Operative Techniques in Otolaryngology (2005) 16, 93-100

ELSEVIER

Operative Techniques in

Otolaryngology

Method for hearing preservation in cochlear implant surgery

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KEYWORDS
Cochlear implantation;
Hearing preservation;
Electroacoustic stimulation;
Cochleostomy;
Electrode trauma;
Bimodal stimulation

Individuals with useful hearing in the lower frequencies (less than 1000 cycles per second) but with severe to profound losses in the higher frequencies often have poor speed discrimination scores, especially in noise. Conventional hearing aids only provide marginal increases in word discrimination for this class of individuals. Consequently, interest has developed in electrically stimulating those regions of the cochlear (apical) that subserve higher frequencies while permitting the individual to continue to hear (with or without a hearing aid) lower frequency sound acoustically. To successfully implement such a strategy, residual hearing must be maintained for lower frequency sounds. Technical alterations in the operative technique of cochlear implantation designed to preserve hearing include: (1) avoidance of acoustic trauma using low speed drills; (2) careful placement of the cochleostomy anterior and inferior to the round window membrane to avoid damage to the basilar membrane and ossea spiral lamina; (3) the use of steroids to protect against injury to the organ of Corti at the cellular level; (4) the use of shorter, thinner, atraumatic electrodes; and (5) a small cochleostomy to prevent buckling of the electrode and escape of perilymph.

The extent to which inserting an electrode into the cochlea produces endocochlear damage and injury to neural structures has been a topic of interest since the inception of cochlear implant technology. Interest in cochlear implant array insertional trauma has recently increased because cochlear implant surgeons now wish to preserve residual hearing. Until recently, complete loss of residual hearing was the expected outcome of cochlear implantation. However, recent efforts at hearing conservation have shown that residual hearing can be preserved in the majority of cases if the operating surgeon pays very close attention to minimizing surgical trauma while inserting the electrode array. However, even when great care is taken, residual hearing is completely lost in at least 10% to 20% of recipients.[1] The precise cause of hearing loss in this group of cochlear implant recipients remains obscure. We believe that a careful assessment of the details of electrode insertional trauma will help eliminate or ameliorate hearing loss in cochlear implant recipients. Questions about the extent to which mechanical insertion of a cochlear implant electrode array damages anatomic structures within the cochlea is a separate question from whether or not chronic electrical stimulation results in injury to residual neural elements. The latter question will not be addressed in this article but has been extensively investigated by other researchers who have concluded that chronic electrical stimulation sustains, rather than injures, spiral ganglion cells.[2]

A number of approaches have been used to determine the extent to which and the mechanism by which mechanical introduction of an electrode array damages endocochlear elements. Traditional methods that have been used to evaluate insertional trauma have included[3-10]:

1. Electrophysiologic assessment of animals into which electrode arrays have been inserted in vivo.
2. Postmortem histopathologic evaluation of animals, principally rodents and cats, into which cochlear implant electrode arrays have been inserted. Animal studies provide useful information but do not allow for control of

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doi:10.1016/j.otot.2005.03.003

individual variability, cause of deafness. or surgical technique.
3. Postmortem evaluation of human temporal bones taken from cochlear implant recipients. Such evaluations are especially useful for determining long-term changes associated with cochlear implantation, especially the assessment of endocochlear new bone formation and fibrosis.
4. Cochlear implant electrode array insertion into cadaveric temporal bones from individuals who have never been implanted. Such temporal bones can be either fresh or formalin fixed. Human cadaveric temporal bones can be used in a variety of different ways. Electrodes can be inserted during fluoroscopy, and the passage of the electrode into the bony structures in the cochlea can be visualized. However, fluoroscopic evaluation does not allow good visualization of soft tissues and does not permit assessment of subtle soft tissue trauma. Electrodes can first be inserted into human temporal bones, fresh or fixed, and then submitted for histopathologic evaluation. Histopathologic evaluation of temporal bones into which cochlear implant electrode arrays have been inserted require special techniques because sectioning of the relatively hard electrode array cannot be performed after simple decalcification. Freezing techniques produce artifacts, and fixation using plastic produces significant swelling artifact.

Opening the cochlea and inserting a cochlear implant electrode array can produce trauma from a variety of mechanisms: (1) opening the cochleostomy, (2) damage can occur as a result of passing the electrode into scala tympani, (3) insertional trauma can lead to subsequent new bone formation and fibrosis within scala tympani, and (4) opening the cochlea is a portal of entry for infection and the development of infectious labyrinthitis.

To avoid injury, a promontory cochleostomy must be placed inferior to spiral ligament, the basilar membrane, and osseous spiral lamina. Scala tympani dips inferiorly and anteriorly as it passes forward from the round window membrane. Because the round window membrane itself cannot generally be visualized when performing a classic cochleostomy, the point on the promontory where drilling can be performed without risking damage to the basilar membrane osseous spiral lamina is unclear. The frequency with which injury to the basilar membrane and ossea spiral lamina occurs has not been reported, but careful study of the relevant anatomy suggests that such injuries may be relatively common. Animal data suggest that localized injuries to the basilar membrane or osseous spiral lamina in and of themselves probably do not result in total hearing loss.[6] However, the effect of penetration into scala vestibule with the attendant introduction of perilymph into scala media is likely to result in significant and widespread injury to the organ of Corti because perilymph is toxic to hair cells.

Passing the electrode array through the cochleostomy can also produce injury by a variety of mechanisms:

1. Endosteal injury. Trauma to the endosteum will increase postoperative fibrosis and osteoneogenesis. At UT Southwestern, we have not been able to show significant endosteal injury in temporal bones, either fixed or fresh, as a result of electrode array insertion. The lateral wall of scala tympani is laced with venules. Injury to these venules with subsequent bleeding has been hypothesized, but damage to venules in the lateral wall has not been verified in our laboratory. However, one must hasten to emphasize that these are postmortem specimens and post-insertional bleeding may be undetectable.
2. The electrode array can become kinked within the temporal bone. We have not seen folding over of the tip with doubling back of the electrode array onto itself in our investigations, but other investigators have. Such kinking occurs when the tip of the electrode array impacts the modiolus, fixing it. Continued insertion then causes the portions of the electrode array just beneath the tip to continue advancing as the electrode array doubles over itself.
3. Fraction and dislocation of the ossea spiral lamina has been seen by most investigators.[3-5] It can occur directly as a result of the tip impacting the osseous spiral lamina and fracturing it or, as seen in our dissections, can occur from buckling of the more proximal portions of the electrode in scala tympani after the tip becomes fixed. The extent to which fracture or dislocation of the ossea spiral lamina produces hearing loss is unclear. Damage to the osseous spiral lamina and basilar membrane in animals appears to produce only a discreet loss of those spiral ganglion cells subserving the fractured or torn segments. Widespread loss of ganglion cells is not seen in animals unless damage to the osseous spiral lamina or basilar membrane involves large portions of the cochlea.
4. Basilar membrane perforation occurs occasionally, and appears to be at least partially related to the stiffness and rigidity of the electrode. However, it appears perforation of the basilar membrane may occur with any electrode, and it may not be possible for the surgeon to prevent basilar membrane perforation reliably in every case. It seems that injury to the basilar membrane itself will only produce a discreet loss of spiral ganglion cells. However, it is hypothesized that if there is mixing of endolymph and perilymph, more widespread hearing loss can occur.
5. Displacement of the basilar membrane appears to be common. Although it is not known with surety whether or not this produces damage to neural elements, it is believed that minor displacements of the basilar membrane inward toward scala media probably have no adverse effect on auditory function.
6. Dissection of the spiral ligament away from the lateral wall of the cochlea appears to occur more frequently than was previously recognized. Again, the extent to which this impacts hearing is unclear, but it probably depends on the extent to which it occurs. Whether or not this is more or less likely in older individuals with age related changes to the spiral ligament is also uncertain.

Hearing preservation

Surgical technique

During the last 5 years, a new method, the combined electricacoustic stimulation (EAS) of the auditory sys-

Table 1 Approaches to ipsilateral EAS

	No. 1	No. 2	No. 3	No. 4
Year of first description	1999	x	x	x
Cochlear implant insertion	Free fitting, 20-22 mm insertions	Perimodiolar, 17-mm insertions	Free fitting, 6 or 10-mm insertions	Extracochlear ball electrode
Risk of hearing loss	High	High	Medium	No
Implant alone performance	Good	Good	Poor	Poor
Residual hearing before implantation	Low	Low	Fairly good	Good
Implant device	MED-EL	Cochlear Corp.	Cochlear Corp.	French company

tem, has been successfully implemented in several clinics.[11,12] This method combines residual acoustic hearing with or without a hearing aid and electrostimulation via cochlear implant on the same ear. EAS candidates should have relatively good residual hearing in the low frequencies, corresponding to apical parts of the cochlea, and substantial hearing loss in the high frequencies.[11] This type of hearing loss usually leads to substantially impaired speech discrimination scores. Also, these patients receive almost no benefit from conventional hearing aids. For example, such individuals discriminate only approximately 10% to 30% of monosyllabic words, which makes them candidates for regular cochlear implantation. Before the development of EAS, residual cochlear function was usually destroyed during surgery. As a consequence, only electric hearing was available to these patients. With the preservation of residual hearing function and the possibility to combine acoustic and electric hearing, everyday listening clarity improves dramatically.[12]

To ensure bimodal stimulation, remaining cochlear function has to be preserved, at least to some extent. Leaving delicate cochlear structures, especially those in the apical, low frequency regions intact, seems to be essential. The concept of EAS is to stimulate basal cochlear regions electrically and leave the more apical portions free of an electrode carrier.[13] As mentioned previously, these areas are responsible for low frequency hearing and contain still working structures that can be stimulated with or without a conventional hearing aid, depending on the extent of residual function. Special surgical techniques contribute to preserving cochlear function and should be applied in every cochlear implantation with residual hearing.[13]

Historically, Lehnhardt was the first to describe a soft-surgery technique for cochlear implantations in 1993.[14] The main focus has been to preserve neural structures and increase the effectiveness of electrostimulation. The possibility of functional conservation was first described by Hodges et al[1] in 1997. In this article, it was observed that some hearing was preserved in approximately 50% of regular implant recipients with residual cochlear function. The concept of EAS itself and, therewith, the possible benefits of preserved hearing and the combined stimulation were first published by Von Ilberg et al[11] in 1999. Since then, several articles regarding combined stimulation have been published.[12,13,15] Currently, several research groups are focusing on EAS. This variety has produced different approaches to EAS using different devices (Table 1).[11,15-17] However, for each approach, hearing preservation of the implanted ear is fundamental.

The initial method described by Von Ilberg et al[11] features implantations with a MED-EL device (MED-EL, Innsbruck, Austria) of a full cochlear turn to guarantee good cochlear implant function. Here, residual hearing is at risk, but even if cochlear function is lost, patients should have all the benefits from cochlear implantation because one full cochlear turn (approximately 20-22 mm implantations) has been implanted. Later, the principle of providing good implant function has also been implemented by another group of researches using the Cochlear Corporation's device (Melbourne, Australia).[17] Although fewer patients have been implanted using this method, results between both devices seem to be comparable.

Another EAS approach features a shorter implant array of only 6 or 10 mm.[16] It is believed that implanting a shorter array increases the probability of preserving cochlear function. However, cochlear implant function alone is poorer compared with the one full-turn implantations described previously. The stimulator-receivers include a second, full electrode array that is left unused in the mastoid. If hearing is lost, the second array can then be implanted in a second surgical procedure. The third approach to realizing EAS is based on an extracochlear, single channel array.[18] Naturally, residual hearing is not at risk, but only frequency coded information is provided by these cochlear implants, resulting in poor implant alone performance.

In addition to ipsilateral, simultaneous combined EAS of a cochlear implant combined with a contralateral hearing aid also provides bimodal stimulation and, therefore, improved speech perception.[12] Because contralateral EAS does not require hearing preservation surgery, it will not be described here. Clinically, both ipsilateral and contralateral stimulation lead to significantly improved speech discrimination scores. This effect is especially robust in conditions of background noise similar to those occurring in normal everyday listening situations, as has been documented in publications from all EAS investigators.[12,15,17] Significant improvements in performance certainly justify the additional surgical effort expended during implantations for hearing preservation described later.

Table 2 Factors contributing to hearing loss/preservation

Mechanism	Example/caused by	Preventive surgical measure
Cochlear trauma		
Necrosis	Surgical or electrode issues	Surgical technique, electrode design
Apical cochlear trauma	Electrode dislocations	Electrode design
Basal cochlear trauma	Basal surgical trauma	Cochleostomy size, location, angle
Primary scala vestibuli insertions	Location and angle of the cochleostomy	Wrong cochleostomy
Electrode dislocations	Electrode stiffness	Electrode design
Late cell loss		
Apoptosis	Intraoperative trauma	Soft surgery
Expansion of limited hair cell loss	Intraoperative trauma	Corticosteroid application
Disturbance of cochlear mechanics	Electrode lies against the basilar membrane	Free fitting arrays
Perilymphatic fluid loss	Large cochleostomy, early opening	Late cochleostomy opening, sealing
Cochlear contamination	Blood influx during surgery	Late opening, clean surgical situs

Implantation technique

General considerations

Several changes in surgical technique contribute to preserving cochlear function.[13] Because not all the mechanisms of hearing preservation are currently known, technical changes are necessarily based on assumptions of how intraoperative and postoperative hearing loss occurs. Some factors seem to be obvious, while others might or might not lead to functional loss. However, because clear scientific data are still missing, the surgeon has to adapt intraoperative technique to address all possible mechanisms (Table 2).

Patient counseling before the operation plays an extremely important part in EAS surgery. In addition to recognizing the risks associated with cochlear implantation in general, the candidate for EAS must have a clear understanding of the preservation. Information about side effects and adverse reactions associated with the drugs used in EAS surgery should also be provided.

Preparing for surgery

The aim of EAS surgery is to insert the electrode array one full turn, a region that corresponds to the 1,000 Hz region,[11] which defines the end of electric and the beginning of acoustic stimulation. Anatomically, a 360° insertion into the scala tympani corresponds to an insertion depth of approximately 20 mm measured from the round window membrane.[19] However, considerable morphologic variations are described.[20,21] Accordingly, when implanting patients during our clinical EAS trial, significant variations in insertion depths in terms of degrees were found with constant surgical depths (ie, millimeters).

In temporal bone studies, deep electrode insertions more than 360° increased the risk of cochlear trauma significantly.[22,23] On the other hand, reduced insertions are believed to result in poor implant hearing performance.[12,13,16] The aim of preoperative radiographic examinations for implantations with a free fitting array, providing a full cochlear turn, therefore, is to define where the 360° region of the specific organ will be.

High resolution computerized tomography imaging and reconstruction can be used to determine the size and geometry of the basal cochlear turn. Special techniques using a multi-slice computerized tomographic scanner provide the most accurate data. Intraoperative fluoroscopy offers an alternative approach. With this method, intraoperative observation of electrode insertion is provided.[24] Because of the live character of this method and the possibility of adapting surgical maneuvers in real-time, accurate 360° insertions are possible. However, both the patient and the surgeon receive additional radiation exposure, and the machine has to be available in the otology theater.

Device selection: Electrode arrays

As seen in histologic specimens of implanted temporal bones, insertion of electrode arrays into the cochlea has the potential to cause damage to cochlear structures.[22,25] The importance of smooth electrode carriers to avoid cochlear trauma has become obvious. New prototype electrode carriers aiming at a reduction of intracochlear trauma have already been evaluated in human temporal bones.[22] With limited insertion depths and electrode contact distribution lengths, cochlear trauma from the array can generally be avoided.[22] Extracochlear placement of ball electrodes offers the possibility of hearing preservation in all implanted subjects. These electrodes do not differ from the ones used in early cochlear implantation and will not be described any further.

MED-EL has modified its standard C40+ electrode to permit limited insertion depths. This array, the C40+ M (Medium), features an electrode contact spacing of 1.9 mm.[26] This results in a length from the very tip of the electrode to the middle of the last contact (#12) of 22.1 mm. The overall length of the implanted portion (until the marker ring) is 25.6 mm, which of course should not be fully inserted during EAS surgery.

A further improvement in the C40+ M array is the Flex^{EAS} (MED-EL). This electrode features the same dimensions as the Medium array except that the apical electrode contacts are not paired but single, which allows a reduction of the tip diameter. In temporal bone studies, this proved to be effective for reducing cochlear trauma.[22]

The Cochlear Corporation's electrode, the Contour Softip, has also undergone some modifications to contribute to soft surgical methods. Recent temporal bone studies

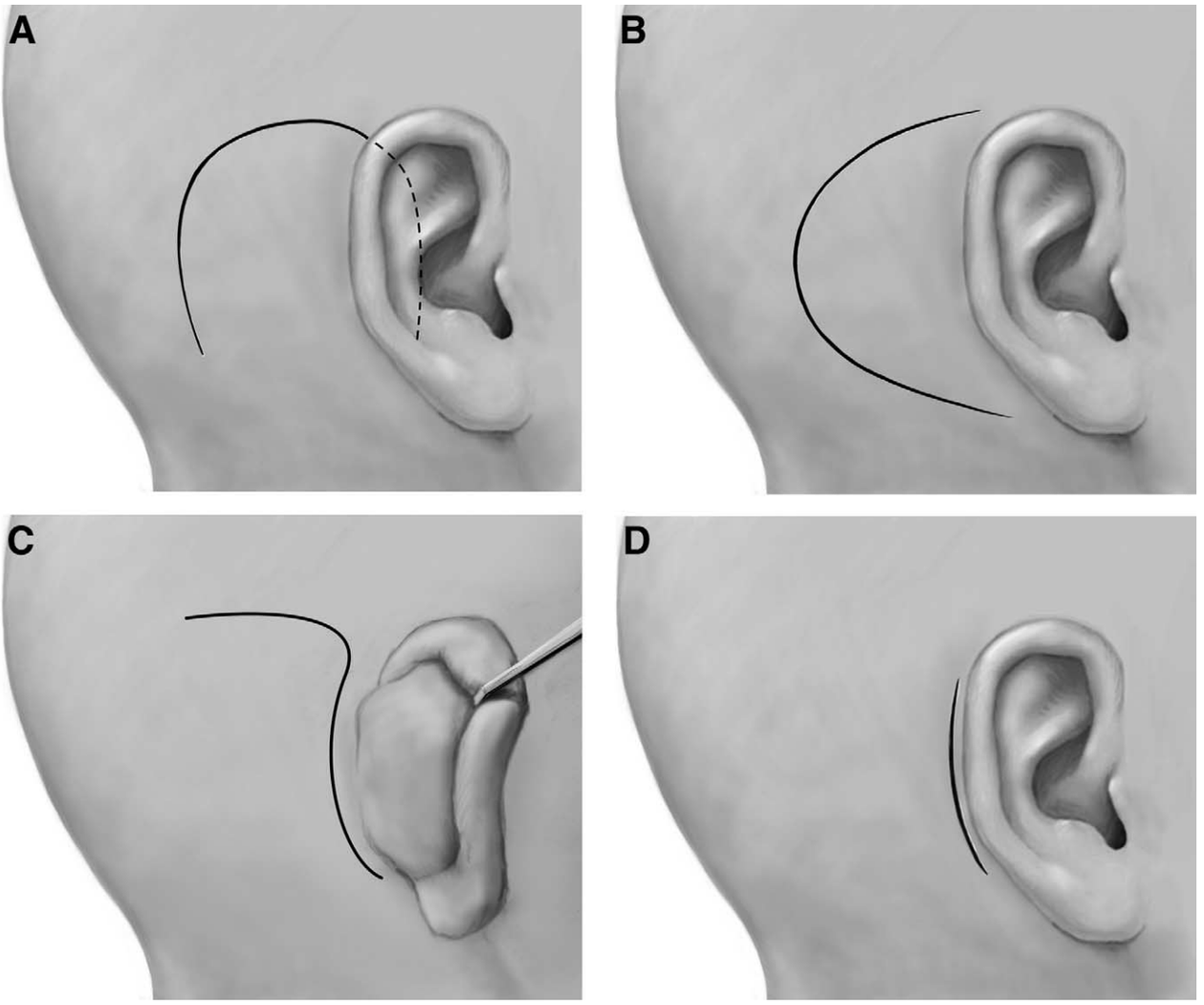

Figure 1 (A-D) Incisions used for cochlear implantation. There is a tendency toward smaller incisions similar to that illustrated in the lower right hand corner.

showed relatively atraumatic insertions of approximately one full cochlear turn.[27] In contrast to the MED-EL device, the Contour array is preshaped and is straightened before insertion using a stylet. During insertions, the stylet is removed, and the electrode conforms to the medial wall of scala tympani in a perimodiolar position.

Approach

Generally, the approach to the cochlea is similar to the one used for regular cochlear implantation (Figures 1-3). Noise induced hearing loss should be avoided. Therefore, electric drills might be better than hydraulic systems. For good exposure of the promontory region, a rather large posterior tympanotomy should be opened. In case of a very narrow facial recess, the view can be enhanced with a transcanal approach. In cases with a large bony overhang over the round window niche, this procedure can be especially helpful.

After opening the posterior tympanotomy, mucosa should be removed from the promontory bone to avoid bleeding when drilling the cochleostomy. Crystalline corticoid solution (Kenalog, Bristol Myers Squibb, Princeton, NJ; Volon A, Bristol Myers Squibb, Munich, Germany) should be applied in the middle ear and into the round window niche, which allows for diffusion while drilling the implant bed.

Entering the cochlea: Cochleostomy –Round window membrane

Opening of the inner ear during surgery for cholesteatoma with perilymph fistula may result in a profound hearing loss through a disturbance of the endolymph and perilymph compartment of the organ of Corti. However, clinical examples of inadvertent surgical ingress into the inner ear that resulted in normal cochlear function postoperatively[28,29] as well as the routine opening of the inner ear during surgery for otosclerosis show the feasibility of inner ear surgery without functional impairment.

Preservation of function of the organ of Corti in the cochlear apex is crucial for the EAS. During surgery,

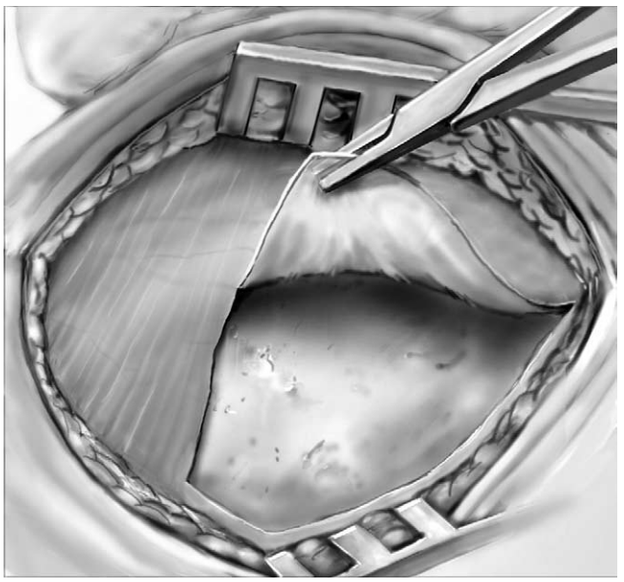

Figure 2 Exposure of the mastoid cortex and lower portions of the temporalis muscle.

trauma to cochlear structures may occur at different locations. The location and the angle of the cochleostomy seem to be important for avoiding trauma to basal cochlear structures. Data of our temporal bone laboratory show that an inferior cochleostomy reduces the risk of fractures of the osseous spiral lamina and of primary scala vestibuli placements during electrode insertion.[30]

A very safe way of approaching scala tympani seems to be to visualize the round window membrane itself and expose the cochlear endosteum anterior inferior to it (Figure 4).[31] Because insertion of the spiral ligament along the outer cochlear wall in this area moves inferior with increasing distance from the round window, this procedure should guarantee safe and atraumatic insertions.

A small (0.5-1.0 mm) drill is used to expose the annulus of the round window by drilling off the bony overhang over

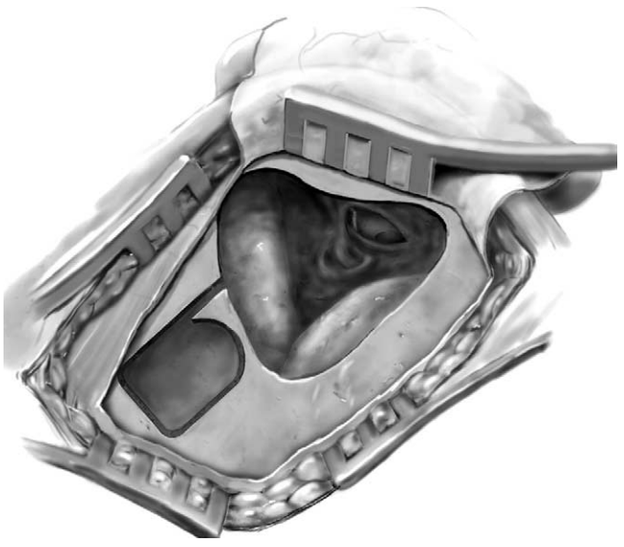

Figure 3 A receptacle site has been produced in the skull to accommodate the stimulator receiver. At this point in the operation extensive irrigation should be used to remove all blood and bone dust.

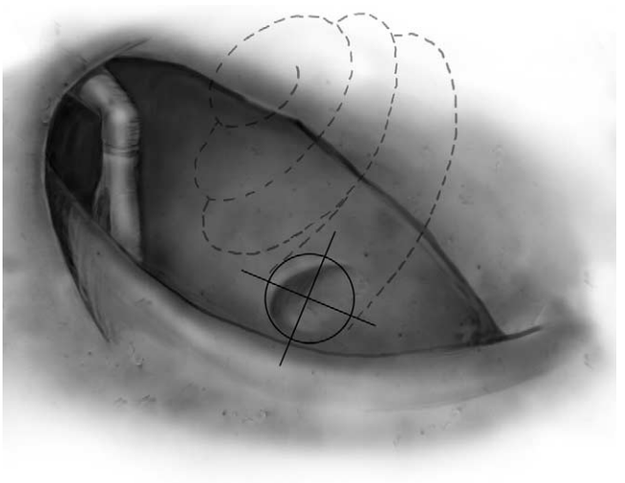

Figure 4 The round window niche is visualized through the facial recess. If the round window niche is divided into quadrants, the conchotomy should be performed in the anterior inferior quadrant.

the niche. Additional bone is then removed anterior and inferior of the window, and the cochlear endosteum is carefully exposed but not penetrated. The goal is to expose the endosteum for a diameter of approximately 1.0 mm. Bigger cochleostomies can result in buckling of the electrode array in the basal cochlear portions and, therefore, increase the risk of trauma.

Electrode insertion

Introduction of the electrode array into the cochlea certainly plays a major part in hearing preservation. Temporal bone studies have shown that deep and forceful insertion procedures can lead to severe destruction of delicate intracochlear

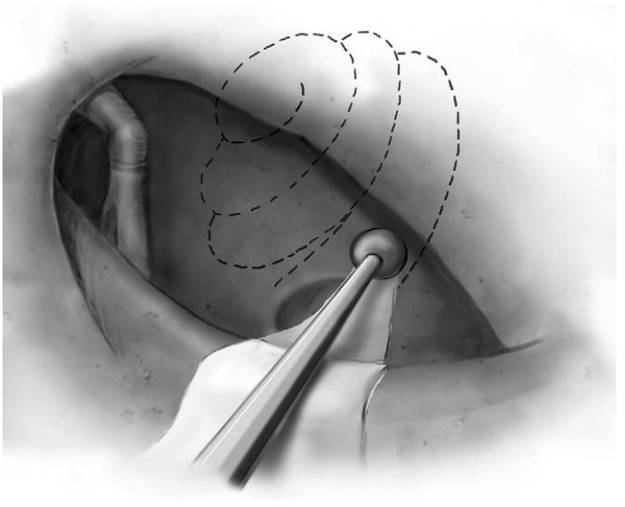

Figure 5 First using a larger 1.5 to 2 mm bur portion of the bony promontory is removed just anterior to the anterior/inferior annulus of the round window membrane. A 1-mm bur is then used to expose the endosteum of scala tympani.

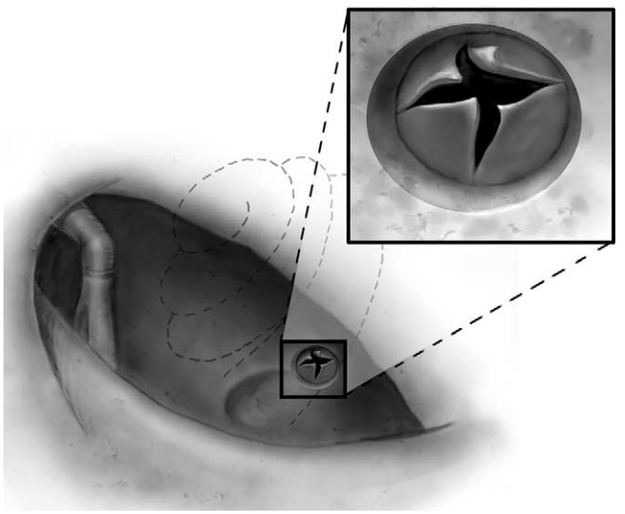

Figure 6 The bone should be carefully removed until the endosteum of scala tympani is clearly visualized. The endosteum can then be opened carefully with a cruciate or linear incision.

structures. However, a 360° insertion should be performed to provide good cochlear implant function.

After opening the endosteum with a small Rosen needle and gently pushing it laterally, an immediate electrode insertion should be performed to prevent loss of perilymphatic fluid. The electrode should not be contaminated with blood or bone dust from the mastoid area before insertion (Figures 5-8). A small Silastic sheet (Dow Corning Corp., Midland, MI) is placed into the mastoid cavity and through the posterior tympanotomy to prevent contamination of the electrode array with blood or bone dust. The aim during electrode insertion is to slide the array along the outer cochlear wall to its final position. To decrease insertion forces, a drop of hyaluronic acid (Healon®, Advanced Medical Optics, Inc., Santa Ana, CA) should be put onto the opened endosteum. Any forceful procedures should be avoided, and insertion should stop when the point of first resistance is reached. No further insertion maneuvers should be performed afterward.

Figure 7 The electrode array is passed very gently through the cochleostomy after a small drop of Healon GV has been placed across the cochleostomy. A sheet of Silastic is used to keep the electrode array from becoming contaminated with bone dust, blood or debris.

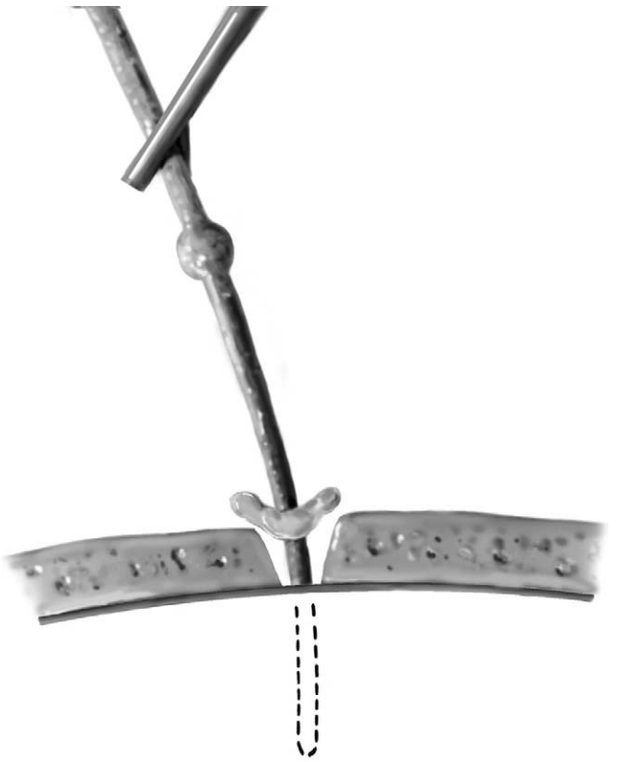

Figure 8 The electrode array is placed through a circle of fascia 2 to 3 mm in diameter. This is then wedged into the cochleostomy by the thickened area of Silastic that indicates the end of the electrode array.

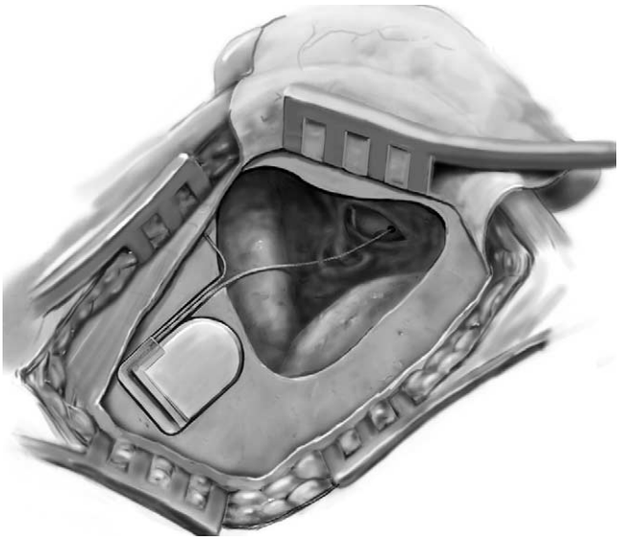

Figure 9 The incision is then carefully closed in layers after the ground electrode has been placed beneath the temporalis muscle directly on the bone of the temporal squamosa.

Sealing

Sealing of the cochleostomy can be achieved with several types of grafts that are placed around the electrode carrier in the cochleostomy region. Up until now, most experience has been with circular or noncircular fascia grafts. Additional fixation with fibrin glue seems to facilitate sealing. Small, free muscle grafts are generally used for sealing the posterior tympanotomy, while bone paté is used to fix the electrode in the mastoid cavity. Wound closing is performed as in any cochlear implantation (Figure 9).

Postoperative care

The aim of postoperative care is to provide protection against prolonged intracochlear cell death. Intravenous corticosteroids are used to prevent or limit apoptosis of functional cells. Here, several schemes are available. However, dosage should exceed 250 mg prednisolone to guarantee sufficient perilymphatic concentrations. Additionally, intravenous antibiotics help avoid postoperative infection, which could compromise residual cochlear function.

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