TITLE: Evaluation of a Revised Indication for Determining Adult Cochlear Implant Candidacy

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OBJECTIVE: To evaluate the use of monosyllabic word recognition versus sentence recognition to determine candidacy and long-term benefit for cochlear implantation.

STUDY DESIGN: Prospective multi-center single-subject design.

METHODS: A total of 21 adults, 18-years of age and older with bilateral moderate to profound sensorineural hearing loss and low monosyllabic word scores. All received unilateral cochlear implantation. The CNC word test was the central measure of pre- and post-operative performance. Additional speech understanding tests included the HINT sentences in quiet, and AzBio sentences in +5 dB SNR. Quality of life (QoL) was measured using the Abbreviated Profile of Hearing Aid Benefit (APHAB) and Health Utilities Index (HUI).

RESULTS: Performance on sentence recognition reached the ceiling of the test after only three months of implant use. In contrast, none of the participants in this study reached a score of 80% on CNC word recognition, even at the 12-month post-operative test interval. Measures of QoL related to hearing were also significantly improved following implantation.

CONCLUSIONS: Results of this study demonstrate that monosyllabic words are appropriate for determining pre-operative candidate and measuring long-term post-operative speech recognition performance.

Level of Evidence: 2c

INTRODUCTION

Since 1985 indications for adult cochlear implantation have evolved from bilateral profound sensorineural hearing loss with 0% open set sentence recognition to bilateral moderate to profound sensorineural hearing loss with limited functional benefit from amplification. Limited benefit is currently defined by scores of 50% correct or less in the ear to be implanted (60% or less in the best-aided condition) on recorded tests of sentence recognition [1]. These criteria have not been updated since the most recent post-market approval study in 2005 (PMA# P970051/S028).

Technological advancements have allowed cochlear implant (CI) patients access to more acoustic cues and achieve high levels of speech understanding [2]. Current outcomes challenge whether implant candidacy criterion should be broadened once again. In fact, recent work has suggested that sentence recognition may be insufficient for determining CI candidacy [3,4] and suggests word recognition may be a better tool for determining candidacy and measuring long-term benefit from a CI. Even more difficult sentences, such as the AzBio sentence test [5], have sufficient semantic content to allow higher levels of performance compared to monosyllabic words. Another recent study examining outcomes of 40 implanted postlingually deafened adults [6] found that 62% of participants scored above 80% on the AzBio sentences test, whereas only 25% of the same individuals scored above 80% on the CNC word test. Speech is a highly complex signal comprised of frequency, intensity and temporal information. Speech understanding, that is, the degree to which spoken language can be resolved, varies greatly in everyday communication. Factors such as noise, reverberation, distance, speaker style (e.g., rate, dialect, accent, etc.), and language proficiency, may all contribute to variability in overall speech understanding. Sentence recognition relies heavily on top-down processing during which the listener uses his/her available cognitive resources—including one's knowledge of the language, topic of conversation, and previous experiences—to fill in missing pieces. The ability to use top-down processing may vary based on things such as linguistic knowledge [7]. Sentence recognition scores, therefore, may not accurately reflect how well a person can detect and process the individual spectral and temporal components of speech—an example of bottom-up processing—but rather the ability to fill in missing pieces. Many studies investigating monosyllabic word recognition and sentence recognition in a within-subjects design have demonstrated significantly higher performance levels for sentences as compared to monosyllables [1,4, 8-14]. Higher sentence scores as compared to word recognition scores are even expected for complex sentences containing multiple talkers with lower context such as AzBio in quiet [10-13, 15] as well as AzBio sentences at +10 dB SNR [16]. A primary theory explaining this phenomenon is related to the ease of language understanding (ELU; 17-19) by which incoming speech stimuli are grouped into known phonological representations and cross-checked against the listener's semantic lexicon. The greater the context for the incoming speech stimulus, the simpler the retrieval process. On the other hand, it is not uncommon for much more difficult sentence measures, such as the TIMIT corpus, to yield equivalent or even lower scores than monosyllables (e.g., King et al., 2012) [20]; however, the TIMIT sentences are not recognized as the industry standard for assessing pre- and post-implant performance for adult CI users and thus this relationship does not hold immediate clinical relevance. Given the well-known relationship between word recognition and sentence recognition—even for the AzBio corpus—word recognition may therefore be a better metric for determining how well one can resolve the incoming speech stimulus in the absence of contextual cues.

The field of cochlear implants also sees a need to move beyond tests of speech recognition and evaluate the whole patient. Specifically, the impact on ease of communication and quality of life should be addressed. Previous studies have unanimously demonstrated significantly higher health-related quality of life (HRQoL) scores among implanted adults at post-operative compared to pre-operative intervals [21-24]. To this end, measures of HRQoL are now considered essential in outcome-based research.

The aim of the current study was to determine if word recognition, versus sentence recognition, was a more appropriate tool for measuring candidacy and long-term benefit for cochlear implantation. Specifically, this study aimed to compare word recognition using the CNC monosyllabic word test [25] and sentence recognition using both the Hearing in Noise Test (HINT) [26] and AzBio sentences [5] in both the pre- and post-implant period. The primary hypothesis was that participants would approach ceiling level (≥80%) on sentence recognition shortly after activation, whereas performance on CNC word recognition would not reach ceiling level for the majority of participants.

METHODS & MATERIALS

This was an FDA approved multi-center, single-arm, repeated measures clinical trial. Recruitment for participants began in 2012. Each participating center obtained Institutional Review Board approval prior to enrolling participants. The 10 participating sites implanted between 1 and 5 patients each.

The protocol was initially approved for use of the Cochlear^{TM} Nucleus® Freedom device with Contour Advance electrode [CI24RE(CA)]. Shortly after the study began, however, the Cochlear Nucleus CI422 electrode was released, which impacted subject accrual. Thus this first phase of the revised indications study with CI24RE(CA) was ultimately closed and re-opened using the CI422. The new study protocol using the CI422 did not match the current study, and therefore, the data from the two cannot be combined.

Participants. All participants had bilateral moderate to profound sensorineural hearing loss in the low frequencies (up to 1000 Hz) and profound sensorineural hearing loss at 3000 Hz and above. Speech recognition criteria required preoperative aided CNC word recognition (mean of two, 50-item lists) between 10% and 40% in the ear to be implanted, and no greater than 50% in the contralateral ear.

Informed consent was given by 43 participants, though 22 did not meet the inclusion criteria for the study. There were 11 who had hearing thresholds that fell below (i.e. too good) the inclusion criterion, 8 who had conductive components exceeding 15 dB at two or more frequencies, and 3 who had risk of cognitive decline as determined by a medical doctor prior to implantation per the clinic's own protocol including open-ended, probing questions regarding temporal and spatial orientation. The final group of 21 participants included 17 males, 4 females, ranging in age from 32 to 88 years (mean = 77 years). Duration of severe-to-profound high frequency sensorineural hearing loss was determined by patient report or medical records and ranged between 4.1 and 65.2 years, with an average of 25.4 years. These details can be found for each participant in Table 1. All participants were implanted with a CI24RE(CA) and used a CP810 sound processor.

Materials. Speech understanding in quiet was assessed using CNC words and HINT sentences. The CNC Monosyllabic Word Test is an open-set measure of word recognition consisting of 10 lists of 50 words. The HINT is comprised of 25, 10-sentence lists. HINT sentences were chosen because they were the industry-standard sentence test for candidacy testing at the time of this protocol approval by the FDA in March, 2011—prior to the release of the adult minimum speech test battery (MSTB, 2011) in July 2011 which specified AzBio sentences for pre- and post-implant assessment. The ability to understand speech in noise (SIN) was assessed using AzBio sentences [5]. The AzBio Sentence Test is comprised of 33 lists of 20 sentences each produced by two male and two female talkers and scored for each word repeated correctly.

Measures used to assess self-perceived benefit included the Abbreviated Profile of Hearing Aid Benefit [APHAB; 27] and the Health Utility Index Mark 3 [HUI3; 28]. The APHAB is a 24-item, self-assessment scored in four subscales: Ease of Communication, Reverberation, Background Noise, and Aversiveness to Sounds. The HUI3 is a 15-item, population-based health utility instrument that postulates the domains of health as hearing, vision, speech, emotion, pain, ambulation, dexterity, cognition and self-care.

Procedures. Speech understanding in quiet was measured using recorded stimuli at a calibrated presentation level of 60 dB sound pressure level (SPL, A-weighted), whereas SIN was measured in a +5 dB signal-to-noise ratio (SNR) with speech at 65 dB SPL(A). The CNC, HINT, and AzBio tests were administered in the unilateral CI only condition at the baseline appointment and again at 3-, 6-, and 12-months post-activation. The same measures were administered in the bimodal condition, though study protocol excluded bimodal testing of CNC word recognition from the 3-month test interval. The APHAB was administered at both baseline and 6-months post-activation, and the HUI3 was conducted at baseline, 6-months, and 12-months post-activation.

Candidacy testing was completed using hearing aids (personal or loaners) set to National Acoustic Laboratories (NAL-R; 29) prescriptive targets within 5 dB.

RESULTS

Statistical analyses were completed using IBM SPSS Statistical Package, v. 21.0.0. An alpha level of 0.05 was used to determine statistical significance, though the alpha level was adjusted in cases where Bonferroni corrections were used. The study protocol was completed by all 21 participants at the pre-operative and 3-month post-activation interval, 18 participants at the 6-month interval, and 14 participants at the 12-month interval.

Speech Understanding. Speech perception scores were calculated as percent correct then subjected to an arcsine transformation [30] prior to statistical analysis. Data are presented either as percent correct or as rationalized arcsine units (RAU).

CNC word test in quiet. Mean CNC word scores, in percent correct, were 23.6% (SD 11.1%) at the preoperative interval, 49.6% (SD 14.6%) at the 3-month post-activation interval, 57.1% (SD 21.2%) at 6-month post-activation interval, and 65.1% (SD 12%) at the 12-month post-activation interval. Following arcsine transformation, the data were analyzed using a repeated measures analysis of variance (RM-ANOVA) using CNC word score, in RAU, as the dependent variable, and test interval (preoperative, 3-, 6-, and 12-months post-activation) as a within-subjects variable. The group averages can be found in Figure 1. Results showed a main effect of test interval, $F(3, 36) = 29.0$, $p < 0.001$, $\underline{r} = .76$. The main effect of time interval was followed up with post-hoc pairwise comparisons between each test interval using Bonferroni corrections. Results showed significant improvement in CNC word recognition in the unilateral condition between the preoperative and 3-months post-activation intervals, $p < 0.001$, between the 3-month and 6-month post-activation intervals, $p = 0.002$, and between the 3-month and 12-month intervals, $p = .001$, but not between the 6-month and 12-month post-activation intervals, $p = 0.74$.

Mean CNC word recognition in the bilateral configuration was 38.7% (SD 11.1) at the preoperative interval, 70.1% (SD 14.6) at 6-months post-activation, and 73.6% (SD 12) at 12-

months post-activation. A RM-ANOVA was used to analyze performance over time using the word score in RAU as the dependent variable, and test interval (preoperative, 6-months post-activation, 12-months post-activation) as the within-subjects variable. Results demonstrated a significant main effect of test interval, $F(2,22) = 31.9$, $p < 0.001$, and pairwise comparisons using Bonferroni corrections showed significant differences in the bilateral listening condition between the preoperative and 6-month post-activation interval, $p = 0.001$, and between the 6-month and 12-month post-activation intervals, $p = 0.02$.

Matched pairs t-tests were used to test for CNC word recognition performance differences, in RAU, between unilateral and bilateral configurations. Bonferonni adjustments were used to correct for possible Type I error from multiple t-tests. Results showed significantly higher performance for the bilateral compared to unilateral conditions at the preoperative interval ($t\ (20) = 5.7$, $p < 0.001$) and 6-month post-activation interval, ($t\ (16) = 2.2$, $p = 0.04$), but not the 12-month interval, ($t\ (9) = 2.1$, $p = 0.06$).

Hearing in Noise Test in quiet. HINT sentence recognition in quiet, in percent correct, is shown in Figure 2. The pre-operative group mean was 62.3% (*SD* = 10.8). The mean scores at the 3-, 6- and 12-months post-activation intervals were 77.8% (*SD* = 20.5), 84.6% (*SD* = 18), and 89.7% (*SD* = 13.4), respectively. The data, in RAU, were subjected to RM-ANOVA, with time as the within-subjects factor, revealing a significant main effect of time, $F(3, 36) = 12.0$, $p < 0.001$, $\underline{r} = .5$. Pairwise comparisons with Bonferonni corrections showed significant increase in performance at the 3-month test interval compared to the pre-operative test interval, $p = .01$, but no change in performance between the 3- and 6-month interval, $p = 0.10$ or between the 6-month and 12-month interval, $p = 0.27$.

AzBio sentence recognition in noise. Mean AzBio sentence recognition scores at +5 dB SNR, in percent correct, are shown in Figure 3. Data were analyzed using RM-ANOVA with test interval and listening condition as within-subject factors. The results demonstrated significant main effects of test interval $F(2,22) = 9.1$, $p < 0.001$, $\underline{r} = .7$ and listening condition, $F(1,11) = 19.2$, $p < 0.001$, $\underline{r} = .3$; the interaction was not significant, $F(2,22) = 0.51$, $p = 0.60$. The main effect of test interval was followed up with pairwise comparisons with Bonferonni corrections which showed significant improvement for the unilateral condition between preoperative and 6-month post-activation, $p = 0.05$, and between 6-month and 12-month post-activation, $p = 0.03$. Results obtained in the bilateral condition were not statistically different between the pre-operative (M = 25.1%, SD = 17.1) and 6-month post-activation interval (M = 34.1, SD = 18.9), p = 0.12. Performance in the bilateral condition at the 12-month interval (M = 46.4, SD = 26) was significantly higher than the 6-month interval, p = 0.04.

Self-Perceived Benefit. Mean total scores for each domain of the APHAB and HUI are shown in Figures 4 and 5, respectively. The scores from each domain were subjected to paired *t*-test to determine statistical significance. Bonferroni adjustments were used to correct for possible Type I error from multiple t-tests. Analysis of the APHAB showed that the 6-month post activation interval was significantly better than the pre-operative interval for the domains of aversiveness, $t(18) = 2.1$, $p = 0.05$, background noise, $t(18) = 5.1$, $p < 0.001$, ease of listening, $t(18) = 5.2$, $p < 0.001$, and reverberation, $t(18) = 5.8$, $p < 0.001$. Results of the HUI revealed a significant improvement between pre- and 6-months post-activation, but only for the hearing domain, $t(18) = -3.2$, $p < 0.001$, and the multifactorial scores $t(18) = 5.3$, $p = 0.03$. Neither the hearing $t(12) = 1.7$, $p = 0.27$, or multifactorial scores $t(12) = 2.4$, $p = 0.15$, changed between the 6-month and 12-month test intervals.

DISCUSSION

Overall, this study demonstrated that cochlear implantation yielded significant improvements in speech recognition in quiet and in noise, and self-perceived HRQoL for this group of adults who were evaluated for candidacy using CNC word recognition. The performance outcomes showed a trend for improved performance compared to results published by Balkany and colleagues [1] with the same internal device but with more restrictive candidacy criteria. In that study, they reported 6-month postoperative CNC and HINT scores of 57.4% and 78.2%, respectively, whereas the current study outcomes were 65.1% and 89.7%, respectively. This suggests that using a criterion of up to 40% CNC word recognition yields at least equivocal, if not higher outcomes, than patients implanted via existing FDA guidelines or up to 30% CNC as outlined by the original CI24RE(CA) clinical trial (Balkany et al., 2007). Not only does this study suggest that the current indications are too strict, the data provide several examples supporting the need to revise current adult candidacy indications for cochlear implantation from a sentence test to a word test. For example, comparing CNC word and HINT sentence recognition demonstrates that simple sentence recognition tasks (sentences spoken slowly and clearly by a single talker) are not useful for tracking performance over time. Mean HINT sentence recognition improved significantly between the preoperative and 3-month post-activation test interval, yet no further improvements were noted beyond that point. One can easily see that sentence recognition scores quickly hit the ceiling. In fact, 11 of 20 participants (60%) of this study achieved HINT scores above 80% by the 3-month point. In contrast, CNC word recognition continued to improve over the entire first year following activation. Unlike performance on HINT test, not one patient scored above 80% on the CNC word test even at 12-months post-activation in the unilateral CI condition—though an alternative explanation is that the relatively small sample size may have restricted our outcomes as other studies have demonstrated unilateral CI recipients achieving ceiling-level performance for CNC word recognition. In these cases, however, we would expect that HINT sentence scores would have also reached ceiling (e.g., Gifford et al., 2008), and likely at an earlier postoperative time point. Thus the clinical utility of CNC words for longitudinal postoperative assessment is greater than that of the HINT sentences.

Speech recognition in noise also improved significantly after implantation. In the unilateral condition, AzBio sentence recognition at +5 dB SNR improved from 9.4% pre-operatively to 34.8% at 12-months post-activation. Previous studies have examined similar groups of postlingually deafened adults and reported mean AzBio sentence recognition at +5 dB SNR ranging from 49.2% to 58.6%, though most had several years of implant experience [6, 31, 32].

Results from the APHAB were significantly improved at 6-months post-activation compared to the preoperative test interval. This finding is similar to previous reports, such as Skarzynkski et al [33] who found a significant decrease in self-perceived hearing handicap scores on the APHAB among a group of 10 adult recipients. Regarding the HUI, only scores in the hearing domain improved significantly between the preoperative and 6-month post-activation test interval. Both outcomes are highly valuable. The APHAB provides critical outcome data on a disease-specific scale. The HUI, though more general, indicates that implantation among adults with better preoperative hearing positively influences hearing, and does not negatively impact other areas of life, such as vision, dexterity or cognition.

There are several limitations to the current study that are worth mentioning. First, this study had a low sample size of 23 participants. The effect size of cochlear implantation on CNC word performance proved to be quite high (r = .71) and significant results were obtained despite recruiting a relatively small number of participants. The study was, therefore, adequately powered, though a larger cohort study is needed in order to generalize the findings to the broader population. Another limitation is the use of sentence recognition in quiet was measured using the HINT sentences instead of the industry standard AzBio sentences. As mentioned previously, the HINT sentences were chosen because they were industry standard at the time the study protocol was approved by the FDA. The AzBio sentences are more difficult since they are spoken at a conversational rate and the lists are comprised of multiple talkers. It is possible that performance on AzBio sentences in quiet would not hit the ceiling as quickly as performance on the HINT sentences. However, there is an overall trend for candidacy to be based on single word recognition, as is the current FDA labeled indications for Hybrid-L24. The trend to use monosyllabic word performance for determining implant candidacy has also been observed in European countries such as France, Germany and Spain. Therefore, using word, as opposed to sentence recognition to determine candidacy for standard cochlear implantation aligns well with other labeled indications for cochlear implantation in the U.S. as well as being the standard criterion from a more global perspective [34-37].

CONCLUSIONS

Overall, results of the current study show significant benefit of cochlear implantation among a group of post-lingually deafened adults who had better preoperative hearing and speech understanding abilities compared to the current FDA candidacy guidelines. Moreover, these results show that the benefits of cochlear implantation reach beyond speech understanding in quiet into speech understanding in noise and quality of life. In addition, the current study suggests that CNC word scores, rather than sentence scores, should be used to determine candidacy and measure long-term outcomes for adults with postlingual hearing loss.

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FIGURE LEGEND

Figure 1. Mean and standard deviations for the CNC word test for the pre-operative and 3-, 6-, and 12-months post-activation test intervals. Scores are expressed in RAU.

Figure 2. Mean percent correct and standard deviations for the HINT sentence test in quiet at the pre-operative and 3-, 6-, and 12-months post-activation test intervals.

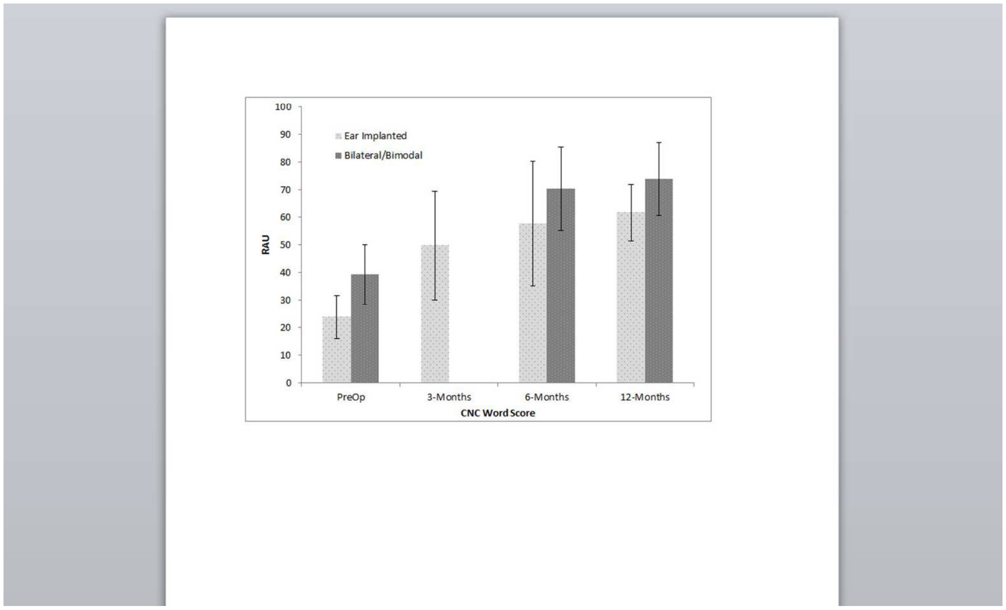
Figure 3. Mean percent correct and standard deviations for the AzBio sentence test in 5 dB SNR for the pre-operative and 6-, and 12-month post-activation test intervals.

Figure 4. Mean percent correct and standard deviations for the four domains of the APHAB at the pre-operative and 6-, and 12-months post-activation test intervals.

Figure 5. Total score and standard deviations for each domain of the Health Utilities Index (HUI) at the pre-operative and 6- and 12-month post-activation test intervals.

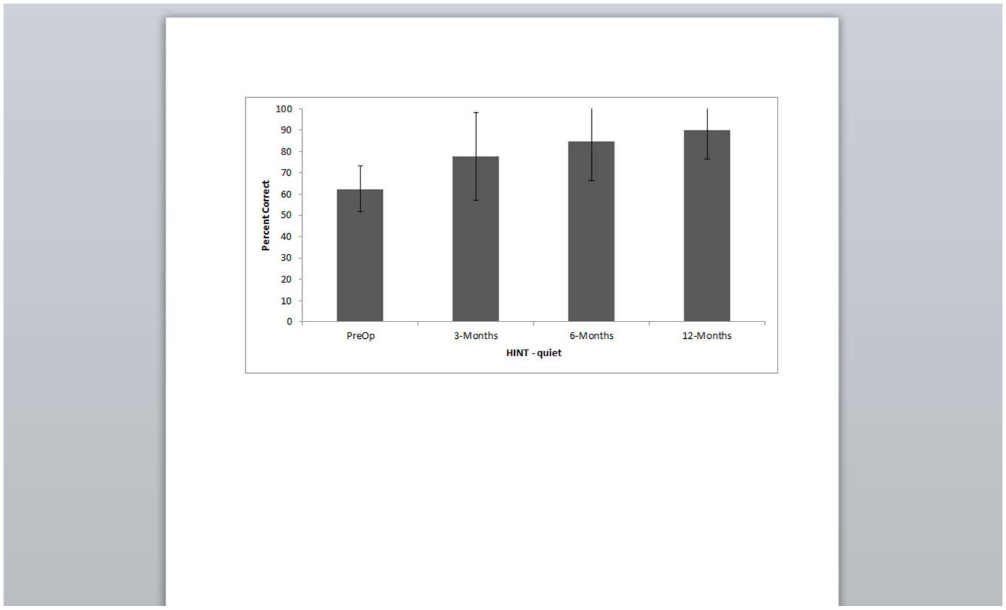
Table 1. Participant demographics

Subject #	Gender	Ear Implanted	Age at Implant	Duration Deafness	Etiology
1	Male	Left	79.3	19.3	Noise exposure
2	Male	Right	64.4	30.4	Unknown
3	Male	Right	87.7	32.7	Noise exposure
4	Female	Right	88.0	33.0	Noise exposure
5	Male	Right	59.5	19.5	Noise exposure
6	Male	Right	83.2	18.2	Unknown
7	Female	Left	32.7	13.7	Wolfram's Syndrome
8	Female	Left	72.0	13.0	Unknown
9	Male	Right	68.3	21.3	Unknown
10	Male	Right	83.0	7.39	Noise exposure
11	Male	Left	63.3	5.09	Unknown
12	Male	Left	50.5	10.5	Familial
13	Male	Left	73.3	10.3	Unknown
14	Male	Right	82.0	4.0	Noise exposure
15	Female	Left	71.7	31.7	Noise exposure
16	Male	Right	79.0	29.0	Noise exposure
17	Male	Right	75.9	55.9	Noise exposure
18	Male	Right	67.8	5.8	Unknown
19	Male	Right	69.1	61.1	Measles
20	Male	Right	61.4	61.4	Unknown
21	Male	Right	69.0	23.0	Noise exposure



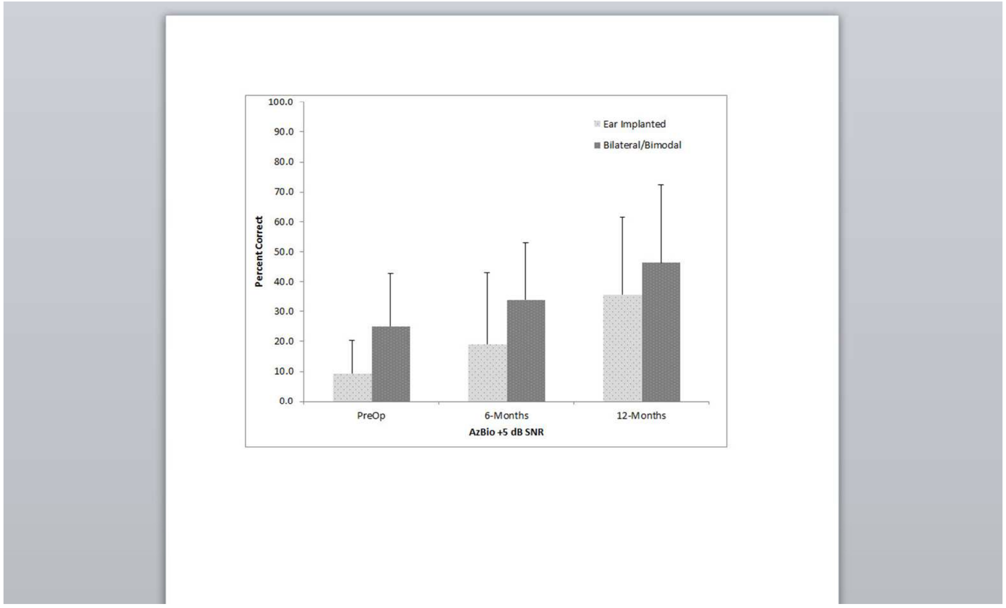
CNC words

354x213mm (96 x 96 DPI)



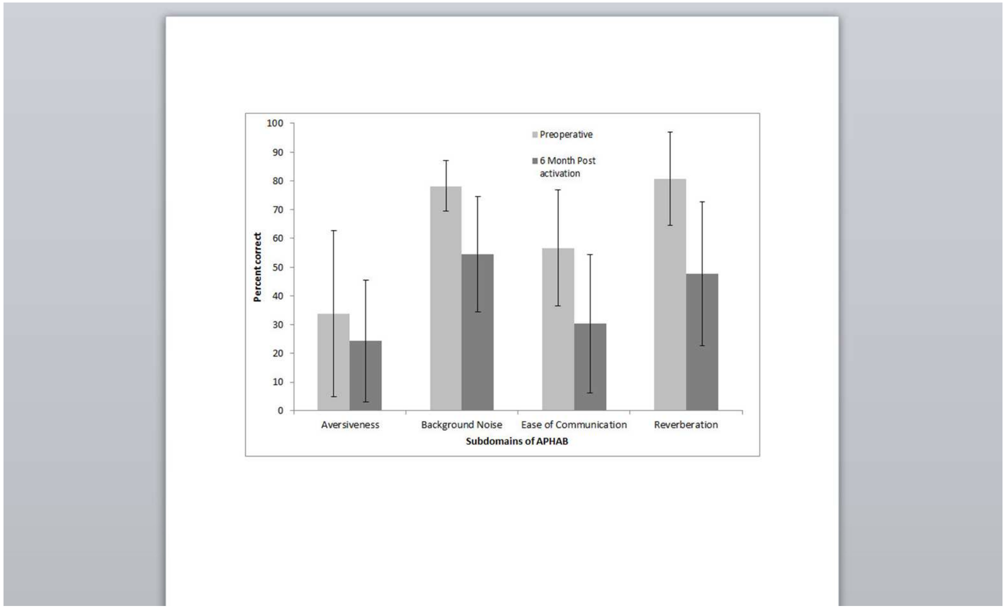
HINT sentences

354x213mm (96 x 96 DPI)



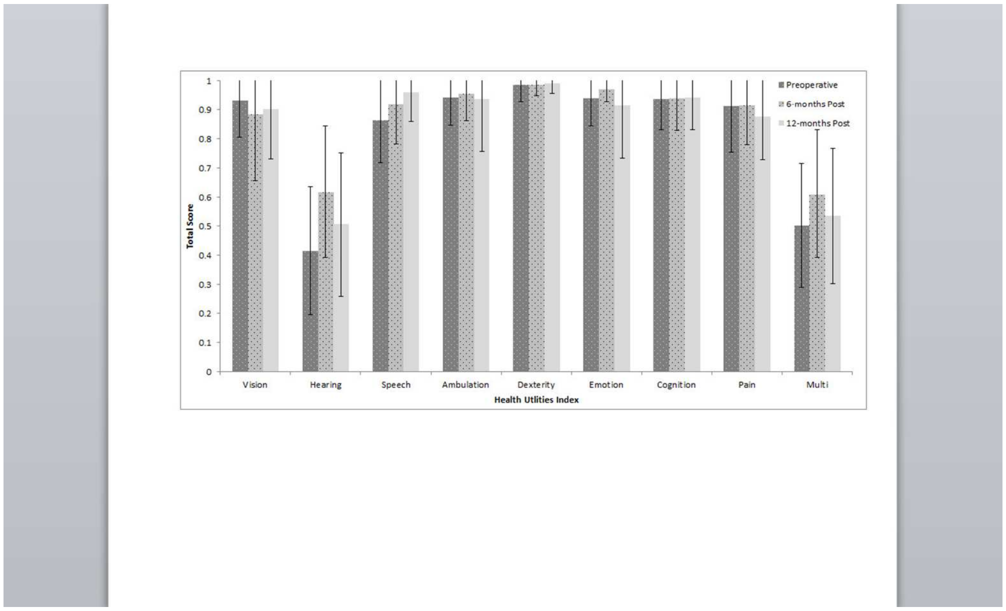
AzBio sentences in noise

354x213mm (96 x 96 DPI)



APHAB

354x213mm (96 x 96 DPI)



HUI

354x213mm (96 x 96 DPI)