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Protective Effects of Patterned Electrical Stimulation on the Deafened Auditory System

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ABSTRACT

In this Quarterly Progress Report, we present results of a study that was reported recently at the 5th European Symposium on Paediatric Cochlear Implantation held in Antwerp, Belgium. The research was conducted primarily by Dr. Peter Wardrop, a specialist registrar in Otolaryngology from the Royal Infirmary in Edinburgh, Scotland, who spent 6 months as a TWJ Foundation research fellow in the Epstein Laboratory. Dr. Wardrop presented his findings in an oral presentation and co-authored a poster prepared by Steve Rebscher, entitled "Second generation designs of cochlear implant electrodes: Relating the incidence, location and severity of trauma to mechanical aspects of electrode design." This poster was honored as "Best Poster of Session" at the Symposium, and it is presented here with only minor modifications.

Two manufacturers of cochlear implant systems, Advanced Bionics, Inc. and Nucleus Corp., have developed modified intracochlear electrodes in an attempt to improve system efficiency and performance by locating the stimulating contact sites closer to the neural targets (spiral ganglion cells) within the modiolus and positioning the stimulating array farther into the scala tympani (to access lower frequency regions of the cochlea). Previous reports indicate that an unintended consequence of these new strategies may be an increase in the frequency or severity of surgical insertion trauma. Such trauma may ultimately reduce performance or make the replacement of a failed device more problematic.

The purpose of this study was to compare the mechanical characteristics and insertion trauma observed of currently available intracochlear electrodes with two second generation arrays developed by the same manufacturers. An additional objective is to relate the insertion properties of each of these electrodes to their mechanical properties and physical dimensions.
Human cadaver temporal bones were implanted with four sets of electrodes: the current Nucleus Banded™, Nucleus Contour™, Clarion™ Spiral and Clarion Self-Guiding HiFocus™ electrodes. Insertions were performed by surgeons selected by the manufacturer based on their experience with each device. A second group of electrodes was implanted by a final year otolaryngology registrar who received training equivalent to the manufacturers' instructional courses. Following insertion, the otic capsule was thinned over the cochlea (to facilitate orientation for sectioning), the specimens were dehydrated, embedded in acrylic resin, and cut in radial sections with a diamond saw. Electrode diameters were measured both before and after the embedding process to assess possible dimensional changes during processing. Electrode stiffness was measured at 2-mm increments along each electrode in the vertical and horizontal planes. Stiffness was defined as the force required to deflect the electrode 30 degrees at a point 2 mm distal to the location measured.

The four electrodes evaluated varied in size, shape, overall stiffness and in the ratio of vertical to horizontal stiffness. We found that the trauma to cochlear structures observed with each design varied characteristically in location and incidence and was predictable based upon the mechanical measurements made in this study. Specifically, the size and shape of the electrodes tested were clearly correlated to the location of damage observed. The ratio of vertical to horizontal stiffness was the most important factor in determining the extent of damage to structures overlaying the scala tympani.

Second Generation Cochlear Implant Electrodes: Relating the Incidence, Location and Severity of Trauma with Mechanical Aspects of Electrode Design.

INTRODUCTION

The remarkable clinical success of multichannel cochlear implants has driven an industry wide effort to develop a second generation of intracochlear electrodes. Ideally these new devices will be superior in three important aspects:

First, improved electrodes should be more efficient than current models. Theoretical and empirical data indicate that the stimulus current required decreases if electrode contacts are located closer to the spiral ganglion cell bodies in the modiolus. This will result in longer battery life and ultimately enable full-feature speech processors that are small enough to be worn behind the ear.

Second, subject performance should improve with modified electrode designs. This improvement will hopefully include increased channel selectivity, deeper location of apical electrode contacts to activate lower frequency regions of the cochlea and a reduction in the number of subjects who are unable to achieve comfortable loudness levels with an implant.

Third, new electrode designs should reduce the incidence and severity of trauma, which results in subsequent neural degeneration. The issue of insertion trauma has become increasingly important as subjects with greater residual hearing are implanted and as the preservation of acoustic hearing becomes an important consideration for combination hearing aid/cochlear implant devices. In addition, our recent studies suggest that the number of spiral ganglion cells present is correlated with both electrical response threshold and temporal resolution capacity.

In the current study, we have used an improved method to evaluate electrode placement and surgically induced trauma in cadaver temporal bones, and we have correlated these findings with measurements of the physical and mechanical characteristics of the devices.

METHODS

Electrodes:

Four different electrode designs were evaluated in this study. Designs #1 and #3 have been well characterized during years of clinical experience with these first-generation designs; designs #2 and #4 represent newly developed second-generation cochlear implant electrodes:

1. Straight, Banded Electrode, Cochlear LTD.
2. Contour™ Spiral Electrode, Cochlear LTD.
3. Spiral Clarion™ Electrode, Advanced Bionics, Inc.
4. HiFocus™ Electrode with Attached Positioner, Advanced Bionics, Inc.

Surgeons and Comparison Groups: Eight electrodes of each type were studied. Four were implanted by a highly experienced implant surgeon selected by each manufacturer based on his experience with the devices to be tested. Dr. Thomas Roland implanted the Cochlear Corporation electrodes and Dr. William Luxford implanted the Advanced Bionics devices. The remaining four of each type of electrode were implanted by Dr. Peter Wardrop, a final year surgical resident and coinvestigator in this study.

Temporal Bones: Cadaver temporal bones were removed within 24 hours postmortem and fixed in 10% buffered formalin for 24 hours. The specimens were stored in 0.1M phosphate buffer for less than two weeks prior to implantation.

Implantation: Each TB was prepared for implantation via a facial recess approach with particular attention given to replicating the access and all constraints of the actual surgical procedure *in vivo* whenever possible. A cochleostomy was performed in each TB and electrodes were inserted as per the usual practices of each experienced surgeon. The resident performed the second series of insertions after observing the experienced surgeons.

Use of Lubricant: A solution of 50% glycerin in saline was used as a lubricant in all insertions with the Cochlear Corp. electrodes at the preference of the experienced surgeon and in the Advanced Bionics electrode insertions performed by the resident. The experienced surgeon implanting the Advanced Bionics electrodes elected not to use lubricant in these insertions. When used, the lubricant was gently infused throughout the cochlea after removal of both the round window (RW) and oval window.

Radiography and Embedding:

1. To facilitate making measurements, a radiopaque marker was cemented above the (RW) on each specimen following the electrode insertion. A plain film x-ray then was taken of each bone to record the electrode position prior to processing.
2. The bone overlying the cochlea was removed and the cochlea was thinned by drilling to reveal the "blue line" of the scala vestibuli through the bone. The apex of the cochlea was opened to provide a marker for determining the mid-modiolar plane at the time of sectioning. This step also permits better resin penetration for the embedding procedure.
3. Specimens were dehydrated in a graded series of ETOH, embedded in L.R. White™ Hard acrylic resin under vacuum and cured at 60°C for 8-12 hours.
4. Cured blocks were again x-rayed to confirm electrode position after processing.

Sectioning: Cured blocks were cut into quarters through the modiolus with a low speed saw (Beuhler, Inc.) using a diamond wafering blade (.012" thickness) and the resulting surfaces were polished for viewing. This method, and the use of a very thin blade, minimizes the loss of specimen material in the cutting process and leaves the majority of the specimen intact for later analysis or further sectioning.

Assessment of Trauma: Polished block surfaces were viewed with both transmitted and reflected light (Figure 1). The condition of the cochlear structures was evaluated for each cross section by two investigators.

Depth Measurement: X-ray images were digitally scanned to allow measurement of electrode placement in each specimen. Canvas™ graphics software was used to make all measurements. The total length of insertion was measured from the RW to the apical tip of the electrode, along its longitudinal axis. The depth of insertion in radial degrees was measured using the modiolus as the centroid with ninety degrees defined as the intersection of a line through the modiolus and perpendicular to the straight line from the RW as shown in Figure 2.

Electrode Stiffness: To evaluate the functional mechanical properties of each electrode design we measured stiffness in the vertical and horizontal planes with the vertical plane defined as the plane parallel to the axis of the modiolus (see Figure 3).

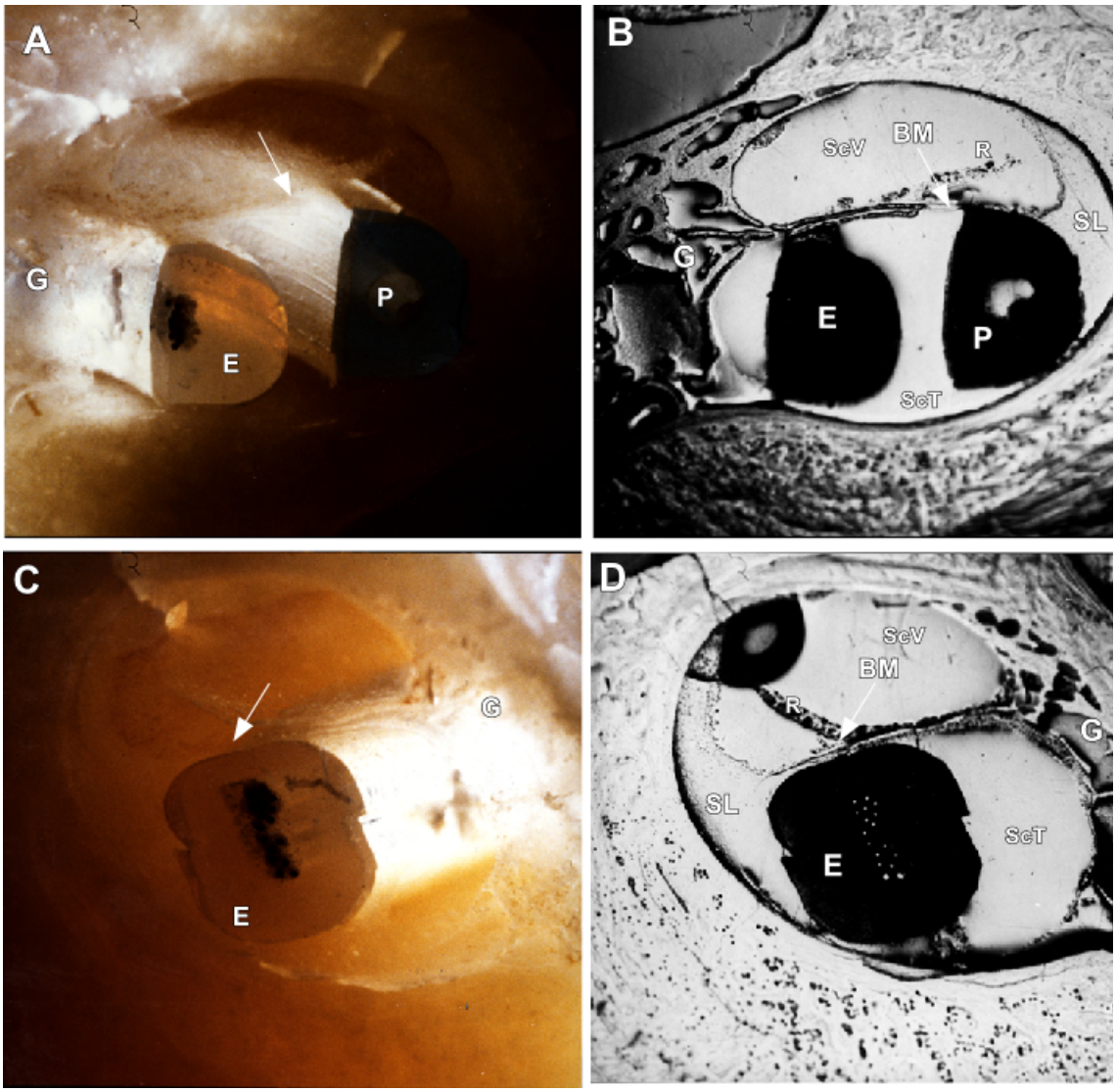


FIGURE 1. The polished surfaces of each block were examined with transmitted light (images at left) and with reflected light (images at right). In the example shown in the upper panels A and B, a HiFocus™ electrode (E) and positioner (P) are shown in good position within the scala tymani (ScT). The basilar membrane (BM, white arrows), spiral ligament (SL), Resisners' membrane (R), and osseous spiral lamina are intact and the electrode is close to the spiral ganglion (G). In the lower images C and D, a spiral Clarion™ electrode is shown. Again the electrode is positioned completely within the scala tympani and no insertion trauma is observed, but this electrode is closely approximated to the lateral wall and hence is farther away from the modiolus and the spiral ganglion (G).

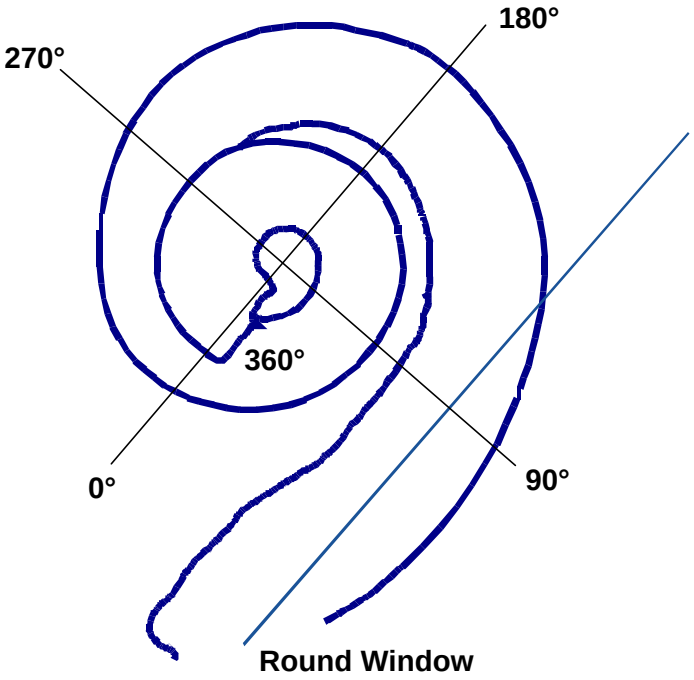


FIGURE 2. To measure insertion depth, rediographic images were taken of each implanted temporal bone. Radiographs were digitized for all measurements. This schematic drawing illustrates the coordinates which were used to define angular insertion depths as an overlay on the outline of the scala tympani. First, a line was drawn through the center of the scala tympani of the lower basal turn and the round window (blue line). A line perpendicular to this line, which passed through the modiolus was defined as an insertion angle of 90°.

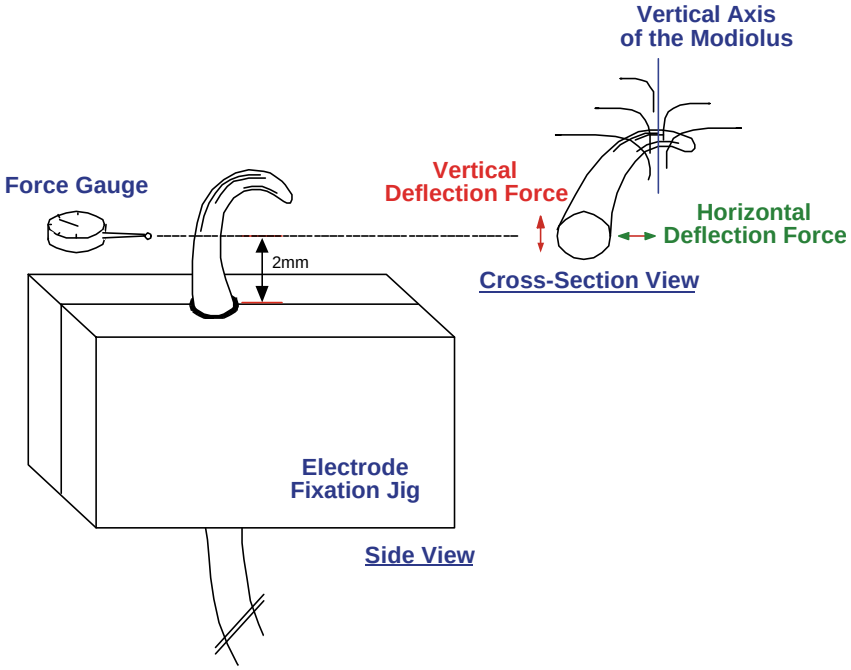


FIGURE 3. The deflection force required to bend each electrode 30° at a distance of 2mm from the surface of a fixation jig was measured with a force gauge. T his stiffness measure was obtained in both the horizontal and vertical planes with respect to the ultimate orientation in the scala tympani. Stiffness was measured at 2mm intervals along the length of the array.

RESULTS

Efficacy of New Designs: Generally, both of the new electrode designs evaluated accomplished at least some of the goals stated above. Figure 4 summarizes the insertion depth in mm and in degrees. The depth data for the Banded and Contour electrodes are combined and for both the experienced and resident surgeons and presented as a single average value in the upper 2 graphs in this figure. The data for the Spiral Clarion™ and HiFocus™ electrodes inserted by the resident surgeon are discussed separately in the section "Electrode Size – Effects on the Occurrence of Trauma." ***In both new designs the radial insertion depth was increased compared to the length of electrode inserted indicating that the electrodes were placed along a shorter longitudinal path closer to the modiolus.***

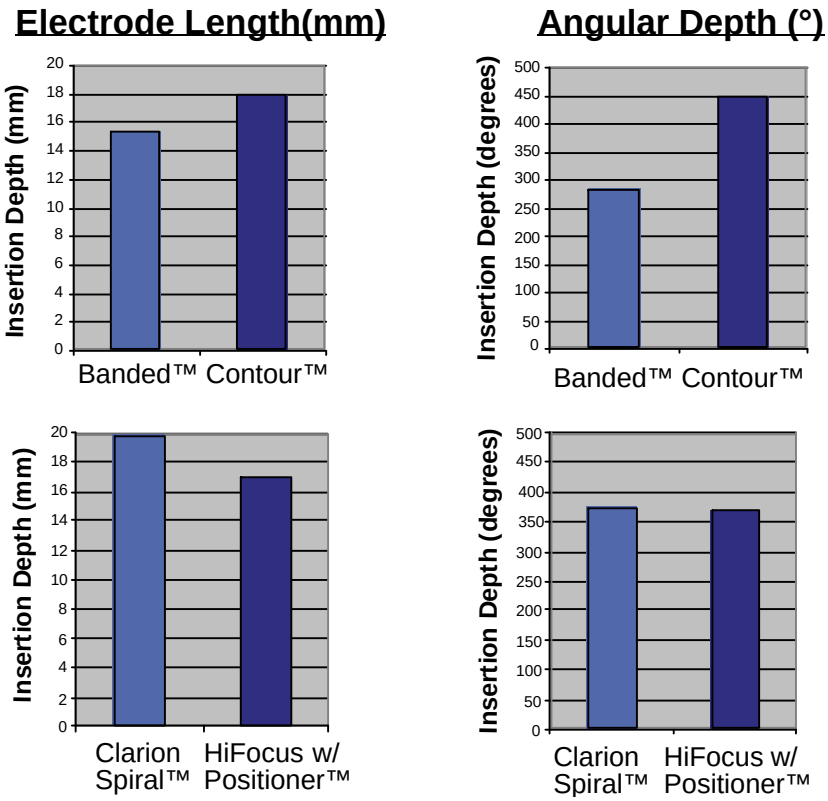


FIGURE 4. Insertion depth summary.
Data for Banded and Contour electrodes show the average for all trials (i.e., both surgeons).
In lower graphs, only data for expert insertions are shown. The insertion data for the resident surgeon's insertions of the Clarion™Spiral and Clarion™HiFocus are presented separately below because the deeper insertions in these trials were uniquely accompanied by severe trauma. All depths were measured from digitized radiographs.

Evaluation of Trauma: The trauma observed in each group of insertions is summarized in Figure 5. Again, The trauma data for the Banded and Contour electrodes are presented for both the experienced and resident surgeons in this figure because there were no marked differences between the two sets of bones. The data for the Spiral Clarion™ and HiFocus™ electrodes inserted by the resident surgeon are presented separately in the next section ("Electrode Size – Effects on the Occurrence of Trauma.") Examples of insertion trauma are illustrated in Figure 6.

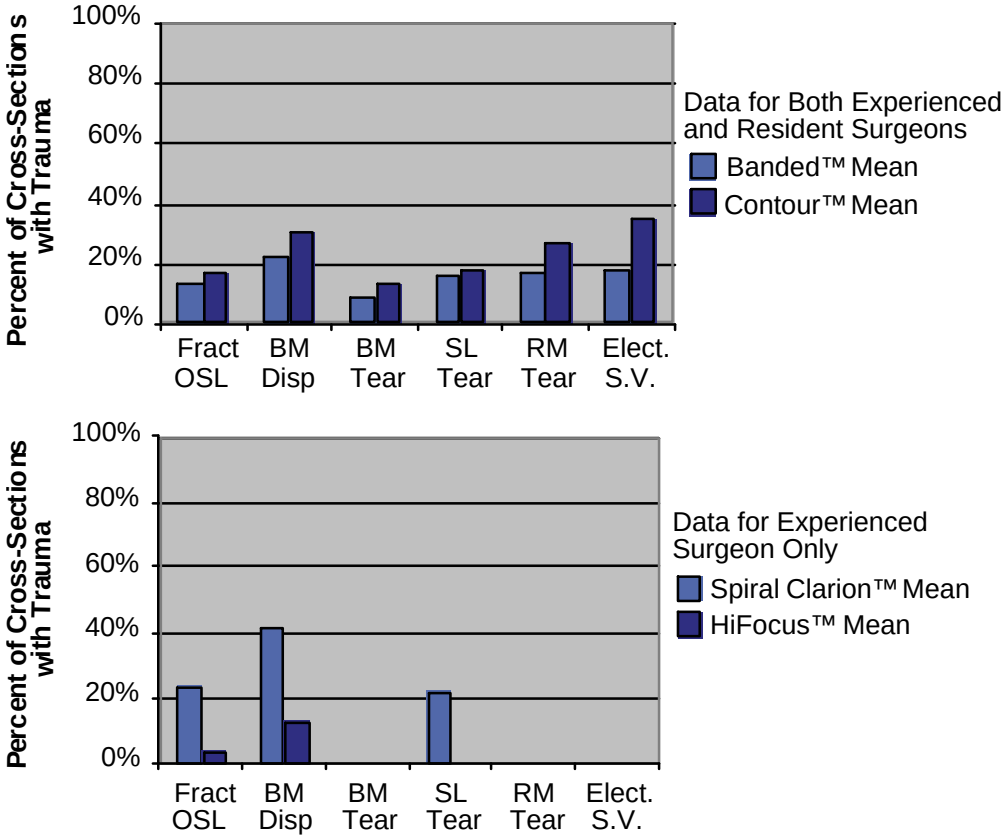


FIGURE 5. Summary of Observed Trauma. After cutting each temporal bone into 4 sections, trauma was evaluated in each of the resulting cross-sections. The percentage of cross-section surfaces which showed trauma are plotted in this summary. Fract OSL= Fracture of the Osseous Spiral Lamina; BM Disp= A distortion or displacement of the Basilar Membrane; BM Tear= clear tearing of the BM; SL Tear= clear tearing or detachment of the Spiral Ligment; RM Tear=clear tearing of Reissner's Membrane; Elect. S.V.= electrode excursion up into the Scala Vestibuli.

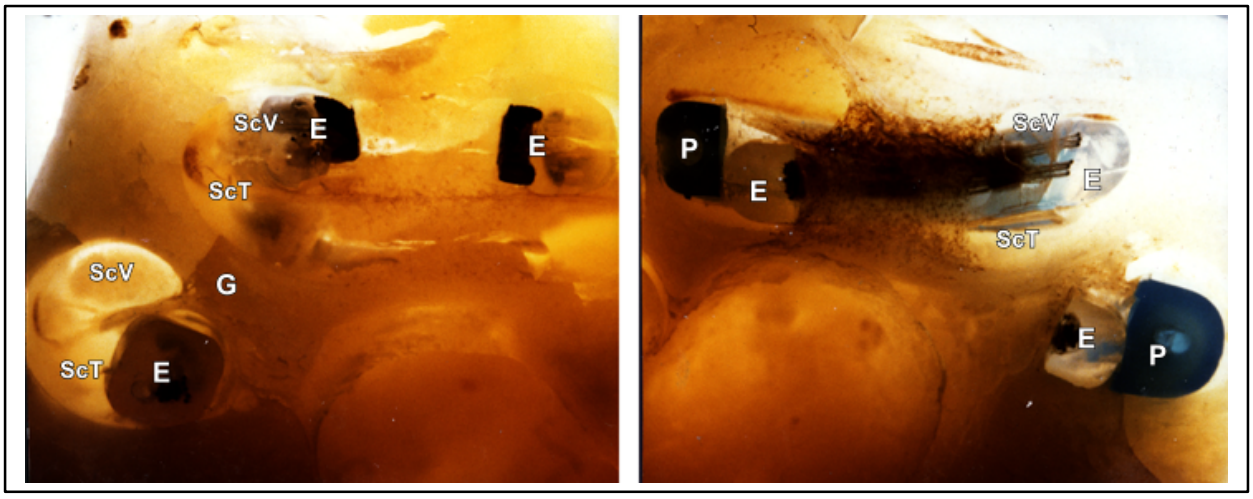


FIGURE 6. Examples of Observed Trauma. These two sections illustrate trauma following electrode insertions. In the example on the left, the electrode (E) is in excellent position in the scala tympani (ScT) of the first turn of the cochlea, but it passes through the basilar partition and is positioned in the scala vestibuli (ScV) in the middle turn. In the image at the right, the electrode positioner (P) has fractured the osseous spiral lamina in the basal turn, is relatively atraumatic in the lower middle turn and then pushes up into scala vestibuli in the upper middle turn.

Electrode Size – Effects on the Occurrence of Trauma: In general, there was no correlation between the depth of insertion and the trauma observed in tests of either the Banded™ or the Contour™ electrodes (both manufactured by Cochlear Corporation). In each case, the size of these electrodes did not appear to limit insertion depth in the temporal bones studied.

In contrast, because of their larger overall size both the Spiral Clarion™ electrode and the HiFocus™ electrode with positioner demonstrated a greater probability of trauma that was directly attributable to over-insertion of the electrode array. Figure 7 compares the insertion depth and observed trauma for each of these electrodes in the sets of temporal bones inserted by the experienced surgeon and those inserted by the resident surgeon.

In each case the experienced surgeon recognized resistance during the insertion before the electrode was inserted to its maximum design depth and stopped the insertion at this point. In each of the tests performed by the resident surgeon, no specific change in resistance was noted during the insertions, and each electrode was inserted to its maximum recommended depth. In almost every case, this depth of insertion resulted in significant trauma over large sectors of the cochlea.

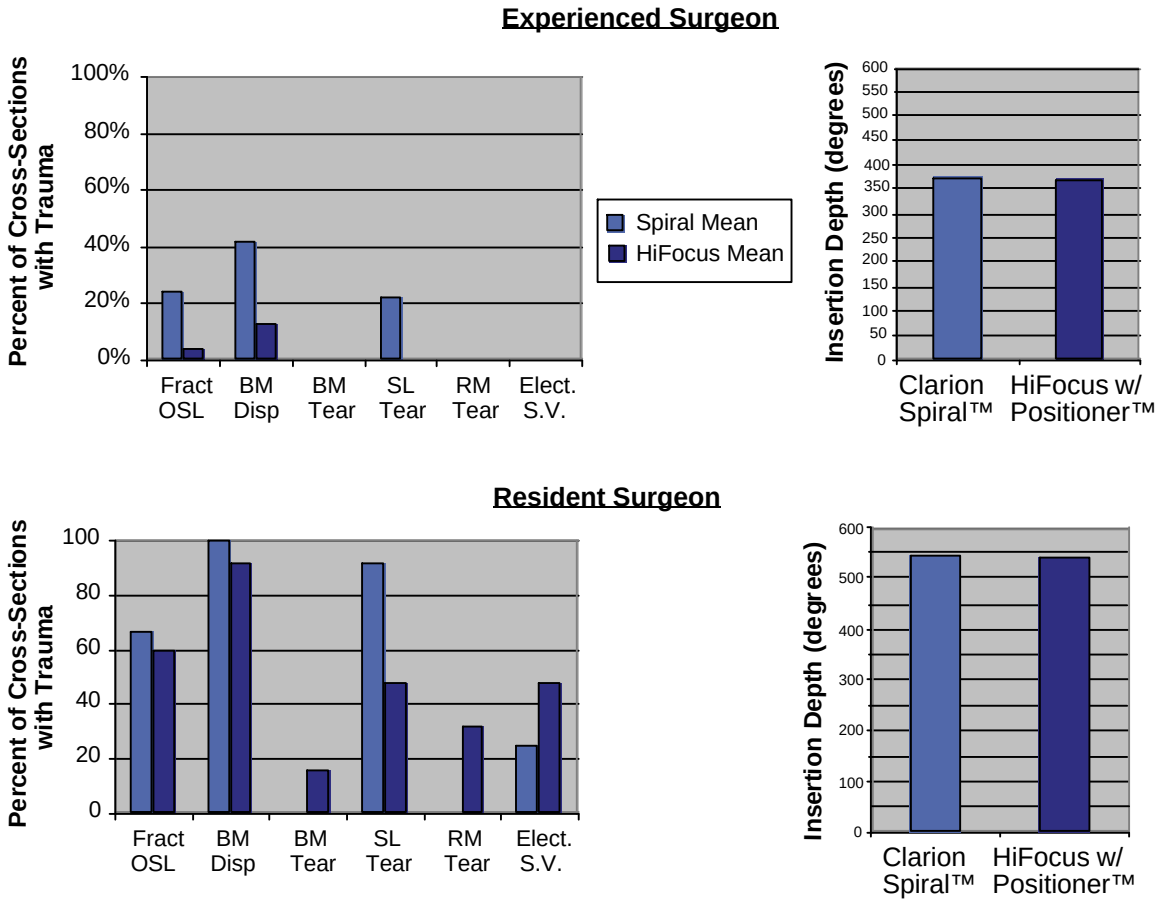


FIGURE 7. With the larger Clarion™Spiral and HiFocus™ electrodes there was a clear correlation between insertion depth and insertion trauma. With both devices the experienced surgeon recognized resistance and stopped insertion at that point. The use of a lubricant by the resident surgeon may also have accounted for decreased tactile sensitivity and increased trauma due to overinsertion. The graphs at the left show details of the location and extent of this damage.

Figure 8 shows induced trauma plotted vs. insertion depth for all insertions of the Spiral Clarion™ and HiFocus™ electrodes. A tendency for surgical trauma to occur with deeper insertions is evident. Advanced Bionics Inc. has identified this problem and has reduced the effective dimensions of the HiFocus™ electrode and positioner system. We hope to evaluate the effects of these modifications in future studies.

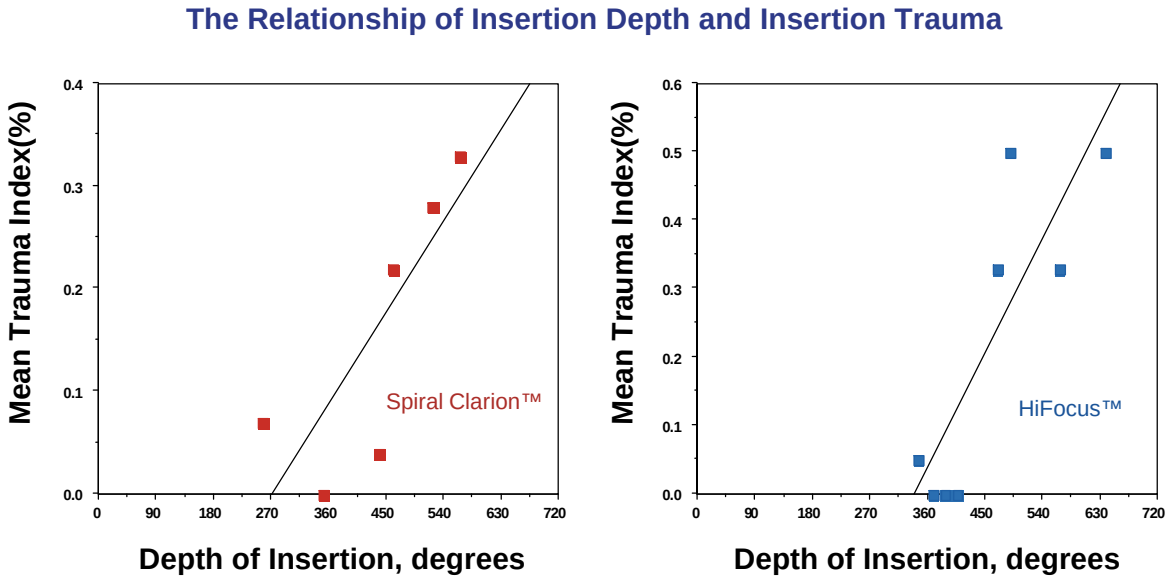


FIGURE 8. To evaluate the relationship between insertion depth and insertion induced trauma these two factors were plotted for all insertions. There was no correlation between these factors for either the Banded or Contour™ electrodes. Conversely, there was a clear relationship between observed trauma and the depth of insertion for both of the Clarion™ devices. It should be noted that the deeper insertions, which were the most traumatic, were performed by the resident surgeon. The trauma index used in these plots combines the scores for OSL fracture, BM tearing and electrodes observed in the Scala Vestibuli.

Electrode Stiffness – The Relationship to Trauma: Figure 9 summarizes the deflection force required to bend each electrode to an angle of 30° from a point 2mm from the fulcrum at the top surface of the fixation jig. As expected, the overall stiffness of each electrode declines from base to tip as the number of wires in the electrode decreases. Figure 10 illustrates the vertical/horizontal force ratio for each electrode and Figure 11 relates the vertical/horizontal stiffness ratio to the trauma measured for each design.

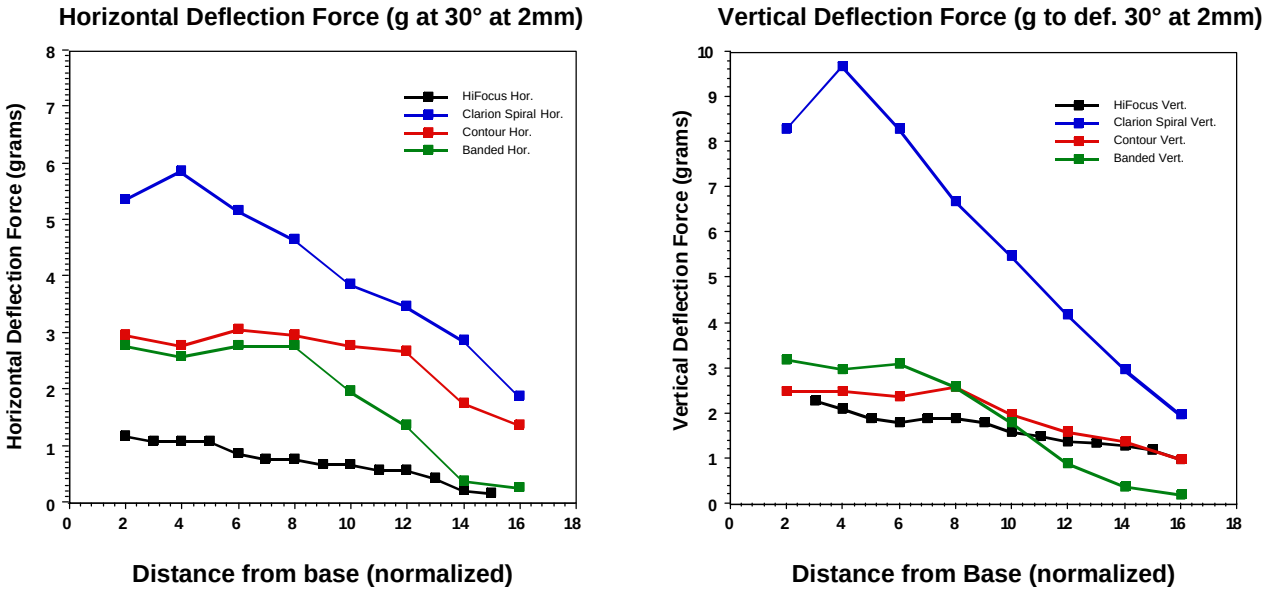


Figure 9. The deflection force required to bend an electrode array 30 from a point 2mm from the top of the fixation jig shown in Figure 3 was measured in the horizontal and vertical planes. As expected, the overall stiffness in these electrodes decreases from base to apex as the number of lead wires decreases.

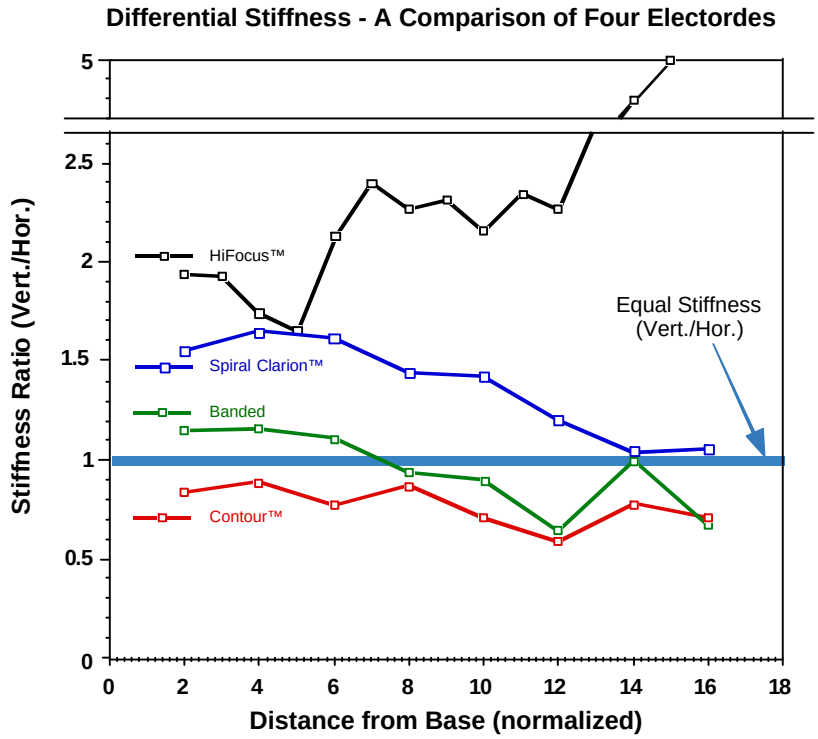


Figure 10. Dividing the vertical deflection force by the horizontal deflection force yields a ratio which indicates the differential stiffness of an electrode array. This ratio will determine the direction an electrode will deflect when it meets resistance or obstruction.

Differential Stiffness - The Relationship to Damage

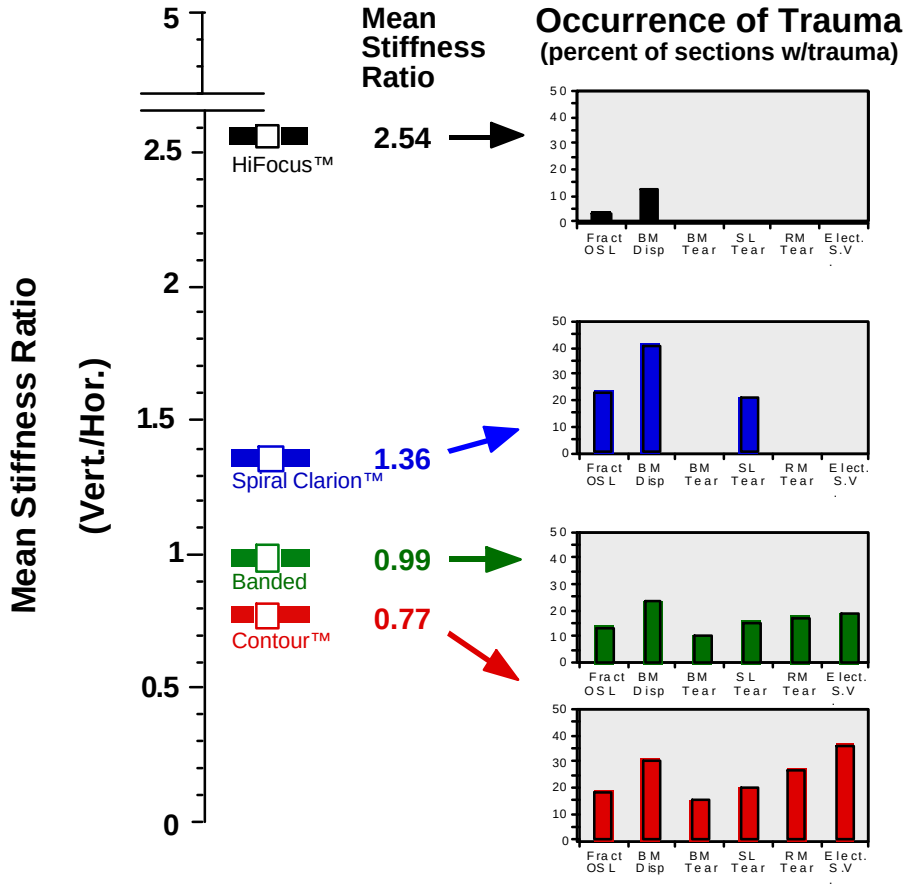
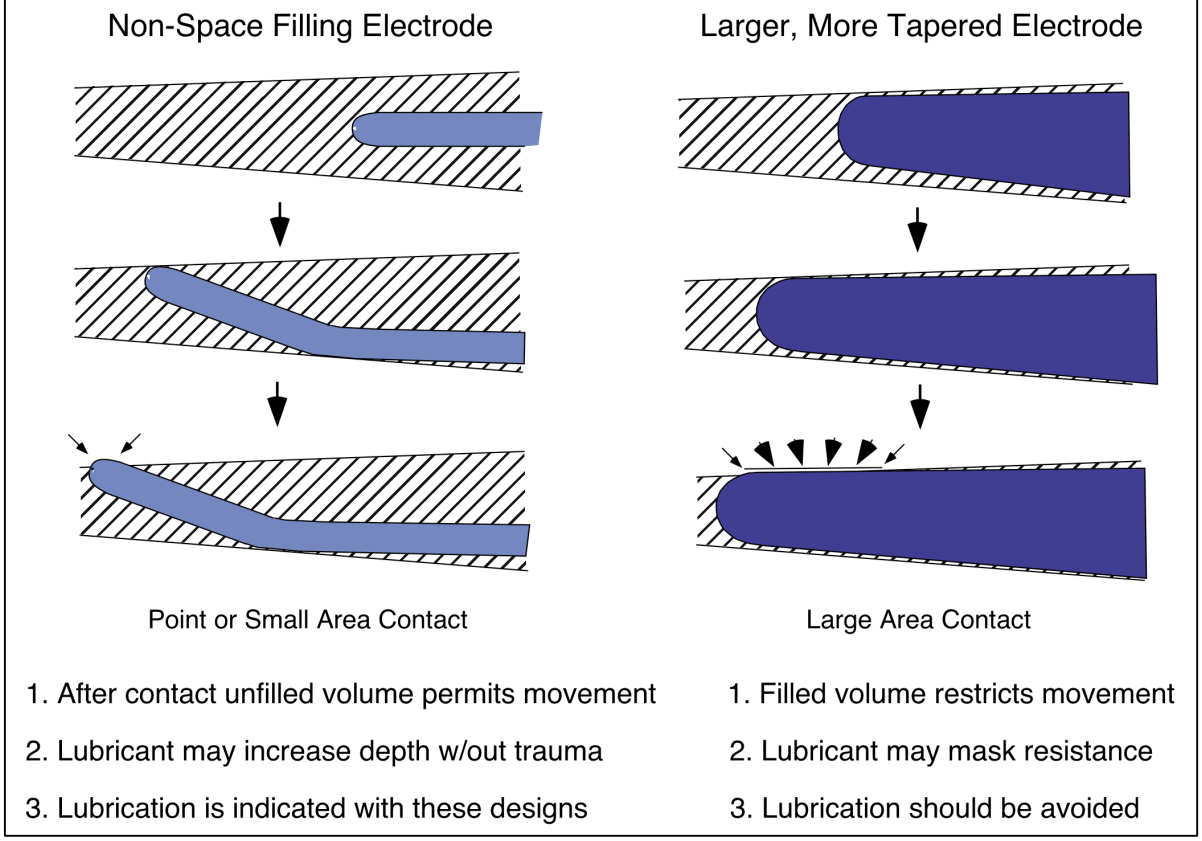


Figure 11. This figure relates the overall V/H stiffness ratio for all electrodes with the respective damage data presented in Fig.5. Although the number of trials is small these data indicate that a vertically stiff electrode is less likely to deviate vertically from the scala tympani cavity and damage surrounding structures.

The Role of Lubrication in Insertion Related Trauma: The use of lubricants, usually glycerin or hyaluronic acid, has become widespread at many implant centers and application of lubricating surface treatments on electrodes has been evaluated by some manufacturers. Because the trauma observed and depth of insertion were very different in the two sets of insertions (experienced vs. resident surgeon) for both the Spiral Clarion™ and HiFocus™ electrodes we felt this result required additional analysis and further study. As mentioned previously, one difference between the two groups of insertions was the use of lubricant by the resident surgeon.

Lubricants may act quite differently when used with different electrode designs. As illustrated in Figure 12 a relatively small electrode may benefit from the reduction in friction that occurs with the use of a lubricant. Trauma, when observed, is often limited in length. However, as a larger electrode with substantial taper reaches the point at which its size approximates that of the surrounding scala tympani a lubricant may mask increasing friction and decrease the tactile feedback to the surgeon. This reduced feedback may result in over-insertion and increase the likelihood of more extensive trauma as shown.

Figure 12. The Effect of Lubricant on Insertion Trauma



PRELIMINARY CONCLUSIONS

1. The second-generation modifications in electrode designs studied place stimulating contacts closer to the modiolus than previous electrodes.

2. In the temporal bones studied, neither of the newer electrode designs represented a clear decrease in frequency or extent of trauma associated with surgical insertion.

3. The observed trauma was highly variable with all four electrode designs studied and among the three surgeons participating in this study. We believe that these results represent the range of trauma occurring in the clinical population. Sources of this variation require further investigation.

4. The use of lubrication during cochlear implantation requires further study. Lubrication may reduce tactile feedback, which may result in significantly increased incidence of trauma, particularly with larger electrode cross sections.

5. The mechanical properties of each electrode design were related to the insertion trauma observed in predictable ways. Although we consider the data in this study to be preliminary, we feel that the parallel analysis of electrode mechanics and temporal bone insertion studies will greatly facilitate future improvements in electrode design.

ACKNOWLEDGEMENTS

We would like to express our gratitude to Dr. Thomas Roland for his assistance in providing the protocol for embedding the temporal bones for this study and in implanting the Cochlear Corporation devices as the experienced surgeon. We also want to thank Dr. William Luxford for implanting the Advanced Bionics devices as the experienced surgeon and for his advice and training.

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Work Planned for the Next Quarter

1) We will continue analysis of data from two neonatally deafened animals that are subjects from the GM1 ganglioside series and were studied in terminal acute electrophysiological studies during the current quarter.

2) One additional neonatally deafened animal in the GM1 ganglioside/2-channel stimulation group will be implanted during the next quarter. One additional subject, deafened at one month of age will be implanted for chronic stimulation during the next quarter.

3) A draft of a paper for Hearing Research will be completed, describing cochlear nucleus data in animals from the first GM1-treatment group, whose spiral ganglion data were reported in a previous QPR.