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Real-time measurement of electrode impedance during intracochlear electrode insertion

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Abstract

Objectives—This pilot study details the use of a software tool that uses continuous impedance measurement during electrode insertion, with the eventual potential to assess and optimize electrode position and reduce insertional trauma.

Study Design—Software development and experimental study with human cadaveric cochleae and two live surgeries.

Methods—A prototype program to measure intracochlear electrode impedance and display it graphically in real time has been developed. The software was evaluated in human cadaveric temporal bones while simultaneously making real time fluoroscopic recordings, and in two live surgeries during intracochlear electrode insertion.

Results—Impedance changes were observed with various scalar positions, and values were consistent with those obtained using clinically available software. Using Contour Advance™ electrodes, impedance values increased after stylet removal, particularly when using the monopolar mode.

Conclusion—Impedance values seem systematically affected by electrode position, with higher values being associated with proximity to the cochlear wall. The new software is capable of acquiring impedance measurements during electrode insertion and this data may be useful to guide surgeons to achieve optimal and atraumatic electrode insertion, to guide robotic electrode insertion, and to provide insights about electrode position in the cochlea.

Keywords

cochlear implants; impedance; electrode position

Introduction

Minimizing electrode insertion trauma and obtaining appropriate electrode placement during cochlear implantation is essential for preservation of residual hearing and improved clinical outcomes¹. Appropriate electrode placement might also assist with programming bilateral

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cochlear implant (CI) patients and facilitate currently evolving programming paradigms such as flexible frequency map allocation². However, other than fluoroscopy, real-time feedback about the trajectory and actions of electrode insertion is not available to the surgeon during surgery. Placement mishaps, such as electrode tip rollover, are usually not detected until some time after surgery when investigating performance issues or at the time of surgery if surgeons obtain intraoperative X-rays, spread of excitation evaluations, or neural response evaluations prior to completing the surgical procedure. Detection and management of a problem with electrode placement often requires the removal of the device and re-implantation either at the time of or at some point in time after original surgery.

Careful surgical technique and training, cochleostomy position, round window insertion, new designs of electrode structure, and novel insertion tools and techniques are some of the emerging concepts that may help reduce insertion mishaps and intracochlear trauma. However, despite the aforementioned, surgeons have no real time feedback about electrode status after it passes through the cochlear opening. As a result, detection of problems often occurs after trauma has already occurred or after the electrode array has been damaged and is no longer reusable.

One possible source of information to help determine the relation of the electrodes to the cochlear walls during surgery is the use of electrode impedance measurements. Previous studies^{3,4,5,6} have shown that perilymph has a 10-fold higher conductivity than bone (i.e., lower resistivity), leading to the hypothesis that measured electrode impedance (which is monotonic with respect to resistivity) should be higher when an electrode approaches the cochlear wall compared to when the electrode is in the middle of the scala. This is particularly expected in the case of electrodes whose stimulating contacts are on a single side of the carrier, typically the side facing the cochlear modiolus. The use of impedance measures is attractive because all CI systems approved in the United States already include hardware and software to obtain such measures for clinical use. Typically, this functionality is only used postoperatively to verify CI functioning and electrode integrity. In the present study impedance measurement functionality has been extended by developing prototype software that can measure continuous impedance values during electrode insertion. This manuscript details our initial experience and presents our current results using this prototype software to measure continuous impedance values in human cadaveric temporal bones and two live CI surgeries.

Materials and Methods

Software

A Continuous Impedance Measurement Tool (CIM) was developed to measure the impedance values from electrodes of Cochlear™ CI systems. This software tool makes impedance measurements using the telemetry feature of the circuit. No special or proprietary equipment is required and only a standard clinical accessory (the “POD” interface for Freedom programming) is necessary along with a Freedom (SP12) speech processor. Both the POD and the speech processor are standard and manufacturer-specific devices that are available at most CI clinics.

The CIM system measures impedance by passing a known current between two (or more) electrodes and measuring the voltage difference produced. The impedance is then calculated by dividing the voltage measured by the current supplied. The input current is a biphasic pulse with a 25 μ s pulse width and amplitude of 74 μ A. The voltage measurement is taken at the end of the first phase. Each impedance measurement is taken individually and the CIM provides continuous impedance measurements on multiple electrodes by sequentially scanning through all electrodes selected by the user.

Cochlear implants provide a number of different parameters which change the way the current flows through the electrodes to stimulate the recipient. The CIM software gives the user control over some of these parameters, including the ability to stimulate several different electrode combinations, and the number of electrodes which are stimulated. The user of the software defines a set of stimulation parameters (such as the specific electrodes to be measured and monopolar vs. bipolar configuration) which then define how the impedance measurements are taken.

A continuous series of impedance measurements is taken and entered into a text log. These measurements can continue for as long as desired, for example during an entire electrode insertion into a cochlea. Once the desired measurements have been gathered, the data can be processed offline and plotted. Using this data, the user is able to see how the impedance at the electrodes changed throughout the measurement run.

Later versions of the software are also able to plot these measurements in real time. As each measurement is taken by the implant, the data is added to a text log, and at the same time, added to a real time plot of the impedance against time for each electrode. There is also a plot of the instantaneous impedance of each electrode. In addition, it is possible to place markers and comments into the text log and plots at a specified time. These functions allow the user to see impedance changes in real time, and document any physical events which may affect the impedance of the system. Actual operation of the system can be observed in the supplementary video clip that shows the program's window (left of the screen) and an electrode insertion in an acrylic model of a human cochlea (right). The program's window shows two plots that change in real time as the electrode array is inserted and impedance values change. The top graph shows longitudinal changes in impedance for each electrode selected by the user for display and the bottom graph shows a bar graph with instantaneous impedance values.

Human cadaveric temporal bone experiments

The cochleas were harvested from fresh fixed cadaveric temporal bone specimens and a 1.2 mm cochleostomy was made just inferior to the round window membrane. The cochleas were fixed in a modified bone holder and flooded with saline prior to each insertion. A separate hole was drilled to fix the free ground electrode to the bone. Figure 1 shows a cochlea in the bone holder with an electrode array partially inserted into it. The ground electrode can also be seen, and the edge of the cochlear implant electronics package is at the top of the figure. The inset at the lower right shows a radiograph of the experimental setup. Numerous insertions were performed under microscopic vision with a fully functioning Freedom™ implant with the Contour Advance™ electrode. Continuous fluoroscopic real time recordings were made and continuous impedance measurements were recorded simultaneously using the CIM software. The collected timed data were analyzed for changes in electrode impedance values with changes in electrode intrascalar position. In particular, five successive measures of impedance were obtained before and after stylet removal. The mean values were compared with unpaired Student t-tests after verifying that the data passed the Shapiro-Wilk normality test. If the data were not normally distributed, the Mann-Whitney rank sum test was used instead. . This was done once using a monopolar electrode configuration and once using a bipolar electrode configuration.

Trials of continuous impedance measuring software during live surgeries

Continuous real time impedance measurements were recorded on two human surgeries. Both surgeries were carried out in the normal fashion. Both patients (R1 and R2) received the Freedom cochlear implant with the Contour Advance™ electrode. The recordings commenced as the electrode first entered the cochlea and continued until full insertion was

completed. Both patients had normal cochlear anatomy as determined on preoperative temporal bone CT scanning. The test was performed during normal CI surgery. For the measurements, a Lenovo X61s notebook was used running the CIM application under Windows XP. All other programs were shut down through the task manager. A POD was connected to a USB port, and then connected to a standard SP12 (Freedom) speech processor. A standard coil was connected to the SP12. The coil, SP12 and cables, up to the POD, were put into a standard sterile bag. After making the cochleostomy, but prior to insertion, the surgeon connected the coil to the cochlear implant device. When the connection to the implant was made successfully, the surgeon gave the signal to start recording impedances and then began electrode insertion.

In R1, the electrode was inserted while electrodes 5, 15, and 22 were monitored for impedances (using a monopolar electrode configuration) until a full insertion was done. In R2, the electrode was inserted while electrodes 5, 9, 10, 15, and 22 were monitored for impedances. However, once a full insertion was done, the surgeon slowly retracted the electrode array approximately 1 mm and then reinserted it. This was done to test if the location changes induced by this movement would become evident on the impedance scan. Five to ten minutes after electrode insertion was complete, intraoperative measures of electrode impedance were made using standard clinical software (Custom Sound™).

Results

Figure 2 shows screen captures of fluoroscopic recordings obtained before and after stylet removal (panels a and b respectively). The difference in position is clear, with electrodes being much closer to the inner wall (particularly in the apical region but also in the basal region), and more deeply inserted, after removal of the stylet. Impedance values for each electrode measured using a monopolar electrode configuration before and after stylet removal are shown in Figure 3, and the changes are shown in Figure 4. These changes were statistically significant at the $p < 0.001$ level for electrodes 19, 20, 21 and 22 and at the $p < 0.01$ level for all other electrodes. Impedance increased systematically throughout the array, but particularly in the basal region. Figure 5 shows electrode position for a second electrode array pre- and post-stylet removal. In this case impedance was measured using a bipolar electrode configuration and Figures 6 and 7 show that impedance differences were clear only in the apical end (electrodes 19–21). Nevertheless, pre- to post-stylet removal impedance changes were statistically significant for electrodes 1, 3, 4, 6, 10, 11, 19 and 21 at the $p < 0.001$ level and at the $p < 0.01$ level for all other electrodes. Throughout these experiments whenever the electrode array was immobile the real time display of the CIM software did not show any impedance changes. Follow up studies should confirm that these “false positives” indeed do not occur.

Figure 8 shows the results for patient R1. The X-axis shows elapsed time in seconds, as returned by the CIM software during measurement. The Y-axis shows the impedance measured in Ohms. We estimate that advancement off the stylet started just before 10 sec, with E05 entering the cochlea around the 12 second mark and stylet removal close to the 32 second mark. Figure 9 shows results for patient R2. For this patient the electrode array was retracted about 1mm after full insertion and then re-inserted. This retraction-reinsertion movement, which takes place between the 43 and the 60 second marks, is clearly visible on all electrodes. The other notable finding is the large change at about 10 to 12 seconds in patient R1 and at 18 seconds in patient R2, which is when the advance-off-stylet process was initiated. The electrode was inserted into the cochlea to approximately 11 mm. At this point the tip just touches the back outer wall at about 180 degrees and the advance off stylet process is initiated, with the more apical electrodes making the biggest changes in position, moving from the outer wall toward the modiolus. Figure 10 shows a scatterplot comparing

the final impedance values for each electrode obtained with the CIM software to those obtained using Custom Sound five to ten minutes later, after the electrode arrays were in place. The correlations between values obtained with CIM and with Custom Sound were very high ($p=0.98$ for R1 and $p>0.99$ for R2, $p<0.001$ in both cases). Measured impedance values were higher with CIM than with Custom Sound (about 1,300 Ohms for R1 and 370 Ohms for R2), which is perfectly consistent with the slow but clear downwards trend in all traces at the end of the CIM recording for both patients, and the fact that Custom Sound measurements were obtained a few minutes after the CIM measurements.

Discussion

The results of these feasibility experiments confirm that real time impedance testing is easily obtainable with this system in human temporal bones and in live surgeries. Impedance changes were obvious when intrascalar position changes occurred as evidenced by fluoroscopy. The largest changes occurred when the contour advance electrode was fully inserted and then the stylet was removed. As the stylet was removed the electrode array moved from the outer wall toward the inner wall and the modiolus. Note that this is not the usual recommended advance-off-stylet technique, but it was undertaken for experimental purposes only. Similar findings were seen in the two human insertion recordings at the point that the advance off stylet technique was initiated. Electrode movement towards the modiolus was associated with increases in measured impedance, especially in the monopolar configuration. Tsuji et al.⁷ also measured electrode impedance before and after stylet removal and did not find a decrease in values with greater proximity to the cochlear wall. However, as they correctly point out, their impedance measurements may have been more influenced by the high current levels that were delivered between the two impedance measures in their study. As Figures 8 and 9 show, impedances were indeed sensitive to the relative movement of the electrodes to the cochlear walls during insertion and shortly thereafter. It is nice to note that the retraction movement in R2 can clearly be seen on the impedance tracks of Fig. 9. As has been shown before⁸, impedances for apical electrodes are higher than those for basal electrodes. Interestingly, our measurements show a similar organization that arises very quickly during insertion.

The ability to steer electrodes to obtain appropriate positioning in the cochlea and prevent trauma to its delicate structures may help improve CI outcomes. Ideally, an electrode should not touch the cochlear walls during insertion thereby preventing any intracochlear trauma. The capability of measuring electrode impedance in real time might also be coupled with robotically steerable insertion systems that are currently under development⁹¹⁰¹¹¹²¹³. To be sure, there are other technologies that can be used for guidance with a robotic or human guided insertion system, including path planning using imaging, optical reflectance, force sensors or even chemical sensing. However, implementation of these types of feedback systems would likely greatly increase the cost of the cochlear implant devices. In contrast, impedance testing is built into every currently available CI system and using it to complement other sources of information to help electrode guidance in a real time manner would not require major development and manufacturing changes or cost increases in a cochlear implant. Results from the present pilot study are encouraging and indicate that continuous impedance measurement technology is worthy of further investigation to determine its potential usefulness as well as its limitations. We plan to further characterize the precise scalar position to impedance relationship with experiments using more refined imaging techniques as well as improved versions of the CIM software. It is not clear at this point whether impedance measurements will help detect tip rollovers, but it is at least possible that they may help complement the surgeon's tactile feedback.

Conclusion

The continuous impedance measurement system described here was able to record as expected and is feasible for use with cochlear implant electrode insertion. The impedance measurements change with electrode position as seen on fluoroscopy. Further development of this system and characterization of scalar position with impedance changes is ongoing.

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Figure 1. Cochlea in bone holder with electrode array partially inserted through a cochleostomy and ground electrode inserted in a drilled hole. Inset: radiograph showing the implant electronics, with its active and ground electrodes in the cochlea.

Figure 2.
Electrode position before and after stylet removal

Figure 3.
Impedance values throughout the electrode array before and after stylet removal, measured using a monopolar configuration.

Figure 4.
Increases in impedance after stylet removal are particularly pronounced at the basal end of the array.

Figure 5.
Electrode position before and after stylet removal

Figure 6.

Impedance values throughout the electrode array before and after stylet removal, measured using a bipolar configuration. Changes are noticeable only at the apex.

Figure 7.
Using the bipolar configuration, impedance changes are more pronounced near the apex.

Figure 8. Impedance measurements during a live surgery at the time of electrode insertion, electrodes 5, 15, and 22.

Figure 9.

Impedance measurements for a second patient during electrode insertion. Notice changes in all five electrode impedances during electrode retraction at 43 seconds, reinsertion at 50 seconds, and release at 60 seconds.

Figure 10.

Scatterplot of impedance values obtained with the Continuous Impedance Measurement tool versus values obtained a few minutes later using standard clinical software.