➢ Paper 1: "A manual insertion mechanism for percutaneous cochlear implantation"

Authors: Daniel Schurzig, Zachariah W. Smith, D. Caleb Rucker, Robert F. Labadie, Robert J. Webster III

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➢ Paper 2: "Insertion of electrode array using percutaneous cochlear implantation technique: a cadaveric study"

Authors: Ramya Balachandran, Jason E. Mitchell, Jack Noble, Daniel Schurzig, Gregoire Blachon, Theodore R. McRachan, Robert J. Webster, Benoit M. Dawant, J. Michael Fitzpatrick, Robert F. Labadie

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A. Intent

Cochlear implantation is a surgical procedure for treating patients with hearing loss in which an electrode array is inserted into the cochlea. In the traditional surgical approach, it is required to mill away a large portion of the mastoid bone to provide anatomical reference and access to the cochlea. This step, which is called mastoidectomy, is associated with the risk of damaging the facial nerve or impinging upon the auditory canal. Upon successful completion of mastoidectomy, cochleostomy is performed by drilling a small hole on the basal turn of the cochlea. Finally the electrode is inserted through this opening. The approximate duration for accomplishing these 3 main steps of the traditional surgery is reported as 171 minutes. The intent of the reviewed studies is to reduce the invasiveness of the procedure and surgery time through a minimally invasive technique - percutaneous cochlear implantation (PCI). Despite an automated robotic solution was developed with the same motivation by the same group previously, there were regulatory-related challenges for human use. For this reason, replacing the automated parts, a manual electrode insertion tool was developed and combined with some previously developed equipment. The researchers report the system mechanical design, surgical workflow, and the performance achieved in cadaver experiments. The team aims to proceed more rapidly towards the clinical use of their system with the new manual tooling design.

B. Technical Summary

In PCI, mastoidectomy is replaced by drilling a linear path from skull to cochlea, passing through the narrow space between the facial nerve and the Chorda Tympani without harming them. This generates a long thin channel which is approximately 35 mm deep and 1.5 mm in diameter. Although it is advantageous to have such access to cochlea for reducing invasiveness of the surgery and overall operation time, such an approach severely restricts the access area. In order to deploy off the electrode inside such a long thin channel it is not possible to use standard tools. Hence, the researchers proposed their own PCI tool design:

B.1. PCI Tool Design

In order to perform advance off-stylet technique through a very small access port, a mechanism was proposed using concentric tuve approach. Three tubes, including the stylet inside the electrode array were used. The outermost tube provided guidance during insertion while the middle tube is used to deploy off the electrode to curl it inside the cochlea channel. The starting location of the curling behavior (and the endpoint for straight insertion) is determined by the surgeon before insertion via an adjustment screw on the tool. When all of these pieces are assembled together, the resultant insertion mechanism is a compact unit with 92 mm long housing 16 mm in diameter. The tip of the instrument has a diameter of 1.3 mm, which is slightly smaller than the drilled hole inside the bone (1.5 mm).

Using the tool during the procedure consists of five fundamental steps:

1. The screw of the mechanism is adjusted to define the depth of straight electrode insertion.
2. The outermost tube (guiding tube) is retracted.
3. The implant is loaded on the tool.
4. The outermost tube is fully extended.
5. When the outermost tube reaches its limit, the insertion is completed. The tool with the stylet is removed.

B.2. Surgical Workflow

The authors present the following workflow for their surgical system:

1. Pre-operative CT scan of the patient is obtained.
2. Significant structures of the ear such as cochlea, facial nerve and the Chorda Tympani are automatically segmented. Based on the segmentation, a safe drill trajectory is built. This step takes about 3 minutes using Intel Xeon 2.4 GHz dual quad-core 64 bit machine with 10 GB RAM.
3. 3 fiducial markers are imlanted on the bone surrounding the ear, which takes about 8 minutes.
4. Intra-operative CT-scan is acquired in about 5 minutes.
5. Rigid registration is done between pre and intra-operative CT scans. The safe drill trajectory is transformed into intra-operative CT scan. The centers of the 3 fiducials are located on the scan.
6. Based on desired trajectory and 3 fiducial center coordinates, a Microtable is designed automatically. The Microtable is fabricated on a computer numeric control milling machine in 5 minutes.
7. The fabricated Mircotable is mounted on the fiducials. The drill is mounted on the Microtable. The long thin channel is drilled into the cochlea.
8. The drill is replaced by the manual insertion tool. The electrode is deployed into the cochlea. Upon completion, the tool, table and fiducials are removed.

B.3. Experiments and Results

The developed system was tested on 3 cadaveric bones following the aforementioned surgical flow. CT scans have shown that the drill reached the cochlea without damaging the facial nerve, and that the insertion was satisfactory in all specimens.

Importance

- The compact manual insertion tool provided access through deep narrow holes. Without such a tool, PCI technique wouldn't have been realized.
- The presented PCI technique reduced average operation time from 171 minutes to 60 minutes, which is a significant improvement in this field.
- The cadaver study is the first reported study demonstrating the insertion of electrode array using PCI.

Relevance

	Our Project	Reviewed Project
Differences	Developed for improving traditional cochlear implant surgery.	For improving percutaneous cochlear implant surgery.
	Using intra-operative OCT images.	Use pre and intra-operative CT images.
	Using steady-hand robot	No robot use
	Nothing is mounted on the patient.	The tool is rigidly fixed to the bone of the patient.
Similarities	Pre-curled electrode is inserted via Advance Off-Stylet technique.	
	Limited cochlea access ports, and thus seeking compact insertion tools.	

Critique

Strengths	Weaknesses
The problem of the current surgical procedure is strongly stated. Problem definition is clear.	The mechanism functionality and drawings are not clear.
Mechanism design criteria, restrictions and requirements are well stated, which has shaped and will further guide our designs.	The final (fifth) step of the tool usage is not shown. It is not clear how the tool is removed after the insertion is completed. (This is why we hadn't used concentric tube approach for our design.)
Surgical workflow is presented in detail, which can be beneficial for our project since we need to have one as well.	Verification of the electrode placement in cadaver experiments is not clear. (based on the presented OCT images.)
Based on the presented results, the improvement in operation-time is significant.	

Web Links

[1] http://dx.doi.org/10.1117/12.878786

[2] http://research.vuse.vanderbilt.edu/MEDLab/pub_files/SchurzigManualDMD10.pdf