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Comparison of Electrode Position in the Human Cochlea Using Various Perimodiolar Electrode Arrays

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Objective: This study was conducted to evaluate the insertion properties and intracochlear trajectories of three perimodiolar electrode array designs and to compare these designs with the standard Cochlear/Melbourne array.
Background: Advantages to be expected of a perimodiolar electrode array include both a reduction in stimulus thresholds and an increase in dynamic range, resulting in a more localized stimulation pattern of the spiral ganglion cells, reduced power consumption, and, therefore, longer speech processor battery life.
Methods: The test arrays were implanted into human temporal bones. Image analysis was performed on a radiograph taken after the insertion. The cochleas were then histologically processed with the electrode array in situ, and the resulting sections were subsequently assessed for position of the electrode array as well as insertion-related intracochlear damage.
Results: All perimodiolar electrode arrays were inserted deeper and showed trajectories that were generally closer to the modiolus compared with the standard electrode array. However, although the precurved array designs did not show significant insertion trauma, the method of insertion needed improvement. After insertion of the straight electrode array with positioner, signs of severe insertion trauma in the majority of implanted cochleas were found.
Conclusions: Although it was possible to position the electrode arrays close to the modiolus, none of the three perimodiolar designs investigated fulfilled satisfactorily all three criteria of being easy, safe, and atraumatic to implant. **Key Words:** Cochlear implant—Perimodiolar electrode design.
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Intracochlear multichannel cochlear implants have successfully provided auditory information for profoundly deaf patients by electrically stimulating discrete populations of auditory nerve fibers via a scala tympani electrode array. The straight, yet flexible, tapered Melbourne/Cochlear electrode array can be safely implanted into the human cochlea. However, histologic and radiologic examination of implanted temporal bones showed that the electrode array is usually positioned along the outer wall of the scala tympani (1–5). The array is, therefore, some distance from the spiral ganglion cells in the Rosenthal canal and their peripheral processes. However, a profound sensorineural hearing loss is often associated with a moderate to complete degeneration of the peripheral processes (6,7), implying that the site of action potential generation is typically at, or central to, the spiral ganglion cell soma. It is likely that positioning the electrode array closer to the modiolus would reduce stimulation thresholds and result in more localized neural excitation patterns. The associated increase in the dynamic range expected with those changes should allow an improved representation of loudness and speech perception (8).

The effect of stimulus site on neural excitation has been previously investigated. Shepherd et al. (9) have shown in cats that moving an electrode array from the outer wall of the cochlea toward the modiolus resulted in both a significant reduction in the threshold of the electrically evoked auditory brainstem response (EABR) and an increase in the dynamic range. Marsh et al. (10) used EABRs to investigate the effect of electrode position in

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the guinea pig. They reported both lower EABR threshold current levels and a wider dynamic range for a stimulating electrode placed directly onto the modiolus, compared with electrodes placed in either the scala tympani or the scala vestibuli.

More recently, studies of perimodiolar electrode arrays have been extended to investigations of potential clinical application. With an early prototype of a curved electrode array, it was shown that a perimodiolar electrode array can readily be inserted into the cochlea and positioned close to the modiolus (11). Since then, different methods of positioning electrodes close to the modiolus have been reported (12,13).

The safety of any electrode array design in regard to insertion-induced damage is best established by insertion trials in human temporal bones, whereas long-term tissue biocompatibility must first be evaluated in animal studies.

In the current study, we investigated the insertion properties of three different advanced perimodiolar array designs—precurved with introducer, precurved coated with polyvinyl alcohol (PVA), and a standard array with positioner—and used image analysis techniques to evaluate the position of the electrode array within the cochlea. Sectioning of the nondecalcified, resin-embedded temporal bones was performed to evaluate the three-dimensional position of the electrode array within the cochlea and to detect possible insertion trauma. The results were compared with those for a standard Melbourne/Cochlear electrode array. The current study has important implications for the development of a safe and reliable perimodiolar electrode array.

Preliminary results of the current study have been described earlier (14). The positioner and the precurved electrode array have been described previously (15).

MATERIALS AND METHODS

Insertion

Thirteen human cadaver temporal bones were prepared as for cochlear implant surgery. In all cases the middle ear appeared normal on inspection. Insertions were performed at the two participating centres (Melbourne and New York). All surgeons (two in Melbourne, one in New York) were experienced cochlear implant surgeons and had previous and equivalent training in handling the new arrays. A cochleostomy was performed anterior-inferiorly to the round window. The electrode array was inserted only by a direct antegrade approach, and fixed close to the round window. All electrode arrays evaluated in this study were inserted with only minimal resistance felt. A new array was used for each insertion.

Electrode arrays

The standard array (No. 1) of a Melbourne/Cochlear Mini 22 Cochlear Implant (16,17) (n = 1) and three different perimodiolar electrode designs (Nos. 2–4) were trialed in the current study (Table 1).

Array No. 2 was a precurved electrode array that had to be inserted into the cochlea by use of a custom-made insertion tool (15) (n = 2), which temporarily straightened the electrode array. This array had a simple circular cross-sectional design without further features, unlike the Clarion implant system (18). It was modeled and cast to conform approximately to the human modiolus. However, the recoil properties of this array design after its release from the insertion tool was insufficient to ensure a tight modiolar-hugging electrode position.

TABLE 1. *Description of the four electrode array designs used in the present study, mean insertion depth and standard deviation for each group, and number of arrays evaluated*

Array ID	Array design	Insertion depth (mean) (°)	Standard deviation (°)	No. of arrays evaluated
1	Standard Mini 22 electrode	355.0	NA	1
2	Precurved electrode array with introducer	374.5	12	2
3	Precurved electrode array with PVA	393.0	7	2
4	Standard array with positioner	394.2	27.4	8

Note: Standard deviation is given as an indication of variation of insertion depth only.
NA, not applicable.

Array No. 3 had a revised geometry and construction compared with array No. 2. It was a precurved electrode array (Fig. 1), which was straightened mechanically and maintained in this shape until insertion by use of a uniform layer of a 25% aqueous solution of the polymer PVA with a molecular weight of 30,000 to 70,000 (n = 2). The insertion of the array required special attention because it had to be orientated correctly to resume a spiral shape consistent with that of the cochlea. Once in contact with perilymph (or other body fluids), PVA first softens and then dissolves, allowing the array to take up its final perimodiolar shape. Its solubility in fluids is a function of both the degree of hydrolysis and polymerization. Whereas PVA with a molecular weight of 30,000 to 70,000 is soluble in cold water, PVA with a molecular weight of 70,000 to 100,000 dissolves in hot water only (>70°C).

Array No. 4 was a standard array with a Teflon positioner attached to its tip (Fig. 2). The electrode array and Teflon strip were inserted simultaneously into the cochlea with the aid of a

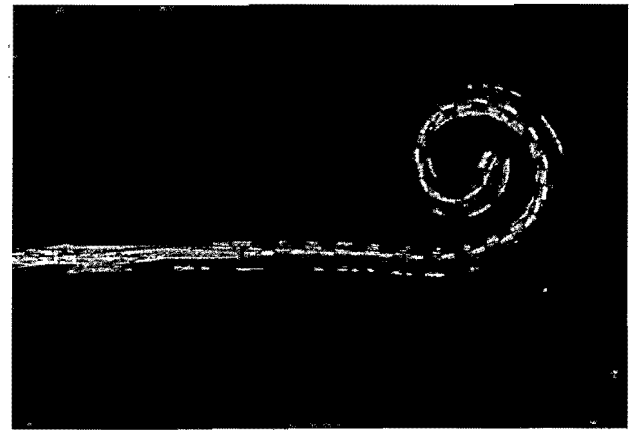

FIG. 1. Array No. 3: Precurved electrode array before straightening and application of polyvinyl alcohol (PVA). The shape was calculated to conform with the human modiolus.

custom-made insertion tool. This insertion tool allowed the electrode array to be located on the modiolar side of the scala tympani, whereas the Teflon strip was located more laterally along the outer scala wall. However, there was no need to place the introducer into the cochleostomy. Once the array was inserted, the Teflon strip was further advanced, thereby pushing the intracochlear electrode into a perimodiolar position. The Teflon strip was held in place by a tight silicone ring located close to the cochleostomy. A total of eight temporal bones were implanted using this design. No attempt was made to change the position of the array after the initial insertion. Of the initial version of this design, three bones were implanted in Melbourne and two in New York. A further three bones were later implanted in Melbourne by use of a modified version of the array featuring a shorter Teflon strip. One temporal bone of this series was implanted with the aid of a lubricant based on phospholipids in solution (R2D2).

Imaging and processing techniques

After electrode insertion, the temporal bones were stored for 1 week to enable the precurved arrays (Nos. 2 and 3) to achieve their final resting position. A radiograph was taken, using the modified Stenver view ("cochlear view"), to enable accurate visualization of the insertion depth and position of individual electrodes. This procedure has been described previously (19–21).

The technique allowing computer analysis of the radiographs has also been described previously (22). Briefly, on a digital image of each temporal bone radiograph, the positions of the apex of the superior semicircular canal and the midpoint of the vestibule were specified. A primary reference line between those points defined the orientation on the radiograph (19,22). In contrast to the standard method, a hypothetical electrode array was positioned ~0.4 mm medially of the outer wall of the cochlea. A mathematical spiral was fitted to the trajectory of this hypothetical array, thus determining a center point relative to which the positions of all actual electrode bands (and of the Teflon strip in array No. 4) could be specified. The lateral positions of those bands were then estimated relative to mean outer and inner wall functions obtained from 11 Silastic molds of the scala tympani (22). Deriving the center point from a hypothetical array rather then the actual array was necessary to avoid the unacceptable errors associated with the original method (22) when a precurved electrode array is used.

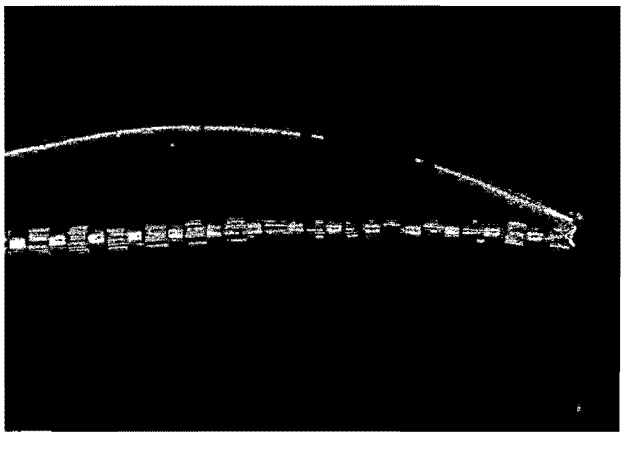

FIG. 2. Array No. 4: Cochlear Mini 22 electrode array with Teflon positioner (T) connected to the electrode tip.

The original method was shown to give estimates of electrode insertion angle and round window position that were quite resistant to the effects of rotation of the cochlea relative to the x-ray beam and to interobserver variations (22). The present modification of the method is intended primarily to estimate the lateral position of the electrode array in the scala tympani. The role of the observer is similar in that the position of the superior semicircular canal and the vestibule must be marked, but different in that the outer wall of the otic capsule must also be marked. Given reasonable quality of the radiographic image, the latter is fairly easy to detect, and major variations would not be expected as a result of interobserver variations, provided the cochlea is accurately oriented in the x-ray beam.

Histology

To evaluate the electrode position within the cochlea and possible damage to cochlear structures, the temporal bones were processed histologically with the electrode array fixed close to the cochleostomy to prevent any movement. Initially, a stereoscopic radiograph was taken to show the three-dimensional image of the electrode spiral within the cochlea and its position within the surrounding temporal bone. The soft tissue was then removed chemically using decreasing concentrations (5% to 0.5% weight/volume) of sodium hypochlorite solution. The temporal bones were then thoroughly washed in distilled water, air dried, and embedded in clear casting polyester resin (UN1866 Cls 3, RF-Services Pty Ltd.). The cochlea was then removed from the temporal bone with a saw microtome. The cut surface was lapped and polished to enable viewing of the cochlea, and a second radiograph was taken for accurate determination of the orientation of the electrode within the cochlea before serial sectioning. These 0.3-mm-thick sections were made perpendicular to the electrode spiral within the cochlea with a saw microtome (Leitz 1600, Germany). Every section was kept for analysis, and both sides of each section were photographed to record the position of the electrode relative to the basilar membrane, modiolus, and lateral wall of the scala tympani.

This study was approved by the Royal Victorian Eye and Ear Hospital Human Research Ethics Committee (Perimodiolar Electrode Array, Human Temporal Bone Study, No. 96/303H).

RESULTS

The standard array (No. 1) followed accurately (Fig. 3 A) the mean insertion trajectory (see Fig. 3, dashed lines) recorded previously in 28 cochlear implant patients for that electrode design (22). Inserted to a depth of 355°, the electrode was positioned close to the outer wall of the scala tympani. There was evidence of buckling of the array close to the round window. Buckling results from inserting the electrode beyond the point of first resistance and may well result in localized trauma to the spiral ligament, the basilar membrane, or the osseous spiral lamina. The resistance is the result of mounting friction as an increasing area of the electrode array contacts the outer wall of the scala tympani (1,3) during insertion.

All perimodiolar electrodes showed trajectories that were generally much closer to the modiolus compared with the standard electrode array. The precurved array (No. 2) required a larger cochleostomy (~1.2 mm diam-

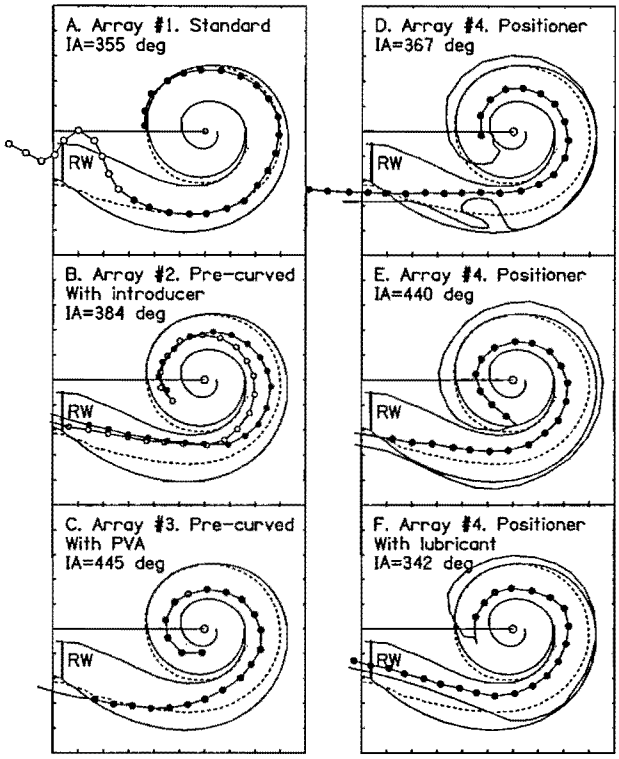

FIG. 3. Reconstructions from radiographs of temporal bones implanted with various electrode arrays (see Table 1 for description of each array). Each frame shows the mean position of the outer and inner walls of the scala tympani (solid lines), the approximate position of the round window and the mean position for the standard Cochlear Mini 22 electrode array (dashed line). The positions of the electrode bands of the experimental arrays are shown (filled circles) for radiographs taken within 24 hours of insertion. Furthermore, the insertion angle (IA) of the most apical electrode band is given (in degrees) to indicate the depth of insertion. (**B**) The position of the array is also shown from a radiograph taken at a later stage of processing (open circles), indicating that the array had moved. In (**D**) through (**F**), where the standard array was used with a Teflon strip, the latter is also shown (solid line).

eter) compared with the standard array (1 mm diameter) for advancement of the introducer into the lower basal turn to insert the electrode array smoothly around the first turn of the scala tympani. The mean insertion depth for this array design was 374.5° (n = 2), slightly deeper than the standard array (Table 1). Image analysis showed these two precurved arrays to be close to the modiolus in both the lower basal turn and the upper basal turn. However, both arrays approached the outer wall of scala tympani between 9 mm and 14 mm from the round window. Light microscopy of the histologic sections confirmed that both electrode arrays were implanted into the scala tympani. Some damage to the basilar membrane was apparent in the lower basal turn and upper basal turn of the temporal bones. This was most likely a histologic artifact, because the electrode arrays lay close to the Rosenthal canal, away from the basilar membrane. One electrode array was observed to be closer to the modiolus than was indicated by image analysis (see Fig. 3 B, solid symbols). Further investigations suggested that the electrode array had been slightly dislodged from the cochlea between the first and second radiograph before embedding. This resulted in the basal section of the array being drawn closer to the modiolus, while the apical portion of the array had not moved. Image analysis of the second radiograph showed the array to lie close to the modiolus (see Fig. 3 B, open symbols), a trajectory consistent with the position of the array seen in the histologic sections.

The mean insertion depth of the PVA-coated precurved electrode array (No. 3) was 393° (n = 2), somewhat greater than the standard array (Table 1). Image analysis indicated that whereas one array lay close to the modiolus for almost its entire length beyond the first 3 mm to 4 mm from the round window (see Figs. 3 C and 4), the apical portion of the second array lay close to the outer wall. Light microscopy of the histologic sections showed that both arrays lay within the scala tympani for their entire length and confirmed the array position indicated by image analysis. No damage to the osseous spiral lamina was apparent, although at particular sites the arrays came into close contact with the modiolus. In some of the sections, the basilar membrane was dislodged, although, judging from the position of the array, this was most likely a processing artifact.

The third perimodiolar design used a Teflon strip con-

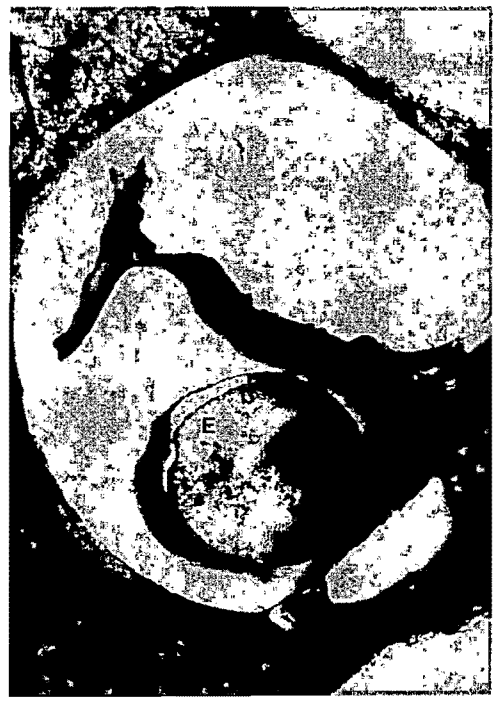

FIG. 4. Photomicrograph of array No. 3, precurved, straightened using polyvinyl alcohol (PVA), in the upper basal turn of the cochlea. The electrode array lies close to the modiolus just touching the modiolar bone underneath the osseous spiral lamina. The Rosenthal canal is visible. This would be an ideal placement for a perimodiolar array. The dislodged spiral ligament (arrow) is considered an artifact (E, electrode array). Bar = 0.5 mm.

nected to the tip of a standard Melbourne/Cochlear electrode array (No. 4; see Fig. 2). The five arrays of the initial design had a mean insertion depth of 374.3°, somewhat more then the standard array (Table 1). Image analysis showed that in the majority of cochleas, the Teflon strip had kinked in the lower basal turn (see Fig. 3 D). Four arrays had a perimodiolar trajectory for most of their length (see Fig. 3 D,E) and light microscopy of the histologic sections showed that all four arrays were inserted into the scala tympani. In three temporal bones, insertion-induced damage to the spiral ligament was observed, induced by the Teflon strip, as well as array-induced fractures to the osseous spiral lamina close to the modiolus. However, the fourth temporal bone showed an ideal insertion without any visible insertion-induced damage or kinking of the Teflon strip (Fig. 5). Image analysis of the fifth array showed only a slight improvement in position compared with the standard array. Light microscopy of the histologic sections revealed that the array had been inserted into the scala vestibuli along the lower basal turn. This was associated with severe damage to both basilar and the Reissner membrane throughout the lower and upper basal turns. In addition, the Teflon strip was kinked in the lower basal turn.

To minimize kinking, the length of the Teflon strip was shortened, and three additional temporal bones were implanted with this modified version of array No. 4. The mean insertion depth of those arrays was 434° (n = 3), deeper than the straight array (see Table 1). The radiographs showed no kinking of the Teflon strip. Image analysis showed the trajectory of two arrays to be close to the modiolus for their entire length (see Fig. 3 F), while the third array was only at particular sites close to the modiolus. Light microscopic evaluation of the histologic sections showed an initial insertion of all arrays into the scala tympani. However, in all three temporal bones, both the Teflon strip and the electrode array appeared to perforate the basilar membrane and project into the scala vestibuli 6 mm from the round window (Fig. 6). This was often accompanied by severe damage to the osseous spiral lamina (Fig. 7). Using a lubricant did not reduce the observed damage.

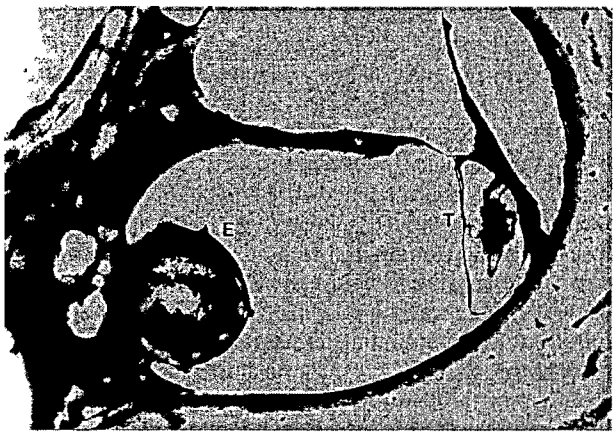

FIG. 5. Photomicrograph of array No. 4 (standard with positioner) in the lower basal turn of the cochlea. The Teflon strip is positioned close to the spiral ligament within the scala tympani without traumatizing the basilar membrane or spiral ligament. The slight dislodgment of the spiral ligament (arrow) is considered an artifact. The array is positioned against the modiolus without damage to the osseous spiral lamina. This shows an ideal position for array No. 4 (E, electrode array; T, Teflon positioner). Bar = 0.5 mm.

FIG. 6. Photomicrograph of a midmodiolar section of a cochlea implanted with array No. 4 (standard with positioner). The Teflon strip in the lower basal turn (right) has deflected the basal membrane upward into scala vestibuli, and the electrode array lies close to the modiolus. In the upper basal turn (left), both the electrode array and the Teflon strip are sited within the scala vestibuli. The electrode array also appears to push into the osseous spiral lamina. (E, electrode array; T, Teflon positioner). Bar = 0.5 mm.

DISCUSSION

In the current study we used an efficient method to verify the position of experimental electrode arrays after their insertion into human temporal bones. This method combines both histologic and radiologic methods as well as image analysis of the radiographs. Information regarding depth of electrode insertion, electrode trajectory, electrode position within the cochlea, and possible insertion trauma was greatly enhanced by use of this method. The results indicate that whereas it seems possible to position multichannel electrode arrays close to the modiolus over all or most of their length using different array designs, the perimodiolar array design investigated in the current study could not be implanted as easily or as atraumatically as the standard Nucleus electrode array.

Although variable, the mean insertion depths of the perimodiolar arrays were generally greater than of the standard Nucleus electrode array. During the insertion, only minimal resistance was met, although surgeons remarked that the ability to feel resistance during the insertion was markedly reduced with those arrays requiring introducers (Nos. 2 and 4). The PVA-coated precurved electrode array (No. 3) and the standard array with Teflon strip (No. 4) had trajectories closest to the modio-

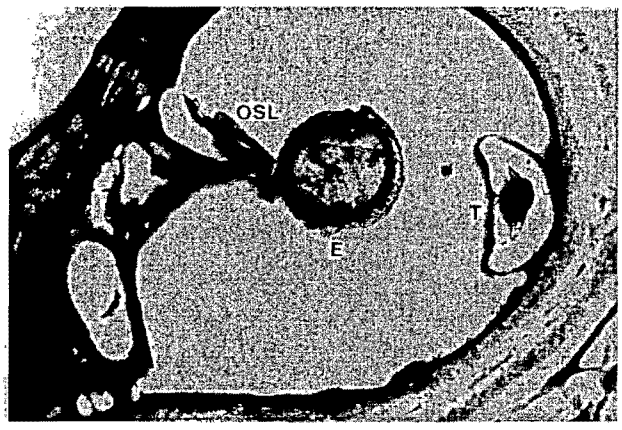

FIG. 7. Photomicrograph of array No. 4 (standard with positioner) in the lower basal turn of the cochlea. The electrode array fractured the osseous spiral lamina (star) on its way from the scala tympani into the scala vestibuli. This type of insertion-induced damage would most likely result in local spiral ganglion loss (E, electrode array; T, Teflon positioner). Bar = 0.5 mm.

lus. However, all electrode designs appeared to have drawbacks, indicating that further investigations using improved array designs are necessary before general clinical use.

Although the trajectory of the precurved electrode with introducer (No. 2) array was closer to the modiolus compared to the standard array, this design did not regain a modiolar-hugging shape after insertion. It also needed a larger cochleostomy for insertion than did the standard array. Although we did not notice any specific damage associated with the larger cochleostomy, it appears preferable from a surgical point of view to have an array that can be implanted through a standard cochleostomy. A small cochleostomy can be sealed more easily to prevent a perilymph leak or labyrinthitis, and the risk of contamination of the cochlea with bone dust or blood during the procedure would also be reduced. The necessity for both a large cochleostomy to insert this array into the cochlea, and the use of an insertion tool to prevent the array from curling on itself within the lower basal turn, makes this design more difficult to implant compared with the standard Nucleus electrode array.

The PVA-coated precurved electrode array showed a trajectory close to the modiolus. While this design appeared promising, PVA is quite brittle if it is dry and could flake off the array during handling before implantation. From a surgical point of view, it would also be paramount that the PVA coat does not dissolve too early on contact with body fluids and keeps the electrode straight for at least several implantation attempts. This is important to keep the electrode from curling on itself before a satisfactory insertion can be achieved.

Usually, PVA has been used as a cytoprotective lubricant for the ocular endothelium in cataract surgery, and findings of biosafety studies have focused on its use in ophthalmology. Both the biocompatibility of PVA and its clinical value have been demonstrated in both long-term in vivo animal studies and in vitro cell culture studies (23,24). However, further studies would have to be conducted to prove the biocompatibility of PVA in the cochlea as well as in soft tissue before clinical use with cochlear implants. These studies are in progress in our laboratory.

During the insertion of the standard array with Teflon strip (No. 4), the surgeon typically noted that the ability to precisely determine the extent of resistance was reduced by the insertion tool. In our opinion, this contributed to the damage that occurred when this electrode design was used. In general, this array showed a trajectory close to, often even hugging, the modiolus. However, considerably more insertion-induced damage was seen in most cochleas implanted with this array than with both other perimodiolar designs and the standard Nucleus electrode array. The most common type of damage was caused by penetration of the Teflon strip and the array into the scala vestibuli (see Fig. 6).

It appeared that the simultaneous insertion of both the electrode array and the Teflon strip into the lower basal turn forced the Teflon positioner initially into a latero-superior position along the outer wall of the cochlea. In the process, the Teflon strip, which was less flexible than the electrode array, often severed the basilar membrane at its junction with the spiral ligament (see Fig. 6). Further insertion pushed both the Teflon strip and the electrode array into the scala vestibuli. The array often fractured the osseous spiral lamina in the process (see Fig. 7). This type of insertion-induced intracochlear damage could result in a significant decrease in the number of remaining spiral ganglion cells in patients, as has been demonstrated previously in animal models (25,26). Although we did not observe this severe damage in every temporal bone implanted by this design, it highlights the potential of mechanically positioned intracochlear arrays to injure intracochlear structures.

The prevention of damage to sensitive cochlear structures during implantation is of utmost importance. This includes the prevention of loss of existing spiral ganglion cells, especially in young children, in whom lifetime use of the device is anticipated. But it also includes the prevention of hair cell damage in patients with residual hearing, which might be used in the future. The ideal perimodiolar device would therefore be atraumatic and easy to implant, and take up a position close to the modiolus with minimal damage to the cochlear structures. Moreover, such an array must also be able to be readily removed without causing damage. While none of the trialed designs in this study featured all those attributes, passively curling designs (Nos. 2 and 3) appear to be less traumatic than the actively curled design (No. 4).

Further improvements in the electrode designs trialed in this study, or designs featuring completely different methods of positioning an electrode array close to the modiolus, are therefore required before clinical trials can proceed. This work is currently being performed in our laboratories.

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