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Force of Cochlear Implant Electrode Insertion Performed by a Robotic Insertion Tool: Comparison of Traditional Versus Advance Off-Stylet Techniques

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Introduction and Relevance:

The Galen Surgical Robot is a hand-over-hand cooperatively controlled surgical robotic system used for head and neck microsurgery. Currently, the Galen detects tool-to-robot forces to reduce hand tremors and increase precision, however, it is beneficial to detect tool-to-tissue forces for certain applications. Our project aims to create a force sensing surgical drill that can measure tooltip forces and communicate them with the Galen system which can be used to implement safety controls, provide surgical skill evaluation, and compare different surgical techniques.

In addition to surgical drills, other surgical tools can benefit from force sensing. For example, cochlear implant tools. Physicians can minimize forces through visualization of force, or determining which surgical techniques lead to smaller forces. In this paper, the authors use force sensing to prove that Advance Off-Stylet (AOS) provide lower average and maximum insertion forces over traditional insertion methods.

Summary:

In this paper, researchers from Vanderbilt University aim to quantify the differences between AOS and traditional cochlear implant electrode array insertion by quantifying the force of insertion. The researchers used an automated robotic insertion method that offers repeatability and minimization of insertion forces, thus leading to decreased intracochlear trauma [1]. Using a robotic insertion tool, the researchers were able to accurately quantify and analyze the force profiles during insertion in both the AOS and traditional insertion methods. To do this, the researchers perform electrode array insertion in an anatomically correct scala tympani model. The researchers found that the average force and maximum force was lower in the AOS method than the traditional method. These findings support the use of the AOS insertion method over the traditional insertion method.

Introduction:

In cochlear implants, an electrode array is inserted into the cochlea to provide a route of communication from the implant to the auditory nerve. Since the cochlea is spiraled, a physician cannot simply insert an electrode array into it [2]. There are two methods of electrode array insertion: The AOS technique and the traditional insertion method. In the AOS method, the electrode is advanced as the stylet is held in place after a specified distance. In the traditional insertion method, the stylet is withdrawn after insertion of the electrode into the cochlea.

This paper aims to quantify the difference in the force profiles during electrode array insertion of both the AOS method and the traditional method. There are two main challenges in doing so: 1) High degree of variability between trials performed by human operators which leads to difficulties in quantifying the difference between the two insertion methods and 2) the low rupture force of basilar membrane, between 0.029 to 0.039 N [3].

This paper offers three main contributions. First, empirical support for the use of the AOS method over the traditional insertion method. Second, evidence that automated insertion can minimize forces over manual insertion. Third, proof that force sensing is beneficial in certain surgical procedures.

Technical Approach:

Insertion tool

A difficulty in quantifying the difference between insertion methods is the high degree of variability between trials performed by human operators. To maximize repeatability and minimize variability between trials, the researchers chose to use an automated insertion technique. Previous reports have shown that automated cochlear implant electrode array insertion with robot devices is clinically feasible [4].

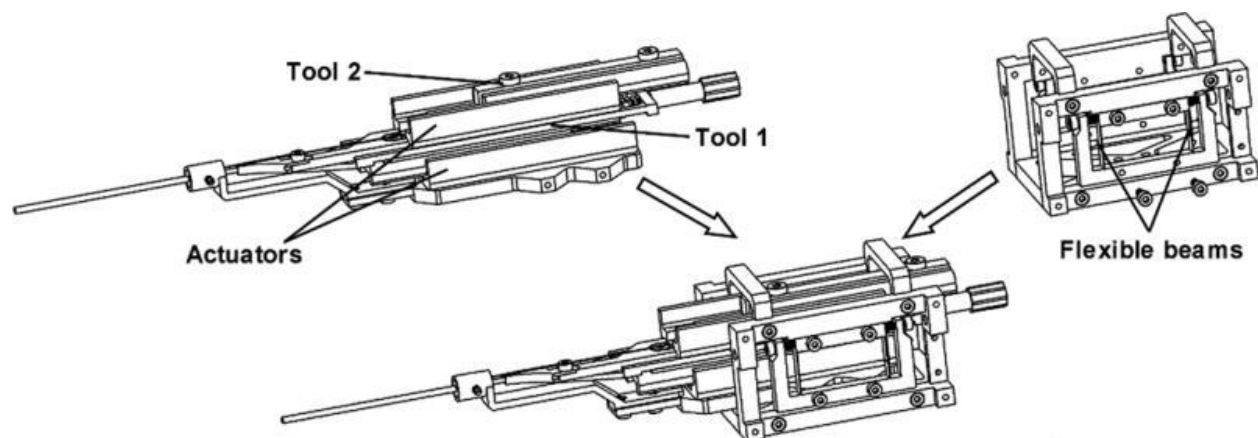


Figure 1: The insertion robot is composed of an insertion mechanism (top left) couple a force sensing unit (top left).

Figure 1 depicts the insertion tool that was used in the researcher's experiments. Central to the design are two linear actuators (Model SL2060; SmarAct GmbH; Oldenburg, Germany) in which tools that grasp specific portions of the electrodes are attached. The first actuator and tool assembly grasp the electrode array through a modified surgical alligator forceps (Model 180800FX; Fentex Medical, Inc.; Neuenhausen ob Eck, Germany). The second actuator and tool assembly hold the stylet through a stainless steel hooked wire. The two-actuator system allow for both the AOS and traditional insertion methods. Since the actuators are independent, the first actuator can advance the electrode array while the second actuator either keeps the stylet in place or retracts the stylet depending on which method is being used and what stage of the method that the insertion is in.

Force Sensing Unit

To provide force sensing, a force sensing unit is coupled with the insertion tool. The force sensing unit uses 4 flexible aluminum beams to transform the force along the axis of insertion into deformation which is measured by 4 semiconductor strain gauges (Model SS-060-033-1000PB; Micron Instruments, Inc.; Simi Valley, CA). The electrical readout of the strain gauges is then calibrated to quantify the force of insertion. This force sensing unit was design so that deformation and electrical readout from the strain gauges can be zeroed out before insertion experiments. With this setup, a .001 N force resolution can be achieved.

Phantom

An anatomically correct, three-dimensional model of the scala tympani component of the cochlea (Med-el Corporation; Innsbruck, Austria) was used for the experiments. The model was filled with soapy water to simulate intracochlear conditions. Figure 2 shows an enlarged view of the described model.

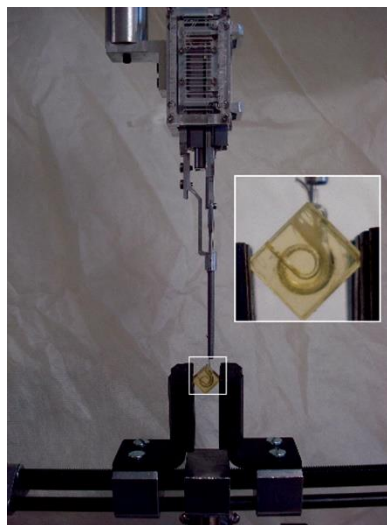


Figure 2: The insertion robot positioned above the scala tympani model for electrode insertion experimentation.

Experiment

The experimental setup is shown in figure 2. The insertion tool was loaded with a cochlear implant electrode and positioned above the model. Five insertions were performed for both the AOS and traditional insertion methods. During the insertions, the force in the insertion direction from the contact between the electrode array and the scala tympani model was measured with respect to the insertion depth in mm. The force profiles were then analyzed by calculating the average and peak insertion forces, then the force profiles were compared using confidence intervals.

Results:

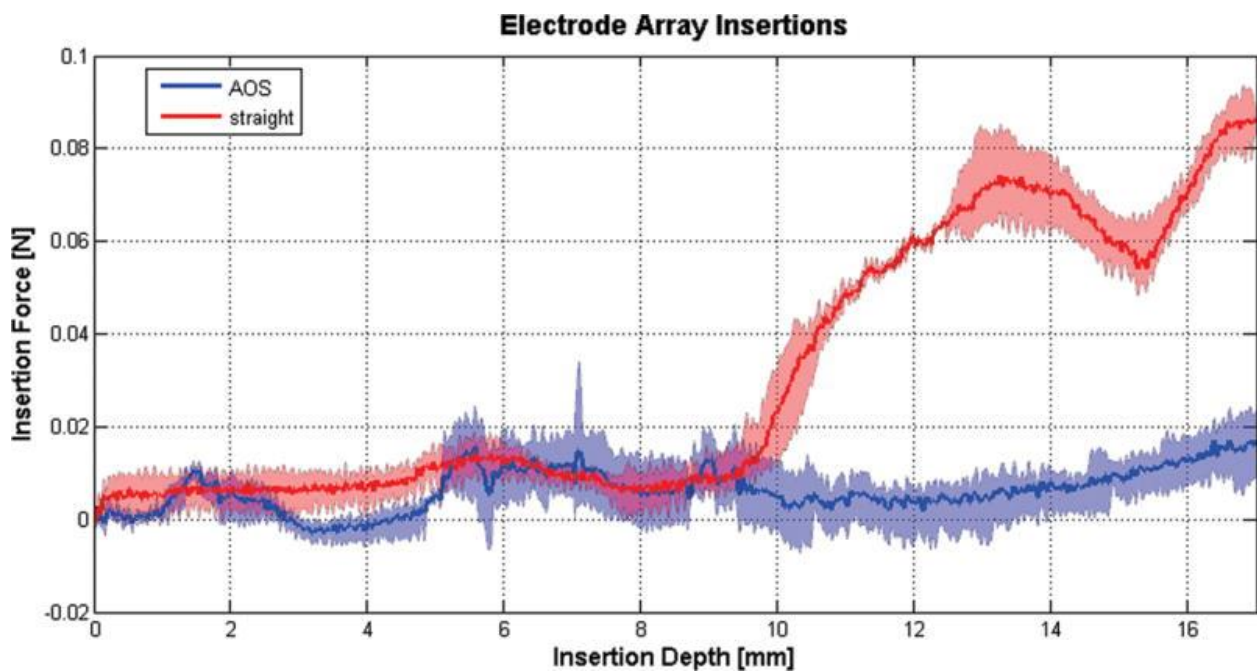
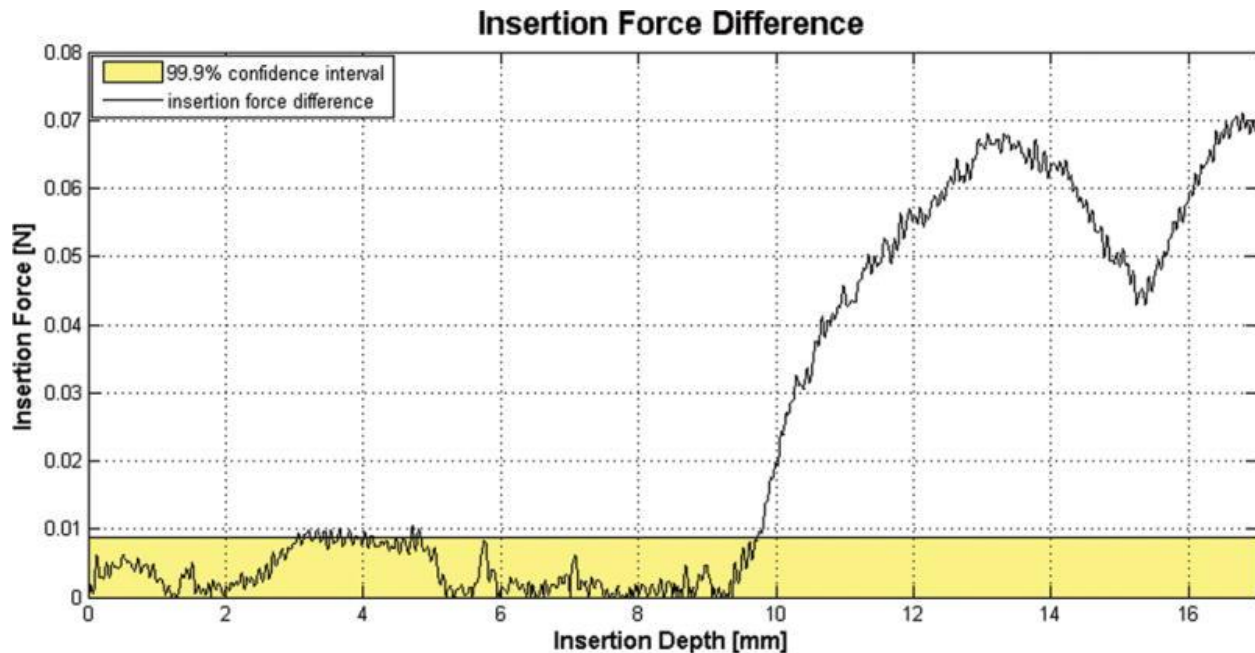


Figure 3: Insertion forces recorded with the force-sensing insertion tool with respect to insertion depth. The solid lines represent the average force of AOS and straight insertion techniques while the shaded regions show the variability in insertion forces.

In all 8 cases, the electrode array was successfully inserted 17 mm deep into the scala tympani model. In figure 3, measured insertion forces are presented where individual experiments in addition to averaged data are displayed. For the first 7 mm of insertion, the average force for recorded was 0.004 ± 0.006 N for the AOS and $.008 \pm .004$ N for the traditional method. Inside the spiral of the cochlea (7 mm to 17 mm insertion depth), the average force for recorded was 0.008 ± 0.006 N for the AOS method and $.046 \pm .027$ N for the traditional method. Force maxima were 0.034 N for the AOS method and 0.093 N for the traditional insertion.

Because the AOS and the traditional methods are the same for the first 7 mm of insertion, the researchers calculated the 99.9% confidence interval for the absolute value difference

between the two techniques. In figure four, this data is presented noting where the difference in the insertion methods exceeds the 99.9% confidence interval at an insertion depth of 9.74 mm. This means that the difference between the two methods beyond 9.74 mm insertion depth is highly significant.



Assessment:

This paper provided three main contributions. 1) Due to the lower force profile, it is proven that AOS should be the preferred method over the traditional method in electrode array insertion. 2) Provided evidence on how auto mated cochlear implant electrode insertion can minimize forces and decrease variability over manual insertion. 3) Proved that force sensing is beneficial in certain surgical procedures by showing AOS insertion forces were routinely below the rupture force of the basilar membrane while the traditional insertion force exceeded it. In providing these three contributions, the paper did some things well and some things poorly.

One strength of the paper is that it proves its hypothesis that AOS is the preferred method of electrode insertion. This was already generally accepted, but the researchers did this differently by using force sensing to quantify the two methods. The results were well quantified, so it was easy to see why the data in the paper led to the conclusions in the paper. In addition, the paper was succinct and provided most of the necessary background to understand the paper. Although the paper did some things well, it did other things poorly.

The paper was ridden with grammar errors and typos. For example, basilar membrane was written as "basilar member", something that brought initial confusion. The figure about the insertion tool was lacking description, so it was difficult to understand how the tool moves. There was a lack of necessary background in the paper, particularly regarding the insertion

methods. The AOS method description was inadequate and the traditional method description was incorrect. In addition, it was unclear what the stylet was used for and why the electrode array is inserted into the cochlea.

References

Reviewed Paper

Schurzig, Daniel et al. "Force of Cochlear Implant Electrode Insertion Performed by a Robotic Insertion Tool: Comparison of Traditional versus Advance Off-Stylet Techniques." *Otology & neurotology* : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology 31.8 (2010): 1207–1210. PMC. Web. 26 Apr. 2018.

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