EVALUATION OF A SEALING DEVICE FOR THE INTRACOCHLEAR ELECTRODE ENTRY POINT

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Experimental evidence in animals indicates that middle ear infection in the presence of an intracochlear electrode may result in widespread cochlear damage due to the passage of organisms or products of inflammation through the electrode entry point.

In this paper, results are presented of a study undertaken to test the efficacy of a titanium electrode entry point seal designed by the principal author, to protect the implanted cochlea from the pathological effects of experimentally induced pneumococcal otitis media in five cats. Intracochlear electrodes were inserted into both cochleas of each cat, one side sealed with the device and the other side left unsealed, as is current operative practice in human cochlear implantation, as a control.

After a minimum of twelve post-operative weeks, pneumococcal otitis media was successfully inoculated in all but one (control) middle ear, which was not inoculated due to accidental removal of the electrode.

One week after inoculation the animals were sacrificed and cochleas removed for histological examination.

Results of histological examination of the cochleas are presented together with bacteriological data. The results of microscopic examination of the bond interface between otic capsule bone and the titanium seal are presented.

Intracochlear implantation of the stimulating electrode via the round window membrane, or other fenestration, breaks down the physiological seal between the inner ear and the middle ear. It is vital that the new seal formed at, or after, the insertion of a cochlear implant electrode be effective in preventing infection entering the cochlea from the middle ear, as it has been shown that infection following an intracochlear implantation can lead to widespread damage of the organ of Corti (Schuknecht 1974) and degeneration of the auditory nerve fibres and spiral ganglion cells (Clark 1977, Schuknecht 1974). Infection following the insertion of an electrode can also result in the scala tympani of the basal turn being filled with fibrous tissue and new bone formation arising from the endosteal lining (Clark 1977, Shepherd et al. 1983). As children have a high incidence of otitis media, this is especially relevant in pediatric cochlear implantation.

In current practice, the electrode at the entry point is either held in place with a fascial or muscle plug, or left as is. It is felt that the tissue plug provides early support for the electrode and that fibrous tissue growing in the vicinity of the plug provides a more permanent seal.

Studies by Franz, Clark and Bloom (1984 and 1987) have demonstrated in cats that both the non-implanted round window membrane and the implanted electrode round window entry point are effective in preventing Group A streptococci from induced otitis media from entering the cochlea. This study however, using horseradish peroxidase as a tracer, demonstrated that a gap existed between the implanted electrode and the membranous seal. Furthermore, in a study by Berkowitz et al (1987) induced pneumococcal otitis media caused enhanced pathological changes in the implanted cochlea when compared with the non-implanted cochlea. This study suggested that young children, given their susceptibility to otitis media, could be considered as unfavourable candidates for cochlear implantation because they would be at risk of developing recurrent pneumococcal otitis media and thereby sustain significant nerve fibre loss if they were fitted with an intracochlear electrode, and that ongoing loss of neural elements would ultimately lead to a poor result from cochlear implantation.

In 1989, a research project was undertaken to design an entry point seal for the intracochlear electrode. A number of factors were considered during the design of the device used in this study.

Any device which is expected to form a seal at the electrode entry point must be capable of forming an effective seal at each of a number of junctions or interfaces. The minimum number of interfaces possible is two, these being the electrode-sealing device interface and the sealing device-body interface.

Failure of the seal at either interface could result in transgression of organisms or products of inflammation into the cochlea hence, in order to assess the efficacy of the seal at one interface, it was necessary to exclude the other interface from the study. This study was primarily...
concerned with whether a seal could be achieved at the sealing device-body interface, so the electrode-sealing device interface was sealed with Silastic A medical adhesive, minimizing the possibility of organisms gaining access to the cochlea via this route.

Theoretically, the sealing device-body interface could consist of an interface between the sealing device and soft tissues such as middle ear mucous membrane, periosteum, cochlear endosteum or round window membrane. Although sealing with one or more of these tissues may be important for prevention of spread of infection, a direct or indirect union with bone at or near the round window, with its inherent strength, is likely to be necessary in order for other, more fragile, tissues to effect a seal, hence it is the ability of the sealing device to form a union with bone which has been considered to be of the most significance in the design of the device evaluated in this paper.

For many years researchers, primarily in the dental and orthopaedic specialities, have examined methods of attaching metal, particularly dental and joint prostheses, directly to bone without the use of polymer cements. A large number of pure metals and alloys have been tried, each with little success. At best the implanted metals were inert with no apparent bony reaction and quickly worked loose when stress was applied. At worst, the metals excited a florid inflammatory foreign body reaction resulting in rejection of the implant.

In the early 1950's, Branemark and others at the Laboratory of Vital Microscopy at the University of Lund, Sweden, were involved in the study of dynamic bone microscopy by the use of an implantable optical device enclosed in a titanium framework. This enabled the study of the micro-circulation in living organisms through specially modified microscopes.

It was noted during these experiments that it was impossible to remove the titanium implants from the bone into which they had been implanted. Analysis of the bone-titanium interface demonstrated that the bone regenerated in the vicinity of the metal, with osteocytes producing cellular processes which adhered to the surface titanium oxide layer. This bonding of bone to an implant was termed osseointegration (Branemark 1983).

The ability of titanium to bond to bone directly has been demonstrated to depend on several factors (Branemark 1983) -

1. Osseointegration is most apparent when the titanium is unalloyed. Branemark recommends the use of 'commercially pure' titanium to 99.75%.

2. The bone to be implanted must be treated delicately to avoid death of osteocytes. Eriksson and Albrektsson (1983) demonstrated that heating bone above 47 degrees C, as could occur with a dental burr or diamond paste drill, resulted in observable vascular damage, cellular changes and bone resorption in rabbits. As demonstrated in experimental studies of healing osteotomies in the rabbit tibia, the more severe the surgical trauma, the more incomplete is the bone healing which ensues. As osseointegration cannot occur without bone healing, it is clear that heat induced surgical trauma will impair osseointegration.

3. The cavity within the bone into which the implant is to be placed should closely match the size and shape of the implant, with as much surgical debris and blood removed from the interface as possible.

4. The implant must be immobilized during the period of bone healing. Relative movement between the implant and bone, such as produced by premature stressing of the implant, will prevent osseointegration.

Considerable success has been achieved in the use of titanium implants into bone in the following clinical situations —

1. As mucous membrane penetrating supports for dental prostheses (Bergman 1983).

2. In facio-maxillary reconstruction of bony defects (Connor et al 1985).

3. As skin penetrating abutments for synthetic eye, ear and nose prostheses (Parel et al 1986).

4. As skin penetrating coupling for bone-anchored hearing aids.

Where osseointegration has not occurred, a fibrous union has often been observed. In situations where the implant must withstand high stresses this is to be avoided. However, where the primary role of the implant is to seal an interface, the presence of a fibrous tissue union may still be satisfactory as long as sealing is obtained.

Currently there are two surgical approaches used for intracochlear electrode insertion. Firstly the electrode can be inserted through the round window, or alternatively a separate fenestration can be made through bone near the round window, entering the scala tympani some distance from the round window, along the straight portion of the basal turn.

Two factors make the round window, and its bony margins, a less attractive site for sealing, and therefore implantation, of the intracochlear electrode:

1. The variable anatomy of the round window orifice from patient to patient dictates that any device which is expected to form a seal with bone within this orifice must be capable of adaption to its variations or, alternatively, the surgical procedure must include modification of the orifice to suit the sealing device.

2. The plane of the orifice lies at a considerable angle to the axis of the straight portion of the basal turn of the scala tympani. This means that the sealing device must contact an oblique rim of bone in addition to providing a channel in the axis of the straight part of the basal turn through which the electrode can pass. Combined with the fact that the round window is in fact oval, rather than round, any seal designed to fit this position would be both expensive to produce and potentially unstable without some form of fixation at another site.

The alternative to using the round window orifice is to make a separate fenestration as described above. This approach appears to have two advantages:

1. It is possible to make fenestrations which do not vary significantly from patient to patient. If the fenestration itself forms the interface with the seal, the creation of a standard fenestration would then only require the manufacture of a standard seal.

2. The axis of the fenestration would closely match that
of the axis of view from a posterior tympanotomy and that of the straight portion of the basal turn of the cochlea. This means that all parts of the sealing device would have the same axis, facilitating both economical manufacture and insertion of the device.

This paper describes a pilot study undertaken to evaluate the efficacy of the seal obtained between the otic capsule bone near the round window and a conical titanium sealing device, fixed to a dummy intracochlear electrode, in preventing the pathological effects of induced pneumococcal otitis in one cochlea in each of five cats, compared with the opposite site where an identical procedure was performed but no sealing device used.

**Materials and Methods**

Five live cats were used in the study. All were examined otologically and audiometrically screened using ABR techniques pre-operatively to minimize the chance of including cats with pre-existing ear pathology.

**Implantation**

The sealing device specified in Figure 1 was made of commercially pure titanium. A dummy intracochlear electrode was passed 6 mm through the sealing device (Figure 2) and fixed, within it, with medical grade Silastic Type A to eliminate the electrode-sealing device interface as a possible route for entry of the inoculated organisms into the cochlea. Under sterile conditions and inhalation general anaesthetic, an operative approach was made to the middle ear by exposing the bulla, which is an eggshell-like capsule of bone which corresponds to the mastoid bone of the human ear. The bone of the bulla was drilled with a rotary burr and the mucosa exposed. The mucosa was divided and the air space entered and inspected for evidence of infection. None was found.

A fenestration was made into the scala tympani through the otic capsule immediately postero-inferior to the round window with a 0.6 mm diameter diamond paste burr (Figures 3 and 4). This fenestration was then enlarged with a steel reamer with a 3.5 degree taper matching the taper
of the titanium sealing device (Figure 5). The burr and reamer were rotated at the slowest speed available and constantly cooled with sterile saline to minimize the possibility of thermally induced bone injury. A bridge of bone approximately 1mm wide was retained between the fenestration and the round window.

The dummy electrode, with the sealing device attached, was then passed into the scala tympani until the ridges on the tapered surface of the sealing device abutted the inner surface of the conical fenestration (Figure 6). Slight pressure was then applied to wedge the sealing device into the fenestration.

The proximal end of the dummy electrode was then fixed to the lateral bony wall of the bulla with braided platinum wire. The wound was closed with 3.0 Dexon sutures.

On the opposite side, an identical procedure was performed except that the fenestration was not enlarged with the conical reamer, and the dummy electrode was inserted with no sealing device (Figure 7).

Post operatively 100 mg of cloxacillin and 100 mg of ampicillin were administered intramuscularly and subcutaneously. Cutaneous sutures were removed on the seventh post-operative day.

Inoculation

After the twelfth post-operative week, allowing adequate time for tissue growth, each of the ears under study was reopened via a posterior bulla approach which avoided manipulation near the electrode. All but one of the bullae were loosely packed with Gelfoam which had previously been saturated with a broth containing between 2.0 to 2.2X10^8 pneumococci per ml (Table 1). The remaining (unsealed) middle ear (660L) was not inoculated because accidental avulsion of the electrode from the scala tympani occurred during the operative exposure. This ear was excluded from the study.

Sacrifice and Specimen Preparation

Seven days after inoculation, a lethal dose of thiopentone was administered intramuscularly. After the onset of anaesthesia but prior to cardioplegia, an intra-arterial
Table 1: Results of middle ear inoculation of pneumococci on sealed and unsealed implanted cochleas.

<table>
<thead>
<tr>
<th>Cat #</th>
<th>Side</th>
<th>Sealed?</th>
<th>Inoculum Dose</th>
<th>Inoculum Concentration</th>
<th>Culture at Sacrifice</th>
<th>Cochlear Inflamed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>599</td>
<td>Right</td>
<td>Yes</td>
<td>0.5 ml</td>
<td>2.0 x 10⁸ org/ml</td>
<td>+ve</td>
<td>minimal chronic</td>
</tr>
<tr>
<td>599</td>
<td>Left</td>
<td>No</td>
<td>0.5 ml</td>
<td>2.0 x 10⁸ org/ml</td>
<td>+ve</td>
<td>minimal chronic</td>
</tr>
<tr>
<td>600</td>
<td>Right</td>
<td>Yes</td>
<td>0.3 ml</td>
<td>2.0 x 10⁸ org/ml</td>
<td>+ve</td>
<td>no</td>
</tr>
<tr>
<td>600</td>
<td>Left</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>601</td>
<td>Right</td>
<td>Yes</td>
<td>0.8 ml</td>
<td>2.2 x 10⁸ org/ml</td>
<td>+ve</td>
<td>no</td>
</tr>
<tr>
<td>601</td>
<td>Left</td>
<td>No</td>
<td>0.6 ml</td>
<td>2.2 x 10⁸ org/ml</td>
<td>+ve</td>
<td>no</td>
</tr>
<tr>
<td>598</td>
<td>Right</td>
<td>Yes</td>
<td>0.5 ml</td>
<td>2.0 x 10⁸ org/ml</td>
<td>+ve</td>
<td>no</td>
</tr>
<tr>
<td>598</td>
<td>Left</td>
<td>No</td>
<td>0.5 ml</td>
<td>2.0 x 10⁸ org/ml</td>
<td>+ve</td>
<td>no</td>
</tr>
<tr>
<td>568</td>
<td>Right</td>
<td>Yes</td>
<td>0.3 ml</td>
<td>2.0 x 10⁸ org/ml</td>
<td>+ve</td>
<td>minimal chronic</td>
</tr>
<tr>
<td>568</td>
<td>Left</td>
<td>No</td>
<td>0.2 ml</td>
<td>2.0 x 10⁸ org/ml</td>
<td>+ve</td>
<td>minimal chronic</td>
</tr>
</tbody>
</table>

* Not inoculated due to electrode removal - cochlea excluded from study.

Perfusion of glutaraldehyde was commenced. After death the temporal bones of each cat were removed. A bacterial swab was taken from each middle ear to assess the presence of pneumococcal otitis media. A macroscopic assessment of tissue growth around the device was made (Figure 8). The cochleas were dissected from the temporal bones and the electrode and sealing device were removed. One sealing device was removed from its cochlea together with a cuff of otic capsule bone with a mini hole saw (Figures 9 and 10) for assessment of the bone-titanium interface. All cochleas were immersed in EDTA until radiographs indicated complete decalcification. They were then embedded in Spurr's resin, sectioned, stained with haematoxylin and eosin, and examined histologically.

The cuff of otic capsule bone removed with the sealing device was split and removed from the titanium. One section of the cuff was decalcified, embedded, sectioned and stained as described above. The remaining section was submitted for scanning electron microscopic examination (Figure 12 and 13).
The titanium sealing device, after removal of the cuff of otic capsule bone, was found to have some residual tissue present between the ridges forming its outer conical surface (Figure 11). Some of this tissue was removed and submitted for routine histological examination. The sealing device and residual adherent tissue was then examined by scanning electron microscopy (Figures 14 and 15).

Results

There was no morbidity among the cats included in the study prior to inoculation and no mortality prior to sacrifice. Pneumococci were isolated from all inoculated middle ears at sacrifice (Table 1). No gaps between otic capsule bone and the implanted titanium sealing devices were noted on macroscopic examination.

No acute inflammation was noted in any of the sealed cochleas. A tissue capsule was seen around the electrode in two of the five sealed cochleas (600R and 568R) (Figure 16). This was associated with mild chronic inflammation indicated by the presence of a small number of mononuclear leukocytes (Figure 17). Minimal chronic inflammation was also seen within the scala tympani in one other of the five sealed cochleas (599R) (Table 1).

Degeneration of the organ of Corti with loss of hair cells occurred in one of the five sealed cochleas (601R). This was limited to the basal turn. Spiral ganglion cell survival was greater than 90% in four of the five sealed cochleas. The remaining cochlea (599R) was noted to have lost approximately 60% of the ganglion cell population. This was limited to the lower basal turn.

One unsealed cochlea (600L) was removed from the study due to accidental removal of the electrode as noted above.
FIG. 15. Details of strip of tissue seen in Figure 14. Longitudinal fibres consistent with collagen are shown. Separation between tissue and titanium is a preparation artifact.

FIG. 16. Sealed cochlea 600R (X48) showing electrode track within scala tympani and minimal ganglion cell loss restricted to basal turn.

FIG. 17. Detail of margin of electrode track seen in Figure 16 (X200) showing mild mononuclear leukocyte infiltrate.

Gross chronic inflammation associated with new bone formation, with complete loss of all normal tissues, including organ of Corti, ganglion cells, membranous labyrinth, osseous spiral lamina, modiolus and distal cochlear nerve, was noted in one of the four remaining unsealed cochleas (598L) (Figure 18). There was also a marked acute inflammatory reaction around the electrode track in this cochlea indicated by the large number of polymorphonuclear leukocytes (Figure 19).

No acute inflammation was seen in any of the remaining three unsealed cochleas. Minimal chronic inflammation was noted in two of these cochleas (599L and 568L) (Table 1). A tissue capsule had formed around the electrode in one of the remaining three unsealed cochleas (568L).

Degeneration of the organ of Corti occurred in one of the remaining three cochleas (599L). Spiral ganglion cell survival was greater than 90% in two of the three remaining unsealed cochleas. However the lower basal turn of one cochlea (599L) was noted to have lost approximately 95% of its ganglion cell population. The rest of the cochlea was normal. There was no significant new bone formation seen within the remaining three unsealed cochleas.

Light and scanning electron microscopy of the cuff of bone removed from the titanium sealing device (Figures 12, 13 and 20) and of the strips of tissue removed from between the ridges of the device (Figures 14, 15 and 21) demonstrated that new bone growth had occurred in the vicinity of the device, but that the tissue abutting the titanium consisted of fibrous tissue. There was no evidence of new bone directly bonding to the titanium.
It is interesting to observe that the bulk of fibrous tissue generated was present between the ridges of the device. In these regions there is no contact with bone at implantation. As apposition between titanium and bone at implantation has been shown to be one of the major factors influencing osseointegration, as noted earlier, it is interesting to contemplate whether designing the seal with a smooth outer surface, instead of ridges, would have encouraged osseointegration.

It is clear that a catastrophic event occurred in the unsealed cochlea 598L. However dating this event is more difficult. Pathological opinion suggests that the inflammation was initiated at least a month prior to sacrifice, indicated by the large number of chronic inflammatory cells, organizing fibrous tissue, blood vessel and new bone formation. This dates the event at least three weeks prior to the inoculation of pneumococci, but it may have occurred much earlier.

Although none of the cats demonstrated signs of middle or inner ear infection or wound infection immediately postoperatively, this cannot be excluded in cochlea 598L. At this early stage, prior to any healing, it is likely that any cochlea, whether implanted with a sealing device or without, would have suffered a similar inflammatory response as the tissues would not have had time to form a seal with either the device or the bare electrode. If the inflammatory event occurred at this early stage, it is merely chance that the event affected an unsealed side and therefore cannot be taken as evidence supporting the efficacy of the sealing device.

A possible means of determining whether cochlear pathology exists immediately prior to inoculation in a future study would be to rescreen the cats with ABR audiometry, and to perform a white cell count and erythrocyte sedimentation rate in addition to the routine otoscopy already performed.

There was a slightly higher incidence of degeneration of the organ of Corti and spiral ganglion cells in the unsealed cochleas. Although these changes can be related to infection, they may also be due to an event such as insertion trauma and should not be considered as definite evidence of infection (Shepherd et al 1985). There are difficulties in simulating childhood otitis media in cats, for several reasons:

1. Cats have excellent Eustachian tube function and unless a foreign body, such as Gelfoam, is introduced into the middle ear as well, merely introducing an inoculum is unlikely to induce significant otitis media.

2. It is difficult to simulate the increase in middle ear pressure which can occur in children with middle ear infection. The well established surgical approach we used to inoculate organisms into the middle ear was via the posterior bulla. This creates a fenestration communicating the middle ear with the soft tissues of the neck and skull base. Any increase in pressure in the middle ear due to infection could be relieved either through this fenestration or via the Eustachian tube.

A study by Leake, Hradek and Rebscher et al (1988) indicated that the ability of a sealing device to resist this increase in pressure may be critical to the success of the seal. In an in vitro study, an “O” ring seal was demonstrated to successfully resist the transgression of organisms from an inoculated culture medium to a sterile

Discussion and Conclusions

The aim of this study has been to assess whether a titanium sealing device could prove effective in resisting the pathological effects of otitis media on the implanted cochlea. In a study involving only ten cochleas it is unlikely that results of statistical significance can be obtained, hence this study must be seen, as originally intended, as a pilot study to assist in the planning of a more comprehensive analysis in the future.

It is encouraging that no acute inflammation developed in any of the sealed cochleas. The titanium was well tolerated by the tissues with no overt rejection of the device, and no inflammatory reaction seen on microscopy. Osseointegration was not demonstrated in the interface subjected to microscopy, nevertheless, belying its reputation as a virtually inactive tissue, the bone of the otic capsule demonstrated an ability to develop new bone in the vicinity of the implant.

As noted above, in a low-stressed implant the fibrous tissue layer observed at the interface may be all that is necessary to effect a seal. The evidence provided by this study indicates that the sealing device is capable of resisting transgression of organisms or products of inflammation from the middle ear.
medium but only when no pressure gradient existed across the seal. Prior to venting the bottle containing the inoculum, the pressure created within the growing culture caused the seal to fail. Although technically more difficult, introducing the inoculum via the Eustachian tube may resolve this problem. Using a blunt metal cannula sheathed with thin plastic except at the tip and the hub, the inoculum, together with fragmented Gelfoam, could be injected until fluid is seen behind the intact tympanic membrane. The active electrode of a unipolar diathermy machine could then be applied to the hub of the cannula, causing thermal injury to the lumen of the Eustachian tube at the cannula tip. Constriction caused by oedema may then closely simulate Eustachian tube dysfunction found in children with otitis media, allowing similar middle ear pressures to develop.

References


Although it cannot be doubted that the loss or a great disturbance of hearing on one side causes a decrease in the power of hearing, the same importance cannot be ascribed to such a loss as to the loss of the power of vision in one eye. The legislator clearly thought of the sense as a whole, and in the new (Austrian) draft, as well as in the German Penal Code, hearing in general is only spoken of, but no difference is made between the hearing in one or both ears, as was done regarding the power of vision. We must also bear in mind that it is only a considerable disturbance of hearing, which may be set down as a defect of the hearing in the sense of the law, and that it is advisable, just as in the case of weakness of vision, that we should confine ourselves in doubtful cases only to the explanation of the nature and of the degree of the functional disturbance, and leave it to the judge and to the jury to say whether after such an explanation they will recognize the case as coming under clause a of paragraph 156 or not.

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