CHAPTER 15

Cochlear Implants, Osseointegrated Bone Conduction Hearing Devices, and Other Implantable Devices

Seilesh Babu, Paulette McDonald, and Eric Sargent

INTRODUCTION

The cochlear implant is an electronic prosthesis that stimulates cells of the auditory spiral ganglion to provide a sense of sound to persons with hearing impairment. Although many thousands of patients have now been implanted, these represent only a fraction of the hearing-impaired individuals worldwide who would potentially benefit from implantation but do not have access to one because of failure to recognize appropriate individuals or socioeconomic reasons.

Although the individual response of a patient to a cochlear implant is highly variable and depends on a number of physical and psychosocial factors, the trend toward improved performance with increasingly sophisticated electrodes and programming strategies has caused the indications for cochlear implantation to be dramatically expanded (Table 15–1). Originally, cochlear implants were thought of primarily as an aid to some sound perception for the profoundly hearing impaired. Now, it is common to find implanted patients have better unaided hearing levels and perform at levels that exceed those obtained by conventionally aided patients. Through the 1970s, devices were implanted only in adults with profound hearing loss under the FDA guidelines of the time. In 1980, the age limit was lowered to 2, and later declined to 18 months. Currently the limit for implantation is 12 months of age. Over time, the adult indications have been broadened to include patients with severe hearing

Table 15–1. Current Pediatric and Adult Cochlear Implantation Guidelines

Pediatric	Adult (>18 years)
12–24 months: Bilateral profound sensorineural (SRT ≥ 90 dB)	Severe-to-profound bilateral sensorineural hearing (SRT ≥ 70 dB)
≥24 months: Severe to profound sensorineural hearing loss.	A score of 50% or less on sentence recognition tests under best-aided conditions (HINT testing in quiet wearing best fit hearing aids).
Limited auditory skill development in conjunction with appropriate amplification and intervention.	No medical contraindications.
An educational program that supports listening and speaking for communication.	
No medical contraindications.	

loss who obtain some benefit from conventional amplification.

Successful cochlear implantation requires a collaborative effort not only from the patient and family, but from a multispecialty team that includes school personnel (in the case of children), audiologist, speech/hearing therapists, and otolaryngologic surgeon. A motivated and properly counseled patient is the most important link in the chain. A deaf patient is not a surgical "problem" who responds to the simple intervention of an implant surgeon. A patient's preoperative expectations largely shape their postoperative satisfaction and use of the implant. All patients and families require proper attention and counseling by an implant team before embarking on a life-changing journey.

AUDITORY TESTS USED TO ESTABLISH CANDIDACY

For adults and children able to reliably respond, standard tests of pure-tone and speech audiometry are used to initially determine likely candidates for cochlear implantation. For children, the speech reception threshold should equal or exceed 90 dB; for adults, the speech reception threshold should equal or exceed 70 dB. If the patient can detect speech with best-fit hearing aids in place a speech recognition test in a sound field of 55 dB (HL) sound pressure level is then performed.

There are a number of speech recognition tests in current use. One of the most commonly used is the Hearing In Noise Test (HINT), a test of speech recognition in the context of sentences.[1] In cochlear implant evaluation, the test is performed in a sound field without noise while the patient is wearing appropriate bilateral amplification. Several versions exist for this testing and each center may find the most appropriate one to utilize to determine candidacy.

Many cochlear implant clinics now use the AzBio Sentences test.[2] Unlike the HINT test, which utilizes the male voice alone, the AzBio includes a variable number of prerecorded sentences presented by both male and female voices. Scores range from 1–100% based on the percent of words correctly identified.

CHILDREN

Severe to profound hearing loss sustained prior to the development of language, whether congenital or acquired, is estimated to occur in 0.5 to 4 in 1,000 births. The most common cause of childhood deafness is genetic (33–50%) with a large number of these cases being single gene mutations. Twenty five to thirty three percent of childhood deafness is due to "non-genetic" or environmental causes. The remaining 25 to 33% are sporadic for which the etiology is not determined. A large proportion of "sporadic" cases will likely prove to be genetic in origin as technology and testing improves.[3]

Meningitis causes about 9% of childhood deafness and can make implantation difficult (see *labyrinthitis ossificans*, below).[3] Of the organisms that commonly cause meningitis (from most common to least common: *H. influenzae*, *S. pneumoniae*, and *N. meningitis*), the organism with the highest incidence of hearing loss is *S. pneumoniae* (31%). Factors that will likely reduce the frequency of deafness caused by meningitis include the increased use of immunization against *H. influenzae* and *S. pneumoniae.*

It has long been known that 3 factors are important in determining the outcome of pediatric implant patients: (1) Age at onset of deafness and duration of deafness before implantation; (2) Progression of hearing loss; and (3) Educational setting. Generally, earlier implantation favors more rapid development of oral communication ability. Placement in a school setting that stresses oral (versus signed) communication is important for the best outcome of implantation. However, many variables remain unknown, as at least 50% of the variance in postimplant performance cannot be predicted from these factors.

A period of hearing aid use to determine the development of aided communication ability is a critical criterion for determining candidacy in young children.

After determining that audiologic criteria have been met, parental expectations and attitudes should be carefully assessed. Unrealistic expectations on the part of the family will frustrate the efforts of the child and the implant team. When counseling families, the need for long-term therapy, the variable outcome of implantation, and the limitations of implantation should be stressed.

Imaging with magnetic resonance imaging (MRI) using FSE T2-weighted images should be performed prior to implantation to evaluate the cochleovestibular apparatus and internal auditory canals. Imaging will reveal the absence or abnormal caliber of the internal auditory canal and/or cochlear dysplasia. This may alter the choice of the implanted ear or raise other issues.

In pediatric or young adult patients with progressive hearing loss, neurofibromatosis II should be excluded with an MRI scan before proceeding with implantation. Although computed tomography (CT) remains a tool for evaluating cochlear patency, occasionally this modality will erroneously suggest a patent scala tympani that proves to be obstructed with bone or fibrous tissue at the time of surgery. MRI offers the ability to better examine the fluid spaces of the cochlea and is increasingly being thought of as the best modality for imaging the cochlea. Both studies may need to be performed for complete evaluation of the cochlea and other auditory structures.

Although 12 months is currently the FDA age limit on implantation, there may be factors that cause the implant team to proceed at an even earlier age. In particular, a child deafened by meningitis may develop *labyrinthitis ossificans* (filling of all the cochlear duct—usually the scala tympani starting near the round window—with bone) that may necessitate special techniques to implant and render the result of implantation suboptimal. For patients at risk for labyrinthitis ossificans, implantation at the time initial ossification or fibrosis is identified may be indicated. Implant teams may follow patients newly deafened by meningitis with serial imaging and implant at the first sign of replacement of the scala tympani with fibrous tissue or bone. Otherwise, implantation in cases of post-meningitic deafness is usually recommended after a six-month period to allow for the possible recovery of aidable hearing in at least one ear.

Children with active middle ear disease should be implanted with caution only after they have been free of middle ear infections.

ADULTS

Hearing loss is the third most common self-reported health problem in adults over the age of 65.[4] Although the most common cause of hearing loss in adults is noise damage, other causes include Ménière's disease, otosclerosis, temporal bone trauma, autoimmune hearing loss, and ototoxic drug exposure.

As in children, adult candidacy can only be determined after performing tests for speech recognition under best-aided conditions. If patients present to the cochlear implant team with inadequate or malfunctioning aids, a trial of more appropriate hearing aids should be undertaken before determining implant candidacy. There is no upper age limit for implantation.

After meeting the audiologic criteria for implantation outlined above, an adult desiring implantation should have an accurate understanding of the possible outcomes. When counseling patients, the implant team must stress the broad range of auditory experience achieved by cochlear implant users. Although rare, some patients may perceive only improved awareness of environmental sounds and improved speech reading ability. Others will be "transparent" users, able to converse with hearing individuals with little evidence of hearing loss, use a telephone, and perform well in other difficult hearing environments. Although increasing numbers of implant users perform like the latter group, most fall into an area between the two extremes.

One of the strongest predictors of performance include duration of deafness and age at implantation. Yet, as with children, these factors account for only part of the variance in cochlear implant performance.[5] Generally, patients implanted soon after the onset of profound hearing loss perform better than those implanted later. Other factors that favor good performance in adult cochlear implant candidates include lip-reading ability and residual hearing before implantation.[6,7] Poor prognostic indicators include implantation of patients as adults with hearing loss that occurred prior to the development of speech and patients who rely primarily on signing for communication.

As in children, imaging of the cochleovestibular structures prior to implantation is mandatory in adults. The MRI may detect cochlear malformations or ossification of the cochlea that mandate a change in the choice of which ear is implanted or the technique used. CT imaging may also be indicated based on the history, physical, and type of hearing loss.

Adults deafened by meningitis are treated in a similar manner to children. Because of the fairly high rate of recovery of hearing in at least one ear following meningitis, an observation period of at least 6 months should be allowed to pass before implantation. As in children, identification of incipient obliteration of the cochlea by fibrous tissue or bone may cause implantation to be recommended early. Thus, serial imaging may be indicated for surveillance.

SURGICAL TECHNIQUE

Because cochlear implantation increases the risk of meningitis, especially in children less than 6 years of age, the CDC recommends age-appropriate vaccination with a polyvalent anti-streptococcal vaccine at least 2 weeks prior to implantation.[8]

Similar to the indications for cochlear implantation, aspects of the surgical approach to cochlear implantation have changed over time while the outlines of implantation remain the same. This surgery is done with continuous facial nerve monitoring. A preoperative broad-spectrum antibiotic is administered.

Before prepping, the position of the implant is marked on the periosteum through the skin with methylene blue using the metal implant dummy as a guide. The C-shaped incision is made 5 mm behind the postauricular crease and carried to the level of the temporalis fascia superiorly. If the scalp is thick, a small curvilinear, posteriorly oriented limb is made in the superior part of the incision to allow for relaxation of the tissues. Often it is found that a minimal postauricular incision is adequate for exposure, but requires some adjustment in technique in creating a pocket to place the implant. Inferiorly, the incision is deepened to the subcutaneous layer while leaving the periosteal layer intact. The scalp is elevated posteriorly for 2 to 3 cm, leaving periosteal tissue intact. An incision in the periosteum is made superiorly along the temporal line and posteriorly at the edge of the mastoid bone, roughly outlining the defect that will be created. The periosteum is then elevated forward, with its broad attachment to the concha left intact to create a flap that will be used to cover the electrode array. This also allows a stepwise, layered closure to reduce the risk of electrode exposure in the unlikely event of wound dehiscence.

Unlike a mastoidectomy in chronic ear surgery where the edges of the mastoid cavity are "saucerized," the mastoid defect in cochlear implantation may be kept small and relatively tight with sharp edges to help retain the electrode in the mastoid cavity. Other differences in surgical technique for cochlear implantation include not needing to identify the sigmoid sinus and allowing some pneumatized bone to remain. It is also extremely useful to thin the bone on the posterior aspect of the posterior external auditory canal to facilitate drilling the facial recess and insertion of the implant electrode into the middle ear. The other aspects of the technique are similar to a "traditional" mastoidectomy such as identification of the tegmen tympani, fossa incudis, and horizontal semicircular canal.

The middle ear is exposed through a conventional facial recess approach, leaving a buttress between the incus and the facial recess (Figure 15–1). However, adequate exposure of the round window may require sacrifice of the chorda tympani nerve. Removing the incus and incus buttress allows exposure of the round window without loss of the chorda tympani nerve. With the increasing incidence of bilateral implantation, sparing the chorda will likely become a more important quality of life issue. The facial recess is enlarged as much as possible, while leaving a bony covering on the facial nerve.

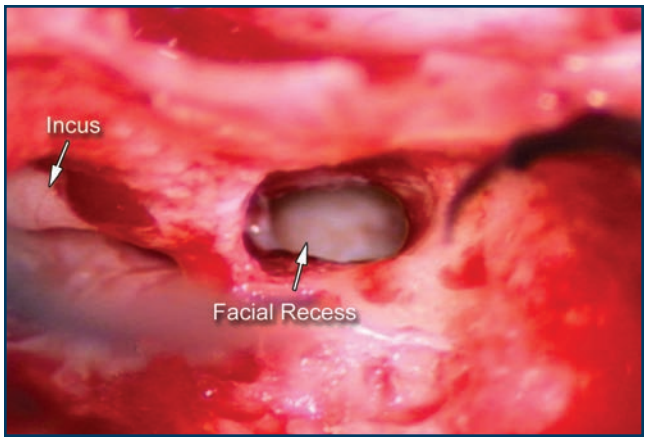

Figure 15–1. Right mastoidectomy with facial recess opened. Long process of incus points to the facial recess. Medial border is the facial nerve; lateral border is the chorda tympani nerve.

The cochleostomy is drilled anterior and inferior to the lip of the round window (Figure 15–2). The lip of the round window can be drilled away to facilitate localization. In patients with otosclerosis obliterating the round window or other anatomical variations that obscure its location, the round window can be found less than 2 mm from the inferior edge of the oval window. The cochleostomy should expose the *scala tympani* without breeching the basilar membrane. A cochleostomy roughly the size of a 1 mm diamond bur is performed to easily admit the electrode. The endosteum of the scala tympani is "blue-lined" and the membrane is opened with a pick. Alternative technique to cochleostomy may be an incision through the round window and direct placement through this opening. The angle and stiffness of the electrode may make this difficult to place in certain patients and with certain implant electrodes. Newer, smaller, and less rigid electrodes may make this easier in the future.

After drilling the cochleostomy, a pocket is made behind the mastoid to accept the implant and a well for the body of the implant is drilled, keeping the anterior edges of the well sharp to prevent forward migration of the implant. A crude but effective retractor for this purpose can be made by inserting the metal implant dummy in the pocket and using the Wietlaner retractor against the metal dummy to elevate the scalp. This, along with rotating the patient toward the surgeon, usually allows sufficient exposure of the site for the well without extending the incision. A trough is drilled extending from the cochlear implant well to the mastoid to allow the electrode to travel this path.

Although many surgeons use tie-down sutures anchored to periosteum of the surrounding skull or forego tie-down sutures entirely, the author uses 1-0 silk sutures through tie-down holes drilled in the bone. A simple way to do this is to use a cutting bur to drill troughs above and below the well and using the 1-mm diamond bur used for the cochleostomy to connect the troughs to the well; 2 holes above and 1 hole below are typically made to anchor the silk suture in three places. If a minimal incision and subperiosteal pocket is utilized instead, usually a single silk suture can be used to secure the implant in the subperiosteal pocket by tightening the tissue around the implant. Care is taken to place the knot of the suture on the side of the device so that there is no chance for erosion of the electrode.

After ensuring hemostasis in the operative field, the wound is irrigated with Bacitracin irrigation and meticulously cleaned of bone debris. The cochlear implant is opened onto the operative field. Monopolar cautery is disconnected to reduce the risk of shunting current through the cochlea if it is inadvertently used later. The electrode is inserted into the cochlea under direct vision (Figure 15–3). Several

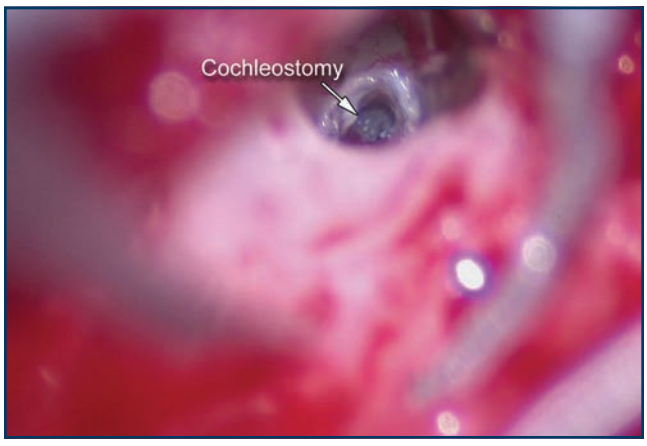

Figure 15–2. Left facial recess opened. Cochleostomy opened anterior and inferior to round window.

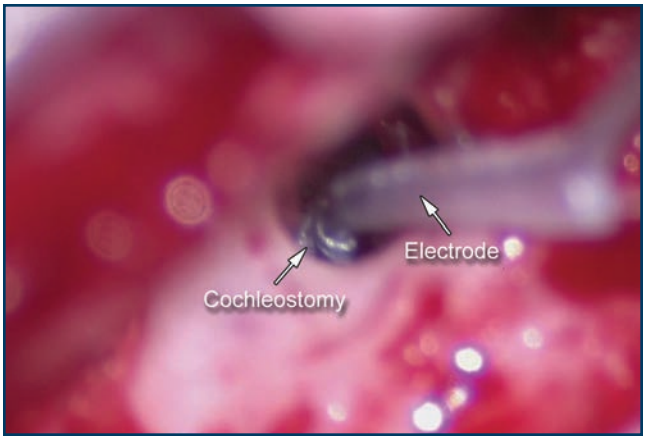

Figure 15–3. Left cochleostomy with cochlear implant electrode in place.