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A New Manual Insertion Tool for Minimally Invasive, Image-Guided Cochlear Implant Surgery

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ABSTRACT

Cochlear implant surgery typically requires a wide-field mastoidectomy to access the cochlea. This portion of the surgery can leave a visible and palpable depression behind the patient’s ear, which can be cosmetically displeasing to the patient. For the surgeon, a wide-field mastoidectomy is challenging to perform because bone must be gradually removed by freehand drilling guided primarily by visual feedback in an effort to detect, yet avoid, vital anatomy including the facial nerve which controls motion of the face. Toward overcoming these issues and standardizing surgery, imaged-guided, minimally invasive approaches have been developed in which the cochlea is accessed using a single pre-planned drill trajectory. This approach promises decreased invasiveness, but the limited surgical view and long narrow opening to the cochlea present significant challenges for inserting electrode arrays. This paper describes the first cadaver experiments using a new manual insertion tool which provides a roller mechanism to enable the physician to deploy a cochlear implant electrode array through the narrow drilled hole created by this minimally invasive, image-guided access technique. Results demonstrate that the new tool enables consistent and successful insertions similar to insertions with the traditional tool while increasing the ease of the insertion and freeing the surgeon to monitor progress and make fine adjustments as needed.

Keywords: Medical Devices, Cochlear Implants, Minimally Invasive Surgery

1. INTRODUCTION

Cochlear implant (CI) surgery traditionally requires a wide-field mastoidectomy. This surgical procedure involves excavating approximately 100mL of bone from the skull base behind the external ear to access the inner ear. After surface excavation, dissection in close proximity to the facial nerve — a vital piece of anatomy that controls motion of the face — takes place as the facial recess is opened. An experienced surgeon can perform a mastoidectomy and facial recess in approximately 40-50 minutes with high variability in the amount of time required.\textsuperscript{1} Wide-field mastoidectomy leads to a visible depression behind the external ear, and thus from a patient standpoint, a less invasive approach is desirable. From a surgical standpoint, access to the cochlea is an ideal application for image guidance technology since vital anatomy is embedded in bone — enabling rigid registration between preoperative and intraoperative or postoperative images. Image guidance can enhance safety by reducing reliance on surgeon hand-eye coordination, spatial awareness, and experience to ensure that the surgical drill does not accidentally damage the vital anatomy embedded in the bone.\textsuperscript{2} Based on these motivations, two groups have developed and clinically translated approaches for minimally-invasive, image-guided cochlear implantation. Clinical realization was first reported by the Vanderbilt group\textsuperscript{3} using customized, micro-stereotactic frames (a.k.a. microtables) affixed to the patient skull and used to constrain the path of a drill to a trajectory specified on a preoperative computerized tomography (CT) scan.\textsuperscript{4} This approach has been expanded upon by a group in Bern, Switzerland where they have made significant progress toward commercialization using a multi-articulated robot and an infrared tracking system to achieve a similar result, namely a patient-customized, minimally invasive tunnel to the cochlea.\textsuperscript{5}
While these approaches have succeeded in accessing the cochlea less invasively, the subsequent threading of a flexible CI electrode array down the drilled tunnel and traversing the air-filled middle ear space to enter the cochlea remains a challenge. Various groups have reported on innovative CI electrode insertion tools. While several of these tools could potentially be modified for or used for our minimally invasive approach, most of the tools either have geometry that would make adherence to our design constraints difficult, or the designs are automated which could necessitate lengthy regulatory oversight to realize clinical translation.

After drilling, the approximate geometry of the surgical workspace is as shown in Fig. 1(a). Inserting the electrode through the air gap between the end of the drill path and the cochlea entrance presents significant insertion challenges because the surgeon is not able to grip the electrode directly at the opening, as would be done with a wide-field mastoidectomy approach. This lack of constraint around the electrode array in the air gap of the middle ear space can lead to undesired buckling of the electrode within that space (see Fig. 1(b)). Attempts to minimize buckling and maximize insertion depth have been aimed at bridging this gap with a tube and having the surgeon push the electrode from the proximal end with forceps. A significant disadvantage of this approach is that the surgeon must blindly maintain consistent axial pressure through the drilled tunnel while focusing his/her vision on the cochlea. One manual insertion tool saw success at improving this step of the implantation within the constraints of Fig. 1(a); however, the current tool design cannot accommodate some of the straight (as opposed to precurved) CI electrode arrays with larger diameters. Here, we envisioned a simple manual tool which would naturally apply a force coaxial to the planned trajectory without the surgeon having to consciously angle their forceps in the correct orientation, freeing the surgeon to guide the distal tip of the electrode into the cochlea. A specific design goal was to keep the device as simple as possible to expedite approval for use in the operating room.

2. METHODS

Prior to designing the insertion tool, we first characterized the surgical workspace and tool design requirements assuming use of the MED-EL Standard straight electrode array. This electrode array has one of the larger diameters and longest intracochlear lengths of commercially available arrays, and therefore, is a conservative choice of array to test the insertion tool’s functionality. The array has a total length of 31.5 mm and tapers over its length from 1.3 mm in diameter at its base to 0.5 mm at its tip. Using these dimensions and constraints from Fig. 1(a), we extrapolated device space constraints. Specifically, the portion of the insertion tool that is within the 1.59 mm medial tunnel cannot take up more than about 0.19 mm of space given the proximal dimension of the electrode array once fully inserted within the cochlea. Furthermore, as the electrode array is permanently...
attached to a much larger internal component consisting of a microprocessing chip, rechargeable capacitor, and magnet for aligning and coupling with an externally worn processor (see Fig. 2), the insertion tool has to have a way of detaching from the array once insertion has been completed.

To satisfy these geometric and task requirements, we constructed a novel, manually actuated insertion tool. This device is shown in Fig. 3. The distal end of the device consists of a polyimide tube thin enough that it can fit inside the 1.59 mm hole yet still have a large enough inner diameter to allow the electrode to slide freely. A roller wheel device was developed for the more proximal end of the tool to attach to the polyimide. This mechanism gives surgeons the capability to slowly and consistently advance the electrode forward along the specified trajectory. The rigid portion of the roller assembly (just above the polyimide) was designed to fit within the 3.8 mm lateral bony tunnel. The device consists of two mirrored components that enable it to be quickly disassembled and removed after insertion of the electrode array, and the polyimide tube is attached to only one half of the tool. Because the device is stabilized by this tube/receiver interface, the surgeon need only blindly roll the wheels to advance the electrode array. Other than the polyimide distal guide tube, the rest of the device can be printed on the Formlabs™ Form 2 stereolithography 3D printer with a biocompatible, autoclavable dental resin (EN-ISO 10993-1:2009/AC:2010, USP Class VI).

In order to test this device, we performed an image-guided, minimally invasive cochlear implantation on two cadaver heads. The workflow of this procedure can be viewed in Fig. 4. Preoperative planning was first performed by segmenting critical structures in the CT scan of the patient using automated segmentation methods described previously. A drilling trajectory was then created based on these preoperative scans targeting the medial axis of the scala tympani (ST) channel of the cochlea (see Fig. 4(a) for results from these steps). Next, a patient-specific microtable was milled using a computer numeric control (CNC) milling machine. This microstereotactic frame was then affixed to the cadaver head and the minimally invasive tunnel was drilled in two steps — a 3.8 mm tunnel lateral to the facial nerve and a 1.59 mm tunnel in close proximity to the facial nerve (see Fig. 4(b)). After this step, the tympanic membrane was raised from an external auditory canal approach enabling visualization and preparation of the cochlea. Such preparation included removal of the bone comprising the round window overhang and reflection of the round window membrane posteriorly creating an opening into the ST. Next, the insertion tool was positioned on the cadaver head and secured by mating of the ~3.8 mm portion of the device tube with the 3.8 mm tunnel. For this initial positioning, a metal stylet was placed through the lumen of the insertion tool such that the stylet could be seen as it approached but did not enter the cochlea. With proper alignment visually confirmed, the stylet was removed and the electrode array was threaded into the insertion tool until the tip could be seen just outside the cochlea. Finally, with the surgeon viewing the cochlea via the external auditory canal (see Fig. 4(c)), the roller wheels of the insertion tool were manually actuated allowing slow, semi-continuous insertion of the electrode array.
3. RESULTS

Initial tests with this device were carried out using two cadaver heads (four ears). Insertions were done using a traditional tool (surgical forceps) and the new insertion tool. Initial testing was done using a mixture of water and a small amount of healon (sodium hyaluronate) for lubrication; however, both the traditional approach and new tool yielded similar partial insertions near only about 250°. These partial insertions were most likely due to a well-known, but poorly understood, post-mortem change in the frictional properties of the ST. As a result, to overcome this increased friction, we used soapy water as the lubricant for testing comparison. Post-insertion CT scans were collected and compared for all four ears. Angular insertion depth results from the cadaveric trials are tabulated in Tab. 1, and a resulting CT scan and a 3D reconstruction from an insertion with the new tool can be seen in Fig. 5. With both insertion techniques, we saw similar insertion success; all trials resulted in complete insertions (12 of 12 electrodes intracochlear). For both techniques, we also saw similar angular insertion depths (average angular insertion depths near 680° for the traditional tool and near 620° for the new tool). Although both techniques resulted in similar insertion success, using the new insertion tool enabled the surgeon to blindly advance the electrode along the optimal trajectory while focusing visual and fine motor attention on the entrance of the cochlea as accessed via the ear canal (see Fig. 4(c)). Using the new tool made it significantly easier to insert the electrode array without buckling.

Figure 4. Surgical workflow: (a) Segmentation and 3D reconstruction of cochlear anatomy from preoperative CT scan with planned drill trajectory,14–17 (b) Drilling of patient-specific trajectory using custom microtable, c) Electrode array insertion using new tool.
After the CI electrode array was inserted, the tool then needed to be disassembled and removed. In these trials, one half of the tool was removed by sliding apart the two device halves using the split feature in the tool (see Fig. 6), and CT scans were taken to investigate whether sliding the device apart would displace the electrode. The maximum angular insertion depth difference upon removing half of the device was 3°, indicating that sliding the device apart will have very little effect on final electrode position. With half of the device removed, the last step of disassembling the tool involved freeing the electrode array from the polyimide tube. In these trials, two methods of performing this step were investigated. One investigated method involved carefully cutting apart the polyimide once the tool had been slid apart such that the second half of the tool could be separated from the electrode. In the second method, a perforated polyimide tube was used on the distal end of the tool and the perforation was torn apart upon complete insertion to fully detach the electrode array from the tool. These removal methods worked well, and we will be developing a simple custom manual tool with built-in safety features to perform this cutting/tearing action in the future.

4. CONCLUSION

We have discussed several of the design requirements for building a minimally invasive cochlear implant insertion tool. This paper presents the first results using a newly designed manual insertion tool for minimally invasive CI surgery in cadavers. We have shown that the tool enables consistent and successful insertions of CI electrode arrays through a narrow, drilled tunnel comparable to insertions without the device, while freeing the surgeon to focus on and fine tune the insertion as visualized via the external ear canal. The specific tool design enables the surgeon to easily insert the electrode along the planned trajectory with minimal chance of buckling in the middle ear space and minimal required effort to maintain device alignment, all while complying with the constraints of the tunnel created when performing minimally invasive CI surgery. From a surgical perspective, the new tool was significantly easier to use in completing the procedure while achieving similar insertion results to the traditionally used tool.
Figure 6. (a) Fully assembled tool just before disassembly, (b) Removing half of tool using the device split feature to slide the two body halves apart and remove the half that is not attached to the polyimide, (c) Tool half removed.

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