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Clinical Validation Study of Percutaneous Cochlear Access Using Patient-Customized Microstereotactic Frames

*Robert F. Labadie, *Ramya Balachandran, †Jason E. Mitchell, ‡Jack H. Noble, §Omid Majdani, *David S. Haynes, *Marc L. Bennett, ‡Benoit M. Dawant, and ‡J. Michael Fitzpatrick

**Department of Otolaryngology—Head and Neck Surgery, Vanderbilt University Medical Center; Departments of †Mechanical Engineering and ‡Electrical Engineering and Computer Science, Vanderbilt University, Nashville, Tennessee, U.S.A.; and §Department of Otolaryngology, Medical University of Hannover, Hannover, Germany*

Objective: Percutaneous cochlear implant (PCI) surgery consists of drilling a single trough from the lateral cranium to the cochlea avoiding vital anatomy. To accomplish PCI, we use a patient-customized microstereotactic frame, which we call a "microtable" because it consists of a small tabletop sitting on legs. The orientation of the legs controls the alignment of the tabletop such that it is perpendicular to a specified trajectory.
Study Design: Prospective.
Setting: Tertiary referral center.
Patients: Thirteen patients (18 ears) undergoing traditional cochlear implant surgery.
Interventions: With institutional review board approval, each patient had 3 fiducial markers implanted in bone surrounding the ear. Temporal bone computed tomographic scans were obtained, and the markers were localized, as was vital anatomy. A linear trajectory from the lateral cranium through the facial recess to the cochlea was planned. A microtable was fabricated to follow the specified trajectory.
Main Outcome Measures: After mastoidectomy and posterior tympanotomy, accuracy of trajectories was validated by mounting the microtables on the bone-implanted markers and then passing sham drill bits across the facial recess to the cochlea. The distance from the drill to vital anatomy was measured.
Results: Microtables were constructed on a computer-numeric-control milling machine in less than 5 minutes each. Successful access across the facial recess to the cochlea was achieved in all 18 cases. The mean ± SD distance was 1.20 ± 0.36 mm from midportion of the drill to the facial nerve and 1.25 ± 0.33 mm from the chorda tympani.
Conclusion: These results demonstrate the feasibility of PCI access using customized microstereotactic frames. **Key Words:** Clinical validation—Cochlear implant—Image-guided surgery—Microstereotactic frame—Minimally invasive surgery.

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In previous reports (1–3), we have demonstrated the feasibility of percutaneous cochlear implantation (PCI), which is access to the cochlea from the surface of the lateral cranium through the facial recess via a single pass of a surgical drill. To accomplish PCI, image-guided surgical technology is used. The workflow for this novel surgical technique is as follows:

1. Placement of bone-implanted fiducial markers/anchors surrounding the mastoid.
2. Computed tomographic scanning of the temporal bone region of the skull.
3. Planning a linear trajectory from the lateral cranium through the facial recess to the cochlea in reference to the bone-implanted fiducial markers.
4. Constructing a customized microstereotactic frame that mounts on the bone-implanted fiducial markers and constrains a surgical drill to follow the specified trajectory.

Address correspondence and reprint requests to Robert F. Labadie, M.D., Ph.D., Department of Otolaryngology–Head and Neck Surgery, Vanderbilt University Medical Center, 1215 21st Avenue S., MCE, Room 7209, Nashville, TN 37232, U.S.A.; E-mail: robert.labadie@vanderbilt.edu

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The authors have applied for multiple patents on this technology, some of which may lead to commercialization with the potential for financial benefit to them.

FIG. 1. Customized STarFix microstereotactic frame mounted on bone-implanted markers for PCI validation.

5. Mounting the microstereotactic frame on the markers and drilling to the cochlea.

The limitation of the current embodiment of this technique is a delay between Steps 3 and 4. More specifically, once bone-implanted markers are placed and the computed tomographic scan is obtained, there is a requisite delay in construction of the microstereotactic frame while the current Food and Drug Administration–approved microstereotactic frame, the STarFix (FHC, Inc., Bowdoin, ME, USA; Fig. 1), is fabricated at a centralized facility using rapid prototyping technology. Ironically, to achieve the submillimetric level of accuracy necessary for this application, the rapid prototyping machine requires hours to construct the customized microstereotactic frame. In addition, because the rapid prototyping machine is expensive to purchase, a centralized facility offers an economic benefit. The minimum 48-hour delay is cumbersome for patients and surgeons.

To overcome this limitation, we have developed a microstereotactic frame, which we call a *microtable*, that can be manufactured in less than 5 minutes. The engineering details of the microtable have been recently published (4). As shown in Figure 2, this device consists of a tabletop that sits on 3 legs, the heights of which are adjustable by countersinking, or recessing, into the table top. The legs attach directly to the fiducial markers implanted into the cranium of the patient via a sphere-and-gripper coupling (see magnified panel in Fig. 2) such that an attachment encompassing arbitrary orientations of the legs to the spheres is possible. By countersinking the legs into the tabletop, it is possible to make the plane of the tabletop perpendicular to the desired trajectory. Next, one needs only to specify the point of intersection of the trajectory with the surface of this tabletop in relationship to the legs. By countersinking the target hole, we set the trajectory distance from the top plane of the target hole to the target at 75 mm.

By means of this technique, we have demonstrated an in vitro targeting accuracy of 0.37 ± 0.18 mm (4). This accuracy matches that of the STarFix (5), and the microtable is much easier to construct because the only parameters that need to be specified are the x and y locations of each leg and intersection of the trajectory with the tabletop and the countersinking depth for each leg and the target hole. As a result, a microtable can be fabricated in less than 5 minutes on a standard computer-numeric-control (CNC) machine. From the standpoint of work flow, this design has revolutionized the procedure by reducing the delay between Steps 3 and 4 from days to minutes, thereby allowing clinical testing without encumbering either the patient or the surgeon. The report

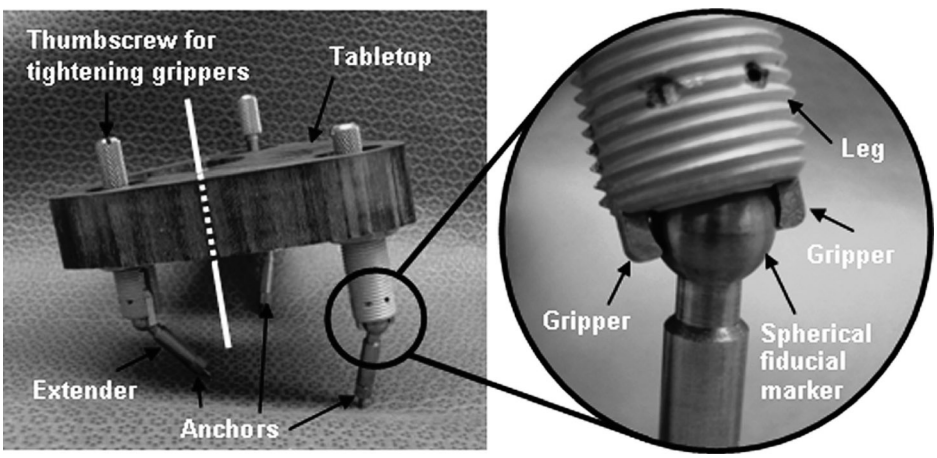

FIG. 2. Microtable. Three spherical fiducial markers are attached to the patient via anchors. The tabletop is elevated above the spherical fiducial markers using legs that are countersunk to orient the tabletop perpendicularly to the trajectory (*shown as solid and dashed line*). Coupling mechanism between the spherical fiducial marker and the table leg is shown in the *inset*. Twisting the thumbscrew tightens the grippers, thereby fixing the leg to the marker.

herein details the application of this technology to clinical testing of PCI.

MATERIALS AND METHODS

Institutional review board approval was obtained for the validation study, and all patients who participated in the study gave informed consent. Inclusion criteria were as follows: patients who were scheduled for traditional cochlear implant surgery, between the ages of 18 and 80 years, and free of comorbid conditions deemed in the judgment of the surgeon or the anesthesiologists to be significant enough that an extra 10 to 20 minutes of operating room time for participation in the research would not jeopardize their health. Each patient enrolled had the following procedures performed:

1. Informed consent was obtained.
2. Three bone-implanted fiducial markers were placed behind the ear—one each at the mastoid tip, the suprahelical region, and region posterior to the sigmoid sinus. These chosen positions were approximately surrounding the desired trajectory (Fig. 3).
3. A clinically applicable temporal bone computed tomographic scan was obtained either in the outpatient setting (spiral cut computed tomographic scan with a slice thickness of 0.8 mm and an overlap of 0.4 mm) or intraoperatively using a xCAT ENT scanner (Xoran Technologies, Ann Arbor, MI, USA) with an isotropic voxel size of 0.3 mm (Fig. 4).
4. By means of automated segmentation methods, the pertinent anatomical features (facial nerve, chorda tympani, cochlea, labyrinth, ossicles, external auditory canal) were identified on the computed tomographic scan (6,7). This process takes approximately 6 minutes, after which a trajectory that optimizes avoidance of the facial nerve and targeting of the scala tympani compartment of the cochlea is automatically determined (8). This trajectory is verified by the surgeon. The centers of the markers are also localized in the computed tomographic scan.
5. A customized microtable was produced on a CNC milling machine (Ameritech CNC, Broussard Enterprises, Inc., Santa Fe Springs, CA, USA) from a blank of Ultem (Quadrant Engineering Plastic Products, Reading, PA,

FIG. 4. Intraoperative computed tomographic scan acquired using the xCAT ENT scanner after marker implantation.

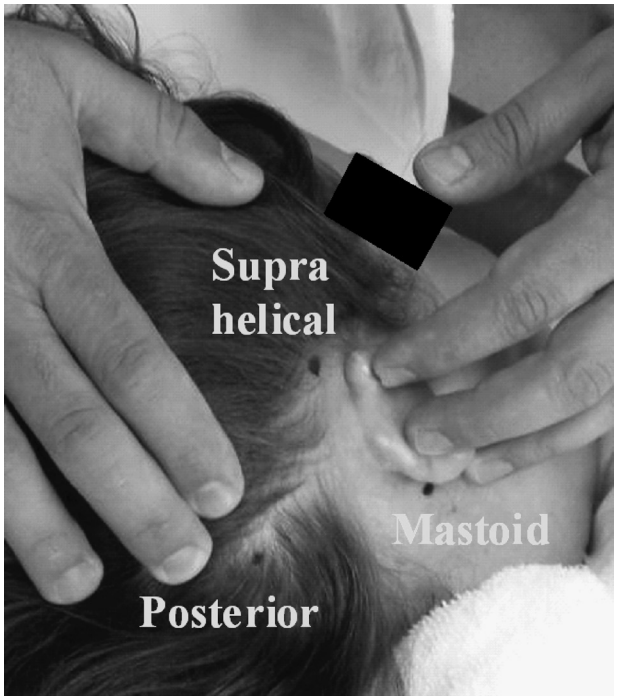

FIG. 3. Approximate locations for the 3 bone-implanted markers.

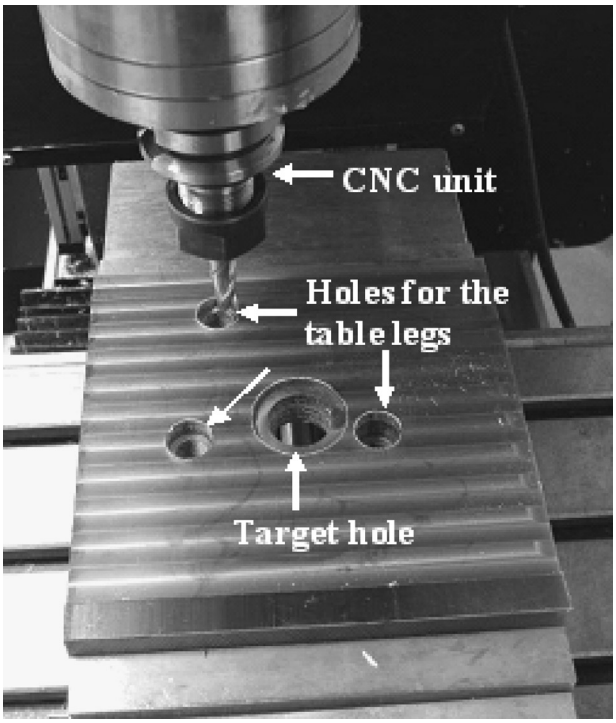

FIG. 5. Construction of microtable using the CNC machine.

USA). Once the center target hole is machined, 3 holes are milled to the correct depths for the leg attachments (Fig. 5). This process takes less than 5 minutes. The legs are then inserted into these holes completing the microstereotactic frame. Postmanufacturing quality control and attachment of coupling devices to join the legs to the microtable require an additional 2 to 3 minutes.

6. The microtable is transported to the operating room and sterilized.
7. Validation of the trajectory is performed by affixing the microtable to the bone-implanted markers and passing sham drill bits of 1 mm and then 2 mm in diameter, if there is clearance, through the already-drilled mastoid and facial recess (Fig. 6). Photodocumentation of the drill bit, as it lies on the plane defined by the facial nerve and chorda tympani, is then made (Fig. 7). Photodocumentation was also made where the sham drill bit would have produced a cochleostomy (Fig. 8).
8. As shown in Figure 7, the digitized photograph is then measured, using the public-domain, digital-measurement program Image J (www.rsbweb.nih.giv/ij/). The measurement involves drawing a straight line at the widest portion of the drill bit to calibrate the pixel size to physical size. Next, the closest distance from the drill bit to the bone covering the facial nerve and chorda tympani is measured and scaled. Of note, the jitter of the drill bit interface with the microtable as measured at the depth of the facial recess is 0.071 ± 0.03 mm.

RESULTS

Eighteen microtables were constructed as per the methods described. For all microtables, clinical validation was performed, and the measurements from the midaxis of the drill to the facial nerve and chorda tympani are presented in Table 1. Summarizing the results, the mean ± SD distance from the midportion of the drill to the facial nerve was 1.20 ± 0.36 mm and that to the chorda tympani was 1.25 ± 0.33 mm. Note that the measurements were made to the bone covering the facial nerve and chorda tympani, thus a small amount of clearance on top of the values reported in Table 1 exists. With this in mind, based on the results reported in Table 1, the success rate of passing a drill safely through the facial recess without impinging the facial nerve is 100% for a 1-mm drill, 94.44% (17/18) for a 1.5-mm drill, and 77.78% (14/18) for a 2-mm drill. Correspondingly, the success rate of passing a drill safely through the facial recess without impinging the chorda tympani is 94.44% (17/18) for a 1-mm drill, 94.44% (17/18) for a 1.5-mm drill, and 77.78% (14/18) for a 2-mm drill. On 1 ear (No. 3), the chorda tympani was hit by the drill—this was a planned hit because the patient had an extremely narrow facial recess shown on the preoperative scan.

Although location of the cochleostomy was difficult to objectively document in all cases, a representative targeting is shown in Figure 8. Here, the surgeon-selected cochleostomy can be observed in panel A (at the site of drilling to remove the round window overhang) and the location of the microtable-specified location in panel B. Subjectively, all targets were loco typico for cochleostomy location.

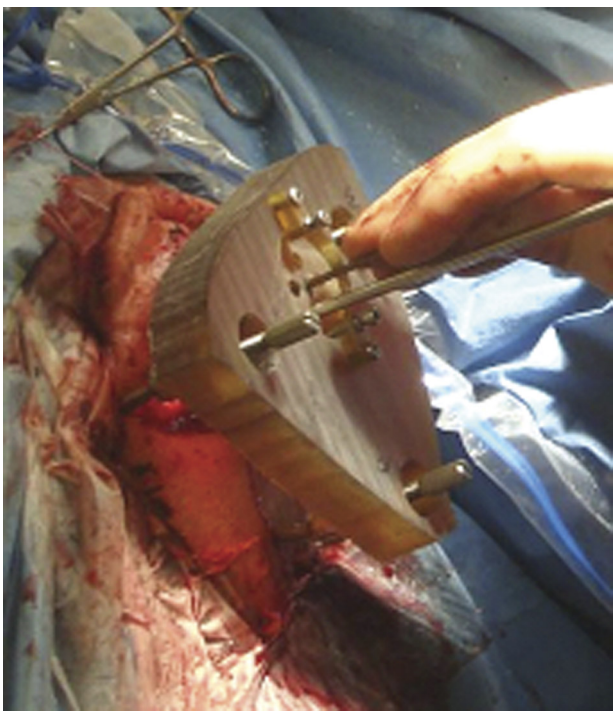

FIG. 6. Microtable mounted on the patient for PCI validation. Sham drill bit is passed in the center target hole and endoscope is used to photodocument trajectory.

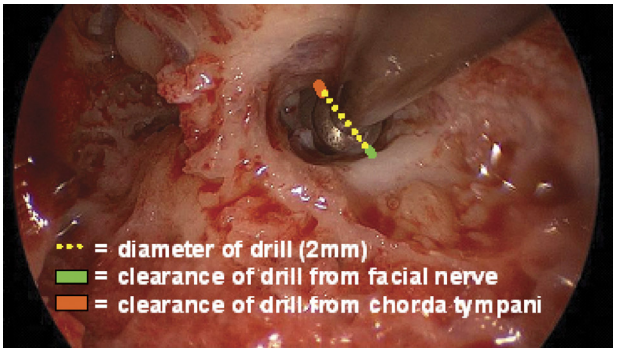

FIG. 7. Measurement technique for estimating the distance from the centerline of the drill trajectory to facial nerve and chorda tympani. On the intraoperative endoscopic photograph, a *line* is drawn over the drill bit, which provides a scale to the true physical size—2 mm in this case. The distance from the edge of the drill to the chorda tympani and the facial nerve is then digitally drawn and calibrated.

DISCUSSION

We present herein a novel microstereotactic frame that can be used for the accurate targeting of intracranial structures, such as the cochlea. We also present clinical validation experiments, showing its accuracy as used for PCI validation. Our previous results indicate an in vitro

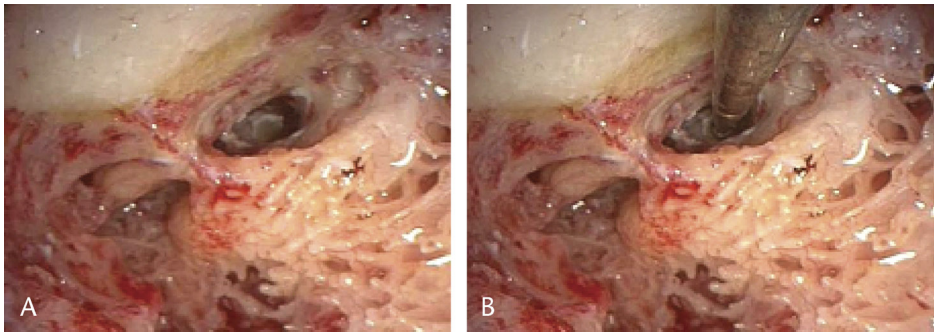

FIG. 8. Location of the cochleostomy. *A*, Cochleostomy site as selected by the surgeon by drilling off the round window overhang. *B*, The 1-mm sham drill bit targeting this location.

accuracy of 0.37 ± 0.18 mm (4). During clinical validation experiments, we safely avoided vital anatomical features and accurately targeted the cochlea. We have demonstrated that a 1-mm drill bit can be passed through the facial recess in 18 of 18 cases without impingement to the facial nerve and with one injury to the chorda tympani. For larger drill bits, the risk of damage is greater—the 1.5-mm drill bit would have contacted 1 of the 18 facial nerves. However, the clearance of the drill bit through the facial recess is visualized during preoperative planning (Step 4 in the Materials and Methods section) at which point, if concern exists regarding potential injury to the facial nerve, the trajectory can be modified, shifting the risk of injury to the chorda tympani. For these validation experiments, we did not modify any trajectories and thus have presented the worst-case scenarios.

In a previous work (3), we demonstrated the feasibility of PCI. However, to participating patients and surgeons, this process involved 2 stages: 1) placement of bone-implanted anchors in clinic at least 48 hours before surgery and 2) clinical testing of the frame in the operating room during a traditional cochlear implant surgery. We sought a solution to make this process achievable in a single stage in an effort to make the process more user-friendly for both patients and surgeons. The microtable offers one such solution as (*a*) it can be constructed on site by a skilled machinist in 5 minutes or less and (*b*) it uses relatively standard machining equipment.

TABLE 1. *Distance (mm) from axis of drill trajectory to facial nerve (FN) and chorda tympani (CT)*

Ear tested	Distance to FN	Distance to CT
1	1.44	1.33
2	0.50	2.1
3	1.62	—
4	0.80	1.32
5	1.10	0.81
6	1.33	1.50
7	0.86	1.32
8	1.11	1.04
9	0.88	0.83
10	1.07	1.42
11	1.39	1.06
12	1.40	1.50
13	2.00	1.63
14	1.00	1.00
15	1.00	1.00
16	1.48	1.33
17	1.06	0.94
18	1.57	1.09
Mean	1.20	1.25
SD	0.36	0.33

The microtable, in conjunction with intraoperative computed tomographic scanning, has allowed us to streamline our clinical testing of PCI by performing PCI validation experiments concurrently with traditional cochlear implant surgery. This approach proceeds as follows: Patients are prepared and draped as per routine cochlear implant surgery and a postauricular incision is made. Using this incision, markers are bone-implanted at the mastoid tip and the superior aspect of the postauricular incision. Next, a posterior stab incision is made, creating an approximately equilateral triangle surrounding the mastoid, and marker bone-implanted. The patient is covered with a sterile plastic drape, and the intraoperative computed tomographic scanner is wheeled in to allow visualization of the markers and the temporal bone anatomy. Next, the surgeon performs traditional cochlear implant surgery, consisting of mastoidectomy and facial recess approach. Simultaneously, the anatomy is automatically identified and the PCI trajectory is automatically computed from the computed tomographic scan. A short time later (<10 min), the program outputs a computer file that specifies the dimensions of the microtable. This file is sent electronically to a machine shop located near the operating rooms, where it is read by the CNC machine and produces a customized tabletop of the microtable in less than 5 minutes. Once off the CNC machine, quality control is performed, and the rigid joints, which connect the microtable to the bone-implanted markers (i.e., ball and socket joints), are attached (Fig. 2). Next, the microtable is transported to the operating room and sterilized. The entire process after computed tomographic scanning is obtained until the microtable is delivered into the surgical suite is less than 30 minutes—less than the time it typically takes for a surgeon to perform a mastoidectomy

and facial recess. As a result, participation in the research is invisible to the patient. This invisibility has promoted recruitment in our validation study.

Whereas the microtable described herein has been clinically tested for access to cochlea, we envision other applications, including placement of deep-brain stimulators in the subthalamic nucleus, access to the petrous apex for drainage of cholesterol granulomas, and access to the endolymphatic sac for treatment of Ménière's disease. Application to each of these is a variant of the process described herein.

REFERENCES

1. Labadie RF, Chodhury P, Cetinkaya E, et al. Minimally invasive, image-guided, facial-recess approach to the middle ear: demonstration of the concept of percutaneous cochlear access in vitro. *Otol Neurotol* 2005;26:557–62.
2. Warren FM, Balachandran R, Fitzpatrick JM, et al. Percutaneous cochlear access using bone-mounted, customized drill guides: demonstration of concept in-vitro. *Otol Neurotol* 2007;28:325–9.
3. Labadie RF, Noble JH, Dawant BM, et al. Clinical validation of percutaneous cochlear implant surgery: initial report. *Laryngoscope* 2008;118:1031–9.
4. Labadie RF, Mitchell J, Balachandran R, et al. Customized, rapid production micro-stereotactic table for surgical targeting: description of concept and in-vitro validation. *Int J Comput Assist Radiol Surg* 2009;4:273–80.
5. Balachandran R, Mitchell JE, Dawant BM, et al. Accuracy evaluation of microTargeting Platforms for deep-brain stimulation using virtual targets. *IEEE Trans Biomed Eng* 2009;56:37–44.
6. Noble JH, Warren FM, Labadie RF, et al. Automatic segmentation of the facial nerve and chorda tympani in CT images using spatially dependent feature values. *Med Phys* 2008;35:5375–84.
7. Noble JH, Dawant BM, Warren RM, et al. Automatic identification and 3-D rendering of temporal bone anatomy. *Otol Neurotol* 2009; 30:436–42.
8. Noble JH, Warren FM, Labadie RF, et al. Determination of drill paths for percutaneous cochlear access accounting for target positioning error. *Proc SPIE* 2007;6509:650925.1–.10.