# NIH Consensus Statement

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Cochlear Implants in Adults and Children

NATIONAL INSTITUTES OF HEALTH Office of the Director

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NIH Consensus Statements are prepared by a nonadvocate, non-Federal panel of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session, (2) questions and statements from conference attendees during open discussion periods that are part of the public session, and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the panel and is not a policy statement of the NIH or the Federal Government.

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# **Reference Information**

For making bibliographic reference to this Consensus Statement, it is recommended that the following format be used, with or without source abbreviations, but without authorship attribution:

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Cochlear Implants in Adults and Children

This statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.

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# Abstract

**Objective.** To provide clinicians and other health care providers with a current consensus on the benefits, limitations, and technical and safety issues that need to be considered in the use of cochlear implants.

**Participants.** A non-Federal, nonadvocate, 14-member consensus panel representing the fields of otolaryngology, audiology, speech-language pathology, pediatrics, psychology, and education and including a public representative. In addition, 24 experts in auditory anatomy and physiology, otolaryngology, audiology, aural rehabilitation, education, speech-language pathology, and bioengineering presented data to the consensus panel and a conference audience of 650.

**Evidence.** The literature was searched through Medline and an extensive bibliography of references was provided to the panel and the conference audience. Experts prepared abstracts with relevant citations from the literature. Scientific evidence was given precedence over clinical anecdotal experience.

**Consensus.** The panel, answering predefined consensus questions, developed its conclusions based on the scientific evidence presented in open forum and the scientific literature.

**Consensus Statement**. The panel composed a draft statement that was read in its entirety and circulated to the experts and the audience for comment. Thereafter, the panel resolved conflicting recommendations and released a revised statement at the end of the conference. The panel finalized the revisions within a few weeks after the conference.

**Conclusions.** Cochlear implantation improves communication ability in most adults with severe to profound deafness and frequently leads to positive psychological and social benefits as well. Currently, children at least 2 years old and adults with profound deafness are candidates for implantation. Cochlear implant candidacy should be extended to adults with severe hearing impairment and open-set sentence discrimination that is less than or equal to 30 percent in the best aided condition. Access to optimal education and (re)habilitation services is important for adults and is critical for children to maximize the benefits available from cochlear implantation.

# Introduction

Cochlear implants are now firmly established as effective options in the habilitation and rehabilitation of individuals with profound hearing impairment. Worldwide, more than 12,000 people have attained some degree of sound perception with cochlear implants, and the multichannel cochlear implant has become a widely accepted auditory prosthesis for both adults and children. The vast majority of deaf adults with cochlear implants derive substantial benefit when the implant is used in conjunction with speechreading. As a result of cochlear implantation, many of these individuals are able to understand some speech without speechreading, and some are able to communicate by telephone. Benefits have also been observed in children, including those who lost their hearing prelingually; moreover, there is evidence that the benefits derived improve with continued use. New speech-sound processing techniques continue to improve the effectiveness of cochlear implants, increasing user performance beyond previous levels.

The NIH sponsored a Consensus Development Conference (CDC) on Cochlear Implants in 1988. Since then, implant technology has improved substantially. Some questions unanswered at that conference have been resolved, and new issues have emerged that must be addressed.

For example, the performance of some severely to profoundly hearing-impaired adults using hearing aids is poorer than that of more severely hearing-impaired individuals using cochlear implants with advanced speech-processing strategies. It is possible that cochlear implants could benefit some of these individuals. Therefore, the criteria for implantation should be re-examined. The ability to predict preoperatively the level of performance at which an individual implant recipient will function is highly desirable. Currently, the limited prediction of implant efficacy in a specific individual remains a pressing problem. Agreement does not exist on the definition of a successful implant user. What are the appropriate expectations for individuals using cochlear implants? How is benefit defined and measured? What are the audiological, educational, and psychosocial impacts of this intervention and is it cost-effective? Advancing technology will allow for the modification of existing devices or the development of new devices. Therefore, it is important to know what risks and benefits are associated with device explantation/reimplantation. Surgical and other risks and possible long-term effects of cochlear implants require evaluation.

Implantation of individuals with multiple disabilities, the elderly, and children, particularly children who are prelingually deaf, engenders special questions. Longitudinal studies are providing information on the development of auditory speech perception and production and language skills in deaf children with a cochlear implant. What educational setting is best for the development of speech and language in these children? Are cochlear implants efficacious in children who are prelingually deaf?

To address the issues that have arisen since the 1988 CDC on Cochlear Implants, the National Institute on Deafness and Other Communication Disorders, together with the NIH Office of Medical Applications of Research, convened a CDC on Cochlear Implants in Adults and Children, May 15–17, 1995. The conference was cosponsored by the National Institute on Aging, the National Institute of Child Health and Human Development, the National Institute of Neurological Disorders and Stroke, and the Department of Veterans Affairs.

The conference was convened to summarize current knowledge about the range of benefits and limitations of cochlear implantation that have accrued to date. Such knowledge is an important basis for informed choices for individuals and their families whose philosophy of communication is dedicated to spoken discourse. Issues related to the acquisition of sign language were not directly addressed by the panel, because the focus of the conference was on new information on cochlear implant technology and its use. The panel acknowledges the value and contributions of bilingual and bicultural approaches to deafness. This conference brought together specialists in auditory anatomy and physiology, otolaryngology, audiology, aural rehabilitation, education, speech–language pathology, bioengineering, and other related disciplines as well as representatives from the public. After 1½ days of presentations and audience discussion, an independent, non-Federal consensus panel weighed the scientific evidence and developed a statement that addressed the following five questions:

- What Factors Affect the Auditory Performance of Cochlear Implant Recipients?
- What Are the Benefits and Limitations of Cochlear Implantation?
- What Are the Technical and Safety Considerations of Cochlear Implantation?
- Who Is a Candidate for Cochlear Implantation?
- What Are the Directions for Future Research on Cochlear Implantation?

# What Factors Affect the Auditory Performance of Cochlear Implant Recipients?

## **Subject Factors**

Auditory performance, defined as the ability to detect, discriminate, recognize, or identify acoustic signals, including speech, is highly variable among individuals using cochlear implants. Since the 1988 CDC on Cochlear Implants, however, some factors associated with outcome variability are now better understood.

**Etiology**. Because of a larger subject sample, the effects of etiology can now be distinguished from other factors such as the duration of deafness and the age of onset. For example, deafness due to meningitis does not necessarily limit the benefit of cochlear implantation in the absence of central nervous system complications, cochlear ossification, or cochlear occlusion. Children with congenital deafness and children with prelingually acquired meningitic deafness, for example, achieve similar auditory performance if the cochlear implant is received before age 6. In general, etiology does not appear to affect auditory performance in either children or adults.

Age of Onset of Deafness. The age of onset continues to have important implications for success with cochlear implantation, depending on whether the hearing impairment occurred before (prelingual), during (perilingual), or after (postlingual) learning speech and language. At the last CDC, data on cochlear implantation suggested that children or adults with postlingual onset of deafness had better auditory performance than children or adults with prelingual or perilingual onset. Current data about auditory performance in children over longer times support this finding. However, the difference between children with postlingual and those with prelingual-perilingual onset of deafness appears to lessen with time. Large individual differences remain within each group, however. Age at Implantation. Previous data suggested that prelingually or perilingually deafened persons who were implanted in adolescence or adulthood did not achieve the same level of auditory performance as those implanted during childhood, although individual differences were recognized. Current data continue to support the importance of early detection of hearing loss and implantation for maximal auditory performance. However, it is still unclear whether implantation at age 2, for example, ultimately results in better auditory performance than implantation at age 3.

**Duration of Deafness**. As deafness endures, even in postlingually deafened individuals, some auditory and linguistic skills may decline and some behavioral traits that work against successful adaptation to a sensory device may develop. Individuals with shorter durations of auditory deprivation tend to achieve better auditory performance from any type of sensory aid, including a cochlear implant, than do individuals with longer durations of auditory deprivation.

Residual Hearing. Initially, cochlear implant use was restricted to persons with profound hearing loss (puretone threshold average (PTA) of greater than 100 dB HL and no open-set speech recognition ability with best-fit hearing aids). The average auditory performance of these cochlear-implant users has been better than the average auditory performance of hearing-aid users with some residual hearing, that is, severe hearing loss (PTA > 90 dB HL) and some (<30 percent) open-set speech recognition ability with best-fit hearing aids. Recent data show that auditory performance in people with residual hearing improves after cochlear implantation relative to preoperative auditory performance, although the degree of improvement could not be predicted from preoperative hearing sensitivity. Research is now addressing the critical distinction between the importance of residual hearing sensitivity compared with overall residual auditory capacities and functional communicative status.

## **Electrophysiological Factors**

Some surviving spiral ganglion cells are necessary for auditory performance with a cochlear implant. Degenerative changes occur in both ganglion cells and central auditory neurons following sensorineural deafening. Although a relationship between the number of surviving ganglion cells and psychophysical performance has been demonstrated in animals, a direct relationship between ganglion cell survival and level of auditory performance in humans has not been shown. Animal studies also suggest that electrical stimulation increases ganglion cell survival and also modifies the functional organization of the central auditory system. The implications of these new findings for humans remain to be determined.

## **Device Factors**

The task of representing speech stimuli as electrical stimuli is central to the design of cochlear implants. Designs vary according to (1) the placement, number, and relationship among the electrodes; (2) the way in which stimulus information is conveyed from an external processor to the electrodes; and (3) how the electrical stimuli are derived from the speech input (and other signals). Changes in cochlear implant design/processing strategies and their effects on auditory performance are discussed in the section on technical and safety considerations.

# What Are the Benefits and Limitations of Cochlear Implantation?

## Impact on Speech Perception in Adults

Cochlear implantation has a profound impact on hearing and speech perception in postlingually deafened adults. Most individuals demonstrate significantly enhanced speechreading capabilities, attaining scores of 90-100 percent correct on everyday sentence materials. Speech recognition afforded by the cochlear implant effectively supplements the information least favorably cued through speechreading. A majority of those individuals with the latest speech processors for their implants will score above 80-percent correct on highcontext sentences, even without visual cues. Performance on single-word testing in these individuals is notably poorer. although these scores have improved significantly with newer speech-processing strategies. Recognition of environmental sounds and even appreciation of music have been repeatedly observed in adult implant recipients. Noisy environments remain a problem for cochlear-implanted adults, significantly detracting from speech-perception abilities. Prelingually deafened adults generally show little improvement in speech perception scores after cochlear implantation, but many of these individuals derive satisfaction from hearing environmental sounds and continue to use their implants.

# Speech Perception, Speech Production, and Language Acquisition in Children

Improvements in the speech perception and speech production of children following cochlear implantation are often reported as primary benefits. Variability across children is substantial. Factors such as age of onset, age of implantation, the nature and intensity of (re)habilitation, and mode of communication contribute to this variability. Using tests commonly applied to children and adults with hearing impairments (e.g., pattern perception, closed-set word identification, open-set perception), perceptual performance increases on average with each succeeding year post implantation. Shortly after implantation, perform-ance may be broadly comparable to that of some children with hearing aids and over time may improve to match that of children who are highly successful hearing aid users. Children implanted at younger ages are on average more accurate in their production of consonants, vowels, intonation, and rhythm. Speech produced by children with implants is more accurate than speech produced by children with comparable hearing losses using vibrotactile devices or hearing aids. One year after implantation, speech intelligibility is twice that typically reported for children with profound hearing impairments and continues to improve. Oral–aural communication training appears to result in substantially greater speech intelligibility than manually based total communication.

The language outcomes in children with cochlear implants have received less attention. Reports involving small numbers of children suggest that implantation in conjunction with education and habilitation leads to advances in oral language acquisition. Data on cognitive and academic development following implantation are not yet available. The nature and pace of language acquisition may be influenced by the age of onset, age at implantation, nature and intensity of habilitation, and mode of communication.

One current limitation is that children are typically implanted at no earlier than 2 years of age, which is beyond putative critical periods of auditory input for the acquisition of oral language. Benefits are not realized immediately, but rather are manifested over time, with some children continuing to show improvement over several years.

Few studies have used language as an outcome measure. The assessment of speech perception, language production, and language comprehension in young children is particularly challenging. Furthermore, results in children have been reported for single-channel or feature-based devices only, which do not include the effects of the relatively rapid evolution of alternatives in speech-coding strategies. Oral language development in deaf children, including those with cochlear implants, remains a slow, training-intensive process, and results typically are delayed in comparison with normally hearing peers.

# Psychologic and Social Issues in Adults and Children

Although psychological evaluation has been a part of the preimplant evaluation process, comparatively little research has been conducted on the long-term psychological and social effects of implantation. Still, the psychological and social impact for adults is generally positive, and there appears to be agreement between preimplantation expectations and later benefit. This benefit is expressed as a decline in loneliness, depression, and social isolation and an increase in self-esteem, independence, social integration, and vocational prospects.

Many adult implant recipients report being able to function socially or vocationally in ways comparable to those with moderate hearing loss. Furthermore, they describe a new or renewed curiosity about the experience of hearing and the phenomena of sound. In some cases the experience of implantation becomes an integral part of the individual's identity, leading these implant users to participate and share experiences in support and advocacy groups.

Negative psychological and social impact is less frequently observed and is often related to concerns about the maintenance and/or malfunction of the implant and external hardware. Other social insecurities may result from the difficulty of hearing amidst background noise, and from unreasonable expectations of aural-only benefit on the part of implant users or their family and friends.

The assessment of psychological impact in children with implants lags behind that for the adult population, in part because psychological outcome is a factor of audiological benefit, which is realized more slowly in children. Additionally, such assessment must consider the child's family setting. Because language acquisition is closely associated with identity, social development, and social integration, the impact of implantation on a child's development in these areas deserves more study to produce useful indicators that can bear upon the parental decisionmaking processes.

## **Rehabilitation and Educational Issues**

Although a cochlear implant can provide dramatic augmentation of the auditory information perceived by deaf children and adults, training and educational intervention are fundamental for optimal postimplant benefit. Access to postimplant rehabilitation involving professionals familiar with cochlear implants must be provided to ensure successful outcomes for implant recipients.

Rehabilitation efforts must be tailored to meet individual needs, and protocols should be developed to reflect therapies effective for various types of individuals receiving implants. Therapeutic intervention with prelingually deaf adults may differ significantly in both time and content from that with postlingually deaf recipients.

Pediatric cochlear implantation requires a multidisciplinary team composed of physicians, audiologists, speech–language pathologists, rehabilitation specialists, and educators familiar with deafness and cochlear implants. These professionals must work together in a long-term relationship to support the child's auditory and oral development. Although the effects of communication mode in implantation habilitation have not been sufficiently documented, it is clear that the educational programs for children with cochlear implants must include auditory and speech instruction using the auditory information offered by the implant.

### Cost-Utility

The cost-benefit or cost-utility of cochlear implantation must be calculated separately for adults and children. For adults, the cost of cochlear implantation includes the initial costs of assessment, the device, implantation, rehabilitation, system overhead, and maintenance. The benefit or utility is estimated as a function of quality of life over time. On this basis, cochlear implantation whether at age 45 years or 70 years compares quite favorably to many medical procedures now commonly in use (e.g., implantable defibrillator insertion).

The cost-utility estimates for children also appear to be quite favorable, but we are still in the early stages of cochlear implant application and cannot yet estimate the cost or potential cost savings that will accrue in the area of (re)habilitation and education.

# What Are the Technical and Safety Considerations of Cochlear Implantation?

# **Cochlear Implant Design Issues**

A cochlear implant works by providing direct electrical stimulation to the auditory nerve, bypassing the usual transducer cells that are absent or nonfunctional in a deaf cochlea. Over the past 10 years, significant improvements have been made in the technology used to accomplish auditory stimulation.

The best performance in speech recognition occurs with intracochlear electrodes that are close to the nerve fibers to be stimulated, thus minimizing undesirable side effects.

Early implants used only a single electrode; these singlechannel implants rarely provide open-set speech perception. Most recent implants use multielectrode arrays that provide a number of independent channels of stimulation. Such devices provide more information about the acoustic signal and give better performance on speech recognition. No agreement exists on the optimum number of channels, although at least 4-6 channels seem to be necessary.

Much of the recent progress in implant performance has involved improvements in the speech processors, which convert sound into electrical stimuli. The best performance comes with speech processors that attempt to preserve the normal frequency code or spectral representation of the cochlea. These are distinguished from feature-based processors, which attempt to analyze certain features known to be important to speech perception and present only those features through the electrodes. A major problem in multichannel implants is channel interaction, in which two electrodes stimulate overlapping populations of nerves. Channel interaction has now been minimized with speech processors that activate the electrodes in a nonsimultaneo us or interleaved fashion; this has been shown to improve speech recognition significantly.

A final design issue is the means by which the stimulus information is passed through the skin from the speech processor to the electrodes. In a transcutaneous system, the skin is intact and the coupling is done electromagnetically to an implanted antenna. In a percutaneous system, the leads are passed directly through the skin. The two systems have slightly different surgical complications, which are discussed below. The percutaneous system (1) provides a more flexible connection to the electrodes in case a change in speech processor is desired, (2) is easier to troubleshoot in case of electrode problems, and (3) is magnetic resonance imaging (MRI) compatible. Percutaneous systems are not commercially available.

## **Issues Related to Magnetic Resonance Imaging**

Magnetic Resonance Imaging (MRI) is increasingly the diagnostic tool of choice for a variety of medical conditions. Implants that use transcutaneous connectors contain an implanted magnet and some ferrous materials that are incompatible with the high magnetic fields of an MRI scanner. Implant manufacturers are redesigning their devices to circumvent this problem. Potential MRI risks should be part of the informed consent procedure for persons considering an implant. The external speech processor cannot be made MRI compatible and should not be taken into the scanner.

### **Surgical Issues**

Cochlear implantation entails risks common to most surgical procedures (e.g., general anesthetic exposure), as well as unique risks that are influenced by device design, individual anatomy and pathology, and surgical technique. Comparative data of major complications incurred in adult implantation show a halving of the complication rate to approximately 5 percent in 1993. The complication rate in pediatric implantation is less than that currently seen in adults. Overall, the complication rate compares favorably to the 10 percent rate seen with pacemaker/defibrillator implantation.

Major complications (i.e., those requiring revision surgery) include flap problems, device migration or extrusion, and device failure. Facial palsy, although considered a major complication, is distinctly uncommon and rarely permanent. No mortalities have been attributed to cochlear implantation. Alterations in surgical technique, especially flap design, have led to a considerable reduction in the flap complication rate, which is particularly relevant to transcutaneous devices. Alterations in surgical technique, particularly in methods used to anchor the device, have contributed to a decrease in device migration or extrusion.

All implants are potentially prone to failure—because of either manufacturing defects or use-related trauma. Pedestal fracture is a problem unique to the percutaneous device, but occurs rarely. Manufacturer redesign has produced newer electrode arrays that are smaller and sturdier than earlier models. For the most commonly implanted device, 95 percent of implants are still functioning after 9 years. Implants with transcutaneous connectors that do not provide self-test capability for the implanted portion preclude detecting electrode failure, such as open and short circuits. Failure recognition is particularly problematic in young children. The newer cochlear implants do, however, include self-test circuitry that allows objective device monitoring.

Minor complications, that is, those that resolve without surgical intervention, include unwanted facial nerve stimulation with electrode activation, which is readily rectified by device reprogramming. In percutaneous devices, pedestal infections are uncommon but can be treated successfully with antibiotics; on rare occasions explantation may be required for control.

Reimplantation is necessary in approximately 5 percent of cases because of improper electrode insertion or migration, device failure, serious flap complication, or loss of manufacturer support. In general, reimplantation in the same ear is usually possible, and thus far individual auditory performance after reimplantation equals or exceeds that seen with the original implant.

Long-term complications of implantation relate to flap breakdown, electrode migration, and receiver-stimulator migration. The potential consequences of otitis media have been of concern, particularly in children. However, as the implanted electrode becomes ensheathed in a fibrous envelope, it becomes isolated from the consequences of local infection.

# Who Is a Candidate for a Cochlear Implantation?

# Adults

Cochlear implants are often highly successful in postlingually deafened adults with severe to profound hearing loss and no speech perception benefit from hearing aids. Previously, individuals eceiving marginal benefit from hearing aids were not considered implant candidates. Ironically, such individuals often have poorer speech perception with hearing aids than do more severely deafened persons who use implants. Recent data show that most marginally successful hearing aid users will have improved speech perception performance with a cochlear implant. Therefore, it is reasonable to extend cochlear implants to postlingually deafened adult individuals currently obtaining marginal benefit from other amplification systems. Prelingually deafened adults may also be suitable for implantation, although these candidates must be counseled regarding realistic expectations. Existing data indicate that these individuals achieve minimal improvement in speech recognition skills. However, other basic benefits, such as improved sound awareness, may provide psychological satisfaction and meet safety needs.

Because of the wide variability in speech perception and recognition in persons with similar hearing impairments, all candidates require indepth counseling about the surgery, its risks and benefits, rehabilitation, and alternatives to cochlear implantation. To give adequate informed consent, adult candidates should understand that large variability in individual audiologic performance precludes preoperative prediction of success. Determining implant candidacy requires consideration of both objective audiological variables as well as the subjective needs and wishes of individual candidates. Specific criteria for potential adult cochlear implant recipients are provided below. Audiologic Criteria. Indications in favor of an implant are a severe-to-profound sensorineural hearing loss bilaterally and open-set sentence recognition scores less than or equal to 30 percent under best aided conditions. Duration of deafness and age of onset have been shown to influence auditory performance with cochlear implants and should be discussed with potential candidates.

In general, when there is no residual hearing in either ear, the ear with better closed-set performance, more sensitive electrical thresholds, shorter period of auditory deprivation, or better radiologic characteristics is implanted. However, when there is residual hearing, the poorer ear should be chosen if there is radiologic evidence of cochlear patency to retain the option for continued hearing aid use and, thus, the potential advantages of binaural sound localization.

**Medical and Surgical Criteria**. Traditionally, implantation candidacy was limited to persons in good health. Although there are specific medical contraindications to surgery and implantation, such as poor anesthetic risk, severe mental retardation, severe psychiatric disorders, and organic brain syndromes, cochlear implantation should be offered to a wider population of individuals. Individuals with low vision may find that implantation promotes independence and other quality-of-life goals. Age, per se, is not a contraindication to implantation.

The medical history, physical examination, and laboratory tests are important tools in candidacy evaluation. Individuals with active ear pathology require treatment and re-evaluation prior to implantation. The standard radiologic evaluation includes high-resolution computed tomography (CT) scanning to detect mixed fibrous and bony occlusions and anatomical abnormalities. MRI provides better resolution of soft tissue structures and should supplement the CT scan when indicated. These imaging techniques should be used to identify abnormalities that may compromise or impede implant surgery or device use.

The results of electrophysiologic tests do not predict implant success. However, in selected individuals, such as those with cochlear obliteration or in decisions regarding ear of implantation, the results of promontory stimulation may be useful.

## Children

Cochlear implants have also been shown to result in successful speech perception in children. Currently, the earliest age of implantation is 24 months, but there are reasons to reassess this age limit. A younger age of implantation may limit the negative consequences of auditory deprivation and may allow more efficient acquisition of speech and language. Determining whether cochlear implant benefits are greater in children implanted at age 2-3 compared with those implanted at age 4-5 might resolve this issue, but sufficient data are unavailable. Also, it is unclear whether the benefits of implantation before age 2 would offset potential liabilities associated with the increased difficulty in obtaining reliable and valid characterization of hearing and functional communication status at the younger age. A small number of children under age 2 have received implants, both internationally and in the United States. Cochlear implants principally have been performed in this population because of the risk of new bone formation associated with meningitis, which might preclude implantation at a later date. Speech and language data obtained on such children will be helpful in determining the potential benefits of early implantation and therefore may help to guide future policy.

Audiologic Criteria. Children age 2 years or older with profound (>90 dBHL) sensorineural hearing loss bilaterally and minimal speech perception under best aided conditions may be considered for cochlear implantation. In the young child, auditory brainstem response, stapedial reflex testing, and otoacoustic emission testing may be useful when combined with auditory behavioral responses to determine hearing status. Prior to implantation, a trial period with appropriate amplification combined with intensive auditory training should be attempted to ensure that maximal benefit is achieved. When the validity of behavioral test results is compromised by maturational factors, the above criteria should be applied in the most stringent manner (i.e., worse hearing sensitivity, longer trial periods, etc.). Current research may broaden audiometric criteria for candidacy to better reflect functional auditory capacity.

Medical and Surgical Criteria. Children should also undergo a complete medical evaluation to rule out the presence of active systemic disease that would contraindicate implantation. The child must be otologically stable and free of active middle ear disease prior to cochlear implantation. The radiologic imaging criteria used in adult candidates are applicable to children.

**Psychosocial Criteria**. Preoperative assessment should entail evaluation of the child in the home, social, and educational contexts to ensure that implantation is the proper intervention. In some instances psychosocial factors may be used as exclusionary criteria; however, in all cases psychosocial data should serve as a baseline for tracking cochlear implant outcomes. Parental expectations must be addressed, and commitment to habilitation is essential.

**Informed Consent**. The parents of a deaf child are responsible for deciding whether to elect cochlear implantation. The informed consent process should be used to assist parents in making this decision. Parents must understand that cochlear implants do not restore normal hearing and that auditory and speech outcomes are highly variable and unpredictable. They must be informed of the advantages, disadvantages, and risks associated with implantation to establish realistic expectations. Furthermore, the importance of long-term habilitation with cochlear implants must

be stressed. As part of the process of informed consent, parents must be told that alternative approaches to habilitation are available, for example through sign language. All children should be included in the informed consent process to the extent of their ability, as their active participation is crucial to (re)habilitative success.

# What Are the Directions for Future Research on Cochlear Implantation?

- Research must attempt to explain the wide variation in performance across individual cochlear implant users. New tools, such as functional imaging of the brain, might be applied to unexplored variables such as the ability of the implant to activate the central auditory system. Investigations of the role of higher level cognitive processes in cochlear implant performance are needed.
- The strides that have been made in improving speech perception of cochlear implant users should continue through improvements in electrode design and signal processing strategies. Noise-reduction technologies and enhancement of performance using binaural implants are promising areas.
- Studies of the effects of cochlear stimulation on auditory neurons have provided clear evidence of plasticity both in the survival of neural elements and in receptive field organization. Comparisons of neural plasticity in animal experiments and of adaptation to cochlear implant electrical stimulation by humans provide a unique opportunity to study the relationships between neural activity and auditory perception.
- Comparative research on language development in children with normal hearing, children with hearing impairment who use hearing aids, deaf children with cochlear implants, and deaf children using American Sign Language should be conducted. These studies should be longitudinal and reflect current theoretical and empirical advances in neurolinguistics and psycholinguistics.
- Studies of the relationship between the development of speech perception and speech production in cochlear implant users must continue. Implanted deaf children provide a unique opportunity to examine these developmental processes and their relationship to the acquisition of aural–oral language. Such information is crucial to understanding and enhancing the performance of implanted prelingually deafened children and may help define optimal age for implantation.

- Adequate tools for the assessment of nonspeech benefits of implantation should be applied to gain a better understanding of the full effects of implantation on the quality of life of implant recipients. This may be particularly useful for implant recipients who do not realize significant speechperception benefit. Such data will help in evaluating the cost-utility of cochlear implantation.
- To identify the components of successful (re)habilitation approaches, model programs that use alternative educational techniques will need to be compared. Likewise, outcome variations between high and routine quality service programs that use similar techniques will need to be studied. The identification of those features and services that correlate with outcome success will facilitate the extension of these features and services to all children and adults receiving cochlear implants.

# Conclusions

- Cochlear implantation improves communication ability in most adults with severe to profound deafness and frequently leads to positive psychological and social benefits as well. The greatest benefits seen to date have occurred in postlingually deafened adults. Cochlear implantation in prelingually deafened adults provides more limited improvement in speech perception, but offers important environmental sound awareness. Cochlear implantation outcomes are more variable in children. Nonetheless, gradual, steady improvement in speech perception, speech production, and language does occur. There is substantial unexplained variability in the performance of implant users of all ages, and implants are not appropriate for all individuals.
- Currently children at least 2 years old and adults with profound deafness are candidates for implantation. Cochlear implant candidacy should be extended to adults with severe hearing impairment and open-set sentence discrimination that is less than or equal to 30 percent in the best aided condition. Although theoretic reasons exist to lower the age of implantation in children, data are too scarce to justify a change in criteria. Additional data may justify a change in age and audiologic criteria.
- Auditory performance with a cochlear implant varies among individuals. The data indicate that performance is better in individuals who (1) have shorter durations of deafness, (2) acquired speech and language before their hearing loss occurred, and (3) if prelingual were implanted before age 6. Auditory performance is not affected by etiology of hearing loss.
- Access to optimal educational and (re)habilitation services is important for adults and is critical for children to maximize the benefits available from cochlear implantation.

- The current generation of intracochlear, multichannel implants with spectrally based speech processors provides a substantial improvement over the previous generation of devices, especially when nonsimultaneous electrode activation is used.
- The low complication rate and high reliability for cochlear implants compare favorably with other implanted electronic devices and continue to improve.
- Most devices are not MRI compatible, and users and physicians should be acutely aware of this problem.
  Implant manufacturers should modify future devices to be MRI compatible and to include internal self-test systems.
- Percutaneous connectors offer many research and clinical advantages, including MRI compatibility, ease of electrode testing, and processor upgrading, and they should not be abandoned.

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# **Speakers**

#### Paul J. Abbas, Ph.D.

"Factors Affecting Auditory Performance: Electrophysiologic Measures" Professor Department of Speech Pathology and Audiology Department of Otolaryngology-Head and Neck Surgery University of Iowa Iowa City, Iowa

#### Peter Blamey, Ph.D.

"Factors Affecting Auditory Performance of Postlinguistically Deaf Adults Using Cochlear Implants: Etiology, Age, and Duration of Deafness" *Principal Research Fellow* Department of Otolaryngology University of Melbourne East Melbourne, Victoria, Australia

#### Derald E. Brackmann, M.D., F.A.C.S.

"Percutaneous Connectors in Cochlear Implantation" *Clinical Professor of Otolaryngology–Head and Neck Surgery/Neurosurgery* University of Southern California School of Medicine *President* House Ear Clinic and Institute Los Angeles, California

#### Judith A. Brimacombe, M.A.

"Multichannel Cochlear Implants in Adults With Residual Hearing" Vice President of Clinical and Regulatory Affairs Cochlear Corporation Englewood, Colorado

#### Patricia M. Chute, Ed.D.

"Residual Hearing in Children" Director Cochlear Implant Center Manhattan Eye, Ear, and Throat Hospital New York, New York

#### Noel L. Cohen, M.D.

"Surgical Complications and Considerations" Professor and Chairman Department of Otolaryngology New York University School of Medicine New York, New York

#### Michael F. Dorman, Ph.D.

"Speech Perception by Adults" Professor Department of Speech and Hearing Science Arizona State University Tempe, Arizona Adjunct Professor Division of Otolaryngology University of Utah Health Sciences Center Salt Lake City, Utah

#### Donald K. Eddington, Ph.D.

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#### Bruce J. Gantz, M.D., F.A.C.S.

"Device Failure" Professor and Interim Head Department of Otolaryngology– Head and Neck Surgery University of Iowa College of Medicine Iowa City, Iowa

#### James W. Heller, P.E.

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#### Darlene R. Ketten, Ph.D.

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#### John F. Knutson, Ph.D.

"Psychological and Social Issues in Cochlear Implant Use" Professor Department of Psychology Spence Laboratories of Psychology University of Iowa Iowa City, Iowa

#### Patricia A. Leake, Ph.D.

"Long-Term Effects of Electrical Stimulation" Professor in Residence Department of Otolaryngology Research Director Epstein Hearing Research Laboratory University of California San Francisco San Francisco, California

#### Hugh J. McDermott, Ph.D.

"Speech Processing Using Selected Spectral Features" *Research Fellow* Department of Otolaryngology University of Melbourne East Melbourne, Victoria, Australia

#### Richard T. Miyamoto, M.D., F.A.C.S.

"Timing of Implantation in Children" Arilla Spence DeVault Professor and Chairman Department of Otolaryngology– Head and Neck Surgery Indiana University School of Medicine Indianapolis, Indiana

#### Jean S. Moog, M.S.

"Rehabilitation and Educational Issues in Children" *Director of Deaf Education* Central Institute for the Deaf St. Louis, Missouri

#### Mary Joe Osberger, Ph.D.

"Effect of Age at Onset of Deafness on Cochlear Implant Performance" "Speech Perception in Children" *Director* Pediatric Clinical Research Advanced Bionics Corporation Sylmar, California

#### Robert V. Shannon, Ph.D.

"Information Transmission in Cochlear Implants: Analysis Channels, Number of Electrodes, and Received Channels" Auditory Implant Research House Ear Institute Los Angeles, California

#### Margaret W. Skinner, Ph.D.

"Audiologic Criteria for Cochlear Implantation in Adults and Children" Associate Professor Director of Audiology Director of Cochlear Implant Program Department of Otolaryngology-Head and Neck Surgery Washington University School of Medicine St. Louis, Missouri

#### Quentin Summerfield, Ph.D.

"Cost-Effectiveness Considerations in Cochlear Implantation" *Professor* Medical Research Council Institute of Hearing Research Nottingham, United Kingdom

#### Emily A. Tobey, Ph.D.

"Speech Production in Children" Professor and Nelle C. Johnston Chair in Early Childhood Communication Disorders Department of Communication Disorders Callier Center for Communication Disorders University of Texas at Dallas Dallas, Texas

#### Susan B. Waltzman, Ph.D.

"Comparison of Implant Systems" Professor Department of Otolaryngology New York University School of Medicine New York, New York

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"Continuous Interleaved Sampling and Related Strategies" *Director* Center for Auditory Prosthesis Research Research Triangle Institute Research Triangle Park, North Carolina

#### Teresa A. Zwolan, Ph.D.

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