
Technology Assessment Report

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Technology Assessment

Cochlear Implants

Prepared under the direction of the
Technology Assessment Committee
James C. Smith, Chairman
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Abstract

Description of Treatment/Procedure

The cochlear implant is a neural prosthetic device which processes sound stimuli into electrical stimulation of the auditory nerve. The brain interprets these electrical signals as sound, thus enabling the person to hear.

Efficacy of Treatment/Procedure

Cochlear implants offer a wide spectrum of hearing benefit. Some implant patients report hearing only sounds such as sirens or slamming doors. Others say that voices they knew before they were deaf sound much the same after having a multichannel implant.

Indications

The cochlear implant is intended to restore a level of auditory sensation via the electrical stimulation of the auditory nerve in adults (age 18 years and older) who have post-lingual, profound sensor neural deafness and in pre- and post-linguistically deaf children (age 2 to 17 years) who cannot significantly benefit from appropriate amplification by a hearing aid.

Contraindications

The cochlear implant is contraindicated when the patient has an active middle ear infection, deafness due to lesions of the acoustic nerve or central auditory pathway, cochlear ossification, absence of cochlear development, or tympanic membrane perforation.

Summary

Cochlear implantation is an evolving technology with advances being made in the electrodes, speech processors, and surgical techniques. It is approved by the FDA for adults and children, and by Medicare for adults. In the properly selected individual there can be substantial lifelong benefit where no alternative treatment is available today.

Institute for Clinical Systems Integration

Technology Assessment

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TA #1

Originally done April, 1990
by the Group Health Inc. Technology Assessment Committee

Revised May, 1993
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Committee Summary

The ICSI Technology Assessment Committee finds that, for the properly selected individual, cochlear implants can give a substantial lifelong benefit where there is no alternative treatment available today.

Scientific Criteria

- Scientific evidence supports the conclusion that cochlear implants affect health outcome in a measurable and positive way.
- The health benefits from cochlear implants may be obtained in a normal clinical setting.

Treatment Alternatives

- Currently, there are no alternative forms of treatment to restore some sound recognition for selected postlingually deaf adults.

Government Approval

- The House device (single channel) was approved by the Food and Drug Administration (FDA) for use in adults in 1984. The Nucleus device (22 channel) was approved for use in adults in 1985, and in children in 1990. The Ineraid (4 channel) device was approved for use in adults in 1989.

Description of Treatment/Procedure

Developed in the 1960s, the cochlear implant is a neural prosthetic device which processes sound stimuli into electrical stimulation of the auditory nerve. The brain interprets these electrical signals as sound, thus enabling the person to hear (see Diagram 1, below).¹ Of the 15 million persons in the United States with significant hearing impairment, fewer than 1% are considered potential candidates for a cochlear implant.²

The apparatus consists of four functional components (two external and two internal):

Internal:

- Signal transfer hardware
- Electrode

External:

- Microphone
- Speech processor

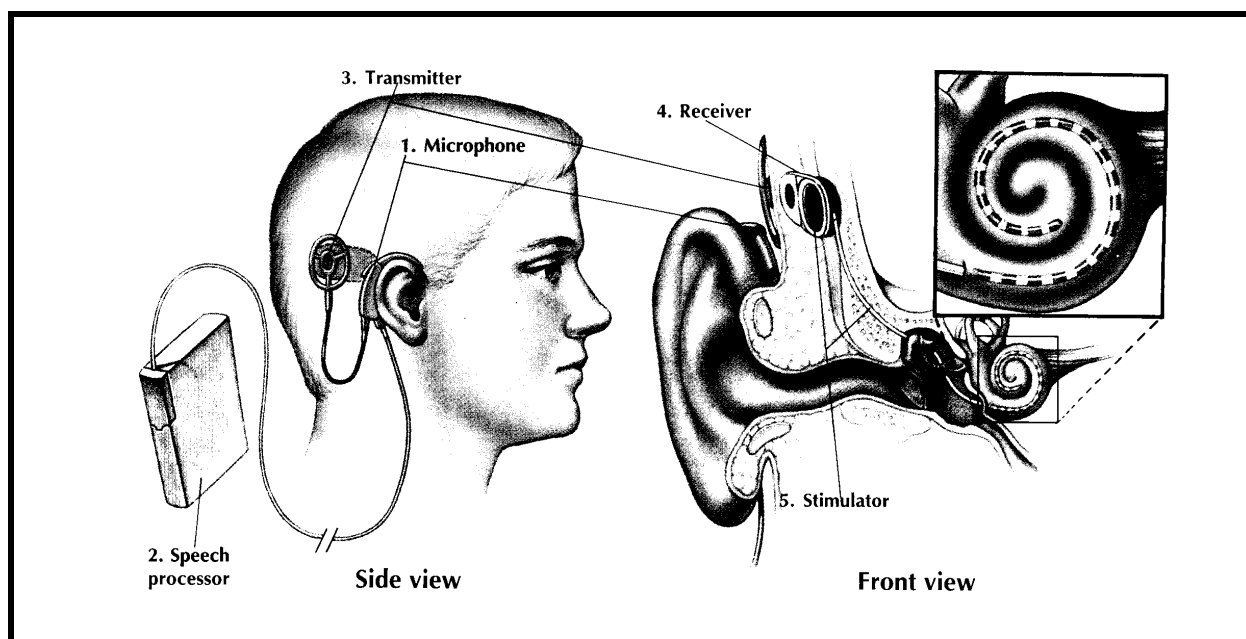
The signal transfer hardware and electrode are surgically inserted beneath the skin, above or behind the ear. The microphone is worn in the shirt pocket or on the belt. The speech processor is worn behind the ear on a small, lightweight headset. It sorts out and processes the frequencies most important to speech comprehension helps exclude background noise. As the electrodes have become more complicated, the external speech processor unit has become more sophisticated and smaller.

In the simplest device, the electrode is implanted outside the cochlea on the round window and transmits through one channel or several channels. The single channel machines are not marketed

much in the U.S. because the multiple channel machines have been shown to be far superior except in certain situations.³

Approximately 300 to 500 cochlear implant procedures are performed each year in the United States. A small but growing number are being performed as outpatient procedures, and Medicare has recently added cochlear implantation to its list of covered surgical services provided at ambulatory surgical centers. There is no evidence that any cochlear implant operation has been performed in an ambulatory surgical center.⁴

Diagram 1: How a Cochlear Implant Produces Hearing.



Efficacy of Treatment/Procedure

Cochlear implants offer a wide spectrum of hearing benefit. Some implant patients report hearing only sounds such as sirens or slamming doors. Others say voices they knew before they were deaf sound much the same after having a multichannel implant.⁵

Environmental Sounds

One important benefit to implanted patients is their ability to recognize environmental sounds. One of the first things implanted patients note after receiving their implant is the enriching exposure to simple background sounds like running tap water or the hum of the refrigerator.

According to a study by Tyler and Lowder⁶ of 65 postlingually deafened adults, patients with House, Nucleus, and Ineraid implants were able to distinguish among environmental sounds (e.g., a dog barking, a baby crying, a plate breaking) 24%, 35%, and 47% of the time, respectively.

Intonation and Intensity

Tyler and Lowder also studied the ability of cochlear patients to detect the changes in intonation and intensity patterns that reflect the numbers of syllables, accent, inflection, and emotion. Although some patients, with all three devices, did not score above chance on tests of this type, on average, there was considerable improvement in this category.

Hearing in noise

Understanding speech in noise is a problem for most cochlear-implant patients, according to the same study. Further development of noise-suppression circuits is needed.

Lipreading Enhancement

All patients studied by Tyler and Lowder showed an improvement in their lipreading scores when using their cochlear implant. The study found that the more information patients received in audition-only conditions (without vision), the larger was their lipreading enhancement.

Word Recognition Alone and in Sentences

Patients were able to recognize words in isolation an average of 1%, 17%, and 12% of the time for House, Nucleus, and Ineraid implants, respectively. Word recognition, when in the context of a sentence, was considerably better: 7%, 46%, and 41%, for subjects with House, Nucleus, and Ineraid implants. The range of performance across patients was striking. Many patients scored 0% correct and several patients scored over 80% correct. It is this vast difference among patients that remains a puzzle to researchers and prevents clinicians from providing accurate predictions to prospective patients about the efficacy of cochlear implantation.

According to a 1989 NIH Consensus Statement on cochlear implants, it was determined that the profoundly postlingually deaf may obtain certain benefits from cochlear implants.⁷ These include:

- Better contact with environmental sounds including telephone ringing, alarms, and household/natural sounds;
- Awareness of when a person is speaking;
- Assistance in lip reading;
- Assistance in voice modulation.

Some patients may progress to a considerable degree of open (random) speech and sound recognition. At a minimum, the implant may help the profoundly deaf to be in closer contact with their environment, can provide warning of danger, and may improve communication with others.

Implant patients are able to detect medium to loud environmental sounds and conversational speech at comfortable listening levels. The device provides improvement in speech recognition with lip reading (aids in the acquisition and improvement of speech reading skills). For a few patients, the device provides limited improvement in speech recognition without lip reading and limited improvement in the recognition of environmental sounds.⁸

In regard to intellectual functioning, a 1990 study by Haas found that improvements in social information and ability to discriminate details are most prominent. The results of this study are consistent with patients' reports that the implant allows them to participate in conversations more readily, to correct misinterpretations, and to gather more information, even if they are simply asking questions about reading that they have done.⁹

The number of elderly cochlear implant recipients has increased since Medicare approval of the device. According to a 1991 survey by Horn *et al* of elderly users of the device, elderly patients obtain similar benefits to younger patients who were implanted with the same device.¹⁰

A recent study by Osberger *et al*¹¹ showed that children with early onset of deafness showed more improvement in speech intelligibility if they received their device before age 10.

Indications

The cochlear implant is intended to restore a level of auditory sensation via the electrical stimulation of the auditory nerve in adults (age 18 years and older) who have post lingual, profound sensor neural deafness and in pre-and post-linguistically deaf children (age 2 to 17 years) who cannot significantly benefit from appropriate amplification by a hearing aid.

Patient criteria include:

1. If adult, the patient must be post-lingually deaf;
2. If a child, the patient must be older than two years of age;
3. The patient's deafness cannot be mitigated by the use of a hearing aid;
4. The patient's auditory cranial nerves can be stimulated;
5. The patient must have the cognitive ability to use auditory clues;
6. The patient must be evaluated as psychologically and motivationally suitable to undergo an extended program of rehabilitation;
7. The patient must have freedom from middle ear infection;
8. The patient must have an accessible cochlear lumen that is structurally suited to implantation;
9. The patient must be free from lesions in the auditory nerve and acoustic areas of the central nervous system.

Contraindications

1. Deafness due to lesions of the acoustic nerve or central auditory pathway;
2. Active middle ear infection;
3. Postoperative radiographic evidence indicating cochlear ossification (which precludes electrode insertion) or the absence of cochlear development;
4. Tympanic membrane perforation.

Risks and Limitations

The surgery for placement of the implant may traumatize the cochlear endosteum and initiate new bone growth, which has the potential for damaging surviving neural elements and for complicating any replacements of the device. There is no present evidence to suggest that implanting the device causes an increase in the spread of infection from the middle ear to the inner ear. There is, however, a risk of post surgical infection at the site of the skin flap behind the ear and of a failure of the flap to heal normally, which could necessitate removal of the device. The operation also may damage the facial nerve or the vestibular system. Use of the implant may interfere with the use of residual hearing cues from the other ear or other modalities. More data are necessary to evaluate the potential deleterious effects of low currents used over long periods or of local heating effects due to high current densities as could be generated by alternative implant designs.¹²

A recent clinical review by Cohen and Hoffman of the surgical experience of 696 adults and 309 children in the United States found that there have been no deaths attributable to the implantation of these devices, few serious major complications, and relatively few minor complications.

Complications were less frequent in children than in adults but were more likely to occur in younger children than in those older than seven years of age.¹³

According to a 1990 study by Haas, the Ineraid cochlear implant does not appear to produce harmful psychological effects in patients who use it for an extended period of time. However, patients who do not achieve increased speech discrimination with the device, either because of mechanical failure or because of other reasons, are at higher risk of psychological dysfunction. Patients whose likelihood of benefiting from the device is questionable may be at increased risk of experiencing pathological levels of depression, resentment, and discouragement if they do not achieve good results.¹⁴

Since the implants are relatively new devices, breakdowns occur often. Patients can expect problems with their device about 2-3 times per year. The repair problems include external processor malfunction, breakages and occasionally internal implant failures.

Recent research indicates that cochlear implantation should pose a contraindication to the magnetic resonance imaging process. This conclusion is based on several findings of in vitro testing of three cochlear implants: the 3M/House and 3M/Vienna designs and the Nucleus device. Specifically, tremendous torques are generated by each of these devices when they are introduced into the coil of a magnetic resonance imager; in addition, the 3M products not only were noted to induce an electrical current, but also were significantly magnetized and rendered afunctional.¹⁵

Alternative Forms of Treatment

Currently, there are no alternative forms of treatment available to restore some sound recognition for selected postlingually deaf adults.

Costs

The cost for the device with surgery including post-transplant rehabilitation is estimated to be approximately \$33,000.

The University of Iowa charges are as follows:

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|---|-----------------|
| Preoperative evaluation | \$ 700 |
| Surgeon's fee | 5,590 |
| Nucleus device | 18,400 |
| Hospital stay (including fees for anesthesiologist and radiologist) | 6,800 |
| Rehabilitation and follow-up | <u>900</u> |
| Total | \$32,390 |

One month after surgery, the external parts of the implant are mapped to the individual needs of the patient and are connected to the internal parts. To insure that patients can use the new sounds provided by the implant, extensive rehabilitation and follow-up is required.

Experience

HMO Group

A 1990 survey of THMOG plans shows a variety of policies. The procedure was not covered at GHC -PS, GHI-MN, CHCP-New Haven, HCP-Buffalo, ANCHOR, and HSMC-Syracuse. Intergroup of AZ excluded the procedure specifically in contract. The following plans covered the procedure for adults and children: CHP-Albany, Fallon Community HP, HIP/Rutgers, RIGHA, and Harvard.¹⁶

MedCenters Health Plan

MedCenters Health Plan approved coverage for cochlear implants for children only on 9/1/89. In 1992, cochlear implants were included as a specific benefit in the Certificate of Coverage with a 20% co-pay. Prior authorization by the Plan Medical Director is required. In October of 1992, a cochlear implant was approved for one MedCenters patient, age 6. The patient has not yet received the implant.

Another MedCenters patient, age 3, had cochlear implant surgery in October 1992, followed by several implant programming sessions at the University of Iowa in December of 1992 - February of 1993. The implant at the University of Iowa was not covered by MedCenters since the implant was available through a contracted provider. In March of 1993, however, speech/language treatment and auditory training were initiated, and was covered 100% by MedCenters. The patient currently has two individual 30-minute sessions of speech/language therapy each week.

Group Health, Inc.

As of March, 1990, GHI had a specific exclusion from the Minnesota Department of Health (MDH) not to cover cochlear implants. However, in June 1990, the FDA approved the multichannel device for the treatment of pre- and post-linguistically deaf children between the ages of 2 and 17. (Cochlear had been marketing the device in post-linguistically deafened adults since 1985.) At this time, GHI Technology Assessment Committee decided that it needed to recognize that the technology was no longer considered experimental. However, coverage did not change until 1992, when GHI reversed its coverage policy. In 1992, GHI approved coverage for one patient.

Summary

Cochlear implantation is an evolving technology with advances being made in the electrodes, the speech processors, and surgical techniques. It is approved by the FDA for adults and children, and by Medicare for adults. In the properly selected individual there can be substantial lifelong benefit where no alternative treatment is available today.

¹Mayo Clinic Health Letter, November 1991.

²Consensus Development Panel. National Institutes of Health Consensus Development Conference statement on cochlear implants. *Arch Otolaryngol Head Neck Surg.* 1989 Jan.; 115(1): 31-6.

³The HMO Group: *Teminex Report Study #87: Cochlear Implants.* February 28, 1991.

⁴Erlichman M, and Holohan, TV: Cochlear Implantation in Outpatient Settings. *Health Technology Review.* Rockville, MD: Agency for Health Care Policy and Research. Office of Health Technology Assessment. August 1992.

⁵Mayo Clinic Health Letter, November 1991

⁶Tyler RS and Lowder MW: Audiological management and performance of adult cochlear-implant patients. *Ear Nose Throat J.* 1992 Mar; 71(3):117-22, 125-8.

⁷Consensus Development Panel: Jan, 1989.

⁸Consensus Development Panel: 1989.

⁹Haas LJ, Psychological safety of a multiple channel cochlear implant device. *International Journal of Technology Assessment in Health Care.* 1990; 6(3): 421-9.

¹⁰Horn KL, McMahon MB, McMahon DC, Lewis JS, Barker MS, and Gherini S: Functional Use of the Nucleus 22-Channel Cochlear Implant in the Elderly. *Laryngoscope.* March 1991, 101:284-288.

¹¹Osberger MJ, Maso M, Sam LK: Speech intelligibility of children with cochlear implants, tactile aids, or hearing aids. *J Speech Hear Res* 1993; 36(1): 186-203.

¹²Consensus Development Panel: 1989.

¹³Cohen NL, Hoffman RA: Complications of cochlear implant surgery in adults and children. *Ann Otol Rhinol Laryngol.* 1991; 100:708-711.

¹⁴Haas, LJ: 1990.

¹⁵Portnoy WM, Mattucci K: Cochlear implants as a contradiction to magnetic resonance imaging. *Ann Otol Rhinol Laryngol* 1991, 100(3):195-197.

¹⁶The HMO Group: February 28, 1991.