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Protective Effects of Patterned Electrical Stimulation on the Deafened Auditory System

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This Quarterly Progress Report presents the first of two manuscripts reporting studies evaluating the newer designs of cochlear implants, which will be submitted to the journal Otology and Neurotology. These studies were conducted by Dr. Peter Wardrop when he was a senior specialist registrar in Otolaryngology at the Royal Infirmary in Edinburch, Scotland and received a TWJ Foundation fellowship to collaborate on cochlear implant research here at UCSF. Preliminary reports of these findings from the extensive series of human temporal bone studies completed by Dr. Wardrop were presented at the 2000 5th European Symposium on Pediatric Cochlear Implantation and the 2001 International Conference on Implantable Auditory Prostheses, at Asilomar, California. Dr. Wardrop is currently a consulting otolaryngologist in the Department of Otolarynoglogy, Crosshouse Hospital in Kilmarnock, Scotland.

A Temporal bone Stud of Insertion Trauma and Intracochlear Position of Cochlear Implant Electrodes. I: Comparison of Cochlear Banded and Cochlear Contour™ Electrodes

Abstract

New designs of cochlear implant electrodes have been introduced in an attempt to improve their efficiency and performance by locating stimulation sites closer to spiral ganglion neurons and deeper into the scala tympani. The goal of this study was to document insertion depth and insertion trauma with the recently introduced Nucleus *Contour*™ electrode and to compare results to those observed with the earlier generation Nucleus banded electrode.

For this comparison 8 electrodes of each type were implanted in cadaver temporal bones using a realistic surgical exposure. An experienced cochlear implant surgeon and a final year otolaryngology resident each performed half of the trial insertions, representing the range of experience of surgeons currently performing the procedure throughout the world. Following insertion of the electrode, specimens were imaged using plain film x-ray, embedded in acrylic resin, cut in radial sections with the electrode in place, and each cut surface was polished. Insertion depth was measured in digitized x-ray images, and trauma was assessed in each cross-section using both transmitted and reflected illumination.

The new *Contour*™ electrode inserted more deeply (mean depth = 17.8 mm or 442°) than the banded electrode (mean depth = 15.4 mm or 286°). The incidence and severity of trauma varied substantially among the temporal bones studied. Overall, the trauma observed was slightly greater with the newer, more deeply inserted device. The *Contour*™ electrode clearly was positioned closer to the modiolus than the banded model, and also appeared superior in ease of use. Based on previous studies we conclude that the *Contour*™ electrode will provide lower thresholds and improved channel selectivity, but frequent occurrence of trauma remains a problem with the new design. The relative influences of electrode positioning and neural degeneration resulting from trauma are unclear.

Introduction

Cochlear implantation has proven to be one of the great medical successes of the latter half of the twentieth century. Approximately 60,000 individuals worldwide have received implants to date (personal communication with Advanced Bionics, Inc., AllHear Inc., Cochlear Ltd. and Med-EL Corporation), and the performance of these implant recipients has improved continuously (1). Forthe most part, these performance gains reflect significant improvements in speech processing technology and rehabilitation strategies. In contrast, until quite recently the intracochlear electrodes available for clinical use have changed relatively little since their introduction in the early 1980s.

Several major cochlear implant manufacturers have recently introduced new electrodes designed to position stimulating contacts closer to the modiolus in order to increase the efficiency and selectivity of electrical stimulation. Theoretical benefits of this modification include more focused stimulation, which may improve speech perception, reduced power consumption and reduced likelihood of unwanted facial nerve excitation. Whether these theoretical benefits will actually translate into improved clinical performance is still being evaluated. One important concern is that these so-called "perimodiolar" electrodes may be more traumatic to the cochlea than their predecessors, due either to size or other physical characteristics related to their modified designs. This insertion trauma, if present, may negate or even outweigh the benefits of closer electrode position.

As the indications for cochlear implantation inevitably expand to include patients with more residual hearing, the long-term consequences of insertion trauma may become more significant. In particular, children with implants will use their devices for decades, and increasingly advanced speech processors may put additional demands on the electrode/neural interface. Combined hearing aid/cochlear implant devices are currently being tested which depend on the preservation of remaining hair cells (2). Maintenance of the vibration mechanics of the basilar membrane is also vital if residual hearing is to be utilized in a combined device.

Previous methods to evaluate insertion trauma have had significant limitations. In some of these studies temporal bones of implantees were examined after death. In most cases the electrodes were removed prior to analysis to allow histological preparation and sectioning (3-5). The test electrodes were also removed prior to processing in some studies with cadaver temporal bones (6-8). This strategy permits observation of trauma and gross electrode location but does not allow precise determination of electrode position or documentation of the path or trajectory followed by the array during insertion, and it is also possible that spurious trauma may be produced during removal of the electrode. In addition, the trauma observed in specimens from previously implanted donors (9-11) has been altered by years of healing and remodeling. Because these unavoidably were retrospective series, there was limited control over, or information regarding, the insertion conditions or specific techniques employed.

A clear plastic model of the human scala tympani also has been devised which permits observation of the path that an electrode follows during insertion and its final placement (12). However, these models do not have the same mechanical characteristics as the human cochlea and do not deform or indicate potential trauma.

Some previous investigators have processed implanted temporal bones by "drilling out" the roof of the scala vestibuli in order to observe electrode position (13). However, this method introduces the possibility of artifact damage from the drilling process, no matter how expertly performed, and subtle trauma may be difficult to assess.

Recently, several studies using cadaver temporal bones processed by resin embedding with the electrodes *in situ* have been presented (14-16). These studies documented electrode position and trauma more accurately than was possible with previous methods. Clearly, temporal bone studies do not allow an assessment of the long term consequences of insertion trauma with respect to neuronal death and

tissue reaction, but the acute damage, when present, can be evaluated in great detail and some predictions of those consequences can be made from *in vivo* studies (17).

In the present study, we have modified the resin embedding techniques developed by Gstoettner and Roland (14-16) to further document trauma and electrode position. Using these methods in freshly harvested human temporal bones we have compared the insertion performance of one of these new electrode designs, the Nucleus *Contour*™ (Cochlear Company of Australia), with the electrode's predecessor, the Nucleus™ straight or "banded" electrode, currently in worldwide use.

Goals

The study aimed to assess the following parameters of insertion performance.

- Depth of insertion – The second generation electrode evaluated was designed to be positioned further into the scala tympani to activate a broader range of frequencies by accessing neurons at more apical locations. Deeper placement of electrode contacts will be achieved with the same electrode length if the electrode carrier follows a tighter spiral, i.e. if the electrodes are indeed positioned closer to the modiolus.
- Proximity of the electrodes to the spiral ganglion – As described above, the position of the electrode within the scala tympani is a function of the length of electrode inserted and the radius of the spiral path of the device. Again, the aim of the new design is to position the electrode closer to the target neurons in order to achieve more selective activation of neurons by each channel and minimize interaction among channels.
- Electrode insertion trauma - Damage to the osseous spiral lamina, basilar membrane, spiral ligament and other structures within the cochlea was evaluated to address the concern that new electrode designs may present an increased risk of insertion trauma. Previous studies have given purely descriptive accounts of trauma to the cochlea. In this study we attempted to quantify insertion trauma to allow approximate comparisons between groups.
- "User-friendliness" - Ease of insertion is an important criterion in application of a new device. Increasing complexity of design may make electrodes more awkward and time-consuming to insert.

In addition, we aimed to develop a reproducible temporal bone model that would simulate surgical conditions as closely as possible, while permitting a full assessment of the electrode trajectory and insertion trauma. We hope that this experimental model might also be used as a tool in the development process for future electrode designs.

Methods

Surgeons

Both the newly introduced *Contour*™ electrode and the standard Nucleus™ multichannel banded electrode (Cochlear Corporation, Englewood, Colorado, USA) were tested by an experienced cochlear implant surgeon and by a final year otolaryngology resident. The experienced surgeon leads an established cochlear implant program and was chosen by the manufacturer as the most skilled surgeon to represent the ideal insertion technique for the new device. The final year otolaryngology resident had received a standard training in otology and a level of implantation training equivalent to that provided in cochlear implant training courses offered by the manufacturer. The inclusion of experienced and residentsurgeons was intended to provide results more representative of the spectrum of results to be expected in the general clinical application of each device.

Electrodes Studied

Eight electrodes of each design were tested in eight lightly fixed temporal bones, four by the experienced surgeon and four by the resident. Figure 1 illustrates the two electrodes evaluated. The

traditional Nucleus™ banded electrode is small in diameter, quite flexible, and has no intrinsic coil. The Nucleus *Contour*™ has an intrinsic spiral shape and a larger diameter. The electrode is held straight during insertion by an internal wire stylet that is removed either during the insertion process or after insertion is complete. Both devices are advanced into the scala tympani using custom made "claws".

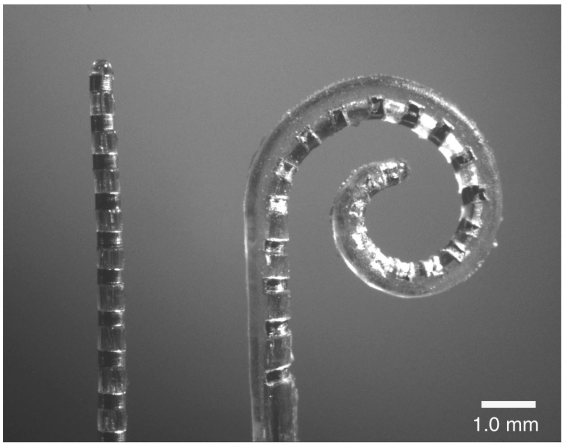


Figure 1. The traditional "banded" and the *Contour*™ (right) electrode arrays are shown in this photograph. The "banded" array has circumferential contacts, is relatively small in diameter, and has no intrinsic coil. The *Contour*™ has contacts on only one side, is slightly larger, and has an intrinsic coil. It is held straight during insertion by a flexible stylet, which is removed after insertion, allowing the electrode to coil tighter around, or "hug", the modiolus. Scale = 1.0 mm.

Temporal Bone Processing and Surgery

Temporal bones were harvested from fresh cadaver specimens within 24 hrs of death and fixed in 10% formaldehyde for 24 hours. Following fixation the specimens were rinsed and stored in 0.1M phosphate buffer (pH 7.4). This brief fixation protocol was chosen to minimize possible effects of prolonged aldehyde fixation on the mechanical characteristics of soft tissues in the scala tympani.

Implantation was performed using standard surgical technique with a posterior tympanotomy via the facial recess, and a 1-2 mm cochleostomy antero-inferior to the round window. After removing the stapes, a lubricant (18,19) (50% glycerin in distilled water) was injected into the cochleostomy until a return was seen at the oval window. Following insertion, the electrodes were secured in position near the round window using histoacryl glue, and the redundant electrode lead was trimmed to minimize possible disturbance of the electrode during processing. The position of the round window was marked with a piece of platinum wire to allow radiographic identification as shown in Figure 2. Radiographs were taken immediately after insertion, then surrounding bone was trimmed from the implanted temporal bones, the bones were bisected, and the cochleae isolated. Embedding was carried out by progressive dehydration of the specimens in ethanol, followed by infiltration with increasing concentrations of L.R. White's ™ hard grade resin (Electron Microscopy Sciences, Fort Washington, PA) (see 14-16).

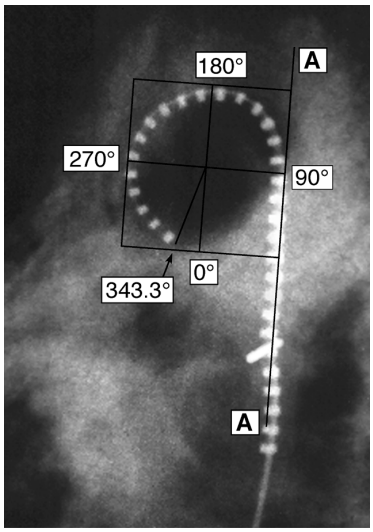


Figure 2. Linear and angular depth measurements were made from digitized X-ray images of each implanted temporal bone using Canvas™ software. Linear depth in mm was measured from a platinum marker placed at the round window to the tip of the electrode. A grid was constructed around the electrode's path as shown hereto allow an estimation of angular insertion depth.

Radiographs were repeated after embedding to confirm that no significant movement of electrodes had occurred during processing. Two of the straight electrodes were found to have slipped during the bisection and trimming of the temporal bones. These were discarded and new bones implanted by the same surgeon. Figure 2 also illustrates how angular and linear insertion depths were estimated from magnified digital images of the radiographs using Canvas™ software. An approximation of electrode proximity to the modiolus was calculated by dividing angular insertion depth by linear insertion depth to yield a value we term "proximity factor". It should be noted that the length of electrode lying in the straight section of the basal cochlea, from the cochleostomy to the beginning of the curved spiral, was subtracted from the inserted electrode length for this calculation of coiling to provide a more accurate coefficient for the remaining curved portion of the cochlea.

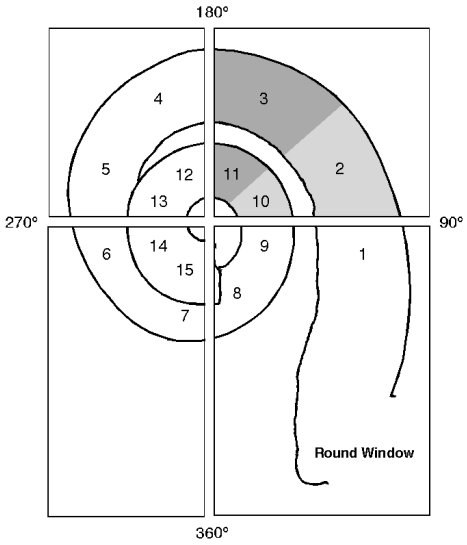


Figure 3. The planes for sectioning the temporal bones and the numbering system used to identify each polished surface are illustrated in this schematic. Quartering each embedded cochlea yielded a series of cut surfaces at perpendicular angles (90°, 180°, etc.). After polishing, each face was evaluated with both transmitted and reflected illumination. The shading between the cut at 90° and that at 180° indicates the depth into the specimen that is clearly visible from each surface with transmitted illumination.

The cured specimen blocks were quartered using a diamond wafering blade in a low speed saw (Beuhler, Inc.), yielding a series of cut surfaces as shown in Figure 3. Each face was polished to permit microscopic evaluation by trans- illumination, or by reflected surface illumination (Figure 4). It should be noted that in many cross sections a gap between the electrode and the surrounding plastic was visible at the time we evaluated trauma. We believe that this is the result of a small amount of solvent being absorbed into the silicone causing some swelling prior to curing. After curing, the device returned to its original size over a period of several days leaving a gap between the electrode and the surrounding plastic. This gap is visible in Figure 4, and swelling of the silicone carrier between the metal stimulating rings can be seen in Figure 10. When observed, this swelling and subsequent shrinkage, were 5-15% of the overall diameter of the electrode. A comparison of the radiographs taken before and after processing indicates that no measurable change in electrode length occurs as a result of this process, and we do not believe that this swelling confounded the assessment of trauma in any of the samples reported in this study. Trauma occurring with each insertion was assigned a score on a rank-order scale (4 scores ranging from "no trauma" to "severe trauma") on each cut surface using the criteria described and illustrated in Figure 5.

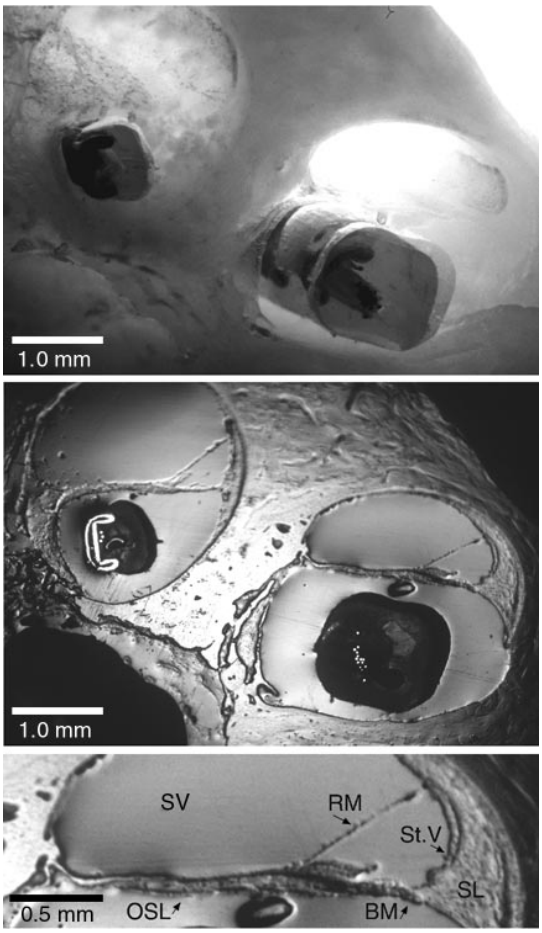


Figure 4. Electrode trajectories and insertion trauma were assessed in light microscopy using two forms of illumination. With light shone from behind (top image), the transparent resin allows the path of the electrode to be observed for several millimeters. With reflected surface illumination (center), i.e., light shone at an angle of 45° and reflected off the cut surface of the polished specimen, a detailed view of the electrode profile and its relationship to the cochlear structures can be seen**.** Note that the white "C" shaped profile within the smaller cross section in the center image is one of the stimulating contacts that was cut through and polished. A higher magnification view of the osseous spiral lamina (OSL) and associated structures (BM= basilar membrane, SL = spiral ligament, St.V = stria vascularis, RM = Reissner's membrane) is shown in the lower image. This enlarged image provides an example of the resolution routinely seen in these specimens and thus indicates the accuracy with which trauma can be evaluated.

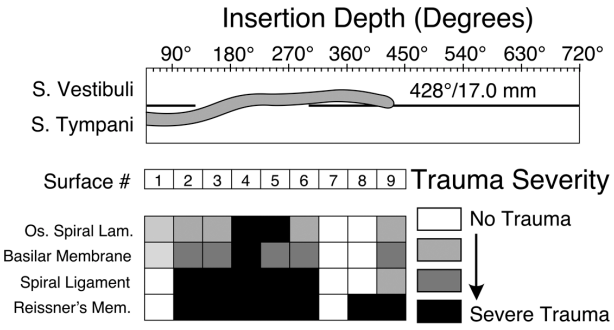
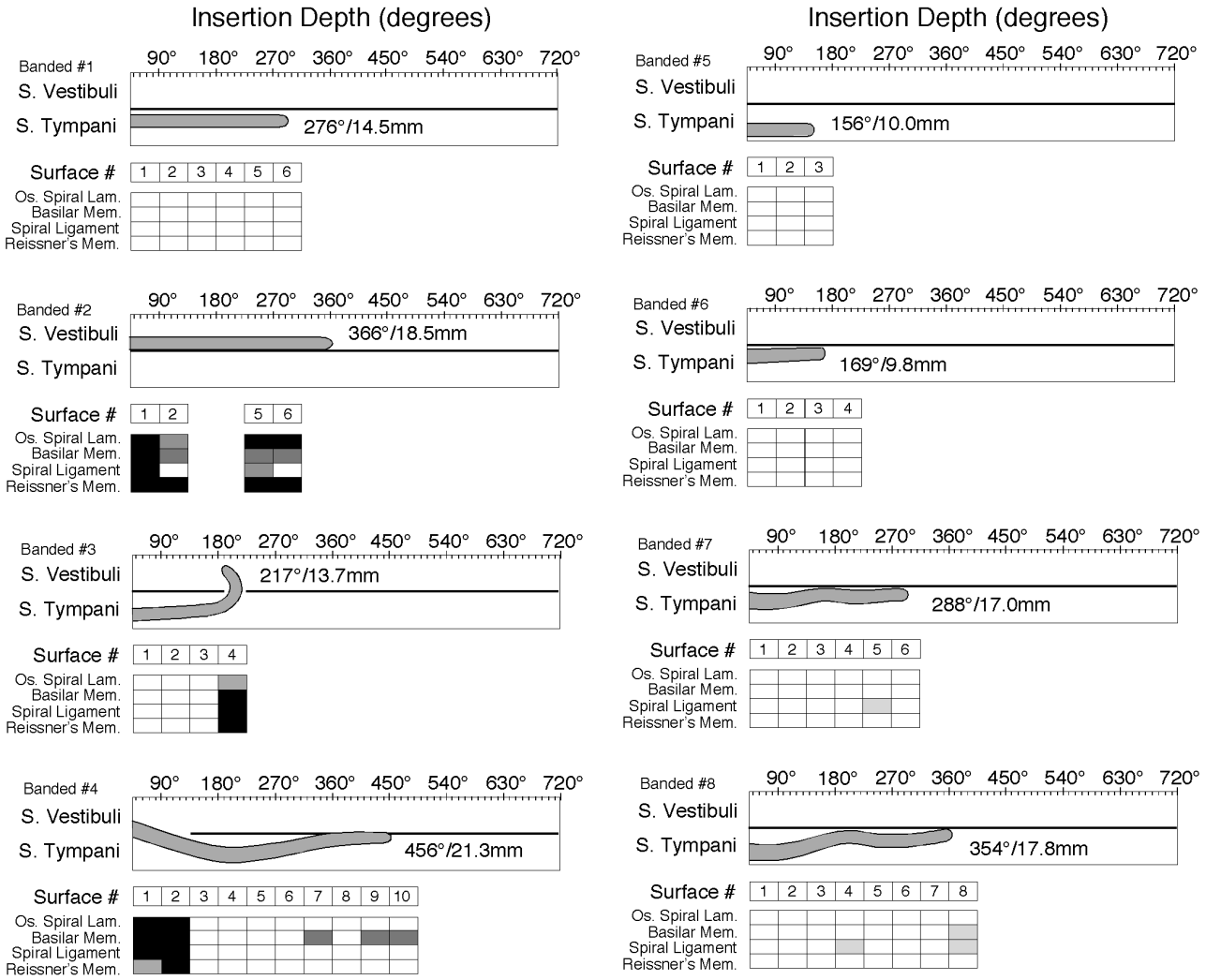


Figure 5. The results of each temporal bone insertion are presented in a two-part data map. The path of each electrode is illustrated by "unwinding" the cochlea with the round window represented at the left side of the diagram. A horizontal line represents the anatomical structures which partition between the scala tympani and overlying scala vestibuli. Each cut and polished block face was examined for injury to the osseous spiral lamina, basilar membrane, spiral ligament and Reissner's membrane. Results were coded as shown from no trauma to slight trauma (moderate distortion of the structure without fracture or tearing) to moderate trauma (more extensive distortion) to severe trauma (clear fracture or tearing of the structure). This "trauma severity grading" scheme gives an estimate of the nature and extent of insertion trauma for each electrode. It is unknown at present whether any specific type of injury is more damaging to the neural elements than others.

Results

Insertion Depth and Proximity to Spiral Ganglion

The insertion depth for each electrode tested is shown in Figures 6 and 7. The average linear insertion depth for the 8 trial insertions of the banded electrode (mean = 15.3 mm) was slightly less than the mean insertion depth of the *Contour*™ electrode (mean = 17.8 mm). However, when the insertions of the two electrodes were evaluated for angular depth, a much greater difference was apparent. The mean *Contour*™ angular insertion depth was 441° as compared with 285° for the banded electrode. This indicates that the *Contour*™ electrode followed a smaller radius of curvature within the scala tympani and thus was positioned closer to the modiolus. To better appreciate this point, note that an insertion depth of 17 mm with the banded array resulted in an angular depth of 288° (banded electrode trial #7), whereas the identical depth of insertion of the *Contour*™ array resulted in angular insertion depths of 338° (*Contour*™ trial #3) and 431° (*Contour*™ trial #6).



Figures 6. Cochlear trauma maps for the 8 insertion trials of the banded electrodes are shown in this figure. Trauma is assessed (see Figure 5), and plotted below each montage showing the distribution and severity of injury to each of the four anatomical structures examined in the cochlea. The insertion depth for each electrode is shown in both degrees and electrode length adjacent to the electrode tip in each map.

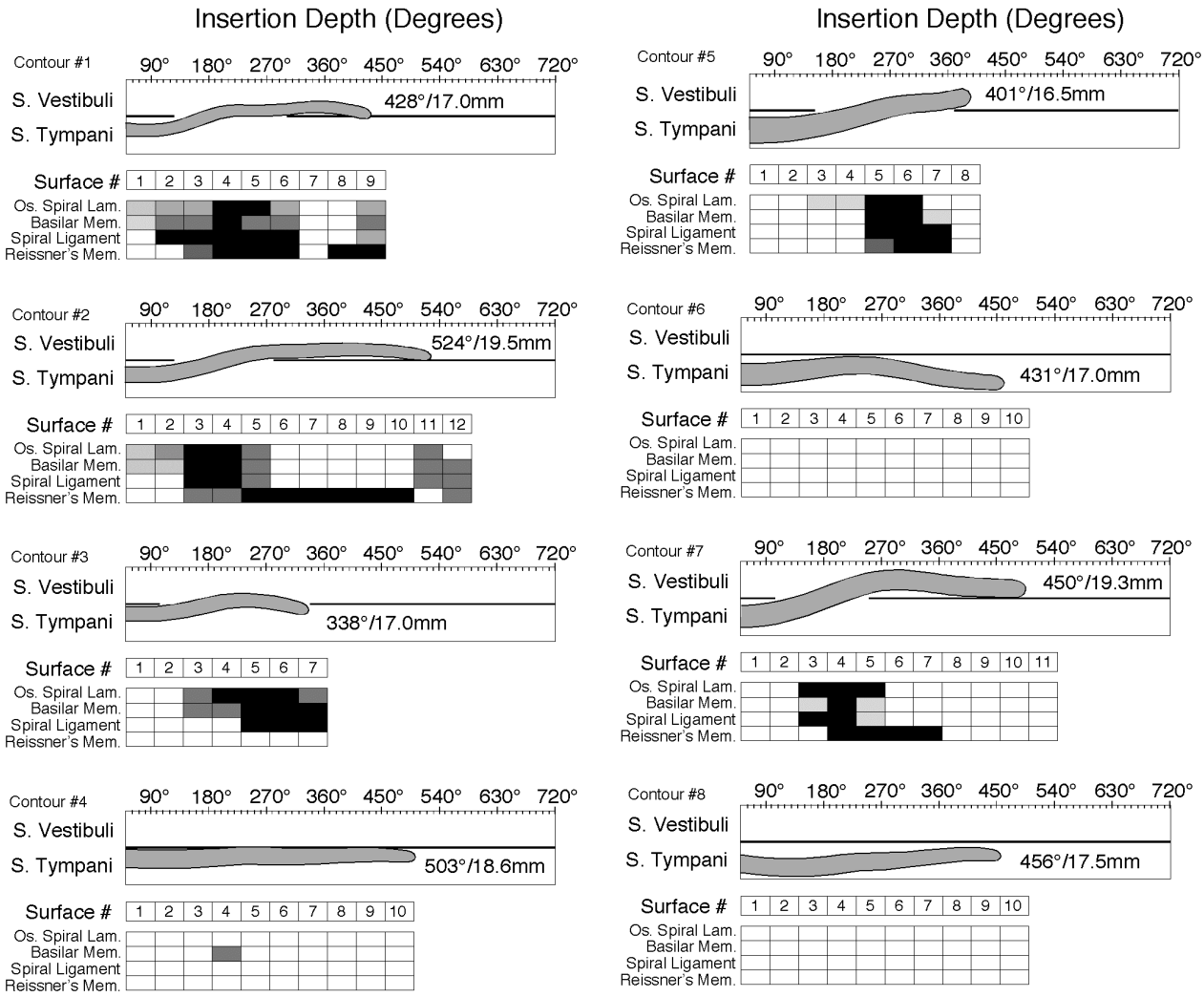


Figure 7. Cochlear trauma maps for the *Contour*™ electrodes. The format and conventions for these figures are identical to those in Figures 6.

Dividing the angular insertion depth (in degrees) by the length of the inserted electrode (in mm) yields a factor describing the tightness of the spiral or, indirectly, the proximity of electrode contacts to the modiolus. Using this equation the banded electrode had a mean proximity factor of 23.8 degrees/mm compared to 33.6 degrees/mm for the *Contour*™ electrode. The difference in the final position of these two electrode designs can be appreciated by comparing representative examples of X-rays of each as shown in Figure 8.

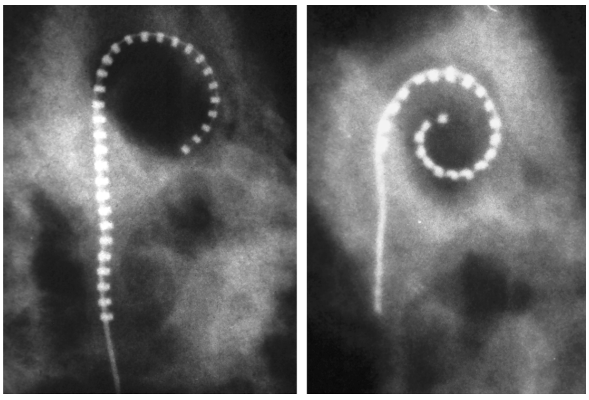


Figure 8. These two radiographs illustrate the typical difference observed in the final position of the banded and *Contour*™ electrodes. These x-ray images clearly show that the *Contour*™ lies closer to the modiolus than the original banded electrode, andis inserted deeper.

It should be noted that when the insertion trials performed by the two surgeons were analyzed separately, the resident inserted the banded electrode to a lesser mean linear and angular depth (13.7 mm and 242°) than the experience surgeon (17 mm, 329°). In contrast, the two surgeons' insertions of the *Contour*™ yielded comparable results, with a mean depth of 17.6 mm and 435° for the resident vs. 18 mm and 448° for experienced surgeon. This finding suggests that the *Contour*™ electrode was somewhat more easily inserted to a deeper location (See Discussion). Moreover, two of the resident's trials with the banded array were exceptionally short placements of 9.8 and 10.0 mm (banded trials # 5 and #6), which would be quite unusual in clinical application of this device in normal temporal bones. This raises a potential concern that the banded insertion trials might have been unduly biased by these exceptional cases toward a poorer result (i.e., with respect to modiolar proximity) as compared with the *Contour*™, especially considering the relatively small number of specimens available for study. In this context, however, it is noteworthy that the proximity factors calculated separately for the two surgeons were virtually identical. The proximity factor for the banded array was 23.4°/mm for the resident and 23.3°/mm for the experienced surgeon, whereas the proximity factor for the *Contour*™ electrode was 33.6°/mm and 33.7°/mm for the resident and experienced surgeons, respectively. This indicates that the proximity factor is a robust measure of this aspect of device performance and provides an objective estimate of modiolar proximity that is relatively insensitive to other possibly confounding variables such as depth of insertion.

Insertion Trauma

The extent of trauma was estimated by identifying four types of cochlear injury. Damage to the osseous spiral lamina, basilar membrane, spiral ligament and Reissner's membrane were evaluated in each available cross-section in each block face and documented as illustrated in Figure 5. Data for each temporal bone are presented in Figures 6 and 7. To provide an overall index of the extent of trauma in each bone for comparison of the two electrodes, the scores indicating severity of trauma to each structure were assigned numbers from 1 to 4 (1= no trauma to 4 = severe trauma), and these values were summed for all faces examined and expressed as percentage of highest possible score. (That is, a value of 100% for a particular structure would indicate that all surfaces examined show the maximum trauma score for that structure.) These data are summarized in Figure 9. Because the relative significance of each type of trauma is unknown, the percentage values in Figure 9 should be seen only as a general index of trauma; no attempt was made to rank order the 4 types of cochlear injuries reported here. As illustrated by these data, the trauma observed with the *Contour*™ insertions was similar in both location and extent to that seen with the banded electrodes, but was slightly higher than for the banded in almost all categories of trauma. However, it is important to bear in mind that the lower trauma index for the banded insertions was clearly influenced by the two exceptionally shallow insertions of 9.8 and 10.0 mm (banded trials # 5 and #6) both of which, not surprisingly, caused no trauma whatsoever. In point of fact, if these 2 cases were deleted from the trauma summary analyses in Figure 9, the results for the banded and *Contour*™ electrodes would be virtually identical for 3 of the 4 trauma categories.

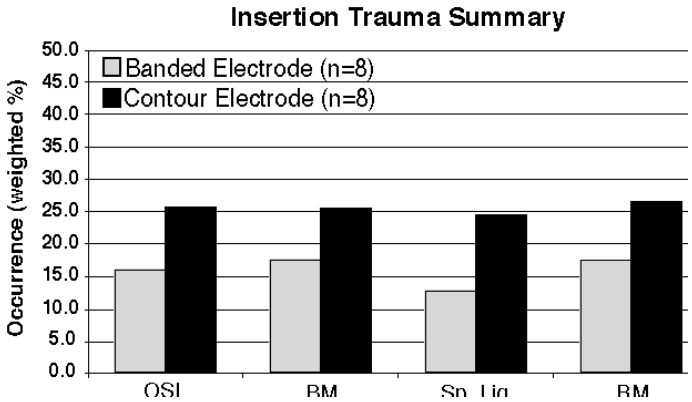


Figure 9. The frequency of occurrence of different types of trauma observed in each of the 16 temporal bones shown in Figures 6 and 7 are summarized here. The gray data bars show the incidence of trauma to each of the four cochlear structures assessed for the banded electrodes, and the black data bars summarize the same data for the *Contour*™ insertions.

Time Required for Electrode Insertion

Including the time required to create the cochleostomy, the experienced surgeon's insertions of the banded electrode required an average of 11 minutes. The resident's average insertion time with this device was longer, averaging 25 minutes per case. In contrast, with the *Contour*™ electrode the experienced surgeon completed the insertions in an average of 16 minutes, and the resident's average insertion time for the *Contour*™ was very similar at 17 minutes. The findings that the resident was able to insert the *Contour*™ electrode with comparable efficiency to the experienced surgeon, but took much longer than the experienced surgeon to insert the banded array, suggest that the new design is easier to use (see Discussion).

Discussion

The data presented in this study indicate that the newly introduced *Contour*™ intracochlear electrode fulfills the primary design goals of positioning stimulating contacts closer to the modiolus and deeper into the scala tympani than the previous design. However, with these improvements we also observed somewhat increased trauma in specimens implanted with the *Contour*™ as compared to those implanted with the original Nucleus™ banded design. We found that the specific type of trauma observed was consistent for each electrode design. In five out of the eight insertions the *Contour*™ electrode penetrated the basilar membrane at a point between 140° and 180°. An example of this type of trauma is shown in Figure 10. In four of these cases the apical portion of the electrode then entered the scala vestibuli and continued in that compartment throughout the remaining insertion. A previous temporal bone study by Tyckocinski et al. also reported this finding of interscalar excursion with the *Contour*™ electrode occurringat this same location, approximately 170°, although the incidence of this finding was lower (2 out of 12 test insertions) in their study (13). Some authors have suggested that the characteristic slope of the floor of the scala tympani at this point may predispose an electrode to upward deviation (Fishmann, Roland et al, personal communication). The finding of such similar results in the type of and location of injury occurring almost identically across studies that included several different surgeons suggests that electrode mechanics, rather than surgical experience or other possible factors, was the main contributory factor. We have suggested that decreasing the flexibility of the electrode in the vertical plane and making the electrode tip more blunt may help to prevent these penetration injuries (1,20).

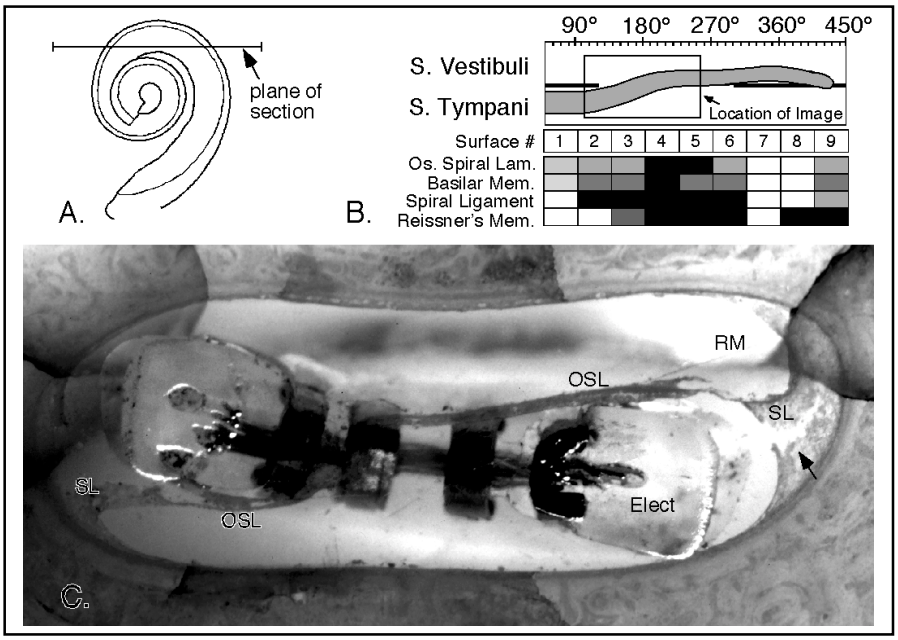


Figure 10. In this image the plane of section does not pass directly through the modiolus (A). This permits an unobstructed view of the *Contour*™ electrode as it penetrates the basilar partition and passes from the scala tympani up into the scala vestibuli. The osseous spiral lamina (OSL), Reissner's membrane (RM) and the spiral ligament (SL) can be clearly seen. In this right cochlear specimen the electrode begins in the scala tympani at the right side of the image. At this point it appears to be pushing the OSL upward producing a tear in the SL (arrow). As shown in the data map (B), and in the image, the electrode perforates the basilar partition at approximately the 180° location. In the left side of the image the electrode has severely depressed the OSL and stripped the SL from its attachment to the lateral wall.

Injuries seen with the traditional banded design were more diverse and seemed to be related to its sharper tip and greater overall flexibility. The banded electrode also produced injury at or near the 180° location as seen in previous studies with this device (6-8). However, these injuries tended to either strip the spiral ligament upwards or resulted when the electrode curled back upon itself at the point where further insertion of the electrode tip was impeded (see Figure 11). In one temporal bone specimen, the banded electrode was inserted directly into the scala vestibuli, which is the result of cochleostomy misplacement and orientation rather than electrode mechanics. Discounting this errant case, the frequency of banded electrode insertions that deviated from the scala tympani into the scala vestibuli was 25% (2/8). That is about the same rate of interscalar excursion of the banded electrode observed by Ketten et al. (21) (5/20 or 25%) in studies of living cochlear implant subjects evaluated by high resolution CT scans. As mentioned previously the *Contour*™ electrode had a somewhat higher total frequency of interscalar excursion of 50% (4/8).

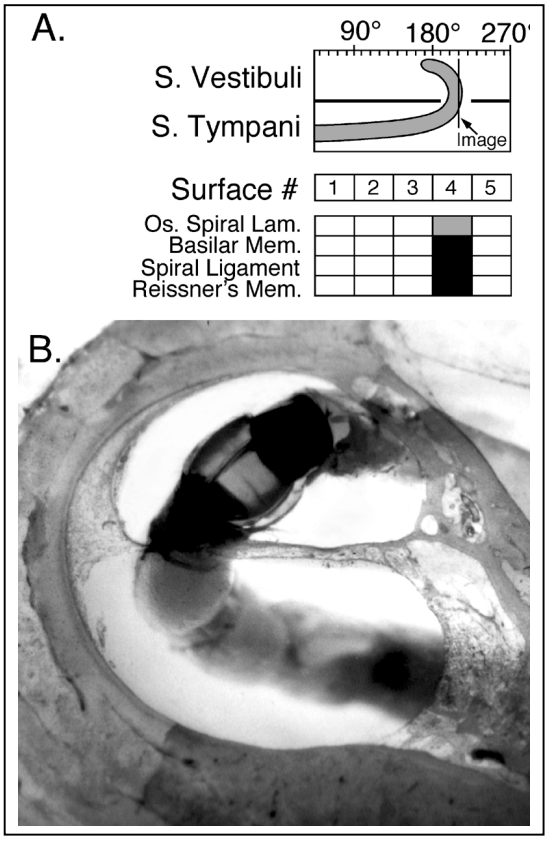


Figure 11. The most typical injury observed with both the *Contour*™ and Banded electrodes was interscalar excursion. In the case illustrated here, a Banded electrode pierced the basilar membrane as it rounded the first turn of the cochlea near 180°. The electrode tip actually bends back upon itself in the scala vestibuli and finally rests in the upper portion of the scala vestibuli with the tip facing the round window. For reference, the data map for this particular temporal bone is reproduced at the top of the figure (A).

Among the test insertions reported in our study, we observed one case in which the banded electrode was introduced directly into the scala vestibuli and a second specimen in which the banded electrode was inserted into the scala vestibuli but then immediately entered the scala tympani for the remainder of its course (see data maps, Fig 6). It has been argued that these events are less likely to occur when placement of the cochleostomy is guided by direct visualization of the round window by first drilling out the niche and when a larger cochleostomy is created (22). Support for this suggestion is also found in the results of Richter et al. (23) who observed significantly less trauma in temporal bone insertions using a larger fenestration (approximately 1.8 mm) as compared to results using a smaller cochleostomy (<1.0 mm). However, the benefits of improved access afforded by a larger cochleostomy must be weighed against any possible damage caused by the more extensive drilling required. It is important to note that the deviation of an electrode array into the scala vestibuli not only results in significant associated trauma and presumed consequent neural loss, but also causes the electrode to become tethered at the point of basilar membrane penetration, thus often compromising perimodiolar positioning.

With respect to the comparison of the trauma observed with banded and *Contour*™ electrodes, it is important to emphasize that because the banded electrode has quite a small diameter, the two very shallow insertions performed by the resident were completely atraumatic. However, such exceedingly shallow insertions are uncommon in clinical practice. For example, in the Ketten et al. (21) study of a representative group of implant subjects the shallowest insertion was approximately 16.5 mm (22 rings intracochlear), and none were as shallow as the 9.8 and 10.00 mm insertions included in the present series. Thus, one caveat with respect to the trauma data is that these very conservative insertions by the resident surgeon may have biased our results toward an underestimation of the trauma with the banded array in comparison to the *Contour*™, especially considering the relatively limited number of temporal bones comprising this series.

Comparison of Resident versus Experienced Surgeon's Results

The findings of our study showed that the resident's and experienced surgeon's insertions of the *Contour*™ electrode were very similar, both in depth of insertion achieved and the time required to complete the implantations on average. In contrast, results with the original banded electrode showed that the resident required significantly more time to complete the insertions than the experienced surgeon. Moreover, the resident was unable to insert the banded electrode as deeply as the experienced surgeon (mean insertion depth = 242°/13.7 mm for the resident vs. 320°/17mm for the experienced surgeon). In this study, therefore, the new design proved superior to the standard one in ease of use, allowing a relatively novice surgeon to achieve similar insertion performance and speed to that of an expert. This similarity in performance with the *Contour*™ electrode is a positive indication that widespread clinical application of the newer device may be accomplished without the need for extensive additional training. Further, it is interesting to note that the resident surgeon felt strongly that the experience of preparing the temporal bone specimens, performing the insertion trials and evaluating the histological specimens proved to be an invaluable training tool for a surgeon embarking on a career that includes cochlear implantation.

The Significance of Trauma

The relative importance of each type of trauma, and indeed the overall significance of insertion trauma have been debated. There have certainly been post mortem studies (10) demonstrating surprisingly good performance in patients with notably traumatic insertions, or poor spiral ganglion or dendrite survival. Some authors hypothesize that there may be a "threshold" effect of trauma whereby performance is unaltered as long as the spiral ganglion cell population remains above a critical number (10). However, it is clear that many factors contribute to a patient's performance with an implant, and in the end there is no way to estimate what level of performance these patients might have achieved had trauma been avoided during implantation.

Perhaps the most compelling direct evidence with regard to the effects of trauma on spiral ganglion survival is seen in animal studies, where tighter control of variables is possible. In this work, even slight trauma, typically occurring at the electrode tip, caused a very marked reduction in the number of spiral ganglion cells in the damaged region as compared to adjacent areas (24). In addition, this loss of spiral ganglion cells has been correlated with several physiologic performance measures including threshold, response selectivity (25) and the capacity of the neural population to represent information in the frequency domain (26). Certainly trauma is intuitively an adverse factor in cochlear implantation, given the characteristically poor regenerative abilities of neuronal tissue.

As the indications for implantation inevitably expand and patients with more residual hearing become potential surgical candidates, the potential effects of insertion trauma will become more significant. This concern is particularly relevant in patients who will receive combination hearing aid/cochlear implant devices intended to provide electrically generated percepts in the basal cochlea and amplified acoustic input to lower frequency regions (2). Clearly, the basilar membrane mechanics, as well as remaining hair cells and neurons, must be preserved if these patients are to receive long lasting acoustic benefit. Moreover, since trauma and mispositioning of electrodes are associated with more extensive new bone formation in the cochlea, such trauma may make replacement of the cochlear implant significantly more difficult should it be required.

Finally, with respect to the potential significance of insertion trauma, it is also important to consider that many cochlear implant recipients are now young infants who will be dependent upon these devices for many decades. It is undeniably the case that many of the devices in this population will be replaced sometime in the future, either to replace failed components or to take advantage of improved technologies. We suggest that optimum conservation of the auditory neurons and prevention of new

bone formation within the cochlea are likely to be critical factors in ensuring optimum long-term outcomes for these young cochlear implant recipients.

The Significance of Modiolar Proximity and Insertion Depth

As described above, the *Contour*™ electrode design positioned the electrode array closer to the modiolus than the previous device. Although there is no clear evidence to date that this positioning will improve patient performance, the results of animal studies (27-29) and computer modeling (30, 31) indicate that this design may produce both lower response thresholds and more selective multichannel stimulation. Preliminary clinical trials suggest improvement in both thresholds and comfort levels in recipients of the newer electrode design (13), findings which are consistent with closer proximity of electrodes to the stimulated neuronal population within the modiolus. How these changes will relate to speech perception measures is unknown at present. Because of the great variability among implant recipients it will be difficult to fully assess outcomes with the new device until larger numbers of subjects have been implanted and evaluated psychophysically.

The *Contour*™ electrode clearly achieved substantially deeper intracochlear positioning than the banded array (mean insertion = 442°/17.8 mm for the *Contour*™ vs. 285°/15.4 mm for the banded electrode) in our insertion series. The value for the banded array group in this study is similar to the mean insertion depth of 254° seen in 5 patients in one previous study (32) and somewhat shallower than another series of 9 cadaver temporal bones with a mean depth of 18.6 mm (8).

Considered relative to the known tonotopic organization of the cochlea, the difference between the frequency represented at the mean apical electrode contact location for the *Contour*™ electrode (approximately 1.1 kHz based on Greenwood, 33) and that of the banded electrode (about 2.2 kHz) in this study reflects a difference of about one octave. The effect of electrode insertion depth in cochlear implant patients has been examined in several studies. Although some studies (34, 35) have reported better speech discrimination in patients with deeper electrode insertion, there have been others which have shown no significant advantage (36, 32), or that performance is not impaired when only a subset of electrodes are activated (37). It should be noted that it is not possible to separate the effect of insertion depth from other anatomic and physiologic variables in these patient studies. In particular, the underlying cause of reduced insertion depth in some patients may be the result of pathologies that also affect neural survival or result in the generation of ectopic bone in the scala tympani, either of which may in turn affect performance scores. Thus, the most meaningful test of the effect of insertion depth would be to evaluate implant performance while moving multichannel stimulation across portions of a deeply inserted array in individual patients. Both Fu (38) and Pfinst (39) have conducted such experiments and found that the longitudinal position of the series of channels presented across a cochlear implant indeed did affect performance in speech recognition tests.

Comparisons across various studies with respect to depth of electrode insertion and its effects are complicated by the fact that insertion depth is reported differently by each author and measured by a variety of methods. Also, as discussed previously the linear insertion depth (length of electrode inserted) and the radial insertion depth (measured in degrees) are codependent on modiolar proximity such that greater modiolar proximity allows a greater angular insertion depth for a given length of electrode.

It is perhaps a natural tendency for a surgeon and manufacturer to strive for full insertion of an electrode in all implantations, even when cochlear anatomy prevents this. Some series have reported that surgeons consistently overestimate insertion depth compared to measured depth on CT scans (21). While some of the studies discussed above suggest that full insertion is desirable, we concur with the manufacturers (40) that it should not be achieved at the expense of increased insertion trauma.

The Temporal Bone Model

The model described here was designed to simulate surgical conditions as closely as possible, while allowing full post-insertion radiological and histological assessment. All insertion trials were performed in specimens in which the facial recess was retained, because we feel that its confines are a major factor limiting vision and latitude during electrode insertion, and which, if removed, would detract from the authenticity of the insertion conditions in the study. Some authors (14, 15, 19) use lubricants in clinical practice, and in temporal bone insertions in an attempt to restore frictional properties more like those of the living cochlea. Animal studies suggest that these lubricants are biologically safe (18) and appear to allow deeper insertion in temporal bones (14, 15).

The question of appropriate histological fixation has also been a much-debated issue, (Luxford W, Roland JT, personal communications). Some argue that aldehyde fixation imparts unnatural tissue strength, thus causing an artificially low incidence or extent of trauma in the temporal bone model. On the other hand, if temporal bones are not fixed, rapid tissue autolysis occurs within a few hours of death, thus potentially exaggerating insertion trauma. Some authors (14, 15) have used temporal bones implanted within a few hours of death and these would appear to be the ideal test specimens for electrode evaluation. However, this clearly creates practical difficulties in procuring and implanting large numbers of comparable specimens within a reasonable period and enabling multiple surgeons to participate in a study. We feel that, together, the excellent preservation of cochlear structures of interest for evaluating trauma, and the greater number of specimens available for evaluation under our protocol produced the highest quality model for these studies.

Conclusions

We conclude that the second generation *Contour*™ electrode successfully positions stimulating contacts closer to the modiolus and deeper into the scala tympani than the previous model, but at a cost of slightly greater trauma to the inner ear. Both designs tested produced consistent patterns of injury to the cochlea suggesting that specific improvements in design may reduce or eliminate this trauma. Insertion performance with the *Contour*™ was similar for the resident and experienced surgeon, but when the original banded electrodes were inserted by the resident, the mean insertion depth was shallower and time required for insertion was substantially longer, suggesting that the *Contour*™ is superior in ease of use.

We also found that the temporal bone model and the methods described in this study provide a practical and effective strategy to evaluate the performance and potential for insertion trauma of current and future cochlear implant electrodes. Finally, although the long-term consequences of intracochlear trauma are still unknown, we submit that there is a critical role for temporal bone insertion studies, both for reaching a better understanding of the performance of the various devices currently in clinical application and particularly for comparing the performance of new or modified devices to their predecessors prior to clinical trials.

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