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Cochlear Implants

Working Group on Cochlear Implants

This technical report was approved by the American Speech-Language-Hearing Association's (ASHA) Executive Board in March 2003. This technical report is an update and supersedes the previous technical report Cochlear Implants, 1986. Members of the working group were: Carolyn J. Brown, Co-Chair; Ann Geers; Barbara Herrmann; Karen Iler Kirk, Co-Chair; J. Bruce Tomblin; and Susan Waltzman. Renee Levinson and Gail Linn served as the National Office liaisons and members of the group. Susan Brannen, ASHA 2001-2003 vice president for professional practices in audiology, provided guidance and support.

Introduction

Cochlear implants are electronic devices that contain a current source and an electrode array that is implanted into the cochlea; electrical current is then used to stimulate the surviving auditory nerve fibers (Wilson, 2000). Cochlear implantation has been an approved method of treating profound, bilateral, sensorineural hearing loss for persons since the mid-1980s (House and Berliner, 1991). Although the original cochlear implants were single channel devices, there are now several commercially available, multichannel cochlear implant systems. Additionally, over the course of the last two decades, technological developments in cochlear implant design have yielded substantial gains in spoken word recognition for the average multichannel cochlear implant user. Along with advances in engineering and speech processor design have come changes in the criteria for cochlear implant candidacy. For example, initially only adults with postlingual profound deafness were considered suitable candidates for cochlear implantation; now, audiometric thresholds are no longer a primary determinant of cochlear implant candidacy for postlingually deafened adults. Similarly, congenitally deaf children initially were not considered suitable candidates for multichannel cochlear implantation. When implantation of children was approved by the FDA it was limited to children 2 years of age and up; now, the FDA has approved the use of multichannel cochlear implants in prelingually deafened children as young as 12 months of age, and many children younger than 12 months of age have been implanted off protocol.

This technical report is intended to update speech and hearing professionals on the current status of cochlear implantation in individuals with hearing loss. It provides a brief overview of the history of cochlear implantation and a description of current technology, candidacy criteria, and outcomes in adults and children. To the best of our knowledge, this information was up-to-date at the time this document was prepared. It should be noted that cochlear implant technologies, and thus cochlear implant outcomes, are continually evolving. The most current information regarding available cochlear implant systems can be obtained from the cochlear implant manufacturers. Finally, this document will consider the impact of cochlear implantation on the selection of a communication strategy and educational program for children who are deaf or hard of hearing.

A Brief History of Cochlear Implants

While commercial cochlear implant systems have only been available since the 1980s, the idea of using electrical rather than acoustic stimulation to activate the auditory system in individuals with profound sensorineural hearing loss is not new. In 1880, Alessandro Volta first reported that electrical stimulation to metal rods inserted in his ear canal created an auditory sensation. He described this sensation as "a boom within the head." In 1957, Djourno and Eyries placed a wire on the auditory nerve of someone who was undergoing surgery. They used this wire to stimulate the auditory nerve directly with electrical current and the person reported a clear auditory percept. This observation lent impetus to the search for a treatment of profound deafness. In 1961, House and Doyle reported data from two adults with profound deafness whose

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auditory nerve was stimulated electrically by an electrode placed on and then through the round window and into the scala tympani of the inner ear. These individuals both reported auditory percepts. They noted that loudness changed with level of stimulation and the pitch of the stimulus changed with variation in the rate of stimulation. In 1964, Simmons placed an electrode through the promontory into the vestibule and directly onto the modiolus of the cochlea. Again, these individuals could detect changes in duration and had the percept of tonality. These observations fueled the push toward the development of functional, permanent CI systems.

The first single channel cochlear implant was introduced in 1972. Over 1000 people were implanted from 1972 to the mid 1980s including several hundred children. This early single channel device, the 3M / House cochlear implant (Fretz and Fravel, 1985) was well tolerated and provided many users with significant speechreading enhancement. Additionally, some individuals enjoyed limited open set word recognition.

In 1984, Cochlear Corporation introduced the first multi-channel cochlear implant system. This device, the Nucleus 22, consisted of an implanted receiver / stimulator and an intracochlear electrode array that consisted of 22 banded contacts. In the original implementation, a headband was used to hold the transmitting coil in close proximity to the implanted receiver coil and radio frequency pulses were used to both provide power for the implanted electronics and to control stimulation. Later versions of the Nucleus device used magnets to hold the transmitting and receiving coils in close proximity. The technology at that time was not sophisticated enough to transmit 22 separate channels of information at a rate that was rapid enough to code speech. Consequently, a feature extraction scheme was developed that allowed transmission of the fundamental frequency as well as the second harmonic of speech (F0 / F2). Later improvements in the speech-processing algorithm allowed transmission of the first formant frequency as well (F0 / F1 / F2).

At approximately the same time, a second multichannel cochlear implant system was being developed in Utah. This system, the Ineraid device, had six intracochlear electrodes that were connected directly to the externally worn speech processor via a permanent percutaneous connector. The Ineraid speech processor was relatively crude by today's standards. It consisted of a microphone, analog electronic circuitry that controlled the maximum output on the individual electrodes, and a series of four bandpass filters. The output of each filter was routed to a different intracochlear electrode. The use of a percutaneous connector allowed for continuous analog signals to be applied simultaneously to four of the six intracochlear electrodes. Unlike the Nucleus speech processor, this was not a feature extraction system. The bandpass filtering and use of multiple electrode contacts replaced the traveling wave and the theory was that the brain would be able to "extract the features of speech." Despite these radically different approaches to cochlear implantation, performance with these early systems was remarkably similar (Gantz, Tyler, Abbas, Tye-Murray, Knutson, McCabe, Lansing, Brown, Woodworth, Hinrichs, and Kuk, 1988). There was still a range of performance with both devices, but users of either device were able to perform significantly above chance on tests that measured open set word recognition skills. Moreover, despite the significant cross-subject variability that was noted, large scale clinical trials in the 1990s concluded that performance with a multichannel cochlear implant was better than performance with a single channel device for postlingually deafened adults (Gantz et al., 1988; Cohen, Waltzman, and Fisher, 1993).

Since that time, a great deal of research has been dedicated to improving the design of the implant system, identifying the best intracochlear array and stimulation mode, refining the processing strategies available and miniaturizing both the external and internal hardware. Currently there are three FDA approved, multichannel CI systems available within the United States. These include the Nucleus Cochlear Implant System marketed by Cochlear Corporation, the Clarion device marketed by Advanced Bionics Corporation, and the Med-El device marketed by Medical Electronics Corporation. All three implants systems incorporate transcutaneous transmission systems to connect the external hardware with the implanted receiver / stimulator. Average performance has improved significantly over the course of the past decade with all three systems. It is no longer just the "star" performers who enjoy open set word recognition. The best cochlear implant users now achieve sound only word recognition scores of 80% or higher regardless of device. However, not all cochlear implant users enjoy such high levels of performance. Some recipients of each device type obtain limited open set word recognition. For these individuals, the largest benefit is demonstrated when sound from the cochlear implant is combined with speechreading cues. One of the largest challenges facing cochlear implant professionals is to find preimplant predictors of postimplant performance. Moreover, finding ways to improve performance for individual cochlear implant users remains a challenge. The following section reviews in more detail the cochlear implant systems available today and outlines the range of speech processing strategies available with these cochlear implant systems.

Current Cochlear Implant Systems and Processing Strategies

There are currently three FDA approved cochlear implant systems available today in the United States (Clarion, Nucleus and MED-EL). Competition among these manufacturers is fierce. Generally, the results of this competition have been good, encouraging all three companies to invest significantly in research and development and to strive for improvements in functioning and packaging. A less desirable outcome of this competition is the resulting increase in marketing. It can be difficult for prospective cochlear implant candidates and their families to sort through all of the information available today and to separate advertising claims from proven facts. The process of becoming an informed consumer is made even more difficult because the terminology used to describe the ear and the individual cochlear implant systems typically is foreign to the average person. The goal of this section is to describe in general terms how cochlear implants produced by each of the three major manufacturers are similar and then to highlight some of the features that distinguish these three different multichannel cochlear implant systems.

Similarities Across Devices

The Nucleus, Clarion, and MED-EL cochlear implant systems have many similar features. The *first* such similarity is that all three different cochlear implant systems provide for multichannel stimulation. This means that all three cochlear implant systems have electrode arrays with multiple contacts that are inserted into the scala tympani of the cochlea via an opening (cochleostomy) that is surgically created just lateral to the round window. The number of contacts (or electrodes) and the way in which those contacts can be configured varies across devices but they all are multi-channel rather than single-channel devices.

A *second* similarity shared by all three major cochlear implant systems is that they use transcutaneous communication between the externally worn hardware and the implanted electronic components. No wires or other electronic components pass through the skin barrier. The external hardware contains a transmitting coil. The implanted device contains a receiving coil and radio frequency transmission is used to both provide power for the implanted electronics and to control the type and level of stimulation provided by the implant. Magnets (one of which is implanted under the skin) are used to maintain contact between the transmitting and receiving coils. The cochlear implant is the first permanently implanted electronic device that is not battery powered but designed to draw power from the externally worn hardware.

Third, all three present cochlear implant systems incorporate technology, known as telemetry, that can be used to monitor the integrity of the intracochlear electrodes after they are implanted. This capability is important because it is possible for the implanted electronics to malfunction and these malfunctions are not always easy to detect, especially in young children or in individuals with very limited auditory experience.

Fourth, all three cochlear implant systems offer a range of different speech processing options. There are many approaches that can be used to convert an acoustic speech signal into an electrical signal. The speech processing strategy is the set of rules that is used to control how that conversion is made. In other words, the techniques the processor uses to translate pitch, timing, and loudness information into electrical signals that are then sent to the internal electrodes. This includes the number and location of electrodes to be stimulated, the type of stimulus that is provided, and the rate and amplitude of stimulation. Much of the improvement in performance with cochlear implants observed over the last decade has been the direct result of improvements in speech processing algorithms. Each cochlear implant device offers several different speech processing algorithms, or strategies, from which the programming audiologist and patient can choose.

Fifth, for all three cochlear implant devices, the general process used to program the speech processor is fairly similar. Programming the speech processor of the cochlear implant typically requires establishing a threshold and a maximum stimulation level for each of the individual intracochlear electrodes. These levels are customized for the individual user and need to be adjusted several times for most individuals during the first year or so of cochlear implant use and less frequently thereafter. The externally worn speech processor can be programmed to allow the user to select from a range of programs and / or programming strategies. This flexibility allows the user to evaluate different programming strategies in a range of real world listening conditions. For pediatric applications, it can allow the parents to work through a set of programs with progressively more intense outputs or wider dynamic ranges as the child accommodates to auditory stimulation. Because speech processor programs are customized for an individual user, speech processors set for one individual should never be placed on any other cochlear implant recipient.

Other similarities include the fact that the cost of these three cochlear implant systems does not vary significantly among manufacturers. All three companies have had device failures and each company maintains statistics regarding cumulative failure rates and

their causes. All three companies offer warranties and service contracts to their customers. All three companies have active ongoing research and development goals and are continually working on ways to improve the function of the device. In addition, the three major cochlear implant companies all are very dedicated to helping their hearing-impaired clientele and supporting the audiologists and physicians who work with their products.

Finally, overall performance with a cochlear implant varies tremendously, even among users of the same device. With all three devices, some recipients attain very high levels of performance in the sound-only mode while others receive only minimal benefit and attain little more than environmental awareness and speechreading enhancement.

Despite these similarities, many important features distinguish these cochlear implant systems from one another. Choosing among cochlear implant devices requires a basic understanding of the nature of these differences. The following section describes basic features of each of the three main cochlear implant systems. Some historical information is provided to allow the reader to put current technology in context with previously available cochlear implant systems.

The Nucleus Cochlear Implant Systems

The Nucleus 22-channel cochlear implant was the first cochlear implant to receive FDA approval for use in adults and children and has been used in more individuals than any other cochlear implant system worldwide. The original design of the intracochlear component of the Nucleus 22 device consisted of 22 banded electrodes spaced at equal intervals (approximately 4 mm). As the electrode array was inserted into the cochlea, the anatomy of the cochlea caused it to curl around the basal turn. This resulted in an intracochlear array that lay along the outer wall of the cochlea opposite the modiolus.

The original Nucleus 22 device could be programmed to stimulate in one of several different bipolar modes or in a stimulation mode that Cochlear Corporation referred to as common ground. In a bipolar mode the current is passed between two intracochlear electrodes. These electrodes may be adjacent to each other (BP) or spaced slightly more widely apart depending on the subject's sensitivity (e.g. BP+1, BP+2 etc). With common ground stimulation, one electrode is designated as the active electrode and the other 21 intracochlear electrodes are shorted together and used as the return path. Monopolar stimulation, where stimulation is applied between one intracochlear electrode and an extracochlear ground electrode, was not possible with the first version of the Nucleus device.

Research from animals had shown that bipolar stimulation, particularly at low stimulation levels, resulted in activation of a small group of auditory nerve fibers located relatively close to the stimulating electrode pair (van den Honert & Stupulkowski, 1984). Good place specificity, achieved via the use of bipolar stimulation, was considered crucial to the success of a multi-channel cochlear implant because there was no longer a traveling wave to provide frequency selectivity. High frequency signals were routed to the most basal electrode pairs and low frequency signals were routed to the more apical electrode pairs.

The Nucleus 22 cochlear implant and all subsequent Nucleus devices provide only non-simultaneous, pulsatile stimulation. That is, the output of the cochlear implant consists of a series of biphasic, current pulses that vary in amplitude depending on the intensity of the incoming signal. No two electrodes can be stimulated simultaneously and analog stimulation is not possible with this cochlear implant system. The advantage of using non-simultaneous stimulation is that no two electrodes are ever stimulated at exactly the same instant. This minimizes the chance of deleterious channel interactions. Additionally, power consumption is significantly lower when pulsatile rather than analog stimulation is used to encode the speech signal. The disadvantage of using pulsatile stimulation is that the amount of information conveyed per unit time is directly dependent on the duration of the individual pulses and the overall stimulation rate.

Early speech processing strategies used with the Nucleus 22-channel cochlear implant employed feature-extraction schemes that conveyed fundamental frequency information as well as information about the first two formants of speech (F0F2 and F0F1F2). In the early 1990's the MPEAK processing strategy was introduced. This strategy still used feature extraction algorithms but also provided additional high frequency information by stimulating two or three fixed, basal electrodes. The goal was to provide additional information about frication that would yield improved consonant recognition scores. The maximum stimulation rate used for these early speech-processing strategies was 250 Hz. Most recipients used speech processor programs constructed using bipolar stimulation, 205 mðs / phase biphasic current pulses with 19-20 electrodes available for stimulation.

Over the course of the next decade, the speech processing algorithms that were used with the Nucleus cochlear implant system moved away from feature extraction schemes. In 1995 Cochlear Corporation introduced the spectral peak (SPEAK) processing strategy. This strategy samples the incoming acoustic signal, converts that signal to the frequency domain,

and identifies 6–10 peaks in the acoustic spectrum. A look-up table is used to determine how the output of the 20 separate frequency bands will be routed to the individual intracochlear electrodes. On each stimulation cycle a subset of 6 to10 intracochlear electrodes are stimulated non-simultaneously at a rate that varies adaptively between 180–300 pulses per second depending on the number of spectral peaks identified.

Early in 1998 a new internal device, the Nucleus 24 system was introduced. The intracochlear electrode array of the Nucleus CI24M device was no different from the array used with the previous Nucleus cochlear implants, however, two additional extracochlear electrodes were added. With this version of the Nucleus cochlear implant it was possible to stimulate in a monopolar stimulation mode using pulse durations as short as 25 us / phase. Stimulation rates on an individual electrode as high 2400 Hz pulses per second could be achieved and the device was designed such that the implanted magnet could be removed if necessary in order to allow for magnetic response imaging (MRI).

The other significant change in the Nucleus 24 device relative to previous versions of the implant was that it was possible to use radio frequency telemetry to transmit information about electrode impedance and device function from the internal device out to the programming system. Additionally, this device has the capability of using implanted electrodes not only to stimulate the ear but also to record electrically evoked auditory potentials from within the cochlea. Such information has proven helpful in programming the speech processor for very young children (Brown, Hughes, Luk, Abbas, Wolaver, and Gervais, 2000). Finally, with the emergence of the Nucleus 24 device, each recipient had the advantage of choosing between a body-worn speech processor or an ear-level speech processor.

Shortly after the Nucleus CI24M cochlear implant was introduced, Cochlear Corporation introduced a revision of this system. They called the new device the Nucleus 24 Contour (CI24RCS). The primary difference between the Nucleus 24 (CI24M) and the Nucleus 24 Contour (CI24RCS) devices was that the intracochlear array of the Contour device is pre-coiled but is held in a straight position during insertion by a stylette, or flexible metal spine, that runs the length of the array. The stylette is removed during the insertion process to allow the array to coil closer to the modiolus of the cochlea where the surviving auditory nerve fibers are located. Closer proximity between the stimulating electrodes and the surviving neural elements within the modiolus resulted in lower thresholds and reduced current spread. Modiolar placement also effectively decreases power consumption and enhances place specificity. The intracochlear electrode contacts are spaced logarithmically along the array with electrodes at the base being more widely separated than electrodes at the apex. The contacts are half bands rather than the full bands used with the Nucleus CI24M device and all earlier versions of this implant. Additionally, the packaging of the internal receiver / stimulator of the Nucleus 24 Contour is thinner and more flexible that earlier versions resulting in a lower profile on the skull.

With these more recent versions of the Nucleus cochlear implant system, the Nucleus 24 (CI24M) and the Nucleus 24 Contour (CI24RCS) devices, it became possible to stimulate in a monopolar mode. With monopolar stimulation, all 22 intracochlear electrodes can be used as active electrodes and stimulation is applied to an intracochlear electrode relative to one of two extracochlear ground electrodes. Monopolar stimulation results in lower thresholds and therefore requires less power consumption than processing strategies using bipolar or common ground stimulation modes. Additionally, the threshold and maximum stimulation levels that are obtained when monopolar stimulation is used are more consistent across the electrode array than those obtained when bipolar stimulation is used. Initial concerns that monopolar stimulation would not be place specific proved unfounded. Persons who use monopolar stimulation are able to pitch rank and generally perceive a monotonic decrease in pitch as the stimulating electrode is moved from the base to the apex of the cochlea. This finding indicates that the electric fields that result when monopolar stimulation is used are concentrated near the stimulating electrode and as such are still relatively place specific.

The Nucleus 24 and the Nucleus 24 Contour devices also offer two additional speech coding strategies. The first was a strategy Cochlear Corporation describes as the *n-of-m* strategy. This speech processing strategy, better known as ACE (Advanced Combined Encoder), allows the programming audiologist to specify both the specific number of spectral peaks (*n*) that should be identified as well as the number of different bandpass filters (*m*) that should be used to divide up the acoustic spectrum on any stimulation cycle. ACE is typically implemented by selecting 8–12 spectral peaks (n) and speech is subdivided into a total of 22 bandpass filters (*m*). This strategy is similar to the SPEAK strategy but operates at a faster stimulation rate. The majority of persons being fitted with Nucleus cochlear implants today use the ACE strategy at stimulation rates between 900 and 1200 Hz per channel.

The second new speech processing strategy available in the Nucleus 24 cochlear implant system that is referred to as Continuous Interleaved Sampling (CIS). The CIS strategy filters the speech signal into a fixed number of bands (typically 8–12), obtains the speech envelope for each band, and provides compression. A look-up table is used to determine which electrode will be stimulated for each of the specified frequency bands. With this stimulation strategy, not all 22 intracochlear electrodes are used, but every electrode is stimulated on each cycle of stimulation and stimulation rates are typically higher than those used with other speech processing strategies. When the CIS programming strategy is used, each electrode is stimulated sequentially with a biphasic current pulse that has an amplitude proportional to the amount of energy in the corresponding frequency band. This strategy is designed to preserve fine temporal details in the speech signal by using high rate, pulsatile stimuli.

Cochlear introduced the first ear-level speech processor, ESPrit 24, for Nucleus 24 recipients in 1998. Ear-level speech processors compatible with the older Nucleus 22 device, known as the ESPrit 22, became available in 2000. Both of these behind the ear processors are powered by two hearing aid batteries and have an average battery life of 50 hours for Nucleus 24 recipients and 35 hours for Nucleus 22 recipients (ESPrit User Manual). These original ear level processors were less flexible than the body-worn Sprint processor. They were designed to implement the SPEAK processing strategy for Nucleus 22 recipients and either the SPEAK or ACE strategies for Nucleus 24 recipients. The newest Nucleus behind the ear processor, ESPrit 3G, can implement all three Nucleus speech processing strategies, SPEAK, ACE, and CIS. It also has an integrated telecoil connection and is powered by three 675 hearing aid batteries.

The Clarion Cochlear Implant Systems

The second cochlear implant system that is available in the United States today is the Clarion multichannel cochlear implant system manufactured by Advanced Bionics Corporation. This device was approved by the FDA for use in adults in 1996 and in children in 1997. Like the Nucleus device, the Clarion cochlear implant system has undergone a series of changes over the past several years. The original Clarion (Versions 1.0 and 1.2) consisted of an array of 16 intracochlear electrodes arranged in 8 closely spaced electrode pairs that were oriented radially, rather than longitudinally, within the cochlea. This "radial bipolar" configuration was selected based on early physiological, electrophysiological, and computer modeling studies that demonstrated this configuration resulted in optimal place specificity (van den Honert & Stupulkowski, 1984). This device could be programmed in either a monopolar or a bipolar mode and resulted in a maximum of 8 stimulation sites (channels). Because each channel or site of stimulation had an independent output circuit, each channel could be programmed independently allowing for either non-simultaneous or simultaneous patterns of electrode (channel) activation. Later iterations of the Clarion electrode array used a stimulation pattern referred to as Enhanced Bipolar. In this stimulation mode, the medial electrode in one pair was stimulated in a bipolar fashion relative to the lateral electrode in the next most apical electrode pair. The wider electrode spacing resulted in lower thresholds and maximum comfort levels and a maximum of 7 distinct stimulation sites (channels) within the cochlea.

The original intracochlear electrode array of the Clarion was pre-curled and inserted through the cochleostomy using a special insertion tool. This array was designed to conform to the contour of the cochlea. Until recently, newer versions of the Clarion used a silastic positioner that was inserted into the cochlea behind the intracochlear electrode array. The effect of the positioner was to move the electrode contacts closer to the cochlear modiolus (medial wall of the scala tympani) in order to reduce power consumption and to improve frequency selectivity. In October 2002, the Clarion electrode positioner was removed from the market due to concerns that its use may be associated with an increased risk of bacterial meningitis in cochlear implant recipients. Subsequently the FDA approved use of the Hi Focus Clarion electrode array without the positioner.

Although the Clarion electrode array always has had 16 contacts, the earliest device was limited to eight channels of stimulation because it used 8 independent output circuits. Each channel would be routed to a bipolar electrode pair or to the eight medial electrode contacts via monopolar electrode coupling. The newest version of the Clarion, the CII system, has 16 independent output circuits that can stimulate each of the 16 electrode contacts either non-simultaneously, simultaneously, or in various combinations.

The HiFocus electrode contacts are arranged longitudinally and can be activated in either monopolar, bipolar, or multipolar mode. Theoretically, because the Clarion allows simultaneous stimulation of multiple channels, it should also be possible to control the pattern of stimulation within the cochlea to provide up to 31 "virtual" channels. The CII system has 31 filter bands to enable experimentation with this form of stimulation but software is not yet available to allow implementation of this stimulation mode.

The Clarion device is packaged in a ceramic case that is set into a bed drilled into the temporal bone. The magnet is contained within the ceramic case and is neither removable nor MRI compatible. The Clarion cochlear implant system functions with both a body worn speech processor and an ear level device (BTE). The ear level processor is capable of implementing all of the processing strategies available with the body worn processor.

The Clarion is the only cochlear implant system capable of simultaneous stimulation of multiple electrodes within the cochlea. It also is the only device that can stimulate with analog waveforms. Like other commercially available cochlear implant systems, the Clarion offers a wide range of speech processing strategies. Clarion was the first commercially available implant system to implement CIS processing in 1991. The Clarion version of the CIS programming strategy was available with the very early versions of the device and was typically implemented using 8 channels of monopolar stimulation. With the original version of the Clarion system, pulse durations of 75 ms / phase were used with a stimulation rate of 833 Hz per channel. The newly introduced Clarion CII cochlear implant system allows for stimulation rates as high as 2,840 Hz per channel with the CIS programming strategy when all 16 channels are active and 5,980 Hz per channel when 8 channels are programmed.

The second strategy available with the original Clarion cochlear implant system was Compressed Analog stimulation (CA). In more recent versions, this strategy has been refined and is referred to as Simultaneous Analog Stimulation (SAS). This speech processing strategy is typically used with bipolar or enhanced bipolar electrode coupling. With SAS, the incoming speech signal is sampled and filtered into seven different frequency bands. The output of each frequency band is routed to an individual electrode or electrode pair. Compression is used to insure that the signal stays within the user's dynamic range. With this strategy, biphasic current pulses are not used. Rather, the amount of current applied to a given electrode varies almost instantaneously according to the energy within that frequency band. When 7 channels are stimulated simultaneously in analog mode the overall stimulation rate is 91,000 samples per second. This processing strategy is designed to preserve the relative amplitude information in each channel and the temporal details of the waveforms.

One potential limitation of speech processing strategies that use simultaneous analog stimulation is that the simultaneous activation of multiple electrodes can result in deleterious channel interactions. Wilson, Lawson, Finley, and Wolford (1993) compared simultaneous analog stimulation to sequential pulsatile stimulation in persons who used monopolar coupling. They demonstrated that speech recognition scores were higher when the non-simultaneous processing strategy was used. Both the original CA strategy and the current SAS strategy are most successfully implemented using a bipolar or enhanced bipolar mode rather than monopolar stimulation. The probability of deleterious channel interactions is minimized with the Clarion device through the use of only 7–8 channels of stimulation and closely spaced bipolar coupling.

In 1999, a variation on these two basic speech-processing strategies was introduced. This variation is the Paired Pulsatile Sampler (PPS). PPS is similar to CIS except that instead of each electrode in the array being stimulated sequentially—without simultaneous stimulation—with PPS pairs of electrodes that are widely spaced across the array are stimulated simultaneously. The advantage of PPS over CIS is that it is possible to achieve stimulation rates that are twice as fast as those used with a fully sequential or non-simultaneous CIS strategy. Increasing the stimulation rate has the effect of increasing the amount of information about the acoustic signal that is transmitted per unit of time. By simultaneously stimulating electrode pairs that are spaced far apart, the effects of channel interaction can be minimized.

Recently, Advanced Bionics has developed and is testing a High Resolution processing strategy for the CII cochlear implant. Although this new programming software has been FDA approved for both adults and children, general release of this software is still pending. When the High Resolution mode is implemented with the CII device, the Clarion system should be capable of reaching the fastest stimulation rates of any of the commercially available cochlear implant systems.

Like all commercially available cochlear implant systems, the Clarion speech processor is flexible, allowing the user to listen to a range of different processing strategies. The current Clarion body worn speech processor, the Platinum Sound Processor, is smaller than the Nucleus body worn processors. Additionally there are two versions of the ear level system, one for use with the earlier Clarion implant system, called the Platinum BTE, and one for use with the new implant system, called the Clarion CII BTE. Because the Clarion Platinum BTE has high power demands, the retrofitted Platinum BTE with a custom designed rechargeable battery has a limited battery life averaging 5 to 6 hours. The Clarion CII BTE is somewhat more efficient, using custom designed rechargeable batteries that average anywhere from 8 to 11 hours of use, depending on the individual's processing strategy and re-

quired stimulation levels. Rechargeable batteries typically must be replaced periodically.

Advanced Bionics was the first cochlear implant system equipped with telemetry capabilities for monitoring electrode integrity and compliance voltages. With their most recent implant, the Clarion CI-II, it is also possible to use the intracochlear electrodes to record electrically evoked auditory potentials. This system offers the same monitoring capabilities as the Nucleus Neural Response Telemetry (NRT) system. Clarion's version is known as Neural Response Imaging (NRI). The software for measuring neural responses from within the cochlea is FDA approved and should be released in the near future.

The MED-EL Cochlear Implant

The third FDA-approved cochlear implant system available in the United States today is the MED-EL Combi 40+ cochlear implant manufactured by the Medical Electronics Corporation. This device has 12 electrode pairs that are inserted deep into the apical regions of the cochlea. The standard array is the longest of all three cochlear implant systems and extends 26.4 mm into the cochlea (2.4 mm contact separation) or two complete turns. The Combi 40+ electrode is a thin, soft, flexible straight array that is threaded into the scala tympani of the cochlea through a cochleostomy and relies on the contour of the cochlear ducts to achieve the spiral form. Like the Clarion device, the internal electronics and the internal magnet of the MED-EL implant are housed in a ceramic case. The MED-EL device has FDA approval for use in MRI machines up to 0.2 Tesla. In Europe, it is used with MRI machines of 1.0 and 1.5 Tesla. A special form available from MED-EL must be submitted to the radiologist before scanning. All safety measures and limitations for scanning are provided on the form. In addition, MED-EL will provide direct information for radiologists if they are contacted. The MED-EL speech processor has up to 9 memories available to hold a range of programs. Originally, a body-worn processor, the CIS-PRO+ was provided with the MedEl device. In 1998, a behind the ear processor, the Tempo+ was introduced. Current recipients standardly are provided with the Tempo+ behind the ear speech processor, even very young children. The Tempo+ offers a variety of wearing options including the option to use a battery pack that is attached to the processor via a cord allowing it to be clipped to a collar, etc. The fact that the processor is tethered to the battery pack, which in turn can be securely mounted on clothing, can help with retention of the behind the ear processor when fitted to young children. The MED-EL Tempo+ offers the longest battery life of all the available behind-the-ear cochlear implant speech processors, with an average battery life of 50 hours.

The MED-EL device has the capacity to provide some of the most rapid stimulation rates of any of the cochlear implant systems currently available (1515 Hz / channel, 18180 Hz overall) using sequential pulsatile stimulation. Older versions of the MED-EL system offered the CIS speech processing strategy, implemented in a similar fashion to the Clarion speech processor. The current MED-EL speech processors offer two sequential stimulation processing strategies, CIS+ which uses a Hilbert transform for envelope detection, thereby eliminating problems with aliasing that may affect other speech processing systems, and *n-of-m* processing that is similar to ACE processing with the Nucleus device

Special Electrode Arrays

Several special electrode arrays have been designed for individuals who are not candidates for standard electrode arrays. This includes persons with obstructed cochleae (i.e., ossified cochleae) or other cochlear malformations and persons who no longer have an intact auditory nerve. For individuals with ossified or malformed cochleae, MED-EL offer a shorter version of the C40+ electrode array with more closely spaced electrode contacts known as the compressed array. In addition, both MED-EL and Cochlear Corporation offer a special split array for individuals with complete cochlear ossification. With split arrays, the surgeon makes two cochleostomies, one at the basal and one at the apical end of the cochlea. One branch of the split array is inserted into each. Both the compressed and the split electrode arrays are FDA-approved

Both Cochlear Corporation and MED-EL have developed a special electrode for combined electric and acoustic stimulation for use with individuals who have moderate amounts of low-frequency hearing. These devices, which are in the preliminary stages of investigation, are designed to preserve as much residual hearing as possible during implant electrode insertion; this requires special electrode insertion techniques.

Cochlear Corporation offers a special electrode array for people with Neurofibromatosis II. These people typically have surgery to remove an acoustic neuroma leaving them without an intact auditory nerve. Therefore, the electrode array is positioned on or near the cochlear nucleus rather than within the cochlea itself.

Device Selection

The device selected for an individual patient depends on several factors including the center at which

the patient is followed, whether or not the device is in FDA clinical trials, and the preference of the surgeon and recipient. Some centers offer cochlear implant candidates a choice of devices from all three major manufacturers whereas other centers may offer only one or two different cochlear implant systems. When a particular device is in FDA clinical trials, availability is limited to individuals who meet the candidacy criteria for that clinical trials' study. For example, some clinical trials protocols restrict implantation to people with no additional handicapping conditions. Typically, device selection is made by the patient in consultation with the surgeon. With current cochlear implant technology, cochlear implant outcomes are similar across devices from all three manufacturers. There is a wide range of patient outcomes within each group of individuals using a given device. For each device, some people obtain substantial auditory-only speech understanding whereas others use the input from their cochlear implant as an aid to speechreading.

The Cochlear Implant Team

Minimally, the role of a cochlear implant team is to determine candidacy for cochlear implantation, to help prospective recipients make informed decisions about cochlear implant surgery and device options, to provide necessary medical care, to carry out the surgical implantation, and to provide postimplant device setting and monitoring. The core personnel required to carry out these responsibilities include the surgeon (otologist / otolaryngologist) and the audiologist. Prior to implantation, the focus of care is determining medical and audiological suitability for cochlear implant surgery and managing any medical conditions that may prevent surgery. Following cochlear implant surgery and postimplant healing, the focus shifts from primarily medical management to primarily audiological management.

Although the surgeon and audiologist have the principal roles in providing services to cochlear implant candidates and recipients, the needs of different populations may require the services and expertise of additional professionals, not all of whom need be involved with each potential candidate or implantee. Additional services might include consultations from other medical specialists such as developmental pediatricians, speech and language evaluations, provision of long-term aural rehabilitation, evaluation of educational programs or provision of family counseling. Cochlear implant teams vary in the scope of services the members are capable of delivering. The scope of service delivery is dependent on many factors including the age and nature of the population seen and the experience of the team. Larger cochlear implant teams may routinely include representatives of multiple disciplines; others may bring in additional specialists or refer to outside specialists as needed. Either way, it is important to have access to the disciplines required to provide quality health care. The following professionals may be actual members of a cochlear implant team, or outside professionals to whom cochlear implant candidates and recipients are referred, depending on the individual profile and demographics.

Additional Professionals Assisting the Pediatric Cochlear Implant Team

Aural rehabilitation specialists, speech-language pathologists and educators play an important role in the preimplant evaluation and / or postimplant management of children with cochlear implants. Prelingually deafened children must learn to use the sound provided by an implant to organize and access spoken language and to produce speech that can be understood by others. Aural rehabilitation specialists and speech-language pathologists are members of some cochlear implant teams. Other teams may not have these professionals on staff; in that case, aural rehabilitation and speech-language pathology may be provided by private therapists or by school personnel. Because many children with cochlear implants require special classroom placement and educational support services, at least during the early years of cochlear implant use, it is important for cochlear implant professionals to work closely with educators in developing and coordinating appropriate intervention strategies.

Hearing loss impacts not only communication and educational development, but also a child's emotional and social development. A number of cochlear implant programs have access to the expertise of psychologists or social workers who can assist families as needed. Close communication among the cochlear implant team and other professionals working with the child is essential for children to receive maximum benefit from a cochlear implant. The role of each of these professionals is described in more detail below.

Aural Rehabilitation Specialists. The type of intervention provided by an aural rehabilitation specialist depends on his or her philosophy of communication development and on the needs of the child. A variety of philosophies exist concerning the appropriate communication methods for children with hearing impairment or deafness. One philosophy, oralism, promotes the development of speaking and listening skills for communication. There are several different approaches within this philosophy. For example, some oral therapists use both lip-reading and listening as a means of learning to speak whereas oth-

ers follow a more unisensory approach emphasizing listening alone without visual cues. An alternative philosophy promotes the use of sign language to develop communication skills, either alone or in conjunction with spoken language. When signing and speech are used together (total communication) the signs typically are manually-coded English rather than American Sign Language. In total communication, reception of language occurs through listening to speech and watching the signs. Expressive language is conveyed via speech and sign.

Speech-Language Pathologist. The speech-language pathologist may be called upon to carry out evaluations of the child's spoken or signed communication abilities and to make recommendations for intervention. Some teams have speech-language pathologists who provide ongoing postimplant speech-language therapy to cochlear implant recipients.

Educational Specialists. School personnel such as teachers of the deaf, itinerant teachers of the hearing impaired, and mainstream classroom teachers often work closely with the implant team during the evaluation and postimplant periods. They provide important information about how the child is functioning in his or her daily environment, and implement suggestions given by the team for maximizing communication. Sometimes a cochlear implant team includes an educator who assists in the planning of the educational placement and protocol. This individual can act as a formal liaison between the implant center and the school system.

Psychologist. The psychologist provides input related to the level of functioning and mental status of the child. The psychologist can also provide intervention when necessary or appropriate. For example, if family dynamics or behavioral problems present potential obstacles to success with a cochlear implant, the patient and family may be referred for counseling before and / or after cochlear implantation.

Social Worker. The social worker can provide guidance and support to the child and the family in all areas, including financial planning. Social workers also may help to coordinate necessary appointments and services and provide counseling for families.

Additional Professionals Assisting the Adult Cochlear Implant Team

Many of the specialists listed above also provide services to adults before and after they receive a cochlear implant. Although adults with postlingual deafness usually do not require extensive aural rehabilitation or speech-language therapy following cochlear implantation, they may benefit from training to make use of the sound they receive. A psychologist or social worker may be called in to assist with personal or family difficulties as needed. In addition to the specialists for a pediatric cochlear implant team listed above, an adult team might also include the following:

Neuropsychologist. Cochlear implant candidates may be referred for a neuropsychological evaluation if there is some concern about their ability to understand and actively participate in the preimplant and postimplant processes. For example, elderly persons who appear to demonstrate cognitive impairment or people who have suffered a brain injury or a stroke would be good candidates for referral to a neuropsychologist.

Vocational Rehabilitation Specialist. A vocational rehabilitation specialist provides guidance related to professional choices and job placement. They also may be able to provide information about financial assistance for the cochlear implantation process.

The Importance of Family Support

Although we have listed only professional staff above, it is important to remember that family members and / or close friends play an invaluable role in the cochlear implant evaluation and rehabilitation process. Cochlear implant candidates need emotional support as they undergo the evaluations required to determine candidacy and consider whether or not to pursue a cochlear implant; sometimes family and friends must help the candidate to develop realistic expectations with support from the surgeon and audiologist. Once an individual receives the cochlear implant device, family and friends can help the user by providing transportation to the cochlear implant center, ensuring that the device is used consistently, and participating in rehabilitative activities. When children are the cochlear implant recipients and the development of spoken language is the goal, it is important for family members to provide every opportunity for the child to incorporate listening and speaking into daily activities. Family members also make a valuable contribution to the implantation process by providing information to the team members regarding the cochlear implant users' day-to-day performance.

Professional Training and Experience of the Cochlear Implant Team

Professional training in cochlear implantation occurs in several ways. Intensive courses provided by each implant manufacturer offer a comprehensive base of knowledge. These courses usually encompass surgical technique, device parameters, programming issues, and all other device related matters. Other

educational opportunities are available through attendance at professional and scientific conferences devoted to cochlear implantation, and in informal dialogue with other cochlear implant professionals. For those cochlear implant teams working with prelingually deafened children, it can be helpful first to gain experience in the postlingually deafened population. For example, an audiologist setting a device for an individual with limited communication skills may call on previous adult experience to guide decisions regarding device setting. In addition, pediatric cochlear implant teams should be experienced in pediatric audiologic testing techniques and management. Due to the constantly evolving technology of cochlear implants, both in their physical and processing properties, continuing education must be a priority for all team members.

Cochlear Implant Evaluations and Candidacy

Cochlear implant candidacy criteria have evolved over time as advances in cochlear implant technology produced subsequent improvements in performance outcomes. At any point, however, candidacy revolves around three basic questions:

- Is physical implantation of the device possible and / or advisable given the medical status of the patient?
- Is it likely that an individual will receive more communication benefit from a cochlear implant than from a hearing aid or, alternatively, from no hearing prosthesis at all?
- Do the necessary supports exist in the individual's psychological, family, educational, and rehabilitative situation to keep a cochlear implant working and integrate it into the patient's life? If not, can they be developed?

Most often the evaluation of these questions with respect to the candidate is accomplished in a team format as described earlier. Guidelines for cochlear implant candidacy are given with the FDA approval of each system and are based on the participant criteria used for the clinical investigation of the system's safety and efficacy. These guidelines have changed substantially over time. For instance, in the 1980's cochlear implants were recommended for post-linguistically deafened adults with hearing losses greater than 100 dB and no discernable communication benefit from a hearing aid (Berliner, 1985; Meyer, Fugain, and Chouard, 1985; Schindler and Kessler, 1985). By the year 2000, FDA approval had extended the implantable age down to 12 months and broadened the general hearing criteria. Current guidelines permit cochlear implantation in persons age 2 years and older with severe-to-profound deafness (i.e., pure tone average thresholds of 70 dB HL or greater), and in children 12 to 23 months of age with profound deafness (i.e., pure tone average thresholds of 90 dB HL or greater.) Whenever possible, outcomes from word and sentence recognition testing are also used to determine candidacy. Current guidelines permit implantation in adults with open-set sentence recognition scores of approximately 50% to 60% words correct. As cochlear implant devices continue to improve, the criteria regarding the degree of hearing loss and the performance with a hearing aid that warrants consideration of a cochlear implant also will continue to evolve. However, the general questions of candidacy listed above will remain the same and will require evaluation of the patient's medical, audiological, and psychosocial / habilitative condition.

Medical Evaluation

The medical evaluation examines the status of the patient's overall health, the history and etiology of the patient's hearing loss, and the physical condition of the ear and cochlea. The general health of the patient impacts his fitness for general anesthesia and surgery, and his ability to complete the necessary post-operative programming of the device. Although general health status is rarely a contraindication for implantation, it may affect the timing and preparation for implantation.

Etiology. At present, the etiology and history of a patient's hearing loss cannot accurately predict a patient's performance with the cochlear implant. However, some general relationships have been reported that can moderate the patient's expectations. For example, persons with deafness subsequent to meningitis commonly develop cochlear ossification that can impede the insertion of the electrode array. The degree of cochlear ossification may affect the prognosis for implant performance and increase the possibility of facial nerve stimulation. Individuals with partial insertion of the electrode array perform similarly to those with complete insertion as long as a sufficient number of electrodes can be activated to program the device (Kemink, Zimmerman-Phillips, Kileny, Firszt, and Novak, 1992; Kirk, Sehgal & Miyamoto, 1997; Rauch, Hermann, Davis, and Nadol, 1997). Individuals with complete cochlear ossification who require a "drillout" of the bone to provide a space to lay the electrode do not achieve as high a level of auditory perception with their implant (Rauch et al., 1997). They also are more prone to complications of facial nerve stimulation and pain associated with implant activation (Niparko,

Oviatt, Coker, Sutton, Waltzman, and Cohen, 1991). The possibility of less than average performance and a higher incidence of stimulation complications in cases of complete ossification needs to be discussed frankly with a patient and can sometimes affect the patient's decision to proceed with implantation.

History of Hearing Loss. Postlingually deafened adults with a history of progressive hearing loss and a shorter duration of deafness tend to achieve higher speech perception scores than those who have been deaf for a long period of time prior to implantation (Blamey, Arndt, Bergeron, Bredberg, Briamacombe, Facer, Larky, Linstrom, J., Peterson, Shipp, Staller, and Whitford, 1996; Geir, Barker, Fisher, and Opie, 1999; Tyler, Moore, and Kuk, 1989; Waltzman, Cohen, and Shapiro, 1995). Adults with prelingual hearing loss generally are not considered good candidates for cochlear implantation, especially if they do not use oral / aural communication (Waltzman and Cohen, 1999).

Similar relationships exist between the history of hearing loss in children and performance with an implant, although they are moderated by a child's development. In contrast to adults, both pre- and postlingually deafened children are candidates for cochlear implantation as long as they receive little or no benefit from conventional amplification. In some instances, better hearing sensitivity before implantation and the use of spoken language in a child's communication and educational setting have been associated with better speech perception (Sarant, Blamey, Dowell, Clark, and Gibson, 2001; Zwolan, Zimmerman-Phillips, Ashbaugh, Heiber, Kileny, and Telian, 1997).

Radiological Examination. High-resolution imaging (Computerized Tomography, CT or Magnetic Resonance Imaging, MRI) is used to estimate the patency of the cochlea and to identify any abnormal anatomical variations that may affect insertion of the electrode. Although imaging may miss some obstructions preventing electrode insertion, this is rare (Jackler, Luxford, Schindler, and McKerrow, 1987; Wiet, Pyle, O'Connor, Russell, and Schramm, 1990). Some obstructions can be anticipated on the basis of the clinical history of hearing loss. As noted above, clinical histories of otosclerosis or meningitis commonly are associated with cochlear ossification.

Audiologic Evaluation

The purpose of the audiological evaluation is to quantify the candidate's preoperative hearing, communicative status, and use of prosthetic devices. The results are useful in determining candidacy by comparing the current communicative status to the expected outcome of using a cochlear implant. Results also are important as pre-outcome measures to quantify the benefit of the cochlear implant after implantation. To this end, the audiologic evaluation includes a pure-tone audiogram including air and bone-conducted thresholds, tests of speech perception such as word and sentence recognition, an evaluation of current amplification, and, if appropriate, a trial use of amplification. Speech perception tests are most decisive in determining the appropriateness of cochlear implantation. Candidates who demonstrate open-set word or sentence recognition performance that is below the average scores seen for cochlear implant recipients should be considered for implantation. As noted above, criteria word and sentence recognition scores continue to evolve.

Performance Measures for Adults. Open-set tests of spoken word recognition are typically used to determine audiological candidacy. Over the years many tests of speech perception have been developed and included in the cochlear implant evaluation (Zwolan, 2000). In order to improve comparability of results across centers, a committee of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) recommended that one monosyllabic word test, the Consonant-Nucleus-Consonant (CNC) (Lehiste & Peterson, 1959; Peterson & Lehiste, 1962) and one sentence test, the Hearing in Noise Test (HINT) (Nilsson, Soli & Sullivan, 1994) constitute the minimum speech perception battery for determining cochlear implant candidacy and measuring postimplant outcome. When a person has little or no open-set word recognition on these measures, it can be helpful also to administer a less difficult, closed-set measure (wherein response alternatives are provided) such as the Four-choice Spondee subtest of the Minimal Auditory Capabilities battery (Owens, Kessler, Raggio, & Schubert, 1985). Similarly, assessing multimodal spoken word recognition pre- and post-implantation can demonstrate that cochlear implant recipients with limited auditory-only word recognition still receive substantial benefit when auditory information via the cochlear implant is integrated with speechreading cues. One test that can be administered in the auditory-only, visual-only and auditory-plus-visual modalities is The City University of New York (CUNY) Sentence test (Boothroyd, Hanin & Hnath, 1985).

History of Amplification. The audiological evaluation also should include an assessment of the candidate's current amplification and history of hearing aid use. Many candidates may be experienced users of amplification and familiar with available hearing aid technologies. For these individuals, a hearing aid trial is not needed. Others may have never tried hearing aids appropriate for their hearing loss and

word recognition abilities (which may include listening to body-style amplification). If a patient has never worn appropriate amplification, a three-to-six month trial period using amplification is warranted.

Aside from the appropriateness of a person's amplification, the history of a candidate's hearing aid use is helpful to document the auditory stimulation for each ear. Sometimes a long-term deafened individual will have one ear that was more consistently aided than the other. Because duration of deafness is consistently shown to be associated with better performance (Blamey et al., 1996; Geier et al., 1999; Tyler et al., 1989; Waltzman et al., 1995), ears with more consistent auditory stimulation over many years may do better with cochlear implants than ears with no auditory stimulation for many years and may be the better choice for the ear of implantation. Alternatively, when the history of auditory stimulation of each ear is similar many recipients prefer to implant the ear with poorer word recognition abilities.

Performance Measures in Children. Similar to the adult, the audiological evaluation of young children for cochlear implantation assesses the ear's sensitivity to sound, and, if possible, includes measures of auditory perception. As the age of implantation decreases, visual reinforcement audiometry and auditory evoked response audiometry are the primary methods of measuring hearing sensitivity. Speech/auditory perception testing depends upon the age and linguistic ability of the child. Again, a large number of pediatric perception tests exist which vary from open-set word and sentence recognition, to closed-set measures of prosodic features, word identification, and speech feature identification (Zwolan, 2000). For the youngest children, parental reporting scales of auditory listening behavior, such as the Infant-Toddler Meaningful Auditory Integration Scale (Zimmerman-Phillips, Robbins, & Osberger, 2000) frequently have been used to assess auditory skill development. For older children, open-set word and sentence tests are employed to determine candidacy. Less difficult tests that include closed-set measures of performance, such as the Early Speech Perception Test (Moog & Geers, 1990) can be included if open-set word recognition is not possible. By using tests appropriate for the age and language level of the child, one can scale the child's ability along a continuum and chart a child's progress over time.

While many tests of auditory perception exist for children, FDA approval guidelines are less specific than for adults and reflect primarily the child's tonal sensitivity and progress in auditory skills development with a hearing aid. Recent FDA clinical trials have employed open-set measures of word recognition, such as the Lexical Neighborhood Test (LNT) and the Multisyllabic Lexical Neighborhood Test (MLNT) (Kirk, Pisoni, and Osberger, 1995) and measures of sentence recognition, such as the Hearing in Noise Test (Nilsson, Soli, & Sullivan, 1994) to determine candidacy. As the age of implantation decreases, candidacy criteria are generally determined by a lack of progress noted on parental scales of auditory skill development over a given period of time (such as three to six months). In very young children, candidacy also may be determined by the child's progress in developing spoken language with amplification, based on studies of spoken language acquisition in children with cochlear implants versus children with different severity of hearing losses and hearing aids (Geers and Brenner, 1994; Geers and Moog, 1994; Svirsky and Meyer, 1999).

Psychological/Rehabilitation Evaluation

An important aspect of cochlear implant candidacy that is much harder to define than the audiological or medical evaluation is the assessment of whether the candidate's overall life situation is one that will integrate and promote the use of a cochlear implant. The anticipation of cochlear implant surgery and the hope for a positive outcome introduces stress into the lives of the candidate and his or her family. In adult candidates, evaluation of the person's living situation, family and life status, and vocational situation by a social work counselor or psychologist can bring to light any potential personal and social complications from introducing a cochlear implant. Although it is rare that a cochlear implant would be detrimental to a recipient's situation, potential problems often can be avoided by proactively addressing areas of concern. These areas may range from complicated social and mental problems to the practical situation of getting to the clinic when necessary. Evaluation of a patient's expectations for life after implantation can be beneficial in tempering unrealistic expectations and anticipating alternative pathways if the postimplant performance is not as expected.

In children, the psychosocial evaluation is more extensive and includes developmental and educational evaluations as well as family assessments. In the pediatric population, the choice of a cochlear implant is usually associated with the choice of spoken language as the primary communication mode of the deaf child and family. Establishing a plan of rehabilitation and education before implantation makes the integration of the implant smoother and reduces the likelihood that progress will be hindered by poor follow-through or gaps in rehabilitative services.

Patient Counseling and Expectations

Candidates for cochlear implantation come for evaluation with all levels of knowledge about cochlear implants and need to be informed of the potential risks and benefits of cochlear implantation and the impact it may have on their life. The surgical procedure and its risks should be described along with a physical description and, preferably demonstration, of the internal and external portions of the device. The various cochlear implant systems available at the center also should be shown and described to the candidate. The post-surgical programming commitment should be described and planned. In addition, potential cochlear implant candidates need to be aware of what day-to-day living with the device entails. This is best done by contacting other cochlear implant wearers and their families. Local chapters of the Cochlear Implant Association Inc. (*www.cici.org*) are good resources. In addition, manufacturers of cochlear implant systems also facilitate discussions between users through their Web sites (*www.cochlearimplant.com*; *www.cochlear.com*; *www.medel.com*).

The most important, yet sometimes difficult, aspect of patient counseling is generating realistic expectations regarding performance outcome with the implant. Almost all candidates (or their families) seek the implant because they want to improve their ability to hear and understand speech. Although the mean and range of performance with implants can be described (see outcome measures), most people will naturally hope for the best of outcomes. Redundantly reviewing the range of performance, including the bottom of the range, during the course of the candidacy evaluation and discussing post-implant plans in case performance with an implant is poorer than anticipated can assist those recipients who obtain minimal postimplant benefit.

Cochlear Implant Surgery

As with many surgical procedures, different surgeons employ different techniques and hold different opinions related to cochlear implant surgery. However, there are some basic principles that underlie all cochlear implant surgical procedures. The major goals are: (1) to insert the electrode array as atraumatically as possible into the scala tympani, (2) to place the device on the side of the head in a manner that most protects it from trauma and (3) to ensure that the device and electrode array are secure enough to prevent movement. The intent is to accomplish these goals without damaging the surrounding tissue, device, and electrode array or causing infection and with an acceptable cosmetic result. Modifications in surgical technique often are determined by the physical and structural properties of a given device. Although the surgical technique is basically the same for both children and adults, some modifications may be required due to head size; no increased surgical risks or complications have been found in very young children (12 months) (Cohen, 2000). Alterations and/or adjustments to the surgical technique also may be required for special cases such as a Mondini deformity (malformed cochlea) or a hearing loss secondary to meningitis accompanied by ossification. Depending on the amount of ossification, the surgeon has choices of technique to maximize the possibility of obtaining a full insertion of the electrode array or of using a specially designed electrode array for the more heavily ossified cochleas (Balkany, Hodges, and Luntz, 1996).

Cochlear implant surgery is performed under general anesthesia, and typically lasts between two and four hours. There is usually a one-night stay in the hospital following the surgery. Recently, some insurance companies have required that the surgery be performed on an outpatient basis in which case there is no hospital stay.

Risks of Cochlear Implant Surgery. Although the rate of complications associated with cochlear implant surgery is very small and thus postimplant complications are rare, there are certain risks involved in both the surgical procedure and postoperative period. With any type of surgery, there is always the risk of a problem with general anesthesia. There is also the possibility of immediate postoperative bleeding and/or infection. Both of these complications, however, are extremely rare. Other possible complications are associated with ear surgery in general: These include injury to the facial nerve and postoperative dizziness. The approach to the inner ear where the implant is placed is via the facial recess. Although this takes the surgeon quite close to the facial nerve, it is an approach used in many other forms of otologic surgery and the risk of damaging the nerve is very small. The risk of facial nerve damage is somewhat greater in those individuals with anatomic malformation of the inner ear such as are found with a Mondini deformity. Meningitis is a rare though potentially serious complication in those people with inner ear deformities. Leakage of cerebrospinal fluid into the ear should be controlled if and when it occurs in order to prevent the onset of meningitis. The vestibular portion of the ear, which controls the balance mechanism, may have remaining function even when there is little or no residual hearing. When this occurs, opening the inner ear to the electrode could cause a temporary imbalance. Although some adults and children have reported postoperative unsteadiness accompanied by nausea, etc., this usually disappears rapidly. Again, this is rare. (Cohen, 1998).

In addition to the risks and complications associated with the surgery and immediate aftermath, there are some long-term considerations. Although cochlear implants are designed to last a lifetime and are reliable, delayed device failures do occur in less than 2% of the population. These failures can manifest themselves in either a change in hearing status or a total lack of auditory stimulation. Following the confirmation of a failure using audiological and psychophysical measures, re-implantation can occur as soon as possible. Fortunately, post-reimplantation results are often equal to or better than pre-implantation performance. There have been some reports of poorer results post-reimplantation although these may have been due to structural abnormalities or other complicating factors.

Another possible complication is device migration or extrusion over time; in its most severe form this requires re-implantation. Despite the fact that excessive movement is rare and that migration of just a few electrodes may not affect performance, fixating the internal receiver / stimulator and / or electrode array can prevent this from occurring.

Facial nerve stimulation is rare but can occur. This occurs most often in persons whose anatomy causes electrical stimulation of the facial nerve or people who have otosclerosis. Fortunately, the electrode(s) causing the problem can usually be programmed out with either no or minimal adverse affects on performance (Cohen, 2000).

In July 2002 the FDA became aware of a possible association between cochlear implants and bacterial meningitis. This was not limited to one specific device but has been reported for all cochlear implant systems. As of October 2002, the largest number of cases was evident in persons who received the Clarion cochlear implant electrode array with the positioner. As mentioned previously, Advanced Bionics withdrew the positioner from the market shortly thereafter. According to the FDA, individuals with malformed cochleae or those who have contracted meningitis prior to cochlear implantation are most at risk. Other predisposing factors may include young age (<5 years), otitis media, immunodeficiency, and surgical technique. Because the cochlear implant is a foreign body, it may act as a nidus for infection when patients have bacterial illness (www.fda.gov / cdrh / safety / cochlear.pdf). The FDA website contains guidelines concerning recommended Pneumococcal and Hib vaccinations in cochlear implant recipients.

Setting the Cochlear Implant Speech Processor

Approximately three to five weeks following surgery, recipients return to the cochlear implant center to receive their external equipment and to have their speech processor programmed. Device programming involves selecting and individually fitting the speech processing strategy or strategies the patient will use.

Processing strategies are used to translate incoming acoustic stimuli into electrical pulses that stimulate auditory nerve fibers. Despite the numerous speech encoding strategies implemented in the various cochlear prostheses, the basic parameters of programming are neither device nor strategy dependent: the audiologist needs to obtain basic psychophysical measures i.e. thresholds and comfort levels on all electrodes.

Although the basic parameters are the same, the techniques used to obtain these measures do depend on individual characteristics such as age, cognitive skills, length of deafness, and other potential factors affecting responses the use of both subjective and objective techniques. If the recipient is an adult or an older child, the subjective method can be used to set the threshold at the lowest level where the patient responds 100% of the time. The implant users also can report the level at which the loudness of the stimuli is most comfortable. After the thresholds and comfort levels are obtained for all electrodes, the computer simulates this information and translates it into an operating program that is transferred to the speech processor; live voice stimulation then can begin. Many parameters, including global increases in loudness, frequency allocation to electrodes, and speed of transmission to name a few, can be manipulated to improve the quality of sound and increase open-set speech understanding for a given patient. The precise characteristics that can be regulated are dependent on the speech processing strategy used and the manifestation of that strategy in a given cochlear implant system.

Whether the patient is a child or an adult, accurate electrical thresholds and comfort levels are critical contributors to postoperative performance. Because of this, it is essential that a comprehensive schedule of programming sessions be established. The number of visits required to adequately program and maintain the speech processor depends on a number of factors including but not limited to patient age, previous auditory experience, and ability to actively participate in the device programming tasks. Furthermore, because responses to auditory stimulation from a cochlear implant can change over time, long-term audiological follow-up is required. It is recommended that cochlear

implant recipients contact their cochlear implant center for speech processor programming if they or their family notices a decrease in auditory responsiveness, perception, discrimination, speech production, or a change in vocal quality in between regularly scheduled audiological appointments.

It is imperative that audiologists involved in device programming take the training courses offered by individual device manufacturers and avail themselves of the support personnel at each company in order to provide the highest quality care to the patient. Because cochlear implant speech processor technology and speech programming software constantly evolve, continuing education is a necessity.

The Use of Objective Measures in Speech Processor Programming

Over the course of the past decade there has been a trend toward implanting children at progressively younger ages. While the FDA has approved cochlear implantation for children as young as 12 months of age, many children younger than 12 months of age have received a cochlear implant. This happens when there is a medical contraindication to waiting (e.g. meningitis) or if the physician feels the child will benefit significantly from very early implantation. Additionally, many cochlear implant centers are implanting greater numbers of children with significant physical and / or developmental delays than they have in the past. Programming the speech processor of the cochlear implant can be challenging if the recipient is either very young or has limited response capabilities. It such cases, programming techniques that are less dependent on the ability of the child to give a behavioral response can prove helpful.

This section reviews the range of programming strategies that can be used to program the speech processor of the cochlear implant for users who are not able to give a conditioned response to stimulation through the implant. These techniques also can be used to reduce the time needed to program the cochlear implant for a child with a limited attention span. Additionally, information obtained using non-behavioral methods can be used to help verify the accuracy of the behaviorally determined programming levels.

While there are several different types of electrically evoked potentials that could be used to assist with device programming, most of the attention in the literature has focused on the electrically evoked auditory brainstem response (EABR), the electrically evoked compound action potential (ECAP) and the electrically evoked acoustic reflex threshold (EART). All three measures have acoustic analogs, have been well studied and can be recorded in young children. The following sections briefly review how these evoked responses can be incorporated into the fitting process. When cochlear implant recipients can actively participate in the speech processor programming process, these techniques typically will not result in speech processor programs that are superior to those constructed using traditional behavioral programming techniques. Additionally, few clinics will use these tools routinely. They are typically incorporated into clinical practice in cases where the audiologist has reason to question the validity of the behavioral measures that were obtained. However, with the decrease in age of implantation and the increase in our understanding about how these tools can be used in the clinical management of cochlear implant recipients, the need for supplemental, non-behaviorally based measures of sensitivity to electrical stimulation increasingly has become evident.

Electrically Evoked Auditory Brainstem Response (EABR). The EABR is a recording of the synchronous neural activity in the brainstem that results when the auditory nerve is stimulated. It is recorded using commercial evoked potential equipment and surface recording electrodes positioned on the head. The EABR can be recorded either in the operating room at the time of surgery or during the postoperative period. However, obtaining a successful recording does require a very quiet or sleeping subject. The stimulus used to evoke the EABR is a biphasic current pulse that is generated by the software used to program the speech processor. Studies have shown that the EABR can be successfully measured using a variety of different implant types both in congenitally deaf children and postlingually deafened adults (Brown, Abbas, Fryauf-Bertschy, Kelsay, and Gantz, 1994; Brown, Hughes, Lopez, and Abbas, 1999; Firszt, Rotz, Chambers, and Novak, 1999; Hodges, Ruth, Lambert, and Balkany, 1994; Mason, O'Donoghue, Gibbon, Garnham, and Jowett, 1997; Truy, Gallego, Chanal, Collet, and Morgon, 1998). The EABR is similar in form to the acoustically evoked ABR (Abbas and Brown, 1991) and EABR thresholds have been shown to correlate well with behavioral thresholds for the electrical stimulus used to elicit the EABR (Brown et al., 1994; Miller, Woodruff, and Pfingst, 1995; Shallop, VanDyke, Goin, and Mischke, 1991). From a clinical perspective, however, the comparison of interest is between EABR thresholds and the levels needed to program the speech processor of the cochlear implant. Research has shown that this correlation is significant but not strong (Brown et al., 1994; Mason, Sheppard, Garnham, Lutman, O'Donoghue, and Gibbin, 1993; Shallop et al., 1991).

In general, EABR thresholds are recorded at levels where the stimulus used to program the speech processor is audible but below the maximum level of stimulation that is comfortable for a congenitally deaf child (Brown et al., 1994; Shallop et al., 1991). This information can be useful in cases where the child is showing little or no reaction to electrical stimulation at the initial device stimulation and there is question about whether or not he / she hears the programming stimulus. The EABR threshold can provide a point to begin conditioning the child to respond to electrical stimulation. EABR thresholds tend to be relatively stable over time (Brown, Abbas, Bertschy, Tyler, Lowder, Takahashi, Purdy, and Gantz, 1995), and therefore this response provides a baseline measure of neural responsiveness to electrical stimulation that can be valuable if problems develop at any point following the initial device programming session, or hookup (Kileny, Meiteles, Zwolan, and Telian, 1995). Additionally, in children with extremely limited response capabilities, the EABR can allow the audiologist to approximate the levels needed to program the speech processor.

Few clinics routinely record the EABR. The primary reason for this is that recording this particular response requires that the subject be sedated or very still during the recording period and the process of establishing threshold on an individual electrode is time consuming. Additionally, in most cases, the relationship between the EABR threshold and the levels used to program the speech processor are not strong enough to warrant routine postoperative sedation.

Some clinics do record the EABR in the operating room at the end of the surgical procedure to implant the device. Unfortunately, time is very limited during surgery and there are data suggesting that the threshold measures made in the OR immediately following insertion may change during the immediate postoperative period (Brown et al., 1994). Nevertheless, the presence of an EABR indicates that the device and the auditory nerve are functioning. It is also possible to identify electrodes that activate the facial nerve. Because facial nerve stimulation can complicate the process of device setting, it can be very helpful to identify electrodes that cause this prior to the initial stimulation of the device. Furthermore, the parents of the child and the surgeon often find intraoperative EABR results reassuring given the necessary delay between surgery and hookup.

Electrically Evoked Compound Action Potential (ECAP). An alternative auditory evoked potential that can be used in much the same way as the EABR is the electrically evoked compound action potential (ECAP). This is a measure of the synchronized response of the auditory nerve to electrical stimulation. Rather than being measured using surface electrodes like those used to record the EABR, the ECAP typically is recorded from an intracochlear electrode. This requires specialized technology. Cochlear Corporation was the first company to develop this technology. Since the introduction of the Nucleus CI24M device in 1998, it has been possible to measure electrically evoked intracochlear potentials in all Nucleus cochlear implant users. Cochlear Corporation refers to the software and hardware used to record this response as Neural Response Telemetry (NRT). Recently Advanced Bionics has also introduced a cochlear implant with neural telemetry capabilities and is in the process of developing software to drive this system. MED-EL Corporation also is planning to implement this technology at some point in the future.

The ECAP has several advantages over the EABR as a tool for assessing the response of the auditory system to electrical stimulation. The fact that the recording electrode is within the cochlea is advantageous for several reasons. First, it is located close to the auditory nerve, which means that the response has a large amplitude (much larger than the EABR). Second, the intracochlear location of the recording electrode results in a recording that is not adversely affected by muscle artifact, which in turn means that sedation is not necessary. This is a distinct advantage for pediatric applications. The lack of contamination by muscle artifact means that for the first time we have an electrophysiologic tool that can be incorporated into the routine post-operative evaluation of an implanted child, rather than being limited to the pre- or intraoperative period.

While using an intracochlear electrode to record the ECAP is advantageous in several ways, it also can present some challenges. The primary challenge is that the close proximity of the stimulating and recording electrodes leads to significant levels of electrical stimulus artifact in the recordings. Early publications describing ECAP recordings dealt primarily with the pragmatics involved with obtaining artifact free responses (Abbas, Brown, Shallop, Firszt, Hughes, Hong, and Staller, 1999; Brown, Abbas, and Gantz, 1998; Brown, Abbas, and Gantz, 1990; Miller, Abbas, and Brown, 2000). Current research focus has shifted to studies designed to assess the response of the auditory nerve to electrical stimulation and to identify potential clinical applications for this technology (Brown et al., 2000; Cullington, 2000; Franck and Norton, 2001; Hughes, Brown, Abbas, Wolaver, and Gervais, 2000; Shallop, Facer, and Peterson, 1999; Thai-Van, Chanal, Coudert, Veuillet, Truy, and Collet, 2001).

One such application for this technology is to assist with the prediction of threshold and maximum comfort levels needed to program the speech processor of the cochlear implant. It has been shown that ECAP thresholds correlate well with behavioral thresholds if the same stimulus is used to evoke both responses (Abbas et al., 1999). Unfortunately, however, the stimulus that results in an optimal ECAP response is a relatively slow rate pulse train ($\leq$ 80 Hz) while the stimulus used to program the speech processor of the cochlear implant is a considerably higher rate pulse train ($\geq$ 250 Hz). Peripheral neural responses such as the ECAP (or the EABR) will exhibit adaptation effects and decrease in amplitude as the rate of stimulation is increased. Perceptually, however, the loudness of a stimulus will increase as the stimulation rate increases. This is due to the fact that the brain is able to integrate neural information over time. It is not surprising, therefore, that ECAP thresholds for an 80 Hz pulse train will exceed behavioral thresholds for the high rate stimulus used to program the speech processor of the cochlear implant. Additionally, temporal integration can vary across individuals (Brown et al., 1999). As a result, the correlation between the evoked potential thresholds and behavioral thresholds used for programming may be expected to weaken as the difference in rate between the two stimuli increases.

Like the EABR, research has shown that the ECAP is typically recorded at levels where the programming stimulus is audible to the child (Brown et al., 2000; Cullington, 2000; Franck and Norton, 2001; Hughes et al., 2000; Shallop et al., 1999; Thai-Van et al., 2001). Thus, one method of using this technology with very young children is to slowly increase the programming stimulus to the ECAP threshold and begin working on conditioning the child to respond at that level. Additionally, ECAP thresholds can be used to cross check the results of behavioral testing. Very young children may let the stimulus become elevated before responding. ECAP thresholds should not be recorded at levels where the programming stimulus is inaudible. If this occurs, the behavioral thresholds should be rechecked and/or decreased to a level that is just less than the ECAP threshold.

Systematic studies comparing ECAP threshold and programming levels have been published only for recipients of the Nucleus cochlear implant. Generally, these studies show correlations between NRT thresholds and the behavioral levels needed to program the speech processor of the cochlear implant that are significant, but only moderately strong (Brown et al., 2000; Cullington, 2000; Franck and Norton, 2001; Hughes et al., 2000). For some people, ECAP thresholds can be recorded near the threshold for the stimulus used to program the speech processor. For other people, the electrophysiologic response is only measurable at levels that exceed maximum comfort levels for the stimulus used to program the speech processor. It is possible to use ECAP thresholds recorded on electrodes spaced across the electrode array to get an idea of how the behavioral threshold and maximum comfort levels vary across while recording electrode array. Furthermore, methods for improving the clinical utility of the NRT measures by combining the physiologic data with a limited amount of behavioral data have been proposed (Franck and Norton, 2001; Brown et al., 2000).

The adequacy of programs constructed using the ECAP data was tested recently in a small group of Nucleus CI24M cochlear implant users (Seyle & Brown, 2002). Speech recognition was measured using sentences in noise for a small group of postlingually deafened adults. Performance using a program that was constructed using traditional behavioral programming techniques was contrasted with programs created based on the ECAP threshold data. The results of this study revealed that on average, individuals tended to perform slightly worse with ECAP-based programs than with programs created using standard behavioral programming techniques but this trend was not statistically significant (Seyle & Brown, 2002). If these results can be extrapolated to congenitally deaf children, they suggest that NRT-based speech processor programs, although not ideal, may be adequate to support speech and language development—at least until the child is older and able to be tested more accurately using behavioral techniques. These data should be reassuring to the families of children with developmental delays, who may never be able to be programmed using behavioral techniques.

Unfortunately, much of this research has focused on the relatively low rate SPEAK programming strategy. Further research is needed to determine how NRT thresholds correspond to MAP T- and C-levels for processors that use higher stimulation rates. Additionally, future research also may demonstrate how these physiologic measures of the response of the auditory nerve to electrical stimulation may be helpful in selecting the most appropriate programming strategy for a particular cochlear implant recipient or in determining the number of electrodes to use to avoid channel interaction.

Electrically Evoked Acoustic Reflex Threshold (EART). An alternative "objective" measure that has shown promise for assisting with device programming is the electrically evoked reflex threshold (EART). In children or adults with normal middle ear function, it is possible to elicit a reflexive contraction of the muscles

of the middle ear in response to the presentation of a loud sound. Stimulation of one ear, either electrically or acoustically, causes the simultaneous contraction of the middle ear muscles in both ears. Contraction of the middle ear muscles in turn results in stiffening of the eardrum that can be measured using instrumentation available in most audiology clinics.

One advantage that the EART has over the ECAP or the EABR is that it can be elicited using the same high-rate stimulus used to program the speech processor. Additionally, recording this response does not require sedation (although it does require that the patient remain still for the time required to perform the test). These facts make the EART an ideal tool for clinical use. Several studies have explored potential clinical applications for the EART (Hodges, Balkany, Ruth, Lambert, Dolan-Ash, and Schloffman, 1997; Shallop and Ash, 1995; Spivak and Chute, 1994; Spivak, Chute, Popp, and Parisier, 1994; Stephan and Welzl-Muller, 1992; Stephan, Welzl-Muller, and Stiglbrunner, 1990; Van den Borne, Mens, Snik, Spies, and Van den Brock, 1994). Many of these studies have shown relatively good agreement between the EART and the maximum comfort levels used to program the speech processor; however, to date most of the comparisons that have been published have used congenitally deaf adults who wore relatively low rate processors. Additionally, these studies report that they were unable to measure the EART for approximately 20–30% of the individuals tested (Hodges et al., 1997). This may be due either to middle ear or tympanic membrane abnormalities, inability to maintain a seal for the period of time required for testing or unusually low loudness discomfort levels.

From a theoretical perspective, limiting the electrical dynamic range based on the level at which a reflex is elicited does make some sense. Congenitally deaf children often have little concept of loudness and can have unusually wide dynamic ranges. In these cases, limiting the upper levels of stimulation provided by the implant to levels that do not evoke an acoustic reflex may make the speech processor program more comfortable for the child. In children who are not responding behaviorally to electrical stimulation, stimulation levels that evoke an acoustic reflex also could be interpreted as evidence that the device is functioning and the auditory nerve is intact. Additionally, levels that evoke an EART are levels that should be audible for the child and so this may also be used for conditioning during the first stimulation settings.

Hodges et al. (1997) reported that speech processor programs constructed using EART thresholds to set maximum stimulation levels are tolerated well by both children and adults. More research is needed to determine how EART measures correlate with behavioral levels used to program the speech processor of the cochlear implant for congenitally deaf children and for persons who use high rate processing strategies and to assess more fully the quality of programs created using the EART.

Outcomes of Cochlear Implantation in Adults

Postlingually Deafened Adults

The majority of adults who receive a cochlear implant are postlingually deafened. That is to say, their hearing loss did not occur, or did not become profound, until after they had acquired speech and language. With extremely limited auditory input, these adults experience great difficulty in understanding the speech of others but have little or no impairment in their speech production skills. Once implanted, postlingually deafened adults must use the auditory signal provided by a cochlear implant to access a mental lexicon developed with normal auditory input. Their task is to map a degraded or impoverished representation of the speech signal onto robust mental representations of speech. Continued refinements in the design of cochlear implant systems and processing strategies over the last 20 years have yielded ever-increasing levels of spoken word recognition in this population (Helms et al., 2001; Holden, Skinner, and Holden, 1997; Osberger and Fisher, 2001; Parkinson, Tyler, Woodworth, Lowder, and Gantz, 1996; Staller, Menapace, Domico, Mills, Dowell, Geers, Pijl, Hasenstab, Justus, Bruelli, Borton, and Lemay, 1997).

Single-Channel Cochlear Implant Systems. The first cochlear implant systems clinically available to individuals were single-channel cochlear implants. Two single-channel cochlear implant systems were utilized in the United States, the 3M / House device (Fretz and Fravel, 1985) and the 3M / Vienna cochlear implant (Hochmair and Hochmair-Desoyer, 1983). Recipients who had been totally deaf prior to implantation demonstrated a number of auditory skills with these devices. These people could detect speech at well below conversational levels (Tyler, Lowder, Gantz, Otto, McCabe, and Preece, 1985), identify environmental sounds with a fair degree of accuracy (Gantz et al., 1988), and discriminate some vowels and consonants from a closed-set (Dorman, 1993; B.J. Gantz, Tye-Murray, and Tyler, 1989; Tyler et al., 1989). Few people demonstrated open-set speech understanding with these single-channel cochlear implant systems but many were able to obtain substantial improvements in speech recognition when the auditory signal received

through an implant was combined with lipreading cues (Gantz et al., 1988; Tye-Murray and Tyler, 1989; Tyler et al., 1985).

Multichannel Cochlear Implant Systems. Multichannel, multi-electrode cochlear implant systems are designed to take advantage of the tonotopic organization of the cochlea. The incoming speech signal is filtered into a number of frequency bands, each corresponding to a given electrode in the electrode array. Thus, multichannel cochlear implant systems use place coding to transfer spectral information in the speech signal as well as to encode the durational and intensity cues provided by a single channel cochlear implant system.

The multichannel cochlear implant systems available in the United States today vary in electrode design and in the signal processing strategies that may be utilized. Despite these differences, the current generation of cochlear implant systems produced by Cochlear Corporation, Advanced Bionics, and Med-El yield remarkably similar results. These current implant systems provide at least some open-set speech understanding for the majority of postlingually deafened adults who receive one (Balkany et al., 1996). Average auditory-only word recognition scores of approximately 35%–45% correct and sentence recognition scores of approximately 65%–80% correct have been reported for users of the Nucleus cochlear implant system with the SPEAK processing strategy (Hodges, Villasuso, Balkany, Bird, Butts, Lee, and Gomez, 1999; Staller et al., 1997), for users of the Clarion device with the Continuous Interleaved Sampling (CIS) processing strategy or the Simultaneous Analog Stimulation strategy (Osberger and Fisher, 2001) and for users of the Med-El device with the CIS processing strategy (J. Helms, Muller, Schon, Moser, Arnold, Janssen, Ramsden, von Illberg, Kiefer, Pfennigdorff, Gstottner, Baumgartner, Ehrenberger, Skarzynski, Ribari, Thumfart, Stephan, Mann, Heinemann, Zorowka, Lippert, Zenner, Bohndorf, Huttenbrink, Freigang, Begall, Ziese, Forgbert, Hausler, Vischer, Schlatter, Schlondorff, Korves, Doring, Gerhardt, Wagner, Schorn, Schilling, Baumann, Kastenbauer, Albegger, Mair, Gammert, Mathis, Streitberger, and Hochmair-Desoyer, 1997). Compared with the results obtained with previous generations of cochlear implants, adults who use the current devices achieve higher word recognition skills and / or acquire those skills at a faster rate (W. Helms et al., 2001; Holden et al., 1997; Hollow, Dowell, Cowan, Skok, Pyman, and Clark, 1995; Osberger and Fisher, 2001; Staller et al., 1997). Many adults now demonstrate substantial speech understanding as early as three months following cochlear implantation (Geir et al., 1999; Waltzman, Cohen, and Roland, 1999).

Prelingually Deafened Adults

Adults with prelingual, long-term deafness who receive a cochlear implant typically do not develop open-set word recognition abilities (Busby, Roberts, Tong, and Clark, 1991; Dawson, Blamey, Rowland, Dettman, Clark, Busby, Dowell, and Rickards, 1992; Zwolan, 2000). However, many of these persons can recognize environmental sounds and may demonstrate lipreading enhancement with their cochlear implants. In addition, some report improvements in their own speech production following implantation (Zwolan et al., 1996). Despite the limited communication gains measured in this population of cochlear implant recipients, Zwolan et al. (1996) reported that most of them liked their devices and continued to use them on a regular basis. Prelingually deafened adults with previous auditory / oral training or experience have the best prognosis for accepting and using their devices.

Factors Associated with Adult Speech Perception Outcomes

On average, multichannel cochlear implant systems provide moderate to good levels of auditory-only speech understanding to the majority of adult recipients. However, there remains a great deal of variability in performance. Within each implant group, there are some listeners who understand a great deal of speech through listening alone (e.g., they can carry on a phone conversation), and others who use the implant primarily as an aid to lipreading. As Wilson and his colleagues pointed out, a number of within-subject factors contribute to successful cochlear implant use (Wilson et al., 1993). Two important factors are age at implantation and duration of deafness (Battmer, Gupta, Alllum-Mecklenburg, and Lenarz, 1995; Blamey, Pyman, Gordon, Clark, Brown, Dowell, and Hollow, 1992; Cohen et al., 1993; B. J. Gantz, Woodworth, Abbas, Knutson, and Tyler, 1993; Geir et al., 1999; Shipp, Nedzelski, Chen, and Hanusaik, 1997). Specifically, recipients who are implanted at a younger age and have a shorter period of auditory deprivation are more likely to achieve good outcomes. Duration of implant use also is associated positively with speech perception performance (Blamey et al., 1996; Rubinstein and Miller, 1999; Rubinstein, Parkinson, Tyler, and Gantz, 1999). Other factors that have been found to significantly correlate with adult outcomes include lipreading ability and / or degree of preimplant residual hearing (Cohen et al., 1993; B. J. Gantz et al., 1993; Rubinstein et al., 1999). That is, cochlear implant recipients with greater amounts of preimplant residual

hearing demonstrate superior postimplant spoken word recognition. Presumably, persons with greater residual hearing have a more intact auditory system with a larger number of surviving neural elements to stimulate.

Outcomes of Cochlear Implantation in Children

The primary benefit of cochlear implant use for adults with profound, postlingual deafness is improved speech perception and spoken word recognition. In contrast, cochlear implantation in children with congenital or prelingual deafness may have a profound impact on all aspects of communication, and the assessment battery employed for children should be broad enough to reflect these changes. Thus, clinical researchers must have available a wide array of age-appropriate outcome measures that allows them to target different aspects of communication development (Kirk, 2000; Kirk, Eisenberg, Martinez, and Hay-McCutcheon, 1999; Kirk et al., 1995). The effects of cochlear implant use on the development of speech perception, speech production, and language skills in children are summarized below.

Single-Channel Cochlear Implant Systems

The 3M / House single-channel cochlear implant was first provided to children in 1980, and 164 children were implanted by 1984. Audiologic performance was similar to that of adults (Thielemeir, Tonokawa, Petersen, and Eisenberg, 1985). The FDA pre-market approval process was never completed, and the 3M / House device never received approval for use in children.

Multiple-Channel Cochlear Implant Systems

The first multichannel cochlear implant system provided to children was the Nucleus 22 device. In early investigations, children who used the Nucleus 22 cochlear implant with a feature-extraction speech processing strategy demonstrated significant improvement in closed-set word identification but very limited open-set word recognition (Miyamoto, Osberger, Robbins, Renshaw, Myres, Kessler, and Pope, 1989; Staller, Beiter, Brimacombe, Mecklenberg, and Arndt, 1991). In one of the first large-scale reports of pediatric outcomes, Staller and his colleagues (1991) reported mean monosyllabic word recognition scores of approximately 10% words correct for a group of 80 children. Similar open-set auditory-only performance was reported by Osberger, Miyamoto, Zimmerman-Phillips, Kemink, Stroer, Firzst, and Novak, (1991a) for 28 children. Although auditory-only performance was limited, the authors found that the majority of children with the early Nucleus device demonstrated significant improvement in spoken word recognition when auditory and visual cues were combined.

At present, there are three multichannel cochlear implant systems approved by the FDA for use in children: the Nucleus devices manufactured by Cochlear Corporation, the Clarion devices manufactured by Advanced Bionics Corporation, and the Med-El devices manufactured by Medical Electronics. Each manufacturer continually is updating their electrode designs and the speech processing strategies available with their systems. Each successive generation of processing strategies has generally yielded increased speech perception benefits in children (Cowan, Brown, Whitford, Galvin, Sarant, Barker, Shaw, King, Skok, Seligman, Dowell, Everingham, Gibson, and Clark, 1995; Cowan, Galvin, Klieve, Barker, Sarant, Dettman, Hollow, Rance, Dowell, Pyman, and Clark, 1997; Osberger, Robbins, Todd, Riley, Kirk, and Carney, 1996; Sehgal, Kirk, Svirsky, and Miyamoto, 1998) just as in adults. The majority of children with current cochlear implant devices achieve moderate or better levels of open-set word recognition (Eisenberg, Martinez, Sennaroglu, and Osberger, 2000; Fryauf-Bertschy, Tyler, Kelsay, Gantz, and Woodworth, 1997; Geers, Nicholas, Tye-Murray, Uchanski, Brenner, Davidson, Toretta, and Tobey, 2000; Kirk et al., 1995; T. A. Meyer and Svirsky, 2000; Papsin, Gysin, Picton, Nedzelski, and Harrison, 2000; Staller et al., 1997; Tyler, Teagle, Kelsay, Gantz, Woodworth, and Parkinson, 2000). For example Cohen, Waltzman, Roland, Staller, and Hoffman, (1999) reported word recognition scores for a group of 19 children that ranged from 4% to 76% words correct with a mean of 44% words correct. Similarly, Osberger and her colleagues have reported average scores ranging from 22% to 36% on a more difficult measure of monosyllabic word recognition administered to children (Osberger, Barker, Zimmerman-Phillips, and Grier, 1999; Osberger, Kalberer, Zimmerman-Phillips, and Barker, 2000). Recognition of isolated words is a very difficult task in that there are no linguistic or contextual cues to aid the listener. When linguistic cues are available, such as in sentence recognition tasks, average performance levels are substantially higher (Geers et al., 2000; T. A. Meyer and Svirsky, 2000). For example, Geers et al (2000) reported mean auditory-only sentence recognition scores of approximately 61% correct for pediatric cochlear implant recipients who used oral communication.

One of the most consistent findings is that the speech perception abilities of children with cochlear implants improve with increased device experience (Fryauf-Bertschy et al., 1997; Miyamoto, Osberger, Robbins, Myres, Kessler, and Pope, 1992; Quittner and

Steck, 1991; Tyler et al., 2000). The average spoken language processing skills of children with cochlear implants do not plateau over five or more years of device use (Papsin et al., 2000; Tyler et al., 2000). This is in contrast to postlingually deafened adults with cochlear implants whose word recognition skills typically plateau within the first few months of device use. Children must use the sound they receive via a cochlear implant to acquire a spoken language. The development rate of children's auditory skills following implantation seems to be increasing as cochlear implant technology improves and as children are implanted at a younger age (Allum, Greisiger, Straubhaar, and Carpenter, 2000; Cohen et al., 1999; Osberger et al., 1999; Osberger et al., 2000; Young, Carrasco, Grohne, and Brown, 1999). However, it should be noted that the auditory development is confounded with a child's language abilities. (Blamey et al, 2001b).

Comparison of Sensory Aids in Children

In children, postimplant improvements in communication abilities may result from implant use, from maturation, or from their combined effects. The use of a within-subject design to assess cochlear implant performance does not permit researchers to separate the effects of maturation and cochlear implant use. Osberger and her colleagues were among the first to address this problem. They compared the communication abilities of children with cochlear implants to those of age-matched children with similar hearing thresholds who used other sensory aids, such as hearing aids or vibrotactile aids and demonstrated that the cochlear implant users generally yielded superior results (Miyamoto, Kirk, Robbins, Todd, and Riley, 1996; Miyamoto et al., 1989; Osberger, Robbins, Miyamoto, Berry, Myres, Kessler, and Pope, 1991c). Similar studies have been carried out by other investigators to examine the effects of pediatric implantation on speech perception, speech production, or the development of language skills in children with prelingual deafness (Eisenberg et al., 2000; Geers, 1997; Geers and Brenner, 1994; Geers and Moog, 1994; T. A. Meyer, Svirsky, Kirk, and Miyamoto, 1998; Svirsky, 2000; Svirsky, Robbins, Kirk, Pisoni, and Miyamoto, 2000a). Although the audiological characteristics of the control groups in these studies evolved over time as persons with more residual hearing were implanted, the vast majority of hearing aid users in these studies were profoundly deaf. Overall, these studies demonstrated that the speech perception abilities of pediatric cochlear implant recipients meet or exceed those of their peers with unaided pure tone average thresholds $\geq$90 dB HL who use hearing aids (T. A. Meyer et al., 1998; Svirsky and Meyer, 1999).

Factors Influencing Spoken Word Recognition by Children with Cochlear Implants

A number of demographic factors have been shown to influence performance results in children with cochlear implants. Early results suggested better speech perception performance in children deafened at an older age with a corresponding shorter period of deafness (Fryauf-Bertschy, Tyler, Kelsay, and Gantz, 1992; M. J. Osberger, S. Todd, S. Berry, A. Robbins, and R. Miyamoto, 1991d; Staller et al., 1991). However, when only children with prelingual deafness (i.e., deafness acquired before age three years) were considered, age at onset of hearing loss was no longer a significant factor (Miyamoto, Osberger, Robbins, Myres, and Kessler, 1993). It is clearly evident that earlier implantation yields superior cochlear implant performance in children (Kirk, Miyamoto, Ying, Lento, O'Neill, and Fears, In press; Lenarz, Illg, Lesinki-Schiedat, Bertram, von der Haar-Heise, and Battmer, 1999; Miyamoto, Kirk, Robbins, Todd, Riley, and Pisoni, 1997; Nikolopoulos, O'Donoghue, and Archbold, 1998; O'Donoghue, Nikolopoulos, Archbold, and Tait, 1999; Waltzman and Cohen, 1998). Although the critical period for implantation of congenitally or prelingually deafened children has not been determined (Brackett and Zara, 1998), preliminary evidence suggests that implantation prior to age two or three years may yield improved results (Kirk et al., In press)

The variables of communication mode and unaided residual hearing also influence speech perception performance in children with cochlear implants (Archbold, Nikolopoulos, Tait, O'Donoghue, Lutman, and Gregory, 2000; Cowan, DelDot, Barker, Sarant, Pegg, Dettman, Galvin, Rance, Hollow, Dowell, Pyman, Gibson, and Clark, 1997; Hodges, Ash, Balkany, Schloffman, and Butts, 1999; Kirk et al., In press; Osberger and Fisher, 2001; Sarant et al., 2001; Zwolan et al., 1997). Oral children, and / or those who have more residual hearing prior to implantation, typically demonstrate superior speech understanding. These factors may co-vary, in that children with greater amounts of residual hearing prior to implantation are more likely to succeed in an oral educational setting than those with very limited residual hearing. The superior performance of individuals with preimplant residual hearing highlights the need to consider both aided thresholds and speech perception abilities when determining candidacy for a cochlear implant. That is, children with some residual hearing should be considered for implantation if their speech perception performance is less than that obtained by the average pediatric cochlear implant recipient. These results also have led to some controversy regarding whether to implant the better or the poorer hearing ear (Zwolan et al., 1997).

Speech and Language Development in Children with Cochlear Implants

Cochlear implants are viewed as auditory prostheses and thus the principal benefits expected of them have been improvements in audition. However, when these devices are used with children who are deafened early in life, the scope of the benefits are substantially broader due to the importance of audition in the acquisition of spoken language. Children with severe to profound hearing loss usually have found the acquisition of spoken language to be challenging even with extensive speech and language training. Research on the language development of children with severe to profound hearing loss has shown better speech and language outcomes in those children with more hearing (Boothroyd, Geers, and Moog, 1991). In light of this, the additional auditory information provided by cochlear implants should allow children fitted with these devices to have improved speech and language outcomes. Some however, have expressed concern that the auditory information provided by a cochlear implant would be insufficient to support speech and language development and thus this promise would be unfilled and that children receiving these devices would be denied the opportunity to acquire sign language systems which would allow their successful participation in the Deaf community (Lane and Bahan, 1998). Much of the research since children began to receive cochlear implants has been directed toward documenting the degree and scope of speech and language benefit provided by cochlear implants and evaluating factors that account for individual differences in outcomes of children receiving these devices.

The research on speech and language development of children who have received cochlear implants has grown substantially during the past 15 years. The first paper to report on speech and language in children with single channel cochlear implants was published in 1985 (Kirk and Hill-Brown, 1985). A small number of studies followed in the next five years, however, most of these consisted of case studies of children with single channel devices. At the beginning of the 1990s, papers reporting initial findings of speech and language development in children using multichannel devices began to appear. By 1995, investigators began to expand their interest in the communication skills of implant users by examining language development in children using multichannel devices; in association with this was a continued increase in the number of studies reporting results on speech and language outcomes. As this research on speech and language expanded in scope and quantity, there were also changes in the nature of devices and the practice of implantation. More sophisticated processing strategies and internal hardware were continually being implemented and the age of implantation was declining dramatically. Thus, although general conclusions can be reached regarding speech and language outcomes, the outcomes that can be expected from current technology and clinical practice remain to be determined by long-term longitudinal studies of newly-implanted children. This literature will be summarized in the sections below beginning with those results that concern speech and language outcome in general and then those factors that have been examined as possibly affecting individual differences in speech and language outcomes.

Speech Sound Production and Speech Intelligibility Outcomes. The initial studies concerning speech development of children receiving multichannel implants provided us with preliminary insight into the potentials of cochlear implants. These studies were limited by the fact that the children were using early generations of processing strategies, short amounts of implant experience—often less than two years—and children implanted very late in childhood. Despite these limitations, gains in speech production were noted, including a greater range of phonetic features and expanded consonant repertoire development (Osberger, Robbins, Berry, Todd, Hesketh, and Sedey, 1991b; Tobey, Angelette, Murchison, Nicosia, Sprague, Staller, Brimacombe, and Beiter, 1991a). Small gains but statistically significant gains in speech intelligibility (i.e., how well the children's speech could be understood by others) over preimplant performance also were found in the early studies (Tobey and Hasenstab, 1991b). Subsequently, several studies compared the speech production skills of children with implants to those of children using hearing aids or vibrotactile aids. After two to three years of implant use, these studies all reported significantly better speech production accuracy and speech intelligibility for the children using cochlear implants (Ertmer, Kirk, Sehgal, Riley, and Osberger, 1997; Tobey et al., 1991a; Tobey, Geers, and Brenner, 1994; Tye-Murray, Spencer, and Woodworth, 1995). Additionally, the performance of children receiving implants was compared with that of hearing aid users with unaided pure tone average thresholds in the 90–100 DB HL range (the "gold" group) and 100 to 110 dB HL range (the "silver" group). After three to four years of implant use, the children receiving implants obtained speech sound production accuracy and speech intelligibility that exceeded that of the silver group and approached that of the gold group (Geers, 1997; Miyamoto et al., 1996; Osberger, Robbins, Todd, and Riley, 1994). More recently, Svirsky et al. (2000b) reported speech intelligibility levels equivalent to that of gold level performance after less than 3 years of cochlear implant use. Similarly, Blamey

and colleagues reported (Blamey, Barry, and Jacq, 2001a) that a group of children implanted at an average age of 3.2 years demonstrated speech production and language skills after three years of cochlear implant use that were similar to children with unaided pure tone average thresholds of 78 dB HL; this would place the pediatric implant users' performance above that of children in the gold hearing aid category in the prior studies. Thus, it appears that children implanted with newer technology and newer clinical practices (earlier age of implantation) may have better speech production outcomes.

The acquisition of speech proficiency requires between five and seven years of auditory experience in the hearing child, therefore, gains in speech resulting from implant experience may extend over a long period of time and require long-term longitudinal designs. A small number of studies have examined the pattern of speech development over time. (Serry and Blamey, 1997) reported that after four years of implant experience, a group of nine children produced 54% of their consonants correctly and demonstrated a pattern of phoneme acquisition that was similar to hearing children. Furthermore, the trajectory of growth in these children was linear with no sign of asymptote. More recently, the growth patterns in these children through six years of implant use was reported (Blamey et al., 2001a). Overall, these children continued to show growth, however, some evidence of asymptotic development was evident. These data indirectly suggest that earlier implantation would have a positive effect on speech outcomes. In two early studies, the speech outcomes of children implanted after the age of 10 was found to be poorer than those implanted at a younger age (Osberger, Maso, and Sam, 1993; Tye-Murray et al., 1995). (Miyamoto, Kirk, Svirsky, and Sehgal, 1999) have presented speech production data favoring implantation at earlier ages, however, these were non-significant trends in their data. Connor and colleagues (Connor, Hieber, Arts, and Zwolan, 2000) recently did find that earlier age at implantation resulted in better speech production outcomes.

Several studies have examined the effect of communication mode (signed / total communication or oral communication) on speech outcomes. Osberger and colleagues (Osberger et al., 1994) reported better speech production outcomes for children with oral communication backgrounds than those from total communication programs. More recently several research groups have reported significantly better speech outcomes by children with cochlear implants in oral programs than those in programs using sign (Archbold et al., 2000; Connor et al., 2000; Geers et al., 2000; Miyamoto et al., 1999) also found that as a group, children in oral programs had better speech development than children in total communication programs. However, this effect was not found for children implanted prior to 5 years of age.

Language Outcomes. The research on language acquisition beyond the sound system in children with CIs is just emerging. Initial reports in the early 1990s consisted of case studies that provided evidence of changes in language associated with receipt of CIs. More recently, there have been several studies comparing the language development of children with implants to either non-implanted children who had similar hearing levels or to predictions of language status based on pre-implant performance. Geers and Moog (1994) compared the language development of a group of 13 children who received CIs with similar groups of children fitted with hearing aids or tactile aids over a three-year period. The language growth of children with CIs equaled or exceeded that of the other groups on receptive and expressive measures of spoken English. In fact, the children with cochlear implants approached the language levels of a group of children using hearing aids who had 20 dB better hearing, on average. Robbins and colleagues (Robbins, Osberger, Miyamoto, and Kessler, 1995) followed prelingually deaf children for 15 months after they received their CIs. The language age equivalent scores obtained at 6 and 15 months post implant were compared to predictions of scores based upon a pre-implant language quotient. Mean obtained receptive and expressive quotients exceeded the pre-implant predicted means for both receptive and expressive scores; furthermore the difference at 15 months was greater than that at 6 months. Later Svirsky and colleagues (Svirsky et al., 2000a) examined the growth in expressive language scores over 30 months of implant experience and compared these changes with those predicted from cross-sectional data obtained from similar children who were deaf, but who had not received CIs. The children with cochlear implants had significantly greater rates of language growth than the non-implanted children who were deaf throughout the follow-up interval and further, the rates of language growth in the children with implants were very similar to that expected of hearing children. These studies as well as several others provide strong evidence that cochlear implants provide an improved auditory experience for children that supports the acquisition of spoken language (Blamey et al., 2001b; Bollard, Chute, Popp, and Parisier, 1999; Connor et al., 2000; Miyamoto et al., 1999; Tomblin, Spencer, Flock, Tyler, and Gantz, 1999).

Several studies have considered whether the variation in language outcomes of pediatric cochlear implant recipients are associated with the type of communication system used in habilitation. The results of these studies are mixed. One set of studies has shown children with total communication training had better language outcomes than children with oral training (Coerts and Mills, 1995; Hasenstab and Tobey, 1991). However, other studies found no differences in language development between children receiving oral and total training (Connor et al., 2000; Robbins, Bollard, and Green, 1999) and finally, one study has found an advantage for children with oral training (Miyamoto et al., 1999). These mixed results suggest that the effect of mode of communication on language development in children with cochlear implants is not large and contrasts with the more robust effects of communication mode on the development of speech perception and production.

A critical language outcome for children who are deaf concerns their development of reading. Most children who are deaf have been shown to have substantial problems with the development of reading. The growth in reading skills in children with severe to profound hearing loss has been found to be between .11 and .50 of that found in hearing children. As a result, most of these children with hearing impairment complete high school with reading levels no greater than that of hearing children in the fourth-grade (Allen, 1986; DiFrancesca, 1972; Kroese, Lotz, Puffer, and Osberger, 1986; Wrightstone, Aronow, and Moskowitz, 1963; Yoshinaga-Itaro and Downey, 1996). Recently, Spencer, Tomblin, and Gantz (1997) reported that the average reading comprehension standard scores of the children with cochlear implants they have been following is 91; this is equivalent to a growth rate of .91 of that of hearing children. Similar results have been reported by Geers & Moog (1999). These data suggest that the reading development in children with cochlear implants is very similar to the language growth of these children. In both cases average rates of development approach those of hearing children and fall well within levels considered to be normal.

Conclusions. Despite considerable concerns over the potential of cochlear implants for aiding speech and language development in children who are deaf, the results of studies concerning speech, language, and reading have provided consistent results showing that children who are implanted during the preschool years or early school years are very likely to benefit from the auditory experience provided by these devices. Throughout these studies, substantial individual differences were reported and therefore benefit was not universal, but was frequent. Factors influencing the individual differences in outcome have been found to be the age of implantation, with early implantation tending to be associated with better outcomes, and receipt of oral communication training benefiting the development of better speech production. Thus, it would seem that implantation in the early preschool years and possibly in infancy followed by high quality aural rehabilitation and speech training should improve the proportion of children with good speech and language outcomes.

Educational Options for Children with Cochlear Implants

The advent of cochlear implants has had a dramatic effect on the achievements of young profoundly deaf children. Spoken language competence is now attainable by many children who previously depended primarily on sign language for communication. Children who receive an implant early in life, followed by a period of appropriate rehabilitation, typically achieve speech perception, production, and oral language skills that exceed levels observed in profoundly deaf children with hearing aids (Geers and Moog, 1994). However there continue to be large individual differences in the performance outcomes of groups of children (Pisoni, Cleary, Geers, & Tobey, 2000). As noted above, possible reasons for poor performance include later age at implantation, poor nerve survival, inadequate device fitting, insufficient cognitive skills, poor motivation, educational and social environment emphasizing manual communication, and limited parental support. Most of these factors are not subject to clinician intervention. However, to the extent that speech and language skills achieved post-implant are affected by educational choices, parents and clinicians may be able to optimize the desired outcome.

Educational choices for children who are hearing impaired include factors such as mainstream or special education class placement, public or private school programs, speech, sign or equal communication mode emphasis, amount of individual speech and language therapy provided, and the characteristics of the clinicians who provide the therapy. One educational variable frequently examined in relation to implant benefit is the communication mode used in the child's classroom. This variable is most often dichotomized into oral communication (OC) approaches and total communication (TC) approaches. Proponents of the oral communication approach maintain that dependence on speech and audition for communication is critical for achieving maximum auditory benefit from any sensory aid. Constant use of auditory input to monitor speech production and to comprehend spoken language provides the concentrated practice needed for optimum benefit from a cochlear implant.

Types of oral communication approaches differ in their emphasis on the auditory and visual channels for the reception of spoken language. Methods range from the cued speech approach, in which manual cues are used to complement lipreading, to the auditory-verbal approach in which lipreading is discouraged and the child is taught from an early age to make use of whatever auditory information is available through his / her sensory device to understand speech.

Proponents of the total communication approach maintain that the child with severe-profound deafness benefits most when some form of manually coded English accompanies speech. The use of a sign system allows for easier assimilation of language through the unimpaired visual modality. The child then is able to associate what he / she hears through the implant with signed representations of language in order to support spoken language development. In practice, total communication programs range from those that rely heavily on signed input with less emphasis on speech and English syntax to those that emphasize speech, audition, and lipreading and maintain careful adherence to English syntax and morphology. Although there is evidence that children enrolled in oral communication programs demonstrate better speech perception, speech production and language improvement post implant than those in total communication programs (Miyamoto et al., 1999; Tobey et al., 2000; Geers,2002), other studies indicate greater vocabulary improvement for children enrolled in total communication programs (Connor et al., 2000; Robbins et al., 1999).

Another approach to educating deaf children, referred to as bilingual-bicultural, emphasizes the development of American Sign Language (ASL) and emersion in deaf culture. Children are expected to acquire fluency in ASL before learning English through literacy. The development of an exclusively visual language system does not capitalize on the auditory speech perception skills provided by the cochlear implant. If the goal of cochlear implantation is the development of competence in spoken English, a bilingual-bicultural approach is not compatible with this objective.

Documenting the effects of educational choices on speech and language outcomes is especially difficult when other factors that could also affect performance vary a great deal. Factors such as the child's age at the onset of deafness, at implant and at test, duration of implant use, family characteristics, and intelligence can have a substantial impact on test scores. Parents and children with particular characteristics may be drawn to certain kinds of programs, and programs emphasizing spoken language may favor the admission of children with certain characteristics (e.g., greater pre-implant residual hearing). Furthermore, factors such as type of device and / or speech processing strategy and pre-implant candidacy criteria are constantly changing, making control of these factors difficult to achieve over time. Failure to control for any of these intervening variables may obscure the underlying causes of exceptionally good or poor performance with a cochlear implant (See Kirk, 2000 for a discussion of these issues). It is important to undertake studies that control for as many of these factors as possible so that the relative benefits of specific educational approaches can be documented.

Geers (2002) reported data for a 136 children who were similar in age (8–9 years), age at onset of deafness (<3 yrs), duration of implant use (4–6 years), age at implant (<5 yrs), family environment (hearing English-speaking parents) and device (Nucleus-22). These children all received their implants when the candidacy requirements included no observable benefit from conventional amplification. Thus, none of these children exhibited any open-set speech perception ability with hearing aids before receiving an implant. The participants do not represent any single educational program or method, but rather come from the full range of educational settings available across the United States and Canada.

Children were tested on a comprehensive battery of tests of speech perception, speech production, language, and reading. A multivariate analysis was used to determine the contribution of educational factors to post-implant outcome after variance due to child, family, and implant characteristics had been removed. The most important child characteristic was found to be nonverbal intelligence. Once this variable was held constant, earlier age at implant and later age at onset of deafness did not contribute significantly to outcome. Children of highly educated parents did not achieve significantly better outcomes than those of less educated parents when the child's intelligence was factored out. There was a significant tendency for smaller families to have children who had somewhat better language development. The overall functioning of the cochlear implant, particularly duration of use of the updated SPEAK coding strategy, had a substantial impact in all outcome areas examined. The educational factor associated with high performance outcomes was an emphasis on oral-aural communication. Communication mode was more important to auditory and spoken language development than any other educational factor examined including classroom placement (public or private; special education or mainstream), amount of therapy, therapist's experience or parent participation in therapy. Children whose educational

program emphasized dependence on speech and audition were better able to use the information provided by the implant to hear, speak, and read. Use of sign communication with implanted children did not promote auditory and speech skill development and did not result in an advantage for overall English language competence, even when the outcome measure included sign language. Oral education appears to be an important educational choice for children who have received a cochlear implant before 5 years of age.

Cochlear Implant Outcomes in Special Populations

Bilateral Implantation

In normal hearing situations, sound reaching one ear differs from sound reaching the opposite ear in two ways: there is a difference in intensity (loudness) and a difference between the times when the sound reaches each ear. These differences allow the listener to identify the direction from which a sound (and speech) emanates and to separate the speech signal from any background noise. Both of these are critical in professional and social situations because the lack of ability to understand speech in the presence of competing noise reduces an individual's ability to communicate effectively.

Traditionally, cochlear implant surgery routinely has been performed in one ear due to the possible loss of residual hearing following cochlear implantation, the belief that one ear should be preserved in order to benefit from future technologies and the cost / benefit issues associated with a second device. However, because of the success of unilateral implantation and the improved functioning of individuals using binaural hearing aids, investigators have begun to explore whether bilateral cochlear implantation could provide increased speech understanding and localization benefits to cochlear implant users. Bilateral implantation is currently being studied in a limited number of cochlear implant recipients with mixed results. In some cases, recipients do experience enhanced speech understanding, especially in noise; in other users the improvement in speech understanding compared with unilateral performance is minimal or absent and the primary advantage of binaural implantation is sound localization (Tyler et al., 2002).

Bilateral implantation outcomes to date are encouraging but inconclusive due to the limited number of participants and the scope of the projects. There is a clear need for further exploration of the many variables that can affect the performance of people with binaural implants before widespread use is warranted. Many of these studies are currently underway and the results will help to define prognosis and optimization of binaural implant usage. Such studies will determine the ultimate benefit and cost effectiveness of bilateral cochlear implantation.

Auditory Brain Stem Implants

Conventional cochlear implants cannot be used by persons whose auditory nerve has been damaged during acoustic tumor removal (Dorman, 1993). For these individuals, electrode arrays have been designed that can be placed on the cochlear nucleus. Drs. William House and William Hitselberger implanted the first auditory brain stem device in 1979 (Edgerton, House, and Hitselberger, 1982). This first device was based on the 3M / House single-channel cochlear implant system and used the same speech processor. These recipients obtained awareness of environmental sounds and lipreading enhancement with the device. In 1992, a multichannel brainstem implant based on the Nucleus 22 channel cochlear implant was developed in a collaborative effort by the House Ear Institute, Cochlear Corporation, and Huntington Medical Research Institutes (Otto and Staller, 1995). This system combines the receiver-stimulator from the Nucleus multichannel cochlear implant with an eight electrode surface array designed for the human cochlear nucleus and state-of-the art Nucleus speech processing strategies. Clinical trials with this device were initiated in 1993 and FDA approval was received in 2001. Although a limited number of recipients achieve moderate levels of open-set sentence recognition, (Otto, Shannon, Brackmann, Hitselberger, Staller, and Menapace, 1998) the primary benefits for most recipients are environmental sound awareness, speech pattern perception, and enhanced lipreading abilities (Briggs, Fagan, Atlas, Kaye, Sheehy, Hollow, Shaw, and Clark, 2000; Lesinski-Schiedat, Frohne, Illg, Rost, Matthies, Battmer, Samii, and Lenarz, 2000; Marangos, Stecker, Sollman, and Laszig, 2000). These benefits can yield substantial improvements in the quality of life experienced by users of auditory brainstem implants.

Cochlear Implants in Persons with Multiple Impairments

The presence of a handicapping condition in addition to deafness, such as vision deficits, cognitive impairments, learning disabilities, etc., is not necessarily a contraindication for implantation in either children or adults. The issue of implantation of the multiply handicapped population has become more compelling because of the fact that children are being implanted at very young ages where it is often difficult to diagnose less obvious handicapping conditions.

From 1995–2000, several investigators examined populations of children with a variety of handicap-

ping conditions and compared them to children whose only deficit was hearing loss (Isaacson, Hasenstab, Wohl, and Williams, 1996; Lesinski-Schiedat et al., 2000; Waltzman, Scalchunes, and Cohen, 2000). In addition to deafness, the handicapping conditions included at least one of the following disabilities: blindness, reduced cognitive ability, mental retardation, global learning disabilities, attention deficit disorder, autism, and pervasive developmental disorder. The results from all the studies were similar in that the children with multiple handicaps received significant auditory benefit post-implantation. However, they progressed more slowly, had poorer perception and linguistic skills and were less stable in their performance than children who are hearing impaired with no additional handicaps. The children with multiple handicaps ultimately achieved a continuum of results from the perception of environmental sounds to the use of oral language as their primary mode of communication. Outcome often was based on the severity of the handicapping condition. Nonetheless, even those children who demonstrated minimal auditory benefit from the implant experienced a link to their environment and to other people. Although these gains often are not measurable using objective tests, nor are the advantages as extensive as those achieved by children who have hearing loss only, they should not be discounted. The determination of cochlear implant "success" should take into account a child's maximum potential rather than merely considering open-set speech understanding scores. Based on the fact that multiply handicapped children demonstrated substantial gains post-implantation, it is recommended that this population be considered as candidates for implantation along with children and adults who are hearing impaired but do not have additional handicapping conditions.

Cost / Benefit of Cochlear Implantation

The impact of profound deafness varies depending upon the age at onset. Adults with postlingually acquired severe-to-profound deafness experience communication difficulties that can result in reduced vocational options and feelings of social isolation. The impact on prelingually deafened children is much greater, as noted above. Many prelingually deafened children demonstrate marked language and academic delays.

A number of investigators have examined the cost-effectiveness of cochlear implantation. Niparko and his colleagues provided an excellent summary of the methods of assessment and the outcomes. In general, these studies have shown that severe-to-profound deafness in adults has a measureable impact on quality of life; in turn, cochlear implantation is associated with substantial improvements in recipients' self-rated quality of life and appears to be an effective use of health care resources (Niparko, Cheng, and Francis, 2000).

According to these authors, the cost-effectiveness of cochlear implantation should be assessed not only with traditional measures of auditory and speech performance (such as speech perception, intelligibility, and language outcome measures, but also with measures of 1) academic performance, 2) the use of special educational and rehabilitative resources, and 3) changes in quality of life. Niparko and his colleagues developed the educational resource matrix (ERM) to map educational placement and the use of rehabilitation resources by children with hearing impairment (Koch, Wyatt, Francis, and Niparko, 1997). Niparko et al. (2000) reported that children with cochlear implants were mainstreamed earlier (i.e., placed in classrooms with their normal hearing peers) and required less special education support services than unimplanted children with hearing impairment. The authors also completed cost-benefit projections based on the trend they observed toward greater educational independence following cochlear implantation. They concluded that cochlear implantation could result in substantial savings in educational expenses.

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