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Minimally-Invasive, Image-Guided Cochlear Implantation for Pediatric Patients – Clinical Feasibility Study

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Abstract

Objective—Minimally-invasive, image-guided cochlear implantation (CI) involves accessing the cochlea via a linear path from the lateral skull to the cochlea avoiding vital structures including the facial nerve. Herein, we describe and demonstrate the feasibility of the technique for pediatric patients.

Study Design—Prospective

Setting—Children's Hospital

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The results were presented at the AAO-HNSF meeting in Vancouver, BC, Canada on October 1, 2013 by Dr. Labadie.

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Subjects and Methods—Thirteen pediatric patients (1.5 to 8 years) undergoing traditional CI participated in this IRB-approved study. Three fiducial markers were bone-implanted surrounding the ear, and a CT scan was acquired. The CT scan was processed to identify the marker locations and critical structures of the temporal bone. A safe linear path was determined to target the cochlea avoiding damage to vital structures. A custom microstereotactic frame was fabricated that would mount on the fiducial markers and constrain a tool to the desired trajectory. After traditional mastoidectomy and prior to cochleostomy, the custom microstereotactic frame was mounted on the bone-implanted markers to confirm that the achieved trajectory was safe and accurately accessed the cochlea.

Results—For all the thirteen patients, it was possible to determine a safe trajectory to the cochlea. Custom microstereotactic frames were validated successfully on nine patients. Two of these patients had inner ear malformations, and this technique helped the surgeon confirm ideal location for cochleostomy. For patients with normal anatomy, the mean and standard deviation of the closest distance of the trajectory to facial nerve and chorda tympani were 1.1 ± 0.3 mm and 1.2 ± 0.5 mm, respectively.

Conclusion—Minimally-invasive, image-guided CI is feasible for pediatric patients.

Introduction

Cochlear implants (CI) overcome sensorineural hearing loss (SNHL) by direct stimulation of the auditory nerve. An electrode array is surgically inserted into the cochlea placing electrical contacts in close proximity to the auditory nerve. This electrode array is coupled to an internal receiver beneath the skin. An external receiver sends a signal through the skin to the internal receiver, which forwards it to the electrode array in the inner ear. Cochlear implantation has been performed on patients as young as five months of age.¹

The current surgical technique, mastoidectomy and posterior tympanotomy, is based on wide surgical exposure to clearly identify anatomic landmarks and avoid injury.² Mastoidectomy involves drilling away the cortical bone to identify major landmarks of the mastoid including the incus, the horizontal semicircular canal, the facial nerve, and the chorda tympani. A posterior tympanotomy is then performed to open into the middle ear via the facial recess, bounded by the facial nerve posteriorly and the chorda tympani anteriorly. The round window (RW) of the cochlea is then identified and the cochlea entered either via the RW or via a separate cochleostomy to allow insertion of the electrode array.

A minimally-invasive approach has been proposed that involves drilling a narrow, linear path from the lateral skull to the cochlea via the facial recess while avoiding damage to critical structures (e.g. facial nerve, chorda tympani) (Figure 1).^{3–7} This path is determined based on anatomical information provided in the patient's CT scan. To clinically achieve accurate, safe drilling along the desired path, custom microstereotactic frames that mount on bone-implanted markers and constrain the drill along the desired path have been utilized. Targeting accuracy of this microstereotactic frame system has been measured to be 0.37 ± 0.18 mm *in vitro*.⁸ Feasibility of this approach has been validated *in vitro*^{3,4,7} and *in vivo* on adult patients^{5,6,8} (Figure 2).

We propose that this minimally-invasive, image-guided approach can be used to perform CI on pediatric patients even though anatomical differences exist between adults and pediatric patients.⁹ We present a clinical validation study to test the feasibility of this technique on pediatric patients.

Methods

Institutional review board (IRB) approval was obtained. Patients under 18 years old undergoing traditional CI surgery were recruited for participation in the study. For each patient the following procedures were implemented with informed consent obtained from the patient and parents/guardians.

1. **Preoperative path planning:** Prior to surgery, path planning was performed on a preoperative CT to determine a safe linear path that targets the cochlea. Custom computer programs have been developed to automate this process. First, vital structures of the temporal bone (i.e. facial nerve, chorda tympani, ossicles, ear canal, cochlea, and semicircular canals) were automatically segmented using model-based algorithms that we have developed.^{10,11} Then, based on these segmentations, a safe trajectory that avoids damage to adjacent structures and targets the cochlea (i.e. aligns coaxially with the basal turn and places a 0.5 mm diameter, 2 mm long cylinder in the scala tympani portion of the cochlea) was automatically computed¹² (Figure 1). This process took approximately five minutes on an Intel Xeon 2.4 GHz dual quad-core 64-bit machine with 16 GB RAM. The surgeon then verified the results confirming the safety of the planned path. Manual modifications to the segmentations and the planned path were performed as required.
2. **Implantation of fiducial markers:** In the operating room, after the standard skin incision for traditional CI surgery, typically about 5 cm long, a fiducial system with three spherical markers was attached rigidly to the skull. In addition to acting as fiducial markers for registering the CT scan to the patient's anatomy, these spheres act as a means to rigidly attach the custom microstereotactic frame to the patient.

Depending upon the thickness of the skull, one of the following two methods was used to attach the fiducial system. (1) Bone-implanted anchors were placed at three locations – typically the mastoid tip, supra-helical region, and at a posterior location. An extender with a spherical top was attached to each of the anchors (Figure 3(a)). This method was used for patients for whom the surgeon felt that the skull was thick enough to support the anchors which have 4 mm depth of penetration. (2) A self-retaining retractor was modified by attaching three spherical fiducial markers to it as well as flanges allowing it to be screwed in to the skull using small facial plating screws (Figure 3(b)). Implantation of the fiducial system took about nine minutes.
3. **Acquisition of intraoperative CT scan:** A CT scan was acquired in the operating room using the xCAT ENT mobile CT scanner (Xoran Technologies, Ann Arbor, MI, USA) with a voxel size of 0.4 mm isotropic. Time taken for acquisition of this

intraoperative CT scan was about seven minutes. After the CT scan was acquired, the surgeon continued to perform traditional CI surgery.

4. Intraoperative path planning: The preoperative and intraoperative CT scans were registered together. This process was performed semi-automatically. First, the scans were manually translated and rotated until a coarse alignment between the scans was achieved. Then, the registration was refined by matching the intensity distributions of the scans.^{13,14} The centers of fiducial spheres were localized in the intraoperative CT using image processing techniques.¹⁵ This step took approximately five minutes following which the surgeon verified the registration, fiducial localization, and safety of the planned path.

If a preoperative CT was not available or there were significant differences in anatomy in the interval from preoperative CT to surgery, a trajectory was manually chosen by the surgeon. Given the current limitations in image quality of the intraoperative CT, automatic segmentation was not performed on intraoperative CTs.

5. Design and fabrication of custom microstereotactic frame: Based on the locations of the spherical fiducials and the desired path, a custom microstereotactic frame was designed and manufactured using a standard computer-numeric-control (CNC) milling machine.⁸ The frame was then transported to the operating room and sterilized. Design and fabrication of the microstereotactic frame including transportation to the operating room took approximately ten minutes and sterilization approximately twelve minutes.
6. Validation of the trajectory: Prior to entering the cochlea, the surgeon secured the microstereotactic frame on the spherical markers (Figure 4). Sham drill bits of 1 and 2 mm diameter were passed through the center of the target hole of the frame and visualized via an endoscope. The path achieved by the sham drill bits was photo-documented (Figure 5) to measure the approximate distance of the achieved trajectory from the facial nerve and the chorda tympani and to confirm targeting of the cochlea. This step took about ten minutes.
7. Removal of hardware: If individual anchors were used (option (1) of Step 2), they were removed after validation. If the modified retractor was used (option (2) of Step 2), it was removed after completion of CI prior to skin closure. This step took approximately two minutes.

Distance Measurements

Post-operatively, the endoscope pictures were analyzed to compute the approximate distance from the achieved trajectory to the facial nerve and chorda tympani (Figure 5). A line (solid straight line, Figure 5) was drawn across the diameter of the drill and used as a scale for scaling. Distances from the centerline of the drill to the closest points on bone covering the facial nerve and chorda were measured and scaled using the drill tip diameter.

Results

Thirteen pediatric ($n=13$) with age range from 19 months to 8 years participated in the study. For all thirteen patients, it was possible to plan a linear path from the lateral skull to the cochlea via the facial recess that avoided both the facial nerve and the chorda tympani.

For five patients, the modified retractor was used as the fiducial system. For eight patients, individual anchors with spherical extenders were used. The trajectory was planned manually by the surgeon for four patients and automatically for nine patients.

In four patients, validation in the operating room could not be performed for the following reasons: For one patient, due to the limited skin incision made, there was difficulty spreading the anchors wide enough to design a microstereotactic frame. For two patients, due to technical difficulties, delays were encountered with manufacturing of the microstereotactic frame. As such, the frame could not be delivered to the sterile field before cochleostomy. For one patient, validation showed that the path was blocked by the most lateral aspect of the external auditory canal. Rather than remove additional bone, the surgeon aborted the validation.

Validation was successful in the nine patients for whom it could be performed with success defined as passing a 1 mm diameter drill bit through the facial recess without touching the facial nerve or the chorda tympani and targeting the cochlea. The closest distances from the trajectory to the critical structures measured from the endoscope pictures are reported in Table I. For patients with normal anatomy, the mean and standard deviation of the closest distance of the trajectory to the facial nerve and chorda tympani were 1.1 ± 0.3 mm and 1.2 ± 0.5 mm, respectively.

Two of the four patients for whom manual trajectory planning was performed had inner ear malformations, and the image-guided technique helped the surgeon confirm cochleostomy location. Prior to mounting the microstereotactic frame, the surgeon marked the expected location of the cochlea for these two patients. The microstereotactic frame, which targeted the cochlea at a location manually picked in the intraoperative CT, targeted the same location marked by the surgeon and provided a second check of the complex anatomy prior to cochleostomy.

Discussion

We present a minimally-invasive, image-guided approach to access the cochlea on pediatric patients undergoing CI. This approach involves drilling a narrow, linear path from the lateral skull to the cochlea via the facial recess without damaging vital anatomy including the facial nerve and chorda tympani. To drill accurately along the desired path, bone-implanted markers and a custom microstereotactic frame were utilized. In our prior studies, we have shown the feasibility of this technique on adult patients.^{5,6} The current study shows that this technique is feasible in pediatric patients with some modifications to the software and hardware.

On the CT scan of all thirteen patients, it was determined that a safe linear path from the lateral skull to the cochlea avoiding damage to critical structures was possible. Validation of the path guided by the custom microstereotactic frame was performed in the operating room if it was possible to perform such without significantly altering the traditional surgical approach and/or if manufacturing of the frame occurred within a reasonable time frame and did not significantly extend the length of general anesthesia. Validation with a microstereotactic frame could not be performed on four patients due to the reasons detailed in the Results section.

For one patient, the microstereotactic frame could not be designed to work as the anchors were located too close together such that one of the legs overlapped with the target hole. Rather than extending the surgical incision, relocating the anchor, and rescanning, this validation was aborted in the interest of patient safety. For the two patients where the microstereotactic frame could not be delivered within the surgical timeframe due to technical difficulties with either software or hardware, the surgeon proceeded with cochleostomy and insertion of the electrode array so as to not significantly increase the length of general anesthesia. For the patient where the sham drill bit hit the lateral external auditory canal, the surgeon had removed bone that was deemed necessary for performing the CI and additional bone take down was not clinically indicated.

While these four patients (30% of the 13 patients) could not undergo intraoperative validation, implementation of novel surgical technology is often associated with unforeseen hurdles. Especially in a pediatric population where additional safeguards for participation in research are mandated, we feel that our 70% validation rate is quite strong. Additionally, the experience with each of the four patients that failed to undergo validation provided us with knowledge that improved the process.

The distances measured using the endoscope pictures (Table I) shows that the achieved trajectory using the microstereotactic frame did not violate either the facial nerve or the chorda tympani. It is important to note that these distances are approximate since they are based on two-dimensional pictures of three-dimensional anatomy and on manual assessment of anatomical structures in the two-dimensional image. Actual distances would be more than the measured distances because the surgeon did not entirely remove bone covering the facial nerve and chorda tympani. Thus the points manually picked as “facial nerve” and “chorda tympani” are points on the bone covering each structure.

Challenges encountered while transforming the technology from adult to pediatric patients included the following:

1. The skulls of pediatric patients may be too thin to securely hold bone-implanted anchors, which is the basis of the fiducial system used in adults. As noticed on an intraoperative CT scan, one anchor penetrated the inner table of the skull and appeared to violate dura. This was confirmed when the anchor was removed and a small leak of clear fluid – presumably CSF – emanated from the hole. This was easily controlled with application of bone wax. To avoid similar situations, which are usually identifiable on pre-operative CT scans, we developed and used a modified self-retaining retractor that had integrated fiducial markers attached to

which the microstereotactic frame could be affixed. In practice, this retractor was screwed into place with short facial plating screws to minimize risk of intracranial extension.

2. Otolologic anatomy of pediatric patients is significantly different from adult patients. As we have reported elsewhere⁹, the facial nerve, being more lateral and anterior, limits the view of the round window niche as compared to adults. Additionally, the branch point of the chorda tympani is often much lower in children than in adults. In at least one case, we identified the branch point to be outside of the temporal bone in the soft tissue of the neck. As the automatic path planning involves segmenting the structures of the ear using an atlas-based technique, modifications – including the creation of a pediatric atlas – had to be made especially in reference to identification of the chorda tympani.¹⁰
3. Anatomy of pediatric patients can change significantly in the interim between preoperative CT and intraoperative CT scanning. While we expected such change if CT scans were taken years apart (e.g. CT scan obtained with work-up of profound SNHL at identification shortly after birth and CI at 18–24 months), we also found subtle changes to occur if the interval was only months. These changes in anatomy affected registration between preoperative and intraoperative CTs during the intraoperative planning step. To solve this problem, we developed a modified registration technique that refines the registration in the area around the ear-of-interest using a locally affine transformation based on image intensity.

The use of the proposed technology requires the availability of (a) intraoperative imaging as well as a (b) computer-numeric-control (CNC) machine. Regarding (a), most major medical centers have intraoperative imaging built into at least a few OR suites (e.g. uni- or bi-plane fluoroscopy machines typically used for vascular and cardiology procedures). In the current study, a portable CT scanner—technically a flat-panel volumetric computerized tomography (fpVCT) machine—was used due to its availability. This machine retailed for approximately \$300,000 in 2009 and is no longer being manufactured. Current portable CT scanners retail for approximately \$600,000 – \$1,000,000. As these machines can be used for multiple applications, cost is typically determined on a per use basis of approximately \$500–\$1000 and may be billable to insurance carriers. Regarding (b), typical CNC machines cost approximately \$15,000 and are ubiquitous in standard engineering machine shops. As with the CT scanner, charges are typically made on a per use basis with an hourly rate of \$100–200 dollars. We estimate that less than \$1000 per surgical procedure would be required for the fiducial markers, the drapes necessary during intraoperative CT scanning, the custom microstereotactic frame, and the drill bits.

The use of the proposed technology involves acquisition of an additional intraoperative CT scan after fiducial marker placement that results in additional radiation exposure to the patient. Low dose CT scanning protocols were chosen for this intraoperative scan to reduce the amount of radiation exposure. In our study, the intraoperative CT scan exposed the patient to about 35 mrem (based on actual measurements done with the machine used in this study) compared to about 200 mrem for a head CT. The reduced radiation dose can result in reduced image quality. However, this is overcome by using the preoperative CT scan to

provide the required anatomical details and the low dose intraoperative CT scan to provide fiducial marker location. Then, by registering the two CT scans together, all the required information to perform the procedure is available.¹⁶

This current study confirms the feasibility of the minimally-invasive, image-guided approach to the cochlea in pediatric patients. We are working on further improvements to the software and hardware to allow safe and easy transition of the technology to the pediatric patients. While routine implementation of this technology for pediatric CI is, at best, years away, image-guidance – such as that used in the present study –has immediate potential to help surgeons during CI on patients with unusual anatomy.

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Figure 1.

(A) Segmented structures and the trajectory in the preoperative CT. (B) Three-dimensional rendering of the segmented structures. The golden cylinder represents a 1.6 mm diameter drill bit along the planned path.

Figure 2. Drilling a minimally-invasive, image-guided path to the cochlea on an adult patient using a custom microstereotactic frame.

Figure 3.
Fiducial systems used for pediatric patients. (A) Anchor with extender at three locations. (B)
A modified retractor with short extenders.

Figure 4.
Validation of the image-guided approach using custom microstereotactic frame attached to the bone-implanted markers.

Figure 5.

Endoscopic views confirming that the sham drill bit targets the cochlea without damaging the facial nerve or the chorda tympani. Distances of trajectory to critical structures were computed using lengths of the three straight lines.

Table I

Measured closest distances of the trajectory to the critical structures. Patients 1 and 2 had inner ear malformations and the distances couldn't be measured. Validation was aborted on Patients 7, 8, 11, and 13 and hence no measurements are reported for them.

Patient	Closest distance of the trajectory to critical structure (mm)	
	Facial Nerve	Chorda Tympani
1	-	-
2	-	-
3	1.0	0.7
4	1.1	0.8
5	0.9	2.0
6	1.3	1.4
7	-	-
8	-	-
9	0.6	1.1
10	1.7	1.6
11	-	-
12	1.0	0.9
13	-	-
Mean	1.1	1.2
Standard Deviation	0.3	0.5