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Further Evidence for the Expansion of Adult Cochlear Implant Candidacy Criteria

Elizabeth Perkins, Mary S. Dietrich, Nauman Manzoor, Matthew O'Malley, Marc Bennett, Alejandro Rivas, David Haynes, Robert Labadie, René Gifford

Department of Otolaryngology/Head and Neck Surgery, Vanderbilt University Medical Center, Nashville, Tennessee

Abstract

Objective: 1) To complete a follow-up investigation of postoperative outcomes for adult cochlear implant (CI) recipients scoring 30% Consonant-Nucleus-Consonant (CNC) preoperatively, and 2) to describe the postoperative performance trajectory for this group of higher performing patients.

Study Design: Retrospective chart review.

Setting: Tertiary referral center.

Patients: One hundred four (105 ears) postlingually deafened adults who scored 30% CNC word recognition in the ear to be implanted preoperatively.

Interventions: One hundred four subjects underwent cochlear implantation.

Main Outcome Measures: Pre- and postoperative CNC word scores and AzBio sentences in quiet and noise in the ear to be implanted as well as the bilateral-aided condition pre-CI and at 1, 3, 6, and 12 months post-CI.

Results: Statistically significant improvement was demonstrated for CNC and AzBio sentences in quiet and noise for the CI alone and bilateral listening conditions. Most improvement was demonstrated by 6-months postoperatively ($p < 0.001$) with the exception of AzBio sentences in noise demonstrating improvement within 3 months ($p < 0.001$). For patients with preop CNC scores up to 40% ($n = 57$), all recipients demonstrated either equivocal ($n = 17$) or statistically significant improvement ($n = 40$) for CNC word recognition in the CI-alone condition and none demonstrated a significant decrement in the bilateral condition. For patients with preop CNC scores $>40\%$ ($n = 47, 48$ ears), 89.3% (42 patients) demonstrated either equivocal ($n = 24, 50\%$) or statistically significant improvement ($n = 19, 39.6\%$) for CNC word recognition in the CI-only condition and none demonstrated a significant decrement in the bilateral condition.

Address correspondence and reprint requests to Elizabeth Perkins, M.D., Department of Otolaryngology—Head and Neck Surgery, The Bill Wilkerson Center for Otolaryngology and Communication Sciences, 7209 Medical Center East South Tower, 1215 21st Avenue South, Nashville, TN 37232-8605; Elizabeth.perkins@vumc.org.

Co-author R.L. is a consultant for Advanced Bionics and Spiral Therapeutics.

Co-author A.R. is a consultant for MED-EL, Cochlear Americas, and Advanced Bionics.

Co-author D.H. is a consultant for MED-EL and Cochlear Americas and serves on the Advanced Bionics surgical advisory board.

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Conclusions: CI candidates with preoperative CNC word scores higher than conventional CI recipients derive statistically significant benefit from cochlear implantation for both the CI ear and best-aided condition. These data provide further support for the expansion of adult CI candidacy up to at least 40% CNC word recognition preoperatively with consideration given to further expansion possibly up to 60%.

Keywords

CNC word scores; Cochlear implant; Expanding indications

Over the last decade, the field of cochlear implantation has been proliferative. Advances in technology and surgical technique have led to expanding indications to hearing preservation, single-sided deafness, and improved speech perception outcomes and quality of life. Despite such advances, a large proportion of individuals who may benefit from cochlear implantation still remain unidentified. Goman and Lin (1) reported that there are over approximately 2.1 million Americans aged 20 years and older with severe-to-profound hearing loss (SNHL). As of late 2019, there had been approximately 155,000 cochlear implant (CI) recipients in the United States, with 60% of those being adults (2). Thus, approximately 93,000 adults have received a CI in the United States as of late 2019 which translates to a mere 4.4% implantation rate for adults with severe-to-profound SNHL.

The current criteria for adult conventional cochlear implantation are determined by audiometric thresholds and open-set sentence recognition with appropriately fitted hearing aids. The criteria for conventional cochlear implantation (i.e., excluding single-sided deafness and hybrid or electric and acoustic stimulation indications) vary between CI manufacturers based on the Food and Drug Administration (FDA) Physicians Package insert labeling for each device. For conventional cochlear implantation, Advanced Bionics (Valencia, CA) and MED-EL (Innsbruck, Austria) specify bilateral severe-to-profound SNHL while Cochlear (Sydney, Australia) specifies bilateral moderate-to-profound SNHL in the low frequencies and profound loss in the high frequencies. The Centers for Medicare & Medicaid Services (CMS) National Coverage Determination for cochlear implantation outlines bilateral moderate-to-profound SNHL (CMS, 2005), which is aligned with Cochlear's labeling for audiometric thresholds (3).

With regard to speech recognition, MED-EL's current label for conventional cochlear implantation requires patients to score 40% for open-set sentences in the best-aided condition and both Advanced Bionics and Cochlear Americas specify up to 50% on open-set sentences in the ear to be implanted. Cochlear's labeling additionally allows up to 60% sentence recognition in the best-aided condition. CMS's indications require that the patient score 40% for open-set sentences, which is aligned with MED-EL's current labeling.

Historically, the FDA-labeling from the three manufacturers leads clinicians to use the Hearing in Noise Test sentences (HINT) to determine CI candidacy (4). Over time, it has been shown that the HINT sentences—as presented in quiet or in fixed-level noise—suffer from ceiling effects and were thus not appropriate to determine candidacy (5–7). In 2011, the revised adult minimum speech test battery (MSTB, 2011) recommended use of the AzBio sentences for both candidacy determination and longitudinal assessment of

postoperative outcomes (8,9). The MSTB also includes the Consonant-Nucleus-Consonant (CNC) monosyllabic words and the Bamford-Kowal-Bench Speech-In-Noise test (Etymotic Research, 2005) (10,11).

In parallel with this evolution of sentence materials for use with adult CI candidates, we have observed a movement toward recommended use of CNC monosyllables for candidacy determination (12–14). A review of recent clinical trials identifying candidacy on the basis of CNC word recognition revealed that the average preoperative CNC word scores were considerably below the specified criterion (12,13,15). For example, in the 2007 Nucleus Freedom clinical trial (n = 71), inclusion criteria allowed CNC word recognition up to 30% in the ear to be implanted; however, the mean preoperative best-aided CNC scores were just 3% (range 0–19%) (12). For the Nucleus Hybrid-L24 clinical trial (n = 50), inclusion criteria allowed CNC word recognition up to 60% in the ear to be implanted; however, mean preoperative CNC scores in the implant ear were just 28% correct (13). For a recent clinical trial specifically tasked with investigating a revised criterion—40% CNC in the ear to be implanted (n = 21), the mean preoperative CNC score was just 23.6% correct (range not specified) (14). Indeed, a recent study describing the typical auditory profile of adult CI candidates in a large academic medical center (n = 287) revealed that mean preoperative CNC word recognition in the ear to be implanted was just 8.7% correct (range 0–68%) (16). Thus, despite broadening indications and improved CI technology, these studies suggest that we are not necessarily recruiting a large population of higher performing patients who may derive significant benefit from cochlear implantation.

In 2010, we reported significantly improved postoperative speech perception outcomes for 22 adult CI recipients who had preoperative CNC scores—30% correct—a cutoff chosen to exceed the criterion outlined by the Nucleus Freedom clinical trial and hence, much higher than the conventional CI recipient (17). Our previous study was limited to just 22 subjects, with multiple subjects lacking pre- and postoperative data. Thus, the aim of this study was to complete a follow-up investigation of postoperative outcomes for adults scoring—30% CNC preoperatively to 1) investigate efficacy of CIs for high performers in a large sample, and 2) characterize the postoperative performance trajectory. Our primary hypothesis was that adult CI recipients scoring—30% CNC in the ear to be implanted would derive significant benefit from cochlear implantation. Because newer clinical trials have investigated the use of a 40% CNC criterion, we additionally decided to stratify our analyses by preoperative CNC ranging from 30 to 40% as well as those scoring >40%.

METHODS

This study was approved by the institutional review board of Vanderbilt University Medical Center. A retrospective chart review was conducted at our tertiary medical center of all patients greater than 16 years of age who underwent cochlear implantation from January 2009 and March 2019. Subjects with postlingual onset of deafness, native English speaking, and a preoperative CNC score of—30% correct in the ear to be implanted and up to 6- or 12-months listening experience were identified. Exclusion criteria included those with preoperative CNC scores < 30% in the ear to be implanted, prelingual onset of deafness, revision surgery, and lack of postoperative follow-up. Retrospective chart review was used

to identify the speech recognition performance CNC words, AzBio sentences in quiet and in noise at + 5 dB signal-to-noise (SNR) before implantation as well as postoperatively at 1, 3, 6, and 12 months after CI activation.

All testing was completed with recorded stimuli at 60 dB SPL presented via a single loud speaker at 0-degree azimuth placed at a distance of 1 m from the listener. Monosyllabic word recognition performance was assessed using one 50-item list of the CNC test (10). AzBio sentence recognition test was used to assess speech recognition in noise (8). One full 20-sentence list was presented in quiet and a different 20-sentence list in continuous 10-talker babble at + 5 dB SNR. Preoperatively, all patients were tested with each hearing aid (HA) alone as well as with bilateral HAs. Postoperatively, all patients were tested in the unilateral CI-only as well as the bimodal (CI + contralateral HA; n = 103) or bilateral CI (n = 1) condition. In accordance with our hierarchical clinical protocol, all adult CI users are assessed first on measures of CNC word recognition followed by AzBio sentence recognition in quiet and in noise. Because clinical time may not allow for all testing to be completed, we have CNC word scores on more patients than we have AzBio sentence recognition. For assessment in the CI-alone condition, the nonimplanted ear was occluded with an earplug. All HAs had been verified to match to NAL-NL2 target audibility for 60-dB-SPL speech (18). Best performance speech recognition scores were collected from the 6- or 12-month time point based on which was available for each patient. For patients who had been tested at both time points, we chose the 12-month score.

Statistical analyses were performed using IBM SPSS Statistics 26 (Armonk, NY) and STATA 15 (College Station, TX). Descriptive statistics summarized the demographic characteristics of the sample and the CNC and AzBio scores at each time of assessment. The speech recognition measures chosen for analysis, CNC words, and AzBio sentences in quiet and +5 dB SNR were chosen given that these are included in our clinical assessment protocol. Because of skewness apparent in some of those distributions of scores, for consistency across all scores and time of assessments, median, IQR, and min, max values were used for the set of summary statistics. Mixed-effects general linear regressions were used to test both the primary research question comparing the preoperative and postoperative (6- and 12-mo) scores, as well as to test for differences among the specific intervals (preoperative, 1-, 3-, 6-, and 12-mo) in the hearing trajectories. Statistical significance testing maintained an alpha = 0.05 and used cluster-robust standard errors to account for the repeated assessments of the patients.

RESULTS

Out of 2,429 adult CI patients in our REDCap clinical outcomes database, a total of 113 patients (115 ears) met inclusion criteria. Of the 113 patients meeting study criteria, 9 were excluded due to lack of postoperative data at 6 and/or 12 months; therefore, a total of 104 patients were included in the final analysis. The median age of implantation was 68 years (IQR = 56, 76). Seventy patients were male (67%), and 56% were implanted in the left ear. Patients were implanted with all three manufacturer's devices including both straight and precurved electrodes with 42 Advanced Bionics, 34 Cochlear, and 28 MED-EL.

Summaries of the scores (CI and bilateral) from each of the hearing measures at each time of assessment are shown in Table 1. Values for the cases who had scores 12-months postoperatively are shown also to illustrate any possible sample bias in the longitudinal analyses. Statistically significant improvements in CNC performance were observed from preoperative to 12-months postoperative for both the CI ear (Wald $\chi^2_{(df=5)} = 137.34, p < 0.001$) and the bilateral listening condition (Wald $\chi^2_{(df=4)} = 105.60, p < 0.001$). The median preoperative score was 40% for the CI ear (IQR = 34, 46), with an improvement to median 60% (IQR = 48, 74) at 12-months postoperatively. Contrasts revealed that the change was not statistically significant between preop and 1-month post ($p = 0.278$) yet demonstrated statistically significant increases between each time of assessment subsequently ($p < 0.05$). Similar magnitudes of change were observed for the bilateral listening condition from a median 52% (IQR = 42, 63) preoperative to 76% (IQR = 61, 86) at 12 months. That improvement was observed between preop and 3-months postoperatively ($p < 0.001$), yet differences among 3-, 6-, and 12-month scores were not statistically significant ($p > 0.05$). Sensitivity analyses for both CI only and bilateral listening conditions revealed essentially identical findings (see Table 1 and Fig. 1).

Figure 1 displays individual CNC word scores in the ear to be implanted ($n = 105$) and bilaterally aided condition ($n = 83$), respectively, with 6- or 12-month postoperative scores plotted against preoperative scores. The dashed lines represent the 95% confidence interval for test-retest reliability on this measure (19). For the 57 individuals scoring up to 40% CNC in the ear to be implanted (circles), no one exhibited significantly poorer postoperative outcomes in the CI-only condition, 17 patients (29.8%) exhibited equivocal performance, and 40 patients (70.2%) demonstrated statistically significant improvement beyond that which would be within the range of expected test-retest reliability (i.e., outside of the dashed ellipse in the figures). For the 47 individuals (48 ears) scoring $>40\%$ CNC in the ear to be implanted (inverted triangles), 5 (10.4%) exhibited a significant decline in CI-ear alone performance, 24 (50.0%) exhibited equivocal performance, and 19 (39.6%) exhibited statistically significant improvement. For the bilaterally aided condition, none of the 82 patients exhibited a significant decrement in postoperative performance and 40 patients (48.7%) exhibited significantly higher postoperative scores.

Statistically significant improvements in AzBio sentences in quiet were observed from preoperative to 12-months postoperative for both the CI ear (Wald $\chi^2_{(df=4)} = 123.45, p < 0.001$) and the bilateral listening condition (Wald $\chi^2_{(df=4)} = 94.14, p < 0.001$). The median preoperative score was 49% for the CI ear (IQR = 36, 65), with an improvement to median 76% (IQR = 59, 90) at 12-months postoperatively. Contrasts revealed a statistically significant improvement between preop and 3-months post and between 3- and 6-months post (both $p < 0.001$). The change leveled off and was no longer statistically significant between 6- and 12-months postoperatively ($p > 0.05$). Similar magnitudes of change were observed for the bilateral listening condition from a median 54% (IQR = 42, 64) preoperative to 91% (IQR = 80, 97) at 12 months with the same findings from the contrasts as those observed for the CI only condition. Sensitivity analyses for both CI only and bilateral listening conditions revealed essentially identical findings (see Table 1 and Fig. 2).

Figure 2 displays individual AzBio sentence scores in the ear to be implanted ($n = 88$) and bilaterally aided condition ($n = 80$), respectively, with 6- or 12-month postoperative scores plotted against preoperative scores. Out of the 57 individuals scoring up to 40% CNC in the ear to be implanted (circles), pre- and postoperative AzBio sentence scores were available for 48 patients. Of these 48 patients, just 1 (2.1%) exhibited a significantly poorer AzBio score in the CI-only condition, 17 patients (35.4%) exhibited no change, and 30 patients (62.5%) demonstrated statistically significant improvement beyond that which would be within the range of expected test–retest reliability. Out of the 47 individuals (48 ears) scoring >40% CNC in the ear to be implanted (inverted triangles), pre- and postoperative AzBio sentence scores were available for 40 patients (40 ears). Out of these 40 patients, 4 (10.0%) exhibited a significant decline in CI-ear alone performance, 15 (37.5%) exhibited equivocal performance, and 21 (52.5%) exhibited statistically significant improvement. For the bilaterally aided condition, 7 of the 80 patients (8.8%) for whom pre- and postoperative AzBio scores were available exhibited a significant decrement in postoperative performance and 47 patients (58.8%) exhibited significantly higher postoperative AzBio sentence recognition.

Finally, AzBio sentences in noise (+5 dB SNR) also demonstrated statistically significant improvements from preoperative to 12-months postoperative for both CI ear (Wald $\chi^2(df=4) = 41.10, p < 0.001$) and bilateral listening conditions (Wald $\chi^2(df=4) = 130.17, p < 0.001$). The median preoperative score was 13% for the CI ear (IQR = 0, 22), with an improvement to median 31% (IQR = 13, 54) at 12-months postoperatively. Contrasts revealed that improvement from preop was not statistically significant between preop and 3-months post ($p = 0.106$) yet reached significance at 6-months ($p < 0.001$). Further improvement between 6- and 12-months was not statistically significant for sentences in noise ($p = 0.486$). Similar magnitudes of change were observed for the bilateral listening condition from a preoperative median of 33% (IQR = 17, 47) to 66% (IQR = 43, 79) postoperatively at 12 months. That improvement was observed between preop and 3-months postoperatively ($p = 0.001$) and showed continued improvement between 3- and 6-months postoperatively ($p = 0.004$). There was no further statistically significant improvement between 6- and 12-months ($p = 0.063$). Sensitivity analyses revealed similar conclusions (see Table 1 and Fig. 3).

Figure 3 displays individual AzBio sentence in noise (+5 dB) scores in the ear to be implanted ($n = 45$) and bilaterally aided conditions ($n = 56$), respectively, with 6- or 12-month postoperative scores plotted against preoperative scores. Out of the 57 individuals scoring up to 40% CNC in the ear to be implanted (circles), pre- and postoperative AzBio +5 scores were available for 24 patients. Out of these 24 patients, none exhibited a significantly poorer AzBio +5 score in the CI-only condition, 10 (41.7%) exhibited equivocal performance, and 14 (58.3%) demonstrated statistically significant improvement beyond that which would be within the range of expected test–retest reliability. Out of the 47 individuals (48 ears) scoring >40% CNC in the ear to be implanted (inverted triangles), pre- and postoperative AzBio sentence scores were available for 21 patients (21 ears). Out of these 21 patients, 2 (9.5%) exhibited a significant decline in CI-ear alone performance, 4 (19.1%) exhibited equivocal performance, and 15 (71.4%) exhibited statistically significant improvement. For the bilaterally aided condition, 3 of the 56 patients (5.4%) for whom pre- and postoperative AzBio +5 scores were available exhibited a significant decrement

in postoperative performance and 35 (62.5%) exhibited significantly higher postoperative AzBio sentence recognition in noise (+5 dB SNR).

Figure 4 displays maximum speech recognition scores—from Figures 1 through 3—as a function of age at implantation for the 104 patients (105 ears). The top row displays scores for the CI-ear alone and the bottom row displays scores for the bilaterally aided condition. As with Figures 1 to 3, patients were coded by their preoperative CNC scores with those scoring 30 to 40% represented by circles and those scoring >40% represented by inverted triangles. Patients for whom we only had 6-month data are coded as gray symbols. Pearson correlation analyses revealed a significant inverse relationship between speech recognition scores at 6 or 12 months and age at implantation for all measures, with all reaching statistical significance. Table 2 displays the correlation coefficients and associated *p* values.

DISCUSSION

In 2010, we reported successful outcomes of 22 adult CI recipients with preoperative CNC monosyllabic word score performance $\geq 30\%$ (17). Ninety-one percent of subjects performed either the same or better postoperatively, and none had a decrement in performance. These results unveiled the benefit of expanding adult indications to those who may have not even been considered for a CI based on existing criteria.

Within this study, we report outcomes of 104 patients implanted over a 10-year time span who met the same criteria with a preoperative performance of 30% or better in CNC monosyllabic word scores in the ear to be implanted. Consistent with our primary hypothesis, the results demonstrate that these patients exhibited significant benefit postoperatively in CNC word scores in the implanted ear and in the bimodal or bilateral CI condition. Our average preoperative performance in CNC word scores was 42%, much higher than recent clinical trials or reports of aggregate clinical populations (14). This analysis also revealed that adult CI recipients achieving preoperative CNC word scores $\geq 30\%$ in the ear to be implanted, either scored the same or had a decline in performance at 1-month postoperatively in CNC word scores in the electric only condition (16). Similar results were observed by Adunka et al. (20) in which subjects with preoperative hearing experienced a decline in performance at 1-, 3-, and even 6-months intervals, but surpassed their preoperative scores by 1 year. This performance trajectory may be explained by the fact that these subjects represent a higher performing population with a higher baseline score. Although an initial decrement in performance may occur, an initial improvement by 1 month can be anticipated in the bilateral CI or bimodal condition.

Consistent with our hypothesis, these results suggest that implant criteria should be expanded to include patients achieving preoperative monosyllabic word scores *up to at least 40% correct*, which was the median preoperative score in this study. These data also suggest that serious consideration should be given to expanding adult CI criteria even beyond that point as even patients with preoperative CNC scores up to 60% correct in the ear to be implanted had a much higher likelihood of deriving a statistically significant improvement by 6 to 12 months of CI (Fig. 1A). Furthermore, none of these patients scoring up to 60% CNC preoperatively in the ear to be implanted did worse following

implantation in the bilateral, best-aided condition. For the five patients who demonstrated a significant decrement in CI-ear performance following implantation, they were 79.4 years at implantation, on average (range 72–86 yr). Additionally, three of these five recipients demonstrated significant CI-ear benefit for AzBio sentences in quiet and noise and only one of the five reported dissatisfaction with their implant. For this single recipient reporting dissatisfaction with the implant, AzBio +5 dB in the preoperative bilaterally aided condition improved from 39 to 80% in the bimodal condition with 12 months' of CI use. These data are consistent with a recent report from Zwolan et al. (21) who investigated audiometric and unaided word recognition for 661 adults seen for preoperative CI candidacy. They found that for the 198 candidates who had preoperative monosyllabic word recognition reported, 92% of that sample scored $\geq 60\%$ correct providing real-world evidence for an expansion of criteria up to at least 40% correct for CNC word recognition with candidacy consideration for adults scoring up to 60% correct (21).

Despite the evidence provided here for expanding CI criteria, we must qualify this recommendation as pertained to the patient's age at implantation. As shown in Figure 4, there is a clear inverse relationship between postoperative speech recognition and age at implantation. These results are consistent with previous studies demonstrating that postlingually deafened elderly adults perform poorer than younger adults (22–24). However, this is not to say that older CI recipients do not derive significant benefit from cochlear implantation; rather, older recipients tend to derive less benefit than their younger counterparts. Consequently, expansion of CI candidacy criteria beyond 40% CNC performance may not provide the same degree of benefit for older candidates as the poorest performers in this sample were generally ≥ 60 years.

In 2011, the adult MSTB was updated to provide guidelines for pre- and postoperative assessment of adult hearing loss and CI candidacy (9). The 2011 update removed HINT sentence testing from the battery and recommended the continued use of CNC words as well as the addition of AzBio sentences in quiet and noise and Bamford-Kowal-Bench Speech-In-Noise. While sentence testing is a part of the recommended speech perception test battery, recent studies suggest that monosyllabic word tests may be superior to sentence testing in determining candidacy and measuring long-term performance (5,7,14,17). Sentence recognition seems to rely heavily on what is known as “top-down processing,” which involves a host of neuro-cognitive function such as previous linguistic knowledge for deriving semantic context, working memory, and processing speed—all of which are particularly useful in the presence of a degraded auditory signal (25). Patients can rely on existing lexical and linguistic knowledge to “fill-in” missing pieces during sentence testing (25–29). This can result in higher sentence scores compared with word recognition scores. Moving toward using monosyllabic word scores to determine CI candidacy may not only be a more truthful representation of candidate performance but also allows better comparability between populations who speak different native languages, although all participants in the current study were native English speaking.

As further data evolve to support expanding indications for adult cochlear implantation, FDA labeling and CMS policy will need to be updated. Continued advocacy by clinicians and industry representatives will also be necessary. The goal of this substantial work will

be to bring CI technology to the 2.1 million candidates within the United States who may be struggling with hearing aids alone and—at present—are likely to be unrecognized as potential CI recipients despite the likelihood of statistically significant improvement.

LIMITATIONS

Though we have recently been tracking daily CI use via data logging in our clinical database, we do not have these data for the majority of the current sample. This is a significant limitation given the known relationship between daily CI use and speech perception (30,31). Additional research is warranted to investigate whether the poorest performers could be partially explained by CI wear time and whether or not said poor performance could be remediated with greater CI experience; however, the causal relationship between CI wear time and speech perception has yet to be demonstrated. In addition to CI use, a larger prospective investigation is warranted to determine the upper limit of preoperative speech perception for adult CI candidacy and considerations for age at implantation.

CONCLUSION

Adult CI candidates with preoperative word scores higher than the conventional CI recipients continue to derive significant benefit from implantation for both the CI ear and best-aided conditions; however, significant improvement may take longer than 1 month of CI use in this already high performing population. These data provide further support for the expansion of adult CI candidacy to at least 40% CNC word recognition preoperatively. Furthermore, expansion up to 60% correct in the ear to be implanted should be seriously considered as such recipients in this study demonstrated a much higher likelihood of statistically significant benefit following cochlear implantation, and none exhibited a significant decrement for CNC word recognition in the bilateral best-aided condition.

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REFERENCES

1. Goman AM, Lin FR. Prevalence of hearing loss by severity in the United States. *Am J Public Health* 2016;106:1820–2. [PubMed: 27552261]
2. Menapace CM. Personal Communication. Centennial, CO: Cochlear Ltd.; 2019.
3. Available at: <https://www.cms.gov/medicare-coverage-database/>. Accessed April 2, 2020.
4. Nilsson M, Soli SD, Sullivan JA. Development of the Hearing in Noise Test for the measurement of speech reception thresholds in quiet and in noise. *J Acoust Soc Am* 1994;95:1085–99. [PubMed: 8132902]
5. Firszt JB, Holden LK, Skinner MW, et al. Recognition of speech presented at soft to loud levels by adult cochlear implant recipients of three cochlear implant systems. *Ear Hear* 2004;25:375–87. [PubMed: 15292777]
6. Litovsky R, Parkinson A, Arcaroli J, et al. Simultaneous bilateral cochlear implantation in adults: A multicenter clinical study. *Ear Hear* 2006;27:714–31. [PubMed: 17086081]

7. Gifford RH, Shallop JK, Peterson AM. Speech recognition materials and ceiling effects: Considerations for cochlear implant programs. *Audiol Neurootol* 2008;13:193–205. [PubMed: 18212519]
8. Spahr AJ, Dorman MF, Litvak LM, et al. Development and validation of the AzBio sentence lists. *Ear Hear* 2012;33:112–7. [PubMed: 21829134]
9. Available at: <http://www.auditorypotential.com/MSTBfiles/MSTBManual2011-06-20%20.pdf>. Accessed April 2, 2020.
10. Peterson GE, Lehiste I. Revised CNC lists for auditory tests. *J Speech Hear Disord* 1962;27:62–70. [PubMed: 14485785]
11. Etymotic Research Inc. BKB-SIN test. 2005.
12. Balkany T, Hodges A, Menapace C, et al. Nucleus Freedom North American clinical trial. *Otolaryngol Head Neck Surg* 2007;136:757–62. [PubMed: 17478211]
13. Roland JT Jr, Gantz BJ, Waltzman SB, et al. United States multicenter clinical trial of the cochlear nucleus hybrid implant system. *Laryngoscope* 2016;126:175–81. [PubMed: 26152811]
14. Sladen DP, Gifford RH, Haynes D, et al. Evaluation of a revised indication for determining adult cochlear implant candidacy. *Laryngoscope* 2017;127:2368–74. [PubMed: 28233910]
15. Parkinson AJ, Arcaroli J, Staller SJ, et al. The nucleus 24 contour cochlear implant system: Adult clinical trial results. *Ear Hear* 2002;23:41S–8S. [PubMed: 11883766]
16. Holder JT, Reynolds SM, Sunderhaus LW, et al. Current profile of adults presenting for preoperative cochlear implant evaluation. *Trends Hear* 2018;22:2331216518755288. [PubMed: 29441835]
17. Gifford RH, Dorman MF, Shallop JK, et al. Evidence for the expansion of adult cochlear implant candidacy. *Ear Hear* 2010;31:186–94. [PubMed: 20071994]
18. Keidser G, Dillon H, Flax M, et al. The NAL-NL2 prescription procedure. *Audiol Res* 2011;1:e24. [PubMed: 26557309]
19. Thornton AR, Raffin MJ. Speech-discrimination scores modeled as a binomial variable. *J Speech Hear Res* 1978;21:507–18. [PubMed: 713519]
20. Adunka OF, Buss E, Clark MS, et al. Effect of preoperative residual hearing on speech perception after cochlear implantation. *Laryngoscope* 2008;118:2044–9. [PubMed: 18813141]
21. Zwolan TA, Schwartz-Leyzac KC, Pleasant T. Development of a 60/60 guideline for referring adults for a traditional cochlear implant candidacy evaluation. *Otol Neurotol* 2020;41:895–900. [PubMed: 32658396]
22. Mahmoud AF, Ruckenstein MJ. Speech perception performance as a function of age at implantation among postlingually deaf adult cochlear implant recipients. *Otol Neurotol* 2014;35:e286–91. [PubMed: 25226375]
23. Chatelin V, Kim EJ, Driscoll C, et al. Cochlear implant outcomes in the elderly. *Otol Neurotol* 2004;25:298–301. [PubMed: 15129109]
24. Blamey P, Artieres F, Baskent D, et al. Factors affecting auditory performance of postlinguistically deaf adults using cochlear implants: An update with 2251 patients. *Audiol Neurootol* 2013;18:36–47. [PubMed: 23095305]
25. Moberly AC, Reed J. Making sense of sentences: Top-down processing of speech by adult cochlear implant users. *J Speech Lang Hear Res* 2019;62:2895–905. [PubMed: 31330118]
26. Gonsalves C, Pichora-Fuller MK. The effect of hearing loss and hearing aids on the use of information and communication technologies by community-living older adults. *Can J Aging* 2008;27:145–57. [PubMed: 18845510]
27. Ronnberg J. Cognition in the hearing impaired and deaf as a bridge between signal and dialogue: A framework and a model. *Int J Audiol* 2003;42 (suppl 1):S68–76. [PubMed: 12918612]
28. Ronnberg J, Rudner M, Foo C, et al. Cognition counts: A working memory system for ease of language understanding (ELU). *Int J Audiol* 2008;47 (suppl 2):S99–105. [PubMed: 19012117]
29. Ronnberg J, Lunner T, Zekveld A, et al. The Ease of Language Understanding (ELU) model: Theoretical, empirical, and clinical advances. *Front Syst Neurosci* 2013;7:31. [PubMed: 23874273]

30. Holder JT, Dwyer NC, Gifford RH. Duration of processor use per day is significantly correlated with speech recognition abilities in adults with cochlear implants. *Otol Neurotol* 2020;41:e227–31. [PubMed: 31789794]
31. Schwartz-Leyzac KC, Conrad CA, Zwolan TA. Datalogging statistics and speech recognition during the first year of use in adult cochlear implant recipients. *Otol Neurotol* 2019;40:e686–93. [PubMed: 31135672]

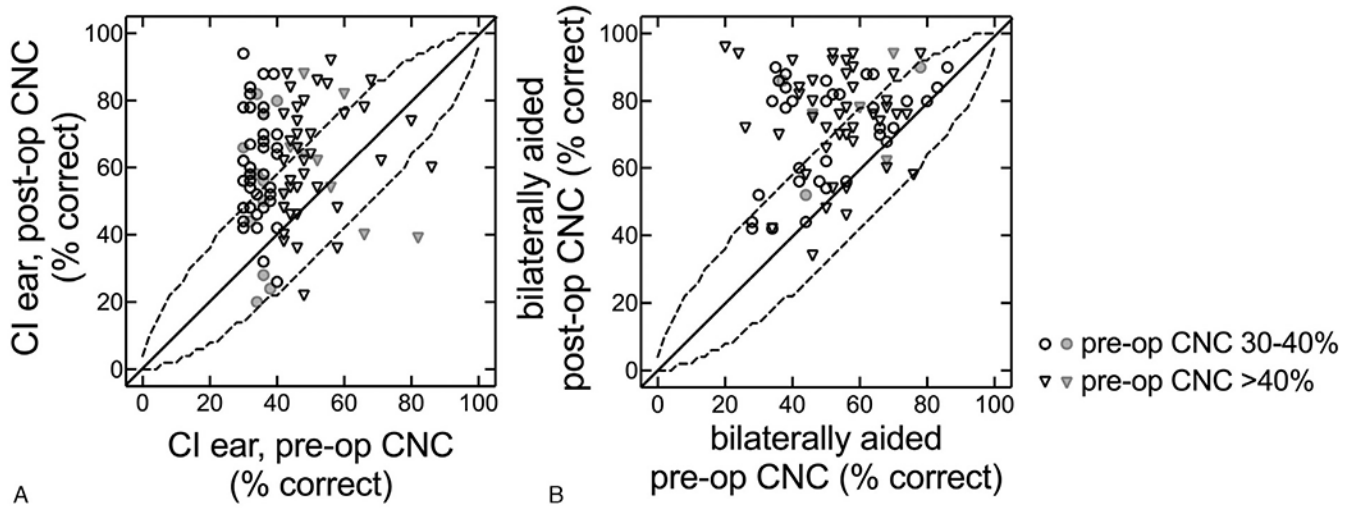


FIG. 1. Preoperative versus 6- or 12-month postoperative monosyllabic CNC word scores. The majority of patients scored the same or better in both the CI-alone (A) and bilateral listening condition (B). Dashed lines represent the 95% confidence interval for test-retest reliability for this metric (19) and the diagonal line represents equivalence across the two time points. Patients are coded by those scoring 30 to 40% CNC preoperatively in the ear to be implanted (circles) and those scoring > 40% CNC preoperatively in the ear to be implanted (inverted triangles). Twelve-month data were available for 81 of 105 patients for the CI-alone condition and 62 of 83 patients for the bilateral condition. Patients for whom we only had 6-month postop data are represented as gray symbols. CI indicates cochlear implant; CNC, consonant-nucleus-consonant.

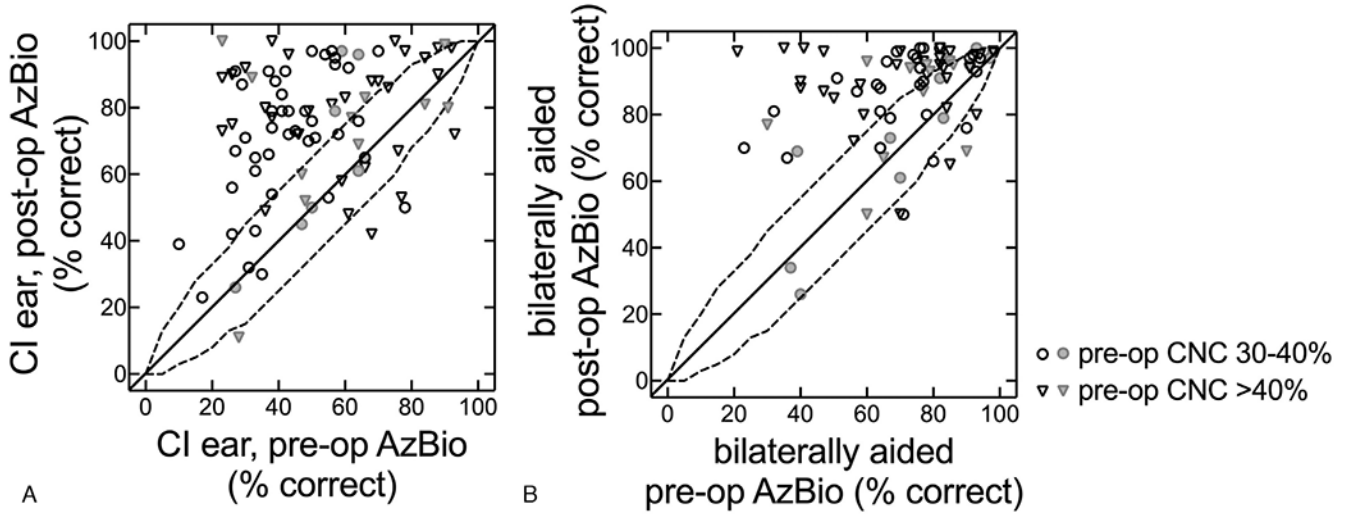


FIG. 2. Preoperative versus 6- or 12-month postoperative scores in AzBio sentences in quiet. The majority of patients scored the same or better in both the CI-alone (A) and bilateral listening condition (B). Dashed lines represent the 95% confidence interval for test–retest reliability for this metric (8) and the diagonal line represents equivalence across the two time points. Patients are coded by those scoring 30 to 40% CNC preoperatively in the ear to be implanted (circles) and those scoring > 40% CNC preoperatively in the ear to be implanted (inverted triangles). Twelve-month data were available for 65 of 88 patients for the CI-alone condition and 57 of 80 patients for the bilateral condition. Patients for whom we only had 6-month postop data are represented as gray symbols. CI indicates cochlear implant; CNC, consonant-nucleus-consonant.

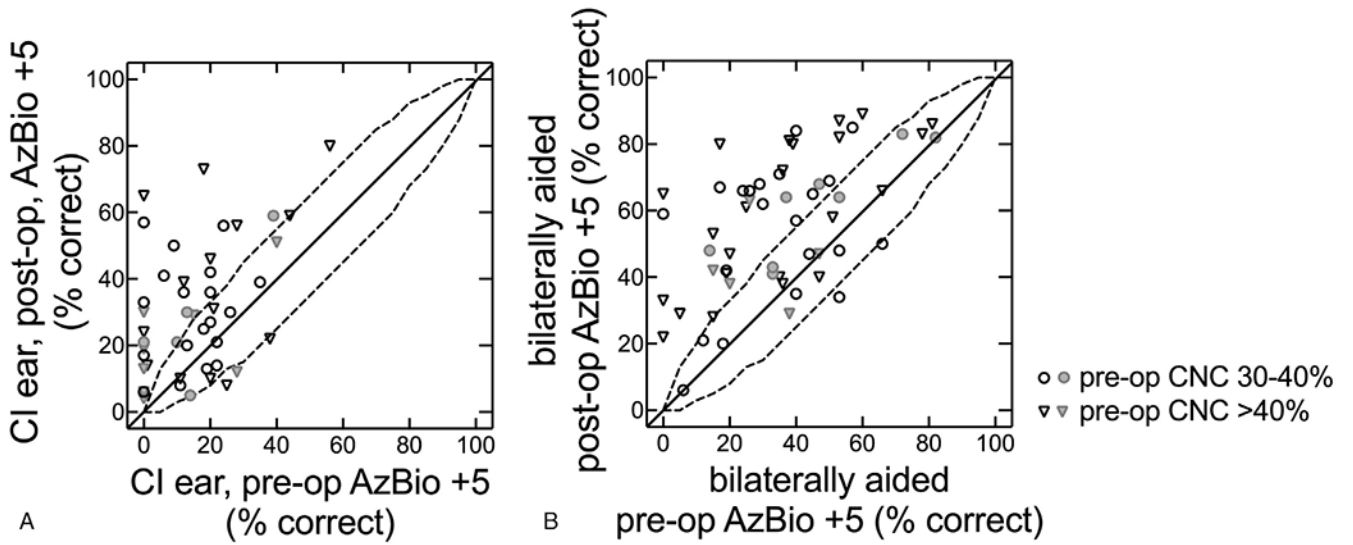


FIG. 3. Preoperative versus 6- or 12-month postoperative scores in AzBio sentences in quiet. The majority of patients scored the same or better in both the CI-alone (A) and bilateral listening condition (B). Dashed lines represent the 95% confidence interval for test-retest reliability for this metric (8) and the diagonal line represents equivalence across the two time points. Patients are coded by those scoring 30 to 40% CNC preoperatively in the ear to be implanted (circles) and those scoring >40% CNC preoperatively in the ear to be implanted (inverted triangles). Twelve-month data were available for 33 of 45 patients for the CI-alone condition and 43 of 56 patients for the bilateral condition. Patients for whom we only had 6-month postop data are represented as gray symbols. CI indicates cochlear implant; CNC, consonant-nucleus-consonant.

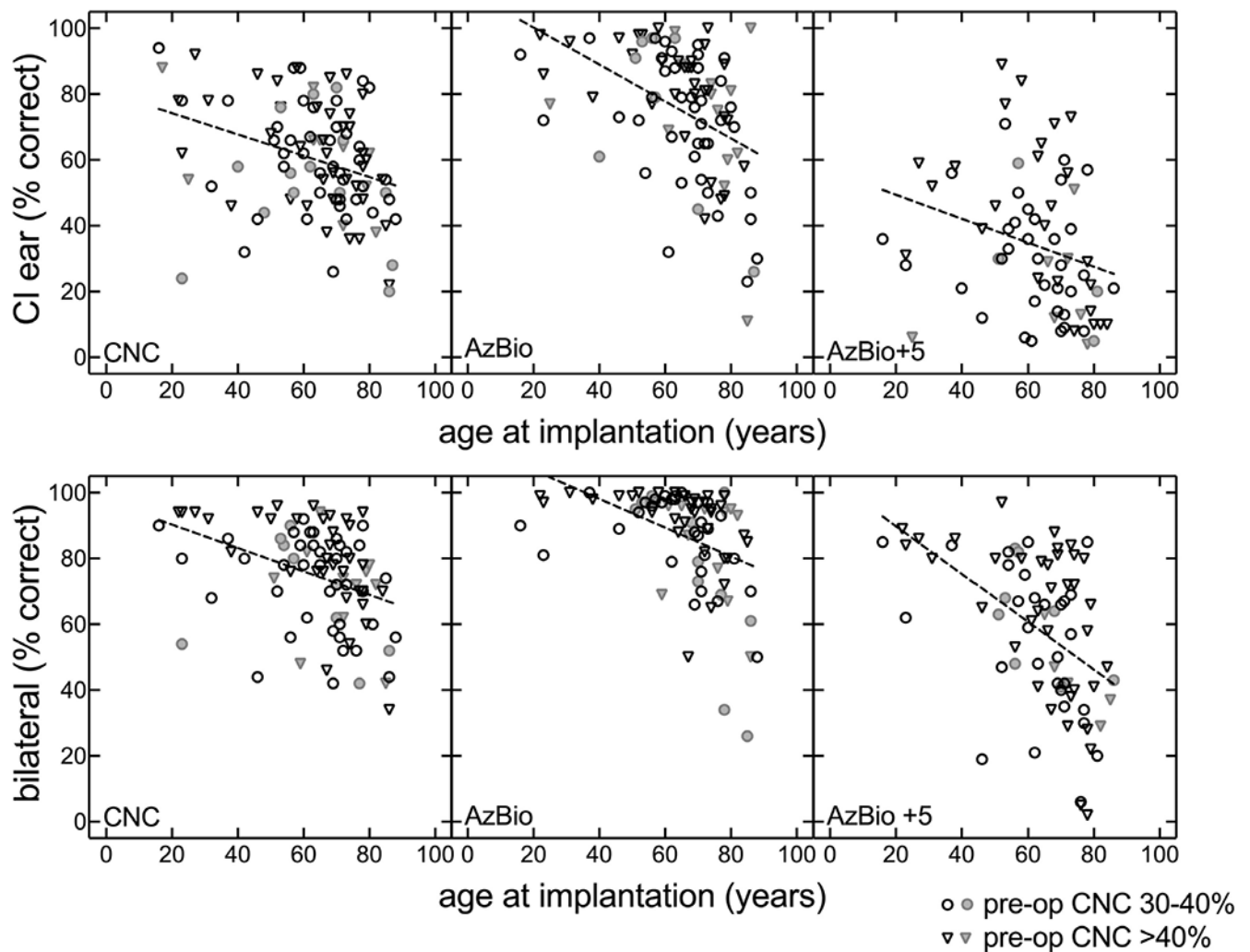


FIG. 4. Postoperative 6- or 12-month postoperative speech recognition scores for the CI-ear alone (*top row*) and bilaterally aided condition (*bottom row*) as a function of age at implantation. Patients are coded by those scoring 30 to 40% CNC preoperatively in the ear to be implanted (circles) and those scoring > 40% CNC preoperatively in the ear to be implanted (inverted triangles). Patients for whom we only had 6-month postop data are represented as gray symbols. CI indicates cochlear implant; CNC, consonant-nucleus-consonant.

TABLE 1.

Median preoperative and postoperative speech perception outcomes

| Measure | CI Only | | | Bilateral | | |
|-------------------|---------|--------------|----------|-----------|--------------|----------|
| | N | Median (IQR) | Min, Max | N | Median (IQR) | Min, Max |
| CNC word scores | | | | | | |
| Preop | 104 | 40 (34, 46) | 30, 86 | 85 | 52 (42, 63) | 20, 86 |
| 1-mo | 75 | 40 (32, 46) | — | 61 | 52 (41, 59) | — |
| 3-mo | 92 | 42 (22, 52) | 2, 82 | — | — | — |
| 6-mo | 67 | 42 (24, 52) | — | 60 | 74 (58, 80) | 26, 96 |
| 12-mo | 92 | 52 (43, 66) | 4, 96 | 42 | 76 (61, 82) | 32, 96 |
| | 67 | 54 (36, 66) | 10, 88 | 73 | 74 (55, 82) | 34, 96 |
| | 92 | 53 (40, 68) | — | 53 | 76 (55, 84) | — |
| | 70 | 53 (41, 71) | — | 61 | 76 (61, 86) | — |
| | 75 | 60 (48, 74) | — | 61 | 76 (61, 86) | — |
| | 75 | 60 (48, 74) | — | 61 | 76 (61, 86) | — |
| AzBio in quiet | | | | | | |
| Preop | 98 | 49 (36, 65) | 10, 96 | 83 | 54 (42, 64) | 20, 86 |
| 3-mo | 66 | 49 (36, 66) | — | 57 | 54 (41, 59) | — |
| 6-mo | 83 | 67 (45, 87) | 11, 98 | 50 | 83 (68, 95) | 34, 100 |
| 12-mo | 55 | 71 (50, 87) | — | 33 | 86 (71, 96) | — |
| | 83 | 76 (58, 89) | 11, 100 | 66 | 93 (78, 97) | 50, 100 |
| | 57 | 74 (59, 89) | — | 45 | 93 (84, 98) | — |
| | 66 | 76 (59, 90) | 23, 100 | 57 | 91 (80, 97) | 43, 100 |
| | 66 | 76 (59, 90) | — | 57 | 91 (80, 97) | — |
| AzBio noise + 5dB | | | | | | |
| Preop | 54 | 13 (0, 22) | 0, 56 | 64 | 33 (17, 47) | 0, 82 |
| 3-mo | 37 | 18 (0, 22) | — | 42 | 37 (17, 52) | — |
| 6-mo | 20 | 22 (1, 52) | 0, 78 | 36 | 46 (27, 70) | 7, 90 |
| | 13 | 26 (9, 66) | — | 22 | 52 (26, 71) | — |
| | 39 | 27 (11, 46) | 1, 89 | 49 | 61 (40, 70) | 19, 88 |
| | 23 | 29 (13, 57) | — | 31 | 64 (40, 72) | — |

| Measure | CI Only | | | Bilateral | | |
|---------|-----------|--------------------|----------|-----------|--------------------|----------|
| | N | Median (IQR) | Min, Max | N | Median (IQR) | Min, Max |
| 12-mo | 37 | 31 (13, 54) | 0, 84 | 42 | 66 (43, 79) | 6, 89 |
| | <i>37</i> | <i>31 (13, 54)</i> | | <i>42</i> | <i>66 (43, 79)</i> | |

The values in *italics* represent patients with both baseline and 12-month assessments for each respective measure. Those values were used to conduct a sensitivity analysis of the results observed requiring only baseline and one subsequent assessment. No meaningful differences were observed between the two sets of results.

TABLE 2.

Pearson product moment correlation coefficients, r , and associated p values for each speech recognition measure and listening condition as a function of age at implantation (in years) as displayed in Figure 4

| | CNC | AzBio | AzBio +5 dB |
|-------------------|--------------|--------------|--------------------|
| CI-ear | $r = -0.33$ | $r = -0.44$ | $r = -0.27$ |
| | $p = 0.0006$ | $p < 0.0001$ | $p = 0.02$ |
| Bilaterally aided | $r = -0.38$ | $r = -0.43$ | $r = -0.49$ |
| | $p = 0.0002$ | $p < 0.0001$ | $p < 0.0001$ |

CI indicates cochlear implant; CNC, consonant-nucleus-consonant.