**Paparella: Volume II: Otology and Neuro-Otology**

**Section 3: Diseases of the Ear**

**Part 4: Inner Ear**

# Chapter 51: Cochlear Implants

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The ability to restore the special sense of hearing has been a miraculous step forward for medical science. Affecting the lives of over 200.000 hearing-impaired patients in the USA alone, cochlear implants have the potential to change the lives of many individuals and their families.

Two devices have been approved for general clinical application and are no longer considered experimental. Several other implant designs are undergoing clinical trials. The US Food and Drug Administration (FDA) has been charged with monitoring these devices and their application. Therefore, each device must meet certain standards of safety and efficacy prior to approval for clinical use.

## Theory of Application

Cochlear implants are electronic devices designed to detect mechanical sound energy and convert it into electrical signals that can be delivered to the cochlear nerve and interpreted by the patient. The components of this system are similar in all devices. A microphone accepts acoustic information and changes it into an electrical signal, which is transmitted to a speech processor. The signal is then coded and amplified in a fashion unique to each device to make it more "understandable". The signal is transmitted to an implanted electrode by a transcutaneous plug, radio frequency, or magnetic induction across the intact skin. Implanted electrodes can be placed extracochlear, intracochlear, or intraneurally.

All three implant designs seem to provide comparable patient performance, and histologic studies have demonstrated that even patients with few surviving neural elements (hair-cells and dendrites) are able to use a cochlear implant (Galey, 1984). These data together with other experimental and histologic evidence suggest that the site of stimulation in cochlear implantation is the spiral ganglion (Javell et al).

## Patient Selection

Patients who are properly motivated and trained derive maximum benefits from the use of a cochlear implant (Berliner, 1985). Congenitally deafened patients have not been able to derive the same effectiveness from an implant as those with the onset of deafness after language acquisition (Eisenberg, 1982). Probably because of the lesser derived benefits, congenitally deafened patients have a higher nonuser rate (Eisenberg, 1982). Thus, most implant programs

have focused on selection of these individuals more likely to derive greater benefit from the device.

Selection criteria vary from group to group, and the selection of individual patients is often based on individual factors. However, in general, the selection criteria listed below are used by most groups in the selection of appropriate candidates.

1. Eighteen years of age or greater.

2. Deafened after the acquisition of language skills.

3. Bilaterally deaf (pure-tone average thresholds of 95 dB or greater).

4. Unable to benefit from conventional hearing aids.

5. Good mental and physical health.

6. Motivation and patience to complete a rehabilitation program.

## Audiologic Criteria

An audiologic assessment is the primary means of determining implant suitability, and audiologic results are the most common reason for rejection of a candidate (patients often do better with a well-chosen hearing aid). Implant teams agree that cochlear implants are the prosthesis of choice only in patients with profound sensorineural hearing loss who cannot substantially benefit from conventional hearing aids. The definition of "substantial benefit from hearing aids" ranges from minimal benefit to not as much benefit as can reasonably be expected from an implanted ear.

As we have gained experience in the House Ear Institute program, we have redefined our audiologic criteria. The present audiologic battery consists of unaided and aided warble tone and speech detection thresholds, as well as a speech discrimination test and an environmental sounds test. The prospective candidate is evaluated with appropriate, powerful hearing aids. Performance in the poorer ear is compared to the mean, minimum, and the maximum in patients using the cochlear implant. Rather than using only the results of these criteria, we also judge the likelihood of the patient's performing better with an implant than with a hearing aid. Other factors regarding function with hearing aid use are considered; these are recruitment, discomfort, and refusal for whatever reason to use the aid.

If the patient cannot obtain an aided speech detection threshold of 70-dB sound pressure level (SPL) and a hearing level (HL) of approximately 53 dB or better, or if the patient performs very poorly on the discrimination tests with conventional amplification, the cochlear implant is likely to provide greater benefit. More than 50 per cent of the patients with implants have no response to the limit of the audiometer for warble tones in the speech frequencies when unaided.

With hearing aids, few have measurable thresholds beyond 2 kHz and some have no response at any of the speech frequencies. Many results are not clear cut, and the patient must make the decision regarding surgery. Some patients may benefit greatly from using a hearing aid in the better ear and the implant in the poorer ear (Thielmeir et al, 1982).

## Medical Evaluation

The medical examination includes a complete history and physical examination to detect problems that might interfere with the patient's ability to complete either the surgical or rehabilitative measures of implantation. Appropriate laboratory studies should be ordered to eliminate any suspected medical disorder.

A detailed radiographic examination of the temporal bone is indicated in each case. Complete agenesis of the cochlea or an abnormal internal auditory canal indicating possible cochlear nerve agenesis are contraindications for surgery. High-resolution computerized tomography can often detect ossification or fibrous occlusion of the cochlea or the round window. Although this does not exclude a patient from implantation, it may influence the choice of implant system. Patients with occlusion of the cochlea are at higher risk of not responding to electrical stimulation and may require substantially higher power output from the signal processor than patients with little or no bone growth (Eisenberg et al, 1984).

An electrical stimulation test is an important component of the preimplantation evaluation. A positive response is the perception of sound when either the round window membrane or the promontory is stimulated. We no longer feel that promontory stimulation is critical in the selection of candidates, because patients with a negative response, as well as a positive promontory test respond to intracochlear stimulation. However, the test often performs an important function by reassuring the patient that sound can be restored to the ear again. In the future, preoperative electrical testing may be used to determine what type of device is best suited for each patient.

## Devices

### Extracochlear Single-Channel Devices

#### London

The device designed by Douek and associates (1983) is a single ball electrode attached to an ear mold. It can be placed or removed by the patient as desired. It was designed specifically for those patients with a radical mastoid cavity where such an electrode can be placed directly on the promontory. However, by performing a myringopexy, the tympanic membrane can be placed against the promontory, and the device can easily be worn by others as well.

The speech processing strategy is relatively simple. The fundamental frequency is delivered to the electrode in a pulsatile manner. Thus, the device provides only the temporal clues

to phonation.

### Vienna

Two different single-channel electrodes, one intracochlear and one extracochlear have been designed by the Hochmair team (Hochmair and Hochmair, 1983). Both are designed to use the same signal processor. The extracochlear device is placed against the round window membrane with a ground wire secured in the temporalis muscle. The intracochlear device is inserted into the scala tympani via the round window. The signal from the processor reaches the electrode via a radio frequency induction coil.

The speech processor uses a broad-band analog of the speech waveform to the coil. A computer is used with patient input to program the equalization and compression applied to the speech signal by the processor. In Austria, occasional patients have been able to attain speech understanding using this device. Such results have not been reported in the USA.

## Extracochlear Multichannel Device

### Cologne

Banfai and colleagues (1984) and others have developed an 8-channel monopolar electrode array that can be placed on the promontory after extensive surgical modification of the middle ear cleft. The electrodes are arranged tonotopically with three electrodes at the basal coil, four adjacent to the middle turn, and one at the helicotrema. The signal processor uses an 8-frequency bandpass filtering scheme. Excellent results have been reported in Germany with this device, but it has not been employed widely elsewhere. Recently, Pulec (1987) described a substantially modified version of this device that could be inserted into the middle ear via the facial recess. Such a modification should make this device more widely applicable; currently, however, no patients have been implanted.

## Intracochlear Single-Channel Devices

### Los Angeles

The first device to be approved for clinical use in the USA, and the most widely implanted, is the House-3M device (Berliner and House, 1982). The device as currently manufactured consists of a single braided platinum wire inserted 6 mm into the scala tympani. In cases of cochlear obliteration by bone or fibrous tissues, the device can be inserted into a trough drilled into the promontory. The wire leads to a magnetic induction coil wrapped around a samarium cobalt magnet hermetically sealed in a titanium case.

The signal processing strategy uses a 16-kHz carrier signal that is amplitude modulated based on an analog signal filtered by a 0.2- to 4-kHz bandpass filter. Nearly all patients report better awareness of environmental sounds and improved speech reading skills with this device.

Recently, open set speech understanding has been reported (Berliner and Isenberg, 1986).

### Vienna

The intracochlear version of the Vienna device consists of a 4-channel array that is inserted up to 22 mm into the scala tympani. Only one of these electrode pairs is stimulated, based on patient preference. The same speech processor is used for both the intra- and extra-cochlear devices. No significant difference in patient performance has been attributed to either design.

### Stanford

Two different intracochlear designs are currently in use: a single-channel device and a multichannel bipolar device. Three different signal processing schemes have been described: a compressed broad-band analog signal, an augmented analog signal, and a pulsatile signal. The device has been in use in a limited number of patients at Stanford University only.

## Multichannel Devices

### Melbourne

One of the most complex devices available, the 22-electrode array of this device is inserted 23 mm into the scala tympani. The array tapers from 1 mm at the base to 0.6 mm at the tip. The internal coil consists of a radio-frequency antenna placed side by side with a magnet to hold the external transmitting coil in place. Signals are transmitted across the skin by radio-frequency induction. The internal coil contains a custom microchip that deciphers a digital pulsatile code transmitted by the speech processor.

The speech coding scheme uses a feature-extraction strategy. The first formant information is extracted from speech material and presented to the apical five to seven electrodes, and the second formant information is delivered to the basal electrodes. The rate of pulsation corresponds to the fundamental frequency. The place of stimulation along the array is determined by the frequency. Intensity of sound is coded as amplitude of the pulses. The array, strictly speaking, provides only single-channel information, as only one electrode pair can be active at a time. However, the rate of switching from one electrode pair to the next, which is one-tenth of a millisecond, allows stimulation of multiple neurons during the time course of any one action potential (Clark et al, 1983).

This device has been approved for distribution by the FDA, and a children's program is currently investigational. At the current time, over 170 patients have been implanted.

## Utah

The Utah device consists of an array of six electrodes 4 mm apart, four of which are designated as active electrodes. The array is 24 mm long, and is inserted into the scala tympani. A percutaneous plug is connected directly to the signal processor. All four active electrodes are referenced to a common ground, making this a monopolar system.

The speech encoding strategy uses a 4-channel band-pass filter, which corresponds to four equally divided portions of the speech spectrum. An analog signal is delivered directly to the electrodes, which are activated simultaneously. The performance of patients with the Utah or the Melbourne device have been reported to be similar. In noisy situations, however, patients with the Utah device seem to retain better speech understanding (Eddington et al, 1978).

## San Francisco

The device designed by the San Francisco team is a 16-electrode, 8-channel electrode array, which is premolded to fit an idealized cochlea. It is inserted 25 mm into the scala, where the electrodes lie in close contact with the osseous spiral lamina, and thus the remaining dendrites of cranial nerve VIII. The electrodes are connected to a four-antenna receiving array. Each channel is fully independent and electrically isolated, allowing for full simultaneous, synchronous stimulation. The external antenna array is held in place by matching magnets in the internal and external devices.

The speech processing strategy uses an analog band-pass filter system. The speech frequencies are divided according to the first formant (0.2 to 0.8 kHz), second formant (0.8 to 2.5 kHz), and third formant and higher information (2.5 to 6 kHz). The electrode pairs are distributed with the apical electrode receiving first formant, the middle two receiving second formant, and the basal electrode receiving third and higher information. All four channels may be stimulated in both a simultaneous and synchronous fashion.

## Paris

The 12-electrode system developed by Chouard and associates requires the accomplishment of a radical mastoidectomy. Fenestrae are drilled throughout the length of the cochlea where individual electrodes are placed and insulated by Silastic. A 12-channel bandpass filter system is used to deliver information to the various electrodes. Only one electrode is stimulated at a time with all other electrodes acting as a ground. The parameters of stimulation, pulse voltage, frequency, and duration are all variable.

## Surgical Technique

The technique for the placement of the cochlear implant devices currently available in the USA is similar to techniques developed for the treatment of chronic ear disease. In addition, a large postauricular skin flap must be developed to provide coverage for the internal coil of the

device. This flap must be large enough to provide coverage for the coil with a margin to prevent extrusion of the device.

The seat for the coil is created in the squamous portion of the temporal bone, immediately posterior and superior to the mastoidectomy site. This should be deep enough to prevent the implant from tenting the skin. Occasionally, dura may be exposed in the bottom of the seat without complication.

A simple mastoidectomy is completed. The posterior canal wall should be thinned as much as possible to maximize exposure of the round window. The facial recess is opened, being careful to maintain a shell of bone over the facial nerve to protect it. The chorda tympani is a good landmark of the eardrum annulus, since the chorda enters the middle ear at the annulus level. If access to the facial recess is restricted, occasionally it is necessary to remove the chorda in order to adequately visualize the round window niche.

Once the facial recess is opened, the lip of the round window niche is usually visible just inferior to the stapedius tendon and the head of the stapes. With a small diamond stone and intermittent suction irrigation, the lip of the niche is removed, and the round window membrane comes into clear view. To avoid possible damage to the facial nerve, the diamond stone must not be rotating when passing through the facial recess to the round window. In cases in which the round window niche is almost hidden under the pyramidal process, one must drill forward and thin the promontory until the scala tympani is entered.

In occasional cases, the round window niche and membrane are replaced with new bone or fibrous tissue. This condition is more frequent in patients whose deafness is attributable to meningitis rather than to other diseases. In these cases, the surgeon must drill forward along the basal coil for as much as 4 to 5 mm. If the white plug of bone that looks different from the surrounding otic capsule is followed, it usually leads to a patent scala tympany that will permit placement of the active electrode. Complete ossification of the cochlea may be a contraindication for the use of a sophisticated electrode array, which requires an insertion of 15 to 25 mm.

This same procedure is applicable to children (Lusford and House, 1985). The cochlea is of adult size at birth and, in general, so are the middle ear, eardrum, and ossicles. Surgical dissection of skulls obtained from newborn infants through children aged 48 months has shown that by 24 months the facial recess is of adult size and that the mastoid antrum and air-cells are well developed. Therefore, access to the round window and placement of the electrode should not be difficult. However, the squamous part of the temporal bone is small and only 2- to 3-mm thick, and the scalp is thin, complicating the placement of the internal receiver.

## Complications

The risks of the procedure are the same as those for chronic ear surgery; infection, facial paralysis, cerebrospinal fluid leakage, meningitis, and the risks of anesthesia. All of these risks are remove in chronic ear surgery and have proven to be so in implant surgery as well.

The possible effects of the implant on the vestibular system and on tinnitus have been evaluated by clinical monitoring, patient questionnaire, and objective study. There is no evidence that the implant has any significant negative impact in any of these areas (Eisenberg et al, 1982).

## Revision Surgery

There are two reasons for revision surgery: (1) to replace a failed device and (2) to upgrade a system. Currently, the major systems available in the USA have all been removed and replaced, without difficulty, with another device either of the same design or of another design. The problems of degeneration of the remaining viable neural elements due to mechanical trauma, osteoneogenesis, degeneration of remaining neural tissue due to electrical stimulation, and spread of infection from the middle to the inner ear or brain have not occurred (Berliner et al, 1985).

## Patient Benefits Derived From Cochlear Implantation

Initially, when offering cochlear implantation to the first patients, all that could be hoped for was to put the patient back in touch with his environment in a remote fashion. Patients spend days in the laboratory helping to design bench-size stimulators that have them a type of auditory awareness. When the House-3M single-channel cochlear implant was approved for clinical use, the educational materials that accompanied the training courses described the device as "an aid to lip reading" and a "guide to environmental sounds". Patients were counseled that the goal of implantation was to improve their ability to lip-read, but not to be able to hear normally again. Many patients described such benefits, but added anecdotal stories. Patients heard ambulance sirens and thus avoided becoming victims of accidents; others were able to hear their children cry for help and express sounds of joy. Such emotional benefits and the relief of the isolation of deafness are difficult to quantify in an objective sense.

At the First International Symposium on Cochlear Implants in Melbourne, Australia in August, 1985, it became clear that true speech understanding could be expected of occasional patients wearing multiple-channel devices. With the Melbourne first and second formant signal processing strategy, and with the Utah device, this result may be expected in up to one-third of patients. Recently, in Los Angeles, children wearing single-channel devices for longer than 3 years have demonstrated speech understanding comparable to that achieved by multichannel implant users.

Today, when counseling patients, the physician can describe the benefits of cochlear implantation much more concretely than he could even 1 year ago. Patients will become more in touch with their environment and lose the sense of isolation that deafness often brings. They will be able to hear and often recognize many warning signs in the environment. Speech, especially with lip-reading, will become much more intelligible. Male and female speakers will be recognized, and the voice of a particular friend may become familiar. Occasional patients may also be able to regain true speech understanding with little visual assistance.

## Directions in Cochlear Implantation

The immediate future of cochlear implantation appears to belong to the children. The House Ear Institute Center for Deaf Children has been involved in the implantation of children with profound hearing losses since 1980. As of 1987, more than 200 children have been implanted. The youngest child was 2.5 years of age at the time of implantation and had been deafened by meningitis. Nearly two-thirds of the currently implanted population lost their hearing due to meningitis. Other causes include trauma, ototoxicity, rubella, heredity, and unknown causes.

The impact of profound deafness on the young child has overwhelming consequences for the long-term quality of life. It is estimated that by the age of 5, a hearing child has a vocabulary of 5000 to 26.000 words and is using these words in grammatically correct sentences. In contrast, a deaf child at age 5 has usually acquired a speaking vocabulary of nor more than 200 words, with little understanding of how to structure a sentence (Schwab, 1977). These skills rapidly deteriorate after the onset of deafness in children with speech and language skills, particularly if the loss occurs at or before 3 years of age.

Given the impact of deafness, the potential benefits of implantation should be significant. The implant can provide auditory thresholds that allow the profoundly deaf child to detect speech and environmental sounds. The implant can also provide timing and intensity information. Prosody is known to play an important role in the early development of speech and language.

Results with implanted children are particularly encouraging in that improvements in speech production continue to occur over time for both the nonsegmentals (prosodics) and the segmentals (vowels and consonants). These improvements are particularly significant in those children implanted during the preschool years (Kirk and Hill-Brown, 1985). Auditory discrimination test scores, likewise, continue to show improvement over time. For several select children, auditory performance may even be exceeding what has been observed to date in adults using the House-3M cochlear implant. At least two children have demonstrated some evidence of "open-set" speech recognition for phonemes, words, and simple phrases. This implies that children have the potential to derive maximal use from the implant. We can conclude from this experience that performance by adult patients may not accurately predict the potential abilities of children and we should not limit our expectations on that basis.

Currently, clinical trials of the Melbourne 22-channel device have begun in postlingually deafened children 2 to 10 years of age and 10 to 18 years old. A program for pre- and perilingually deafened children is in the initial stages of patient acquisition. These programs remain investigational and are limited to a few centers at the current time.

## Conclusion

For the first time in history, we are able to restore one of the special senses: hearing. The implication of this momentous event are enormous and will impact nearly 200.000 hearing-impaired Americans. Several devices are able to restore some speech understanding to groups of users, but the means of predicting implanted performance are elusive. Improved devices and better speech processing strategies will likely improve patient performance. The greatest application of these devices appears to be in children, who will continue to amaze us with the benefits derived over a lifetime.