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Comparative Study of Cochlear Damage With Three Perimodiolar Electrode Designs

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Objective: **To describe intracochlear insertion trauma caused by three perimodiolar cochlear implant electrodes.** ***Study Design:*** **Descriptive histological study of 15 human cadaver temporal bones.** ***Methods:*** **Fifteen cadaver temporal bones underwent surface preparation and were implanted with one of the following perimodiolar electrode arrays: Combi 40+PM (MedEl Corporation), HiFocus II (Advanced Bionics Corporation), or Contour (Cochlear Corporation). A cryosectioning technique was used to study horizontal sections at 200-μm intervals with the electrode in place. Image-enhanced videofluoroscopy and computer-assisted morphometrics were used to assess the mechanism of insertion trauma and to determine electrode position within the modiolus.** ***Results:*** **Histological examination revealed varying degrees of damage to the spiral ligament, basilar membrane, and osseous spiral lamina. Using a novel grading system for electrode trauma, there was no statistically significant difference among the three electrodes. A literature search of histological studies of a commonly used "standard" electrode showed damage equal to or greater than that seen in the current study.** ***Conclusions:*** **Insertion trauma caused by periomodiolar electrodes occurs to an acceptable degree. Refinement of electrodes based on mechanisms of trauma may be able to further reduce damage.** ***Key Words:*** **Deafness, temporal bone, cryomicrotomy, inner ear, cochlear implant, perimodiolar electrode, cochlear trauma.**

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INTRODUCTION

Perimodiolar electrodes are designed to place stimulating contacts close to the spiral ganglion cells, to reduce power consumption and increase stimulation selectivity.[1–5] Because of increasing implantation of young children and patients with residual hearing, as well as a new trend for use of hybrid electric/acoustic devices and bilateral implantation, it is of growing importance to prevent damage to cochlear structures during implantation.

Histological evaluations of trauma resulting from the insertion of cochlear implant electrodes have demonstrated damage to the spiral ligament, basilar membrane, osseous spiral lamina, and other structures.[6–11] The impact of localized damage to the spiral ligament during implantation is uncertain,[6] but osteoneogenesis may be stimulated and secondary localized tears of Reissner's membrane may occur. There is general agreement that damage to the osseous spiral lamina, basilar membrane, and Reissner's membrane results in at least localized loss of spiral ganglion cells[7] and that the extent of neural damage may be proportional to the degree of cochlear tissue injury.

The purpose of the present study was to compare cochlear damage resulting from insertion of three perimodiolar electrodes. A cryo-histological technique was used to study the cochleae with the electrodes in situ. An additional aspect of the study, assessment of electrode contact proximity to the modiolar wall, is presented elsewhere.[5]

MATERIALS AND METHODS

Electrode Designs

Three perimodiolar implant electrodes were examined: the experimental Combi 40+PM developed by MedEl Corporation (Innsbruck, Austria), the HiFocus II by Advanced Bionics Corporation (Sylmar, CA), and the Contour by Cochlear Corporation (Denver, CO). In the Combi 40+PM electrode, a restraining arm is placed within a microgroove on the antimodiolar electrode surface. After insertion into scala tympani, the electrode is slightly withdrawn while the restraining arm is being held in place, with the electrode contacts being positioned closer to the modiolus. In the HiFocus II electrode, a Silastic positioner holds the electrode close to the modiolus. The Contour electrode is initially held straight with a stylet that is withdrawn after insertion so that the array curves closer to the modiolus, because of its elastic memory.

Electrode Insertion

Fifteen fresh-frozen cadaver temporal bones underwent surface preparation to remove all excess bone and to thin the otic capsule. A cochleostomy as prescribed by each implant manufac-

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turer was made, and the stapes footplate was removed. The cochlea was irrigated with cool, normal saline using extreme care to avoid trauma. A small amount of hyaluronic acid lubricant (Healon, Pharmacia and Upjohn, Inc., Kalamazoo, MI) was infused into the cochlear lumen immediately before cochlear implant electrode insertion. All insertions (five electrodes for each electrode design were provided by the manufacturers) were performed by the senior author (T.J.B.) under microscopic visualization using standard insertion tools for each electrode type as recommended by the manufacturers. Image-enhanced videofluoroscopy was used to assess insertion dynamics.[5] Each insertion was stopped at the point of first resistance. After insertion, the electrodes were fixed close to the cochleostomy with cyanoacrylate glue to prevent any additional movement. A representative of each manufacturer was present during insertion of the corresponding electrode.

Cryosectioning Technique

Horizontal sections of the implanted cochleae were examined at 200-μm intervals using a previously described cryosectioning technique.[12] The positioning of the electrode and any resulting damage could be assessed with the electrode in place. The three steps in the technique are summarized as follows:

1. Fluid immersion and air extraction. The cochlea was filled with saline. The temporal bone then was immersed in a bivalved canister of saline. A vacuum was applied to extract dissolved air within the fluid-filled cochlear lumen.

2. Freezing and mounting. The temporal bone was removed from the fluid and placed into a commercial freezer to allow the fluid within the cochlea to solidify. Each temporal bone then was immersed totally in a thick, semifrozen slurry of methyl cellulose (Metylan Cellulose Wallpaper Paste, Conross Corp., Detroit, MI) in a small specimen container. The bone was allowed to freeze in this position for 12 hours to form a large block of reinforced ice that could be positioned properly and held securely on a cryomacrotome tissue holder.

3. Cryosectioning and photographic documentation. A Leica CM3 600 Cryo-Microtome (Leica Microsystems, Nussloch, Germany) was used to section the undecalcified temporal bone specimens with the cochlear implant electrodes in situ. The sections were cut at a thickness of 10 μm using a tungsten-carbide knife set at an angle of 35°. After every 20th section, the remaining specimen block was removed from the cryo-chamber and the exposed face of the cochlea was viewed under magnification (original magnification $\times$1.6 and $\times$2.5) using a Zeiss 0PMI-1 FC microscope on a table mount (Carl Zeiss, Oberkochen, Germany). A 70% glycerol–water solution was spread on the surface of a coverslip, which was placed on the exposed surface of the temporal bone. Photographic documentation was carried out with a microscope-mounted, 35-mm camera using Iso-64 tungsten slide photographic film.

Analysis of Electrode Position and Structural Damage

The insertion depth and position of each electrode were assessed using computer-assisted morphometric analysis of the photographic images. The extent of cochlear trauma was rated on a scale of 0 to 4 in which 0 represented no observable trauma; 1, elevation of the basilar membrane; 2, rupture of basilar membrane; 3, electrode in scala vestibuli; and 4, severe trauma such as fracture of the osseous spiral lamina or modiolus or tear of stria vascularis. This scale was developed with the help of Noel Cohen and Thomas Roland of New York University (personal communication, 1999).

RESULTS

The average depth of insertion measured by videofluoroscopy was 410° ($\pm$ 52.9 SD) for the Contour, 393° ($\pm$ 69 SD) for the Combi40+PM, and 378° ($\pm$ 40 SD) for the HiFocus II. The distance from the modiolus for each stimulating contact has been reported previously.[5]

Examination of the undecalcified human temporal bone sections revealed no observable trauma in three bones implanted with the Contour electrode (grade 0) (Fig. 2). However, the remaining two bones implanted with the Contour showed fractures of the osseous spiral lamina (grade 4) (Fig. 3). One of the HiFocus II bones had no observable trauma (grade 0). The other three bones showed various degrees of trauma including elevation of basilar membrane (grade 1) (Fig. 4) in two, basilar membrane rupture in one (grade 2), and electrode displaced into scala vestibuli in one (grade 3). For the Combi40+PM electrode, two bones did not show any observable trauma (grade 0) (Fig. 5). For the other three Combi40+PM preparations, one bone showed a fracture of osseous spiral lamina (grade 4) (the insertion was stopped at 285° because of resistance), one exhibited elevation of basal membrane (grade 1), and one showed a rupture of basilar membrane (grade 2).

The mean scores for degree of trauma were 1.6 ($\pm$ 2.19) for the Nucleus Contour, 1.4 ($\pm$ 1.67) for the Combi40 + PM, and 1.4 ($\pm$ 1.14) for the HiFocus II. Differences in these scores were not significantly different. In all bones with higher classes of damage (scored grade 3 or 4), the electrode array penetrated the basilar membrane or fractured the osseus spiral lamina at approximately 180° insertion depth. In two HiFocus II preparations, elevation of the basilar membrane occurred at 360° insertion depth adjacent to the tip of the electrode array. In two other HiFocus II preparations with basilar membrane rupture, the damage extended for up to 180°, whereas only short segments of rupture were caused by Contour or Combi40 + PM. In the two Combi 40 + PM preparations that were scored 0, the electrode was not as close to the modiolus as the three Combi 40 + PM preparations that were scored 1, 2, and 4.

DISCUSSION

Histological examination of 15 bones revealed varying degrees of damage to the spiral ligament, basilar mem-

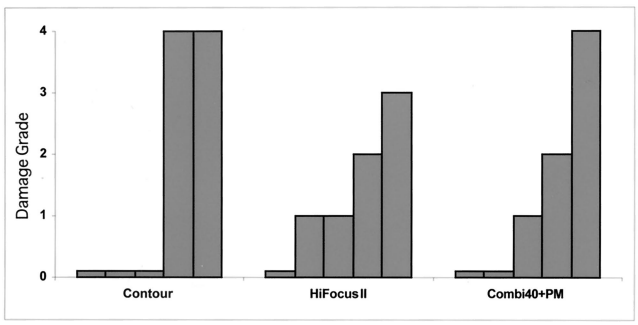

Fig. 1.

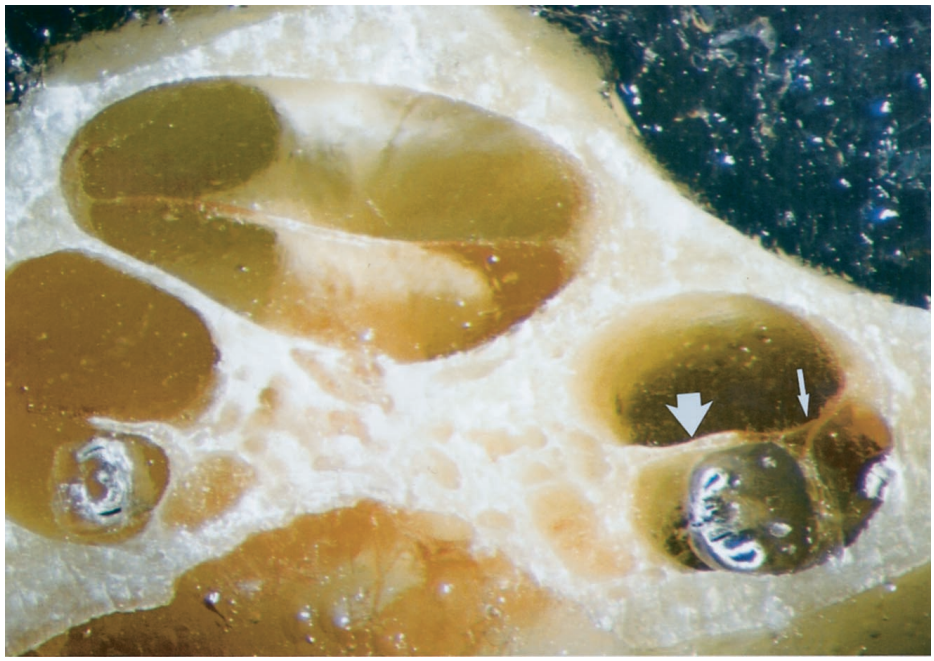

Fig. 2. Near-modiolar section of Contour electrode shows no evidence of damage to basilar membrane (small arrow) or osseous spiral lamina (large arrow) (grade 0).

brane, and osseous spiral lamina. Nonetheless, using the grading system described, the degree of trauma was comparable for the three electrode designs and equal to or less than the damage reported for the most commonly used previous-generation multichannel electrode.[3,4,7,9] However, post hoc analysis demonstrated that the greater length of basilar membrane ruptures seen with HiFocus II was not reflected in the grading system.

In a previous report using videofluoroscopy and computer-assisted morphometrics, we showed that all three perimodiolar designs were effective in placing contacts close to the modiolar wall.[5] The Contour electrode was closest in the apex and the Combi 40 + PM and HiFocus II were closest at the base.

For any insertion of an intracochlear electrode array, some damage to the inner ear occurs as a result of the insertion process. The trauma at the cochleostomy was universal in implanted cochleae. For this reason, that damage was not included in the trauma rating.

The study of temporal bone histopathology has led to the development of numerous methods of temporal bone preparation and examination. In the evaluation of mechanisms of trauma to, and changes in, intracochlear structures resulting from cochlear implant electrode insertion, previous

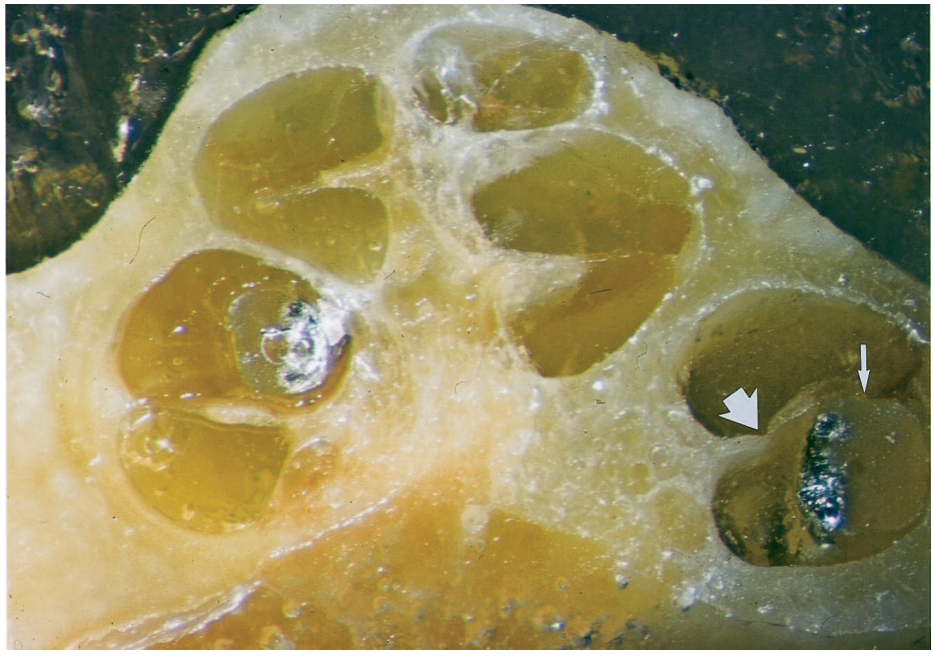

Fig. 3. Modiolar section of Contour electrode demonstrating fracture of osseous spiral lamina (large arrow) and penetration of basilar membrane at 180° (small arrow). Electrode is evident in scala vestibuli at 360° (grade 4).-

Fig. 4. Near-modiolar section of HiFocus II electrode demonstrating elevation of basilar membrane (small arrow) (grade 1) at 200°. Large arrow shows normal osseous spiral lamina at 340°.

studies have used the classic technique of formaldehyde fixation, celloidin embedding, serial sectioning, mounting, and staining.[7,9–11] A disadvantage of this classic technique is that electrodes typically are removed before histological processing of the bones. Consequently, the position of the electrode in the cochlea cannot be assessed and the trauma caused by electrode removal cannot be separated from trauma resulting from electrode insertion.

In contrast, the crysectioning technique used in the present study, like techniques that use embedding in epoxy resins followed by saw microtome sectioning, allow the evaluation of temporal bones with the cochlear implant electrodes in situ.[1,2,13,14] Consequently, the relationship of the electrode to the intracochlear structures can be ascertained. Moreover, in combination with videofluoroscopy, the dynamic mechanisms underlying insertion trauma can be determined.

The cryosectioning technique has significant limitations. The cut sections are not preserved, so evaluation of the temporal bone is limited to the time during which sectioning is performed and depends on the quality of the photographic documentation. Although the technique allows an excellent low-power view of the microscopic anatomy of the temporal bone, cellular level

Fig. 5. Near-modiolar section of MedEl Combi 40 + PM electrode showing no evidence of damage (grade 0). Intact basilar membrane (small arrow) and osseous spiral lamina (large arrow) are evident.

analysis is limited as a result of the low degree of magnification.

Another drawback to the present study, as in most studies of cochlear implants and human temporal bones, is that temporal bones from normal-hearing individuals were used. Temporal bones from profoundly deaf individuals, especially those with osteoneogenesis or intracochlear fibrosis, may significantly affect electrode positioning and resultant trauma.

Videofluoroscopic observations of the electrode insertions do not generate hard data but do demonstrate the dynamics of some of the trauma. For example, the tip of the Contour electrode may elevate or penetrate the basilar membrane or osseous spiral lamina at the moment of first resistance when the manufacturer's recommended technique is followed. Based on this finding, slight withdrawal of the stylet during the insertion process may reduce this type of trauma. In addition, because tissue damage generally occurs when the Contour tip encroaches on the basilar membrane, insertion should proceed with the tip directed away from it.

The HiFocus II electrode may cause damage when the actual size of the scala tympani is smaller than expected. Therefore, if resistance is met during HiFocus II insertion, the positioner may be separated from the electrode and inserted independently at a shorter depth.

In retropositioning the developmental MedEl Combi40+PM, trauma was generally caused by the restraining arm. For this reason, extremely gentle pressure should be applied when retropositioning the electrode arm.

The relationship among cochlear trauma, the number of surviving ganglion cells, and the benefit experienced by cochlear-implant recipients is unknown. Histopathological findings in deceased cochlear implant users have shown that survival of only a small portion of the normal ganglion cell population can provide usable auditory information.[8,15,16] Moreover, some of those studies found that factors other than auditory neural integrity are important in performance with multichannel cochlear implants (e.g., abnormalities in the central auditory pathways).[15,16] Further studies will illuminate the relationships among electrode design, electrode placement, site of damage, spiral ganglion cell survival, and hearing benefit in patients with cochlear implants.

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