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Journal
The Laryngoscope, 123(5)

ISSN
0023-852X

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Publication Date
2013-05-01

DOI
10.1002/lary.23833

Peer reviewed

The Laryngoscope

Transcanal Approach for Implantation of a Cochlear Nerve Electrode Array

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Objectives/Hypothesis: To evaluate a transcanal approach for placement of a stimulating electrode array in the cochlear nerve.

Study Design: Prospective cadaveric temporal bone study.

Methods: Ten human cadaveric temporal bones were dissected. Both a facial recess approach with mastoidectomy and a transcanal approach using the novel technique were performed in each bone. A middle fossa dissection of the internal auditory canal was performed to confirm the position of the electrode in the cochlear nerve.

Results: The transcanal approach offered a direct approach to the cochlear nerve in all 10 bones. The procedure was quicker than the facial recess approach and did not endanger the facial or chorda tympani nerves. Inspection of the medial end of the internal auditory canal confirmed correct placement of the electrode in the cochlear nerve. In contrast, anatomical constraints, specifically the position of the facial nerve, blocked access to the cochlear nerve by the facial recess approach in three of the specimens to achieve the exposure to place the electrode at a perpendicular angle to the cochlear nerve. Sacrifice of the chorda tympani was necessary in five of the seven bones in which the cochlear nerve could be accessed.

Conclusions: The transcanal approach offers a simpler, safer approach for cochlear nerve implantation compared to the facial recess approach. This approach can be accomplished in less time and avoids the hazards of dissection around the facial nerve. Use of the proposed approach will facilitate development of intraneural stimulation for an improved auditory prosthesis.

Key Words: Cochlear nerve, cadaver, facial recess approach, human, implant, temporal bone, transcanal approach.

Level of Evidence: N/A.

***Laryngoscope*, 123:1261–1265, 2013**

INTRODUCTION

Present-day cochlear implants consist of an array of electrodes inserted into the scala tympani of the cochlea. The electrodes are intended to replace the function of missing hair cells by stimulating the spiral ganglion cells electrically. Since the 1980s, cochlear implants have been used extensively as the standard surgical option for patients with severe-to-profound sensorineural hearing loss.[1] Recent studies in animals have demonstrated that stimulation of the cochlear nerve with a penetrating electrode array offers significant advantages over a cochlear implant.[2] Such cochlear nerve electrode arrays could provide increased spectral resolution, a greater number of independent channels of stimulation, and access to a broader range of frequencies; plus they would require lower activating current and power consumption and would not require normal cochlear anatomy. Early attempts at cochlear-nerve stimulation with penetrating electrodes used bundles of platinum-iridium wire electrodes, each wire 75 μm in diameter. Performance was limited by insertion trauma and imprecise placement.[3] New technological advances have led to the development of new high-density micromachined electrode arrays that would be better suited for implantation in the cochlear nerve in human patients.

Cochlear implants most often are placed through a transmastoid facial recess approach, which consists of canal wall-up mastoidectomy, posterior tympanotomy, and a cochleostomy in the region of the round window.[4] One might consider a variation of the facial recess approach for placement of penetrating auditory-nerve arrays. Although the facial recess approach has been widely used for many years throughout the world, it is a delicate and time-consuming procedure that requires considerable training and expertise of the otologist.[4,5] Facial nerve damage occurs in 0.2% to 1% of cases,[4] and the chorda tympani can be injured during the posterior tympanotomy in 5.2% to 20% of cases.[6] This procedure is made especially challenging in patients with cochlear ossification or contracted mastoids.

In the current study, we evaluated a transcanal approach for placement of cochlear nerve-stimulating

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Editor's Note: This Manuscript was accepted for publication September 26, 2012.

Supported by the National Institute of Health (NIH), National Research Service Award 1T32DC010775-01 from the University of California, Irvine (S.K.), and NIH Contract N263-2009-00024C (J.C.M.). The authors have no other funding, financial relationships, or conflicts of interest to disclose.

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DOI: 10.1002/lary.23833

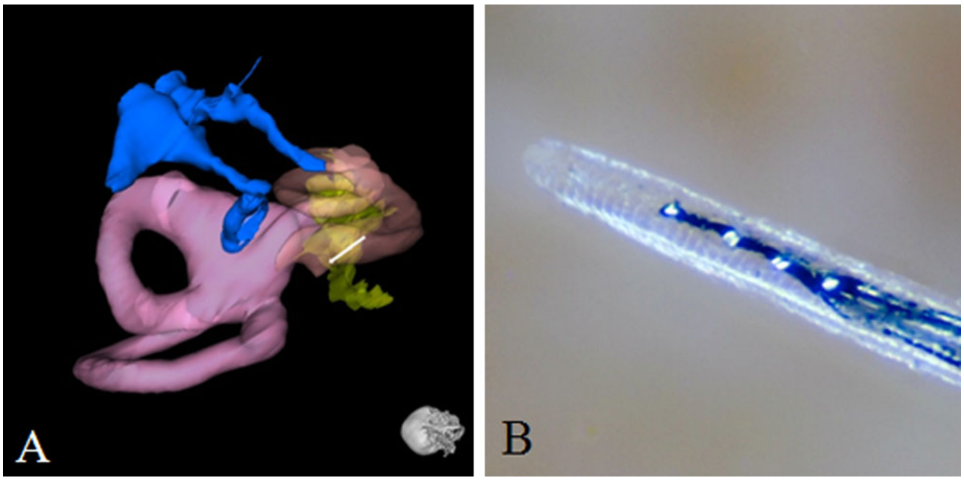

Fig. 1. (A) A schematic model of the inner ear including the site and angle of the electrode insertion (from http://research.meei.harvard.edu/otopathology/3dmodels/temporal_bone.html), accessed June 6, 2012. (B) Sample microelectrode array, which resembles what may be used in human neural tissue in future, by Modular Bionics, Inc. (Irvine, CA) (Patent Pending). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

arrays. Transcanal and facial recess approaches were compared using a cadaveric temporal bone model.

MATERIALS AND METHODS

This study was exempt from the Institutional Review Board. In 10 fresh cadaver temporal bones, the modiolus was accessed using the transcanal method, an opening was made in the wall of the modiolus, and a 125-μm-diameter tungsten wire was inserted to simulate a single-shank electrode array. The tungsten wire has a larger cross-sectional area compared with the single-shank 16-electrode arrays used in functional studies in animals[2]—an intraneural array suitable for use in humans is not yet available. Proper placement of the wire in the cochlear nerve was confirmed by inspection of the wire in the nerve at the meatus of the internal auditory canal (IAC). In each specimen, a posterior tympanotomy approach was performed after the transcanal approach had been performed in the same specimen on the same side. The modiolar opening was visualized through the facial recess approach. In each bone, the senior author (H.R.D.) made an evaluation of whether a facial recess approach would have been possible to perform the modiolar opening. The primary criterion used was the ability to place the microelectrode into the modiolar opening without damage to the facial or chorda tympani nerve.

Microcomputed tomography (CT) imaging was obtained from one of the cadaver temporal bones after performing the transcanal approach for viewing the position of the tungsten wire relative to bony structures. For this purpose, the tungsten wire used as an electrode was secured to the cochleostomy using bone wax. The images were obtained using Inveon CT scanner (Siemens Medical Solutions, Inc., Hoffman Estates, IL), with a large-area detector (4,096 $\times$4,096 pixels, 10 $\times$10 cm field of view). The CT projections were acquired with the detector-source assembly in medium-high magnification mode and rotating in steps around the object over 360 degrees and 1 degree/step. The X-ray source settings were 80kVp/5mA and the exposure time was 600 ms.

Surgical Approach

After postauricular and periosteal incisions, a tympanomeatal flap was raised without making canal incisions. The tympanic membrane and flap were raised to have a clear view of the posterior mesotympanum. A 2-mm trough was drilled in the posterior-superior quadrant of the external canal to allow for placement of the electrode wires. The bony annulus might have needed to be drilled posteriorly to obtain a clear view of the round window niche. The round window niche was drilled to fully visualize the round window membrane. The drilling was continued anterior to the round window membrane with a 1-mm bur, and the scala tympani was opened to view the modiolus. Using a 0.5-mm bur, the modiolus was opened by drilling toward the cochlear nerve (aiming posteromedially). The level of this opening provided access to the cochlear nerve at a level basal to the spiral ganglion cell bodies of the basal cochlear turn. The microelectrode was placed into the cochlear nerve. A schematic model of the inner ear, including the site and angle of the electrode insertion and a sample microelectrode array, which resembles what may be used in the future are depicted in Figure 1.[7] The electrode was advanced gently until the full length of the segment of the electrode containing the stimulation sites was placed. In a live patient, the electrode wires could be secured into the previously drilled trough using hydroxyl apatite bone cement, covered by bone pate and a fascia graft. The cochlea would be sealed with bone wax, fascia, and fibrin glue. The tympanomeatal flap could be replaced and the canal could be packed with gelfoam.

RESULTS

Ten formalin-fixed temporal bones were drilled (5 right ears, 5 left ears). A reliable modiolar opening was made with the transcanal approach in all bones (Fig. 2), and a suitable position of the electrode in the cochlear nerve was confirmed by inspection at the acoustic meatus. Micro CT imaging performed in one of the bones also revealed good positioning of the electrode in the cochlear nerve relative to the internal auditory canal (Fig. 3). We also confirmed that the electrode was in the correct position by passing the tungsten wire through the modiolar opening and seeing the end exit the internal auditory canal. This confirmed the placement of the electrode in all the specimens. The facial recess approach yielded an appropriate exposure to the modiolar opening in only seven (70%) of the 10 bones without the sacrifice of the facial nerve. In five of the seven bones where exposure of the modiolar opening was accessible with the facial recess approach, the chorda tympani nerve had to be sacrificed. In addition, the bony

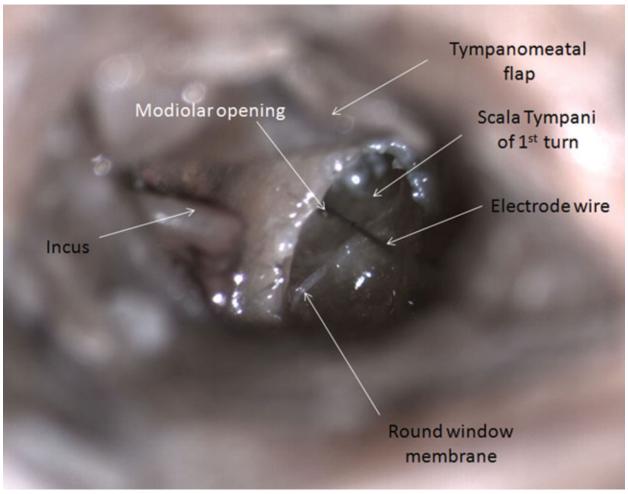

Fig. 2. A completed transcanal approach in a cadaveric human temporal bone preparation. The round window membrane has been preserved as a reference point. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

fallopian canal had to be maximally thinned to obtain the exposure.

DISCUSSION

Transcanal approach to cochlear nerve implantation without mastoidectomy has several advantages. Most significantly, the risk of facial nerve damage in the mastoid is reduced to almost zero as the drilling is performed away from the facial nerve. Facial nerve damage is a recognized complication in classic cochlear implantation using the mastoidectomy and posterior tympanotomy, and its incidence in larger series has been reported to be 0.3 to 1.7 %.[5,6,8] It is caused by either direct trauma due to the drilling during posterior tympanotomy or, more frequently, by an indirect heat effect through the bone. This occurs commonly during cochleostomy, when rinsing and cooling of the thin bony layer covering the facial nerve in the mastoid portion is not sufficient and the shaft of the bur causes heating of the fallopian canal.[9] The second advantage of the new technique is the reduced operation time, as no mastoidectomy cavity needs to be drilled.

The facial recess approach offers somewhat restricted visualization of the round window and cochlea. Indeed, several instances of electrode malpositioning and electrode misplacement have been reported in previous studies using the facial recess approach for implantation of conventional cochlear implants.[5,10,11] The visualization issue is particularly important in approaching the cochlear nerve, because the opening of the modiolus must be performed precisely to ensure that the electrode array has access to fibers from the entire cochlear spiral. In the current study, the facial recess approach did not allow proper placement of the intraneural electrode in the proper angle in 30% of the temporal bones. The electrodes could be placed in 100% of the bones using the transcanal approach. There were two anatomic constraints while trying to reach the modiolus through the facial recess approach. First, the chorda tympani nerve blocked a posteriorly angled view onto the cochlea. Second, even with the removal of the chorda tympani nerve, we found that in 30% of the specimens the cochlear position and rotation precluded a direct access to the modiolar opening in the perpendicular angle necessary to feed the electrode properly into the cochlear nerve. The access to the modiolar opening should allow for the electrode to be placed in a perpendicular and direct fashion. The placement of the straight, rigid, shank electrode was not possible from the facial recess approach in three of the 10 specimens. In these specimens, only a tangential angle could be obtained to the cochlear aperture, which limited the proper placement of the electrode.

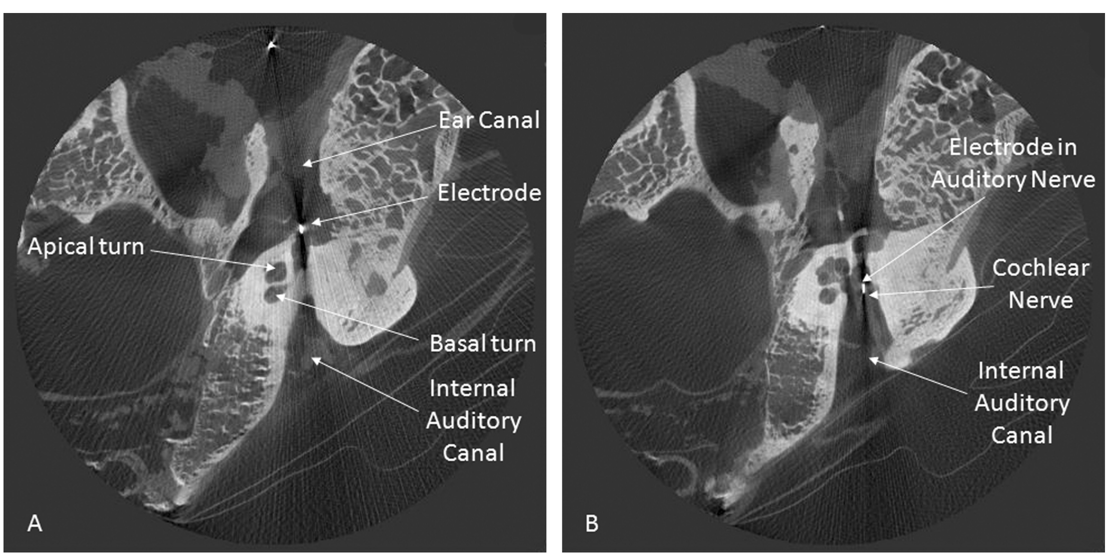

Fig. 3. Micro-computed tomography images of the cadaveric temporal bone demonstrating (A) the electrode entering the basal turn cochleostomy, and (B) placement of the electrode in the cochlear nerve.

Transcanal approach for the cochlear nerve implant theoretically could be associated with an increased risk of infection, meningitis and/or electrode extrusion due to the proximity of the electrode to the canal. However, the transcanal approach for cochlear implantation performed in multiple different centers has not been found to be at an increased risk of electrode exposure, infections, or meningitis. There are seven studies in the literature that have described different modifications of the transcanal approach for cochlear implantation on a total of 470 patients, with a range of follow up of 6 months to 7 years.[9,10,12–16] No cases of meningitis or CSF leakage have been reported and there only has been one reported case of electrode extrusion among the 470 patients.[16] Another potential complication of our approach could be a damage to the spiral ganglion cells in the basal turn while approaching the modiolus through the scala tympani. However, we think that the probability of direct damage to spiral ganglion cell bodies is very low, because the electrode array will be implanted basal to the basal cochlear turn. Long-term (>60-day) implantations in animals are ongoing in our center. We will monitor changes in threshold for electrode stimulation over the 60 days and will do a histological analysis postmortem.

It is possible that performing both techniques on the same cadaver bone may have influenced the results of the current study. Although this could be a potential limitation, it is noteworthy that the anatomy and characteristics of each temporal bone could be different. Therefore, splitting the cadaver bones into two separate groups could have resulted in one group randomly receiving the bones that have a favorable anatomy, and then the study would have been biased. Applying both transcanal and facial recess approaches on the same temporal bones was feasible for this study since alterations of the temporal bone anatomy by the two described techniques have minimal overlap. In other words, performing any of them before the other would not bias the outcomes as they implement two different trajectories. Having separate groups of temporal bones for each approach is feasible, but it would require many more cadaver temporal bones to reduce the potential bias.

Our study is the first to describe a transcanal approach for the cochlear nerve implant. Currently there are only two other published articles in the literature that describe surgical techniques for cochlear nerve electrode implantations. Both studies tested the "Utah" electrode array, which has up to 20 shanks, with one electrode site per shank. The first study by Badi et al.[17] described the cochlear nerve implantation through an extended facial recess approach, with sacrifice of the chorda tympani to access the cochlear nerve in two human cadaveric temporal bones. Using the same surgical technique, Miller and Hillman evaluated the rate of cerebrospinal fluid (CSF) leakage following cochlear nerve implant in 10 temporal bones.[18] They found a quantifiable CSF leakage in 80% of the specimens. Still, there is not any electrode array suitable for implantation in human patients, but one would assume that a human array would resemble the device used in short-term functional studies in animals.[2] The array in the current study was a single shank, 15-μm thick, 150-μm wide, and tapered to $\approx$30 μm wide near the most distal stimulating site. The 16 electrode sites were circular, 703 μm^2 in area, spaced at 100-μm intervals, center to center. The use of a single-shank electrode array would require a smaller modiolar opening, which would allow for a potentially lower chance of CSF leakage and a better chance at CSF leakage control. A single-shank device achieves a large number of simulation sites with a minimum number of potentially traumatic insertions through the cochlear nerve. Pulsation of the cochlear nerve against a multi-shank array may theoretically lead to a higher likelihood of shredding of the nerve than a single shank. Long-term results of animal studies are underway to assess the histology of the nerve in the long term.

In comparison to the facial recess technique, the transcanal approach provides a better view of the modiolus and allows for better placement of an electrode perpendicular to the long axis of the nerve. In addition, the better exposure of the middle ear allows for better control of a possible resultant CSF leakage during this procedure. The surgeon can obliterate the cochlea with tissue and, if necessary, even close the Eustachian tube to control a CSF leakage, which would be difficult to perform using a facial recess approach given the wider opening into the middle ear afforded by the transcanal method. Finally, transcanal surgery would allow for preservation of the chorda tympani in all cases.

CONCLUSION

The transcanal approach offers a simpler, safer approach for cochlear nerve implantation compared to the facial recess approach. This approach can be accomplished in less time and avoids the hazards of dissection around the facial nerve. Use of the proposed approach will facilitate development of intraneural stimulation for an improved auditory prosthesis.

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