

Systematic Review

Meta-analysis of Quality-of-Life Improvement After Cochlear Implantation and Associations With Speech Recognition Abilities

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Objectives: Determine the impact of cochlear implantation on quality of life (QOL) and determine the correlation between QOL and speech recognition ability.

Study Design: Two authors independently searched PubMed, Medline, Scopus, and the Cumulative Index to Nursing and Allied Health Literature to identify studies reporting hearing-specific or cochlear implant (CI)-specific QOL outcomes before and after cochlear implantation, and studies reporting correlations between QOL and speech recognition after cochlear implantation. Data from the included articles were obtained independently by two authors. Standardized mean difference (SMD) for each measure and pooled effects were determined to assess improvement in QOL before and after cochlear implantation.

Results: From 14 articles with 679 CI patients who met the inclusion criteria, pooled analyses of all hearing-specific QOL measures revealed a very strong improvement in QOL after cochlear implantation (SMD = 1.77). Subset analysis of CI-specific QOL measures also showed very strong improvement (SMD = 1.69). Thirteen articles with 715 patients met the criteria to evaluate associations between QOL and speech recognition. Pooled analyses showed a low positive correlation between hearing-specific QOL and word recognition in quiet ($r = 0.213$), sentence recognition in quiet ($r = 0.241$), and sentence recognition in noise ($r = 0.238$). Subset analysis of CI-specific QOL showed similarly low positive correlations with word recognition in quiet ($r = 0.213$), word recognition in noise ($r = 0.241$), and sentence recognition in noise ($r = 0.255$).

Conclusions: Using hearing-specific and CI-specific measures of QOL, patients report significantly improved QOL after cochlear implantation. However, widely used clinical measures of speech recognition are poor predictors of patient-reported QOL with CIs.

Key Words: Cochlear implant, quality of life, speech recognition, word recognition, outcomes research.

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INTRODUCTION

Cochlear implantation is the standard treatment for severe-to-profound bilateral sensorineural hearing loss. Over 500,000 cochlear implants (CIs) have been implanted worldwide, with this number expected to rise with an aging population and expanding indications.^{1,2} With rising healthcare costs, increased focus has been

placed on comprehensive assessments of functional outcomes to ensure that procedures such as cochlear implantation are having a significant positive impact on patients' lives.³

Open-set word and sentence recognition are widely considered the standard CI outcome measures.⁴ However, speech recognition alone does not adequately represent the complex communication and other experiences that patients encounter on a daily basis. There is also a lack of consensus in the published literature about how accurately improvements in speech recognition scores represent the full impact of cochlear implantation on an individual's life.⁵⁻⁷ Cochlear implantation likely impacts an individual's quality of life (QOL) beyond speech recognition ability alone. Given that assessments of word and sentence recognition are the widely accepted standard outcome measures, it is of great importance to determine the extent to which QOL, as measured through patient-reported outcome measures (PROMs), correlates with speech recognition abilities.

Health-related QOL is the patients' perceived mental and physical health status that encompasses many aspects of their life. The Centers for Medicare and Medicaid Services Quality Strategy report has targeted QOL

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PRISMA 2009 Flow Diagram

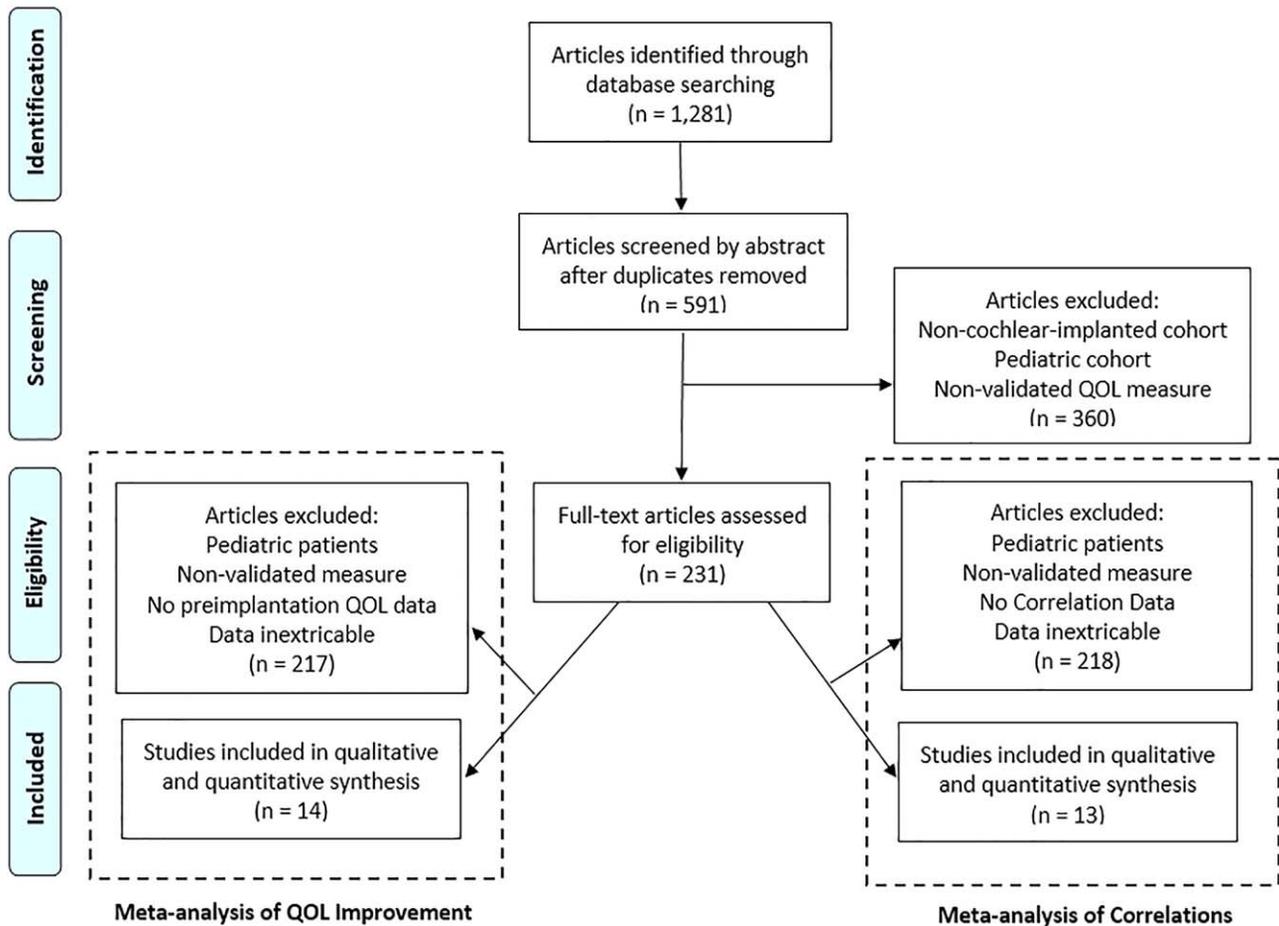


Fig. 1. Literature review process utilizing the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) search method. The flowchart details the methods used to select articles for inclusion in the meta-analysis of quality-of-life (QOL) improvement and meta-analysis of correlations. Four articles satisfied criteria for both meta-analyses. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

improvement as a primary outcome measure.⁸ Although several studies have evaluated QOL in the adult CI population, all have included relatively small numbers of patients from single institutions. To address these gaps, the current study reports the results of a meta-analysis that collates hearing-specific and CI-specific QOL measures to better understand the impact of cochlear implantation on individuals' QOL. A second meta-analysis reviewed associations among various measures of speech recognition and QOL.

MATERIALS AND METHODS

Literature Search

Search was performed following the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA)

statement.⁹ Two authors independently searched the PubMed, Scopus, and Ovid/MEDLINE databases in June 2016 for the following search terms: "cochlear implant" or "cochlear implantation" and "quality of life." This resulted in 591 unique articles that were reviewed by abstract for inclusion and exclusion criteria (Fig. 1). After review by abstract, 231 articles underwent full-text review for inclusion. These articles were included in either the meta-analysis of QOL improvement or the meta-analysis of correlations (four articles satisfied criteria for both). Disagreements regarding the inclusion of a study were mediated with a third author to reach a mutual consensus. As best as possible, articles were also reviewed to ensure that overlapping study populations were not included. All included subjects were CI candidates with bilateral severe to profound sensorineural hearing loss. When adding "patient reported outcome measures" to the search terms, no additional articles met inclusion criteria.

Case reports, letters to the editor, abstracts, articles not published or translated into English, and book chapters were excluded. No date range limitations were used. Studies with pediatric patients (less than 18 years old) in the study cohort were excluded. Studies using QOL PROMs translated to languages other than their native English format were included.

This study analyzed either hearing-specific or CI-specific PROMs that assessed the impact of cochlear implantation on QOL. Therefore, studies were excluded that used general health QOL instruments, such as the Health Utility Index (HUI-3)¹⁰ or Short Form-36 (SF-36),¹¹ which were not validated on individuals with hearing loss. These general health QOL instruments were included in a previous meta-analysis by our group.¹² We defined hearing-specific QOL PROMs as those instruments that focus on how hearing loss influences a patient's well-being, but have not been validated in the CI population. CI-specific PROMs are those that have been specifically created and validated for CI users.

Data Extraction

Articles selected for meta-analysis of QOL improvement met the following inclusion criteria: collection of either hearing-specific or CI-specific PROM data in an adult CI cohort before and after CI; sample size, mean, and standard deviation available for QOL PROM data; and postimplantation follow-up of at least 3 months. Data from the included articles were obtained independently from two authors including author, year of publication, number of patients, patient demographics, speech recognition scores, and QOL PROM data obtained pre- and postimplantation (mean and standard deviation).

Articles selected for meta-analysis of correlations between speech recognition and QOL PROMs met the following inclusion criteria: correlation of speech recognition scores versus either hearing-specific or CI-specific PROM data in an adult cohort after CI; sample size and Spearman or Pearson correlation values available; and follow-up of at least 3 months. Data from the included articles were obtained independently from two authors including author, year of publication, number of patients, patient demographics, speech recognition scores, and correlation values. Reporting of pre- and postimplantation QOL measures were not required for the meta-analysis of correlations, as we were evaluating correlations between speech recognition abilities and QOL at the latest time point following implantation.

Data reported in graphical plots were not extracted for meta-analysis unless numerical points were available and verifiable. We attempted to obtain complete details of published results from authors in the event of incomplete data to allow inclusion of their study. PROMs that use a reverse scale (lower scores represent a better QOL) had values multiplied by -1 for analysis. If the study followed patients after sequential implantation, only data obtained after the first implantation were included.

Statistical Methods: Meta-analysis of QOL Improvement

Meta-analysis evaluating the impact of CI on QOL with a continuous measure (comparison of means and standard deviations between pre- and postimplantation) was performed with Cochrane Review Manager version 5.3 (Nordic Cochrane Centre, Cochrane Collaboration, Copenhagen, Denmark). For this analysis, the null hypothesis was not different between pre and postimplantation QOL using hearing-specific or CI-specific PROMs. Both the fixed-effects model and the random-effects

model were used in this study. Under the fixed-effects model, it is assumed that all studies come from a common population and that the effect size (standardized mean difference) is not significantly different among the different studies. This assumption is tested by the heterogeneity test or I^2 statistic. If this test yields a low probability value ($P < .05$), then the fixed-effects model is likely invalid. In this case, the random-effects model is more appropriate, in which both the random variation within the studies and the variation between the studies are incorporated. Under the random-effects model, the true effects are assumed to vary between studies, and the summary effect is the weighted average of the effects reported in the different studies.¹³ The random-effects model provides a more conservative estimate (i.e., with a wider confidence interval), but the results from the two models typically agree when there is no heterogeneity. For the current analyses, the random-effects model was the preferred model when heterogeneity was present. Additionally, Sterne and Egger tests were performed for assessment of risk of publication bias.^{14,15} For this test, a low probability indicates a high likelihood that included articles were more likely to be published as their results were statistically significant.

Effect size is represented by standardized mean difference (SMD), a unitless numerical value also known as Cohen's d , which assesses the magnitude and certainty of benefit.^{16,17} Positive values indicate the treatment has a positive effect on outcome measures with the following thresholds for subjective interpretation being suggested by Cohen: 0.2 = small effect, 0.5 = medium effect, and 0.8 = large effect.¹⁶ The total SMD with 95% confidence interval is given for both the fixed-effects model and the random-effects model. Data are presented as SMD (95% confidence interval).

Statistical Methods: Meta-analysis of Subdomains From the Nijmegen Cochlear Implant Questionnaire

For subdomain analysis, only studies that used the Nijmegen Cochlear Implant Questionnaire (NCIQ)¹⁸ met inclusion criteria. Each study's sample data were combined, with the weighted mean and weighted standard deviation determined. Differences were noted using the variable delta (Δ). Preimplantation and postimplantation pooled means of each subdomain were compared using a comparison of weighted means test through the program MedCalc (MedCalc Software, Ostend, Belgium).

Statistical Methods: Meta-analysis of Correlations

A meta-analysis of correlations was performed for correlations between speech recognition and QOL PROMs after cochlear implantation. The program MedCalc 16.8.4 lists the results of the individual studies included in the meta-analysis, number of cases, and the mean correlation coefficient with the 95% confidence interval. These data were used to construct forest plots using Microsoft Excel (Microsoft Corp., Redmond, WA). The pooled correlation value with 95% confidence interval is given for either the fixed-effects model or the random-effects model. Model selection was performed as described in an earlier section. Each study was weighted according to the number of included patients. 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.¹⁹ Under the random-effects model, the heterogeneity statistic is incorporated to calculate the summary

TABLE I.
Studies Included in Meta-analysis of QOL Improvement

Article	Level of Evidence	Patient Age		Follow-up Period, mo
		Mean ± SD (Range)	Male %/Female %	
Damen 2007 ³³	3	49.6 ± 10.9	54/46	≥12
Hawthorne 2004 ⁴⁶	4	49 ± 13	47/53	6
Klop 2008 ³⁷	4	54.7 ± 15.7	34/66	12
Knopke 2016 ⁴⁷	4	82.9 ± 2.7	NA	6
Krabbe 2000 ³⁰	4	51 ± 16	47/53	≥12
Mo 2005 ³⁴	4	57.6 ± 14.5 (28–82)	44/56	12
Mosnier 2015 ⁴⁸	4	72 (65–85)	NA	12
Olze 2011 ⁴⁹	4	51.7 ± 16.9 (19–77)	27/73	≥6
Ottaviani 2016 ³⁸	4	50 ± 16 (26–76)	46/54	≥6
Park 2011 ²⁷	4	56 ± 15	39/61	12
Sanchez-Cuadrado 2015 ²⁵	4	60 (24–85)	46/54	≥6
Tavora-Vieira 2015 ⁵⁰	4	53.8 ± 11.6	46/54	24
van Dijkhuizen 2011 ³⁹	4	39 (20–62)	52/48	12
Vermeire 2005 ²⁸	4	58	NA	≥4

QOL = quality of life; SD = standard deviation.

correlation coefficient.²⁰ For this analysis, the null hypothesis was that speech recognition ability and QOL following cochlear implantation are not correlated. The following thresholds were used for subjective assessment of correlation values (*r*): 0 to 0.3, negligible; 0.3 to 0.5, low; 0.5 to 0.7, medium; 0.7 to 0.9, high; 0.9 to 1.0, very high.^{21,22}

RESULTS

Meta-analysis of QOL Improvement

Fourteen articles met the inclusion criteria for this analysis (Table I).^{5,7,23–34} Although 37 articles had pre- and postimplantation data, 23 articles did not have extricable and complete data (sample size, mean, or standard deviation). A total of 697 subjects were included in the analysis. Of 510 patients identified by sex, 42% were male and 58% were female. The mean ages of patients for individual studies ranged from 32.0 to 82.9 years.

Sterne and Egger testing ($P < .000001$) suggested a relationship between the sample size of these studies and their effect sizes indicating a high likelihood of publication bias. These data were significantly heterogeneous ($I^2 = 92\%$, $P < .00001$). Thus, meta-analysis was performed with a random-effects model, including the subset analyses of CI-specific measures ($I^2 = 95\%$, $P < .00001$) and hearing-specific measures ($I^2 = 84\%$, $P < .00001$), which had similarly high heterogeneity.

Overall, a very large improvement in QOL from pre- to postimplantation was found when combining hearing-specific and CI-specific QOL data (SMD = 1.77 [1.28 to 2.26]) (Fig. 2). Similar significant improvements were found when separately evaluating hearing-specific QOL (SMD = 1.82 [0.81 to 2.83]) and CI-specific QOL (SMD = 1.69 [1.24 to 2.14]). A negligible association was found between date of article publication and improvement in QOL.

The two studies in our analysis with published subdomains of Hearing Handicap Inventory in Adults³⁵/Elderly³⁶ (HHIA/HHIE) improvement (emotional and social) showed similar improvements in both subdomains.^{27,28} These subdomains of the HHIE/HHIA gauge the emotional morbidity and social interaction function associated with hearing loss, respectively.³⁶ No other measures in the current analysis included published domain or subdomain scores except for the NCIQ (discussed in a later section).

Meta-analysis of NCIQ Subdomains

Nine studies had published subdomain scores of the NCIQ before and after cochlear implantation, from which a meta-analysis of the NCIQ subdomain scores was performed.^{25,30,33,37–39} All subdomains showed improvement in QOL after implantation ($P < .0001$), although a wide range of improvements was observed (from largest to smallest): Basic Sound Processing ($\Delta = 52.7$), Advanced Sound Processing ($\Delta = 39.7$), Activity ($\Delta = 30.3$), Social ($\Delta = 24.8$), Speech Production ($\Delta = 23.6$), and Self-esteem ($\Delta = 22.2$).

Meta-analysis of Correlations

After applying inclusion and exclusion criteria, 13 articles were included in this analysis (Table II).^{5–7,23–29,31–33} From the 13 articles, 715 patients were included. Of 553 patients identified by sex, 42% were male and 58% were female. The mean ages of patients for individual studies ranged from 40.0 to 67.0 years.

Pooled correlation values were low between hearing-specific QOL and speech recognition scores and between CI-specific QOL and speech recognition scores (Fig. 3, Table III). When pooling all QOL PROMs, negligible positive correlations with QOL were observed with

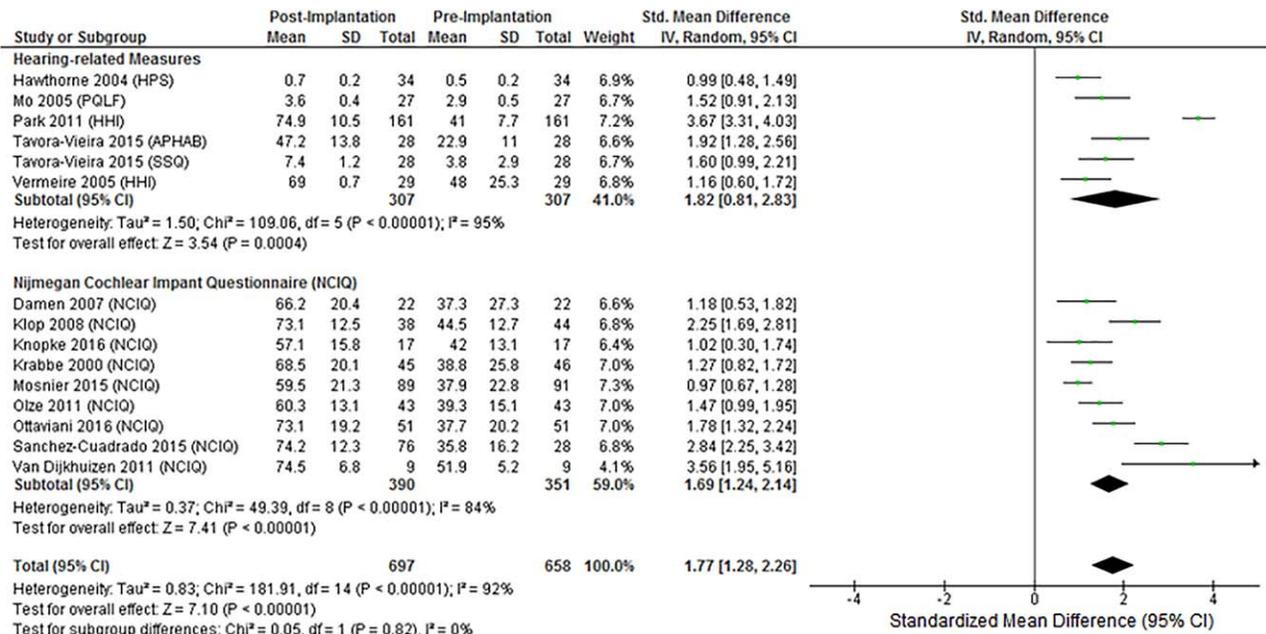


Fig. 2. Forest plot of PROMs including subset analysis of hearing-specific and cochlear implant-specific QOL PROMs. Cochlear implant-specific QOL PROMs included only the NCIQ, as only this PROM met inclusion criteria for this subset analysis. APHAB = Abbreviated Profile of Hearing Aid Benefit; CI = confidence interval; HHI = Hearing Handicap Inventory; HPS = Hearing Participation Scale; IV = inverse variance; NCIQ = Nijmegen Cochlear Implant Questionnaire; PQLF = Patient Quality of Life Form; PROMs = patient-reported outcome measurement studies; QOL = quality of life; SD = standard deviation; SSQ = Speech, Spatial, and Qualities of Hearing Questionnaire.

word recognition in quiet ($r = 0.239$ [0.166 to 0.309]), sentence recognition in quiet ($r = 0.219$ [0.118 to 0.316]), and sentence recognition in noise ($r = 0.238$ [-0.054 to 0.493]). Subset analysis of hearing-specific QOL revealed low correlations with word recognition in quiet ($r = 0.276$ [0.142 to 0.367]) and sentence recognition in quiet ($r = 0.204$ [0.070 to 0.330]); only one study met criteria for analysis correlating hearing-specific QOL and sentence recognition in noise, so this subset analysis could not be performed. Subset analysis of CI-specific QOL revealed low correlations with QOL and word recognition in quiet ($r = 0.213$ [0.117 to 0.304]), sentence recognition in quiet ($r = 0.241$ [0.083 to 0.386]), and sentence recognition in noise ($r = 0.255$ [0.078 to 0.537]).

Speech, Spatial, and Qualities of Hearing Scale

Two studies utilized the Speech, Spatial, and Quality (SSQ) PROM.^{3,18} Capretta et al.⁵ found an overall low correlation of SSQ with word recognition in quiet ($r = 0.34$) and negligible correlation with sentence recognition in quiet ($r = 0.17$). In evaluating the individual domains of the SSQ, Capretta et al.⁵ found a medium correlation in the Speech domain with speech recognition ability (word recognition in quiet, $r = 0.56$; sentence recognition in quiet, $r = 0.61$). However, correlations between the Spatial and Quality domains and word and sentence recognition in quiet were negligible or low (0.09, 0.13; 0.33, 0.11, respectively). The other study utilizing the SSQ²⁶ found an overall medium correlation of the SSQ and word recognition in quiet ($r = 0.52$) with individual correlations in the Speech, Spatial, and Quality domains of 0.59, 0.483, and 0.516, respectively.²⁶

Satisfaction With Amplification in Daily Life

Granco et al.⁶ found a medium correlation ($r = 0.69$ [0.196 to 0.906]) between the Satisfaction with Amplification in Daily Life (SADL)⁴⁰ PROM and word recognition in quiet. Medium to high correlations with word recognition in quiet were found in the SADL subdomains of Positive Effect ($r = 0.71$) and Personal Image ($r = 0.50$), which includes hearing performance, personal satisfaction, and social interaction benefit.⁴⁰ The SADL subdomains of Service and Cost ($r = 0.39$) and Negative Effects ($r = 0.40$) showed low correlations with word recognition in quiet. The SADL had overall negligible correlations with sentence recognition in quiet ($r = 0.126$) and sentence recognition in noise ($r = 0.116$).

Hearing Handicap Inventory in Adults/Elderly

Four studies utilized the HHIA/HHIE to correlate QOL with speech recognition scores. All 4 studies of the HHIA/HHIE found a negligible correlations either with word recognition in quiet ($r = 0.05, 0.20, 0.21$) or sentence recognition in quiet ($r = 0.21, 0.22$). One study published domain correlations of the HHIA/HHIE (emotional and social). Within these domains, negligible correlations were observed with word recognition in quiet and sentence recognition in quiet ($r = 0.18, 0.26$).

Nijmegen Cochlear Implant Questionnaire

Studies using the Nijmegen Cochlear Implant Questionnaire (NCIQ) reported negligible correlations of QOL with word recognition in quiet (-0.08 to 0.29), negligible to low correlations with sentence recognition in quiet

TABLE II.
Studies Included in Meta-analysis of Correlations

Article	Level of Evidence	Speech Recognition Task	Patient Age		
			Mean ± SD (Range)	Male %/Female %	Follow-up Period (Months)
Calvino 2015 ²⁴	4	NS	52.8 ± 14.0	45/55	≥6
Capretta 2016 ⁵	4	Words in Quiet: CID, Sentences in Quiet: AzBio, Sentences in Noise: AzBio	67 (53–88)	35/65	≥9
Cohen 2004 ²³	4	Sentences in Noise: CID/HINT	67.0 ± 8.5	63/37	≥12
Damen 2007 ³³	3	Words in Quiet: Antwerp-Nijmegen, Words in Quiet: NVA	49.6 ± 10.9	54/46	≥12
Fuller 2012 ²⁶	4	NS	65.6 ± 11.9	40/60	≥12
Granco 2013 ⁶	4	Words in Quiet: NS, Sentences in Quiet: HINT (quiet), Sentences in Noise: HINT	40 (19–59)	NA	≥12
Maillet 1995 ³²	4	NS	(30 - 80)	NA	24
Olze 2012 ⁷	4	Words in Quiet: Freiburg monosyllable, Sentences in Quiet: HSM	58.4 ± 17.0	36/64	≥6
Olze 2012 ³¹	4	Words in Quiet: Freiburg monosyllable, Sentences in Noise: HSM, Oldenburg	53.8 ± 14.0	28/72	≥6
Park 2011 ²⁷	4	Sentences in Quiet: HINT (quiet)	56 ± 15	39/61	12
Sanchez-Cuadrado 2015 ²⁵	4	NS	60 (24–85)	46/54	≥6
Vermeire 2005 ²⁸	4	Words in Quiet: NVA	58	NA	≥4
Vermeire 2006 ²⁹	4	Words in Quiet: NVA	62 (40–78)	NA	≥3

CID = Central Institute for the Deaf; HINT = Hearing in Noise Test; HSM = Hochmair Schulz Moser; NS = not specified; NVA = Dutch Audiological Society; SD = standard deviation.

(0.173 to 0.42), and negligible to medium correlations with sentence recognition in noise (−0.11 to 0.56). When investigating the NCIQ subdomains of QOL, Olze et al.^{7,49} found negligible or low correlations of QOL

with word recognition in quiet (−0.34 to 0.30) and sentence recognition in quiet (−0.29 to 0.24). Capretta et al.⁵ found a medium correlation with word recognition in quiet and the Advanced Sound Perception subdomain

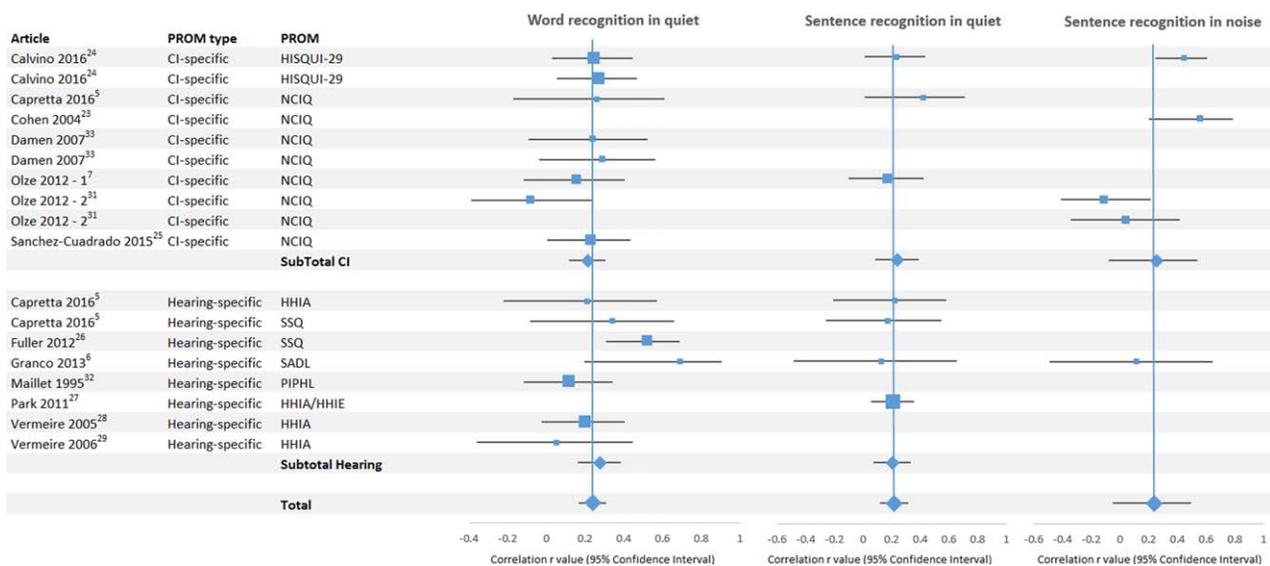


Fig. 3. Forest plots pertaining to meta-analysis of correlations for articles reporting CI-specific (top) and hearing-specific (bottom) QOL measures. Pooled correlations are represented by diamonds. CI = cochlear implant; HHIA = Hearing Handicap Inventory in Adults; HHIE = Hearing Handicap Inventory in the Elderly; HISQUI-29 = Hearing Implant Sound Quality Index; NCIQ = Nijmegen Cochlear Implant Questionnaire; PIPHL = Performance Inventory for Profound Hearing Loss; PROM = patient-reported outcome measure; QOL = quality of life; SADL = Satisfaction With Amplification in Daily Life; SSQ = Speech, Spatial, and Qualities of Hearing Questionnaire. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

TABLE III.
Meta-analysis of Correlations Results

	<i>r</i>	95% CI	<i>I</i> ²	<i>P</i>
Subtotal: CI-specific QOL				
Word recognition in quiet	0.213	0.117 to 0.304	0.00%	.7679
Sentence recognition in quiet	0.241	0.0830 to 0.386	0.00%	.5840
Sentence recognition in noise	0.255	−0.0783 to 0.537	75.61%	.0064
Subtotal: Hearing-specific QOL				
Word recognition in quiet	0.276	0.142 to 0.367	48.09%	.0726
Sentence recognition in quiet	0.204	0.0701 to 0.330	0.00%	.9925
Sentence recognition in noise	NA	NA	NA	NA
Total				
Word recognition in quiet	0.239	0.166 to 0.309	14.58%	.2902
Sentence recognition in quiet	0.219	0.118 to 0.316	0.00%	.9716
Sentence recognition in noise	0.238	−0.0535 to 0.493	68.19%	.0135

CI = confidence interval; NA = not available; QOL = quality of life.

of QOL ($r = 0.55$), but negligible or low correlations with word recognition in quiet and sentence recognition in quiet and the other subdomains of QOL (0.11 to 0.47).

DISCUSSION

We report the first comprehensive meta-analysis of QOL improvements in an adult CI population using the standardized PRISMA methods. This is also the first meta-analysis of correlations between CI patient self-report QOL and speech recognition scores. Two previous meta-analyses of QOL PROMs after cochlear implantation have been reported, but neither performed a meta-analysis of correlations of QOL and speech recognition.^{41,42} Gaylor et al.⁴¹ included many studies that reported preimplantation QOL using a retrospective question format, that is, asking patients after implantation about their health status prior to implantation. This retrospective approach to data gathering is limited by recall bias; therefore, studies that included data gathered in this manner were excluded in the current analysis. In contrast to Gaylor et al., we did not include the Glasgow Benefit Index⁴³ in our meta-analysis of QOL improvement, as this measure requires patients to subjectively assess their improvement following implantation.⁴³ The review by Loeffler et al.⁴² included qualitative analyses of QOL improvement and correlations and did not perform a quantitative analysis.

In the current study, we found that patients reported significant improvements in QOL following cochlear implantation when measured using hearing-specific or CI-specific QOL PROMs. Although analysis of the published literature showed heterogeneity in outcomes, as noted by the I^2 values, a consistent improvement in QOL was seen. This is in contrast to relatively modest improvements in QOL reported (SMD = 0.61)¹² when using general health-related QOL measures, such as HUI-3 and SF-36, which do not typically include questions that assess communication abilities and focus on subdomains that may be unrelated to cochlear implantation. Given that economic benefits of CIs are

often determined using general health-related QOL measures not validated in the CI population, these QOL instruments are likely to greatly underestimate the quality-adjusted life year and other economic impacts of cochlear implantation.

The NCIQ was the only validated CI-specific QOL PROM that reported individual domain data. Evaluation of the domains revealed that Basic Sound Processing and Advanced Sound Processing were the major drivers of QOL improvement with Self-esteem, Speech Production, and Social domains having much less impact. Two factors may explain these differences. First, cochlear implantation may simply have a greater impact on sound processing than other nonhearing domains. Second, the questions in the QOL instrument in the other domains may not reflect the concerns that contribute most to QOL in CI patients. To date, no CI-specific QOL instrument has been developed using modern standards as developed by the National Institutes of Health's (NIH) Patient Reported Outcomes Measurement Information System (PROMIS), including the involvement of patients in item development (as discussed in a later section). Therefore, current QOL instruments may not be sensitive to concerns most important to CI patients.

In the analyzed articles, speech recognition was measured using words in quiet, sentences in quiet, and sentences in noise. A narrow range of low correlations was consistently found between these speech recognition categories and QOL ($r = 0.20$ – 0.26). Correlation values < 0.3 are considered negligible by most statisticians.^{21,22} The coefficient of determination (R^2) provides a means to understand the proportion of variance explained by the independent variable (speech recognition). In this study, the corresponding R^2 range of 0.048 to 0.058 signifies that only 4.8% to 5.8% of the variance of patient-reported QOL can be attributed to speech recognition scores, with the vast majority of the variation in QOL unexplained. Unfortunately, only a small number of published studies reported domain-specific correlation data, which precluded subset analysis. The few

studies that reported communication-related domain data showed medium correlations with speech recognition ($r = 0.55\text{--}0.61$).

Speech recognition ability is the gold standard and required reporting outcome for cochlear implantation despite the well-established weak association of speech recognition and patient self-reported benefits and QOL with CIs.⁴⁴ Although important and easily measured in a clinic setting, how a person listens, communicates, and interacts with his or her environment is far more complex than currently available speech recognition tasks in which patients repeat lists of words or sentences, even tasks that include background noise. Additionally, individual dependent factors not limited to age, duration of deafness, preoperative outcome expectations, and functional ability may impact QOL in ways unrelated to results from speech recognition testing. Patient-reported QOL instruments having become increasingly important in assessing the impact of an intervention in a patient's life. Recently, the Centers for Medicare and Medicaid Services identified QOL improvement as a primary outcome measure, and the Food and Drug Administration (FDA) now requires PROMs to be included in all clinical trials where an intervention seeks FDA approval.^{8,45} These measures are especially important when the intervention does not alter quantity of life (i.e., survival), but rather QOL. In such situations, the use of PROMs allows the population of interest to provide the individual's perspective of their ability or functional level beyond standard clinical metrics.

The meta-analysis results provide further support for the need for more regular use of QOL instruments to assess CI outcomes. Although significant improvements in QOL were reported after cochlear implantation, all of the instruments used were either not specifically developed for CI patients or do not meet the rigorous development and reporting standards, as described in the PROMIS guidelines.^{44,45} The need for a CI-specific QOL instrument that meets these standards has been recognized in the Minimal Reporting Standards for Cochlear Implantation of the American Academy of Otolaryngology–Head and Neck Surgery and the 2017 to 2021 Strategic Plan of the National Institute on Deafness and Other Communication Disorders of the NIH. One of the most significant limitations in current CI-specific QOL instruments is the lack of CI patient involvement in developing the instruments' item banks. Using focus groups of CI patients to develop the item bank provides a better understanding of the factors that significantly impact CI patient QOL. This may greatly alter our understanding of the health utility of cochlear implantation, and specific questions such as the impact of a second implant and an implant combined with a hearing aid.

Our study is limited by biases inherent to all systematic reviews, as authors and journals are biased to publish statistically significant findings. In addition, the speech recognition tasks varied widely among the included studies. We attempted to minimize the effect of these differences by performing separate analyses for word recognition in quiet, sentence recognition in quiet,

and sentence recognition in noise. These study differences are common in meta-analyses, and error related to these differences is accounted for through the use of pooled estimates.

Individual patient data such as age, sex, hearing, and CI-related information were not adequately reported to allow for a multivariable analysis. The impact of patient follow-up period on QOL improvement could not be determined, primarily due to the way the data were reported. In addition, the results of this study are limited to the impact of unilateral implantation on QOL, because we did not include results with sequential implantation. With respect to correlations, many studies excluded from our analysis stated that no significant correlations were found, but did not cite numerical data; therefore, these studies could not be included in our analysis. Many studies were also excluded from our analysis due to incomplete statistical data, particularly standard deviations.

CONCLUSION

A meta-analysis of QOL improvement showed a very large positive effect of cochlear implantation on QOL using hearing-specific or CI-specific PROMs. However, a meta-analysis of correlations showed negligible pooled correlations between speech recognition scores and hearing-specific or CI-specific QOL. Systematic assessment of the published literature also revealed that no CI-specific QOL PROMs meet modern development and reporting standards.

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