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Expansion of Audiologic Criteria for Pediatric Cochlear Implantation

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Keywords

Pediatric audiology; Hearing aids; Cochlear implants; Implant candidacy; Speech recognition

INTRODUCTION

Cochlear implants (CIs) have dramatically impacted communication, education, and quality of life for children with severe-to-profound sensorineural hearing loss. Just a few decades ago, children born with profound deafness were routinely sent to a residential school for the deaf to acquire language, socialization, and academic instruction. Today, children with congenital deafness are routinely implanted at 12 months of age or younger and are capable of achieving age-appropriate speech, language, and preliteracy skills before entering a mainstream kindergarten.[1] To this end, CIs have been termed the most successful sensory neuroprostheses of all time.[2,3]

In June 1990, the Food and Drug Administration (FDA) approved CIs for children ≥2 years with bilateral profound sensorineural hearing loss. The minimum age for FDA-labeled CI indications was later lowered to 18 months in 1998, 12 months in 2000, and 9 months in 2020. The latest age adjustment for pediatric CI candidacy took 2 decades, despite considerable evidence for CI benefits as early as 6 months of age on development of auditory skills, speech, and language.[4–8]

In addition to age, there are audiometric criteria and aided speech recognition criteria for older children capable of completing speech perception tasks. Currently, all FDA-approved systems list bilateral profound sensorineural hearing loss in their labeled indications; however, since 2000, Cochlear Americas Corporation has also listed bilateral severe-to-profound hearing loss for children ≥2 years. As of July 2019, there is also an FDA-approved indication for cases of single-sided deafness (SSD) and asymmetric hearing loss for children ≥5 years (MED-EL); however, SSD and highly asymmetric hearing losses are beyond the scope of this article.

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DISCLOSURE STATEMENT

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With respect to aided speech perception, pediatric CI candidates were originally expected to demonstrate no evidence of open-set speech recognition with appropriately fitted hearing aids (HAs). Current labeling at this time specifies 12% to 30% aided word recognition (Advanced Bionics [AB]: <12%; Cochlear <30%; MED-EL: <20%) or up to 30% sentence recognition (AB) for pediatric CI candidacy.[9–11] Paradoxically, pediatric CI criteria are more restrictive than adult indications. Specifically, adults can demonstrate a bilateral moderate sloping-to-profound sensorineural hearing loss with aided sentence recognition up to 60% correct in the best-aided condition.[11,12] Thus, it is the case that children with bilateral sensorineural hearing loss—who require full auditory access in the first years of life to achieve auditory, speech, and language development—must have the most severe hearing losses and the poorest speech perception to qualify for implantation.

Despite the restrictive nature of pediatric CI indications, there is considerable evidence to support the expansion of pediatric candidacy. At present, several CI programs are routinely implanting children who may not meet the typical profile, but who are demonstrating significant communication difficulty and/or delayed speech and language development despite appropriate amplification and speech/language intervention. Nonetheless, there are too many children not being referred for CI evaluation because of better than severe-to-profound audiometric thresholds and/or aided speech perception scores exceeding 12% to 30% correct. Thus, the purpose of this article is to describe evidence from the peer-reviewed literature as well as from a new data set to provide data-driven recommendations for expansion of pediatric CI indications.

PEDIATRIC OFF-LABEL COCHLEAR IMPLANTATION

Historically, many CI centers strictly adhered to FDA indications, implanting only children who clearly met those guidelines. However, in recent years, more implant centers have started implanting children outside these guidelines for “off-label” indications. Carlson and colleagues[13] completed a survey of CI surgeons in the United States, and results demonstrated that 78% of the surgeons surveyed (63 of 81) were completing CI surgeries for off-label indications in children and adults. Pertinent to the pediatric population, 43% of surgeons reported implanting children with profound hearing loss less than 12 months of age and 31% implanted children with asymmetric hearing loss whereby at least 1 ear was better than the performance cutoff for age.[13] Consistent with this report, large CI centers in North America have also reported a progressive increase in the number of children being implanted off-label. For example, Na and colleagues[14] reported that 26% of the 389 children implanted at a large Canadian center between 1992 and 2018 had preoperative residual hearing with more than half of the children implanted in the past 2 years having residual hearing. Almost half of these children were reported to have had better than a severe hearing loss in their better ear at the time of diagnosis (43%).[14] Likewise, data from a large academic referral center in the United States also showed a significant increase in the number of children implanted with more residual hearing in recent years.[15]

CHALLENGES OF ASSESSING PEDIATRIC OUTCOMES

Despite a significant increase in the frequency of off-label implantation, obtaining a collection of comprehensive data demonstrating CI benefits in this population is complex and not as straightforward as simply comparing preoperative and postoperative scores on measures of aided speech perception. Unlike adults, children of different ages and developmental abilities will vary in their readiness to complete such assessments with some children being too young to complete any formal measures of speech recognition and older children requiring assessment using different measures appropriate for their age and language level. Assessment of benefit is further complicated by the fact that as a child progresses and ages, assessments previously used become too easy and more difficult material is needed; this can complicate a child's longitudinal assessment. In addition, many centers have historically lacked a formalized protocol for CI candidacy for the pediatric population and/or used monitored-live-voice presentation for assessments, resulting in high across-test variability and significantly inflated speech recognition scores as compared to tests completed using recorded stimuli.[16] In recent years, the pediatric minimum speech test battery (PMSTB[17]) was developed to help standardize the pediatric test protocol. Even with a pediatric test battery now available, it has not been widely implemented in its entirety. In addition, approximately 40% of children with hearing loss have additional disabilities or comorbidities,[18] many of which affect speech and language development, resulting in the need for frequent refinement and modification of assessments used even when the PMSTB is followed.

RESEARCH SUPPORTING EXPANSION OF PEDIATRIC COCHLEAR IMPLANT INDICATIONS

As FDA indications for adult cochlear implantation have evolved, a growing number of CI surgeons are performing off-label CI surgery for children as well. As the frequency of implantation in this population has increased, studies have emerged documenting and quantifying the benefit of cochlear implantation in children who do not meet traditional CI candidacy. Early studies sought to compare performance between children using CIs and children using HAs in an attempt to determine a point at which clinicians could reasonably expect a child to perform better with CIs versus HAs. One such study conducted by Lovett and colleagues[19] demonstrated that children with a 4-frequency pure tone average (PTA; unaided threshold average of 500, 1000, 2000, and 4000 Hz) ≥ 80 dB HL in both ears should be considered candidates for implantation given that children with hearing in this range had more than an 80% chance of better speech recognition with CIs vs bilateral HAs. Leigh and colleagues[20] also compared speech recognition results for children receiving CIs before 3 years of age to children using HAs who had moderate, severe, or profound hearing losses. They demonstrated that children with CIs significantly outperformed bilateral HA users who had similar unaided audiograms. Drilling down further, they showed that for children with unaided PTA greater than 60 dB HL, there was a 75% chance that a child would perform better with CIs as compared to bilateral HAs.[20] Their data also suggested that a more conservative referral recommendation—an unaided PTA greater than 82 dB HL—was associated with a 95% chance of achieving significantly higher speech recognition

with CIs vs bilateral HAs.[20] Thus, these data offer clinicians a graded recommendation for audiometric-based candidacy established on relative risk vs reward.

In addition to studies assessing benefit in heterogenous groups of children who do not meet traditional indications for cochlear implantation, other studies have investigated benefit in children with specific configurations and/or degrees of hearing loss. For example, Gratacap and colleagues[21] reviewed CI outcomes for children having (1) residual low-frequency hearing, (2) severe sensorineural hearing loss with poor speech understanding, (3) asymmetric hearing loss, (4) progressive sensorineural hearing loss, and (5) fluctuating sensorineural hearing loss. Their results showed significant improvement on measures of open-set word recognition at 12 months postimplantation in all groups except the low-frequency residual-hearing group. However, this was a small sample (n = 5) with an average implant age of 17 years, and group mean performance still improved by the 24-month point (86%) as compared with the preoperative mean score (79%). Similarly, another study of young children with residual low-frequency hearing and profound high-frequency hearing loss showed significant postoperative improvement, even in cases when hearing was not preserved.[22] Notably, these investigators reported greater improvement in children who were implanted at younger ages.

More recent studies have further described postoperative outcomes in larger populations of nontraditional candidates. Carlson and colleagues[23] described postoperative outcomes for a group of 51 children who had not met labeled indications based on either (1) audiometric thresholds being better than severe-to-profound, and/or (2) aided speech recognition exceeding 30% for preoperative word or sentence recognition. They demonstrated a significant improvement of 63-percentage points in the implanted ear and 40-percentage points in the bimodal condition. Furthermore, every single child achieved benefit in both the implant-only and the bimodal conditions[23]—a rare observation in the literature. Consistent with these results, Park and colleagues[24] reported significant postoperative word recognition benefit for 26 children with a preoperative 4-frequency PTA ≤ 75 dB HL. On average, they showed postoperative word recognition scores improved nearly 50-percentage points to a postoperative mean score of 75% as compared with the preoperative time point. A recent retrospective chart review completed by Na and colleagues[14] showed similar postoperative improvement for a group of 34 pediatric CI recipients who had residual hearing before surgery defined as an unaided PTA ≤ 90 dB HL in at least 1 ear (median PTA = 77.6 dB HL). They demonstrated significant benefit in monosyllabic word recognition with mean scores improving from 34% (preoperatively) to 90% (postoperatively). They also noted that the proportion of children with preoperative residual hearing who were receiving implants at their center had increased from just 30% of the population in 2004 to 60% in 2018.[14]

There is considerable evidence for the expansion of pediatric CI indications to include children with better than severe-to-profound hearing losses, as children demonstrate significant improvements in speech understanding with CIs as compared with HAs. Despite the growing evidence base, many studies have been limited in scope because of the use of various test metrics necessary to assess a wide range of ages as well as developmental differences in their speech and language skills. This motivated the current study that aimed to investigate benefit of cochlear implantation for children having better than severe-to-

profound hearing losses and/or better performance on measures of aided word and sentence recognition than listed by FDA indications. The primary objective of this retrospective review was to assess postoperative word and sentence recognition abilities using the same metrics preimplantation and postimplantation in an updated sample.

METHODS

A retrospective chart review was conducted per institutional review board–approved study (#211178) of pediatric CI recipients being followed for audiological care at a tertiary academic referral center. Medical records of pediatric CI recipients followed at Vanderbilt University Medical Center were reviewed to identify preoperative pure tone thresholds (500, 1000, and 2000 Hz PTA) and preoperative performance on age-appropriate tests of speech recognition. All children included in this study met one or both of the following criteria as originally defined by Carlson and colleagues[23]: (1) greater than 30% correct on an age-appropriate test of aided speech recognition in one or both ears, and/or (2) PTA less than 90 dB HL if younger than 2 years of age or PTA less than 70 dB HL if older than 2 years of age in one or both ears. Children identified with auditory neuropathy spectrum disorder, cochlear nerve deficiency, SSD, or any other developmental conditions expected to negatively impact speech and language development were excluded from review. Children who were not proficient in spoken English were also excluded.

The following information was collected from each participant's medical record: cause of hearing loss, age at time of CI surgery, implant make and model, preoperative unaided PTA in the implanted and nonimplanted ears, and preoperative and postoperative word and sentence recognition scores with HAs or CIs in the ear-specific and bilaterally aided conditions. Word recognition tests included Northwestern University Children's Perception of Speech,[25] Multi-Syllabic Neighborhood Test,[26] Lexical Neighborhood Test,[26] and Consonant Nucleus Consonant.[27] Sentence tests included Hearing in Noise Test for Children,[28] Arizona Biomedical sentences (AzBio[29]), and Pediatric AzBio.[30] Preoperative word and sentence recognition scores and unaided PTAs were obtained from the child's CI candidacy evaluation. In cases for which children were implanted sequentially, data for the second ear were obtained from the most recent assessment before implantation of the second ear. Data for the second implanted ear were only included if the second ear also met inclusion criteria for this study at the time of implantation. Postoperative word and sentence recognition scores were obtained from the most recent audiological evaluation completed 6 or more months postactivation. In some cases, children did not yet have 6-month postactivation scores, and scores obtained sooner than 6 months postactivation were used if postoperative performance already exceeded preoperative performance by the earlier timepoint selected.

Although the chosen assessment measures necessarily varied across patients because of age and language development, preoperative and postoperative comparisons were completed only for children who had been tested using the same recorded measure at both preimplant and postimplant intervals. When preoperative and postoperative comparisons were made for a child having multiple evaluations with the same test metric, the postoperative score

selected was the most recent score obtained at least 6 months postoperatively in which no significant equipment or wear time challenges were identified at the time of evaluation.

PARTICIPANTS

Eighty-three patients met inclusion criteria, but 4 of these patients were excluded from final analyses because of diagnoses of intellectual disability and/or developmental delay (n = 3) or lack of postoperative data (n = 1). Analyses were completed on data collected from the medical records of the remaining 79 subjects (44 female subjects). Twenty-nine of the 79 subjects included herein were also included in the authors' previous study.[23] The cause of hearing loss was unknown in over half of the group, and enlarged vestibular aqueduct was the most common cause reported. The distribution of other causes are reported in Table 1.

Of the 79 patients, 54 were unilaterally implanted and 25 were bilaterally implanted (4 simultaneously, 21 sequentially). For the 25 bilateral recipients, 21 met study inclusion criteria for 1 ear and the other 4 met criteria in both ears. The mean age of implantation was 8.1 years (range 0.6–18.0 years). Mean unaided PTA was 91.9 dB HL (standard deviation [SD] = 21.1) for all implanted ears and 66.4 dB HL (SD = 21.9) for all nonimplanted ears. All children received the newest technology at the time of implantation with 57.0% of the children having Cochlear devices (n = 45), 27.8% having AB (n = 22), and 15.2% having MED-EL (n = 12).

RESULTS

Fig. 1 displays individual and mean speech recognition scores in quiet and noise for the implanted ear (first column), the bilateral aided condition (second column) preoperatively, as well as for the first postoperative visit (mean CI experience = 2.0 years; range 0.3–7.8 years) and last postoperative visit (mean CI experience = 5.2 years; range 0.3–12.6). Individual data are represented by thin gray lines, and mean data are in bold with error bars representing ±1 standard error of the mean (SEM). Data analysis was completed using repeated-measures analysis of variance with a Geisser-Greenhouse correction for sphericity. Post hoc analyses were completed via Tukey multiple comparisons. Effect sizes were calculated using eta squared values (η^2). The independent variable was the timepoint, and the dependent variable was speech recognition score. Data were analyzed only for participants with both preimplant and postimplant scores for a given measure (see Fig. 1).

WORD RECOGNITION

For word recognition in the implant-alone condition, mean scores were 20.6% preoperative, 67.2% first postoperative, and 71.6% second postoperative. Statistical analysis revealed a significant effect of timepoint ($F_{(1.7, 92.3)} = 201.0$, $P<.0001$, $\eta^2 = 0.79$). Post hoc analysis showed a significant difference between both preoperative and first postoperative ($P<.0001$), as well as preoperative and second postoperative ($P<.0001$); however, there was not a difference between the first and second postoperative scores ($P = .18$). For the bilaterally aided condition, mean scores were 56.8% preoperative, 74.6% first postoperative, and 77.6% second postoperative. There was a significant effect of timepoint ($F_{(0.8, 22.3)}$

= 19.7, $P = .0003$, $\eta^2 = 0.44$). Post hoc analysis showed a significant difference between both preoperative and first postoperative ($P = .0006$), as well as preoperative and second postoperative ($P < .0001$); there was not a difference between the first and second postoperative scores ($P = .21$).

SENTENCE RECOGNITION IN QUIET

For sentence recognition in quiet in the implant-alone condition, mean scores were 30.6% preoperative, 77.4% first postoperative, and 80.8% second postoperative. Statistical analysis revealed a significant effect of timepoint ($F_{(1.1, 33.1)} = 111.8$, $P < .0001$, $\eta^2 = 0.78$). Post hoc analysis revealed a significant difference between both preoperative and first postoperative ($P < .0001$), preoperative and second postoperative ($P < .0001$), as well as between the first and second postoperative scores ($P = .006$). For the bilaterally aided condition, mean scores were 69.3% preoperative, 86.1% first postoperative, and 87.9% second postoperative. There was a significant effect of timepoint ($F_{(0.6, 12.3)} = 29.5$, $P = .0006$, $\eta^2 = 0.58$). Post hoc analysis revealed a significant difference between both preoperative and first postoperative ($P < .0001$), as well as preoperative and second postoperative ($P < .0001$); there was not a significant difference between the first and second postoperative scores ($P = .15$).

SENTENCE RECOGNITION IN NOISE (+5 dB)

For sentence recognition at a +5 dB signal-to-noise ratio (SNR) in the implant-alone condition, mean scores were 25.2% preoperative, 60.3% first postoperative, and 61.0% second postoperative. Statistical analysis revealed a significant effect of timepoint ($F_{(1.9, 15.7)} = 22.8$, $P < .0001$, $\eta^2 = 0.74$). Post hoc analysis revealed a significant difference between both preoperative and first postoperative ($P = .0005$), as well as preoperative and second postoperative ($P = .0009$); however, there was not a significant difference between the first and second postoperative scores ($P = .99$). For the bilaterally aided condition, mean scores were 54.6% preoperative, 67.5% first postoperative, and 69.1% second postoperative. There was not a statistically significant effect of timepoint for sentence recognition in noise in the bilaterally aided condition ($F_{(1.1, 12.8)} = 3.2$, $P = .09$, $\eta^2 = 0.21$).

DISCUSSION

Consistent with previous studies, the results from this retrospective review demonstrate that children with better than severe hearing losses and/or greater than 30% aided speech recognition derive significant benefit from cochlear implantation in both the implanted ear and the bilaterally aided conditions. Although the authors did not demonstrate a statistically significant effect of cochlear implantation for sentence recognition in noise in the bilaterally aided condition (see Fig. 1, lower righthand panel), over half of those tested demonstrated clinically significant benefit based on 95% confidence interval data for test-retest variability,[30] and the 1 child exhibiting a clinically significant decrement had a documented period of poor device use including a 3-month period of nonuse. Thus, this data set provides further support for expansion of pediatric CI criteria and warrants referrals for children exhibiting auditory and communication difficulties irrespective of whether they meet FDA-labeled indications for implantation.

Despite numerous studies documenting benefits, clinical utilization of cochlear implantation in this population remains poor at many implant centers across the country. More commonly, families of children with greater degrees of residual hearing receive some, but poor, benefit from HAs, and families do not pursue further intervention, often because of fears related to the risk of losing residual hearing and or lack of knowledge that cochlear implantation could provide benefit for their child. Likewise, many pediatric audiologists outside CI centers might not be familiar with outcomes in this population and, thus, are hesitant to refer for a candidacy evaluation. For these reasons, it is common for referring audiologists to rely on the guidelines set forth by traditional FDA indications, which overlook a population of children who would derive significant auditory and communicative benefits. In fact, Park and colleagues[24] showed that for nontraditional pediatric implant recipients, delaying implantation 3 or more years was associated with significantly poorer word recognition outcomes than those implanted within 1 year.

As detailed in the introduction, several methods have been proposed to identify nontraditional pediatric CI candidates for referral. One approach is to refer children with hearing losses exceeding a certain degree, such as that documented by Leigh and colleagues[20] for children with unaided PTA ≥ 65 dB HL. Another approach incorporates consideration of both the degree of hearing loss and unaided word recognition abilities. Zwolan and colleagues[31] proposed referring adult recipients for CI evaluation if they demonstrated a best-ear unaided monosyllabic word score ≤60% correct and an unaided PTA in the better ear ≥60 dB HL. They termed this data-driven recommendation the “60/60 guideline.”[31] Although use of this approach has not been assessed in the pediatric population —which could prove difficult for younger children still developing speech and language— there is great potential for applying the 60/60 approach to older children, particularly those with postlingual onset of severe-to-profound hearing loss.

LIMITATIONS

The results of this study are limited by its retrospective nature. Clinical protocols have changed and evolved, resulting in the use of multiple test metrics and test conditions within and across subjects, making it difficult to assess postoperative performance and progress in some patients who would have otherwise met inclusion criteria for this study. Much data were collected before the accessibility of data logging; thus, average device wear time was not available for many of the patients. Although it is possible that poor wear time could have affected outcomes in some cases reported here, it is noteworthy that postoperative speech recognition was significantly higher than preoperative levels for all but 1 measure: sentence recognition in noise in the bilaterally aided condition. Given the correlational relationship between device wear time and speech recognition performance for both adult[32,33] and pediatric[34–36] implant recipients, it is possible that had we been able to account for data logging information, effect sizes would have been larger. Finally, this study did not collect information on aural (re)habilitation completed after implantation.

SUMMARY

The results of this retrospective review are consistent with several previous studies demonstrating significant auditory and speech recognition benefits of cochlear implantation for children who do not meet current FDA labeled indications. Given the critical window for auditory, speech, and language development in children, delays in referral and subsequent implantation could result in significantly poorer auditory outcomes than could have been accomplished if implantation was pursued earlier. There is now considerable evidence in support of revised criteria for pediatric cochlear implantation to include children with better than severe-to-profound sensorineural hearing. Because regulatory changes often lag behind scientific evidence, it is critical that we assess each child individually and refer those who are struggling with auditory speech recognition, age-appropriate speech production, language, and academics.

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KEY POINTS

- Children with better than bilateral severe-to-profound sensorineural hearing loss and better than 30% aided word or sentence recognition achieve significant benefit from cochlear implantation.
- On the basis of published data, children with an unaided pure tone average > 60 dB HL should be referred for cochlear implant evaluation.
- Limiting cochlear implant candidacy to children with bilateral profound or severe-to-profound sensorineural hearing loss as outlined in outdated Food and Drug Administration–approved indications is not aligned with current outcomes research and best clinical practice.

CLINICS CARE POINTS

- Children with better than severe-to-profound sensorineural hearing loss and those scoring above 30% correct for aided word and sentence recognition demonstrate significant benefit from cochlear implantation.
- Based on evidence in the literature, it is recommended that audiologists and otolaryngologists refer children who have an unaided pure tone average greater than 60 dB HL for a preoperative cochlear implant evaluation.

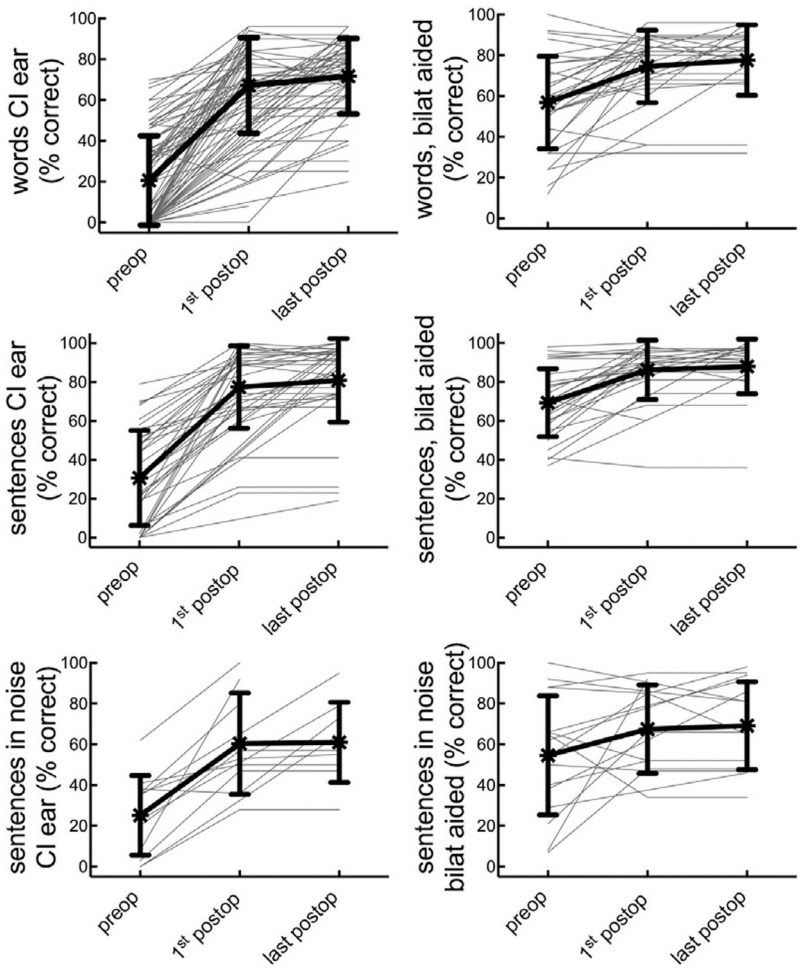

Fig. 1.

Individual and mean speech recognition scores for the implanted ear (first column) and bilateral best-aided condition (second column) for word recognition, sentence recognition in quiet, and sentence recognition in noise at +5 dB SNR. Error bars represent ±1 SEM.

Table 1

Cause for the 79 study participants included in the retrospective review

Cause	Number
Unknown	38
Enlarged vestibular aqueduct	19
Congenital cytomegalovirus	6
Meningitis	5
Prematurity	3
Usher syndrome	3
Connexin	1
Genetic—other	3
Ototoxicity	1