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ABSTRACT

This paper reports the results of a Consensus Development Conference on Cochlear Implants sponsored by the National Institutes of Health to improve the hearing of children and adults with hearing impairments. The following questions are addressed: (1) Who is a suitable candidate for a cochlear implant? (2) What are the advantages and disadvantages of the different types of cochlear implants? (3) How effective are cochlear implants? (4) What are the risks and limitations of cochlear implantation? (5) What are the special considerations for children? and (6) What are the important directions for future research? The paper points out the importance of considering audiological, electrophysiological, medical surgical, psychophysical, psychological, and linguistic criteria in selecting suitable candidates. It outlines features of intracochlear, extracochlear, single channel, multichannel, feature-extraction, and non-feature-specific systems. The difficulty in predicting the outcome for a particular person is emphasized, but general expectations are suggested. Risks involved in cochlear implantation include medical complications, interference with residual hearing cues from the other ear, and possible corrosion of platinum electrodes. Limitations, such as refraining from contact sports, are also noted. Discussion of special considerations for children focuses on criteria for success, the minimum trial period, long-term prosthesis-tissue interactions, and other factors. Members of the consensus development panel are listed. (JDD)

Cochlear Implants

National Institutes of Health
Consensus Development
Conference Statement

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Since the development of cochlear implants in the 1960s, more than 3,000 persons—children and adults—have been implanted with a variety of these devices. Controversy exists on several issues, including determination of appropriate candidates, selection of a single-channel or multichannel device, suitable preimplantation and postimplantation assessments, and rehabilitation procedures.

Some reports have claimed a spectacular return of hearing in deaf persons with cochlear implants. Unfortunately, to date, no person can be documented to have had normal hearing restored by this device. On the other hand, the cochlear implant does provide significant benefits for some in a variety of ways.

Currently, we do not have the degree of understanding of disease mechanisms and disorders of function for hearing disorders that is common to other human organs and functions. This is partly because the organ of hearing is encased in bone and cannot be visualized during life. In addition, there are only limited numbers of qualified laboratories and scientists to prepare and evaluate specimens obtained after death. These methods are the essentials by which great strides have been made for disorders of other organs and systems.

Further, in our efforts regarding disorders of communication, particularly those related to language, we must not discount possibilities of new medical, surgical, and technological methods.

The charge of this panel, however, is appropriately restricted to the development of a consensus regarding five questions related to cochlear implants. These are addressed separately for adults and children because of special considerations necessary for the developing child. (A section on special considerations for children follows the fourth question.)

- Who is a suitable candidate for a cochlear implant?
- What are the advantages and disadvantages of the different types of cochlear implants?
- How effective are cochlear implants?
- What are the risks and limitations of cochlear implantation?
- What are the special considerations for children?
- What are the important directions for future research?

To address these questions the National Institute of Neurological and Communicative Disorders and Stroke and the Office of Medical Applications of Research of the National Institutes of Health convened a Consensus Development Conference on Cochlear Implants on May 2-4, 1988. Cosponsors of the conference were the National Institute on Aging and the National Institute of Child Health and Human Development of the National Institutes of Health, the Food and Drug Administration, and the Veterans Administration. After a day and a half of presentations by experts and discussion by the audience, a consensus panel drawn from specialists and generalists from the medical profession and related scientific disciplines, clinical investigators, and public representatives considered the evidence and came to the following conclusions.

The National Institutes of Health urges that this summary statement be posted, duplicated, and distributed to interested staff.

1.

Who is a suitable candidate for a cochlear implant?

Of the 15 million persons in the United States with significant hearing impairment, less than 1 percent are potential candidates for a cochlear implant. The selection of a specific person for a cochlear implant is not straightforward. There are no strict standardized criteria for accepting or rejecting a candidate. Traditionally, the cochlear implant subject has been a postlingually deafened adult who met certain audiological, medical, and psychological criteria, which differed partially from one implant team to the next. In general, it was considered crucial that the subject show no residual hearing (total hearing loss) and no significant benefit from a conventional hearing aid. These seemingly straightforward criteria did not always work well in practice, and there emerged different definitions of "residual hearing" and "significant benefit from a hearing aid." Needs and wishes of individual subjects are also significant variables for implant candidacy. Finally, the issue of candidacy is further complicated because it has not been possible, preoperatively, to predict success with a cochlear implant in a specific person.

Recognizing the uncertainty about the operational meaning of "residual hearing" and "successful hearing aid use," potential conflicts between subjects' wishes and objective criteria, and the absence of prognostic tools with regard to specific implants, the following discussion attempts to specify characteristics of adults who are potential users of cochlear implants. Because of the lack of data predicting the success of implants, the following stringent criteria are suggested:

- **Audiological Criteria.** Indications in favor of an implant are a profound sensorineural hearing loss bilaterally, aided thresholds greater than 60 dB HL, 0 percent correct on open-set speech recognition, and a lack of substantial increase in lipreading with an appropriately fitted hearing aid.
- **Electrophysiological Criteria.** Measurement of electrical auditory brainstem responses as well as of middle and long-latency evoked potentials should be a basic component in candidate selection. The absence of neural responses to electrical stimulation may or may not prove to be a contraindication.
- **Medical Surgical Criteria.** The usual candidate is a healthy, postlingually deafened adult. The medical history, physical examination, and laboratory tests are used to include or exclude candidates and to assist the implant team in planning a total program, including auditory training.

  There are a number of possible complicating factors, including anatomical features, that affect implantation of the device: previous stapedectomy, temporal bone fractures, ossification of the cochlea, and congenital anomalies such as absence of the cochlea or auditory nerve. The question of candidacy should be reevaluated after preexisting ear problems such as eustachian tube dysfunction, chronic ear disease, and cholesteatoma have been treated.
- **Psychophysical Criteria.** Although a number of psychophysical data are available on implant subjects (temporal integration, gap detection, forward masking, pitch, loudness), none are considered critical in the candidacy issue. Rather, psychophysical data are critical to issues of efficacy and implant design. To date, preoperative psychophysical performance has not been a good predictor of speech recognition performance.
- **Psychological and Linguistic Criteria.** With respect to candidacy, most psychological testing is done for exclusionary reasons, usually mental retardation and psychiatric disorders.

The Issue of New Criteria for Cochlear Implant Candidacy

The field of cochlear implantation is changing rapidly, particularly technology, assessment procedures, and the significant firsthand experience by several groups of dedicated clinical investigators. One major result, which seems particularly noticeable as multichannel implants become more common, is exceptional performance by a small percentage of implantees on open-set tests of speech recognition. These results are truly encouraging and raise theoretical and practical questions. One theoretical question is "What is the upper limit on performance by cochlear implantees on open-set tests of speech recognition?" A practical question concerns the

possibility for revising the criteria for candidacy.

Consider the following example. A subject obtains open-set performance of 10 percent with a conventional hearing aid, and the expected (mean or median) performance for similar subjects with a particular implant is 38 percent. Is the subject a suitable implant candidate? This question has several important ramifications. Revision of current criteria should be considered only after a rigorously controlled trial with a small, select group of persons has been completed. Such rigor is required because of the unpredictability of success with an implant and the possibility of decreased performance in persons who have measurable preoperative open-set speech recognition.

2.

What are the advantages and disadvantages of the different types of cochlear implants?

Cochlear implants can be categorized in at least three important ways. Electrodes may be inserted either within the cochlea **(intracochlear)** or placed outside the cochlea **(extracochlear)**; the signals may be transmitted through either one channel **(single channel)** or several independent channels **(multichannel)**; and only certain features of the speech signal may be transmitted **(feature-extraction)**, or the input signal may be transmitted to the electrodes without extracting specific speech cues **(non-feature-specific)**. These methods of categorization are the most important.

Cochlear implants also may be categorized according to the types of electrodes used (e.g., monopolar, bipolar), method of stimulation (e.g., pulsatile, continuous), or signal transmission through the skin by wires (using a percutaneous plug) or by electromagnetic means.

In an extracochlear implant, the electrodes may be attached to the round window niche or, in some cases, to the promontory. Single-channel stimulation is more common in this form of implant. In an intracochlear implant, an electrode or electrode array is inserted into the cochlea. For multichannel operation, the electrode array is usually inserted quite deeply into the cochlea (toward the apex), whereas for single-channel operation, a short single-channel electrode that does not extend beyond the first bend in the cochlea can be used. Multiple electrode arrays have been developed with as many as 22 electrodes that can be stimulated independently. Speech-feature processing typically involves extraction of the voice-fundamental frequency, formant frequencies, and determination of whether the speech sound is voiced or voiceless. In non-feature-specific processing, the signals are usually transmitted directly to the electrodes without radical transformation. In a multichannel system of this type, known as a filter-bank system, signals in different frequency bands are transmitted separately to different electrodes.

Extracochlear stimulation, in contrast to intracochlear stimulation, has the advantage that the procedure does not invade the cochlea and is reversible. The disadvantages of extracochlear stimulation are narrower dynamic range, higher current density, and, concomitantly, a greater potential for stimulating other neural tissue, possibly resulting in facial nerve stimulation or vertigo. An additional concern is maintaining long-term contact between the external electrode and the round window or promontory.

The major advantages of intracochlear stimulation are relative ease of placement (particularly for short electrodes), closer proximity to neural structures, potential for lower current density, wider dynamic range, and more convenient tonotopic stimulation. The potential disadvantages of intracochlear stimulation include the usual hazards of surgery, insertion trauma, the possibility of mechanical damage to the cochlea, osteoneogenesis, possible release of ototoxic corrosion products, and the difficulty of replacing the device, should the need arise.

Several of the above disadvantages are reduced by the use of a short, single-channel electrode. There is, however, no general agreement as to the relative advantages of using short electrodes.

Multichannel stimulation has the advantage that information can be transmitted in a form that is easier for the user to understand. Because of interactions between the stimuli of electrodes activated simultaneously, the number of effective independent channels may be reduced. Feature-extraction systems are predicated on the assumption that certain aspects of the speech signal can be identified as being especially important and that these features can be transmitted effectively to the

electrode array. Feature-extraction systems have the advantages of reducing inter-electrode interference and, if the preceding assumption is correct, simplifying the understanding of signals received from the implant. A disadvantage of feature-extraction systems is that of possible errors in the estimation of speech parameters.

The current evidence suggests that multichannel intracochlear stimulation produces superior speech-recognition performance compared with single-channel stimulation. However, interpretation of the present data is complicated by differences in subject selection procedures among research groups and the lack of a common body of standardized tests. Speech-recognition performance is similar for single-channel intracochlear implants in comparison with single-channel extracochlear implants, and for multichannel feature-extraction implants in comparison with non-feature-specific filter-bank-type implants.

3.

How effective are cochlear implants?

Few medical interventions yield outcomes as varied as those for cochlear implantation. Though no persons with implants can be said to have their hearing fully restored, some communicate face-to-face with comparative ease, and even a few (about 5 percent) can carry on normal conversation without lipreading. The most common outcome is some improvement in speechreading ability. On the other hand, some persons with implants can barely distinguish between simple environmental sounds such as car traffic and the doorbell. Different studies report an appreciable number of persons with implants (2 to 15 percent) who may choose to discontinue the use of their prostheses. Despite the variability of these results, a large majority of persons welcome their implants—a reaction that is understandable and testifies to their strong desire to maintain or achieve some awareness of sound stimulation.

Variability in results arises partly because of differences among the implanted persons. Although all suffer profound hearing difficulties, the medical, linguistic, and psychological histories, as well as general cognitive skills, differ widely among them. In addition to these factors, the condition of the peripheral and central auditory system, both before and after surgery, is often impossible to assess with any accuracy. Finally, the efficacy of implantation is difficult to assess because of the variety of different procedures and tests used for this purpose. There are simply no standardized procedures presently available for such evaluation, although their presence would materially increase research progress in this field.

All of these reasons make it impossible to predict with any degree of accuracy the outcome for a particular person. However, despite these uncertainties, the available evidence suggests the following broad generalizations:

- Speechreading is nearly always facilitated when using the implant, either of the single-channel or multichannel variety.
- Persons who have previously acquired language skills and have experienced hearing seem to benefit more from the implant than those without these characteristics.
- The bulk of the evidence from the United States suggests that speech recognition performance is superior in multichannel implants compared with single-channel implants. This generalization needs to be qualified somewhat. (See Question 2 on Advantages and Disadvantages of Different Types of Cochlear Implants, page 3.)
- The process of cochlear implantation represents a major change in the person's life. A strong interdisciplinary rehabilitation team provides a prudent support system to aid in this difficult transition. Consulting and counseling the person with an implant and his or her family, coupled with a training program of aural rehabilitation, facilitates the maximal use of the implant.
- There is convincing evidence of improved speech production in some implanted persons.

4.

What are the risks and limitations of cochlear implantation?

Risks

Medical complications include all of the risks associated with surgery conducted under general anesthesia. These are small but finite for persons in good general health but increase with age and other confounding conditions.

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 there is an increase in the spread of infection from the middle ear to the inner ear caused by implanting the device. There is, however, a risk of postsurgical 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. Most cases of postimplant facial nerve paralysis and vestibular symptoms appear to have been transient. However, data on vestibular effects of implants have only been obtained from individuals with intact visual and proprioceptive systems. More data are necessary to evaluate risks of total incapacitation that could potentially result from complications of implantation in a unilaterally functioning labyrinth in a person with other sensory deficits. Passage of current through the implant at levels necessary for auditory stimulation may cause stimulation of the facial nerve. Data suggest that current in the implant is unlikely to produce vestibular symptoms. Placement of the implant may cause a reduction in tinnitus in some individuals but also may cause an increase in a smaller percentage of persons with implants.

Use of the implant may interfere with the use of residual hearing cues from the other ear or other modalities. The need for replacement surgery after equipment failure or for upgrading to another device exposes the person with an implant to the same risks and has the potential to cause the same damage as the initial operation.

Although there are encouraging data suggesting that corrosion of platinum electrodes used for 3 years was minimal, the effects of current passage and solubilization of metal from the electrode tip in the fluid medium of the scala tympani of the cochlea have the potential for deleterious effects on surviving neural elements. More data are necessary to evaluate these risks. Similarly, more data are needed to evaluate the potential deleterious effects of low currents used over long time periods or of local heating effects due to high current densities as could be generated by alternative implant designs.

Finally, there is a possibility of psychological problems developing for the person with an implant and/or his or her family because of unrealistic expectations about improvements related to implant use.

Limitations

The effective use of cochlear implants is limited by a number of considerations. Some disease processes associated with hearing loss cause changes in the temporal bone that may prevent or compromise the appropriate insertion of the device. Chief among these are congenital malformations, whose anatomy increases the difficulty of inserting the electrode array in proximity to the neural elements to be stimulated, and osteoneogenesis secondary to meningitis, suppurative otitis media, and obliterative otosclerosis, which may obscure the round window niche and make it difficult to insert the electrode. Previous otologic trauma or surgery may result in fibrosis and osteoneogenesis, which produce the same difficulties. Another concern with hearing loss caused by meningitis is the small number of patients who spontaneously recover hearing. Because implantation may destroy cochlear structures necessary for normal hearing, there is a need to balance waiting a suitable interval to ensure that spontaneous recovery does not occur and placing an implant before osteoneogenesis has obliterated the cochlea.

Some candidates for implantation with congenital malformations may not be suitable because of increased difficulty of accurate electrode placement and increased likelihood of damage to the neural elements, the facial nerve, and endosteum. Some congenitally deaf adults also may be inappropriate candidates for implants because of psychological commitments to the deaf world and nonauditory communication modes.

Placement of an implant also limits the ability of the implantee in several activities. All persons with implants need to avoid activities that could physically damage or displace the implant (e.g., boxing or contact sports). Several medical tests and treatments are incompatible with preservation of implant function, including the use of magnetic resonance imaging (MRI), electrocautery near the implant, and diathermy and radiation therapy of the implant area.

It is not yet clear what minimum neural elements must be present for effective transmission of the electrical signal, although absence of all spiral ganglion cells and all auditory nerve fibers precludes success.

Special Considerations for Children

At the present time, cochlear implants for children are classified by the FDA as investigational devices. A minimal age limit of 2 years may be appropriate for cochlear implant candidacy for anatomic and neurodevelopmental reasons. In principle, the same criteria that apply to adults apply to children, whenever possible. It is recommended that hearing loss in children be corroborated with both behavioral and electrophysiological techniques. Indications in favor of an implant are profound sensorineural hearing loss bilaterally and aided thresholds greater than 60 dB HL, with confirmation of test/retest reliability.

A minimum of a 6-month trial with appropriate amplification and rehabilitation is recommended, with the addition of a trial for a tactile aid. The latter is recommended so that children may learn stimulus/response associations that will be useful in the later evaluation of a cochlear implant. It is suggested that the criterion for lack of success with a hearing aid in younger children be the failure to improve on a closed-set task of simple pattern perception. This observation should be corroborated with subjective reports from parents and others for younger children. Adult criteria may be applied to older children. As with the adult subjects, the **a priori** prediction of success with a cochlear implant for a particular child does not appear possible at this time.

The loss of even minimal residual hearing has far more serious consequences for a child in the language and speech acquisition process than it has for an adult. For this reason, greater caution is recommended in the implantation of children with measurable thresholds at 4000 and 8000 Hz. Any change in guidelines for the implantation of children should follow additional trials for adults.

Children have received both intracochlear and extracochlear and single-channel and multichannel devices. Presently, it is not possible to determine which type of device—single-channel or multichannel—is superior based on the available evidence. Even fewer data exist for specific speech perception tasks with multichannel extracochlear devices. It is advisable that children receive an implant in only one ear.

Children with implants still must be regarded as hearing impaired, even with improved detection thresholds in the range of conversational speech. These children will continue to require educational, audiological, and speech and language support services for long periods of time.

Efficacy measures, comparing preimplant and postimplant performance, are complicated by the continuing development of the children, particularly in speech and language skills. There are no studies that adequately separate the effect of the implant from improvement due to maturation and training. The interaction of cochlear implants with training approaches, such as Total Communication and Cued Speech, should be studied.

The long-term changes due to prosthesis-tissue interactions are currently unknown. Further, it is not known how the implant would affect the developing auditory pathways. In considering cochlear implantation in children, the potential and possibly long-term effects of the implant, either beneficial or deleterious, are unknown.

5.

What are the important directions for future research?

There are numerous research issues in connection with candidate selection. One is the criteria for candidacy for prelingually deafened adults and the possible need for novel preimplant and postimplant training programs. A second issue is special populations, including visually impaired, learning-disabled, and retarded persons. The third involves the ear to be implanted, either the ear with "better hearing" or the ear with "poorer hearing." A fourth issue involves the use of a hearing aid in one ear and an implant in the other. A related issue is the efficacy of vibrotactile devices; such devices may have significant utility as a supplement to an implant, as a preimplant training device, or possibly as an alternative to a cochlear implant in some persons. Finally, data on high-frequency hearing (>4kHz) are needed on implant candidates because part of the variance in the performance of implantees may reflect differences in preimplant capability at high frequencies.

Improved methods for predicting success with a cochlear implant need to be developed, possibly with tests using data from new imaging techniques such as positron emission tomography (PET) and electromagnetic recordings of auditory cortex activity (SQUID).

Standardized methods should be developed for the evaluation of implant effectiveness. This would then permit comparative study of single-channel and multichannel implants and investigation of alternative methods of signal coding. Improved networking among research groups is recommended and would clearly help in developing a common body of standardized tests and standardized selection criteria.

There should be continued study of presently implanted and yet-to-be-implanted adults to assess long-term effectiveness of cochlear implants.

The inability to predict who will be able to use implants or which signal components are critical for language comprehension reflects our lack of information about basic auditory mechanisms. To address this, we need information about many aspects of audition, including the perception of speech and other auditory signals. Appropriate measures of the integrity of the central auditory pathways need to be developed.

More work is needed on the effects of long-term electrical stimulation at varying levels of intensity, and the effects of new implant procedures and reimplantation in animals.

Further information is needed to identify the mechanisms leading to surgically obtained or spontaneous return of hearing following losses due to meningitis and other pathologic processes.

To further our understanding of basic mechanisms, there is a critical need for correlated histopathological evaluation of the temporal bones and brains of implanted persons and others with documented hearing losses from a variety of causes.

It is important to develop methods to assess the efficacy of the cochlear implant in improving the wearer's quality of life and daily functioning.

There is a clear need for standardized tests for young children, both for the selection of cochlear implant candidates and for the measurement of implant efficacy. These tests need to be based on tasks appropriate for younger, prelinguistic children. More research is required on effective aural rehabilitation procedures. In addition, research is necessary to determine effective ways to educate professionals in the new technology of cochlear implants and its effects on implanted children. Research on the plasticity of the nervous system should be encouraged in both animal and human studies.

The preliminary findings of some benefit and the confounding effects of maturation and training indicate the need for well-controlled, prospective studies in children. Ideally, these studies should be small, randomized trials with precisely defined endpoints and should include appropriate audiological, behavioral, and biostatistical input into the design, analysis, and interpretation. These studies should not only control for maturation and training, but should compare the effect of cochlear implants with alternative methods of treatment.

Conclusion

The cochlear implant is an important step in our long-range goal of understanding, preventing, and treating hearing impairment and resulting language disorders.

There are candidates for whom a cochlear prosthesis implant is appropriate. The specific type of implant chosen for a given person depends upon many variables. It appears that multichannel implants may have some superior features in adults when compared with the single-channel type.

In some persons there is a substantial improvement in speech recognition after implantation, although, more typically, there is improvement in speechreading.

The risks are few but definite. The limitations are many. Foremost of these is that implantation does not restore normal hearing.

There are very special needs concerning the evaluation and treatment of children.

Finally, future research goals should include not only improvements in cochlear implants and methods of testing, but, more importantly, a search for the understanding of mechanisms of disorders and diseases of the ear.

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