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Association of Patient-Related Factors With Adult Cochlear Implant Speech Recognition Outcomes
A Meta-analysis

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➕ Editorial

➕ Supplemental content

IMPORTANCE Multiple studies have evaluated associations between post–cochlear implant (CI) speech recognition outcomes and patient-related factors. Current literature often appears equivocal or contradictory, so little is known about the factors that contribute to successful speech recognition outcomes with CIs.

OBJECTIVE To use a meta-analysis to pool data from the extant literature and provide an objective summary of existing evidence on associations of patient-related factors and CI speech recognition outcomes.

DATA SOURCES A literature search was performed using PubMed, Scopus, and CINAHL databases in January 2019 using the following search terms: *cochlear implant* or *cochlear implants* or *cochlear implantation* and *speech recognition* or *word recognition* or *sentence recognition*. Studies of postlingually deafened adult CI recipients that reported word or sentence recognition scores were included.

STUDY SELECTION Inclusion criteria were postlingual adult CI recipients 18 years or older with word or sentence recognition scores at minimum 6-month postimplantation. Studies that included patients undergoing revision or reimplantation surgery were excluded.

DATA EXTRACTION AND SYNTHESIS Following the Preferred Reporting Items for Systemic Reviews and Meta-analyses (PRISMA) guidelines, 1809 unique articles underwent review by abstract, and 121 articles underwent full-text review, resulting in 13 articles of 1095 patients for a meta-analysis of correlations. Random-effects model was used when the heterogeneity test yielded a low *P* value (*P* < .05).

MAIN OUTCOMES AND MEASURES The planned primary outcome was the pooled correlation values between postimplant speech recognition scores and patient-related factors.

RESULTS Of the 1095 patients included from the 13 studies, the mean age at implantation ranged from 51.2 to 63.7 years and the mean duration of hearing loss ranged from 9.5 to 31.8 years; for the 825 patients for whom sex was reported, 421 (51.0%) were women. A weak negative correlation was observed between age at implantation and postimplant sentence recognition in quiet (*r* = −0.31 [95% CI, −0.41 to −0.20]). Other correlations between patient-related factors and postimplant word or sentence recognition were statistically significant, but all correlations were absent to negligible (*r* = 0.02-0.27).

CONCLUSIONS AND RELEVANCE Given that most associations were weak, negligible, or absent, patient-related factors often thought to affect CI speech recognition ability offer limited assistance in clinical decision-making in cochlear implantation. Additional research is needed to identify patient-related and other factors that predict CI outcomes, including speech recognition and other important variables related to success with CIs.

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Cochlear implantation has become the standard of care for the millions of adults with severe-to-profound sensorineural hearing loss. Despite advances in cochlear implant (CI) technologies, speech recognition outcomes remain highly variable.[1,2] Reasons for this variability are uncertain but likely involve several device-specific and patient-specific factors. Some of the device-specific variables that have been studied include signal processing strategies,[3-7] intracochlear electrode location,[8-15] and operative approach.[16-19] However, intrinsic patient-specific demographic and audiologic factors, including age at implantation, duration of hearing loss, preimplant audiologic measurements, and hearing aid (HA) use prior to implantation, likely affect CI outcomes independent from these device-related variables.

The success of cochlear implantation is currently evaluated primarily by open-set speech recognition scores,[20] which most often include word recognition in quiet, sentence recognition in quiet, and sentence recognition in various levels of background noise. Although many patient-specific factors are thought to be associated with these outcomes, the strength of the associations of these factors with CI speech-recognition outcomes has been equivocal. For example, Kim et al[21] and Francis et al[22] both showed that older age at implantation was associated with poorer postimplant speech recognition abilities as compared with younger CI users, whereas Park et al[23] and Guerra-Jimenez et al[24] did not report this association. Similar inconsistencies exist for the majority of patient-specific factors that have been studied and reported.

To date, most published reports examining the effect of patient-specific factors on CI outcomes have small sample sizes and are from single institutions, so results may not be broadly representative of CI users and can generate contradictory findings. To address this limitation, the present study uses meta-analyses of correlation to pool data across studies with the goal of identifying patient-specific factors that predict CI speech recognition outcomes. Meta-analyses provide the means to combine data from smaller studies to increase statistical power and precision to detect associations and provide an objective summary of existing evidence.

The current meta-analysis examines the association between patient-specific factors and speech recognition outcomes in adult CI users. A better understanding of the strength of associations between patient characteristics and postimplant outcomes is important to inform CI candidates and provide appropriate advice regarding likely postoperative success. Poor postimplant performance and low perceived benefit coupled with inappropriate expectations have been associated with elective nonuse,[25] which makes careful candidate selection essential to justify the cost of intervention. In addition, it is important to identify and target patient characteristics that are potentially modifiable in order to improve CI outcomes.

Methods

Literature Search

A literature search was performed following the Preferred Reporting Items for Systemic Reviews and Meta-analyses

Key Points

Question What are the associations between patient-related factors and cochlear implant (CI) speech recognition outcomes?

Findings In this meta-analysis of 13 studies comprising 1095 patients, CI speech recognition outcomes were found to be negligibly associated with age at implantation, duration of hearing loss, preimplant pure-tone average, and preimplant word recognition.

Meaning Patient-related factors often thought to influence CI speech recognition ability offer limited assistance in clinical decision-making in cochlear implantation, which presents an opportunity for additional research to identify patient-related and other factors that predict CI outcomes.

(PRISMA) guidelines.[26] Two reviewers (E.E.Z. and C.L.) independently searched the PubMed, Scopus, and CINAHL databases in January 2019 for studies of postlingually deafened adult CI recipients that reported word or sentence recognition scores. The following search terms were used: *cochlear implant* or *cochlear implants* or *cochlear implantation* and *speech recognition* or *word recognition* or *sentence recognition*. These searches resulted in 1809 unique articles that were reviewed by title and abstract for inclusion and exclusion criteria. Inclusion criteria were as follows: postlingual adult CI recipients with word or sentence recognition scores at minimum 6-month postimplantation. Case reports, letters to the editor, conference proceedings, and full-text articles not available in English were excluded. Studies that included patients younger than 18 years, revision or reimplantation surgery, and prelingually deafened patients were excluded. A minimum of 3 pure-tone thresholds at frequencies of 500, 1000, or 2000 Hz were required for inclusion in analysis of preimplant pure-tone average (PTA). Studies that included patients with a single condition (eg, Meniere's disease[27]) were excluded. No exclusions were made based on time range or publication date.

After review of 1809 unique abstracts, 121 articles underwent full-text review for inclusion. After full-text review, 13 articles were included in the meta-analysis (**Table 1**).[1,21,22,24,28-36] Disagreements among reviewers were mediated by the senior author (T.R.M.). Articles were reviewed to ensure no overlapping study samples were included. In studies with bilateral CI recipients, data were included if implanted ears were reported separately. **Figure 1** displays the study selection process.

Data Extraction

Articles were selected for the meta-analysis of correlations based on a priori inclusion and exclusion criteria as previously described. Data were reviewed by 2 independent reviewers (E.E.Z. and C.L.) who recorded the author, sample size, patient demographics, year of publication, and correlation values.

In studies with multiple time points longer than 6 months, the 6-month postimplant data were included to ensure consistency. In studies that reported results for more than 1 test within the same category of speech recognition measurements (eg, AzBio and HINT [Hearing in Noise Test] for sentence recognition in quiet) correlation and number of

Table 1. Studies Included in the Meta-analysis of Correlations[a]

Source	Patient-related factors	Postoperative speech recognition task	Follow-up, mo
Beyea et al,[28] 2016	Age at CI, DoHL	Sentences in quiet: HINT, AzBio	≥12
Derinsu et al,[29] 2018	Age at CI, DoHL, WR	Words in quiet: phonetically balanced monosyllable word lists	≥12
Fabie et al,[30] 2018	PTA, WR	Words in quiet: CNC	
		Sentences in quiet: AzBio in quiet	≥6
		Sentences in noise: AzBio in noise	
Francis et al,[22] 2005	Age at CI, DoHL, PTA	Words in quiet: CNC	6
Guerra-Jimenez et al,[24] 2016	Age at CI, DoHL	Words in quiet: NS	≥12
Holden et al,[1] 2013	Age at CI, DoHL	Words in quiet: CNC	≥24
Holden et al,[31] 2016	Age at CI, DoHL, PTA	Words in quiet: CNC	≥6
		Sentences in quiet: AzBio in quiet	
		Sentences in noise: AzBio in noise	
Kamakura et al,[32] 2016	Age at CI	Words in quiet: CNC, NU-6	>12
Kim et al,[21] 2018	Age at CI, DoHL	Words in quiet: NS	24
Li et al,[33] 2007	Age at CI	Words in quiet: NU-6 or CNC	≥12
Medina et al,[34] 2017	DoHL	Words in quiet: DWR	6
		Sentences in quiet: NS	
Plant et al,[35] 2016	DoHL	Words in quiet: CNC	12
Rubinstein et al,[36] 1999	DoHL	Words in quiet: NU-6 or CNC	9

Abbreviations: CI, cochlear implant; CNC, consonant-nucleus-consonant test; DoHL, duration of hearing loss; DWR, disyllabic word recognition; HINT, Hearing in Noise Test; NS, not specified; NU-6, Northwestern University Auditory Test Number 6; PTA, preimplant earphone pure-tone average; WR, preimplant-aided word recognition.

[a] Studies listed satisfied inclusion criteria for meta-analysis of correlations, factors analyzed, speech recognition measure used, and follow-up time in months.

patients were both listed as separate samples. Data reported in graphical plots were extracted if numerical values were available. Authors were contacted for more complete data when necessary for inclusion into the study. Level of evidence for each selected article was determined to be level 4, as determined by the Oxford Centre for Evidence-Based Medicine.[37]

Biostatistics

A meta-analysis of correlations was performed using MedCalc, version 18.10.2 (MedCalc Software). The resulting forest plot shows the correlation coefficients (with 95% CIs) found in the different studies included in the meta-analysis, as well as the overall effect with 95% CIs. Under the fixed-effects model, it is assumed that all studies come from a common population and that the correlation coefficient is not statistically significantly different among the different trials. This assumption is tested by the *heterogeneity test*. If this test yields a low *P* value (*P* < .05), then the fixed-effects model may be invalid. In this case, the random-effects model might be more appropriate, in which both the random variation within the studies and the variation between the different studies is incorporated.[38] Each study was weighted according to the number of patients included. MedCalc uses the Hedges-Olkin method for calculating the weighted summary correlation coefficient under the fixed effects model, using a Fisher *z* transformation of the correlation coefficients.[39] Under the random-effects model, the heterogeneity statistic is incorporated to calculate the summary correlation coefficient.[40]

For this analysis, the null hypothesis was that there was no association between preimplant patient-specific factors (eg, age at implantation, duration of hearing loss, preimplant PTA) and postimplant word and sentence recognition scores. The following criteria were used for subjective assessment of correlation values (*r*): 0 to 0.3, negligible; 0.3 to 0.5, low; 0.5 to

Figure 1. PRISMA Diagram
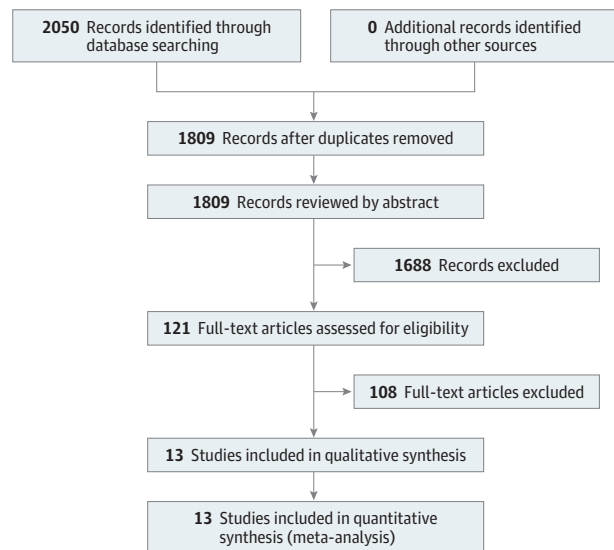
Literature review process using the Preferred Reporting Items for Systemic Reviews and Meta-analysis (PRISMA) guidelines.

0.7, medium; 0.7 to 0.9, high; 0.9 to 1.0, very high.[40,41] Potential publication bias was evaluated by visual inspection of the funnel plot and Egger regression test, which examines the asymmetry of the funnel plot[42] (see eFigure in the Supplement). In a funnel plot, treatment effect is plotted on the horizontal axis, and MedCalc plots the standard error (SE) on the vertical axis.[43] The vertical line represents the summary derived using fixed-effect meta-analysis. Two diagonal lines represent (pseudo) 95% CIs (effect ±1.96 SE) around the summary effect for each SE on the vertical axis. These show the

Table 2. Patients Included in the Meta-analysis of Correlations[a]

Patient-related factor	Studies	No. of patients	Sex, No. (%) Male	Female	Mean range
Age at implantation	9	518	152 (46)	179 (54)	51.2-72 y
Duration of hearing loss	10	738	205 (44)	264 (56)	9.5-31.8 y
Preimplant					
Earphone PTA	3	478	201 (55)	166 (45)	87.6-96.3 dB
Aided word recognition	2	404	182 (55)	146 (45)	7.2%-8.6%
All studies	13	1095	405 (49)	421 (51)	NA

Abbreviations: NA, not applicable; PTA, pure-tone average.

[a] More than 1 factor for each article could be included in a meta-analysis, so all studies are not totals. Subject sex was not reported for all subjects.

Table 3. Meta-analysis of Correlations[a]

Characteristic	r (95% CI)	I^2, %	P value
Age at implantation			
Word recognition in quiet	−0.27 (−0.35 to −0.19)	0.0	.58
Sentence recognition			
In quiet	−0.31 (−0.41 to −0.20)	0.0	.87
In noise	NA	NA	NA
Duration of hearing loss			
Word recognition in quiet	−0.25 (−0.41 to −0.07)	79.9	<.001[b]
Sentence recognition			
In quiet	0.02 (−0.08 to 0.12)	7.7	.37
In noise	NA	NA	NA
Preimplant earphone PTA			
Word recognition in quiet	−0.16 (−0.26 to −0.06)	0.0	.76
Sentence recognition			
In quiet	−0.15 (−0.25 to −0.05)	0.0	.67
In noise	−0.19 (−0.34 to −0.04)	10.5	.33
Preimplant word recognition			
Word recognition in quiet	0.22 (0.13 to 0.32)	18.5	.27
Sentence recognition			
In quiet	NA	NA	NA
In noise	NA	NA	NA

Abbreviations: NA, not applicable; PTA, pure-tone average.

[a] Pooled correlation values and heterogeneity statistics (I^2 and P value) for meta-analysis of correlations.

[b] Indicates significance for heterogeneity. Random effect is used.

expected distribution of studies in the absence of heterogeneity of selection bias. In the absence of heterogeneity, 95% of the studies should lie within the funnel defined by these diagonal lines. The need for institutional review board approval was waived by the Medical University of South Carolina, and all data analyzed in this study were deidentifed before data access, handling, or analysis.
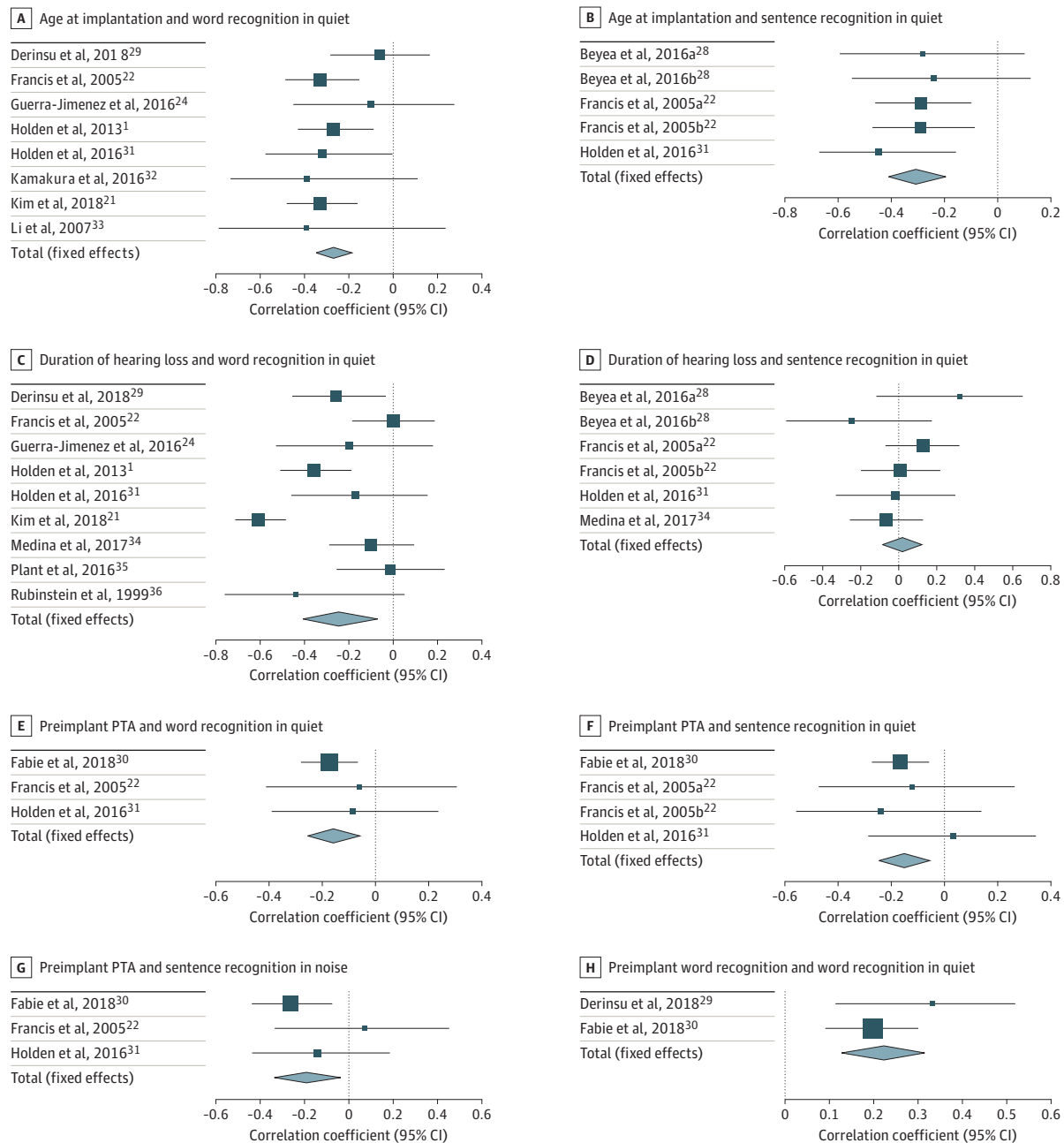
Results

Studies that met criteria for inclusion in the meta-analysis of correlations are summarized in Table 1. **Table 2** summarizes the patient characteristics of studies included in the meta-analysis of correlations, and **Table 3** summarizes the patient-related factors and correlations. Thirteen studies were included with a total of 1095 patients. Sex was reported for 825 of these patients: 405 (49.1%) were men and 421 (51.0%) were women. The mean age at implantation ranged from 51.2 to 63.7 years. The mean duration of hearing loss ranged from 9.5 to 31.8 years. Nine studies were included in the meta-analysis of correlations for age at implantation, 10 for duration of hear-

ing loss, 3 for preimplant PTA, and 2 for preimplant word recognition. Reasons for exclusion beyond the a priori criteria were incomplete statistics, overlapping study samples, insufficient follow-up time, use of phonemes as sole postoperative speech recognition outcome, combined reporting of word recognition and sentence recognition as a single correlation value, and grouping data for patients older and younger than 18 years. Egger regression test suggested an association between the sample size of these studies and their effect sizes, which indicates a high likelihood of publication bias for the analysis of duration of hearing loss and post-CI word recognition (I^2 = 79.9%; P < .001). The funnel plot of the meta-analysis of duration of hearing loss and word recognition in quiet is available as eFigure in the Supplement. There was no indication of publication bias for any other meta-analyses of correlation performed.

Age at Implantation and Postoperative Speech Recognition Outcomes

Results from 9 studies showed age at implantation had a negligible negative correlation with postoperative word recognition (r = −0.27 [95% CI, −0.35 to −0.19]) and a low negative

Figure 2. Forest Plots of Meta-analysis of Correlations by Patient-Related Factors

A Age at implantation and word recognition in quiet

B Age at implantation and sentence recognition in quiet

C Duration of hearing loss and word recognition in quiet

D Duration of hearing loss and sentence recognition in quiet

E Preimplant PTA and word recognition in quiet

F Preimplant PTA and sentence recognition in quiet

G Preimplant PTA and sentence recognition in noise

H Preimplant word recognition and word recognition in quiet

Studies with more than 1 task for the same speech recognition measurement are listed as separate samples. Beyea 2016a[28] tested patients with HINT (Hearing in Noise Test), and Beyea 2016b[28] tested patients with AzBio. Francis 2015a[22] tested patients with CID sentences, and Francis 2015b[22] tested subjects with HINT.

Abbreviation: PTA, pure-tone average.

correlation with postoperative sentence recognition in quiet (*r* = −0.31 [95% CI, −0.41 to −0.20]), as shown in **Figure 2**A and B.[22,28,31] Association of age at implantation with postoperative sentence recognition in noise was not analyzed because only 1 study[31] met inclusion criteria for review. Results showed no significant heterogeneity for word recognition in quiet ($I^2 = 0\%$; *P* = .58) or sentence recognition in quiet ($I^2 = 0\%$; *P* = .87).

Duration of Hearing Loss and Postoperative Speech Recognition Outcomes

Ten studies of duration of hearing loss were included in the analysis (Figure 2C and D).[1,21,22,26,28,29,31,34-36] A negligible negative correlation was observed between duration of hearing loss and postoperative word recognition scores (*r* = −0.25 [95% CI, −0.41 to −0.07]). Notably, postoperative sentence recognition in quiet showed no correlation with duration of hearing

loss (r = 0.02 [95% CI, −0.08 to 0.12]). Due to only 1 study[31] reporting association of duration of hearing loss and sentence recognition in noise, no analysis was performed. Word recognition results showed significant heterogeneity (I^2 = 79.9%; P < .001), while sentence recognition in quiet did not (I^2 = 0%; P = .48).

Preimplant PTA and Postoperative Speech Recognition Outcomes

Three studies had sufficient data for analysis of preimplant earphone PTA. Out of the 3 studies, 2 studies[22,30] used 3-frequency averages of 500, 1000, and 2000 Hz thresholds, and 1 study[31] used 4-frequency averages of 250, 500, 1000, and 2000 Hz to calculate PTA. Given the lack of frequency-specific data, we were not able to standardize how PTA was calculated for the meta-analyses. All postoperative speech recognition tests showed negligible negative correlations with preimplant PTA (word recognition in quiet, r = −0.16 [95% CI, −0.26 to −0.06]; sentence recognition in quiet, r = −0.15 [95% CI, −0.25 to −0.05]; sentence recognition in noise, r = −0.19 [95% CI, −0.34 to −0.04]) (Figure 2E, F, and G).[22,30,31] These results indicate that poorer preoperative hearing thresholds (as measured by higher preimplantation PTA) are associated with statistically significant, but negligibly lower, postimplant speech recognition scores. No significant heterogeneity was observed for word recognition (I^2 = 0%; P = .76), sentence recognition in quiet (I^2 = 0%; P = .67), and sentence recognition in noise (I^2 = 10.5%; P = .33).

Preoperative Aided and Postoperative Word Recognition Ability

We then sought to evaluate the association between preoperative and postoperative speech recognition ability. A negligible positive correlation was observed between preimplant aided word recognition and postoperative word recognition in quiet (r = 0.22 [95% CI, 0.13-0.31]) with low heterogeneity (I^2 = 18.5%; P = .27) in data pooled from 2 studies. A forest plot of correlation of preimplant hearing and postoperative speech recognition is shown in Figure 2H.[29,30] Only 1 study compared preoperative and postoperative sentence recognition (in noise or quiet) and met inclusion/exclusion criteria; analysis could not be performed.

Discussion

The original intent of this study was to perform a metaregression of commonly reported patient-specific variables to assess the independent influence of each while controlling for confounders. However, only 3 studies that fulfilled the inclusion criteria contained the necessary data. Most studies that included correlation values did not report preimplant and postimplant audiologic data. As a result, we were only able to perform univariate analyses. In doing so, the preimplant patient-specific factors available for analysis were found to have absent to low correlations with postoperative speech recognition outcomes. While these results showed statistical significance in most of the factors analyzed, the clinical significance of these

associations is likely minimal. To illustrate, the correlation between age at implantation and sentence recognition is one of the strongest noted in the present study (r = −0.31). However, the coefficient of determination for this value means that age accounts for only 9.6% of the variance in sentence recognition ability. This degree of correlation is fairly consistent for all investigated factors—all account for fewer than 10% of variance in postimplant speech recognition scores. This suggests that these patient-specific factors that are routinely reported in the literature offer limited assistance in clinical decision-making in cochlear implantation. Moreover, there is evidence that the influence of patient factors on speech recognition outcomes has decreased over time. Blamey et al[44,45] found a lower association between speech recognition ability and age at implantation and onset of hearing loss in more recent data when comparing 2 large cohorts separated by 17 years. Reasons for the differences may be related to changes in CI candidacy or implant technology but are not completely understood at the present time. Owing to the limited number of available studies, we were unable to analyze these associations based on date of publication.

Care should be taken in interpreting data from analyses where high heterogeneity (I^2) exists, such as the correlation between duration of hearing loss and post-CI word recognition (I^2 = 79.9%). This suggests that there may be features of the included studies that introduce variability in outcomes. For example, multiple word-recognition and sentence-recognition tests were used in the included studies. In addition, the different means by which duration of hearing loss was defined and quantified likely introduced additional variability in the analyses. Many authors relied on self-report, and many failed to report their criteria at all.

In addition, duration of severe profound hearing loss is likely more influential for patient outcomes than onset of self-reported symptomatic hearing loss, but these are seldom differentiated in the literature. Holden et al[1] and Derinsu et al[29] measured the association between word recognition scores and duration of hearing loss defined as the duration of severe-to-profound hearing loss. The reported correlation values (−0.380 and −0.256, respectively) were within the confidence interval of the pooled correlation for word recognition and duration of hearing loss for all studies included in the current meta-analysis. To determine how *duration of hearing loss* should best be quantified to serve as a predictor of adult CI user outcomes, a study design is needed that includes a large cohort of CI recipients with severe-to-profound hearing loss who have had serial audiologic testing for an extended period of time prior to implantation, or a prospective, longitudinal study design that includes serial audiologic testing. However, given the relatively rare progression of hearing loss to the severe/profound range, the number of patients needed for these studies may be prohibitive. Similar inconsistencies are unfortunately found in many of the factors studied in this analysis, which likely introduce variability in the studies leading to a poor understanding of the patient-specific factors that may influence CI outcomes.

To that end, in our literature search, we identified several factors studied for CI outcomes that were too scarce to ana-

lyze in the current study but warrant discussion. One such factor was duration of preimplant HA use. Unfortunately reporting on the influence of HA use is inconsistent and variable, with some studies reporting significant positive correlations with postimplant word recognition,[21] while several others found no or even negative significant associations.[1,46,47] In theory, preimplant HA use may provide auditory stimulation to the affected ear, which has been suggested as a possible protective factor for maintaining central auditory neuroplasticity[47]; however, only 1 study met our inclusion criteria,[21] and this topic was unable to be addressed in the current meta-analysis of correlations. Although we were able to analyze preimplant PTA and preimplant word recognition ability, the analysis included only 3 and 2 studies, respectively, which made interpretation difficult.

Overall, we found that the literature assessing the effects of patient-specific factors on CI speech recognition outcomes is limited to only a few factors, but evidence is growing that other factors may contribute. For example, working memory and cognition have been more recently cited as potential indicators for CI performance. Moberly et al[48] found positive correlations between working memory capacity and visual working memory capacity with preimplant AzBio sentences in quiet and postimplant AzBio sentences in noise, respectively.[49] In addition, Heydebrand et al[50] found verbal learning measures to be the best predictor of postimplant CNC (consonant-nucleus-consonant) 6-month performance. The numerous constructs that contribute to cognitive ability and the many available tests used to measure these constructs make it difficult at this time to pool these results in a quantitative analysis. Therefore, we were not able to perform a meta-analysis of correlations for this topic.

Limitations

The present study is limited by the availability and quality of published data. As in any meta-analysis, the possibility of a publication bias exists. For example, some studies might have provided only significant correlation values, which excluded nonsignificant factors from these analyses and influenced our pooled results. We attempted to contact the authors of all studies that did not report a nonsignificant correlation value; however, additional data were not always available. In addition, the reporting of follow-up interval in this literature is limited. CI candidates often reach peak performance between 6 and 12 months postimplantation.[1] Several of the included studies provided a standard follow-up time for all patients; however, many studies lacked consistent follow-up or failed to report these data. It is possible that the patient-specific factors analyzed might have a greater effect on speech recognition scores after 6 months, but available data from this time frame are very limited. Finally, the standardization of statistical reporting in journals and following recently published guidelines for reporting CI outcomes[51] would greatly advance the ability to synthesize available evidence for future meta-analyses.

Conclusions

The current meta-analysis of correlations demonstrated statistically significant low to negligible associations between patient-specific factors and postimplant speech recognition. These correlations provide limited guidance in counseling patients regarding expectations and should not be the sole deciding factor for patients considering CIs. Further studies are needed to determine associations with postimplant sentence recognition in noise because this is rarely reported. Complete and standardized data reporting and exploration of additional patient factors in future studies may identify clinically significant predictors that can guide clinical practice.

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