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A MANUAL INSERTION MECHANISM FOR PERCUTANEOUS COCHLEAR IMPLANTATION

Daniel Schurzig
Vanderbilt University
Nashville, TN, USA

Zachariah W. Smith
Vanderbilt University
Nashville, TN, USA

D. Caleb Rucker
Vanderbilt University
Nashville, TN, USA

Robert F. Labadie
Vanderbilt University
Nashville, TN USA

Robert J. Webster III
Vanderbilt University
Nashville, TN, USA

ABSTRACT
Percutaneous Cochlear Implantation (PCI) is a recently developed minimally-invasive technique that utilizes image-guidance and a custom-made microstereotactic frame to guide a drill directly to the cochlea. It enables cochlear access through a single drill port, reducing invasiveness in comparison to mastoidectomy. With the reduction in invasiveness PCI enables comes a corresponding reduction in visualization and space in which to work at the cochlear entry point. This precludes standard cochlear implant deployment techniques, and necessitates a new insertion tool that can deploy a cochlear implant into the cochlea while working down a deep, narrow channel. In this paper we describe a manual insertion tool we have developed for this purpose. The tool is capable of inserting an electrode array into the cochlea using the Advance Off-Stylet technique, using simple manual controls on its handle.

INTRODUCTION
The development of the cochlear implant (CI) has given surgeons the ability to partially restore hearing to a large portion of the deaf population. CIs do this by bypassing the ear's (nonfunctioning) hair-cell mechanism for converting sound to electrical impulses, directly electrically stimulating auditory nerves within the cochlea. A complete cochlear implant system consists of an external speech processor, and an internal receiver connected to an electrode array within the cochlea, as shown in Figure 1.

Surgical installation of a CI system requires access to the inner ear, and specifically the cochlea, through the mastoid – the bone of the skull located directly behind the ear. In traditional cochlear implant surgery, a mastoidectomy is first performed to expose the cochlea. Mastoidectomy involves manual milling of the mastoid bone, with special care not to damage the facial nerve or impinge upon the auditory canal. After the mastoidectomy is completed, the round window of the cochlea is identified, and a small hole, called a cochleostomy is created in the basal turn of the cochlea. The

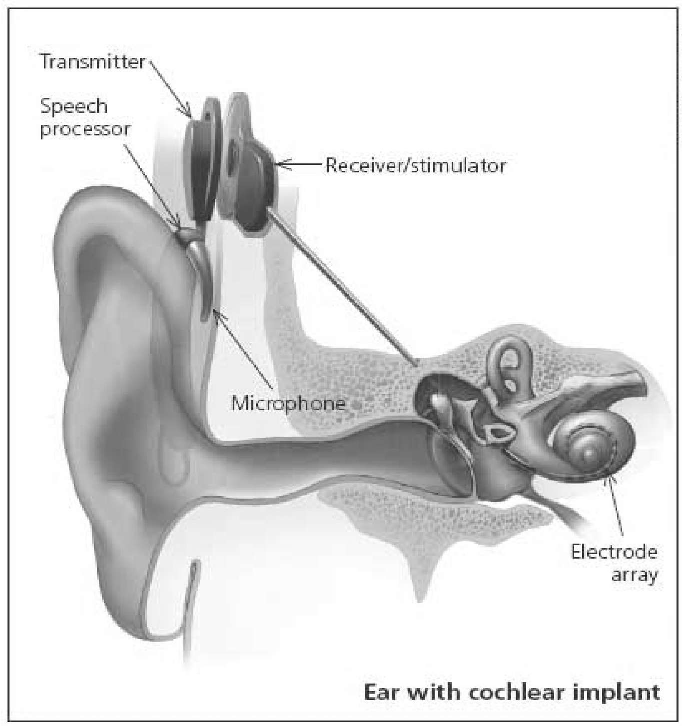

Figure 1: The human auditory system with a cochlear implant (NIH public domain image). A cochlear implant consists of a speech processor which transmits through the skin to a receiver, which is connected to an electrode array within the cochlea.

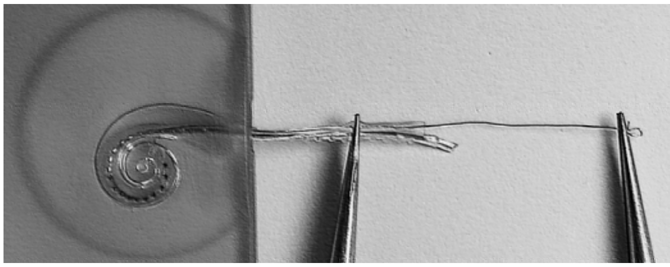

Figure 2: The Nucleus 24 Contour Advance Electrode (Cochlear Corporation, Inc.), is advanced off the stylet and returns to its naturally curved shape as it deploys into a cochlea model.

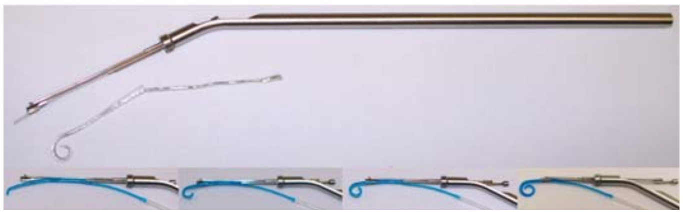

Figure 3: Top: A conventional insertion tool is shown with an implant. Bottom: Illustration of an implant advancing off of the stylet as the insertion tool is pushed forward by the surgeon while holding the stylet in place.

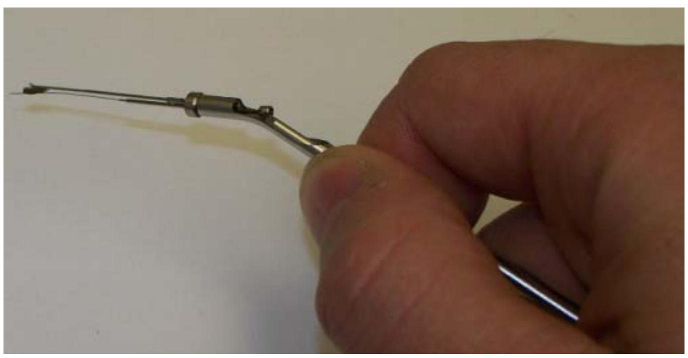

Figure 4: The insertion tool of Advanced Bionics is designed for direct open access to the facial recess. Thus, it is not suitable for deploying the implant through the narrow drill shaft and microstereotactic frame used in PCI.

curved silicone electrode array is then deployed into the cochlea under direct visualization (see Figure 2).

The method of insertion differs for various commercially available electrode arrays. For example, the Nucleus 24 Contour Advance Electrode (Cochlear Corporation, Inc.) used at Vanderbilt is advanced using tweezers. An alternative deployment mechanism for an electrode array made by Advanced Bionics involves the manual insertion tool shown in Figures 3 and 4. Whether using tweezers or the manual tool of Advanced Bionics, the open space around the cochlea created during mastoidectomy is required for insertion. This is due to the diameter of the insertion instruments, the need to visually position them at the cochleaostomy, and the need to visualize markings on the implant during insertion.

A popular technique for inserting the electrode array, which can be accomplished using both of the above electrode types, is known as Advance Off-Stylet (AOS). In this technique, the electrode array is initially held straight by a stiff wire called a stylet that is inserted into a central channel within

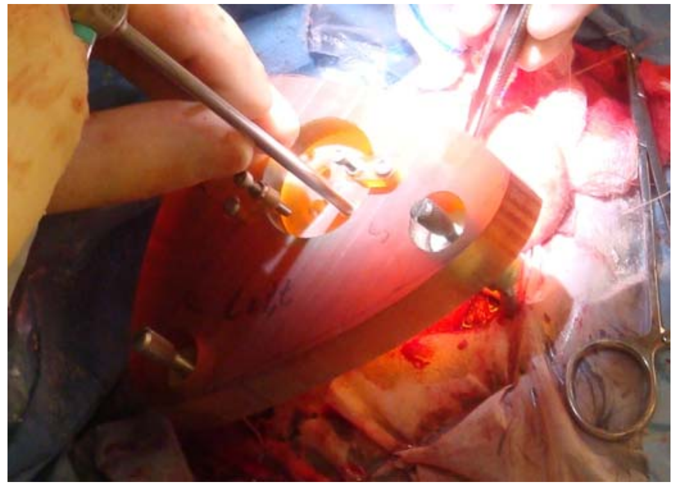

Figure 5: Customized microstereotactic frame of Labadie, et. al. This frame enables PCI by guiding the drill through the trajectory planned on preoperative images.

it. Deployment occurs in two stages, first the electrode and stylet are advanced together a short distance, up to a depth indicated by a white mark on the implant itself. Then the stylet's motion is stopped, and the electrode is advanced off the stylet up to a knob on the electrode array, causing it to return to its natural curved shape and thus conform to the spiral shape of the cochlea (see Figure 2).

Percutaneous Cochlear Implantation

Percutaneous cochlear implantation (PCI) is a newly developed, minimally invasive, and potentially safer method of accessing the cochlea. PCI consists of a single plunge of a surgical drill from the lateral skull to the cochlea without requiring a mastoidectomy. The drill trajectory passes through the narrow space between the facial nerve and the Chorda Tympani, avoiding them. This trajectory is mechanically enforced by a customized microstereotactic frame (see Figure 5). Registration and planning is enabled by three spherical bone anchors, which are screwed into the skull prior to intraoperative imaging, and to which the microstereotactic frame is attached. For further information on PCI and the required accuracy of the procedure see [1–4]. For purposes of the insertion tool described in this paper, we assume the drill hole to the cochlea has been accurately drilled and the cochleaostomy created – the insertion tool we describe provides a means of deploying the electrode into the cochlea under these conditions.

With respect to inserting the electrode array into the cochlea, the primary difference between PCI and traditional cochlear implant surgery is that the access to the cochlea is restricted. The electrode must be delivered and deployed through a hole approximately 35mm deep and 1.5mm in diameter. This precludes the use of standard manual deployment tools, which require greater access to the insertion site for visualization and/or to admit deployment tools as discussed previously.

Prior Work on Electrode Insertion Tools

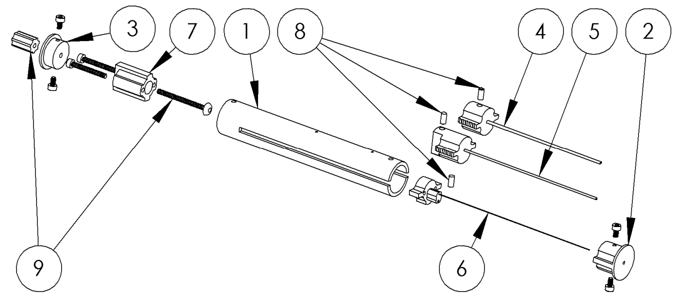

Figure 6: Exploded view of the insertion tool showing (1) the housing, (2) the front plug, (3) the back plug, (4) the guide tube and its slider, (5) the push tube and its slider, (6) the stylet and half of its slider, (7) the other half of the stylet slider that fixes its forward travel, (8) ball nose spring plungers that snap into various detents on the interior of the housing and (9) the adjustment screw.

Initial work toward developing an insertion tool for PCI has focused on a robotic solution, known as an Automated Insertion Tool [5–8]. This device can simultaneously manipulate both the electrode and the stylet to perform insertions, and the latest version is also able to measure insertion forces [7,8]. Zhang et al. have also developed a robotic mechanism for automated electrode array insertion [9], although their focus has been primarily on designing an improved, actuated electrode array rather than on the insertion robot itself.

While these robotic solutions may ultimately prove to be the most effective means of inserting an electrode down a long, narrow drill channel, there remain many regulatory-related challenges in applying them to human use. These are the same challenges of ensuring safety that are intrinsic to the use of any motorized robot in surgery. Thus, as a more rapid means to initial clinical implementation of PCI, we present in this paper a manual insertion tool capable of deploying an electrode into the cochlea during PCI.

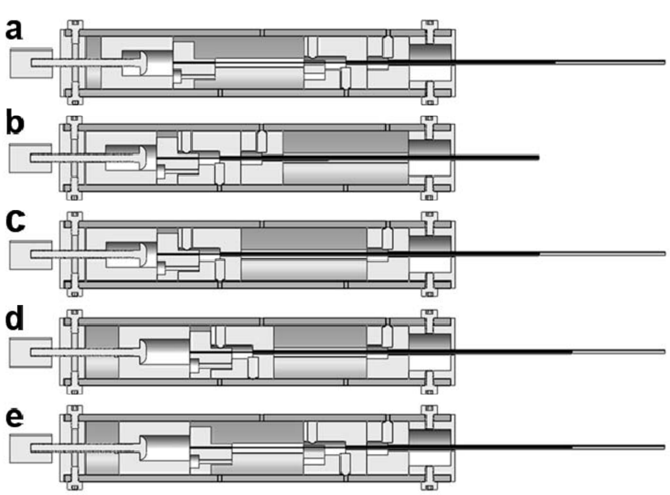

Figure 7: Illustrated above are the steps in the insertion process. (a) setting the adjustment screw defines the stylet travel, (b) retraction of the guide tube enables loading of the implant, (c) pushing guiding tube back into insertion position readies the device for deployment, (d) during deployment, the push tube and stylet advance together until the stylet hits the adjustment screw plunger, stopping it, (e) continued advancement of the push tube advances the electrode off the stylet into the cochlea.

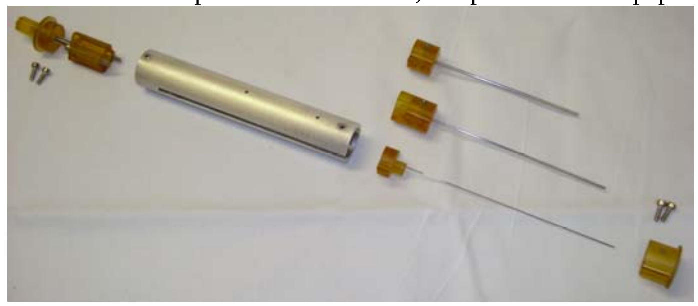

Figure 8: Photograph of the disassembled insertion tool prototype. The housing material is lightweight aluminum, and the interior components are made of Ultem® (Quadrant Engineering Plastic Products, Reading, PA), a special kind of plastic also used for manufacturing the microtable.

While the manual insertion tool we describe in following sections can be used independently, our intent is to couple it to the microstereotactic frame shown in Figure 5, which is currently used in PCI, so that depth and orientation of the insertion tool tip can be precisely set based on medical images, with reference to the microstereotactic frame.

MANUAL PCI INSERTION TOOL DESIGN

The basic concept of the insertion tool we designed is a sequence of concentric tubes that are used to support and deploy the electrode array, as shown in Figure 6. This concentric tube approach was motivated by the narrow 1.5mm diameter of drill channel, which precludes the use of bulkier insertion mechanisms (e.g. those involving grippers). To position the implant and achieve all motions necessary for AOS, three tubes are necessary: an outer 1.3mm diameter guide tube supports the implant up to the cochlea entry point. Within this outer tube is a second tube that can be translated with respect to the handle and outer tube, and serves to push the implant out into the cochlea. The third “tube” is actually the

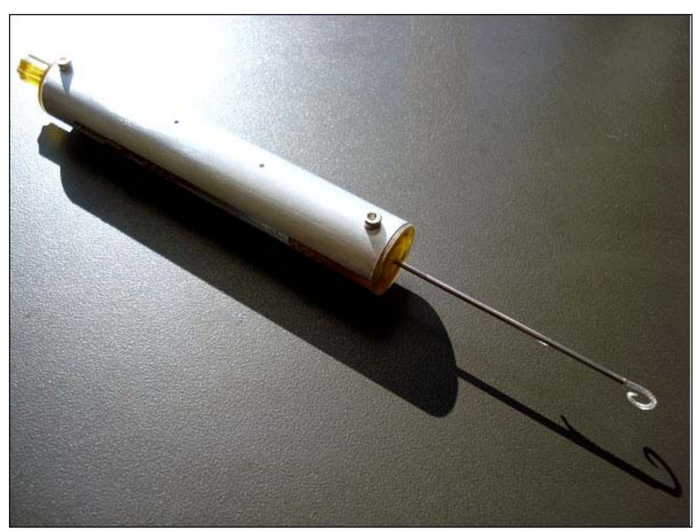

Figure 9: Photograph of the assembled prototype of the manual insertion tool.

stylet itself, which resides inside the electrode array. All tubes are held by mechanisms sliding inside a cylindrical housing with an outer diameter of 16mm and a length of 92mm.

The interior of the housing contains several sliding mechanisms, fixed to the base of each tube, as can be seen in Figure 6. Each of these sliders can be repeatably repositioned at several configurations by ball nose spring plungers attached to the sliders that snap into 1mm detents in the interior of the handle. The positions of the detents are 1) the loading position where the outer tube is retracted to enable access to inner tubes 2) the pre-insertion position where the outer tube is extended, 3) the start position of the push tube, and 4) the end position of the push tube. These positions are shown in Figure 7

One important feature of the device is that the initial straight insertion before the stylet stops (where the electrode begins advancing off the sytlet) can be accurately set manually by rotating an adjustment screw at the back of the device. This screw sets the translation of a stopper that sets the maximum forward translation of the base of the stylet. These components can be seen in Figures 6 and 7. Photographs of the actual disassembled and assembled insertion tool prototype can be seen in Figure 8 and 9, respectively.

Procedure for Use of Insertion Tool

Use of the insertion tool to deploy an electrode requires the following procedure. First, the adjustment screw at the base of the device must be adjusted to set the depth of straight travel of the electrode into the cochlea before AOS begins, which can be selected based on the surgeon's preference or based on analysis of preoperative CT images. Second, the slider attached to the guide tube must be fully retracted until its ball plunger snaps into the appropriate detent. Due to the design, this automatically sets all other sliders at their correct initial positions. Third, the implant must be loaded onto the stylet at the tip of the tool. Fourth, the guide tube must be fully advanced forward, covering the implant, at which time its ball plunger snaps into the appropriate detent. The tool is now ready for insertion.

Next, the surgeon manually grasps the handle and inserts the tubes into the hole drilled through the mastoid to the cochlea. Lastly, to accomplish deployment, the surgeon simply slides the lever attached to the push tube forward until its ball plunger snaps into the detent indicating maximum forward travel has been reached. The electrode array is now fully inserted into the cochlea, and the entire device may be removed, leaving the electrode array in place.

CONCLUSIONS AND FUTURE WORK

We have presented a manual insertion tool for cochlear implant deployment down a deep, narrow hole. This tool can facilitate deployment of the electrode array in percutaneous cochlear implantation, a newly developed technique that uses image guidance to reduce invasiveness in cochlear implant surgery. In future work, we intend to attach the insertion tool described in this paper to the microstereotactic frame used in PCI, known as the microtable (Figure 5), and perform experiments verifying the insertion tool's ability to insert electrodes as intended into 1) phantom models, 2) cadaver temporal bones, and 3) human subjects. After addressing sterilization of the device (likely gas sterilization, although this is a topic of future investigation), we expect translation to clinical use to proceed rapidly due to existing IRB approved protocols for microtable validation in human subjects. The microtable itself has already been validated in 27 human subjects to date, in vivo after mastoidectomy, using simulated drill bits to verify the accuracy of the trajectory it defines to the cochlea.

ACKNOWLEDGEMENTS

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