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BANDED INTRACOCHLEAR ELECTRODE ARRAY: EVALUATION OF INSERTION TRAUMA IN HUMAN TEMPORAL BONES

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A banded free-fit scala tympani array was inserted into the basal turn of nine human cochleas to evaluate the trauma produced by the procedure. These nine cochleas, together with five nonimplanted controls, were serially sectioned and examined microscopically for damage to the membranous labyrinth, in particular the spiral ligament, the basilar and Reissner's membranes, the stria vascularis, and the osseous spiral lamina. The severity and location of any trauma along the cochlear spiral were recorded. The results indicate that the insertion of the banded scala tympani array resulted in minimal mechanical damage, occurring primarily to a localized region of the spiral ligament. This would not result in significant neural degeneration, and therefore would not compromise the efficacy of the multichannel cochlear prosthesis.

KEY WORDS — cochlear implant, intracochlear electrode, trauma.

INTRODUCTION

A number of safety issues are associated with artificial electrical stimulation of the auditory nerve. First, insertion trauma should be minimal and not lead to degeneration of the auditory nerve. Second, long-term electrical stimulation must not be harmful to the residual nerve population. Third, the materials used must be biocompatible, and the metal electrode must not be susceptible to significant dissolution as a result of long-term stimulation. Fourth, the device and the implant surgery must be designed to minimize the chances of infection. This paper examines the trauma associated with the insertion of a free-fit scala tympani electrode array in human temporal bones; previous papers from this laboratory have examined the other safety issues outlined.[1-4]

Investigators have used a number of anatomical approaches to electrically stimulate the eighth nerve in order to provide auditory information for the profoundly and totally deaf.[5-10] The most popular approach has been to introduce the electrode array along the scala tympani via the round window; this approach has also been supported by a number of animal studies.[4,11-14] The scala tympani array developed by the University of Melbourne, Department of Otolaryngology, in association with Nucleus Limited (Lane Cove, New South Wales, Australia) consists of 22 platinum band electrodes and a Silastic MDX-4-4210 carrier. The present study evaluates the trauma associated with the insertion of this array. Human cadaver temporal bones were used, and the insertion technique followed the surgical protocol developed by this group.[1]

METHODS AND MATERIALS

Electrode Array. Each electrode array consisted of 22 to 28 platinum bands in a Silastic MDX-4-4210 carrier (Fig 1). The most apical 22 platinum bands each had an 0.025-mm Teflon-insulated platinum iridium (90 10) wire welded to it; the remaining bands were added to improve the mechanical stiffness of the proximal section of the array and were not used as electrodes. Each platinum band was 0.3 mm wide and the interelectrode spacing was 0.45 mm. Two types of array dimensions were used, the stepped array and the tapered array. The stepped array had two step reductions in the diameter over the most apical 10 mm, from 0.6 to 0.5 mm and 0.5 to 0.4 mm. The tapered array had an even reduction in diameter from an 0.6 to 0.4-mm tip, over a 25-mm length. Both arrays were manufactured using injection molding techniques, ensuring a smooth array with no irregularities between the electrode bands and the carrier material.

Preparation of Temporal Bones. Fourteen temporal bones were used in this study, five of which were controls. The temporal bones were obtained at postmortem examination and were from men ranging from 67 to 90 years of age. These temporal bones were not frozen or fixed prior to electrode insertion, which was carried out within 24 hours of death.

Following the resection of the temporal bone, the tympanic membrane was ruptured and the roof of the middle ear opened. The bones were stored in normal saline at 4° C prior to electrode insertion. A brief medical history was obtained, and temporal bones from patients thought to have suffered otosclerosis,

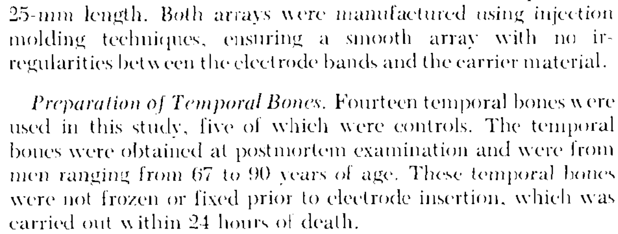

Fig 1. Diagram of tapered multiple-electrode array. (Reprinted with permission of Nucleus Limited.)

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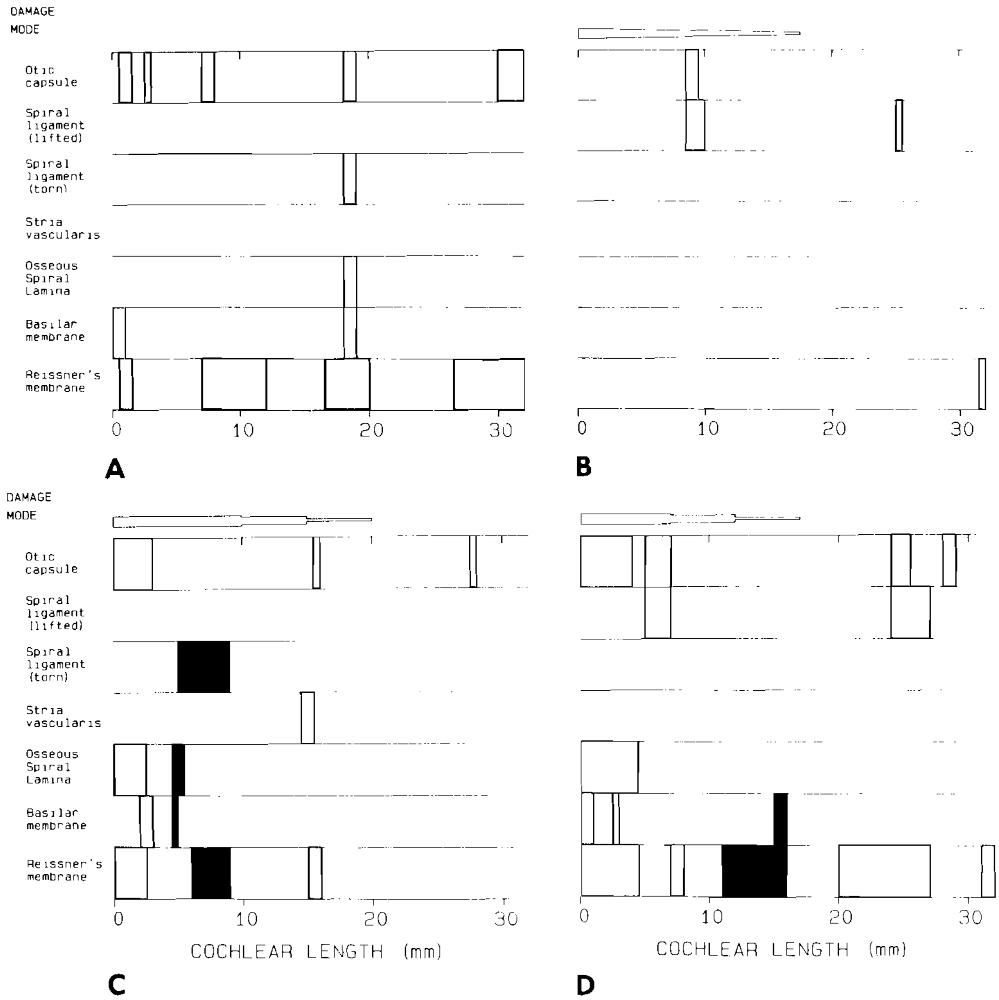

Fig 2. Temporal bone cochleograms. □ — artifact, ■ — electrode insertion trauma. A) Control IS-8. Five small holes drilled into otic capsule resulted in widespread damage to Reissner's membrane and localized damage to basilar membrane and osseous spiral lamina. B) Bone IS-18. Tapered electrode array inserted with ease to 17.5 mm produced negligible damage as result of insertion. C) Bone IS-20. Stepped electrode array was inserted to 10 mm where resistance was felt. Array was withdrawn and reinserted to 17 mm with ease. Microclaw assisted further insertion to 20 mm, and buckling in basal turn prevented further insertion. Insertion trauma included 4-mm tear along spiral ligament, 3-mm tear along Reissner's membrane, and 1-mm fracture of osseous spiral lamina. Associated with this fracture was 0.5-mm tear of basilar membrane. Other damage was due to preparation artifact. D) Bone IS-15. Stepped electrode array was inserted with ease to 17 mm, the point of first resistance. Damage as result of insertion was restricted to 1-mm tear of basilar membrane, 15 mm from round window, and associated 5-mm tear along Reissner's membrane. The perforation in basilar membrane was slightly larger than array tip diameter. Other damage was due to preparation artifact.

obliterative labyrinthitis, and tumors or fractures of the region were not included in the study. The temporal bones were prepared for cochleotomy by a standard mastoidectomy and posterior tympanotomy. The preparation of the round window proceeded under magnification. The bone overhanging the round window was drilled away, and the round window membrane was exposed and incised using a fine hook. Care was taken to avoid damage to the osseous spiral lamina superomedially to the round window. If the exposure of the basal turn was not adequate, the opening was enlarged anteroinferiorly using an 0.6-mm diamond paste drill. A record of the anatomical features of the round window and the basal turn of the scala tympani was made for each cochlea. The electrode array was then gently inserted using a microclaw designed for this procedure.[1] A new array was used for each temporal bone, and it was inserted to 25 mm or to a point where slight resistance was felt. No attempt was made to force the electrode beyond the point of first resistance; however, in a number of cases the array was withdrawn and a second insertion attempted. Following each insertion, the array was gently withdrawn and the insertion distance measured using vernier calipers.

Each temporal bone was then prepared for histological examination; the stapes footplate was removed, the oval window opened, and the superior semicircular canal exposed. The temporal bones were placed in formal saline at 4° C for at least 48 hours, and then rinsed in distilled water. During the fixation schedule, each temporal bone was trimmed and the otic capsule thinned to within 1 mm of the membranous labyrinth using diamond paste drills. Openings were made into the cochlea, and although this led to the production of a histological artifact, it was essential for adequate infiltration of the embedding resin into the cochlea. The cochleas were decalcified in 14% EDTA in neutral buffered formalin and embedded in Spurr's resin. The blocked cochleas were sectioned at a thickness of 3 μm, and sections every 130 μm were collected and stained with hematoxylin and eosin.

Histological Examination. Graphic reconstruction of each cochlea was carried out using a technique described by Schuknecht.[15] This enabled the turns of each section to be located along the length of the cochlea. Damage to the osseous spiral lamina, basilar membrane, spiral ligament, stria vascularis, and Reissner's membrane were recorded. In addition, damage to the

Fig 3. Cochlear photomicrographs. A) Bone IS-18 (original x23). Tapered electrode array was inserted 17.5 mm without damage to membranous labyrinth. Bone dust (d) in middle and apical turns is preparation artifact. B) Bone IS-21, basal turn, approximately 10 mm from round window, showing tear in spiral ligament of scala tympani (arrow) (original x58).

otic capsule during histological preparation and the resultant trauma to the membranous labyrinth were also noted. Cochleograms showing the trauma of different cochlear structures plotted along the length of the cochlea were constructed for implanted and control cochleas.

RESULTS

The electrode insertion distance for the nine cochleas varied from 15.5 to 27 mm with a mean insertion distance of 18.6 mm (SD = 3.5 mm).

Examination of the five control cochleas revealed that drilling the otic capsule during the histological preparation was generally associated with damage to a number of structures within the scalae. Figure 2A is an illustrative cochleogram showing the artifact produced as a result of drilling trauma. Lifting of the spiral ligament from the otic capsule adjacent to the site of drilling occurred in four bones and a tear of the spiral ligament was present in one bone. Tears along Reissner's membrane were frequently associated with this damage, and were up to 5 mm long. Occasionally, tears were observed in Reissner's membrane in regions remote from the site of drilling. Other cochlear structures damaged included the osseous spiral lamina and the basilar membrane. Both forms of damage were localized to the area of drilling, and were generally associated with severe damage to the otic capsule; they were observed in all five control temporal bones.

Trauma resulting from the insertion of an electrode array was examined in nine temporal bones. In three bones there was no evidence of any trauma to the cochlear structures that could be attributed to the electrode insertion (Figs 2B and 3A). The most common injury was a tear in the spiral ligament which typically occurred 7 to 11 mm from the round window in five of the nine cochleas (Fig 2C). A photomicrograph of one of these tears is shown in Fig 3B. Three of these cochleas (IS-12, 20, and 21) had an associated tear in Reissner's membrane (Fig 2C). In one of the nine cochleas (IS-15), it appeared that the tip of the electrode array penetrated the basilar and Reissner's membranes, coming to rest in the scala vestibuli (Fig 2D). The surgeon reported that the electrode array was inserted to a point where resistance was felt. Although the basilar membrane was torn, damage did not extend to the osseous spiral lamina. This was the only cochlea where the electrode array had deviated from the scala tympani and had penetrated the basilar membrane. In another cochlea (IS-21) there were two breaks in the basilar membrane totalling 3 mm in length, and these were associated with tears along the spiral ligament. Damage to the osseous spiral lamina as a result of electrode insertion was observed in one cochlea (IS-20), resulting in a 1-mm fracture approximately 5 mm from the round window, and was associated with a tear of the basilar membrane (Fig 2C). This damage resulted from the array buckling in the basal turn.

Examination of the type and frequency of electrode insertion-induced trauma revealed no significant difference between the stepped and tapered electrode arrays.

DISCUSSION

The present study indicates that the insertion of the banded scala tympani array into the human cochlea results in minimal mechanical trauma to the membranous labyrinth. Damage to the osseous spiral lamina and basilar membrane — damage which would result in neural degeneration — was observed in three of the nine implanted cochleas, and was restricted to a few small locations along the cochlea. It was primarily due to attempts to force the electrode in farther after significant resistance had been felt, and could have been avoided by care in this respect.

The most common mode of cochlear trauma present was a tear along the spiral ligament in the scala tympani, typically between 7 and 11 mm from the round window. This is the region where the array would first come against the outer bony wall, following insertion through the round window. It is significant that the surgeons reported some difficulty introducing the arrays past the 10-mm region in four of the five cochleas with these tears (IS-12, 13, 17, and 20). The histopathological consequences of this mode of trauma have not been thoroughly investigated. Johnsson et al[16] reported that the site of maximum spiral ligament damage in a patient who had received bilateral cochlear implants resulted in a very small fibrotic reaction. It is also possible that osteogenesis would be associated with the fibrosis, as new bone growth following damage to the endosteum has been reported in animal studies.[17] However, tears in the spiral ligament without damage to the basilar membrane or osseous spiral lamina should not result in neural degeneration.

In contrast, local neural degeneration would have been expected following tears in the basilar membrane (IS-15 and 21), and the fracture of the osseous spiral lamina (IS-20). Both modes of trauma have been extensively investigated in animal studies, and the results have consistently demonstrated that such trauma will result in severe neural degeneration localized to the site of injury.[4,11-14] All investigators report subsequent new bone growth in the region associated with a fracture of the osseous spiral lamina; however, there is conflicting data available concerning the repair of the basilar membrane. Simmons[11] reported a periendolymphatic fistula after 9 months following trauma to the basilar membrane in a cat cochlea; however, Johnsson et al[16] reported considerable repair of both ruptured basilar and Reissner's membranes in both cochleas of a bilaterally implanted patient. The ability of a fistula to repair may restrict the area of neural degeneration.

In three cochleas (IS-12, 20, and 21), tears along the spiral ligament in the scala tympani were associated with tears of Reissner's membrane. There is limited and conflicting animal data available from which to draw the probable histopathological consequences of this trauma. In a study using guinea pigs, where damage was restricted to a perforation in Reissner's membrane, the membrane healed within 2 weeks and resulted in localized outer hair cell and occasional inner hair cell loss.[18] On the other hand, in a study where electrode arrays were fed along the scala vestibuli following an apical exposure in cat cochleas, perforation of Reissner's membrane resulted in an 80% to 90% loss of spiral ganglion cells in an area localized to the site of trauma.[12] Significantly, in this study the perforation of Reissner's membrane resulted in a permanent periendolymphatic fistula. Thus it is possible that the degree of local neural degeneration associated with trauma to Reissner's membrane depends on the ability of the membrane to heal, and is less likely if the electrode penetrates the membrane.

In the present study, the trauma associated with the insertion of the banded scala tympani array indicates that the array follows the outer bony wall of the scala tympani as it passes around the cochlea. Micrographs showing the location of other free-fit arrays within the scala tympani also support this observation.[14,16] This finding indicates that the passage of the free-fit array is well away from the osseous spiral lamina, therefore reducing the chance of trauma to this structure. However, the array appears to pass close to the basilar membrane, thus making this membrane susceptible to tearing if the array deviates from its course along the scala tympani. In the single case where the basilar membrane was perforated by the array, the osseous spiral lamina was not damaged.

We attempted to maintain the mechanical properties of the cochlear membranes so that they would approximate the condition of the cochlea at surgery. It was felt that freezing or fixing the temporal bones prior to insertion could result in significant changes in the mechanical properties of the membranous labyrinth.[19] In addition, the effect of postmortem autolysis was kept to a minimun by ensuring that the temporal bones were stored in cold normal saline, and by inserting the electrode arrays within 24 hours of death. There are a number of limitations of this study that should be noted. First, all the temporal bones were obtained from men, and thus are not representative of the size variations among the normal population. Second, the age of patients from which temporal bones were obtained may also effect the results, as there is evidence that the spiral ligament and basilar membrane change their structural characteristics in old age.[19,20]

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