Published in final edited form as:

Acta Otolaryngol. 2010 ; 130(1): 31–36. doi:10.3109/00016480902998281.

Force measurement of insertion of cochlear implant electrode arrays in-vitro: Comparison of surgeon to automated insertion tool

O Majdani, D Schurzig, A Hussong*, TS Rau**, J Wittkopf, T Lenarz**, and RF Labadie

D Schurzig: danielschurzig@gmx.de

Department of Otolaryngology-Head and Neck Surgery, Suite 7209 Medical Center East South Tower, Vanderbilt University, Nashville, TN 37232

*Institute for Robotics, Leibniz University of Hannover, Appel Street 11, 30167 Hannover, Germany

**Department of Otolaryngology-Head and Neck Surgery, Hannover Medical School, Carl Neuberg Street 1, 30625 Hannover, Germany

Abstract

Conclusions—We have demonstrated that an automated insertion tool (a.k.a. robot) can be used to duplicate a complex surgical motion in inserting cochlear implant electrode arrays via the “advance-off-stylet” technique (AOS). As compared to human operators, the forces generated by the robot were slightly larger but the robot was more reliable (i.e. less force maxima).

Objectives—We present force data collected during cochlear implant electrode insertion by human operators and by an automated insertion tool (a.k.a. robot).

Methods—Using a three-dimensional, anatomically-correct, translucent model of the scala tympani chamber of the cochlea, cochlear implant electrodes were inserted either by one of three surgeons (26 insertions) or by the robotic insertion tool (8 insertions). Force was recorded using a load beam cell calibrated for expected forces of less than 0.1 Newtons. The insertions were also videotaped to allow correlation of force with depth of penetration into the cochlea and speed of insertion.

Results—Average insertion force by the surgeons was 0.004 ± 0.001 N and for the insertion tool 0.005 ± 0.014 N ($p < 0.00001$, Student’s t-test). While the average insertion force of the automated tool was larger than that of the surgeons, the surgeons did have intermittent peaks during the AOS component of the insertion (between 120° and 200°).

Keywords

cochlear implants; robot-assisted surgery; insertion force

Correspondence to: D Schurzig, danielschurzig@gmx.de.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

Introduction

Cochlear Implants (CI) are standard of care for individuals with profound to severe sensorineural hearing loss with over 120,000 having been implanted worldwide. Since their clinical introduction over 30 years ago, surgical strategies have progressed from simply getting the electrode array into the cochlea to precisely placing the electrode array in the scala tympani in close proximity to the modiolus while preserving residual hearing. This is becoming more and more important as newer hybrid implants (a.k.a. short electrodes for electro-acoustic stimulation) are geared towards individuals with more residual hearing. Surgical technique is being critically analyzed and a new approach, termed “soft surgery,” has been popularized [1, 2]. Soft surgery consists of atraumatically opening the cochlea following which the electrode is slowly inserted without violating the basilar membrane. Studies indicate that “soft surgery” is associated with a higher degree of post-operative residual hearing [3].

To enhance atraumatic insertion, yet still affect perimodiolar positioning, cochlear implant manufacturers have modified their electrode designs as well as insertion recommendations. Cochlear Corporation (Sydney, Australia) has modified their electrode to include a soft tip (Contour Advance). Further, they advocate a novel insertion technique, called the “advance off-stylet technique” (AOS), where the electrode is inserted approximately 9mm into the cochlea at which point it is advanced-off of the straightening stylet which is held steady by the surgeon. Theoretically, this avoids trauma encountered at 10–12mm of insertion when the electrode hits the first turn of the cochlea (basal turn) and is often redirected into the basilar membrane causing cross-over. Using the Contour Advance electrode with AOS technique has resulted in less cochlear trauma and better perimodiolar positioning as assessed in temporal bone studies [4].

However, to achieve these tangible benefits, surgeons must change to the more demanding AOS technique abandoning the traditional approach of complete insertion of the electrode followed by stylet removal. Difficulties encountered during transition to AOS may include increased cochlear trauma and electrode fold-over. In an effort to make AOS easier, Cochlear Corporation designed a manual insertion tool in which the electrode was advanced to the 9mm depth following which a thumb switch was depressed which engaged a device to hold the stylet stable. AOS could then be achieved by further advancement of the electrode now with the stylet held in place. This device won accolades from the engineering community winning the 2004 Australian International Design Award but was not adopted by the surgical community as temporal bone studies showed intracochlear trauma in 3 of 9 specimens including 2 cases of violation of the basilar membrane with electrode migration to the scala vestibuli and 1 case of fracture of the osseous spiral lamina [4].

Independently, Hussong et al. [5] designed an automated insertion tool capable of achieving AOS. To do this, they first analyzed the geometric pattern of soft tip displacement which occurs with removal of the stylet. Then, the trajectory of the soft tip could be specified by the linear motion of the electrode and stylet which optimized tip trajectory to stay within the scala tympani minimizing cochlear trauma while maximizing perimodiolar positioning. Two micro-linear actuators were then programmed to achieve the optimized motion of the

electrode and stylet. Early results showed that the tip trajectory stayed within the confines of an acrylic model of the scala tympani. Building on this prior work, we sought to compare the insertion forces associated with AOS insertion both manually and using the robotic insertion tool of Hussong's design.

Material and methods

Force measurement station

A force measurement station was set-up as shown in Figure 1. Force was measured using a load beam cell (LCL-113G, Omega Engineering, Inc.; Stamford, CT) and signal conditioner (DRF-LC-24VDC-20MV-0/10, Omega Engineering, Inc., Stamford, CT) with output recorded on a laptop computer using an analogue-digital-interface card (Model PC-Card DAS 16/330", Measurement Computing Corp.; Norton, MA) and MATLAB software (version 2008a, MathWorks Inc.; Natick, MA). A three-dimensional, anatomically-correct, translucent model of the scala tympani chamber of the cochlea (Figure 2; MED-EL Corporation, Innsbruck, Austria) was mounted on the load cell using a binder clip. Prior to each experiment the system was calibrated using a 1 and 2 gram weight allowing conversion of the input voltage signal to a force reading.

Experimental Protocol

Nucleus Contour Advance electrodes (Cochlear Corporation, Sydney, Australia) which failed electrical quality control but were otherwise identical to clinically used electrodes were used for this study. These electrodes are molded in a precurled coil and have a central lumen for a platinum wire (stylet) which holds the electrode straight prior to insertion. With removal of the stylet, the electrode assumes the precoiled shape intended to place it in close proximity to the modiolus. The stylet can be reinserted using a reinsertion tool which straightens the electrode array allowing replacement of the stylet. Through experience we found that the stylet could be reliably replaced at least 10 times without compromising electrode integrity.

For each scenario described below (manual AOS, and robotic insertion tool AOS), up to 9 insertions were performed using the same electrode. The cochlear model was filled with soap solution to mimic biological conditions and minimize friction. Insertion was recorded using high-magnification cinematography. To allow correlation of the real-time video signal with the real-time force acquisition, a synchronization signal was employed consisting of touching the cochlear model with a surgical needle affecting a spike in force. Insertion of the electrode was then performed following the scenario described below in data processing.

Manual Insertion

Manual insertion was performed using "AOS technique" as follows: The electrode is inserted straight into the basal turn of the cochlear to the location of a white ring at approximately 9mm from the tip. At this point, the stylet is held in place with a jeweler's forceps following which the electrode is advanced off the stylet using a second jeweler's forceps. Insertion was considered complete when the 2nd of 3 elevated silicon rings (signaling the distal base of the electrode array and intended to plug the cochleostomy) were

inserted into the cochleostomy. Three different surgeons performed 26 AOS insertions with surgeon 1 doing 8 insertions, surgeon 2 doing 9 insertions, and surgeon 3 doing 9 insertions.

Automated insertion

Robotic AOS insertion was accomplished using a unique insertion tool previously described by Hussong et al. [5] Briefly, it consists of two independent piezoelectric step-motors with positional accuracy of 1µm and maximum velocity of 5 mm/s (SmarAct GmbH; Oldenburg, Germany). The first motor determines the position of the stylet and uses a set of surgical forceps to grasp and/or release the stylet. The second motor drives the electrode array. Both motors are rigidly affixed to a housing plate which is lined up at the location of the cochleostomy prior to insertion of the electrode. After alignment, robotic insertion is achieved by advancing the electrode array and stylet into the cochlea to a depth of 9mm following which the stylet is retracted and the electrode advanced. The autonomous insertion ended when the 2nd of the 3 silicon rings approximated the cochleostomy. A total of 8 insertions were performed using the robot at an insertion speed of 0.3mm/sec.

Data processing

Video data was analyzed using Final-Cut Express software (Apple Corp.; Cupertino, CA). A translucent overlay with angle units was overlaid on the video image to define the angle of insertion at each specific time period. The center of the cochleostomy site was defined as 0° insertion depth as shown in Figure 2. The start position varied between 0° and 17° owing to variability in the surgeon defined start point. Using this model a time-insertion/angle table was produced and correlated with the force measurement data based on the synchronization signal. Data results are presented in the results section as average force, maximum force, and speed of insertion versus angle of insertion.

Results

Figure 3 shows the raw data. The top panel shows the 26 manual insertions and the bottom panel the 8 robotic insertions. All insertions were made to at least 250°. As can be seen from this figure, there is greater variability in the manual insertions than in the robotic insertions. A summary of the insertion forces is shown in Figure 4, where the solid black tracing indicates the average force, the gray line represents the maximum force, and the dotted line represents the speed of insertion. Across the insertion depth, the average insertion force for the robot was 0.005 ± 0.014 N and for the surgeon it was 0.004 ± 0.001 N. This difference was highly significant ($p < 0.00001$, Student's t test). While, on average, the surgeons outperformed the robot, the surgeons had higher peak insertion forces during the AOS component (between 120° and 200°) during which manual insertion speed was over four times higher than automated insertion speed. The relative peaks associated with robotic and manual insertion can be seen in Figure 5, where single insertion force data are shown for both the insertion tool (gray) and surgeon (black). These data show a force peak at the initiation of insertion by the robot where the electrode first encounters the model (between 0° and 15°) and a force peak at the initiation of AOS by the surgeon (at approximately 105°).

Discussion

Cochlear implant surgery has progressed from rough placement of the electrode array into the cochlea to the current standard where great care is taken to ensure accurate placement within the scala tympani in an atraumatic fashion. In such microsurgical applications, lessons from other fields indicate that automated machines can consistently perform at least as good as if not better than human operators (e.g. LASIK eye surgery). Towards this end, our group addressed one cochlear implant electrode insertion technique (i.e. AOS) to determine how well an automated machine would perform as compared to a human operator. In prior work, we describe our automated insertion tool in detail. In this work, we have compared force measurements for CI electrode insertion between the automated insertion tool and human operators using an in-vitro model. Not surprisingly, the highly-trained human operator can outperform the machine and achieve lower average force recordings. However, during the AOS insertion component of the surgery, the robot achieves more repeatable results (fewer relative force peaks) than the surgeon at a force (0.005N) which, while statistically higher than the manual insertion average (0.004N), may not be clinically significant.

Our force value readings compare well with those previously reported. Todd et al [6] compared human operators inserting Nucleus Contour and Nucleus Contour Advance electrodes in a two dimensional scala tympani model and recorded force using an Instron 5543 machine. As per the manufacturer's specification sheet, this load cell is not factory calibrated for force measurements below 0.04 N, which included the range of forces reported by this group [7]. Nonetheless, they compared standard insertion technique (i.e. withdrawal of the stylet after complete insertion of the electrode array) to the AOS technique. For standard insertion, a force peak of 0.095-0.098N was noted after insertion to 9–12mm, the insertion depth at which the electrode touches the basal turn. Complete insertion was associated with another peak, this time up to 0.113N. Applying the AOS technique they noted a remarkable decrease of the applied forces down to an average of 0.005N. At complete insertion, an average peak force of 0.05N was recorded.

Roland [8] also used the same force measurement tool (Instron) to record forces associated with insertion of the Contour Advance electrode in a cochlear model. For the manual insertion technique, a peak of 0.07 N was recorded at 4mm insertion depth, the location where the electrode first has contact with the pars ascendens. As the electrode array made contact with the lateral wall of the basal turn, measured forces reached 0.1N. Using the AOS technique, minimal force was exerted on the outer wall except when the tip first contacted the outer wall of the pars ascendens before advancing off the stylet. All force values for the AOS technique were under 0.01 N.

Our findings are unique in that they report for the first time a machine, or robot, capable of reproducing a complex surgical task (insertion of a cochlear implant electrode array) at force reading similar to those of a human operator. While other groups have attempted similar approaches, they have used custom made electrodes which are not FDA-approved and are not intended for manual, human insertion [9].

In short, we have demonstrated that a highly-skilled human operator can outperform an automated insertion tool. However, during the AOS component of the insertion, the robot outperformed the human operator having fewer peak maximal forces. The clinically-relevant question is whether the difference in force or the transient peak forces are more damaging to the cochlear substructure. A report from 1995 indicates that the force required to rupture the basilar member is 0.029-0.039 N [10] suggesting that the transient peak forces – which occurred both with the robot (at initial insertion) and the human operator (during AOS) – are most damaging to the intracochlear anatomy. Interestingly, the speed with which the human operator inserted the electrode was highest during the peak forces associated with AOS.

Conclusion

We report herein on the use of an automated insertion tool or robot to place cochlear implant electrode arrays into a three-dimensional model of scala tympani. Compared to human operators, the machine was more reliable during AOS but had slightly higher average force values overall.

Acknowledgments

Funds were provided by the NIH (R21 EB006044 and R01 DC008408). Electrodes were provided by Cochlear Corporation.

References

1. Lehnhardt, E.; Laszig, R. Specific surgical aspects of cochlear implant*/soft surgery. In: Hochmair-Desoyer, IJ.; Hochmair-Desoyer, ES., editors. *Advances in cochlear implants*. Vienna: 1994. p. 228_9
2. James C, Albegger K, Battmer R, Burdo S, Deggouj N, Deguine O, Dillier N, Gersdorff M, Laszig R, Lenarz T, Rodriguez M, Mondain M, Offeciers E, Ángel R, Ramsden R, Sterkers O, Von Wallenberg E, Weber B, Fraysse B. Preservation of residual hearing with cochlear implantation: How and why. *Acta Oto-Laryngologica*. 2005; 125:5,481–491. [PubMed: 15799566]
3. Fraysse B, Ángel R, Sterkers O, Burdo S, Ramsden R, Deguine O, Klenzner T, Lenarz T, Rodriguez M, Von Wallenberg E, James C, et al. Residual Hearing Conservation and Electroacoustic Stimulation with the Nucleus 24 Contour Advance Cochlea Implant. *Otology & Neurology, Inc*. 2006; 27:624–633.
4. Stöver T, Issing P, Graurock G, Erfurt P, ElBeltagy Y, Paasche G, Lenarz T, et al. Evaluation of the Advance Off-Stylet Insertion Technique and the Cochlear Insertion Tool in Temporal Bones. *Otology & Neurology, Inc*. 2005; 26:1161–1170.
5. Hussong, A.; Rau, T.; Eilers, H.; Baron, S.; Heimann, B.; Leinung, M.; Lenarz, T.; Majdani, O. Conception and Design of an Automated Insertion Tool for Cochlear Implants. 30th Annual International IEEE EMBS Conference; Vancouver. 2008.
6. Todd C, Naghady F, Svehla M. Force application during cochlear implant insertion: an analysis for improvement of surgeon technique. *IEEE Transactions of Biomedical Engineering*. 2007; 54(7): 1247–55.
7. Product specification sheet for Instron 5500 series (page 16) available from URL http://www.instron.us/wa/products/universal_material/5540.aspx.
8. Roland JT. A model for cochlear implant electrode insertion and force evaluation: results with a new electrode design and insertion technique. *Laryngoscope*. 2005; 115:1325–1339. [PubMed: 16094101]

9. Zhang J, Xu K, Simaan B, Manolidis S. A pilot study of robot-assisted cochlear implant surgery using steerable electrode arrays. MICCAI. 2006:33–40. [PubMed: 17354871]
10. Ishii T, Takayama M, Takahashi Y. Mechanical properties of Human Round Window, Basilar and Reissner's Membranes. Acta Otolaryngol (Stockh). 1995; 519(Suppl):78–82.

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Figure 1.
Experimental set-up. Shown is the cochlear model affixed to the load cell using a binder clip.

Figure 2.
Definition of angular insertion depth based of the translucent scala tympani model.

Figure 3.

Raw force data for manual insertions (top panel) and robotic insertions (bottom panel). Force is shown on the y-axis in Newtons (N). Depth of insertion is shown on the x-axis in degrees. Each trace represents 1 insertion, with 26 manual and 8 robotic insertions. Greater variability of Force is evident in the manual insertion data.

Figure 4.

Insertion force (Newtons) is plotted on the left ordinate, speed of insertion (degrees/second) on the right ordinate, and insertion depth angle (degrees) on the abscissa. Shown are average force (solid line), maximum force (gray line), and speed of insertion (dotted line). Left panel – results for insertion tool (average of 8 insertions), right panel – results for manual insertion (average 26 insertions by three surgeons).

Figure 5. Single insertion data showing relative peaks for the robotic insertion tool at 0°, where the electrode first encounters the model, and for the surgeon at 105°, where AOS is initiated.