JAMA Otolaryngology–Head & Neck Surgery | Original Investigation

Conditional Minimal Detectable Change for the Cochlear Implant Quality of Life-35 Profile Associated With Improved Functional Abilities 12 Months After Cochlear Implantation

Theodore R. McRackan, MD, MSCR; Bryant A. Seamon, PT, DPT, PhD; Christian M. Shannon, BS; Brittany N. Hand, PhD, OTR/L; Craig A. Velozo, PhD, OTR/L; Judy R. Dubno, PhD; The Cochlear Implant Quality of Life Development Consortium

Supplemental content

IMPORTANCE It is essential to measure an individual patient's baseline and follow-up abilities to demonstrate changes in clinical outcomes over time. Inherent in this strategy is interpreting whether the measured change is clinically significant and beyond measurement error. Conditional minimal detectable change (cMDC) values are widely used in many disciplines but have rarely been established for outcome measures in otolaryngology or hearing research, and never in cochlear implantation.

OBJECTIVE To determine cMDC values for the Cochlear Implant Quality of Life-35 (CIQOL-35) Profile instrument to enhance our understanding of the initial and ongoing changes in functional abilities from cochlear implants (CIs).

DESIGN, SETTING, AND PARTICIPANTS Item response theory analyses of responses from a multi-institutional cohort of 705 CI users at a tertiary CI center were used to derive standard error (SE) values for each possible CIQOL-35 domain score. Using an iterative approach, these SE values were used to calculate cMDC values for every possible pre-CI and post-CI domain score combination. We then compared pre-CI to 12-month post-CI CIQOL-35 domains scores in an independent cohort of 65 adult CI users to determine whether the measured change exceeded error to be clinically significant. The analysis took place on December 14, 2022.

INTERVENTIONS The CIQOL-35 Profile instrument and cochlear implantation.

RESULTS The cMDC values were smaller for the communication domain, and global measure and cMDC values for all domains were larger at the extremes of the measurement scale. Overall, 60 CI users (92.3%) demonstrated improvement beyond cMDC at 12 months post-CI for at least 1 CIQOL-35 domain, and no patients' scores declined beyond cMDC for any domain. The percentage of CI users demonstrating improvement beyond cMDC varied by domain, with communication (53 [81.5%]) showing the largest number of CI users improving, followed by global (42 [64.6%]) and entertainment (40 [60.9%]). In general, CI users who demonstrated improvement in CIQOL-35 domains had greater improvement in speech recognition scores than patients who did not, but the strength and significance of these associations greatly varied by domain and speech material.

CONCLUSIONS AND RELEVANCE This multistep cohort study found that cMDC values for the CIQOL-35 Profile provided personalized thresholds for detecting real changes in patient self-reported functional abilities over time across multiple domains, which may inform clinical decision-making. Moreover, these longitudinal results reveal the domains with more or less improvement, which may aid in patient counseling.

JAMA Otolaryngol Head Neck Surg. doi:10.1001/jamaoto.2023.1090
Published online June 15, 2023.

Author Affiliations: Author affiliations are listed at the end of this article.

Group Information: The members of the Cochlear Implant Quality of Life Development Consortium appear at the end of the article.

Corresponding Author: Theodore R. McRackan, MD, MSCR, Medical University of South Carolina, 135 Rutledge Ave, MSC 550, Charleston, SC 29425 (mcrackan@musc.edu).

In longitudinal research studies and when monitoring changes in clinical outcomes, it is essential to measure an individual patient's baseline and follow-up abilities to demonstrate changes over time. Inherent in this assessment strategy is the ability to determine whether the change in the outcome of interest exceeds measurement error and is clinically significant, which is imperative for clinicians to make informed assessments and collaborate with patients, based on their goals, to establish or modify a plan of care. Clinically important outcome value (CIOV) is the accepted term for describing clinically meaningful improvement in patient outcomes. These CIOVs include values that consider the measurement limitations of outcome measures, termed minimal detectable change (MDC) and patient-centered approaches, termed minimally clinically important difference (MCID).[1-3] Clinically important outcome values are widely used in many disciplines, but they have rarely to our knowledge been established for patient-reported outcome measures (PROMs) used in otolaryngology and hearing research, and never in cochlear implantation.[4-6]

Without availability of CIOV thresholds, researchers and clinicians must solely rely on statistically determined differences (ie, *P* values) to detect a change in PROM scores.[7-11] This approach relies on group-level data analyses that are dependent on sample size and cannot be applied to an individual patient to monitor change.[2,12,13] Therefore, determining CIOVs for PROMs, and other widely used outcome measures, is essential for interpreting the results of a research study and when discussing clinical decisions and care plans with individual patients.

In cochlear implant (CI) research and clinical practice, patients' baseline (pre-CI) functional abilities are measured and then assessed at regular intervals after cochlear implantation.[14] At each follow-up, clinicians review progress to determine whether a clinically significant improvement has been achieved relative to baseline and between follow-up intervals. The Cochlear Implant Quality of Life-35 (CIQOL-35) Profile is a PROM that evaluates functional abilities across 6 domains (communication, emotional, entertainment, environmental, listening effort, social) as well as a global assessment with scores ranging from 0 (low) to 100 (high). It was created and validated using a thorough mixed-methods approach[15,16] that included a multi-institution design, stakeholder engagement, and advanced psychometric analyses.[17-24] These methods, which, to our knowledge have never been used before in CI outcome research, incorporated item response theory (IRT), an advanced psychometric modeling technique with many potential measurement advantages compared with traditional test-level psychometrics used in developing legacy PROMs.[25-27]

One major advantage of IRT is that it provides the level of precision, quantified using standard error (SE), for every possible outcome score. In contrast, PROMs developed using classic test theory derive only a single measurement error value that is applied for all scores. This difference is extremely important because SE is not uniform for all scores (0-100) and is known to be lower in midrange scores and larger at the extremes.[28,29] Therefore, application of a single error value, or single MDC value, may result in interpretation errors. These include misrepresenting small changes at the extremes of the range (eg, near 0 or near 100) as meaningful when they are within measurement error or incorrectly interpreting smaller changes in the midrange as insignificant when they are beyond the measurement error. Fortunately, the value known as conditional MDC (cMDC) has been developed to account for this phenomenon, which personalizes the interpretation of changes in outcome scores and assists clinicians and individual patients in shared decision making.[30,31]

The purpose of the current study is 2-fold. First, we establish cMDC values for the CIQOL-35 Profile instrument from a large sample of adult CI users using methods novel to CIs, hearing research, and, more broadly, otolaryngology. Second, we apply these cMDC values to quantify the changes in self-reported functional abilities in an independent cohort of adult CI users before and 12 months after receiving a CI.

Key Points

Question Is the conditional minimal detectable change (cMDC) value an effective metric for monitoring self-reported functional abilities following cochlear implantation?

Findings In this multistep cohort study, we first established cMDC values for the Cochlear Implant Quality of Life-35 (CIQOL-35) Profile instrument. Next, we demonstrated that most patients report improved functional abilities 12 months after cochlear implantation, with patterns of improvement varying substantially across CIQOL-35 domains.

Meaning Establishing clinically important outcome values (CIOVs) such as the cMDC may provide a means to quantify the effect of medical interventions on patients' lives.

Methods

Calculating cMDC Thresholds for the CIQOL-35 Profile Instrument

Institutional review board approval was obtained through Medical University of South Carolina. Informed consent was not required to be obtained because the study was classified as minimal risk. The cMDC values were derived using an iterative process. First, SE values were obtained for each possible score for each domain using IRT analyses from CIQOL-35 Profile responses of 705 CI users recruited through the 30-institution CIQOL Development Consortium.[25,32] Participants were (1) aged between 18 and 89 years (because individuals aged >89 years are considered a special population), (2) used a CI for 1 year or more, (3) had postlingual deafness, and (4) did not receive a CI for single-sided deafness or known retrocochlear pathologic findings. Details regarding the CIQOL-35 Profile instrument (items, response options, scoring) can be found in our previous publications[22,25] along with demographics and hearing history of this patient cohort.[18]

Next, cMDC thresholds for each possible combination of pre-CI and post-CI scores with a 95% confidence threshold were calculated using the following formula:[29,31]

$$cMDC = ([SE_{time\ 1}+SE_{time\ 2}]/2) \times 1.96 \times \sqrt{2}$$

Table 1. Conditional Minimal Detectable Change (cMDC) Values for CIQOL-35 Domains and Global Measure[a]

					Communication							
Prescore	0	8.61	14.22	17.91	20.78-74.14			76.95	80.26	84.47	90.78	100
Δ Needed to meet cMDC threshold	22.5	15.5	13.1	12.0	10.4			11.9	12.5	13.6	16.0	22.8
					Emotional							
Prescore	0	11.12	19.08		24.62-78.02					82.9	89.83	100
Δ Needed to meet cMDC threshold	29.2	21.4	18.7		16.6					18.1	20.7	28.7
					Entertainment							
Prescore	0	11.48	18.55		23.13-64.39			68.79	73.65	79.42	87.69	100
Δ Needed to meet cMDC threshold	33.7	23.4	20.0		18.1			19.3	19.8	21.0	24.2	34.2
					Environment							
Prescore	0	9.59	16.06		20.58-75.26					81.01	89.06	100
Δ Needed to meet cMDC threshold	27.6	19.9	17.4		16.3					18.4	21.0	28.3
					Listening effort							
Prescore	0	9.3	15.9		20.6-68.21				73.28	79.6	88.7	100
Δ Needed to meet cMDC threshold	26.1	19.1	16.8		15.5				17.0	18.3	20.7	27.0
					Social							
Prescore	0	10.28	17.62		27.24-76.72					82.1	89.6	100
Δ Needed to meet cMDC threshold	27.9	20.4	18.0		16.2					18.1	20.5	27.9
					Global							
Prescore	0	9.14	14.86	18.53	21.36	23.74-69.04	71.49	74.34	77.82	82.42	89.54	100
Δ Needed to meet cMDC threshold	24.5	16.5	13.8	12.7	12.0	10.7	12.1	12.6	13.4	14.7	17.6	25.2

Abbreviation: CIQOL-35, Cochlear Implant Quality of Life-35.

[a] The cMDC values are presented for each outcome score or range of outcome scores for all CIQOL-35 domains and global measure. To apply the cMDC values, identify a patient's baseline or prescore for a domain. Then, if the difference in the patient's follow-up score is larger (or smaller) than the cMDC value for the baseline score, then the change can be considered improved (or worsened).

The CIQOL-35 Profile has 5567 possible pre-CI to post-CI score combinations. We used a stepwise approach to reduce the number of cMDC values to improve the utility of cMDC thresholds in clinical settings.[29,31] First, we calculated the cMDC thresholds for each possible score combination. Second, we averaged the cMDC thresholds for each possible pre-CIQOL-35 score. This consolidated similar cMDC thresholds where the variation in cMDC was less than a 1-point change and would not be observable in practice. Third, we collapsed ranges of cMDC when the pre-CI and post-CI score had an SE of 1 or lower because differences in the cMDC are minimal (often <0.01) and are not likely to be observed clinically or communicated to patients. For example, communication domain scores of 36.77 and 38.21 had SE values of 3.04 and 3.05, with resulting mean cMDC values of 9.99 and 9.97, respectively. Final cMDC thresholds are presented in **Table 1**.

Applying cMDC Thresholds to a Prospective Patient Cohort

Calculated cMDC thresholds were used to determine change in an independent cohort of 65 adult CI patients at our CI center who met the same inclusion criteria as above. Participants were required to have both preoperative and 12-month postoperative CIQOL-35 Profile scores. In addition, speech recognition scores included CNC Monosyllabic Word Test words and AzBio sentences in quiet (AzBio Quiet) that were measured pre-CI using best aided condition with hearing aids (personal or clinic owned hearing aids) fitted to National Acoustics Laboratory-Revised Linear (NAL-RL) targets[33] and 12 months post-CI for the implanted ear. Speech recognition testing was performed in a sound-treated room in the sound field with speech presented at 60 dB sound pressure level (0 degrees azimuth). AzBio +10 dB signal-to-noise ratio (SNR) is routinely performed at our institution for any patient scoring 50% or higher on AzBio Quiet testing. However, pre-CI to post-CI comparisons for AzBio +10 dB SNR were not included in this analysis because few patients (n = 15) had pre-CI AzBio Quiet scores that met criteria.

The difference between pre-CI and 12-month post-CI scores for each domain and global measure of the CIQOL-35 Profile was calculated and compared to the cMDC thresholds to determine whether the CI users' change in score exceeded measurement error, or no change. Based on this, the cohort was stratified into 3 groups (positive change, negative change, no change) for each domain. Effect sizes (Cohen *d*) for average changes in word and sentence recognition scores (pre-CI to 12 months post-CI) for each group were calculated. Effect sizes were used to quantify differences in speech recognition changes between the CI users who demonstrated CIQOL-35 domain and global improvement and those who demonstrated no change. We excluded patients whose change declined beyond cMDC thresholds because of a small sample size. Effect sizes were calculated using SPSS statistical software (version 28, IBM Corp). An effect size of 0.2 to 0.49 was considered small; 0.5 to 0.79, medium; 0.8 to 1.29, large; and larger than 1.3, very large.[34] The analysis took place on December 14, 2022.

Results

cMDC Thresholds for the CIQOL-35 Profile Instrument

The cMDC thresholds for each domain and global measure are presented in Table 1. To apply and interpret these data, a patient's baseline score for a specific domain is identified from this table (eg, first row for communication). Then if the difference in a follow up score is larger (or smaller) than the cMDC threshold listed in the table (eg, second row for communication), the change is considered to exceed measurement error and can be interpreted as improvement (or decline). For example, if a patient has a baseline CIQOL-35 communication score of 20.8, then the follow-up score would need to be 31.2 (cMDC = 10.4) or higher to be a detectable change. There were 2 noticeable patterns in reported cMDC thresholds that followed the SE changes across the measurement scale. First, there were more cMDC threshold values reported at the extremes of the scale compared with the middle of the scale. This pattern was related to more error associated with extremes (eg, high and low scores) and less near the middle of the scale. The smaller SE near the middle of the scale facilitated collapsing of cMDC thresholds (eg, initial scores of 20.78-74.14 for communication each had a cMDC threshold of 10.4). Second, cMDC thresholds were larger at the extremes (eg, 22.5 and 22.8 for communication) and smaller toward the middle of the score range (eg, 10.4) and were larger in general for some domains vs others (eg, the communication and global domain cMDC thresholds were lower than others) measure. Once again, this pattern was related to more error associated with extreme scores and variability in error across domains.

CIQOL-35 Changes After Cochlear Implantation

We then applied the cMDC values to determine pre-CI to post-CI change in an independent cohort of 65 adult CI users. Participant demographic and hearing history data are displayed in **Table 2**. The CIQOL-35 and speech recognition outcome scores are displayed in **Table 3**. The distribution of CI users who demonstrated clinically meaningful improvement, no change, or decline of CIQOL-35 domain and global scores is displayed in the **Figure**. Overall, 60 (92.3%) patients demonstrated improvement in at least 1 CIQOL-35 domain and 12 (18.5%) patients demonstrated improvement for all CIQOL-35 domains. In contrast, 7 (10.8%) CI users had poorer function for at least 1 domain but 0 had declines in all domains. The communication domain had the largest percentage of CI users (n = 53; 81.5%) demonstrating improvement, followed by the global score (n = 42; 64.6%) and entertainment domain (n = 39; 60.0%). Importantly, the listening effort and social domains had equal or nearly equal percentage of CI users who demonstrated improvement compared with those who had no change in abilities.

Finally, we compared pre-CI to post-CI changes in speech recognition scores between patients who did and did not demonstrate CIQOL domain and global improvements (**Table 4**).

Table 2. Participant Demographic and Hearing History Data[a]

Characteristic	No. (%)
Sex	
Female	41 (63.1)
Male	24 (36.9)
Race	
Black	8 (12.3)
White	57 (87.7)
Ethnicity	
Not Hispanic or Latino	57 (87.7)
Hispanic or Latino	0
Unknown	8 (12.3)
Age at implantation, mean (SD), y	65.3 (15.9)
Duration of hearing loss, mean (SD), y	23.9 (15.3)
Pre-CI hearing aid use	
Yes	51 (78.5)
No	14 (21.5)

Abbreviation: CI, cochlear implant.

[a] Race and ethnicity data, duration of hearing loss, and pre-CI hearing aid use were self-reported. Hearing aid use was defined as using a hearing aid in the ear to be implanted for the majority of awake hours.

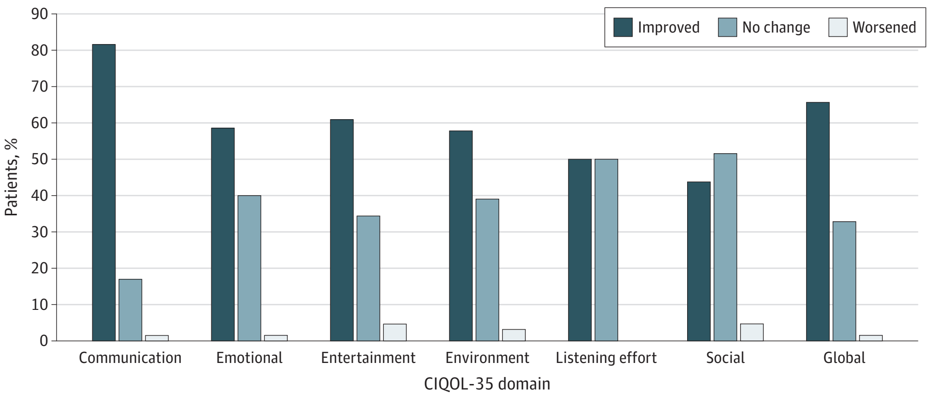
Table 3. Pre-CI and 12-month Post-CI CIQOL-35 and Speech Recognition Scores[a]

Variable	Pre-CI, Mean (SD)	12 mo post-CI, Mean (SD)
CIQOL-35 domains		
Communication	26.24 (11.59)	47.57 (13.48)
Emotional	41.17 (12.87)	61.00 (20.05)
Entertainment	31.32 (15.98)	54.74 (24.74)
Environment	29.57 (18.93)	55.09 (18.48)
Listening effort	19.54 (13.89)	39.45 (15.69)
Social	46.94 (20.55)	63.16 (20.75)
Global	33.90 (8.66)	51.26 (13.88)
Speech recognition scores		
CNC-phonemes	25.9 (22.4)	72.7 (20.1)
CNC-words (n = 64)	12.6 (15.7)	56.4 (22.8)
AzBio quiet	12.3 (16.1)	72.8 (23.0)
AzBio +10 dB SNR (n = 15)	11.8 (20.4)	56.3 (22.9)

Abbreviations: CI, cochlear implant; CIQOL-35, Cochlear Implant Quality of Life-35 Profile instrument; CNC, the Monosyllabic Word Test; SNR, signal-to-noise ratio.

[a] Scores were available for all patients other than where noted.

Figure. Percentage of CI Users Who Demonstrated Improvement, No Change, or Poorer CIQOL-35 Scores With Respect to the cMDC Values for Each Domain and Global Measure



CI Indicates cochlear implant; CIQOL-35, Cochlear Implant Quality of Life-35 Profile instrument; cMDC, conditional minimal detectable change.

Table 4. Comparison of Pre-CI to Post-CI Change in Speech Recognition Scores Based on Improvement (+), No Change (No Δ) Relative to cMDC Values[a]

CIQOL-35 domain	+/No Δ cMDC (n)	Δ CNC, mean (SD)	Effect size, *d* (95% CI)	Δ AzBio quiet, mean (SD)	Effect size, *d* (95% CI)
Communication	+ (53)	49.0 (21.4)	1.03 (0.36 to 1.71)	62.3 (25.5)	0.74 (0.09 to 1.41)
	No Δ (11)	26.2 (24.1)		42.4 (31.3)	
Emotional	+ (38)	47.4 (22.6)	0.25 (−0.25 to 0.75)	65.4 (25.6)	0.55 (0.04 to 1.06)
	No Δ (26)	41.4 (25.9)		50.6 (28.2)	
Entertainment	+ (39)	46.8 (26.5)	0.25 (−0.27 to 0.78)	61.3 (28.2)	0.19 (−0.34 to 0.71)
	No Δ (22)	40.6 (19.8)		56.1 (26.7)	
Environment	+ (37)	48.0 (26.8)	0.26 (−0.24 to 0.78)	60.1 (27.2)	0.06 (−0.45 to 0.57)
	No Δ (25)	41.5 (19.9)		58.4 (29.2)	
Listening effort	+ (32)	52.3 (20.1)	0.71 (0.21 to 1.22)	62.3 (25.8)	0.31 (−0.18 to 0.81)
	No Δ (32)	35.7 (25.6)		53.5 (29.9)	
Social	+ (28)	52.3 (25.1)	0.51 (−0.01 to 1.02)	63.0 (30.2)	0.20 (−0.30 to 0.71)
	No Δ (33)	40.4 (21.5)		57.5 (24.4)	
Global	+ (42)	51.9 (21.9)	0.93 (0.38 to 1.48)	63.1 (26.3)	0.49 (−0.04 to 1.02)
	No Δ (21)	31.1 (22.8)		49.7 (29.0)	

Abbreviations: CI, cochlear implant; CIQOL-35, Cochlear Implant Quality of Life-35; cMDC, conditional minimal detectable change; CNC, the Monosyllabic Word Test.

[a] 12-month CNC word scores were not available for 1 CI user who had a decrease in CIQOL-35 communication scores after cochlear implantation.

Overall, greater speech recognition improvement was associated with patients who demonstrated improvement in CIQOL scores beyond cMDC. However, the strength of these associations varied by domain and speech material. Greater word recognition improvement demonstrated stronger associations with CIQOL improvement category than sentence recognition. Specifically, patients who improved in the communication domain (d = 1.03; 95% CI, 0.36-1.71), listening effort domain (d = 0.71; 95% CI, 0.21-1.22), and global score (d = 0.93; 95% CI, 0.38-1.48) had greater improvement in word recognition. In contrast, patients who demonstrated improvement in the communication (d = 0.74; 95% CI, 0.09-1.41) and emotional (d = 0.55; 95% CI, 0.04-1.06) domains had only a medium association with sentence recognition improvement.

Discussion

The findings of this cohort study establish the psychometrically based CIOVs, termed cMDC, for the CIQOL-35 Profile instrument. Our innovative approach takes advantage of the advanced psychometric analyses used to develop the CIQOL-35 Profile to account for variability in precision along the score continuum. Given the known differences in measurement error at the extremes of the scale compared to the middle, cMDCs provide a more precise estimate of change for individual patients and avoids the misclassification or misinterpretation of changes in CIQOL-35 domain scores. Our approach to reduce the number of cMDC values for each domain strikes a balance between maximizing clinical utility and measurement rigor.[29,31] Specifically, it is not remotely feasible to apply the 5567 cMDCs calculated for all possible score combinations in current clinical practice. Therefore, collapsing values for score ranges with similar associated error greatly reduced the number of cMDC scores to 7 to 12 per domain, with a single cMDC value representing most of the possible outcome scores for all domains (Table 1). However, future technology-based solutions may provide the ability to apply the full range of cMDC thresholds to further enhance measurement precision.

Establishing detectable change thresholds for PROMs or other outcome measures has rarely been performed in CI or hearing research or, more broadly, in otolaryngology research or for clinical outcome measures.[4-6,35] Application of these values enhances the interpretation of PROMs and increases the potential for their use for individual patient care. On the most basic level, knowing whether an intervention had a measurable, desired effect on a patient's health and well-being is fundamental for providing appropriate patient care. In addition, these values can be applied to identify patients who are not progressing as anticipated within a certain domain and may need additional interventions or treatment for an optimal outcome. In both scenarios, these thresholds provide clinicians with the information needed to interpret clinical outcome measures for individual patients. Understanding how error changes across a measure is also invaluable when designing or interpreting results from clinical trials. Without this knowledge, researchers must rely solely on group-level statistical analyses to understand whether an intervention resulted in an outcome difference. Incorporation of CIOV, including change thresholds, into power analyses and sample size calculations ensure that measured differences are not only statistically distinct, but have inherent meaning.[2,36]

Application of personalized change thresholds (cMDCs) in this cohort of adult CI users may provide insight into the functional benefits obtained by individual patients who undergo cochlear implantation. First, these results show that most patients obtained benefit from their CI in at least 1 functional domain, with few demonstrating poorer function. Second, individual CI user improvement patterns differed based on the domain being measured. Not surprisingly, because communication is being most directly affected by cochlear implantation, the communication domain showed the largest percentage of CI users demonstrating meaningful improvement (53 [81.5%]). Yet, communication domain improvement was not always associated with improvement in the other domains, as observed in the lower rates of improvement in the noncommunication domains. This highlights the importance of using PROMs that include multiple domains to provide a more comprehensive understanding of the effect of an intervention on patients' lives. Finally, these findings, if replicated, can begin the process of developing a shared decision-making protocol for the CI evaluation process. Establishing the threshold needed for an individual to show change is an important step in developing a better understanding of the wide-ranging functional outcomes of cochlear implantation on the lives of individual patients. Such results can then be used during the CI evaluation process to provide potential CI users insight into the benefits and limitations of cochlear implantation, providing them with the opportunity to make an informed decision. This is especially important given the broadening of CI candidacy over time, which allows patients with greater residual hearing and better communication abilities to be implanted. Although the decision to proceed with implantation may be fairly obvious for patients with minimal to no residual hearing, this decision is likely to become more complex as the indications become less restrictive.

The stratification of CI user benefit from cochlear implantation using CIOV thresholds provides the opportunity to further examine the relationship between functional benefits and improvements in speech recognition abilities measured in controlled clinical settings. Prior research has consistently demonstrated the absent-to-low correlations between CI users' self-reported communication and other abilities and speech recognition scores.[25,37-40] However, prior studies have been cross-sectional, focusing on the relationship between self-reported communication abilities and speech recognition scores of experienced CI users, and have not compared pre-CI to post-CI changes in each outcome measure. In the current study, we found that CI users with improvement in certain CIQOL domains, in particular communication, listening effort, and the global score, was associated with greater improvements in speech recognition scores. Although this relationship may seem predictable, it has not previously been measured or reported to our knowledge. Less obvious was the finding that the associations between speech recognition improvement and CIQOL domain improvement were not uniform. Specifically, CI users who demonstrated improvement or no change in the entertainment and environment domains had similar improvements or no change in speech recognition abilities. Importantly, these results warrant additional investigation to establish thresholds for changes in speech recognition scores that could be considered meaningful.

Limitations

The primary limitation of this study was the calculation and application of solely psychometrically based CIOV thresholds (cMDC). We are in the process of establishing anchor-based MCID values, which is necessary to understand patients' perspectives on meaningful improvement and will need to be done in comparison to the findings of the current study. Specifically, MCID values should not be smaller than the cMDC values because these represent the measurement limitations of the CIQOL-35 Profile. Thus, the present study is a necessary precursor to MCID determination. Although determination of cMDC values was based on a broad national sample of adult CI users, the application in a prospective cohort from a single institution is an additional limitation. Future research will need to broaden the application of cMDCs to allow the research to be more generalizable.

Conclusions

This cohort study found that the use of IRT-informed measure-level precision estimates to determine cMDC values enhanced the ability to monitor individual patient improvement and inform clinical decision making. Although applied here specifically for the CIQOL-35 Profile instrument, these methods can be used to enhance psychometrically based MCID calculations for many outcome measures. In our prospective patient cohort, most CI users demonstrated improvement in some, but not all, CIQOL-35 domains. These results may help inform patient counseling and future work will investigate potential mediators for improvement.

ARTICLE INFORMATION

Accepted for Publication: April 21, 2023.

Published Online: June 15, 2023. doi:10.1001/jamaoto.2023.1090

Author Affiliations: Department of Otolaryngology–Head and Neck Surgery, Medical University of South Carolina, Charleston (McRackan, Shannon, Dubno); Division of Physical Therapy, Department of Rehabilitation Sciences, College of Health Professions, Medical University of South Carolina, Charleston (Seamon); School of Health and Rehabilitation Sciences, The Ohio State University, Columbus (Hand); Division of Occupational Therapy, Department of Rehabilitation Sciences, College of Health Professions, Medical University of South Carolina, Charleston (Velozo).

Author Contributions: Dr McRackan had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: McRackan, Seamon, Velozo, Dubno.
Acquisition, analysis, or interpretation of data: McRackan, Seamon, Shannon, Hand, Velozo.
Drafting of the manuscript: McRackan, Seamon, Shannon.
Critical revision of the manuscript for important intellectual content: McRackan, Seamon, Hand, Velozo, Dubno.
Statistical analysis: Seamon, Shannon, Hand, Velozo.
Obtained funding: McRackan.
Administrative, technical, or material support: Dubno.
Supervision: McRackan, Dubno.

Conflict of Interest Disclosures: Dr McRackan reported grants from National Institutes of Health, National Institute on Deafness and Other Communication Disorders (NIH/NIDCD) and grants from American Cochlear Implant Alliance (ACIA) during the conduct of the study; and advisory board membership from Envoy Medical outside the submitted work. Dr Dubno reported grants from NIH/NIDCD and ACIA during the conduct of the study. No other disclosures were reported.

Funding/Support: This research was supported (in part) by a grant from the NIH/NIDCD, Grant Number K23 DC016911, and a grant from the ACIA.

Group Information: The CIQOL instruments are available for download at: https://education.musc.edu/CIQOL. The Cochlear Implant Quality of Life Development Consortium consists of the following institutions (and individuals): Columbia University (Justin S. Golub, MD, MS), Duke University Hospital (Erin Blackburn, AuD; Howard Francis, MD; Amy Walker), Eastern Virginia Medical School (Stephanie Moody-Antonio, MD), Georgetown University (Michael Hoa, MD), House Ear Clinic (Eric P. Wilkinson, MD; Dawna Mills, AuD), Johns Hopkins University (John P. Carey, MD), Kaiser Permanente-Los Angeles (Nopawan Vorasubin, MD), Kaiser Permanente-San Diego (Vickie Brunk, AuD), Loyola University Medical Center (Matthew Kirchner, MD), Massachusetts Eye and Ear Infirmary (Kevin Frank, PhD; Elizabeth DesRoche, AuD), Mayo Clinic Rochester (Matthew L. Carlson, MD; Collin L. Driscoll, MD, Medical University of South Carolina (Kara C Schvartz-Leyzac AuD, PhD; Elizabeth L. Camposeo, AuD; Paul R. Lambert, MD; Ted A. Meyer, MD PhD), New York Eye and Ear Infirmary (Maura Cosetti, MD), The Ohio State University (Aaron C. Moberly, MD), Rush University (Mike Hefferly, PhD; Mark Wiet, MD), Stanford University (Nikolas H. Blevins, MD; Jannine B. Larky, AuD), State University of New York-Downstate (Matthew Hanson, MD), Summit Medical Center (Jed Kwartler, MD), University of Arkansas for Medical Sciences (John Dornhoffer, MD), University of Cincinnati (Ravi N. Samy, MD), University of Colorado (Samuel P. Gubbels, MD), University of Maryland School of Medicine (Ronna P. Herzano, MD, PhD), University of Miami (Michael E. Hoffer, MD; Meredith A. Holcomb AuD; Sandra M. Prentiss, PhD), University of Pennsylvania (Jason Brant, MD), University of Texas Southwestern (Jacob B. Hunter, MD; Brandon Isaacson, MD; J. Walter Kutz, MD), University of Utah (Richard K. Gurgel, MD), Virginia Mason Medical Center (Daniel M. Zeitler, MD), Washington University-Saint Louis (Craig A. Buchman, MD; Jill B. Firszt, PhD); Vanderbilt University (Rene H. Gifford, PhD; David S. Haynes, MD).

Data Sharing Statement: See the Supplement.

REFERENCES

1. Jaeschke R, Singer J, Guyatt GH. Measurement of health status. ascertaining the minimal clinically important difference. *Control Clin Trials*. 1989;10(4):407-415. doi:10.1016/0197-2456(89)90005-6

2. Kallogjeri D, Spitznagel EL Jr, Piccirillo JF. Importance of defining and interpreting a clinically meaningful difference in clinical research. *JAMA Otolaryngol Head Neck Surg*. 2020;146(2):101-102. doi:10.1001/jamaoto.2019.3744

3. Cepeda NA, Polascik BA, Ling DI. A primer on clinically important outcome values: going beyond relying on *P* values alone. *J Bone Joint Surg Am*. 2020;102(3):262-268. doi:10.2106/JBJS.19.00817

4. Adamchic I, Tass PA, Langguth B, et al. Linking the Tinnitus Questionnaire and the subjective clinical global impression: which differences are clinically important? *Health Qual Life Outcomes*. 2012;10:79. doi:10.1186/1477-7525-10-79

5. Zeman F, Koller M, Figueiredo R, et al. Tinnitus handicap inventory for evaluating treatment effects: which changes are clinically relevant? *Otolaryngol Head Neck Surg*. 2011;145(2):282-287. doi:10.1177/0194599811403882

6. Kerezoudis P, Yost KJ, Tombers NM, Celda MP, Carlson ML, Link MJ. Defining the minimal clinically important difference for patients with vestibular schwannoma: are all quality-of-life scores significant? *Neurosurgery*. 2019;85(6):779-785. doi:10.1093/neuros/nyy467

7. Reeder RM, Firszt JB, Holden LK, Strube MJ. A longitudinal study in adults with sequential bilateral cochlear implants: time course for individual ear and bilateral performance. *J Speech Lang Hear Res*. 2014;57(3):1108-1126. doi:10.1044/2014_JSLHR-H-13-0087

8. Zhang J, Tyler R, Ji H, et al. Speech, Spatial and Qualities of Hearing Scale (SSQ) and Spatial Hearing Questionnaire (SHQ) changes over time in adults with simultaneous cochlear implants. *Am J Audiol*. 2015;24(3):384-397. doi:10.1044/2015_AJA-14-0074

9. Klop WM, Boermans PP, Ferrier MB, van den Hout WB, Stiggelbout AM, Frijns JH. Clinical relevance of quality of life outcome in cochlear implantation in postlingually deafened adults. *Otol Neurotol*. 2008;29(5):615-621. doi:10.1097/MAO.0b013e318172cfac

10. Wick CC, Kallogjeri D, McJunkin JL, et al; CI532 Study Group. Hearing and quality-of-life outcomes after cochlear implantation in adult hearing aid users 65 years or older: a secondary analysis of a nonrandomized clinical trial. *JAMA Otolaryngol Head Neck Surg*. 2020;146(10):925-932. doi:10.1001/jamaoto.2020.1585

11. Noble W, Tyler RS, Dunn CC, Bhullar N. Younger- and older-age adults with unilateral and bilateral cochlear implants: speech and spatial hearing self-ratings and performance. *Otol Neurotol*. 2009;30(7):921-929. doi:10.1097/MAO.0b013e3181b76b3b

12. Gaeta L, Brydges CR. An examination of effect sizes and statistical power in speech, language, and hearing research. *J Speech Lang Hear Res*. 2020;63(5):1572-1580. doi:10.1044/2020_JSLHR-19-00299

13. Kraemer HC. Is it time to ban the *P* value? *JAMA Psychiatry*. 2019;76(12):1219-1220. doi:10.1001/jamapsychiatry.2019.1965

14. Adunka OF, Gantz BJ, Dunn C, Gurgel RK, Buchman CA. Minimum reporting standards for adult cochlear implantation. *Otolaryngol Head Neck Surg*. 2018;159(2):215-219. doi:10.1177/0194599818764329

15. PROMIS. PROMIS: Instrument Development and Validation Scientific Standards. Accessed May 5, 2022. http://www.healthmeasures.net/images/PROMIS/PROMISStandards_Vers2.0_Final.pdf

16. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res*. 2010;19(4):539-549. doi:10.1007/s11136-010-9606-8

17. McRackan TR, Hand BN, Chidarala S, Dubno JR. Understanding patient expectations before implantation using the cochlear implant quality of life-expectations instrument. *JAMA Otolaryngol Head Neck Surg*. 2022;148(9):870-878. doi:10.1001/jamaoto.2022.2292

18. McRackan TR, Hand BN, Chidarala S, Velozo CA, Dubno JR; Cochlear Implant Quality of Life Consortium. Normative Cochlear Implant Quality of Life (CIQOL)-35 Profile and CIQOL-10 Global Scores for experienced cochlear implant users from a multi-institutional study. *Otol Neurotol*. 2022;43(7):797-802. doi:10.1097/MAO.0000000000003596

19. McRackan TR, Hand BN, Velozo CA, Dubno JR; Cochlear Implant Quality of Life Development Consortium. Development and Implementation of the Cochlear Implant Quality of Life (CIQOL) Functional Staging System. *Laryngoscope*. 2022;132(Suppl 12)(suppl 12):S1-S13. doi:10.1002/lary.30381

20. Laplante-Lévesque A, Dubno JR, Mosnier I, Ferrary E, McRackan TR. Best practices in the development, translation, and cultural adaptation of patient-reported outcome measures for adults with hearing impairment: lessons from the Cochlear Implant Quality of Life Instruments. *Front Neurosci*. 2021;15:718416. doi:10.3389/fnins.2021.718416

21. McRackan TR, Hand BN, Velozo CA, Dubno JR, Consortium CIQoL. Validity and reliability of the Cochlear Implant Quality of Life (CIQOL)-35 Profile and CIQOL-10 Global instruments in comparison to legacy instruments. *Ear Hear*. 2021;42(4):896-908. doi:10.1097/AUD.0000000000001022

22. McRackan TR, Hand BN, Velozo CA, Dubno JR; Cochlear Implant Quality of Life Development Consortium. Cochlear Implant Quality of Life (CIQOL): development of a profile instrument (CIQOL-35 Profile) and a Global Measure (CIQOL-10 Global). *J Speech Lang Hear Res*. 2019;62(9):3554-3563. doi:10.1044/2019_JSLHR-H-19-0142

23. McRackan TR, Hand BN, Velozo CA, Dubno JR, Consortium CIQoLD. Development of the Cochlear Implant Quality of Life Item Bank. *Ear Hear*. 2019;40(4):1016-1024. doi:10.1097/AUD.0000000000000684

24. McRackan TR, Velozo CA, Holcomb MA, et al. Use of adult patient focus groups to develop the initial item bank for a cochlear implant quality-of-life instrument. *JAMA Otolaryngol Head Neck Surg*. 2017;143(10):975-982. doi:10.1001/jamaoto.2017.1182

25. McRackan TR, Hand BN, Velozo CA, Dubno JR; Cochlear Implant Quality of Life Consortium. Validity and reliability of the Cochlear Implant Quality of Life (CIQOL)-35 Profile and CIQOL-10 Global instruments in comparison to legacy instruments. *Ear Hear*. 2021;42(4):896-908. doi:10.1097/AUD.0000000000001022

26. Prieto L, Alonso J, Lamarca R. Classical Test Theory versus Rasch analysis for quality of life questionnaire reduction. *Health Qual Life Outcomes*. 2003;1:27. doi:10.1186/1477-7525-1-27

27. De Champlain AF. A primer on classical test theory and item response theory for assessments in medical education. *Med Educ*. 2010;44(1):109-117. doi:10.1111/j.1365-2923.2009.03425.x

28. JM L. Standard errors and reliabilities: Rasch and Raw Score. *Rasch Meas Trans*. 2007;20:1086.

29. Seamon BA, Kautz SA, Bowden MG, Velozo CA. Revisiting the concept of minimal detectable change for patient-reported outcome measures. *Phys Ther*. 2022;102(8):pzac068. doi:10.1093/ptj/pzac068

30. Stratford PW, Riddle DL. When minimal detectable change exceeds a diagnostic test-based threshold change value for an outcome measure: resolving the conflict. *Phys Ther*. 2012;92(10):1338-1347. doi:10.2522/ptj.20120002

31. Kozlowski AJ, Cella D, Nitsch KP, Heinemann AW. Evaluating Individual Change With the Quality of Life in Neurological Disorders (Neuro-QoL) Short Forms. *Arch Phys Med Rehabil*. 2016;97(4):650-654.e8. doi:10.1016/j.apmr.2015.12.010

32. McRackan TR, Hand BN, Velozo CA, Dubno JR; Cochlear Implant Quality of Life Development Consortium. Development of the Cochlear Implant Quality of Life Item Bank. *Ear Hear*. 2019;40(4):1016-1024. doi:10.1097/AUD.0000000000000684

33. Byrne D, Dillon H. The National Acoustic Laboratories' (NAL) new procedure for selecting the gain and frequency response of a hearing aid. *Ear Hear*. 1986;7(4):257-265. doi:10.1097/00003446-198608000-00007

34. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. 2nd ed. Erlbaum Associates; 1988.

35. Peterson AM, Miller B, Ioerger P, et al. Most-cited patient-reported outcome measures within otolaryngology-revisiting the minimal clinically important difference: a review. *JAMA Otolaryngol Head Neck Surg*. 2023;149(3):261-276. doi:10.1001/jamaoto.2022.4703

36. Embry TW, Piccirillo JF. Minimal clinically important difference reporting in randomized clinical trials. *JAMA Otolaryngol Head Neck Surg*. 2020;146(9):862-863. doi:10.1001/jamaoto.2020.1586

37. McRackan TR, Hand BN, Velozo CA, Dubno JR. Association of demographic and hearing-related factors with cochlear implant-related quality of life. *JAMA Otolaryngol Head Neck Surg*. 2019;145(5):422-430. doi:10.1001/jamaoto.2019.0055

38. McRackan TR, Bauschard M, Hatch JL, et al. Meta-analysis of cochlear implantation outcomes evaluated with general health-related patient-reported outcome measures. *Otol Neurotol*. 2018;39(1):29-36. doi:10.1097/MAO.0000000000001620

39. McRackan TR, Bauschard M, Hatch JL, et al. Meta-analysis of quality-of-life improvement after cochlear implantation and associations with speech recognition abilities. *Laryngoscope*. 2018;128(4):982-990. doi:10.1002/lary.26738

40. Capretta NR, Moberly AC. Does quality of life depend on speech recognition performance for adult cochlear implant users? *Laryngoscope*. 2016;126(3):699-706. doi:10.1002/lary.25525