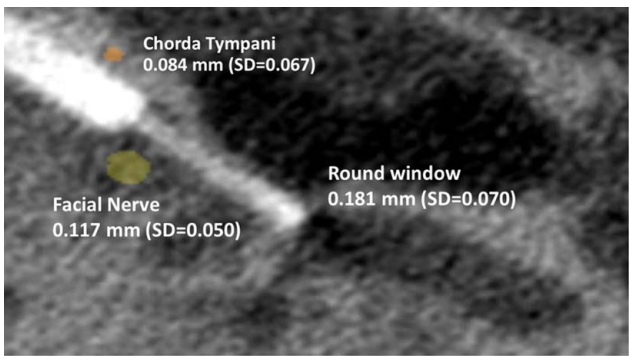

FIGURE 4. The mean absolute drilling accuracy to the FN, the ChT and RW. ChT indicates chorda tympani; FN, facial nerve; RW, round window.

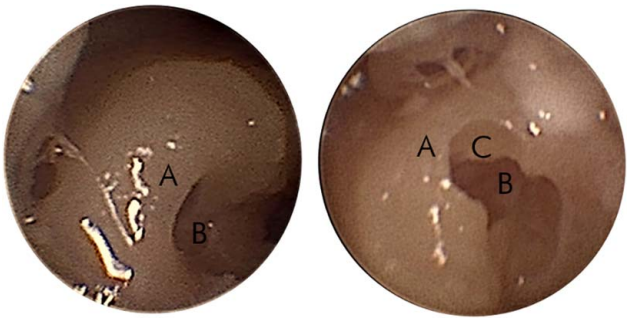

FIGURE 5. Left side shows an example of the endoscopic view of the canonus (A) and the RW niche (B). Right side shows a partial canonectomy (C) during intraoperative surgical check. RW indicates round window.

Surgical Insertion of Array Through the Trajectory

In all 9 cases, it was possible to insert the electrode array into the drilled keyhole tunnel using the insertion tube. In 5 out of 9 cases, the surgeon preferred to enlarge the canonostomy to prepare the insertion. This was either carried out to be able to open the RW or to subjectively assure a swift passage of the array through the canonostomy. The unusual perspective for the surgeon seemed to be a great burden. In only four cases was the surgeon convinced of a full insertion after the removal of the insertion tube. This was later confirmed with postoperative imaging, and the electrode insertion results are shown in Supplementary Table 1, Supplemental Digital Content 1, http://links.lww.com/SCS/H74. The rate of completed HEARO procedures in this cadaver study was nine out of ten in terms of robotic drilling because of one user mistake. However, in terms of a full insertion (100%), the success rate was 4 out of 10. The mean insertion percentage was 94% for the used array that embraced 12 electrodes. Furthermore, classic surgical steps such as embedding the implant housing, drilling the array lead into the bone, and even sealing the RW niche did not seem to be of great difficulty for a trained CI surgeon.

Postoperative Imaging and Quality Analyses

In 9 cases, the average insertion was 525 degrees, which is equivalent to 1.5 turns of the cochlea, and the min and max insertion angles were recorded as 442 degrees (1.2 cochlear turns) and 622 degrees (1.7 cochlear turns), respectively (Supplementary Table 1, Supplemental Digital Content 1, http://links.lww.com/SCS/H74). Furthermore, the postoperative image did not show any tip fold-overs of the arrays or scala deviation in the 9 cases of completed HEARO procedures. No collision or damage to critical structures could be substantiated. There were no collisions observed with FN and ChT even in the 4 cases of "2AD", "4AD", "5AD", and "3AS" that had unsafe trajectories in terms of distance. For case "5AD", the planned distance to the ChT was 0.020 mm and the intraoperative analysis showed a distance of 0.001 mm to the ChT, which

means that they are practically touching. In all 9 cases, the electrode was found to be within the ST, and no scala deviation or tip fold-over was observed on the postoperative image (postoperative image with CI in situ and potentially one that is segmented with the electrodes).

DISCUSSION

The HEARO procedure offers RACIS that warrants inner ear access. It can execute a surgical plan automatically under the supervision of a surgeon. In contrast, telemanipulators allow surgeons to perform a procedure with robotic arms and a camera.[32] RACIS has delivered safe middle ear access, already bypassing the facial recess in 2017 with the Otobot system.[11] The FN is nearly 19.22 mm away from the cortex of the mastoid.[33] In this study, we aimed to drill inner ear access on the C with a mean depth of 24.8 mm (2.1 mm SD) in our data. This tiniest advancement in distance of ~2 to 3 mm took 2 to 3 years of development and research in RACIS. Nevertheless, here, we confirm that the HEARO procedure can provide a canonostomy for successful insertions that is safe to the FN. By achieving this, it has started a new era in RACIS. Many mechanical, biological, and even anatomical parameters of inserting an array into the human cochlea are unknown. Individualized inner ear access that considers all of these parameters is much more fundamental for future-generation robots in otology than merely controlled insertion speed devices. Future RACIS has to push these borders and face challenges on a micro-scale that no surgeon has faced before.

This preclinical study resulted in an overall electrode insertion percentage of 94%. However, more attention should always be paid to the specific electrodes that could not be inserted into the cochlea. One explanation for why we did not reach 100% is because the array lengths were not tailored: we chose 28 mm electrodes for every case, whereas, clinically, this would be tailored.[5] The 2 electrodes that remained outside the cochlea in case 2AS could perhaps be attributed to its predicted CDL of 29 mm. However, case 5AS was predicted to have a CDL of 35.8 mm, and, additionally, 2 electrodes remained out of the cochlea. An additional consideration for the difficulty with cadaveric insertions, specifically with flexible lateral wall electrode arrays, is the lack of perilymph or fluid in the cochlea, which allows the electrode array to use hydrostatic forces to advance more easily into the cochlea. Another explanation could be the use of formalin to conserve the cadavers. It has been reported before that postmortem insertions are more challenging when the cochlea is exposed to formalin.[34] In general, insertions in vivo are easier because of less intracochlear resistance of vital tissues. The clinical report on the Otobot study demonstrated safe middle ear access in 6 out of 9 cases, with an overall electrode insertion percentage of 90% even after performing a manual canonectomy, which warrants larger inner ear access.[12] Moreover, all cases were screened to be within safety margins and, in 2 cases, the electrode length choice was tailored to a patient's characteristic CDL by opting for a 24 mm array.

It emphasizes that individualized inner ear access as demonstrated here is the next step in RACIS and is a step in the right direction. Individualized inner ear access has many challenging determinants. Firstly, patient-specific determinants such as anatomical variants determine the necessity for an individual approach and potentially also hearing levels, but that is out of the scope of this cadaver study. From lateral to medial, the following critical anatomical structures are accounted for in today's models for RACIS: the F, the C, and the CDL.

Secondly, device-specific determinants such as the diameter of the burr have an important role. The cutting burr size used here was 1.8 mm, causing 4 out of the 10 cases to be ineligible RACIS because of a mitigation protocol for FN damage.[27] In this study, this applied mitigation protocol demonstrated a large safety margin for FN because three cases that would not have passed the screening did not show FN damage on postoperative imaging. In the postoperative image of case 5AD, there might have been contact between ChT and the drilled trajectory, although a distance of 0.01 mm was estimated. Every experienced CI surgeon has probably carried out this as well when drilling a posterior tympanotomy. In some otological procedures, even ChT needs to be touched and moved away, that is, stapes surgery. Although not all patients incur harm from a little touch, RACIS may not allow for this freedom. The screening of suitable patients remains important for today's RACIS.

Thirdly, the strategy used to enter the inner ear is a key determinant for individualized inner ear access. This study was the first to apply the in-plane and out-plane angles of a trajectory to the inner ear by RACIS in a cadaver study.[29] The mean in-plane angle was 15.52 degrees and the mean out-plane angle was 16.80 degrees. Angles closer to zero represent more ideal trajectories for insertion but are also closer to FN (angles of zero degrees would either go through FN or stapes).[29] A negative out-plane angle should be avoided as it causes a scale deviation in the electrode. Neither negative angles nor scale deviation were seen in this study. Case 2AS, which had the highest in-plane angle in our series, indeed had two electrodes out of the cochlea (Supplementary Tables 1, Supplemental Digital Content 1, http://links.lww.com/SCS/H74 and 2, Supplemental Digital Content 2, http://links.lww.com/SCS/H75). However, this was the same case with a CDL of 29 mm, resulting in a strong suspicion that the array was simply too long. In fact, this highest angle of 31.09 degrees (mean 15.52 deg) in 2AS was probably an outlier. The highest in-plane angle was 21.66 degrees (not such an outlier, with a mean in-plane angle of 16.80 deg) and correlated with a full insertion. Conversely, the lowest out-plane angle had one electrode out, whereas the lowest in-plane angle had a full insertion. It is clear that our data here are too limited to perform any statistical analyses or attempt to find a trend in the correlation of angles and insertion percentage. This would not only require more data but also potentially an in vivo study as insertion is difficult in cadavers. Although they are popular parameters, too much emphasis may be placed on these angles may be. The ideal trajectory to the cochlear basal turn is defined as a straight line, which was also the case in this study. These straight lines also need to be coaxial with the central axis of the ST, allegedly to avoid intracochlear damage. The ideal angles can never be implemented for such trajectories because they would go through the FN.[16] Moreover, classic (manual) CI surgery never guarded a straight line from the cortex. It is worth noting that the human cochlear is curved by nature and endeavoring to achieve a straight-line insertion must have been raised as a result of other considerations. The safety of extra-cochlear structures such as the FN and ChT or minimizing noise exposure by the drill are good arguments for striving for a straight drill trajectory. However, inevitably, somewhere after insertion, the array needs to deviate from that straight line to curl in the cochlea. Therefore, where the target point is set in RACIS is also very important because it will also determine these angles of approach. Further research will either demonstrate the optimal values of in- and out-plane angles or come up with another inner ear strategy. In addition, future research should ensure that robot-based assistance for CI array insertion, which has been successfully performed in

adults[35] and children[36] previously, is integrated into the HEARO procedure. This is because, in a cadaver study, it was shown that intracochlear trauma can be reduced with optimized robot-based array insertion,[21] and, in another study, the number of displaced electrodes after robot-assisted insertion was lower than manual insertion.[37]

The HEARO procedure studied here can execute crucial steps in minimal invasive RACIS. It offers the possibility to plan and execute a direct keyhole tunnel approach to the cochlea and accommodates the desired and individualized inner ear access. Constructing an autonomous system demands very much of the required technology. Under the current technological developments, it does not seem possible for a robot to replace a surgeon. However, that does not eliminate the chance of its occurrence in the future works. The more complex tasks that a robot is required to perform, the more challenging the facets that are usually involved. Anatomic variants such as patient awakening and changes in blood pressure are a great challenge for programmers, and unexpected bleeding is perhaps too demanding for robotic surgery, whereas a surgeon flawlessly anticipates such aspects based on previous surgical training. Nevertheless, the more steps that a robot can autonomously perform in a procedure, the more standardized the surgical outcome can become. Therefore, otological robots are always of interest for otologists because they value accuracy and precision very highly in their procedures. They provide accuracy and precision with surgical navigation and robotic surgery precision using preoperative radiological data.[38] In other words, a robot always outperforms human capabilities regarding dexterity, acuity, and consistency. Moreover, a well-programmed robot does not have a surgical learning curve but rather a very difficult development phase, which will never harm a patient but will probably harm the investors.

CONCLUSION

This study demonstrated the feasibility of RACIS using the HEARO procedure in a preclinical cadaver study. The accuracy of performing a robotic workflow, or, more specifically, robotic inner ear access, was reported to meet the current criteria for insertion. In 9 out of 10 experiments, the surgeon could complete the HEARO procedure, with a mean insertion percentage of 94%. Future generations of RACIS will focus on improving imaging CBCT, automated segmentation and trajectory, robotic insertion with controlled speed, and potentially haptic feedback.

Institutional Review Board Statement

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by Bernese cantonal ethical commission, Switzerland (KEK BE 2018-00770).

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