IMPLANTATION OF THE MELBOURNE/COCHLEAR MULTIPLE-ELECTRODE EXTRACOCHEAR PROSTHESIS

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The Melbourne/Cochlear multiple-electrode extracochlear implant is designed for deaf patients who are unsuited to multiple-electrode intracochlear implantation. The implant consists of a receiver-stimulator package connected via a lead wire assembly to six individual stimulating electrodes. There is a choice of two alternative surgical procedures, both of which are via a combined middle ear approach using anterior and posterior tympanotomies. Four active electrodes shaped into compressible platinum-iridium soft-balls are fed through the mastoid cavity and across the facial recess, and placed into cavities that are made over the cochlear turns that project to the medial wall of the middle ear. One hard-ball active electrode is placed into the round window niche. One hard-ball reference electrode is placed into the hypotympanum. An additional electrode wrapped around the lead wire assembly can be used as an alternative reference electrode. A specially designed insertion needle facilitates the placement and the fixation of the soft-ball electrodes.

KEY WORDS — hearing loss, multiple-electrode extracochlear prosthesis.

INTRODUCTION

Multiple-electrode intracochlear implants have proved to be superior to single-electrode implants in many patients.¹ Not all patients, however, can benefit from a multiple-electrode intracochlear implant. Chronic otitis media, labyrinthitis ossificans, and possibly malformations of the inner ear can render the patient unsuited to an intracochlear device, and the possibility of residual hearing and the associated risks of otitis media can make intracochlear implantation unsuitable for infants and young children. Otitis media, however, has not been demonstrated to be a risk for extracochlear electrode placement.

Although studies have shown that some pitch discrimination can be obtained by extracochlear stimulation at different sites over the cochlea,² this finding is not conclusive. Nevertheless, multiple-electrode extracochlear stimulation may be preferable to single-electrode extracochlear stimulation not only because of the possibility of providing additional place pitch information, but because multiple electrodes provide a choice of stimulus electrodes that can reduce the inherent side effects of extracochlear stimulation, in particular stimulation of the facial nerve, the tympanic branch of the glossopharyngeal nerve, and the vestibular nerve.

In a preliminary anatomic study on six human temporal bones it was concluded that an extracochlear electrode array placed via a combined middle

ear approach would overlies less than a third of the length of the cochlear turns.³ This would limit the number of electrodes that could be used, and five active electrodes are recommended from this study. This recommendation was based on the anatomic findings and the assumption that the size of each electrode would not exceed 1 mm in diameter. This placement of the electrodes should be close enough to individual nerve fiber groups and provide channel separation.

This presentation describes two surgical approaches for the Melbourne/Cochlear multiple-electrode extracochlear implant. The preservation of the middle ear ossicles was considered important when developing the first approach. In the second, better access to the middle ear is achieved, but with limited loss of middle ear structures.

DESCRIPTION OF IMPLANT

The Melbourne/Cochlear multiple-electrode extracochlear implant is shown in Fig 1. The titanium package containing the stimulator electronics and the receiver coil are the same as those of the conventional intracochlear device and are placed underneath the skin. The section containing the titanium package has a diameter of 22 mm and is 6 mm thick. This section is placed into a circular bed drilled in the temporal bone. The section containing the receiver coil and a titanium-encapsulated magnet for attaching the transmitter coil is 24 mm wide

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Fig 1. Photograph showing Melbourne/Cochlear multiple-electrode extracochlear implant device. I — receiver-stimulator package, II — electrode array, a — receiver coil, b — magnet, c — electrode soft-balls, d — electrode hard-balls, e — reference electrode, f — ripples, g — Silastic collar.

and 3 mm thick. The whole device is embedded in medical-grade Silastic. The lead wire assembly contains six Teflon-coated platinum (90%)–iridium (10%) wires with a diameter of 100 μ m that are spiralled to protect against metal fatigue. These wires are embedded in a Silastic tube with an outside diameter of 2 mm. The lead wire assembly emerges from the receiver-stimulator device at an angle of 45° and is 35 mm long. The electrode array consists of six individual wires. Four active electrodes are held together with a movable Silastic collar. This facilitates their introduction through the posterior tympanotomy and placement over the cochlea. The group of four active electrodes terminates distally in platinum-iridium soft-balls. These balls are made by loosely winding the terminal 40 mm of the platinum-iridium wires. The length of these active electrodes is staggered. The shortest is 35 mm and they increase in 5-mm steps to a length of 50 mm. This facilitates the placement of the electrodes at different locations. The two electrodes that terminate distally in a platinum-iridium hard-ball have a diameter of 1 mm. One of these electrodes can be selected as a reference electrode, and the other as an active electrode placed into the round window niche. The lead wire assembly is wrapped around proximally with bared platinum-iridium wire for a distance of 15 mm and acts as an alternative reference electrode. The thick part of the lead wire assembly is rippled for better fixation with the Dacron mesh ties.

SURGICAL PROCEDURES

Two alternative surgical approaches are described and may be chosen according to the surgeon's preference.

Procedure 1. An incision is made in the postaural sulcus through skin and subcutaneous tissue and extended superiorly and posteriorly to create an inferiorly based flap.⁴ An anteriorly based deep

fascial and periosteal flap also is created. A partial cortical mastoidectomy is performed, and the short process of the incus and the lateral semicircular canal are identified. A posterior tympanotomy is carried out after visualizing the course of the facial nerve, and the round window niche exposure is the same as for intracochlear implantation.

The skin of the osseous external ear canal is incised from a point superiorly, at the 12-o'clock position, through 270° around the anterior and inferior aspect of the canal to create a posterosuperiorly based tympanomeatal flap. The flap is pushed backward, and the fibrocartilaginous ring of the tympanic membrane is mobilized from the tympanic sulcus as far as is necessary to expose the round window niche. As the cochlea lies beneath the wall of the anterior part of the middle ear, it is not necessary to remove the malleus or other ossicles for access. Better access to the cochlea through the anterior part of the middle ear also may be achieved by exposing the anterior recess of the ear canal and by removing bone over the temporomandibular joint. A thin bony plate is left over the joint for protection. The package bed and the groove for the electrode lead wire then are created. This procedure is the same as that described for the Melbourne/Cochlear multiple-electrode intracochlear receiver-stimulator.⁵

After the package bed is prepared, the tensor tympani muscle is resected where it runs across the apical region of the cochlea. This is facilitated by opening its bony canal and slightly reducing the inferior ridge of the canal with use of a diamond bur. A 0.6-mm diamond bur is used next to drill the anteroinferior overhang of the round window niche to accommodate the active hard-ball electrode, and a groove for the electrode wire is drilled in the overhang superiorly (Fig 2). The positions are selected for the four active soft-ball electrodes to be placed directly over the cochlear turns that project to the

Fig 2. Photograph through external ear canal demonstrating groove (star) in posterosuperior overhang of round window niche and placement of hard-ball electrode.

medial wall of the middle ear. The sites for the cavities are chosen to ensure that all electrodes are separated by at least 1 mm. The electrode position over the apical region of the cochlea is drilled first (Fig 3). This electrode should lie toward the apex of the triangle bordered by the internal carotid artery, the eustachian tube, and the bony bed of the tensor tympani muscle. A 0.6-mm diamond bur is used to drill a saucer-shaped cavity in the bone without exposing the endosteum of the cochlea. Entry into the cochlea can be avoided if notice is taken of the appearance of the endochondral bone while drilling. When the bone changes from a woven texture to an amorphous ground-glass appearance, there is only a thin layer of bone remaining. The drilling should cease at this point and certainly before a blue line appears. The cavity is undermined to create an overhang. Two electrode positions over the middle turn are drilled on a direct line connecting the anterior edge of the oval window with the internal carotid artery (Fig 3). With a 1-mm diamond bur two cavities again are drilled into the bone until the appearance of the bone changes as described above. With a 0.6-mm bur the bone is undermined to create an overhang. A fourth electrode position is drilled over the basal turn on the promontory (Fig 3), and this cavity is made in the same way. The tympanic nerve is resected where it runs across the promontory. The resection of the nerve is necessary in order to drill a cavity in the promontory and to avoid pain on electric stimulation.

After cavities are drilled in the bone overlying the cochlea, the electrodes are put into position. One hard-ball or stimulating electrode is inserted first and fed into the middle ear via the aditus ad antrum. The electrode is passed anterior to the stapes and the wire is placed in the groove in the superior overhang, and the electrode ball in the round window niche (Fig 2). The second hard-ball or reference electrode is inserted into the middle ear via the posterior tympanotomy and placed into a hypotym-

panic cell. This electrode can be chosen as an alternative reference electrode to the one wrapped around the proximal lead wire. The soft-ball stimulating electrodes then are inserted into the middle ear via the posterior tympanotomy. This procedure is facilitated when the Silastic collar is pushed distally. After the insertion, the Silastic collar is moved backward to allow better handling of each individual electrode. The soft-ball electrode with the longest wire is placed apically and pressed into the prepared cavity with the angled blunt insertion needle (Fig 4). This then is followed by the second-longest electrode, which is placed into the prepared cavity overlying the proximal portion of the middle turn, and the third-longest electrode, placed into the cavity overlying the distal portion of the middle turn. The soft-ball electrode with the shortest wire is placed into the cavity in the promontory overlying the basal turn.

The receiver-stimulator is placed into the package bed and the electrode lead is fixed with Dacron

Fig 3. Diagram showing sites for electrodes. m — handle of malleus, tm — tensor tympani muscle, ica — internal carotid artery, rw — round window.

A **B**

Fig 4. A) Diagram demonstrating insertion needle being used to fix soft-ball electrodes into cavity in bone overlying cochlea. B) Photograph through external ear canal demonstrating hard-ball and soft-ball stimulating electrodes in position. a — soft-ball electrode in apical region of cochlea, b — soft-ball electrodes over middle turn, c — soft-ball electrode on promontory, d — hard-ball electrode in round window niche, stars — internal carotid artery.

mesh ties. The wound is irrigated with an antibiotic solution. Fascia is placed over the electrodes for additional support. The tympanomeatal flap is repositioned, gauze packed into the ear canal, and the wound closed. Finally a pressure dressing is applied.

Procedure 2. Similar to the Heermann incision, the endaural incision begins in the floor of the ear canal close to its entrance and runs around the canal's posterior wall to the 12-o'clock position. It then extends superiorly in the incisura terminalis between the crus of the helix and the tragus before proceeding posteriorly around the upper part of the auricle in a wide curve, finishing about 80 mm behind the postaural sulcus (Fig 5). The skin, subcutaneous tissue, muscle, and periosteum are incised simultaneously to create an inferiorly based flap that includes the auricle. The limited mastoidectomy, package bed, groove for the electrode lead wire, posterior tympanotomy, and exposure of the round window niche are completed as described for procedure 1.

The posterior and superior osseous walls of the external ear canal are removed carefully, with the skin preserved. Alternatively, the posterior wall of the external ear canal could be thinned carefully and then cracked forward still attached to the canal skin to ensure its viability. Both the skin and the eardrum are pushed forward. To do this it is necessary to remove the incus and the head of the malleus, and cut the tendon of the tensor tympani. The middle ear is now wide open. The tensor tympani muscle then is resected, and the drilling of cavities and the fixation of electrode balls is completed according to the description for procedure 1. All electrodes are fed through the mastoid cavity and across

the facial recess into the middle ear.

The outer ear canal is filled with Gelfoam to reform its original shape. The posterior and superior walls then are rebuilt with bone meal mixed with fibrin glue (available in the Federal Republic of Germany). The remaining surgical steps are completed as described for procedure 1.

DISCUSSION

Not every cochlear implant candidate is suited to a multiple-electrode intracochlear system. A very young age, labyrinthitis ossificans, and possibly

Fig 5. Diagram showing incision for alternative middle ear approach for multiple-electrode extracochlear implantation.

malformations of the inner ear can render the deaf patient unsuited. In these cases an extracochlear device is an alternative.

Multiple-electrode intracochlear devices give better speech perception results than single-electrode intracochlear or single-electrode extracochlear devices.¹ These advantages are attributed to the closeness of electrodes to individual nerve fiber groups so that the tonotopic organization of the cochlea can be used. In order to achieve similar results with an extracochlear system it would be necessary to place an equal number of electrodes as close as possible to individual nerve fiber groups around the cochlear turns. Multiple-electrode extracochlear devices may be able to stimulate localized groups of auditory nerve fibers on a place basis, but for the results to be comparable to those for multiple-electrode intracochlear stimulation it would be important to maximize the number of electrodes that can provide discrete stimulation of auditory nerve fibers. This is likely to be difficult because of the distance of the electrode from the auditory nerve fibers and the small length of the cochlear turns underlying the medial wall of the middle ear.

The number of electrodes that can be placed over the cochlea is determined by the length of the cochlear turns that project to the medial wall of the middle ear, the size of the electrodes, and the surgical approach chosen. The total length of the cochlear turns ranges from 31 to 33 mm.⁶ According to our own anatomic studies it appears that 9 to 10 mm of the cochlear length is accessible via an endaural middle ear approach.^{3,7} This means that less than a third of the whole cochlear length would be available for the placement of electrodes. Our findings, however, are in contrast to those of anatomic studies that indicate that more than half of the cochlear turns are accessible via an endaural middle ear approach.⁸⁻¹⁰

Our anatomic studies show that the restricted access is caused by the internal carotid artery, the facial nerve, and the middle cranial fossa, and also by the temporomandibular joint, which limits access to the cochlear turns from a posterolateral direction, and not anterolaterally. Because the axis of the cochlea lies in an anterolateral and superior direction and because access to the cochlea is only possible posterolaterally, the turns of the cochlea that face the coronal plane anteriorly and the middle cranial fossa superiorly are not accessible.

The restriction that only 9 to 10 mm of the cochlear turns can be reached via an endaural middle ear approach without destroying major structures of the middle ear raises the question of the number of electrodes it is practicable to place over these turns. Since the size of each electrode is about 1 mm, and for good electric insulation and channel separation the distance between the electrodes

should be at least 1 mm, a restricted number of only five electrodes appears to be possible. Despite this restriction, the selected cavities along the cochlear turns allow the placement of one electrode over the apical region, two electrodes over the middle turn, one electrode over the basal turn, and one electrode in the round window niche.

The electrode cavities are drilled with 0.6- and 1-mm diamond burs. It is important that the cavities are made deep enough for adequate current flow through the cochlea, but drilling must be stopped as soon as the texture of the bone changes and before a blue line becomes visible. When further drilling is carried out there is danger of breaking into the cochlea. The preservation of the endosteal lining is possible only when drilling is stopped before the blue line is reached. Studies have not yet demonstrated to what extent bone underneath the electrode impairs the localized stimulation of spiral ganglion cells.

The cavity over the apical turn is the most difficult one to make with procedure 1, because of the angle of approach to the anterior part of the cochlea. When a 1-mm bur is used, only a groove can be made in this area. A 0.6-mm bur, however, will enable a cavity to be drilled instead of a groove. This difficulty does not arise with procedure 2 because of a more favorable angle of approach to the medial wall of the middle ear. Additionally, the generous exposure of the medial wall of the middle ear in procedure 2 is safer for the horizontal portion of the seventh nerve. The improved exposure, however, is accomplished through the loss of the malleus head and the incus. The cavities over the middle and basal turns are much easier to drill, as access is good with both procedures.

The placement of the hard-ball stimulating electrode in the round window niche is carried out best via the aditus ad antrum prior to the placement of the soft-ball electrodes. A hard-ball electrode inserted into the middle ear via the posterior tympanotomy can sit insecurely, because small movements of the electrode wire are transmitted immediately to the tip, and displacement can occur. On the other hand, movements applied to the electrode array (inserted via the aditus ad antrum) are not so likely to be transmitted to the electrode tip in the round window niche (B.K.-H.G.F., G.M.C., D. M. Bloom, unpublished observations). Furthermore, inserting the hard-ball electrode after the soft-ball electrodes can be difficult because of obstruction from other wires.

The fixation of the soft-ball electrodes is accomplished best when an adequate bed is prepared. This is achieved by undermining the bone with a 0.6-mm diamond bur and thus creating an overhang. The soft-ball tip pressed into such a bed will sit firmly. Four electrodes placed in this manner

can lift a temporal bone weighing about 100 g. The soft-balls are pressed into the holes with a blunt, angled needle (Fig 4A). Pressure must not be excessive, however, or a break into the cochlea will occur.

Two options are available for the reference electrode. One hard-ball electrode can be placed into a hypotympanic cell. This may allow current flow away from the facial nerve. The alternative reference electrode wrapped around the lead wire assembly would correspond to an electrode placed close to the temporal muscle.

Clinical experience has been obtained with three patients. The results will be published elsewhere. Preliminary evaluation 6 months after implantation showed that their performance was equivalent to group 3 of 75 Hannover patients who received multiple-electrode intracochlear implants.¹¹

SUMMARY

The Melbourne/Cochlear multiple-electrode extracochlear receiver-stimulator has been described. Two surgical procedures for its implantation have been outlined. Procedure 1 provides access with the preservation of the ossicles. Procedure 2 provides better access for the placement of an electrode over the apical turn, but the malleus and the incus need to be removed. Five stimulating electrodes are placed over the cochlear turns that project to the medial wall of the middle ear. One soft-ball electrode is placed over the apical region of the cochlea, two soft-ball electrodes over the middle turn, one soft-ball electrode over the basal turn, and one hard-ball electrode in the round window niche. There is an option of two reference electrodes, one a hard-ball electrode placed into a hypotympanic cell, and the other an exposed wire around the proximal lead wire and near the temporal muscle.

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