A Manually Operated, Advance Off-Stylet Insertion Tool for Minimally Invasive Cochlear Implantation Surgery

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February 11, 2013
Introduction

Fig. 1. Cochlear implant system. Sound is detected with an external microphone and transmitted electromagnetically through the skin to a subcutaneous receiver/stimulator, which delivers electrical impulses to an array of electrodes implanted within the cochlea. Image credit: National Institute of Health/Department of Health and Human Services.

Fig. 2. The microtable is a microstereotactic frame that serves to constrain a surgical drill to a linear trajectory from the lateral cranium through the facial recess to the cochlea. Each Microtable is custom-manufactured in less than 4 min using data obtained by automatic processing of a preoperative CT scan, and has a mechanical coupling for attachment of additional tools.

Fig. 3. (a) NCA electrode array preinserted with a stylet, shown on a 1-mm grid. (b) After insertion, the stylet is removed and the electrode array returns to a coiled shape, causing electrodes to rest in close proximity to the modiolus. (c) Magnified view of a section of the electrode array.
Insertion Tool Design

Fig. 4. Insertion tool includes three main components, each built from stainless steel and Ultem. The stylet arrester hooks to the stylet handle to enable AOS insertion and includes (a) a steel stylet latching tube, (b) an Ultem plunger, and (c) a stylet adjustment set screw. The electrode array pusher drives the electrode array into the cochlea and includes (d) a steel driver tube, (e) an Ultem spacer, (f) a steel piston tube, and (g) a thumb rest. The guide assembly includes (h) a steel containment tube, (i) an Ultem spacer, (j) a steel guide tube, and (k) an Ultem set screw catch.

Fig. 5. Stylet latching mechanism securely grasps the small handle of the NCA electrode stylet for AOS insertion. (a) Oblique view of concentric components within the containment tube, rendered transparently. (b) To load the stylet, the electrode array is pushed into the containment tube until the stylet handle is visible in the rectangular hole. (c) Electrode array pusher is advanced until (d) the stylet handle is observed by the user to be latched by the tip of the stylet latching tube.
**Tool Operation**

Fig. 6. AOS insertion is achieved with a single pushing motion. (a) Plunger and the spacer of the electrode array pusher are temporarily connected at the beginning of insertion by a frictional fit. (b) Advancing the electrode array pusher also advances the stylet arrestor plunger. (c) Upon reaching the preset stylet insertion depth, the set screw catch stops further advancement of the plunger, allowing the electrode array to be pushed off the stylet.

Fig. 7. Operation of the manual insertion tool. (a) After the drill has been removed from the Microtable, a linear slide holding the insertion tool is attached to the Microtable. (b) Linear slide carriage is advanced until reaching a mechanical stop, bringing the containment tube opening to the cochleostomy. (c) Push tube handle is pressed to perform AOS insertion of the electrode array into the cochlea. (d) Side view of thumb rest contacting the top ledge of the linear slide at full insertion depth. (e) Enlarged view of containment tube placement within the temporal bone.
Validation Method

Fig. 8. Experimental insertions were performed using Microtables customized for cadaveric temporal bone specimens using the technique developed for PCI surgery. A Microtable was used to drill to the cochlea of each specimen, and then the insertion tool was attached to a linear slide and mounted to each Microtable for electrode array insertion.

Fig. 9. Preoperative planning software automatically segments vital structures and determines an optimally safe trajectory from the lateral skull to the cochlea. This trajectory is used both for drilling to the cochlea and for the electrode array insertion tool. The software is also used to customize the stylet insertion depth and to determine the proper angle of the electrode array about the insertion axis.
Fig. 10. Endoscopic visualization of electrode array insertion in specimen 1. (a) View of the containment tube of the insertion tool positioned at the cochleostomy hole to begin insertion. (b) After removal of the insertion tool, the electrode array is fully placed in the cochlea.

Fig. 11. Postoperative results from three cadaveric temporal bone specimens implanted with electrode arrays using the manual insertion tool. (Top row) Microdissection images (created by C.G. Wright, University of Texas Southwestern Medical Center) (Bottom row) Reconstructions of electrode array positions using an automatic segmentation technique. For specimen 1, the electrode array was entirely within the scala tympani. The horizontal arrow indicates part of the osseous lamina injured during implantation and vertical arrow indicates contact with the modiolus. Specimen 2 had a similar defect in the osseous lamina, and the electrode array was also fully implanted in the scala tympani. In specimen 3, the electrodes were implanted lying on the osseous lamina in the scala vestibuli.