Cochlear Implants
Clinical and Societal Outcomes

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KEYWORDS

• Cochlear implantation outcomes • Speech perception • Language development
• Cost utility • Quality of life • Education

KEY POINTS

- The primary goal of cochlear implantation in children is to facilitate comprehension and expression through the use of spoken language.
- Early educational intervention is associated with improvements in language development after cochlear implantation.
- Recent analyses show that in adults, the age at implantation carries minimal or even statistically insignificant predictive power on postimplantation outcomes. The duration of deafness and preoperative speech-perception scores have the highest predictive power on postimplantation outcomes across the adult population.
- Age-related degeneration of the spiral ganglion and progressive central auditory dysfunction raise potential concerns about the efficacy of cochlear prostheses in the elderly, but comparable gains in speech understanding have been reported for both elderly and younger groups of implant recipients.

INTRODUCTION

Over the past 30 years, hearing care clinicians have increasingly relied on cochlear implants to restore auditory sensitivity in selected patients with advanced sensorineural hearing loss (SNHL). This article examines the impact of intervention with cochlear implantation in children and adults. The authors report a range of clinic-based results and patient-based outcomes reflected in the reported literature on cochlear implants. The authors describe the basic assessment of the physiologic

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response to auditory nerve stimulation; measures of receptive and productive benefit; and surveys of life effects as reflected measures of quality of life, educational attainment, and economic impact.

AUDITORY OUTCOMES

Auditory performance is measured at preimplant and postimplant intervals, allowing the assessment of candidacy criteria and longitudinal tracking of the patients' progress. Measurement variables associated with auditory testing should be standardized as much as possible. Clinicians can choose between closed-set tests (eg, forced choice of 1 answer from a list of 4) and open-set tests (auditory alone without context) of words and/or sentences. Closed-set tests and sentence tests typically produce substantially higher correct percentages than do open-set tests and tests of single words. This difference reflects the amount of contextual information available when word and sentence material are presented. Voice presentation can also affect speech-perception scores,[1] with live presentations typically producing higher rates of correct responses than taped presentations.

Trends toward higher rates of open-set speech recognition with newer implant technology and longer implant experience have prompted calls for more stringent assessments of receptive capability. Increasing the difficulty of a speech-perception test has the effect of limiting the ceiling effect that results from testing with simple, everyday phrases. For the purpose of generating more meaningful comparative data, increasing the test difficulty tends to normalize distributions across populations, thereby enabling more powerful statistical analyses of differences between groups.

TESTS OF IMPLANT PERFORMANCE

The Minimum Speech Test Battery (MSTB) for adult cochlear implant users is a standardized set of comprehensive tests of preoperative and postoperative speech recognition.[2] To minimize the effects of learning and memorization, the word and sentence tests have different lists for at least 6 testing trials. The average and range of performance of cochlear implant users are critical to defining audiologic performance boundaries for implant candidacy, monitor postimplantation results, and facilitate in comparisons across implant designs and coding strategies.

The major components of the MSTB are the Hearing in Noise Test (HINT) and the Consonant/Nucleus/Consonant (CNC) test. The HINT[3] provides a measure of speech-reception thresholds for sentences in quiet and in noise. For high levels of recognition in quiet, the background noise is filtered to match the long-term average spectrum of the sentences. In the MSTB, the HINT sentence lists are presented at 70 dB in quiet and at a +10 dB signal-to-noise ratio (ie, noise at 60 dB). Smaller signal-to-noise ratios (eg, +5 dB or 0 dB) may also be used to avoid ceiling effects. Normal-hearing listeners can comprehend sentences effectively with signal-to-noise ratios down to −3 dB, whereas implant recipients typically show degraded speech recognition when signal-to-noise ratios are lowered beyond +10 dB.

The CNC test consists of monosyllabic words with equal phonemic distribution, with each list of words having approximately the same phonemic distribution as the English language.[4] CNC lists enable performance testing that is likely to represent daily experience with speech stimuli. These tests measure the percentage of words correctly recognized. Revised CNC lists[5] were developed to eliminate relatively uncommon words and proper nouns. More recent observations have stressed the importance of speech test materials that reduce contextual cues in the interest of assessing

auditory performance (bottom-up processing) rather than cognitive (top-down processing) components of speech recognition.[6]

Improved speech perception is the primary goal of cochlear implantation. Initial clinical series judged implant efficacy mostly on environmental sound perception and performance on closed-set tests, whereas greater emphasis is now placed on measures of open-set speech comprehension. Speech-perception results from early clinical trials have served to guide the evolution of cochlear implantation.

Clinical observations in patients with current processors indicate that for patients with implant experience beyond 6 months, the mean score on open-set word testing approximates 30% to 60%, with a range of 0% to 100%.[7–10] Results achieved with the most recently developed speech-processing strategies reveal mean scores more than 75% on words-in-sentence testing, although once again with a wide range of 0% to 100%. Although patients perform substantially poorer on single-word testing, these mean scores continue to improve as the speech-processing strategy evolves.[11] After implantation, speech recognition by telephone[12] and music appreciation are often observed. Again, these benefits seem to be best achieved through more recently developed processing strategies.

The high prevalence of SNHL among the elderly has prompted evaluations of the benefit of cochlear implantation in this age group.[10,13–16] For recipients of the cochlear implant after the age of 65 years, open-set speech-recognition scores are not as high as those reported in younger cohorts, potentially representing an effect of longer duration of deafness as opposed to age per se. Nonetheless, implant usage is high among elderly recipients, with nonuse observed in few patients.

PREDICTORS OF BENEFIT IN ADULTS

The evaluation of the benefit of cochlear implantation in adults has largely focused on measuring gains in speech perception. Assessments of speech recognition in implanted adults offer the opportunity to develop models of benefit prediction. As investigators identify the salient predictive factors, patients' choices regarding candidacy, device and processing strategy, and the degree of postoperative auditory rehabilitation necessary can be better informed. Various statistical methods have been used to assess speech comprehension using cochlear implants. Multivariate analysis, a statistical technique that determines the contribution of individual factors to variations in performance, is the most commonly used methodology.[7,8,17–19] The following factors have been evaluated:

- Patient variables: age of onset, age of implantation, deafness duration, cause, preoperative hearing, survival and location of spiral ganglion cells, patency of the scala tympani, cognitive skills, personality, visual attention, motivation, engagement, communication mode, and auditory memory.
- Device variables: processor, implant, electrode geometry, electrode number, duration and pattern of implant use, and the strategy used by the speech processing unit.

Although the factors identified as most determinative have varied with different study populations, the most recent analyses[8,17–19] showed that age at implantation carries minimal or even statistically insignificant predictive power on postimplantation outcomes. Rather, it was the duration of deafness and preoperative speech perception scores that had the highest predictive power on postimplantation outcomes across the adult population.

The resulting models of postimplantation outcomes follow a similar mathematical structure with a patient's postoperative word score starting at a constant value *k*, which is either increased by the addition of a term dependent on the pre–cochlear-implant sentence score or decreased by the subtraction of a term dependent on the duration of deafness.

$$\text{Predicted percentage of words in everyday sentences} = k - (\text{Dur Yrs df}) + (\%\ \text{words pre-CI})$$

where *CI* is cochlear implant, *Dur Yrs df* is duration of deafness in years from onset and *% words pre-CI* is consonant-nucleus-consonant (CNC) monosyllabic word score before implantation.

In addition to the previously mentioned factors, the choice of which ear to implant has been a frequently discussed issue. Several studies, particularly the Iowa model, have emphasized the utility of implanting the better-hearing ear. At Johns Hopkins Hospital, the authors have advocated the implantation of the poorer-hearing ear. Although greater data are needed, the authors' studies thus far reveal no significant difference in implant performance based on whether the better- or worse-hearing ear is implanted. **Fig. 1** shows a regression plot of the predicted postoperative word scores for each patient as modeled by the Johns Hopkins (implant poorer ear) and Iowa formulas (better ear).[17] There are virtually identical scores predicted from each patient's duration of deafness and preoperative sentence recognition scores. These data suggest that results obtained through cochlear implantation of the poorer-hearing ear are

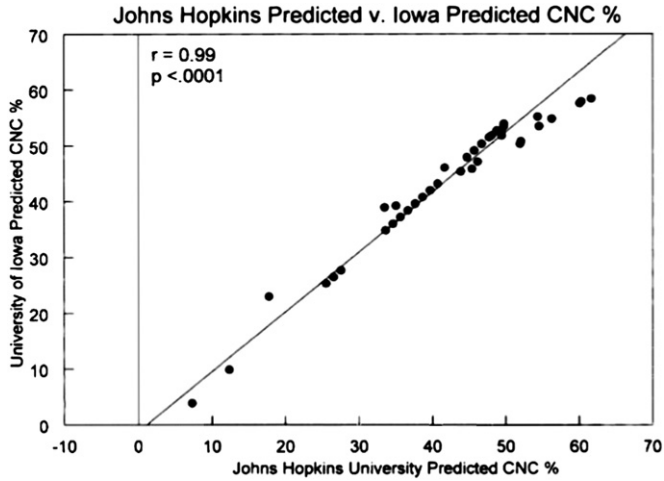

Fig. 1. Regression plot of the predicted postoperative word scores for each patient as modeled by the Johns Hopkins (implant poorer ear) and Iowa formulas (better ear). There are virtually identical scores predicted from each patient's duration of deafness and preoperative sentence-recognition scores. These data suggest that results obtained through cochlear implantation of the poorer-hearing ear are statistically equivalent to results obtained through implantation of the better-hearing ear. The similarity of results obtained through both methods suggests that implantation may have a beneficial effect on central auditory pathway development regardless of sidedness. (*Adapted from* Friedland DR, Venick HS, Niparko JK. Choice of ear for cochlear implantation: the effect of history and residual hearing on predicted postoperative performance. Otol Neurotol 2003;24(4):582–9; with permission.)

statistically equivalent to results obtained through implantation of the better-hearing ear. The similarity of results obtained through both methods suggests that implantation may have a beneficial effect on central auditory pathway development regardless of the choice of ear to be implanted, a finding which was later confirmed by Francis and colleagues[20] (2005).

Another variable that influences speech perception is technological sophistication of the implanted device. Improvements in speech perception have been associated with generational improvements in signal processing strategies, speech processors, and electrode arrays,[21,22] but may reflect clinical trends in patient selection as well as technological advances.

IMPLANT PERFORMANCE IN CHILDREN

The era of pediatric cochlear implantation began with House-3M single-channel implants (a collaboration between House Ear Institute and Minnesota Mining and Manufacturing Company) in 1980. Investigational trials with multiple-channel cochlear implants began with adolescents (aged 10 through 17 years) in 1985 and with children (aged 2 through 9 years) in 1986. Implantation of infants and toddlers younger than 2 years of age began in 1995.[23] Although clinical experience with cochlear implantation is considerably shorter in children than in adults, a large body of evidence is now available (reviewed by[24,25]).

AUDITORY PERFORMANCE ASSESSMENTS FOR CHILDREN

Auditory performance in children is assessed with a battery of audiological tests that can address the wide range of perceptual skills exhibited by children with severe to profound sensorineural hearing loss. Although substantial auditory gains are apparent in implanted children, the range of quantifiable improvement varies widely between children and depends heavily on the duration of use of the device as well as preoperative variables. For this reason, testing should survey a range of levels of speech recognition, including simple awareness of sound, pattern perception (discrimination of time and stress differences of utterance), closed-set (multiple choice) speech recognition, and open-set (auditory only) recognition.

Methodological variables must be considered when attempting to objectively rate the effect of cochlear implants on the development of speech perception in children who are deaf. There are obvious difficulties inherent in objectively rating communication competence in very young children; older children may exhibit advantages by virtue of greater familiarity with a test's context, independent of perceptual skills.[1] Objective assessment also mandates a structured setting. Given its unfamiliarity, children may not be in an optimal frame of mind in cooperating with testing. Investigators must also account for discontinuity in the age-appropriate measures necessary for longitudinal assessment.[26] Kirk and colleagues[1] (1997) have examined the methodological challenges and developmental considerations inherent in pediatric implant assessment and categorized variables relating to

- The child's age and level of language and cognitive development (internal variables)
- The child's ability and willingness to respond as influenced by reinforcement and required memory task (external variables)
- The procedure of voice presentation, the test administered, and the available options from which to choose a response (methodological variables)

Tests of speech perceptions typically used for childhood assessment have been described in detail[1,27–29] and typically consist of closed-set tests that assess word identification among a limited set of options with auditory cues only, open-set tests (scored by percentage of individual words correctly repeated), and structured interviews of parents using criteria-based surveys to assess the response to sound in everyday situations and behaviors related to spoken communication.

SPEECH COMPREHENSION RESULTS IN CHILDREN WITH COCHLEAR IMPLANTS

Early assessments of pediatric hearing outcomes were performed by House and colleagues[30] (1983) and showed substantial improvement in auditory thresholds and closed-set speech recognition, albeit with limited open-set speech recognition using early technology (House-3M single-channel implant). In 1994, Miyamoto and colleagues[31] provided systematic, well-controlled assessments of childhood cohorts and consistently demonstrated performance advantages of multichannel over single-channel implants. Other early studies by Fryauf-Bertschy and colleagues[32] (1992), Waltzman and colleagues[33] (1994), Miyamoto and colleagues[34] (1993), and Gantz and colleagues[35] (1994) observed that implanted children gain substantial speech-perception capabilities for 5 years after implantation. Furthermore, the fact that many of the implanted children tracked in these studies were congenitally or prelingually deaf indicates that implantation can provide auditory access during critical developmental stages to form the early correlates of spoken language. More recent auditory outcomes publications reflect advances in implant technology and information processing, yielding ever-improving means in speech recognition results.

Over the past 15 years, a wealth of reports has documented further gains in speech recognition in young children who are deaf using multichannel cochlear implants.[26,27,36,37] Miyamoto and colleagues[34] (1993) noted that in 29 children with 1 to 4 years of experience with a cochlear implant, roughly half achieved open-set speech recognition. Subsequent assessments using greater duration of postimplantation follow-up suggest that this percentage has increased through the rest of the 1990s and 2000s, with open-set speech-recognition scores averaging as high as 80%.[37–39]

Variability in speech-perception performance across patients is widely recognized.[7,26,40,41] Factors implicated in speech recognition variability include

- Amount of residual hearing[42,43]
- Age of implantation[40,44,45]
- Mode of communication[33,46]
- Family support[47]
- Length of deafness[43,48]

Miyamoto and colleagues[31] (1994) found that the duration of deafness, communication mode, age at onset of deafness, and the processor used accounted for roughly 35% of the variance in closed-set testing, with the length of implant use accounting for the largest percentage of variance in measures of speech perception. O'Donoghue and colleagues[40] (2000) found that age at implantation and mode of communication had a significant effect on speech-perception development in young children after implantation.

Zwolan and colleagues[44] (2004) and Manrique and colleagues[45] (2004) reported improved speech perception in children implanted at younger than 2 years of age compared with children implanted at an older age. Multicenter data reported by Osberger (2002)[49] indicate that implantation performance of children implanted at younger than 2 years of age is significantly better than that of children implanted

between 2 and 3 years of age. However, Osberger also identified an important confounding variable that exists in the children who receive a cochlear implant at a younger age: they are more likely to use an oral mode of communication. This finding, by itself, may be a predictor of higher implant performance, which is an observation borne out in early studies of a national childhood cohort assembled by Geers and colleagues[46] (2000).

Osberger (2002) also found that children with more residual hearing were undergoing implantation relative to earlier cohorts. Gantz and colleagues[50] (2000) compiled data from across centers that indicate children with some degree of preoperative open-set speech recognition obtain substantially higher levels of speech comprehension. Taken together, these studies suggest the strongest potential for benefit exists with implantation at a young age, when intervention is provided early and, in the case of a progressive loss, before auditory input is lost completely.

Cheng and colleagues[24] (1999) performed a meta-analysis of relevant literature on speech recognition in children with cochlear implants. Of 1916 reports on cochlear implants published since 1966, 44 provided sufficient patient data to compare speech recognition results between published (n = 1904 children) and unpublished (n = 261) trials. Meta-analysis was complicated by the diversity of tests required to address the full spectrum of speech reception in implanted children. An expanded format of the Speech Perception Categories[51] was designed to integrate results across studies. The main conclusions of this meta-analysis were that earlier implantation is consistently associated with a greater trajectory of gain in speech-recognition performance with an absence of a plateau in speech-recognition benefits over time. More than 75% of the children with cochlear implants reported in peer-reviewed publications have achieved substantial open-set speech recognition after 3 years of implant use.

In an effort to provide the first reference for evaluating postimplant speech recognition in children with cochlear implants, Wang and colleagues[26] (2008) mapped the speech-recognition trajectory of implanted children from baseline up to the 24-month post–cochlear-implant evaluation (**Fig. 2**). The growth in speech-recognition development over the first 24 months after the implantation was spread widely among children with cochlear implants. A substantial number of children implanted at younger ages demonstrated growth patterns very similar in range or well into the trajectories of the normal-hearing children. A few children implanted at older ages showed slower trajectories of development after implantation. In contrast, the trajectories of speech-recognition development among normal-hearing children showed much less variability, forming a much tighter band of normal development.

LANGUAGE DEVELOPMENT IN CHILDREN

The above-mentioned studies have helped to characterize gains in speech recognition. However, the primary goal of implantation in children is to facilitate comprehension and expression through the use of spoken language.

By improving auditory access, cochlear implants augment sound and phrase structure. Although difficult to characterize, benefits in receptive language skills and language production after implantation are the crucial measure by which effectiveness of implants in young children should be assessed. One approach is to compare language performance on standardized tests.

The Reynell Developmental Language Scale evaluates both receptive and expressive skills independently.[52] These scales have been normalized by performance levels of hearing children over an age range of 1 to 8 years and have been used extensively in populations of children who are deaf. Children who are deaf without cochlear implants

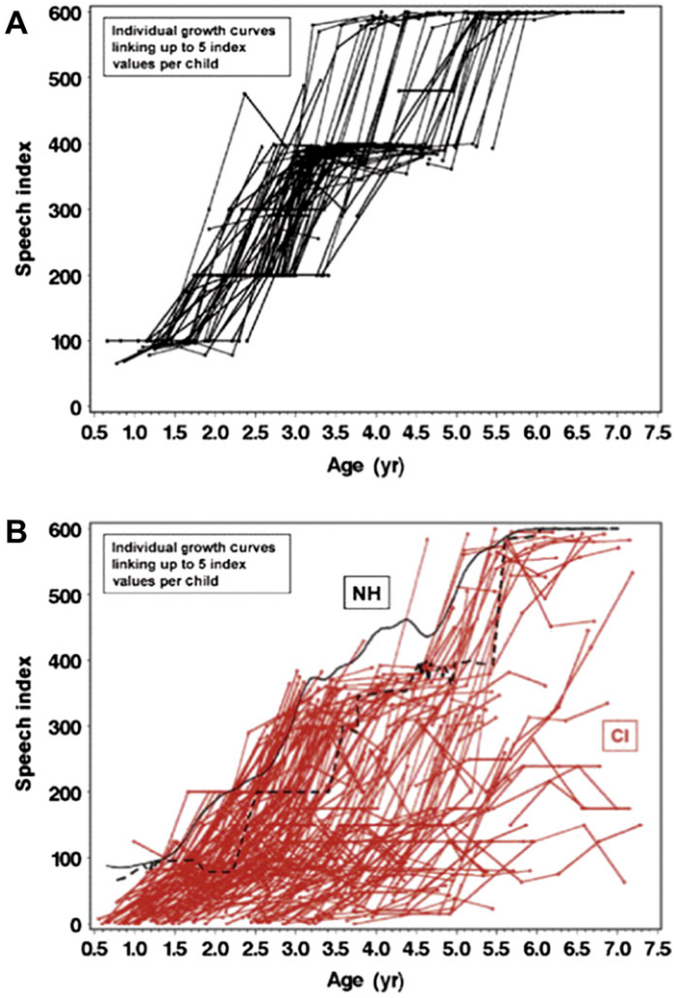

Fig. 2. Growth trajectories between baseline and 24-month follow-up visit using Speech recognition in quiet (SRI-Q) index for (*A*) 97 normal-hearing (NH) children in *black solid lines* and (*B*) 188 children with cochlear implants (CI) in *red solid lines*. The *black solid curve* (*B*) indicates the nonparametric mean trajectory of SRI-Q index by age for all 97 NH children. The *black dashed line* indicates the estimated lower boundary of SRI-Q score, by age, achieved by the NH children. (*Adapted from* Wang NY, Eisenberg LS, Johnson KC, et al. Tracking development of speech recognition: longitudinal data from hierarchical assessments in the Childhood Development after Cochlear Implantation Study. Otol Neurotol 2008;29(2):240–5; with permission.)

achieved language competence at half the rate of their normal-hearing peers, whereas implanted patients exhibited language-learning rates that matched, on average, those of their normal-hearing peers[52,53] (Niparko and colleagues,[54] 2010). In a study of 188 children deafened before 3 years of age assessed language development following cochlear implantation. The average age of implantation in this cohort was approximately 27 months. They found that cochlear implantation is consistently associated

with a significant improvement in comprehension and expression of spoken language over the first 3 years of implant use. The development of spoken language was positively associated with younger age at implantation and greater residual hearing before implantation. The rate of improvement in performance on spoken-language measures was less steep in children undergoing cochlear implantation at later ages, with clinical gaps that persist with longitudinal follow-up (**Fig. 3**). The implication of this study is that cochlear implantation not only improves spoken-language expression and comprehension of children who are severely to profoundly deaf but does so early at a significantly increased rate in infants and toddlers.

In addition to younger ages at implantation, Moog and colleagues[55] (2010) found that early educational intervention is also associated with improvements in language development after cochlear implantation. The effect of this benefit was increased when implantation took place at younger ages. Moreover, a recent study by Geers and colleagues[56] (2009) showed that more than half of implanted children who used early educational intervention exhibited age-appropriate vocabulary scores by kindergarten.

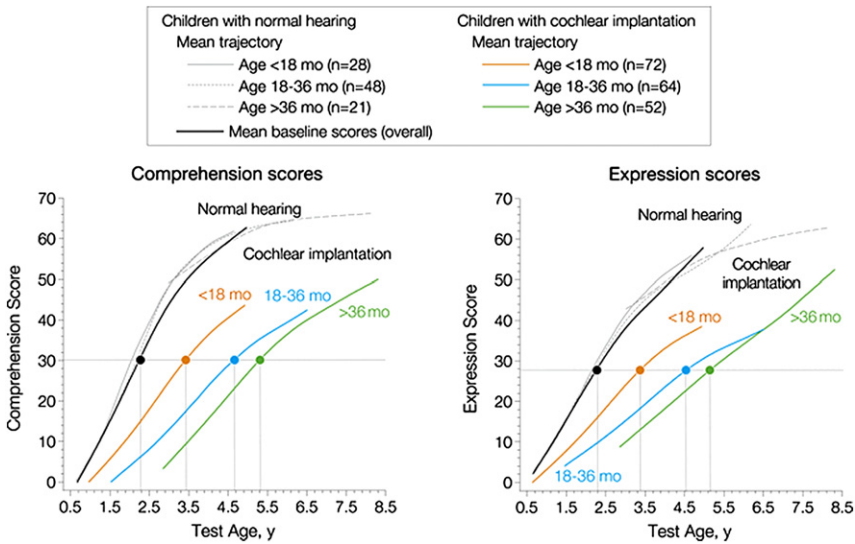

Fig. 3. Nonparametric fit of Reynell Developmental Language Scales raw scores of comprehension and expression stratified by age at baseline and test age. The effect of cochlear implantation in children on language development. The horizontal dotted line projects the chronologic age at which the mean scores of normal-hearing children at baseline (30.1 for comprehension and 27.6 for expression) were obtained by subgroups of children undergoing cochlear implantation at different ages. Vertical drop lines indicate ages at which this score was obtained for each group of children. On the comprehension scale, the ages were 2.3 years for normal-hearing children and among children undergoing cochlear implantation, 3.4 years for children younger than 18 months at implant, 4.7 years for those aged 18 to 36 months at implant, and 5.3 years for those older than 36 months at implant. On the expression scale, the ages were 2.3 years for hearing children and among children undergoing cochlear implantation, 3.4 years for children younger than 18 months at implant, 4.5 years for those aged 18 to 36 months at implant, and 5.2 years for those older than 36 months at implant. (*Adapted from* Niparko JK, Tobey EA, Thal DJ, et al. Spoken language development in children following cochlear implantation. JAMA 2010;303(15): 1498–506; with permission.)

From a communication perspective, Robbins and colleagues[52] (1997) noted that implantation improved language-learning rates for children in both oral- and total-communication settings based on the Reynell Developmental Language Scale. Geers and colleagues[46] (2000), also assessing language skills in implanted children enrolled in oral and total communication (TC) settings, found that the groups did not differ in language level, although the oral group demonstrated significantly better intelligibility in their speech production. Additionally, performance on language measures can be influenced by the child's mode of communication such that results may not directly reflect the influences of auditory perception or prosthetic intervention.[57,58] Clinical findings, however, support the hypothesis that some children who are deaf are able to use the acoustic-phonetic cues provided by the implant in ways that may reduce the language gap between normal-hearing and deaf children.

Central nervous system processing is a primary determinant of the level of verbal language ultimately attained after cochlear implantation. Pisoni and colleagues[59] (1995) assessed performance in 2 groups of pediatric cochlear implant users:

1. *Stars* were children whose Phonetically Balanced Kindergarten (PBK) test scores placed them in the top 20%.
2. The second group, children with scores in the bottom 20%, composed the control group.

Children with superior implant performance were consistently better on measures of speech perception (ie, vowel and consonant recognition), spoken-word recognition, comprehension, language development, and speech intelligibility than the control children. However, the two groups did not differ in their vocabulary knowledge, nonverbal intelligence, visual-motor integration, or visual attention. It was concluded that a star performance on measures of spoken-language processing and speech intelligibility was not caused by global differences in overall performance but to differences specifically in the task of processing auditory information provided by the cochlear implant. A strength-of-correlation analyses revealed a highly significant association between spoken-word recognition, language development, and speech intelligibility for the stars group but not for the control group. A star performance seemed to result from an increased ability to process language and to develop phonological and lexical representations for words.

Pisoni and colleagues[60] (2000) further posit that the exceptional performance of the stars seems to be caused by their superior abilities to perceive, encode, and retrieve information about spoken words from lexical memory. They described the capacity for processing tasks that require the manipulation and transformation of the phonological representations of spoken words as "working memory."

OUTCOMES AFTER COCHLEAR IMPLANTATION

Educational Placement and Support of Implanted Children

Children with hearing impairments are at substantial risk for educational underachievement.[61,62] Educational achievement by children with hearing impairments can be enhanced by verbal communication, and traditional methods of speech instruction are more successful with children who have enough residual hearing to benefit from early devices of hearing rehabilitation.[63] Improved speech perception and production provided by cochlear implants offer the possibility of increased access to oral-based education and enhanced educational independence.

Koch and colleagues[64] (1997) and Francis and colleagues[65] (1999) tracked the educational progress of implanted children by using an educational resource matrix

to map educational and rehabilitative resource use. The matrix was developed from observations that changes in classroom settings (eg, into a mainstream classroom) are often compensated by an initial increase in interpreter and speech-language therapy. A follow-up of 35 school-aged children with implants indicated that, relative to age-matched hearing-aid users with equivalent baseline hearing, implanted students are mainstreamed at a substantially higher rate, although this effect is not immediate and requires rehabilitative support to be achieved. Within 5 years after implantation, the rate of full-time assignment to a mainstream classroom increases from 12% to 75% (**Fig. 4**).

This greater rate of mainstream education in the implanted population has, in turn, led to increased benefits for implanted children. In one of the most comprehensive studies of the effects of educational placement on outcomes from cochlear implantation, Geers and colleagues[66] (2008) has followed a group of 85 patients from the elementary grades to high school. A battery of tests was used to assess student performance in speech perception, language, and reading. Speech-perception scores improved significantly with long-term cochlear implant use. Mean language scores improved at a faster-than-normal rate, but reading scores did not keep pace with normal development. Not surprisingly, oral communication at school (an educational

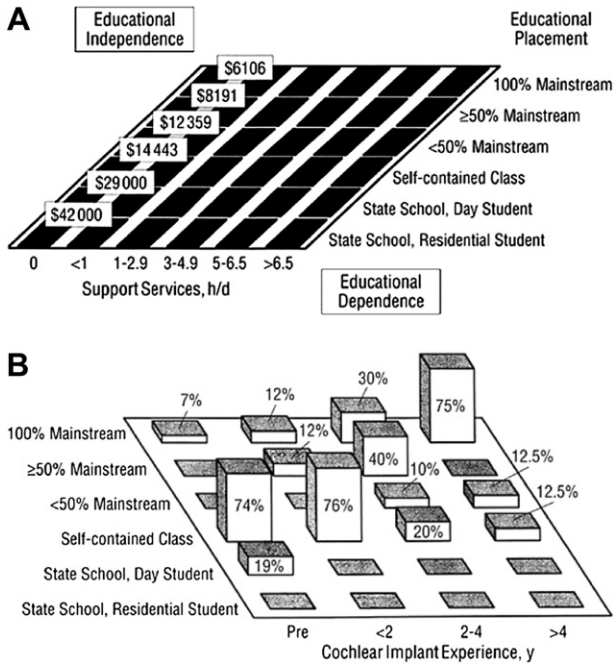

Fig. 4. Matrix of educational resources usage by implanted children. (*A*) The Educational Resource Matrix plot classroom placement (*ordinate*) versus rehabilitative (speech-language and interpretive) support (*abscissa*). (*B*) Relationship between educational placement and duration of implant experience. Patterns of change in use of educational resources in a cohort of children within 6 years of implantation. Note the higher levels of mainstreaming and reduced use of support services with prolonged use of the cochlear implant. (*Adapted from* Francis HW, Koch ME, Wyatt JR, et al. Trends in educational placement and cost-benefit considerations in children with cochlear implants. Arch Otolaryngol Head Neck Surg 1999;125(5):499–505; with permission.)

mode used in mainstream classes) contributed significantly to the improvement in the previously mentioned categories. However, the study observed that implant recipients achieving high scores on the previously mentioned tests in elementary school also continued performing better than the rest of the study population in high school, suggesting the presence of additional factors, such as nonverbal intelligence, influencing postimplantation outcomes.

Quality of Life and Cost-Effectiveness

Prior studies of the cost utility of cochlear implants have assessed quality of life and health status to determine the utility gained from cochlear implants.[67–70] Utility is a concept that reflects the true value of a good or service. Cost-utility methods determine the ratio of monetary expenditure to change in utility as defined by a change in quality of life over a given period. The assessment of cost utility is based on the following:

$$\begin{aligned}\text{Cost-utility} &= \text{costs (in \$)}/\Delta(\text{quality-adjusted life-years})\\ &= \text{costs (in \$)}/\Delta(\text{life-years} \times \text{health utility})\end{aligned}$$

The term life-years is the mean anticipated number of years of implant experience based on a life-expectancy analysis of the participating cohort. The change in health utility reflects the difference between preimplant and postimplant scores on survey instruments that have been designed and validated to reflect quality of life. In the early 2000s, health interventions with a cost-utility ratio less than $25 000 were generally considered to represent an acceptable value for the money expended (ie, they are cost-effective).[71–73] More recent studies in the United Kingdom have used a £30 000 ($46 000) societal willingness-to-pay cutoff in the determination of cost-effective interventions in health care.[74]

STUDIES IN ADULTS AND THE ELDERLY

Costs per quality-adjusted life-year (QALY) for the cochlear implant in adult users were determined using cost data that account for the preoperative, postoperative, and operative phases of cochlear implantation.[67,68,70,75,76] Benefits were determined by the functional status and quality of life. The precise cost-utility results varied between studies mostly because of methodological differences in the determination of benefit, level of benefit obtained, and differences in costs associated with the intervention. Nonetheless, these appraisals consistently indicated that the multichannel cochlear implant in adult populations is associated with cost-utility ratios in the range of $14 000 to $16 000 per QALY for unilateral implantation in the United States, indicating a highly favorable position in terms of cost-effectiveness (**Table 1**). Moreover, recent studies have focused on evaluating the cost-effectiveness of bilateral cochlear implantation. Although not as cost-effective as the first implant, Bichey and colleagues[76] (2008) showed that bilateral cochlear implantation carried an incremental cost-utility ratio of $38 198 per QALY in US adults and still ranks among the most cost-effective interventions in health care.

Hearing impairment is one of the most common clinical conditions affecting elderly people in the United States.[77] Hearing loss is so profound in 10% of the aged hearing-impaired population that little or no benefit is gained with conventional amplification.[78] Assessing the effectiveness of cochlear implants in the elderly requires consideration of both audiological and psychosocial factors. The social isolation associated with acquired hearing loss in the elderly[79] is accompanied by a significant decline in quality of life and an increase in emotional handicaps.[80] The rehabilitation of hearing loss is,

Table 1
Cost-utility ratio of the cochlear implant in adults and children

Study	Instrument	Country	Population	Cost-Utility Ratio ($)/QALY: Unilateral vs No CI	Cost-Utility Ratio ($)/QALY: Bilateral vs Unilateral CI
Summerfield et al,[74] 2010	TTO	United Kingdom	Children	34 824	37 100
	VAS			23 026	30 973
Bond et al,[70] 2009	HUI	United Kingdom	Children	25 519	70 470
	HUI		Adults	33 132	86 425
Bichey et al,[76] 2008	HUI	United States	Children	10 221	39 115
	HUI		Adults	11 092	38 189
Summerfield et al,[75] 2002	HUI	United Kingdom	Adults	45 215	118 387
Cheng et al,[69] 2000	TTO	United States	Children	9029	—
	VAS			7500	
	HUI			5197	
Palmer et al,[96] 1999	HUI	United States	Adults	14 670	—
Wyatt et al,[68] 1996	HUI	United States	Adults	15 928	—

Variability on cost-utility metrics is largely attributable to different methodologies of direct cost calculation across countries. A threshold of $25 000/QALY or lower is considered an acceptable cost-utility ratio for a given health intervention in the United States and Canada. A £30 000 ($46 000) willingness-to-pay threshold has been recently proposed as a cutoff threshold in the United Kingdom.

Abbreviations: CI, cochlear implant; HUI, Health Utilities Index; TTO, time trade-off; VAS, visual analog scale.

therefore, an important goal in this vulnerable population, providing both functional and psychological contributions to quality of life.

Age-related degeneration of the spiral ganglion[81,82] and progressive central auditory dysfunction[83,84] raise potential concerns about the efficacy of cochlear prostheses in the elderly. Comparable gains in speech understanding have been reported for both elderly and younger groups of implant recipients,[85] but the implications of these functional gains on the quality of life of older adults have not been well characterized. The determination of both auditory efficacy and quality of life is critical to any cost-benefit analysis in the elderly and may help guide clinical resource allocation, particularly in light of the high costs associated with cochlear implantation as a non–life-saving intervention.

Reports of quality-of-life gains in elderly patients with cochlear implants have been favorable[86–88] but are based on questionnaires that are difficult to correlate with function and cost utility. Francis and colleagues[14] (2002) evaluated 47 patients with multichannel cochlear implants, aged 50 to 80 years, who completed the Ontario Health Utilities Index Mark 3 (HUI 3) survey as well as a quality-of-life survey. This study assessed preimplantation and postimplantation (6 months and 1 year after implantation) responses to questions related to device use and quality of life. There was a significant mean gain in health utility of 0.24 (SD 0.33) associated with cochlear implantation ($P<.0001$) (**Fig. 5**). Improvements in hearing and emotional health attributes were primarily responsible for this increase in health-related quality-of-life measure. There was a significant increase in speech-perception scores at 6 months after surgery ($P<.0001$ for both the Central Institute for the Deaf (CID) everyday sentence and monosyllabic word tests) and a strong correlation between the magnitude of health-utility gains and postoperative enhancement of speech perception ($r = 0.45$, $P<.05$).

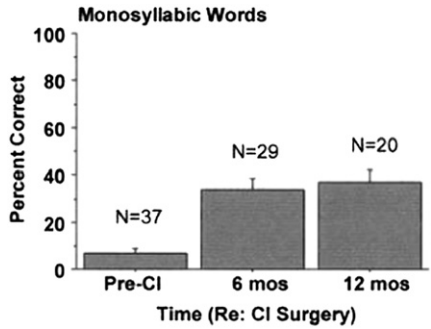

Fig. 5. Impact of cochlear implants (CI) on the functional health status of older adults. Mean monosyllabic word scores obtained in older adult patients with postlingual hearing impairment just before CI surgery and at 6 and 12 months afterward (error bar = 1 SE). Monosyllabic word scores, which are generally considered one of the most difficult tests of speech perception, clearly increase during the first year after CI. (*Adapted from* Francis HW, Chee N, Yeagle J, et al. Impact of cochlear implants on the functional health status of older adults. Laryngoscope 2002;112(8 Pt 1):1482–8; with permission.)

Speech-perception gain was also correlated with improvements in emotional status and the hours of daily implant use. The investigators concluded that cochlear implantation has a statistically significant and cost-effective impact on the quality of life of older patients who are deaf.

STUDIES IN CHILDREN

Published cost-utility analyses of the cochlear implant in children have been limited by using either health utilities obtained from adult patients[70,72,74–76,89] or hypothetically estimated utilities of a child who is deaf.[90–93] These studies yielded cost-utility ratios that spread out over a wide range ($3141 to $25 450 per QALY). Utility assessments derived from adult-patient surveys may not capture the impact of issues unique to childhood deafness.[24] To address this issue more rigorously, Cheng and colleagues[69] (2000) surveyed parents of 78 children (average age 7.4 years, with 1.9 years of cochlear implant use) who received multichannel implants at the Johns Hopkins Hospital to determine direct and total cost to society per QALY. Parents of children who were profoundly deaf (n = 48) awaiting cochlear implantation served as a comparison group to assess the validity of recall. Parents rated their child's health state now, immediately before, and 1 year before the cochlear implant using the time trade-off (TTO), visual analog scale (VAS), and HUI 3. Mean VAS scores increased 0.27 on a scale of 0 to 1 (from 0.59–0.86), TTO scores increased 0.22 (from 0.75–0.97), and HUI scores increased 0.39 (from 0.25–0.64) (**Fig. 6**). Discounted direct medical costs were $60 228, yielding cost-utility ratios of $9029 per QALY using the TTO, $7500 per QALY using the VAS, and $5197 per QALY using the HUI 3. Including indirect costs, such as reduced educational expenses, the cochlear implant yielded a calculated net savings of $53 198 per child. Based on assessments of this cohort based in a single center, childhood cochlear implantation produces a positive impact on quality of life at reasonable direct costs and results in societal savings.

The educational resource matrix used by Koch and colleagues[64] (1997) and Francis and colleagues[65] (1999) also offers a basis for assessing overall cost-benefit ratios. Although initial educational costs for implanted students remained static or increased

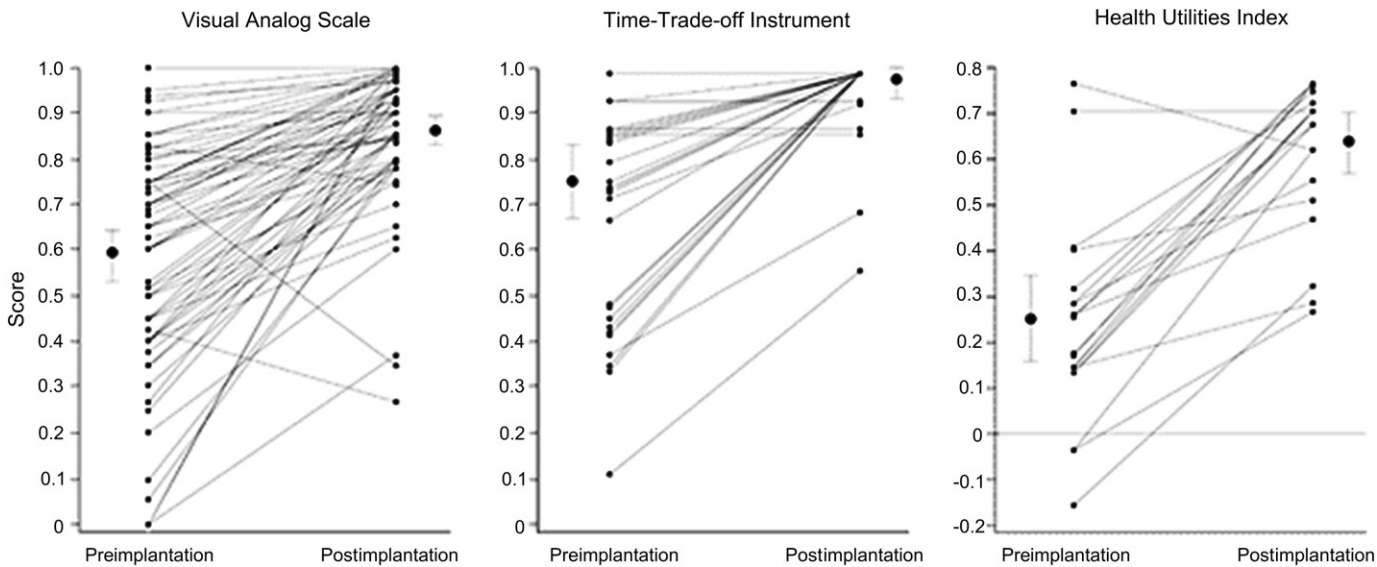

Fig. 6. Retrospective health utility scores from parents of children with cochlear implants. This figure shows 3 different methods of assessing health-utility scores. The mean change in utility (postintervention – preintervention scores) was 0.27 for the VAS, 0.22 for the TTO instrument, and 0.39 for the HUI 3. The error bars on the side of each graph show mean scores with 95% confidence intervals. (*Adapted from* Cheng AK, Rubin HR, Powe NR, et al. Cost-utility analysis of the cochlear implant in children. JAMA 2000;284(7):850–6; with permission.)

over the first 3 years, an ultimate achievement of educational independence for most implanted children produced net savings that ranged from $30 000 to $100 000 per child, including the costs associated with initial cochlear implantation and postoperative rehabilitation. Language- and education-related outcomes in children with cochlear implants have been supplemented with parental perspectives of quality-of-life effects to yield cost-utility ratings.[69,89] Even with conservative assumptions, both studies supported the view that cochlear implantation is, relative to other medical and surgical interventions, highly cost-effective in young children who are profoundly hearing impaired.

Recent trends in cost-effectiveness have aimed at analyzing the comparative effectiveness of pediatric cochlear implantation by the age at procedure. These studies have shown that younger ages at implantation are associated not only with more favorable auditory outcomes but also with lower direct and indirect costs.[45,94,95]

SUMMARY

Cochlear implants offer an option in the auditory rehabilitation of congenital, as well as acquired, profound SNHL for candidates across the age spectrum. Although a cochlear implant facilitates sensitive hearing reliably, actual listening capabilities are less easily characterized. Speech-recognition results are variable, and there is increasing awareness that epiphenomena surrounding implantation and the postimplant experience affect performance. Thus, expected results depend heavily on the environment in which cochlear implants are used as well as case selection. Children with early onset deafness lack a base of auditory memory with which to pair implant-mediated percepts and they may harbor other disabilities that may prevent instinctive language learning. Such conditions can produce a wide range of individual variability, particularly when intervention with a cochlear implant is delayed. Adults with cochlear implants exhibit a similarly wide range of results usually owing in large part to factors outside of the device per se. These facts mandate comprehensive preimplant assessment. Screening for other handicapping conditions, particularly those that will impair the acquisition of receptive and productive communication skills, will help determine candidacy and direct rehabilitative strategies. By enabling simultaneous input of multiple perspectives, a multidisciplinary team is the most effective approach to assessing a candidate's needs and desires and the potential for an implant to meet them.

In the 1980s, candidacy requirements for a cochlear implant required total or near-total sensorineural hearing losses as characterized by a pure-tone average of 100 dB or greater, amplified thresholds that failed to reach 60 dB, and an absence of open-set speech recognition despite the use of powerful, best-fit hearing aids. Because clinical experience has indicated that the mean speech-reception scores of implant recipients generally exceed the aided results of individuals with lesser impairments, the audiologic criteria have been progressively relaxed over the past 30 years to include those with a range of pure-tone averages, focusing instead on functional benefits provided by amplification. In children, initial reports suggest that implantation before the age of 3 years provides distinct advantages over later implantation in cases of early onset deafness. Whether earlier implantation may yield greater benefits will require longitudinal follow-up of the development of the ever-younger infants undergoing implantation.

Additionally, postimplantation rehabilitation can be important for some adult implant recipients but seems critical for children to optimize the usefulness of an implant. It is often assumed that effective interactive skills and language comprehension directly result from the sensitivity with which sound is perceived through a cochlear implant.

However, hearing is not a sufficient condition for these higher skills, and there is a compelling rationale for a high priority to be placed on auditory rehabilitation to enhance fundamental skills in verbal communication.

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