Cochlear Implant Devices for the Profoundly Hearing Impaired

Number 2
FOREWORD

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OHTA is part of the National Center for Health Services Research and Health Care Technology Assessment, Public Health Service, DHHS.

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INTRODUCTION

The cochlear implant is a neural prosthetic device that delivers electrical stimuli to the eighth, or auditory, cranial nerve. Its purpose is to provide an awareness of sound and to facilitate communication for individuals who are profoundly hearing impaired. This is accomplished by the transformation of sound and speech information into electrical signals that create auditory perceptions upon their application to the auditory nerve. The device is intended for patients with sensorineural deafness who are unable to achieve benefit from a conventional hearing aid. These are people with a defect of the inner ear that disables the sensory hair cells of the cochlear organ of Corti. For the purpose of this assessment, sensorineural deafness refers to those conditions in which vibratory sound perception is completely lost, such that a conventional hearing aid is no longer useful; but the auditory nerve can still be electrically stimulated by an intra-cochlear implant device to produce the awareness of sound perception. In order for the cochlear implant to serve its purpose, electrically excitable auditory nerve fibers must be accessible for stimulation. Continuity between these nerve fibers and the brain must exist so that the electrical impulses that are applied may be appropriately conveyed and interpreted as useful information.
Cochlear implant systems may be considered to have four functional components: an external microphone, a speech processor, signal transfer hardware, an electrode that interfaces with the auditory nerve, and in addition, the perceptual mechanisms of the implantee (1). Sound normally travels through the external ear canal to the tympanic membrane which vibrates in synchrony with the sound waves. The vibrations are transmitted through a series of small bones in the middle ear to the cochlea, or inner ear. The innermost of the small bones, the stirrup, is in contact with the membranous oval window at the base of the cochlea and is held in place by an annular ligament. Sound vibrations are thus conveyed to the fluid-filled interior of the cochlea where they are sensed by longitudinal lines of hair cells that follow a spiral path along its length (2). Because the cochlea is embedded in the temporal bone of the skull, vibrations of the entire skull can also cause the cochlear fluid to vibrate. The cochlea itself is a snail-shaped structure with three spiral parallel canals: the scala vestibuli, scala tympani, and scala media. The scala vestibuli and scala media are separated longitudinally by an extremely thin partition, the vestibular membrane, which serves to maintain a fluid called "endolymph" within the scala media. In contrast, the scalae vestibuli and tympani are continuous at their distal ends and filled with "perilymph." These scalae are separated by the basilar membrane which supports a structure known as the "organ of Corti" along its length. Mechanically sensitive hair cells, the sensory end-organs that generate auditory nerve impulses, are part of the organ of Corti. Whereas the scala vestibuli commences at the oval window, the scala tympani ends distally at the cochlear round window. Endolymph contains a very high concentration of potassium and low concentration of sodium. Perilymph is high in sodium and low in potassium, with a composition similar to cerebrospinal fluid. This ionic differential is responsible for the existence of an electrical potential of about 80 millivolts between perilymph and endolymph with positivity found within the scala media. In perhaps oversimplified terms, the back and forth motion of the cochlear hairs in response to sound vibrations
transmitted through the cochlear fluid causes alternating localized changes in electrical potential that stimulate auditory nerve fibers which terminate distally on the hair cells. There are many thousand hair cells distributed along the basilar membrane. Each of the sensory nerve cells that enmesh them leads to the spiral ganglion of Corti in the modiolus of the cochlea which in turn sends axons into the central nervous system (2,3). In accord with the "law of specific nerve energies" each nerve fiber specifically carries only one modality of sensation. The type of sensation perceived when a sensory nerve is stimulated is determined by the specific area in the central nervous system to which the fiber leads (3). Thus, whether the auditory nerve is stimulated by its sensory end-organ hair cell, or by direct electrical signals, a perception of sound is created. This phenomenon forms the fundamental basis of the implanted cochlear prosthesis.

When sound of a specific frequency is applied to the oval window at the base of the cochlea it causes the basilar membrane to vibrate selectively with the greatest amplitude at a particular point which is mechanically tuned to the frequency of the applied sound (1). A complex sound will cause the basilar membrane to vibrate at multiple points along its length. As has been noted, the hair cells of the organ of Corti transform this mechanical motion into electrical stimuli. Hair cells at the base of the cochlear spiral are most likely to resonate with high frequency sound while those at the apex conversely respond to lower frequencies. This spatial organization of cochlear sensitivity to the sound spectrum is known as the "place-pitch" principle. Since cochlear nerve fibers correspond in their spatial organization to that of the hair cells, specific neurons will be activated by specific frequencies that cause differential vibration of particular areas on the basilar membrane. This spatial organization of neural sound information continues through the medulla to the cerebral cortex (2,3). It must be noted that "pitch" is the conscious perception of sound frequency and may vary from the true vibratory frequency.
In addition to the principle of place-pitch, the encoding of pitch by the normal auditory apparatus can also be accomplished in a limited manner based on neural discharge rates that occur in synchrony with sound vibrations. Low frequency sounds can produce synchronized low frequency volleys of nerve discharges between about 50 Hz to 300 Hz that are discriminable as pitch changes. There is some evidence that this phenomenon, known as "rate-pitch" may extend to 1000 Hz, or perhaps 2000 Hz after training, but differentiation of pitch tends to deteriorate with rising frequency above 300 Hz (5,6). Since the typical adult voice has a frequency range greater than 400 Hz, rate-pitch is of importance to the design of cochlear implants, especially for single electrode devices.

Loudness is discriminated by the normal auditory mechanism in three different ways. It is thought that an increase in the amplitude of basilar membrane vibrations tends to increase the rate of stimuli from hair cells that serve to excite their nerve endings. In addition, the number of hair cells that respond will increase as the area of vibrating basilar membrane expands causing "spatial summation" of impulses to increasing numbers of nerve fibers. It is also believed that certain specialized hair cells do not respond to sound vibrations until relatively high levels of amplitude have been reached. The central nervous system may interpret signals from these specialized hair cells as loud sound (3). True variations of sound level are centrally interpreted in proportion to the cube root of the actual sound intensity. This principle is known as the "power law." It results in compression of loudness perception by the auditory system which allows discrimination of an extremely wide range of sound intensities (3). It has been reported that the dynamic range for direct electrical stimulation of the auditory nerve is very limited compared to the dynamic range for acoustic stimulation. The intensity range for electrical stimuli is generally measured between perceptual threshold and discomfort level. Between these limits, loudness grows in proportion to stimulus intensity although it is somewhat dependent on frequency.
Cochlear implant patients do not discriminate loudness levels with the same growth graduations as normal hearing subjects (5,6). Loudness growth with implants tends to increase with stimulus amplitude, however intensity discrimination is best from about 300 Hz to the upper limit of an implant's frequency range. Thus, a cochlear implant must be designed to stimulate the auditory nerve in a manner that exploits the ability of the cochlea and central nervous system to discriminate the frequency, cadence and intensity of ambient sound in ways that may assist the wearer to recognize its source and information content.

BACKGROUND

Basic Principles of Cochlear Prostheses

The suggestion that electricity might provide auditory sensations first attracted notice during the late 18th and early 19th centuries. Both Benjamin Franklin and Alessandro Volta are among those who noted the effects of electrical stimulation in the ear (7-9). Systematic investigation of this phenomenon probably began when Djourno and Eyries placed a temporary electrode on the auditory nerve of a bilaterally deaf patient undergoing otic surgery for removal of a tumor (7). The patient perceived sounds produced by the electrical stimuli with an awareness of qualitative variations that conformed to changes in frequency. Speech was not discernible, but the cadence of sounds could be appreciated. Simmons repeated this work in 1964. He implanted six electrodes at different locations on the eighth nerve in the cochlear modiolus of a patient with bilateral deafness and found that pitch varied with the electrode location and the frequency of stimulation. Loudness varied with amplitude (7,9). At about the same time, House and others began experimenting with single electrodes inserted directly into the scala tympani through the round window at the base of the cochlea. They found that although the patients did not immediately recognize speech, they were
placed in closer contact with their environment (7).

During the late 1960s, and early 1970s, Michelson, Eddington, Hochmair and Clark each developed scala tympani systems that employed multiple electrodes capable of stimulating auditory nerve fibers at distinct points along the length of the cochlea (9). This permitted the design of prostheses that could carry multiple channels of information to discrete electrodes, or alternatively could carry a single channel to one or many select electrodes. Considerable attention has been given to the arrangement and polarity of electrodes in an implanted array (10). With a common ground pole relatively distant from single or multiple cochlear electrodes, electrical stimuli will be spread over a large, ill-defined area of eighth nerve fibers. Conversely, designs incorporating many closely spaced pairs of miniature positive and negative electrodes are more apt to deliver stimuli to specific focal areas of the cochlear apparatus. Technical requirements related to electrical charge densities and electrode reliability have also been subjects of extensive research (11). The choice of specific wave forms to achieve optimal effects with each device has been a concern of biomedical engineers, but is beyond the scope of this assessment.

All cochlear prostheses employ a microphone and speech processing circuitry to receive sound and render it meaningful for deaf persons. Diverse strategies have been exploited for this purpose (12-16). Research into the auditory processing of those speech sounds that are essential for perception of significant phonetic units has been of abiding interest to scientists concerned with communicative impairments. The problems faced by designers of cochlear prostheses generally involve identification of the elements of speech or other sounds that efficiently provide the biological senses with clues that can be interpreted as understandable environmental sound or speech (14). Auditory speech information has been classified as "prosodic" and "phonemic". Prosodic information includes tempo, stress and intonation of clues (9). Phonemes are the phonetic elements of spoken language; the speech sounds. English is considered to have a total of 37
phonemes consisting of 25 consonants and 12 vowels. Despite an inexact scientific understanding of normal speech perception, investigators have striven to devise methods of extracting and encoding the essential elements of complex speech and environmental sounds. Their goal is to transmit those basic relevant sound characteristics that facilitate interpretation by the hearing impaired person. Technical approaches depend on whether signal processing is intended for a single- or multichannel cochlear implant, and the type of electrode array that is to be used. It is possible to employ various strategies that emphasize rate-pitch, place-pitch, tempo and intensity effects to achieve an understanding of sound content. Current cochlear prostheses variously depend on sound processing schemes that range from analog representation of complex speech and environmental sounds to the selective extraction of speech information for presentation to the auditory nerve (9). One of the most elaborate speech encoding methods presently in use extracts speech features that are deemed useful in phoneme discrimination and applies the resultant electrical stimuli to predetermined sites along the basilar membrane. Where multiple electrodes are used, an isolated stimulus may be delivered to a specific electrode, or several stimuli may be delivered simultaneously via a number of electrodes. Multielectrode devices can carry one or as many channels of information as there are electrodes. Single electrode devices can carry only a single signal channel.

The surgical implantation procedure is not complex. Its purpose is to fasten an electrode array in the vicinity of auditory nerve fibers while maintaining the integrity of both the inner and middle ears. Electrode placement into the scala tympani via the round window has met with the most success (17). Passage of an externally derived signal to the intra-cochlear electrode requires either percutaneous "hard wiring" or an implantable transcutaneous receiver-stimulator device (13,17,18). The latter approach has been most favored since some investigators consider percutaneous wiring to be subject to infection, and therefore unsuitable for general long-term use (17). Transcutaneous transmission of electrical potentials carrying a representation of sound
has been achieved using electromagnetic induction, radio frequency signals, and infrared energy. To date, electromagnetic transmission has been preferred. Either analog or digital information can be employed (1,17,18). Such techniques require an external sending coil to be held in alignment with an implanted receiving apparatus which converts transmitted signals into electrical signals that are appropriate for neural stimulation. A mastoidectomy is performed with an approach through the facial recess to the middle ear that exposes the round window of the cochlear base. A seat is formed in the temporal bone to retain the signal receiving and stimulation device which may be from 1.5 cm to 2.5 cm in diameter and about 0.5 cm thick. The electrode array is inserted into the scala tympani via the round window and the receiving coil fastened in its surgically formed recess. Skin closure then follows. The procedure takes from 3 to 4 hours and is performed under general anesthesia (17, 19). A surgical recovery period from 3 to 8 weeks has been suggested before fitting of the external speech/sound processor and before performing an initial trial of electrical stimulation (13, 17-19). Variations of technique will occur depending on the cochlear implant design and anatomic variation among patients.

A postsurgical rehabilitation program which requires the skills of audiologists or speech/language pathologists, psychologists, and otologists is undertaken following implantation and healing. Its goal is to acquaint the patients with the cochlear prosthesis and train them to obtain maximum benefit from it. About 20 to 30 hours of basic postoperative guidance has been recommended to introduce the patient to the implanted cochlear system (20).

Extracochlear prosthetic devices that stimulate via an electrode superficially placed on the round window membrane have been investigated as a less invasive alternative to electrode insertion in the scala tympani. Extracochlear devices require surgical access to the middle ear and are inherently single channel (10,15,16). Only a small number of patients have received extracochlear prostheses. These were implanted
in Vienna and London. No such device is being marketed in the United States nor are scientific comparisons available between extracochlear instruments and the intracochlear prostheses presently approved for marketing. It has been suggested that extracochlear devices might ultimately find their most appropriate application among profoundly deaf patients with some remaining residual hearing (16). This would avoid further surgical damage to the structures of the inner ear.

Tactile aids for the deaf have been known for about 5 decades (21). These devices are designed to substitute the sense of touch for the hearing process. Models that apply vibratory or electrical stimuli to the skin have been developed with both single and multichannel capabilities (22,23). However, the skin is markedly less sensitive to stimuli than the ear and spatial resolution between channels requires relatively wide distances between stimulators. An electro-tactile aid with 36 channels of speech information arrayed across 36 locations along the abdomen has been tested. Much of the interest in tactile devices stems from their potential value to prelingually deaf children where normal auditory pathways to the brain have not developed. Tactile aids are difficult to compare with cochlear implants since most tests have involved small heterogeneous groups of patients using wearable tactile devices of widely divergent design. Those interested in the subject of tactile aids are referred to a comprehensive bibliography assembled by Proctor (24).

**Epidemiology**

Data on the prevalence of deafness has been collected by the National Center for Health Statistics (NCHS). A hearing supplement was included in the National Health Interview Survey of 1971 and 1977 (25). It was found that hearing trouble is the most prevalent of all impairments. An estimated 367,000 persons 3 years of age or over could not hear shouted speech in either ear. About 60 percent of these persons were 65 years old or older. Since objective audiometric data were not collected to validate the
interviews, it is difficult to project how many of these persons might be assisted by hearing aids or cochlear implants. Thirty-seven percent of respondents 65 years old and over with "severe" impairment did report using some type of hearing aid. Jerome Schein of New York University, in an unpublished analysis of the NCHS data, made projections of the postlingually profoundly deafened adult population age 19 years or over with a bilateral hearing threshold for speech equivalent to 90 decibels or greater. He estimated that about 125,000 persons age 19 or over were thus affected, with 75,000 of that number age 65 or older. Of the latter group, about 68,000 persons were estimated to have bilateral speech thresholds greater than 97 decibels. No information is available concerning real or potential benefits these people might obtain from conventional amplification. Schein considered the total group of 125,000 individuals as possible candidates for cochlear implants.

Cost

At the present time there are five companies in the United States that are manufacturing or sponsoring clinical trials of cochlear implants. Two devices, a single channel unit and a 22 channel multielectrode unit, have been given premarket approval (PMA) by the Food and Drug Administration (FDA). In mid-1985 the American Speech-Language-Hearing Association published the results of a survey (26). The total cost of one single channel device with the required diagnostic, surgical, and rehabilitative services amounted to about $15,000 per patient. A 22 electrode multichannel unit that has also been granted PMA, by contrast had total cost and associated services that amounted to about $20,000.
The purpose of the implantable cochlear prosthesis is to restore auditory sensation and to present hitherto unavailable speech information to the profoundly deaf by direct electrical stimulation of the auditory nerve. It is postulated that the transmission of such information via auditory pathways will enhance sound and speech recognition. This presupposes the presence of excitable eighth nerve fibers that are surgically accessible within the cochlea. Benefits are limited to persons with sensorineural deafness where otic damage is largely confined to the organ of Corti and its hair cells.

Acoustic information from the environment must be received by the device, transformed to a system of electrical signals, and applied to the cochlear apparatus in a manner that results in neural transmissions to the brain. In addition, the cochlear implant is designed to be conveniently employed full time without discomfort or risk for the wearer.

Devices range in complexity due to variations in sound processing programs and the number of electrical channels that independently stimulate fibers of the auditory nerve. Basically, tone, tempo, and intensity data are provided. Prostheses with a single channel and a single electrode provide this data to a single locus of variable dimensions within the cochlea. Multichannel units can separate acoustic data into multiple components for application at distinct cochlear sites. This exploits the place-pitch principle and is presumed to stimulate more nerve fibers in cases where cochlear neural damage has been scattered. Because a multichannel design permits a wider choice of sound processing strategies, proponents feel that speech and sound recognition is enhanced when compared to single electrode prostheses.
Methodological Considerations

The audiometer is the standard clinical instrument for measurement of hearing impairment. It consists of a tone generator that is calibrated to produce stepped sound frequencies that usually range between 125 Hz and 12,000 Hz with varying degrees of intensity, and a pair of headphones that is worn by the patient. A 0 decibel standard reference curve is used which represents the sound intensity level at each frequency step that can barely be heard by a person with normal hearing (3). The elevation of average sound threshold levels for 250, 500, 1,000, and 2,000 Hz by more than 90 decibels is considered an extreme degree of handicap (27). Where average threshold levels in both ears exceed 110 decibels, the limit of most audiometers, the person can be considered totally deaf with no residual hearing. Where there is less than total hearing impairment, the ability to discriminate speech may vary independently from the degree of audiometric threshold rise. Additional tests involving recognition of spoken words, environmental sounds, sentences, and phonemes with their component phonetic elements have been developed to measure speech and sound recognition in the profoundly deaf with minimal levels of residual hearing.

In 1980 Owens and his colleagues developed an auditory measuring instrument for evaluation of the profoundly deaf that can be used for both marginal hearing aid users and patients with cochlear implants called the "Minimum Auditory Capabilities" (MAC) battery (28, 29). The test battery consists of 13 auditory tests and one lipreading test. This test was originally compiled for evaluating severe postlingual senorineural deafness in patients using amplification devices. It is well suited for comparing the performance of patients with hearing aids and cochlear implants and is also useful for comparing different types of implants. Its component tests measure the recognition of prosodic features, phonemes, noise vs. voice, environmental sounds, sentence recognition,
and one- and two-syllable word identification. They represent a group of standardized audiometric measures that are now considered a reasonable way to judge the communication skills of profoundly deaf persons (39). Supplementary elements have been used by subsequent researchers to expand the MAC battery and evaluate cognitive processes, psychological influences, and additional communicative factors (31,32).

Although the MAC battery represents a convenient touchstone for the basic assessment of prosthetic benefits, there are many direct audiologic measures which have been used in various combinations since the initial experiments with cochlear devices undertaken by House in the 1960s. In fact, the greatest number of implantees, those using the House single-channel prosthesis, has been evaluated using a variety of tests that differs from the MAC battery, although certain tests are common to both procedures (33-36). Much of the inconsistency in testing cochlear implants stems from the diverse aims of their designers. Both Pickett and Fourcin have discussed these difficulties in forming comparisons between cochlear prostheses, tactile devices, and hearing aids (15, 23). Millar, Tong and Clark published an analysis of the relationship between auditory perceptual mechanisms, testing materials, and the design characteristics of eight cochlear implant systems (1). They found that sound processing using both analog and feature extracting methods were promising. However, many important factors for success depended on the personal characteristics of each implantee. A patient's performance on particular audiologic test elements could be attributed to the degree of match between implant design and the pattern of nerve fiber survival, or on the mental capacity and personality traits of the individual.

Implantation of a cochlear prosthesis involves surgery, considerable expense, and the possible destruction of residual auditory function. For this reason, selection of patients deemed likely to benefit from the procedure has received widespread attention. Since all current implants depend on stimulation of auditory nerve fibers at some point in their course through the cochlea, certain selection criteria must logically
be met (12, 13, 30). Nadol noted a number of anatomical and histological impediments to implantation (37). Active chronic infection or an open middle ear are considered contraindications as are all congenital or acquired conditions that result in significant obliteration of the cochlear fluid spaces. Otic dysplasias may impede surgical access to the round window or inner ear. Some defects may result in cerebrospinal fluid leakage.

To the extent that such known causes of deafness can be identified anatomically, the presence or absence of an inner ear amenable to prosthetic implantation can be determined. Radiologic studies and physical examination for this purpose are recommended by all investigators. Determining whether sufficient viable auditory nerve cells or ganglia are present that can be accessed for stimulation is difficult. Nadol remarked that structures other than cochlear neurons per se may be important factors for a successful implant. He cited the need for integrity of the ionic gradient between the scalae media and tympani as well as the possible role of an ionic pathway serving as a "wick electrode" bridging gaps where no viable neurons remain. Uncertainty remains concerning the minimum number of nerve fibers needed for predicting auditory stimulability.

Some investigators have recommended a procedure known as "promontory testing" to distinguish between auditory sensory loss (hair cell deficiency) and neural loss (nerve cell deficit) for selection of implant candidates. House and Brackmann published their experience with 225 patients in 1974 (38). They reported a testing protocol that combined evoked response audiometry and direct electrical stimulation by means of an electrode needle passed through the tympanic membrane and placed in contact with the bone of the promontory of the cochlea. Evoked response audiometry measures electrical potentials produced in response to sound stimuli. The promontory test ascertains patient response to external electrical stimulation of the cochlear innervation. It was suggested that a negative response to evoked response audiometry and a positive response to the promontory test would identify patients with sensorineural deafness who were candidates
for cochlear implantation. Of their group of 225 patients with total sensorineural hearing impairment, House and Brackmann found that two-thirds responded to promontory stimulation. This was considered evidence of a hair cell deficit (thus, sensory impairment) combined with the presence of viable remaining auditory neurons. By 1983, Spelman reported difficulties with promontory testing that involved inter- and intra-patient variations (39). The perceived nature of responses was said to vary with stimulus polarity. Histologic verification of neural survival was not completely consistent with promontory test predictions. It was suggested that the value of the test for screening implant candidates required further clarification of variables that might influence the results. However, Brown and associates reported continuing satisfaction with promontory testing (40). They suggested employing brain stem evoked audiometry in conjunction with promontory stimulation to better define true auditory sensation from possible overriding tactile sensations produced in the middle ear. At the present time, patients who do not respond to promontory testing are not considered for implantation by their group which has developed the 22 channel device (13). Simmons has commented that there is as yet no way to be completely certain about nerve fiber survival regardless of the etiology of deafness (30). In fact, he found that almost all postlingually deaf patients do hear sound by electrical stimulation. He suggested that although the total number of surviving nerve fibers might be directly related to the achievement of good implant results, no way of predicting or confirming this effect now exists. House and his group no longer use the promontory test for screening of implant candidates despite their early enthusiasm for it (12). They reported that "after testing hundreds of patients, almost all patients with sensorineural hearing losses will either have positive responses to the promontory test or will respond with an intracochlear electrode." It is suggested that some future role for the test might be the selection of electrode type when a choice must be made between several devices.
Clinical Applications

In reviewing the experience of the House Ear Institute, Berliner concluded that among over 250 adults and 50 children that had been implanted over a 10 year period, patients with "any etiology of hearing loss that produces a profound sensorineural deafness are suitable implant candidates (41)." She also found that neither age at time of implant nor years of deafness were significant in predicting implant performance. A tendency toward poorer recognition of environmental sounds and certain speech sounds among patients that had been deaf for the longest periods was noted. This result was not statistically significant. Berliner suggested that it might reflect a difficulty in remembering certain sounds over extended periods of impairment.

Edgerton, Brimacombe, and House reported their results in a subset of 53 postlingually deaf patients with single channel implants from the House Ear Institute (36). All patients had profound bilateral deafness that had occurred after age 5 and was known to be caused by ototoxic drugs (eight), otosclerosis (twenty-one), head trauma (seven), and meningitis (seventeen). Their mean age at implantation was 51 years (range, 18-75 years), and their mean age at onset of impairment was 35 years (range, 6-64 years). Experience with the implant ranged from 9 months to 11 years. The comprehensive House Ear Institute test battery was employed to evaluate patient performance with their prostheses (33). An additional indicator of implant utility, the patients' willingness to wear the device on a daily basis, was included in this study. Edgerton did not demonstrate significant differences in patient performance with the implant that might be attributed to the cause of deafness. While post-meningitis and head trauma patients scored lower on word stress discrimination testing, the possibility of a spurious statistical effect was recognized. Ninety-one percent of these patients continued to use their cochlear implants daily. The authors found this pattern to be typical of the total adult population with House implants. At the time of their study daily use was noted among 90% of 231 patients implanted. Variation in the amount of
daily use was not a function of etiology. The mean hours of daily implant use ranged from 9 to 12.4 hours in the four subgroups studied.

Brown, et al, as well as Mecklenburg and Brimacombe, have described patient selection procedures for the Nucleus 22 channel cochlear implant (40, 13). They defined 4 essential criteria for patient selection: 1. postlingually deafened adult age 18 years or over; 2. patency of the basal turn of the scala tympani as seen by roentgenography; 3. profound bilateral deafness; 4. no help from a sensory device (hearing aid or tactile) defined by no significant open-set discrimination when an aid is used (13). To distinguish individuals who might best be fitted with a hearing aid or tactile device in preference to an implant, Brown described a procedure wherein the profoundly deaf patient is given a trial with a powerful body-worn aid having a maximum power output of about 140 decibels (40). The best ear is employed. If no discernible aided threshold is found for sound up to 100 decibels, a vibrotactile bone conductor is tried. After a period of home use, the patient is evaluated with a battery of auditory and visual speech and non-speech tests, including an expanded MAC battery, to determine the degree of aided benefits that might be possible without implantation of a prosthesis. As a result, patients are categorized into 3 groups: 1. suitable for implantation of either ear (0% auditory speech discrimination for both open- and closed-set tests, no significant aid to lip-reading); 2. suitable for implantation of the unaided ear (0% open-set auditory speech discrimination, no significant aid to lip-reading, significant scores on closed-set auditory tests); or 3. unsuitable for implantation at this stage as results with a hearing aid are similar to or better than those obtained for multiple-channel cochlear prosthesis patients (open-set auditory discrimination, significant aid to lip-reading). Medical and otologic examination accompany this testing including x-ray studies of the temporal bone to identify cochlear abnormalities that might impede placement of the electrode array. By mid-1985, 86 post-lingually deaf patients were implanted using these protocols. Their ages ranged between 18 and 79 years. All were found to be stimulable. The average daily use of the
device was 11 hours with 98% of the patients using the implant regularly. An additional feature of the 22 channel cochlear prosthesis involves its capability for discrete programming of each bipolar electrode pair (13). This permits the implant to be adjusted for the optimal intensity of stimulus for each channel of processed signal, balancing between channels, and shift of stimulation site to either exploit the place-pitch principle or compensate for gaps in viable auditory nerve fiber distribution within the cochlea.

The implantation of cochlear prostheses in children remains the most controversial subject in this technology. By March of 1985, Berliner, Luxford and House reported that 140 children had been implanted (12). Both pre- and postlingually deafened patients were studied. Twenty six additional children in Europe were noted to have been implanted with other intracochlear devices. A clinical investigation of cochlear implantation in children is currently underway with an approved Investigational Device Exemption from the Food and Drug Administration. The authors reported no serious adverse effects in children who used the device up to 3 years. Audiologic results were similar to those found in adults. No problems related to skull growth or deterioration of performance that might indicate neural damage have been encountered.

Downs and Black reviewed implantations in children (42). Although data are limited, they expressed serious reservations about specific risks linked with childhood. The possibility of eventual neural damage due to long-term electrical stimulation or trauma due to the cochlear electrode were cited. The risk of otitis media among children, and the threat of meningitis were also of concern. Since the temporal bone is not completely developed until age 6 years, displacement of the implanted device is possible if procedures were performed in younger children. In addition, the risks of general anesthesia, infection, and facial nerve damage were mentioned. A specific warning was expressed with regard to multichannel cochlear prostheses. Young children cannot describe variations in loudness, pitch and sound quality that are required to properly adjust the sound processing program. The authors concluded that the ethical
considerations inherent in making decisions of life-long consequence for children preclude the general use of cochlear implants in childhood at this time. Schein added his concern over the lack of proven strategies for the education of implanted children (43). He emphasized the need for research in this area. Since the acoustic processing program for each type of device is somewhat different, training must necessarily be consistent with the design goals of the prosthesis.

There is a paucity of information concerning implantation in prelingually deaf people (12, 39, 40). Most authors have commented on the inability of such patients to make full and effective use of stimuli from cochlear prostheses without a background of developed normal language skills to prompt their interpretation. There is general agreement that further research is required in this area. The perceptual mechanisms that are called into use by the implantee in response to specific auditory sensations are critical to the successful use of the entire prosthetic system (1).

The evaluation of patients' benefits from cochlear implants is made difficult by the many variables of auditory anatomy, physiology, cognition, rehabilitation, and engineering design which must be reconciled. Millar, Tong and Clark have proposed three basic ways that such systems may be evaluated: 1. measure activity in the auditory system which is caused by electrical stimulation of the cochlea; 2. examine the dimensions of perceptions generated by electrical stimulation; and 3. directly assess the performance of the prosthesis in receiving speech and environmental information (1). The latter approach incorporates the phonetic, linguistic and experiential knowledge of the implantee to shape and modulate perceptions. The authors found that there is no completely successful method of objectively evaluating the effects of prosthetic electrical stimulation in the human auditory system.

In 1982, Thielemeir, Brimacombe and Eisenberg reported ten years of experience with the House single-channel cochlear implant (33). Since standardized testing for implantation did not exist at the onset of their program in 1972, they felt a need for
methods to select candidates, compare performance across different groups of implantees, and follow performance over time to identify long-term effects. The test battery included measures of general audiometric capability as well as recognition of 30 common environmental sounds. It also included a closed-set speech perception test involving word identification. One-hundred-thirty-five profoundly deaf patients were studied. Their average age at implantation ranged between 18 to 75 years with a mean age of 46 years. A large percentage of the group had no measurable unaided hearing in either ear within the limits of audiometry. Seventy-three patients were retested after they had been provided hearing aids producing amplification with maximum power output that reached, but did not exceed, 130 decibels. If a sound threshold could be determined, the most comfortable loudness level was identified and further testing was conducted. Mean aided warbletone detection thresholds ranged between 83 and 108 decibels for this group across frequency steps from 250 to 3000 Hz. Again, a large percentage of patients had no aided response at the limit of the audiometer. Aided speech detection thresholds reached a mean value of 68 decibels. The authors noted that although in some cases minimum sound and speech detection values reached relatively low threshold levels, these patients were unable to benefit from conventional hearing aid amplification for other reasons. It was found that after implantation, these same subjects achieved significantly improved auditory thresholds at all test frequencies when compared to their performance with hearing aids. Whereas no response to aided auditory inputs had been recorded in 25 to 78 percent of patients depending on test frequency, all patients responded to stimulation after the implantation of a cochlear prosthesis. Among a subgroup of 37 patients with the best aided preoperative thresholds for speech detection, all scored significantly better on environmental sound and speech discrimination testing after implantation. Both speech and environmental sound discrimination were found to improve over time when scores obtained during the basic guidance period, 2-3 months after surgery, were compared with scores after at least 6 months more experience with
the device. No predictive value was found between initial unaided auditory thresholds and thresholds with a powerful hearing aid when compared to auditory thresholds with a cochlear implant. Speech and environmental sound discrimination scores related inversely to years of deafness. The authors attributed this phenomenon to a dimming of auditory memory with time, or possible physiological effects in the auditory system. It was concluded that profoundly deaf adults can benefit significantly from the single channel cochlear implant. Audiometric thresholds, and discrimination of closed-list speech/stress and environmental sounds were noted to be significantly better than preimplant scores in the same ear with a hearing aid. The perception of sound described by these implantees was reported to be quite consistent. It was said to be sensed deep within the ear compared to sound from a hearing aid. A "mechanical" or "static-like" quality was noted. With rehabilitative training in the use of timing and intensity cues, learning was observed that led to improved sound recognition. Some environmental sounds were described as sounding "natural" such as "running water, footsteps, knocking on a door, clapping, hitting or banging on metal, shuffling cards, and crumpling paper." Background noise was troublesome initially, but was less dominant with time. Speech could generally be discerned, but not discriminated without lipreading.

Crary, et al, conducted a series of yearly interviews beginning one year after implantation (34). They found certain common sentiments among patients with the single channel device. These included a reduction in sensed isolation from the world, increased confidence in interpersonal functioning, improved lipreading, and an appreciation for the ability to hear warning sounds. The principal frustration they expressed concerned the inability to discriminate open speech. Overall satisfaction with the cochlear protheses was observed. Less than 10 percent of their total implant population were classified as "nonusers," with the majority continuing to use the device over many years. No
psychological testing instrument could be identified that reliably predicted nonuse behavior. However the small size of the "nonuser" subpopulation has hindered its study. Details of the interview design employed was reported by Wexler et al (35).

Shannon found that 9 centers around the world were doing research on cochlear implants by 1983 (44). At that time, the majority of cases were implanted with the House single channel device (350 patients). Most of the remainder were implanted with a 14 electrode prosthesis developed by Chouard in Paris (58 patients). Among the other seven centers, a total of 42 additional implants was performed. These included 30 multielectrode units of various designs. The Chouard prosthesis is composed of 12 individual electrodes that are placed through 12 discrete fenestrae that are surgically created in the lower two cochlear curves. This approach has not been adopted in the United States. Shannon sought to reconcile speech recognition data reported by each cochlear implantation research group in addition to other benefits such as environmental awareness, lipreading, and assistance in voice modulation. It was concluded that multichannel stimulation offered no dramatic advantage at that time. However there were indications that multichannel techniques held the best potential for improvement in speech recognition. Shannon also found that the existing implants employed biocompatible materials and all methods allowed trauma-free insertion of cochlear electrodes. He emphasized that the perceptual effect of electrical frequency applied to the cochlea is not the same as the effect of acoustic frequency and can produce a different pattern of perceptions. For this reason, the translation of acoustic into electrical signals has received a major share of scientific attention as evidenced by the various sound processing methods being tested. In 1983, Owens, Kessler, and Raggio studied the results obtained with single and multichannel prostheses in 11 patients by means of their MAC battery of tests (29). Four patients had single channel devices. The remaining seven subjects had been fitted with multielectrode arrays using 8 bipolar leads. These investigational multielectrode units used a single channel stimulator in 6
patients and a single or three channel stimulator in one patient. The authors found that multichannel stimulation of a multielectrode array held the most promise for future advances in speech recognition. Although the majority of subjects showed improvement in certain MAC test results including lipreading, the limited nature of this study makes its findings difficult to interpret.

Safety and Efficacy

Owens reviewed cochlear implantation in 1984 (45). He noted the shortcomings of existing studies with particular attention to criteria for selection of patients and the need for better communication between investigators. He suggested that work remained to be done in comparing the results of implantation with the use of an appropriate hearing aid. The advantageous use of high powered hearing aids by some people with residual hearing levels between 93 and 110 decibels was cited. He concluded that "postlingual deafness must be an overwhelming experience beyond the imagination of those who have not experienced it." Although he noted that controversy continues concerning further damage to hearing from high powered aids, the evidence was considered inconclusive. Owens suggested that almost any response on open-response tests by a hearing aid user would mitigate against a cochlear implantation recommendation. He felt that recognition of the human voice might be the basic consideration in the degree to which a hearing aid is beneficial. Patients with postlingual profound hearing loss who are unable to derive any benefits from hearing aid use, were considered "strong candidates for cochlear implants." The principal communicative benefits of implantation were regarded as a spontaneous improvement in self-monitoring of vocal loudness and quality which can be of significant social importance, and immediate enhancement in lipreading for many, but not all, patients. Prediction of the ultimate role for the cochlear prosthesis was felt to be as yet undetermined.
By 1985, 28 patients had received an intracochlear prosthesis implanted by Hochmair and Hochmair. This is a device with four pairs of electrodes and a single channel full-bandwidth analog sound processing scheme (10,16). Most patients with this prosthesis were implanted in Austria. There is an interest in its use for patients in this country as well (31). Functionally, it is a single channel, single electrode unit. The best of four possible sites in the cochlea is selected by clinical trial. The sound processor is ultimately fitted to the electrode providing the greatest degree of speech understanding. When this stimulation methodology was compared with trial results employing multiple channels in the same device, no distinct advantage could be identified (16). The authors concluded that full-bandwidth analog sound processing may produce results with single channel devices that are comparable to multichannel implants employing sound feature extraction schemes. Overall, satisfactory results were claimed, but testing methods are unique to this group and the patients were all German speakers making their findings difficult to compare.

Mecklenburg and Brimacombe reported on a multichannel cochlear implant program in early 1985 (13). At that time, 51 patients had been implanted with this 22 electrode-22 channel device. Stimulation is applied through only one electrode at a time based on a speech feature extracting scheme that exploits the place-pitch principle as well as a sound coding system designed to foster speech recognition. All patients were postlingually deaf and had no significant open-set word discrimination when using a hearing aid. Only patients who were stimulable by promontory testing were implanted. After implantation, each device was individually programmed to meet the needs of the patient with respect to signal coding and neural survival patterns. The MAC battery was employed as the basic evaluation instrument. Speech tracking, in which the person must repeat verbatim passages of connected discourse, was also used as a measurement of speech comprehension (46). Since all patients had not completed postsurgical evaluation, the data was limited to results from subgroups of 14 to 22 patients. Statistically
significant post-implant performance on closed-set word recognition and prosodic features of speech was reported. Open-set materials, where the implantee is exposed, without preparation, to randomly selected speech sounds, was improved in 11 of 20 patients tested. Among 14 patients, speech tracking scores were compared for lipreading only and lipreading with the prosthesis. The patients showed an average improvement in lipreading of 29 words per minute when assisted by the cochlear implant. Their range of improvement was 13 to 72 words per minute. Among the patients implanted, none has failed to be stimulable with the implant and all have achieved hearing sensations as a result.

Further data on the multichannel device have become available as a result of the premarket approval process conducted by the Food and Drug Administration (47). Eighty-six patients (87 ears) that had been implanted at 18 clinics between 1982 and 1985 were evaluated. Of this number, 80 had completed some audiological testing. No device failure requiring replacement had occurred in the total group. Ages ranged from 18 to 79 years and duration of profound deafness ranged between 5 months to 54 years. No patient was lost to follow-up. The findings of Mecklenburg and Brimacombe were essentially replicated (13). It was concluded that the device could restore a level of auditory sensation and assist adults who are bilaterally profoundly deaf who cannot benefit from a hearing aid. Some patients showed a significant improvement in speech recognition without lipreading, as well as an improvement in recognition of environmental sounds. Important gains were also noted in lipreading ability after implantation.

Gantz, Tyler, McCabe, et al, have embarked on a comparative study of various cochlear prostheses (31). Their initial publication reported on results obtained in 9 patients implanted with three devices. It was found that all implants provided significant improvement in lipreading and sound awareness. Evaluation was accomplished with the MAC battery and 12 additional tests developed by the research group. The authors
suggested that a correlation existed between cognitive skills and patient performance requiring synthesis of the limited information provided by cochlear implants. This continuing study has been extended to include 5 patients with a 4 channel implant and 3 additional patients with a 22 channel unit. The 4 channel device employs 6 individual electrodes that are inserted into the scala tympani to depths of 4 to 22mm (10). Only 4 electrodes and a ground are ultimately placed in use after programming. This unit uses a percutaneous electrical plug to which the external sound processor is connected. Electrical stimuli are administered after separation into 4 channels of frequency-filtered analog sound information. The highest frequencies are applied at the basilar electrode in accord with the place-pitch principle. Channel intensity, filtering frequencies, and electrode choice are independently adjustable. In an unpublished paper presented during August, 1985, Gantz and his colleagues reaffirmed their earlier work and found that the multichannel devices were beginning to provide the information required by the profoundly deaf to communicate effectively through sound only. Multichannel patients were generally found to be gaining greater benefits from their implants although all devices enhanced lipreading and provided useful sound information.

By December of 1985, over 150 patients had been implanted with one multichannel system worldwide as reported by the manufacturer in an unpublished letter to the Office of Health Technology Assessment (OHTA). Of this number, no implant failures have been noted. Mecklenburg extracted the evaluation data on 15 patients of age 60 years or over (range 60 to 74 years) who have been implanted with this prosthesis. All had completed at least 3 months follow-up testing after implantation. Selection protocols and evaluation procedures were essentially the same as those applied to the total group of implantees. Mecklenburg's unpublished conclusions were that the 15 patients with a mean age of 65.8 years obtained significant benefit from their implants that was equivalent to the improvement among a cohort of younger patients with a mean age of 36.7 years (range, 21 to 57 years). This report is unusual in that it presents specific
findings in older patients. To date, although some other types of prosthesis have been implanted in patients over age 60 years, they have not been addressed as a separate group. Maddox and Porter reviewed the experience with a single channel device in 1983 and concluded that "absolute age is no longer an important variable in patient selection, provided the subject is a good health risk for general anesthesia and all other aspects of the selection criteria are met (48)." Simmons was in general agreement with this review and felt that selection of patients might vary with the physiologic, rather than chronologic, age of the prospective implantee (30).

There is a general consensus that the clinical management of cochlear implant patients requires a multidisciplinary team. Specific training and experience with the device being implanted is considered essential since testing and rehabilitation would logically be linked to the sound processing scheme, device programming, and the electrode placement strategy being employed (13,30,49). The combined skills of an otologist, audiologist, speech/hearing pathologist, and psychologist have been recommended (20). The development of specialized evaluative devices such as the MAC battery to gauge patient progress has in itself defined specific professional skills required for the conduct of a rehabilitation program (45).

After surgical healing has taken place, a rehabilitation program is begun to assist patients with the use of their implants. The principal elements involve counselling, psychophysical evaluation to ensure the match between patient and prosthesis, and auditory as well as auditory-visual training to assist the patient in developing communicative and perceptive skills. There is little information concerning the optimum duration and intensity of rehabilitation programs for various cochlear implants. Mecklenburg has stated that multichannel devices require a distinctive rehabilitative plan that allows for the wider variety of sensations that these implants produce (13).

Edgerton has described rehabilitative procedures at the House Ear Institute (20). He estimated that postlingually deafened adults require 20 to 30 hours of a "basic
guidance program" with the single channel prosthesis. The purposes include determination of an optimal electrical setting, education of the patient and family on the long-term care and maintenance of the device, introduction to listening and communication skills, and assessment of specific long-term training needs. Home study by patient and family are an integral part of rehabilitation. Information that might assist in evaluating the rate of patient progress toward optimal performance limits is not available.

Reports have appeared in the literature suggesting the use of electrical stimulation for tinnitus. Thedinger, House, and Edgerton have reported on 5 patients who received cochlear implants exclusively for tinnitus relief (50). The affliction was considered to be debilitating in all cases. Results were inconclusive with one patient considered a definite therapeutic success. Other reports indicate that tinnitus may increase after implantation (47). This procedure remains the subject of continuing research.

Facer editorialized on the status of cochlear implants in 1985 (52). He commented that "a profoundly deaf patient who is unable to benefit from a hearing aid can certainly be considered for implantation of an extracochlear device." Facer suggested that patients with profound postlingual bilateral sensorineural hearing loss caused by ototoxicity, otosclerosis, meningitis, syphilis, Meniere's disease, trauma, or idiopathic sensorineural hearing loss should prompt consideration of an intracochlear implant. It was felt that development of normal speech before impairment was a prime requirement for selection of candidates. One month of postoperative healing followed by a 6 month to 1 year rehabilitation period was advised. The rehabilitation period is used to train implantees in the recognition and use of new auditory clues and improve communication. Instruction in lipreading, speech production, and a home practice program involving the family are included. The benefits of implantation were considered to be restored ability to hear and recognize environmental sounds "at a level that
approximates normality." Male and female voices could be distinguished and lipreading was generally improved. A "tremendous psychologic gain" stemming from increased self-esteem and a sense of security was also attributed to the ability of implantees to recognize noises that might signify danger and otherwise be placed in better contact with their environment.

Safety

The safety of cochlear implants has been addressed with respect to the surgical risks of implantation as well as the longer term effects of chronic electrical stimulation on both bone and auditory nerve fibers. Brackmann, in describing the surgical implantation techniques commented that postoperative complications have been "remarkably few (18)." In 200 cases he reported that "there have been no cases of meningitis, cerebrospinal fluid leak, middle ear infection, persistent unsteadiness, vertigo, facial nerve spasm, or facial paralysis." Adverse neurological and psychological effects were also absent. Two cases of improper wound healing and one case of persistent leakage of perilymph were reported. Postoperative antibiotics have not been used routinely. Hospitalization for 24 to 48 hours after surgery was generally required. "Mild unsteadiness" for a few days after discharge was noted.

Berliner, Luxford, and House reviewed the deleterious effects of cochlear implantation within the cochlea (12). They concluded that the 6 millimeter length of their active electrode ensures minimal risk of insertion trauma. The FDA summary of safety and effectiveness data appended to the cited article indicated that the majority of implanted patients were stimulable. About 5 percent had no response to the cochlear prosthesis. Eight patients had revision surgery calling for removal of an earlier device and reinsertion of a new electrode. One patient has had a single-electrode replaced with a multi-electrode unit. These revisions have been accomplished with no reported change in electrical stimulation thresholds. Osteogenesis may occur as a result of mechanical
trauma or electrical fields, however no significant impairment of prosthetic function was found. In the temporal bones of three deceased implant patients, new bone growth was confined to the round window and lower basilar turn of the cochlea. No adverse effect on the innervation was seen. The authors have not noticed any deterioration in electrical thresholds of stimulability or dynamic range in their patients over time. Several patients have been available to study during an 8 year period, and one for over 10 years. Although the stimulus current and charge density of the House device are within limits acknowledged to be safe for neural tissue as established by animal studies, there has been little human evidence due to the lack of tissue samples for study. Extracochlear growth of fibrous tissue was found to seal the round window and encapsulate the electrode within the cochlea.

Miller has also acknowledged the difficulty in determining the degree to which cochlear implants can cause pathology (9). Since human tissue from implanted subjects is scarce, most data has been derived from animal experiments. In reviewing the animal literature he found that with proper attention to surgical technique, selection of materials, and construction of the device, there was little to be feared. The potential for chronic tissue damage was linked to the intensity and wave form of the electrical stimulus that is employed. Miller noted that the relationship between histologic change and implant function is not clearly defined. Unfortunately, much of the animal research that has been performed was based on prototype devices using materials, designs, and electrical charge patterns that were intended for specific experiments. Sutton reviewed much of this animal data and has suggested paths for future research (51).

The most recent data available on the safety of a multichannel implant is contained in the FDA summary of safety and effectiveness for the Nucleus cochlear prosthesis (47). Eighty-six patients with 87 implants were included. This device extends about 25 mm within the scala tympani of the cochlea. Surgical complications were minor and quite similar to the experience of House and his group. No device has failed nor has
implant replacement been required. The longest period of use in this group of patients was greater than 24 months. During that period audiologic performance and dynamic range remained constant.

DISCUSSION

There is a consensus in the medical and audiologic literature that cochlear protheses can transmit auditory information by direct electrical stimulation of auditory nerve fibers. Such stimuli, when appropriately processed, are interpretable as perceptions of pitch, tempo, and sound intensity.

The two devices now approved for marketing share certain common attributes. However, they differ significantly in their sound processing strategies and in the number of active electrodes which are inserted into the scala tympani of the cochlea. These differences are not necessarily disadvantageous, since a measure of clinical flexibility is afforded which allows selection of the cochlear device best suited to the needs of a particular patient. For example, the single channel implant extends only 6mm into the cochlea; an advantage to patients with structural deformities that block deeper penetration into the scala tympani. On the other hand, where damage to the auditory nerve within the cochlea is scattered, the 25 millimeter penetration of the Nucleus device with its multiple paired electrodes permits a match between the site of stimulus delivery and the location of viable neurons. A similar situation exists with sound processing methodology. Pfingst has remarked on the possible selection of various sound encoding schemes based on the specific rehabilitation goals that offer a patient the greatest clinical benefit (6). Tasks such as recognition of environmental sound, lipreading, open-speech recognition, and use of cochlear prostheses in a noisy environment may be accomplished by different sound processing methods. Undoubtedly,
comparison studies between cochlear implant designs will continue long into the future. To the extent that sound and speech recognition, and the adaptation of a patient to a device can be improved, there will be research to achieve increasingly better results.

At the present time the benefits that have been provided to virtually all stimulable patients are a significant improvement in lipreading and sound awareness. A correlation between a patient’s cognitive processes and the ability to utilize information presented by the cochlear implant has been noted (31). In the postlingually deaf, this serves to facilitate recognition of speech and sound characteristics. Many patients have attained additional benefits that have reached open-speech recognition, telephone conversation, and identification of many environmental sounds (53). Approximately 5 percent of patients with the single channel prosthesis failed to achieve a sensory response to their implants. All patients implanted to date with the multichannel device have responded (12, 47). It is difficult to predict which specific postlingually deaf implant patients will achieve benefits beyond speech and sound detection.

Patients selected for cochlear implantation should be adults with bilateral profound sensorineural deafness, who developed normal language skills before impairment. Implantation in children under age 18 is generally considered investigational as is its use in prelingually deaf individuals (12, 42, 54). The use of implants solely for relief of tinnitus also remain investigational and to date has not been approved by the FDA (50).

The preoperative work-up and post-implantation rehabilitation program for cochlear implant patients requires the skills of a team composed of an otologist, audiologist or speech/language pathologist, and psychologist. They should be trained and experienced in the specific prosthesis to be used. It is expected that preoperative polytome or CT radiographic studies will be required to establish the structural features of the cochlea and skull. Magnetic resonance imaging has been used to visualize the cochlear nerve and auditory areas in the brain. At the present time promontory testing
is being employed by some implant groups to identify stimulable patients but others have argued against its routine use. It appears to be a reasonable test procedure to be employed at the discretion of the implantation team for selection of patients, however additional research is required to assess its ultimate predictive value. In adults age does not appear to be a significant factor in predicting success with an implant, although years of deafness duration may be indirectly related to sound recognition ability.

There are insufficient data at this time to assess the feasibility of electrode replacement to keep pace with future technological advances. A few patients have been reimplanted successfully for various reasons, but the safety of replacement procedures on a routine basis has not been established.

The audiometric testing criteria that are employed to define "profound deafness" for the purpose of selecting cochlear implant candidates remain somewhat elusive. Bilateral hearing loss of a degree that cannot be remedied by a modern powerful aid is usually specified (12,31,39,55). "Benefit" from a hearing aid has not been well defined as a criterion mitigating against implantation. At this point in the development of the cochlear prosthesis, it appears justified to conclude that patients with any residual auditory ability to detect sound in either ear will most likely achieve results with a powerful hearing aid and a program of rehabilitative therapy, that equal the benefits that can be expected from an implanted device. Patients with a degree of residual audition have been implanted by some investigators with the goal of restoring lost speech recognition. However, the risk that surgery and chronic electrical stimulation may damage their remaining capacity for auditory sensation militates against the routine use of intraco cochlear prostheses in such cases.

Vibro-tactile and electro-tactile aids have been used to provide speech and sound perception for the profoundly deaf (21-23). Some groups have routinely tested cochlear implant candidates with tactile devices to screen out patients who might achieve equal benefits from a noninvasive technology (13). Proponents of tactile systems have
demonstrated their use for improvement of lipreading skills, but they have been noted to "present unfamiliar patterns of sensation" to the postlingually deaf (23). The benefits of tactile aids with respect to voice modulation guidance and recognition of environmental sound are not well established. Published comparisons of patient performance with cochlear implants as opposed to tactile devices have involved a limited scope of investigation and small numbers of heterogeneous subjects. Some authors have suggested that tactile aids might best be used for prelingually deaf children whose normal patterns of audition have not yet developed. At this juncture, all tactile aids to hearing are considered to remain in the area of research. However, their noninvasive nature certainly invites a trial in some profoundly deaf patients. Extensive rehabilitation has been cited as a requirement for the successful use of tactile aids.

Because modern high powered hearing aids, and possibly tactile devices, represent alternatives to implantation, the presurgical evaluation of implant candidates is quite important. Selection of patients for intracochlear implants should be routinely limited to those with average hearing thresholds that exceed 110 decibels for pure tone stimuli between 250 Hz and 2,000 Hz. In addition, an aided auditory sound detection threshold should not be measurable. It is recognized that under conditions of extreme amplification an aid may produce tactile, rather than auditory, effects. For that reason, absence of the aided ability to detect sound through auditory pathways is emphasized. Limitation of cochlear implantation at this time to patients who are totally deaf to external sound vibrations but not to intracochlear electrical stimulation, within this narrow definition, would serve to identify a disabled population with no other feasible prospects for rehabilitation. This conclusion is based on the observation that patients with any residual auditory capacity to detect sound will generally derive equivalent benefit from less invasive measures. Thus, the implantation of cochlear prostheses in patients with measurable residual hearing, aided or unaided, should be considered not yet
established. At such time as additional scientific evidence of the superiority of implants over aided sound detection is available, more liberal use of this prosthetic procedure could be considered.

There is general agreement that the postimplantation rehabilitation program should continue to be a team effort similar to presurgical evaluation procedures. The otologist, audiologist or speech/language pathologist, and psychologist all have their roles. Some groups recommend a 20 to 30 hour initial basic guidance period. This encompasses the fitting and adjustment of the sound processor after surgical healing, counselling, and beginning a program of rehabilitation with the patient and family. Further training in lipreading and sound recognition may extend for 6 months to 1 year after implantation. Clearly defined endpoints for auditory or functional improvement have not yet been described.

The risks associated with cochlear implantation are attributable to general anesthesia, mastoid surgery, and electrode insertion, or the direct effects of electrical stimulation. Patients should be free of middle ear infection, have an accessible cochlear lumen structurally amenable to implantation, and be free of lesions in the auditory nerve and acoustic areas of the central nervous system. Electrical stimulation within the limits employed by commercially marketed devices has demonstrated no safety problems to date. Risks of cochlear osteogenesis or neural damage due to electrode insertion trauma or direct electrical effects may exist over long-term use, but these are not generally considered impediments to implantation at this time.

Psychological evaluation and counseling of candidates for implantation has been noted to serve several functions. A patient must possess the cognitive capacity to constructively employ cochlear stimuli and be capable of benefiting from an extended rehabilitation program designed to enhance the utility of an implanted prosthesis. Expectations of the patient and family that normal hearing will be restored should be
tempered so that a more realistic view of results is imparted. Several authors have also emphasized that most hearing impaired people experience social and psychological difficulties that can be ameliorated with professional counselling.

Cochlear implants were evaluated by the Council on Scientific Affairs of the American Medical Association in 1983 (56). It was agreed that the profoundly postlingually deaf obtained certain benefits from cochlear implants such as: (1) better contact with environmental sounds including telephone ringing, alarms, and household and natural sounds, (2) awareness of when a person is speaking, (3) help in lipreading, and (4) help in modulation of their own voice. The procedure was considered to be indicated in postlingually deaf adults who cannot discriminate speech with an appropriate (powerful) hearing aid and in whom a hearing aid does not allow them to perceive common environmental sounds. An extensive program of auditory rehabilitation was recommended after implantation to achieve maximum benefits in the areas of monitoring environmental sounds and speech, and in lipreading. The Council endorsed the practice of cochlear implants as an acceptable procedure for postlingually profoundly deaf adults.

In 1985, the American Academy of Otolaryngology-Head and Neck Surgery provided OHTA with a statement of policy on cochlear implants. The Academy considers cochlear implantation an accepted procedure in adults and an investigative procedure in prelingual children. Multiple channel implants are approved in the same conditions as single channel cochlear implants. Rehabilitation and the clinical evaluation of prospective implant candidates by a team that includes the otologist and audiologist were considered to be essential elements that are inseparable from surgical implantation. The role of clinical judgment in the choice of an appropriate prosthesis and anticipating the benefits a candidate might expect from implantation were emphasized.

The American Speech-Language-Hearing Association has provided OHTA with materials to be used in this assessment. The services of an interdisciplinary team for the selection, treatment, and rehabilitation of cochlear implant patients was recommended
as a minimum standard for implantation. Audiologists and speech/language pathologists, working together with the otologist and psychologist were considered necessary for the provision of diagnostic and rehabilitative services for the hearing impaired. Emphasis was placed on the crucial role that aural rehabilitative technologies play in cochlear implant programs. The importance of determining whether a noninvasive procedure can produce similar results to an implant was cited. This permits individuals who might benefit from other rehabilitative measures to be aware of their alternatives. Implantation in children was considered experimental. It was urged that the guarantee of a comprehensive rehabilitative program be a requirement for future clinical implantation activities.

The Food and Drug Administration (FDA) has defined the cochlear implant as a "device that electrically stimulates the auditory nerve of profoundly or totally deaf patients to provide them with a perception of sound." There are now two cochlear implant devices that have received premarket approval from the FDA. These are the House/3M single channel/single electrode device and the Nucleus 22 channel/multielectrode device. Both are "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 profound sensorineural deafness and who cannot significantly benefit from appropriate amplification by a hearing aid" in accord with their approved labeling.

The National Institutes of Health has informed OHTA in 1985 that there were at least 6 different cochlear implant devices currently under development that are substantially different from each other. Both the House/3M device and the Nucleus 22 channel device were considered to be efficacious in supplementing lipreading, improvement of speech, to help in recognition of certain environmental sounds, and to be psychologically satisfying. In addition, the Nucleus 22 channel device was considered to supply more information to the auditory system than the single channel House/3M unit
which was reflected in improved lipreading scores. Neither device was considered able to restore normal hearing. The incidence of potential risks due to surgery or electrical stimulation was considered low. Whereas damage to auditory nerve fibers may occur with implantation, the electrical thresholds for auditory sensations remain constant over time and subjective perceptions of sound have remained stable.


SUMMARY

The cochlear implant is a neural prosthetic device that provides a perception of hearing and facilitates communication for persons who are profoundly deaf. Speech and sound information is transformed into electrical signals that create a perception of sound upon their application to fibers of the auditory nerve within the cochlea. The device is intended for persons with profound sensorineural deafness. This condition exists when the sensory hair cells of the organ of Corti are disabled while fibers of the auditory nerve and their connections in the central nervous system remain functionally intact. The electrical stimuli that are applied within the cochlea are then appropriately conveyed and interpreted as audible information.

Cochlear prostheses are designed to stimulate the auditory nerve in a manner that exploits the ability of the cochlea and central nervous system to discriminate the frequency, tempo and intensity of ambient sound in ways that assist the wearer to recognize its source and information content. Selection of candidates for implantation involves confirmation of profound bilateral sensorineural deafness that cannot be mitigated by the use of a modern powerful hearing aid capable of providing benefits equal to those obtainable from an implant. In addition, the cognitive ability to make use of auditory clues, and the willingness to conscientiously pursue an extended program of aural/visual rehabilitation, must be present. Patients who have become deaf after
developing normal language skills are most amenable to implantation since sound recognition is aided by established associations and memory. Cochlear implantation in the prelingually deaf is considered investigational. The implantation procedure requires that patients be in sufficiently good health to undergo general anesthesia and a 3 to 4 hour surgical operation.

Cochlear implants may incorporate a single channel, or multiple channels of electrical information that is transmitted to the auditory nerve via one or more electrodes within the cochlea. Various combinations of sound processing methodology and choice of stimulation site have afforded a degree of flexibility in prosthetic design. At this time multielectrode-multichannel devices appear to offer the patient somewhat greater improvement in the ability to recognize sound and speech. However, clinical judgment must be exercised in the selection of an implant for a specific patient since patency of the cochlear lumen and other structural factors must be considered.

Specific prostheses require preoperative evaluation and postoperative rehabilitation programs that are designed to obtain maximal results with a specific device. It has been estimated that 20 to 30 hours of basic guidance is required to initially adjust the implant and familiarize the patient and family with its use. Six months to one year of rehabilitation is estimated to be necessary. A team of otologist, audiologist or speech/language pathologist, and psychologist, that is trained in evaluation and care of patients with the device to be implanted, represents a reasonable minimum standard for an implantation program. Patients must be willing and able to comply with the comprehensive course of evaluation, implantation, and rehabilitation provided by this team.

The benefits of cochlear implants include the restoration of auditory sensation, detection of speech at normal listening levels, and improved voice modulation. With visual contact, lipreading improvement can also be expected. Some patients may progress to a considerable degree of open speech and sound recognition. At a minimum,
it allows the profoundly deaf to be in closer contact with their environment, can provide warning of danger, and improves communication with others.

Cochlear implantation is considered a safe and efficacious therapy for adult patients with postlingual, profound, bilateral, sensorineural deafness who are stimulable and who lack the unaided or aided residual auditory ability to detect sound.

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REFERENCES


43. Schein JD. Cochlear implants and the education of deaf children. AAD, June 1985; 324-331.


The cochlear implant is a neural prosthetic device which transforms speech and sound information into electrical signals which create a sense of audition upon their application to fibers of the auditory nerve within the cochlea. Its components are: a microphone, speech processor, signal transfer hardware, and an intracochlear electrode array. Cochlear prostheses stimulate the auditory nerve in a manner that permits the central nervous system to discriminate frequency, tempo and intensity of sounds to assist the wearer in recognizing its source and information content. Benefits reported in the literature are restoration of auditory sensation, detection of speech, and improved voice modulation. Lipreading is also improved. Some patients attain a considerable degree of open speech and sound recognition. A surgical procedure under general anesthesia is required for implantation followed by a program of aural rehabilitation. Safety and efficacy are best documented for adults with profound post-lingual sensorineural deafness which cannot be mitigated by a high powered conventional hearing aid, and whose auditory nerve is stimulable.