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Multicenter Clinical Trial of the Nucleus® Hybrid™ S8 Cochlear Implant: Final Outcomes

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Abstract

Objective—The concept expanding electrical speech processing to those with more residual acoustic hearing with a less invasive shorter cochlear implant has been ongoing since 1999. A multi-center study of the Nucleus Hybrid S8 CI took place between 2002–11. This report describes the final outcomes of this clinical trial.

Study Design—Multi-Center longitudinal single subject design

Methods—Eighty-seven subjects received a Nucleus® Hybrid™ S8 implant in their poorer ear. Speech perception in quiet (CNC words) and in noise (BKB-SIN) was collected pre- and post-operatively at 3, 6, and 12 months. Subjective questionnaire data using the APHAB was also collected.

Results—Some level of hearing preservation was accomplished in 98% subjects with 90% maintaining a functional low-frequency pure-tone average (LFPTA) at initial activation. By 12 months, 5 subjects had total hearing loss and 80% of subjects maintained functional hearing. CNC words demonstrated that 82.5% and 87.5% of subjects had significant improvements in the Hybrid and Combined conditions. The majority of had improvements with BKB-SIN. Results also indicated that as long as subjects maintained at least a severe LFPTA, there was significant improvement in speech understanding. Furthermore, all subjects reported positive improvements in hearing in three of the 4 subscales of the APHAB.

Conclusion—The concept of hybrid speech processing has significant advantages for subjects with residual low-frequency hearing. In this study, the Nucleus® Hybrid™ S8 provided improved

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word understanding in quiet and noise. Additionally, there appears to be stability of the residual hearing after initial activation of the device.

Level of evidence—2c

Keywords

Hybrid cochlear implant; speech perception; hearing preservation; short electrode; acoustic plus electric

The cochlear implant has been highly successful in restoring hearing in individuals with post-lingual deafness and in children who are prelingually deafened and are implanted early. When cochlear damage includes large numbers of missing inner hair cells, electrical stimulation (via cochlear implant) of the auditory nerve is the only existing method to deliver sound stimulation. Until recently, those with residual hearing have not been candidates for standard cochlear implants because implantation of the device destroys most useful remaining hearing. Generally, if someone has pre-implant residual hearing, it is usually in the low-frequency (LF) apical region of the cochlea. Hearing in this region enables the listener to use fine-timing and spectral cues which aide the listener in hearing complex auditory tasks such as understanding speech in noise, sound localization, and music appreciation. In contrast, cochlear implant speech processing usually does not provide the fine spectral information that residual LF hearing provides. Thus, developing a cochlear implant that could provide stimulation to the damaged high-frequency regions of the cochlear while at the same time preserving the LF hearing offers numerous advantages to these individuals.

The concept of the Hybrid cochlear implant began in 1995 when the senior author approached Cochlear Americas to design an electrode that could be implanted into the base of the cochlea while preserving LF hearing in individuals with mild to moderate residual hearing. It was unknown if placing an electrode into the basal turn of the scala tympani would allow preservation of acoustic hearing. The original device was designed to be inserted 6 mm into the scala tympani so as to not advance the electrode into the ascending basal turn of the cochlea. It was known that the anatomy of the 1st basal turn of the scala tympani tends to push the electrode toward the fragile basilar membrane as the electrode is advanced. This device had 6 separate electrode channels and was implanted into 3 subjects in 1999 as part of a Food and Drug Administration (FDA) feasibility trial. The most important finding of the feasibility trial was that residual acoustic hearing and residual word perception could be preserved in these subjects. There was also an improvement in consonant perception; however, the sound perception was perceived as too high-pitched by the subjects and was not conducive for continued use[1]. It was recognized that the electrical stimulation was being transmitted too basally into the cochlea where standard implants rarely deliver information and likely had little residual neural substrate. The electrode was lengthened to 10 mm with the 6 electrode contacts spaced more toward the apex of the array. This became the Nucleus® Hybrid™ S8 implant and has been termed the Iowa/Nucleus 10 mm Hybrid implant or short electrode in various publications [2–11]. The Hybrid S8 FDA multicenter clinical trial began in 2002 and was completed in 2011 involving 19 surgeons across 17 centers in the United States (see acknowledgement). A preliminary account of the

S8 implant data was published in 2009[12] and this report describes the final outcome of the clinical trial.

Methods

Participants

Eighty-seven subjects in the U.S. received Nucleus® Hybrid™ S8 implants (with 6 contacts across 10 mm electrodes) under an Investigational Device Exemption (IDE). The subjects in this prospective FDA multicenter clinical trial were implanted under study protocols in 3 distinct stages:

- A single-site feasibility study began in 1999 at the University of Iowa involving a design based on the Nucleus 24 receiver/stimulator (CI24M). In this phase, 4 subjects were implanted with 10 mm electrodes incorporating 6 stimulating contacts.
- In 2002, the feasibility study was expanded to a multicenter trial involving 9 investigational sites, in order to determine if the initial results from the University of Iowa could be more widely duplicated. This stage was referred to as the "Phase 1 trial." Twenty-five subjects received Nucleus 24-based devices with 10 mm electrodes during this phase.
- In 2005, the study again expanded, to a total of 17 investigational sites, in order to further broaden surgical and clinical experience. In addition, the device design was altered to incorporate the existing 10 mm electrode array and the current-generation Nucleus Freedom™ (CI24RE) receiver/stimulator. This was referred to as the "Phase 2 trial." Fifty-eight subjects received Nucleus Freedom-based 10 mm devices under the Phase 2 multicenter study protocol.

The preliminary report of the multicenter clinical trial included 68 of the present cohort [12].

The subjects ranged in age from 19.6 years to 82.3 years, with a mean age of 58.9 years (SD =14.8 years; median = 59.8 years). Thirty-nine (44.8%) of the subjects were male, and 48 (55.2%) were female. Average age of onset of hearing loss in the implanted ear was 26 years (SD = 13.4 years; median = 24 years).

Case histories elicited from the subjects, by the surgeons and/or audiologists, indicated that for the majority of subjects, etiology of the hearing loss was unknown (41/87 or 47.1%), with many describing a family history of hearing loss (22/87 or 25.3%). Etiologies of hearing loss in the remaining subjects included: history of noise exposure (15/87 or 17.2%), autoimmune inner ear disease (2/87 or 2.3%), measles (2/87 or 2.3%), ototoxicity, neuritis, large vestibular aqueduct syndrome, Usher's Syndrome and endolymphatic hydrops (each 1/87 or 1.1%). The mean duration of high-frequency hearing loss was 26.3 years (SD = 13.3 years; median = 22.8 years).

The study was conducted according to the guidelines for the protection of human subjects as set forth by the Institutional Review Board (IRB) at each implant center. Inclusion criteria for the feasibility and clinical trials included the following: low-frequency pure-tone

acoustic thresholds between 125 Hz and 500 Hz at or better than 60 dB HL; pure-tone acoustic thresholds above 1500 Hz poorer than 75 dB HL; aided Consonant-Nucleus-Consonant (CNC)[13] word scores between 10% and 60% in the ear to be implanted and up to 80% in the contralateral ear. The ear with the poorer hearing, determined by the ear with poorer word recognition score and/or poorer audiometric thresholds if word recognition was equivocal, received the cochlear implant device. Subject selection for this study was based entirely on audiometric criteria. Duration of high-frequency hearing loss, age at implantation, and etiology were documented, but not used as exclusionary criteria.

Test Materials

Auditory function was evaluated pre- and postoperatively at 3, 6, and 12 months using a common battery of speech perception measures. The CNC (Consonant-Nucleus-Consonant[13]) word recognition test and the BKB-SIN (Bamford-Kowal-Bench Sentences-In-Noise[14,15]) test were the primary speech perception measures. Self-assessment data were also captured using the Abbreviated Profile for Hearing Aid Benefit (APHAB[16]). A description of each test measure is given below.

CNC Monosyllabic Words—This open-set word recognition test was used to assess speech perception in quiet, unilaterally and bilaterally. The CNC test consists of 10 lists with 50 monosyllabic words in each list. Two lists are administered for a total of 100 words per test condition. Subject responses were scored for the number of words correct, expressed as a percentage.

BKB-SIN Test—The BKB-SIN test consisted of 36 lists of sentences with three to four key words per sentence. The 36 lists were paired to create 18 predetermined list-pairs that are matched for difficulty level. The sentences were presented with four-talker babble as a competitor at prerecorded signal-to-noise ratios, which decrease in 3 dB steps from easy to difficult, sentence-to-sentence within each list. For each sentence, the number of keys words correctly repeated by the subject was recorded. The test permitted performance to be expressed in terms of the signal-to-noise ratio (S/N) required to obtain 50% of the key words spoken correctly; the Speech Reception Threshold or SRT. Improvement for this test was noted by a downward change in score; a lower SRT indicated that the subject could maintain speech understanding at a more aversive SNR. This test was administered pre- and postoperatively in unilateral and bilateral conditions. Two list-pairs were given per condition and the scores for each list-pair averaged.

Abbreviated Profile of Hearing Aid Benefit (APHAB)[16]—This questionnaire was used to measure subjective benefit perceived by the subjects when using their preferred listening mode pre- and postoperatively. The APHAB was a 24-item self-assessment scored in four subscales (6 items per subscale). Three subscales, Ease of Communication (EC), Reverberation (RV), and Background Noise (BN) addressed speech understanding in everyday life. The fourth subscale, Aversiveness to Sounds (AV), measured negative reactions to environmental sounds. The items in the APHAB were statements concerning communication abilities or perception of sound in everyday life situations, with the

respondent's task to indicate the frequency to which each statement is true. The subjects were presented with a seven-point scale as follows:

- Always (99%),
- Almost Always (87%),
- Generally (75%),
- Half-the-time (50%),
- Occasionally (25%),
- Seldom (12%), and
- Never (1%).

For the purpose of pre- to postoperative comparisons, administration of the APHAB was conducted preoperatively and at the 6-month postactivation interval. Administration was anchored to the preoperative administration, as recommended by the authors for the type of comparisons made in this study. That is, subjects were able to review their prior responses made preoperatively with acoustic stimulation alone when making their responses at the 6-month evaluation. The APHAB was added in Phase 2 of the study, and were not administered to those implanted prior to Phase 2.

The CD-recorded speech perception tests were administered in a calibrated sound-field at 70 dBC, with participants seated within the sound-field at a constant azimuth (0 degrees) and distance from the transducer. Before beginning the required sound-field testing, each subject was asked to adjust the hearing aid and/or speech processor's volume and/or sensitivity controls to achieve a comfortable listening level. Investigators instructed the subjects to maintain those settings for the remainder of the testing.

Pre-Operative Candidacy and Baseline Procedures

To document residual acoustic hearing, standard pure-tone air-conduction thresholds were measured in each ear at all frequencies from 125 – 8000 Hz using ER-3A insert earphones. Bone-conduction thresholds were also obtained between 250 Hz and 4000 Hz to verify a sensorineural hearing loss.

All subjects in this study used broadband bilateral hearing aids on a daily basis. At candidacy evaluation, if a patient presented with no amplification or an unsatisfactory fitting (e.g., not meeting fitting targets), a minimum 2-week hearing aid trial was initiated with optimally fitted amplification prior to baseline testing. Optimally fitted amplification characteristics were determined based on targets derived from the National Acoustics Laboratories (NAL) hearing aid fitting procedure[17,18].

Preoperatively, the CNC words and BKB-SIN tests were administered:

1. with acoustic stimulation provided in the ear to be implanted,
2. with acoustic stimulation provided in the contralateral ear, and
3. with acoustic stimulation provided bilaterally.

Surgical Procedure

The 10mm Iowa/Nucleus Hybrid electrode was designed to be minimally invasive and only enter the descending basal turn of the scala tympani between 190 and 200 degrees. This short intracochlear electrode had a reduced diameter of 0.2 X 0.4 mm as compared to standard-length cochlear implants. Six electrodes (channels) are located in the distal 5 mm of the electrode. The device was placed through a 0.5–0.6 mm cochleostomy located anterior and caudal to the round window annulus using "soft surgical" techniques similar to those used during a "drill-out" stapedectomy. Diamond burs of 1 mm and 0.5 mm were used to create an opening in the otic capsule without disturbing the endosteum. The opening into the cochlea was created with micro footplate hooks and/or instrumentation[11]. All devices were placed through a cochleostomy surgical approach.

Post-operative Procedures

Programming of Electric and Acoustic Devices—Approximately 1 month following surgery, subjects returned to their audiologist for activation of their cochlear implant. Pure-tone air- and bone-conduction thresholds were measured in each ear to determine preservation of residual hearing at activation, 3 months, 6 months, 12 months, and at yearly intervals. For the purposes of documenting pre- to post-operative changes in hearing, a low-frequency pure-tone average (LFPTA) was calculated using thresholds over the range 125, 250, 500, 750 and 1000 Hz. The LFPTA was compared pre vs. post operatively in both the implant ear and the contralateral non-implanted ear (though only data for the implanted ear are presented herein). This allowed us to contrast any post-operative loss of hearing as a result of implantation versus as a result of continued hearing loss associated with the patient's ongoing disease process.

All patients' processors were programmed with a standard CIS (ACE with the number of maxima = number of channels) type processing strategy, with frequency MAPs chosen to begin at the upper frequency cutoff of functional residual hearing in the implanted ear. This typically resulted in speech information allocated to the 6 electrodes in frequency ranges of 688–7938 Hz or 1063–7938 Hz. "Functional" acoustic hearing was defined by frequencies with thresholds better than 90 dB HL and provided with acoustic amplification. Subjects continued to use a hearing aid in the implant ear, with amplification provided up to the cutoff of functional hearing. The amplification characteristics applied to the low-frequencies were also based on targets derived from the NAL hearing aid fitting procedure. Broadband amplification was applied to the contralateral ear for all subjects, again based on the NAL hearing aid fitting procedure. Adjustments were made to amplification postoperatively, per NAL guidelines, only if necessary (e.g., to compensate for changes in acoustic hearing).

Two subjects preferred to use their natural low-frequency hearing in both ears, rather than hearing aids, with the implant (both had mild to moderate hearing thresholds up to 750 Hz in both ears) and were tested in this listening mode. These two subjects were still considered to be using combined electric and bilateral acoustic hearing. Two subjects (one with profound low-frequency hearing loss and one with complete loss) did not use amplification in the implanted ear and were tested with the cochlear implant alone and with contralateral amplification. An additional subject with profound loss of hearing in the implant ear likely

did not receive benefit from and did not use amplification on a daily basis in that ear, but was tested with acoustic amplification in both ears in addition to the cochlear implant. All other subjects used amplification in both ears with the cochlear implant. In cases where a subject lost sufficient hearing that amplification in the implant ear was not beneficial, the implant processor MAP was programmed to correspond with the upper frequency cut-off of the *contralateral* ear as well as a broadband MAP.

Speech Testing—Speech discrimination in quiet and in noise was measured using the CNC word test and the BKB-SIN test under some or all of seven different conditions: 1) acoustic hearing implant ear, 2) acoustic hearing bilaterally, 3) bilateral hearing aids plus implant (**Combined mode**), 4) implant ear + hearing aid (**Hybrid mode**), 5) implant only (**CI only**), 6) implant + contralateral hearing aid (**Bimodal**), and 7) ipsilateral acoustic only. See Table 1 for definitions used to classify device use and post-operative testing configurations. Post-operative testing occurred at 3, 6, and 9 months for Phase 1 and 2. Subjects in Phase 2 were also tested at 12 months. The speech scores obtained by the subjects using hearing aids preoperatively were compared to the post-operative scores obtained by the subjects using the cochlear implant with bilateral hearing aids.

Defining Hearing Preservation: Functional vs Non Functional Acoustic Hearing—One of the risks of any cochlear implant surgery is the loss of residual hearing. For subjects who were implanted under this study, it was unknown if a shorter device could be implanted into the basal region of the cochlea while still preserving their good LF acoustic hearing. As we began analyzing results of the subjects implanted, we found it difficult to accurately describe hearing loss. Originally, we described hearing loss by the amount of loss in decibels. We realized that this would only define how much hearing was lost, but would not define functionality of hearing. For example, if a subject had a preoperative threshold at 500 Hz of 25 dB HL and then lost 30 dB HL of hearing at initial activation, that person still had useable hearing at 500 Hz (55 dB HL threshold). Contrast this to a person with a preoperative threshold of 60 dB HL at 500 Hz and then lost 35 dB HL of hearing at initial activation. This person no longer had functional hearing at 500 Hz (95 dB HL threshold). Thus, an important concept that emerged out of studying this dataset is the notion of functional versus nonfunctional residual hearing. Specifically, those with profound hearing loss poorer than 90 dB HL are unable to receive the benefits of amplification[19,20,21,22]. Thus, for low frequency hearing to be functional and for the subject to be able to take advantage of the acoustic plus electric processing, it must be preserved better than 85–90 dB HL pure tone average (PTA) of 125–1000 Hz. Furthermore, hearing loss was also classified by degree using the following definitions:

- Mild: 26 to 40 dB HL,
- Moderate: 41 to 55 dB HL,
- Moderately severe: 56 to 70 dB HL,
- Severe: 71 to 90 dB HL,
- Profound: > 90 dB HL,
- Total: No measurable thresholds for any frequency.

Statistical Analysis

In line with a within-subject study design, results were initially analyzed for each subject individually. The binomial confidence interval was selected to compare measurements between pre-implant and 12 month post-implant. If a participant did not have a 12 month score, then the 9 month score was carried forward for the purposes of this analysis. The aggregated results provide the reader with the total number of subjects who demonstrated statistically significant performance improvements or decrements. Aggregation of the individual subject data in this way provided a measure of the strength and consistency of the single-subject findings across the independent experimental replications.

Multiple regression models were used to examine the impact of age at implantation, duration of deafness, and post-operative LFPTA hearing thresholds impact speech perception scores. The post-operative scores were used as the outcome variable and the pre-operative scores were included as covariates in the model. In addition, a paired t-test was used to determine if scores significantly changed from pre-implant to 12 month post-implant for both CNC and BKB-SIN. All statistical analyses were carried out using SAS v9.4

Results

Hearing Preservation

The surgical implantation of a 10 mm electrode in the scala tympani resulted in hearing preservation in nearly all of the subjects. Only 1.3% (n= 2/87) of subjects experienced total hearing loss within one month following implantation. Total loss of hearing was recorded as 130 dB HL and this value was used in the averages described below. Evaluation of individual thresholds at initial activation showed that 94% of the subjects maintained functional hearing from 125 to 500 Hz. This would suggest that the surgical technique itself is sound in achieving good retention of useful LF hearing postoperatively for the majority of subjects. In Figure 1, we show the average thresholds over the range 125 to 1000 Hz in the implanted ear both preoperatively and post-operatively at initial activation, 3 months, 6 months, and 12 months. The greatest shift occurs between the pre-operative and initial activation time points. The preoperative LFPTA (calculated using thresholds over the range 125, 250, 500, 750 and 1000 Hz) was 48.9 dB HL and post-operatively at initial activation it was 63.6 dB HL, decreasing 14.8 dB HL as a direct result of surgical implantation of the short electrode device. The decrease in hearing was evenly distributed across all of the low frequencies with no particular frequency being impacted more than another. A second smaller change in acoustic hearing was observed following the activation of the speech processor and hearing aid through the first 3 months of use of the devices. Acoustic hearing then appeared to stabilize during the remainder of the trial.

In Figure 2, we show the change in LFPTA at initial activation and longitudinally through 12 months post-implantation for individual subjects. For the Panels detailed in Figure 2, the pre-operative LFPTA is shown on the horizontal axis and the post-operative LFPTA at a particular time point is shown on the vertical axis. The black diagonal line indicates no change in LFPTA. The horizontal dashed line shows the cutoff for functional hearing. An individual who has a PTA poorer than 90 dB HL (dashed horizontal line) would be

considered to have nonfunctional acoustic hearing. In Panel A we show the LFPTA for initial activation. This figure includes all 87 subjects in this study. There were two instances of immediate post-operative total hearing loss. Furthermore, an additional six subjects also lost enough hearing in the low frequencies to be considered nonfunctional. This resulted in a total of eight subjects with non-functional hearing loss. In Panel B, we show the LFPTA at 3 months post-activation for 83 subjects. By the 3 month appointment, five subjects had withdrawn from the study. However, one of the subjects who withdrew from the study prior to the 3-month evaluation experienced a profound loss of hearing. To accurately reflect the number of subjects with significant change in hearing, the audiometric results obtained for this subject were carried forward such that data for 83 subjects are reflected in this panel. As indicated in Panel B, an additional three subjects experienced a total loss of hearing and the number of subjects with nonfunctional hearing increased to 14 at 3 months post-activation. Panel C depicts data on 84 subjects at 6 months post-activation. Data were available for 82 subjects at the 6-month evaluation. However, for consistency in reporting, observations for an additional 2 subjects who experienced a significant loss of hearing and withdrew from the study prior to the 6-month evaluation were carried forward resulting in 84 subjects in Panel C. There were no further subjects with total hearing loss and the number of subjects with non-functional hearing loss increased by 2 to a total of 16 (19%). In Panel D we show the LFPTA at 12 months post-activation for 80 subjects. Specifically, data were available for 75 subjects at the 12-month evaluation. However, observations for 5 subjects who experienced significant loss of hearing and withdrew from the study prior to the 12-month evaluation were carried forward such that data for 80 subjects are reflected in Panel D. At this visit, there were no additional subjects experiencing total hearing loss and the number of subjects with non-functional hearing loss remained 16.

A detailed description of the number and percent of total subjects within each hearing loss classification pre-operatively and post-operatively through 12 months is shown in Supplemental Table 1. It appears that most of the nonfunctional hearing loss change occurred between initial stimulation at one month and 3 month post activation of the speech processor. At initial activation 9.2 % of subjects were unable to use their acoustic speech processing. This increased to 16.8% at 3 months and stabilized at 19.6% at 12 months.

Speech Perception

In Supplemental Figure 1, we show the unaided CNC word scores of 82 subjects (data was not collected on 5 subjects) in the implanted ear both preoperatively and at initial activation. Sixty-eight percent of the subjects did not show a significant change in their CNC score, according to the binomial confidence interval, which is a secondary way of verifying preservation of some residual hearing. Six subjects scored significantly better (using the binomial model) at initial activation and 20 of the subjects scored significantly worse. It is not unusual, however, for subjects to have some residual fluid in their middle ear for a few weeks following surgery. Thus, it is not surprising that some subjects performed worse with their unaided CNC perception at initial activation.

In Figure 3, the individual scores preoperatively with a hearing aid(s) and postoperatively at 12 months in the Hybrid condition (Panel A), Combined condition (Panel B), CI only (Panel

C), and Ipsilateral Acoustic only (Panel D) on CNC words in quiet are shown. To compute the postoperative value, we relied on the value carried-forward method described previously. Using a binomial confidence interval, we evaluated the percentage of participants who improved their CNC word score post-operatively versus those whose CNC word scores decreased. In the Hybrid condition, 82.5% of the subjects had significant improvements and 87.5% of the subjects in the Combined condition had significant improvements. For the Electric only condition, 60% demonstrated significant improvement. There were 15 individuals that achieved more than 60% correct on the CNC word test even with the limited frequency range of the programmed Hybrid implant. The electric only score was tested with the individual's map that had a restricted frequency distribution between 750–8000 Hz. This demonstrates that some individuals are able to understand speech with stimulation of a very circumscribed region (4.6mm) within the cochlea[23]. In the Ipsilateral acoustic only condition, 60% demonstrated no change in discriminating CNC words in the implanted ear and 32% demonstrated a decrement. This is remarkable since these individuals have been using combined processing for 12 months.

The individual signal-to-noise ratio (S/N) scores preoperatively with a hearing aid(s) and postoperatively at 12 months in the Hybrid (Panel A), Combined (Panel B) on the BKB-SIN test are presented in Figure 4. To compute the postoperative value, we again carried-forward values as described previously. The within subject binomial confidence interval is not appropriate for the BKB-SIN scores, however we evaluated the percentage of participants who improved their BKB-SIN score post-operatively versus those whose scores had no change or decreased in performance. In both the Hybrid and Combined conditions, 55% of the subjects had improvements in speech understanding in noise.

In Figure 5 are averaged results for listeners pre-operatively and over time in the Combined, Hybrid and CI only conditions post-operatively at 3, 6, 9, and 12 months for CNC words in Panel A and BKB-SIN Test in Panel B. Two subjects lost their residual hearing in the implanted ear prior to 3 months and one subject lost their residual hearing after 6 months. For these subjects, data in the Bimodal Condition are used in place of the Combined Condition and in the CI-Only Condition rather than the Hybrid Condition. Speech perception data are available at 9 or 12 months on 76 subjects for CNC and for 69 subjects for BKB-SIN. The CI-only scores are collected with 6 electrodes in basal turn with the frequency allocation of the electric stimulation unchanged from the Combined and Hybrid conditions. Scores for the CNC words scores are shown in percent correct whereas scores for the BKB-SIN scores are shown in signal-to-noise (S/N) ratio. Results show that averaged performance improved after cochlear implantation in both the Hybrid and Combined conditions for both the CNC and BKB-SIN tests with the greatest improvement occurring by 3 months. Using a linear regression model with autoregressive correlated errors, the Hybrid condition for the CNC test yielded statistically significant changes from 0 to 3 months ($p<0.0001$) and from 9 to 12 months ($p=0.0128$) but not from 3 to 6 ($p=.0582$) or 6 to 9 months ($p=0.5621$). The BKB-SIN test in the Hybrid condition resulted significant changes from 0 to 3 months ($p=0.0002$) and again from 3 to 6 months ($p=0.0061$), but not 6 to 9 months ($p=0.4851$) or 9 to 12 months ($p=0.2568$). We see similar but not identical results in the Combined condition where we have CNC significant changes from 0 to 3 months ($p<0.0001$) and 3 to 6 months ($p=0.0135$) but not 6 to 9 months ($p=0.5203$) or 9 to 12

months (p=0.0507). The BKB-SIN also saw significant changes from 0 to 3 months (p<0.0001), 3 to 6 months (p=0.0006), but not from 6 to 9 months (p=0.1574) or 9 to 12 months (p=0.1942). Therefore, the scores generally showed a statistically significant improvement out to 6 months, but not after 6 months. In the CI only condition, the scores for both the CNC and BKB-SIN tests shows minimal improvement over time, but no decrement in performance, nonetheless. The CNC test had a significant change from 3 to 6 months (p=0.0329), but not at any other times. The BKB-SIN test did not have any statistically significant changes over time in the CI only condition.

The influence of LFPTA on CNC word scores at 12 months post-operatively are shown in Figure 6. LFPTA for subjects in the implanted ear, recorded as either functional or non-functional, was included in the linear regression model to evaluate the impact of residual hearing on CNC word scores. Scores are shown by amount of functional hearing where the subjects' LFPTA was in the moderate, moderately-severe, or severe hearing range. The line represents the median and the "X" denotes the mean. Separate multiple regression models were constructed for the Hybrid (Panel A) and Combined conditions (Panel B). In the Hybrid condition (Panel A), the pre-implant CNC score (p=.0072) and residual acoustic hearing category (p=.0064) at 12 months were significant predictors of CNC 12 month Hybrid score. Post-hoc tests reveal that individuals with Profound hearing loss score significantly different from individuals with moderate (p=.0005), moderately-severe (p=.0327), and severe loss (p=.0375) in the Hybrid condition. The scores from profound hearing loss group were poorer. The moderate and moderately-severe groups were not significantly different (p=.0638), and no other comparisons were near significance (p >0.1). In addition, we used a paired t-test to examine whether or not CNC scores changed significantly from pre-implant to 12 month post-implant within each of the hearing categories. We found that CNC scores significantly increased for individuals with LFPTA hearing losses in the moderate (p<.0001), moderately-severe (p<.0001), and severe (p=.0047) ranges, but not for those with profound hearing loss (p=.4154). It is important to understand that those in this trial that maintain even a severe hearing loss in the LFPTA benefited from the combination of acoustic plus electric speech processing.

In the Combined condition (Panel B), only the pre-implant CNC score was a significant predictor of the 12 month post-implant CNC score (p=.0003), while there was no significant effect due to hearing level (p=.2444). Using a paired t-test, significant changes in CNC scores from pre-implant to 12 month post-implant were found for individuals with LFPTA hearing losses in the moderate (p<.0001), moderately-severe (p<.0001), severe (p=.0002), and profound (p=.0035) ranges, suggesting that the contralateral ear is contributing to the speech preception results in the combined condition.

Similar results were also found for the BKB-SIN test (Supplemental Figure 2). The LFPTA for subjects in the implanted ear, were again recorded as either functional or non-functional, and was included in the linear regression model to evaluate the impact of residual hearing on the BKB-SIN scores. Scores are again shown by amount of functional hearing where the subjects' LFPTA was in the moderate, moderately severe, or severe hearing range. Separate multiple regression models were constructed for the Hybrid (Panel A) and Combined conditions (Panel B). For the Hybrid condition in Panel A, both the BKB pre-implant score

(p=.0004) and category of hearing loss (p=.0002) were again significant predictors of 12-month BKB-SIN score. Those with profound hearing loss had BKB scores that were significantly different from those with a moderate (p<.0001), and moderately-severe (p=.0014), but not for severe (p=.0626) LFPTA. Those with a moderate LFPTA were also significantly different from those with a severe (p=.0058) LFPTA and the only other comparison approaching significance were those with a moderate versus moderately-severe (p=.0827) LFPTA. When we examine amount of change in BKB within each hearing category, we find that there is significant change in the moderate (p=.0001) and in moderately-severe groups (p<.0001), but not in severe (p=.2201) or profound (p=.5622) groups. The profound group was also singled out for the analysis of BKB in the Combined condition (Panel B). Both the BKB pre-implant score (p<.0001) and LFPTA category (p=.0150) were significant predictors of BKB 12 month implant score in the Combined condition. The profound group had scores that were significantly different from moderate (p=.0013), and moderately-severe (p=.0260), but not for the severe (p=.0552) groups. No other comparisons were statistically significant (p>0.1). The change in BKB within each hearing category was significant for all LFPTA groups.

In Figure 7, we show the influence of age at implantation (Panel A) and duration of deafness (Panel B) on 12-month CNC word scores. Linear trendlines for the Hybrid and Combined conditions are shown in each Panel. In Panel A, age at implantation was found to be a significant predictor of the CNC score in the Hybrid condition (p=0.0150), but not in the Combined condition (p=0.2658). For the Hybrid condition, this indicates that the older a patient was at the time of implantation, the lower their CNC score at 12 months post-implantation. This effect was not evident in the Combined condition. In Panel B, duration of deafness was also a significant predictor of CNC score in both the Combined (p=0.0140) and the Hybrid (p=0.0315) conditions, indicating the longer the duration of deafness, the lower their CNC score at 12 months post-implantation.

APHAB Results

For the APHAB, subject responses indicated the frequency with which various listening environments presented a problem for communication or sound comfort[16]. The APHAB was used in this study to compare two *aided* conditions:

1. Preferred listening mode (for most subjects bilateral hearing aids) preoperatively,
2. Preferred listening mode 6 months postactivation (for most the Combined mode).

The preferred listening mode was with bilateral hearing aids for most of the subjects (55/57 or 96.5%) preoperatively and in the combined mode for most subjects postoperatively (38/49 or 77.6%) at 6 months. For 10.2% of the subjects, their preferred listening mode was Bimodal (5/49).

Four out of the 58 subjects in the Phase 2 study did not complete the APHAB postoperatively. Two subjects had withdrawn prior to the 6-month evaluation; one subject did not complete the 6-month evaluation, and subsequently withdrew from the study not having completed any postoperative evaluations, and one subject did not complete the

APHAB at 6 months. One of the 58 subjects did not complete the APHAB preoperatively leaving a total of 53 for analysis.

On an individual subject basis quite large changes were required on the individual subscales related to hearing speech in quiet and in noise or reverberation (EC, BN, and RV) in order to have a high degree of confidence that a meaningful pre-to-post change had occurred. According to the authors of the APHAB, changes in ratings of 22% and 26% are reasonable estimates of the critical differences for 90% and 95% confidence for the individual communication subscales when comparing two *aided* conditions.

In Supplemental Figure 3, we show the averaged results preoperatively for each of the subscales in this questionnaire (background noise, ease of communication, reverberation, and aversiveness to sound) and at 6 months postoperatively. Subjects reported changes in three of the subscales (background noise, ease of communication, and reverberation) that were consistent with the creators of the scales' reasonable estimates of the critical differences at a 90% confidence interval. The fourth subscale (aversiveness to sounds) did not show differences that would be considered different. However, since this measure indicated the level to which the subjects found environmental sounds too loud, or bothersome in some way, a no change score can be considered a positive outcome. In other words, this would indicate that environmental sounds were no more bothersome with the Hybrid implant than they were with hearing aids alone.

Re-implantation

Fourteen individuals requested that the Hybrid S8 implant be removed for various reasons of dissatisfaction with the device and had a standard length Nucleus Freedom cochlear implant placed. Most experienced a progressive loss of acoustic hearing in the implant ear. Two subjects (US14-HYB-1050 and US01-HYB-1015) who opted to have the Hybrid S8 device removed did not experience a significant ipsilateral threshold shift, but did not have good speech perception outcomes with the Hybrid device. Subject US14-HYB-1050 had a Hybrid electrode array that was not completely inserted (although all 6 contacts were intracochlear). After reimplantation scores were available for US14-HYB-1050. Unfortunately, CNC scores did not improve for this subject with a longer device. Two subjects experienced two shifts in low-frequency hearing prior to explanation and reimplantation. Supplemental Table 2 provides detailed information regarding degree of hearing loss and CNC word scores before and after reimplantation in the implanted ear. It is interesting that only a few subjects who were re-implanted performed significantly better with the standard implant than they did with the Hybrid prior to losing hearing. In fact, some actually performed similar or worse with the longer device.

Discussion

The Hybrid S8 clinical trial is the first large scale muliticenter clinical trial of a new class of cochlear implant specifically designed to preserve functional residual acoustic hearing, thus combining acoustic and electric speech processing. Several outcomes of this trial have improved our understanding of the auditory system challenging former concepts and demonstrating the more robust nature of the inner ear than previously perceived. The ability

of the central auditory system to combine two different types of signals that have dissimilar timing characteristics was not previously appreciated. The combined speech preception scores demonstrate a significant improvement for a group of individuals that were not candidates for a standard cochlear implant because their word understanding scores preoperative did not qualify them for a cochlear implant. These persons were frustrated by their lack of word understanding and their hearing loss was limiting their abilty to work and engage in normal social interaction.

The combination of acoustic + electric processing significantly improved monosyllabic word scores in quiet and noise for the majority of subjects enrolled in this study. Over 87% significantly improved their word understanding using the acoustic + electric combination when listening with both ears + the Hybrid S8 device. Only one subject tested at 12 months was worse than their preoperative score with hearing aids only. It is remarkable that with only 6 electrodes stimulating 4.6mm of the cochlea 60% of the subjects improved their word score using the electric only condition while 82.5% demonstrated an improvement combining acoustic + electric in the same ear (hybrid ear).

This trial demonstrated for the first time that an electrode array could be placed within the scala tympani and the vast majority of subjects maintained functional acoustic hear. The technique of hearing preservation was translated to multiple surgeons and multiple centers. In this study a cochleostomy was the only surgical strategy for electrode placement, but others have been able to achieve similar results using a round window approach[24]. In fact an analysis of published results suggests that cochleostomy or round window achieves similar acoustic hearing preservation[25]. Originally the cochleostomy was selected to prevent any disruption of the round window membrane mobility. Neither approach appears to limit the travelling wave of the basilar membrane. There does appear to be a shift of approximately −15 dB PTA by placing an electrode in the cochlea, but there is a range of about +30dB to −20dB PTA shift for those that maintain functional hearing at the one month initial activation audiogram as seen in Figure 2A. The cause of this shift is unknown but could be the result of some alteration of the acoustic wave from placement of an electrode in the inner ear. Similar shifts are seen in other short electrode studies[26,27,24]. It is of interest that about 8% of subjects experience a further drop in acoustic hearing following the activation of the combined electrical processing and acoustic amplification and 3 month test period. The six month and 9–12 month testing suggests that the inner ear stablizes as there does not appear to be more profound loss occuring during that period of time (9.2% profound loss at initial activation, 16.8 % at 3 months, 19% at 6 months and 19.4% at 12 months.) The etiology of this further decline in acoustic hearing sensitivity is unknown, but could be the result of some inflammatory response within the cochlea, increased release of glutamate at the inner hair cell/neural synapse or excitotoxic reaction, or other process. Research to better understand this process is ongoing. The preservation of functional acoustic hearing for the 10 mm implant in this study are better than the results for the Hybrid L24 (FDA Clinical Trail Hybrid L24, 2013) or the results with the 20 mm or 24 mm placement of the Nucleus 422 cochlear implant[28].

An important finding of this research is that if one maintains functional hearing regardless of the extent of loss between moderate to severe hearing loss the addition of acoustic plus

electric hearing results in a significant improvement in speech perception in the hybrid ear compared to ears with profound or non functional acoustic hearing. In the past it was believed that loss of 30 dB PTA was a poor result. The functionality of the acoustic plus electric processing depends on the preoperative pure tone average of the low frequencies. For instance if the preoperative PTA is 45 dB the loss of 30 dB would continue to allow the individual to benefit from the acoustic hearing. However, if the preoperative PTA was 60 dB, a 30 dB loss of hearing would push the individual into the non-functional acoustic hearing range and result in electric only processing in that ear. In some individuals the bimodal format improves their speech perception, but often times not at the level that it does when functional hearing is preserved in both ears. Research by our Center as well as others demonstrates that loss of functional acoustic hearing in the implant ear would reduce the ability to localize sound which is an important safety issue for the individual[29,30].

Finally, several demographic features present in this population have an impact on outcome with the 10 mm Hybrid implant. Age at implantation and duration of high frequency hearing loss have a negative effect on performance. In addition, a history of noise exposure and male gender also has a negative impact on performance with the implant[31]. When this research was initiated, some of these demographic features were important in standard cochlear implant patient counseling, however, it was not appreciated that similar factors would impact the Hybrid implant subjects as they had residual hearing[32]. It appears that some of the subjects are able to use the limited stimulation region offered by the 10 mm electrode better than others. These differences in performance are most likely related to the residual neural substrate that is available at the base of the cochlea. Those with shorter duration of hearing loss and better preoperative hearing most likely have a better neural survival compared to those with poor performance with the Hybrid electrode. We have shown that some individuals have the ablility to adapt to the place pitch off-set of up to 3 octaves more readily than others[3, 33]. It is of interest that about 7/12 of those in which the Hybrid S8 implant was replaced with a longer electrode did not experience significant improvement in CNC word score compared to their preoperative acoustic hearing or their combined score with the Hybrid S8 implant. Others however did benefit from a longer electrode. It appears that those that did not benefit initially from the combined processing with the Hybrid S8 might be in the group that needed a longer electrode as they may lack sufficient neural elements in the base of the cochlea to benefit from limited electrical stimulation. Those that did not improve demonstrate that length of the electrode alone is not always the issue. It should be remembered that there continues to be variabiltiy in performance with standard cochlear implant subjects and other unknown issues have a significant impact on implant outcome[34].

In summary, the concept of combining acoustic + electric speech processing has significant advantages for hearing impaired subjects with residual low frequency hearing. This clinical trial demonstrates many of the advantages of preserving low frequency hearing. In this study, a very short electrode of 10 mm with 6 channels of stimulation provided improved word understanding in quiet and noise. Additionally, there appears to be stability of the residual hearing after initial activation of the device. The reasons for the loss of hearing after activation of the implant + acoustic amplification requires more research. The advantages in noise over traditional implantation without preservation of low frequency hearing is

important as selection of those with more residual hearing receive cochlear implants. At this time electrical speech processing can not provide the fine structure of the acoustic signal that is necessary to separate speech from noise and also is an advantage in recognizing melody and timbre or music[6]. The recognition of the importance of functional acoustic hearing should assist in selection of subjects for hearing preservation as well as the electrode length and type in the future. The subjects' demographic characteristics are important as a selection criteria for the risk vs benefit for the type of device for implantation. All of these issues support continued research into management strategies for the hearing impaired. The most important outcome has been the recognition that the inner ear is more robust than originally thought and opens the door to approaching those that struggle in daily hearing situations. It also says that one-size does not fit all for rehabilitation of hearing loss and clinicians will have more options for the hearing impaired in the future.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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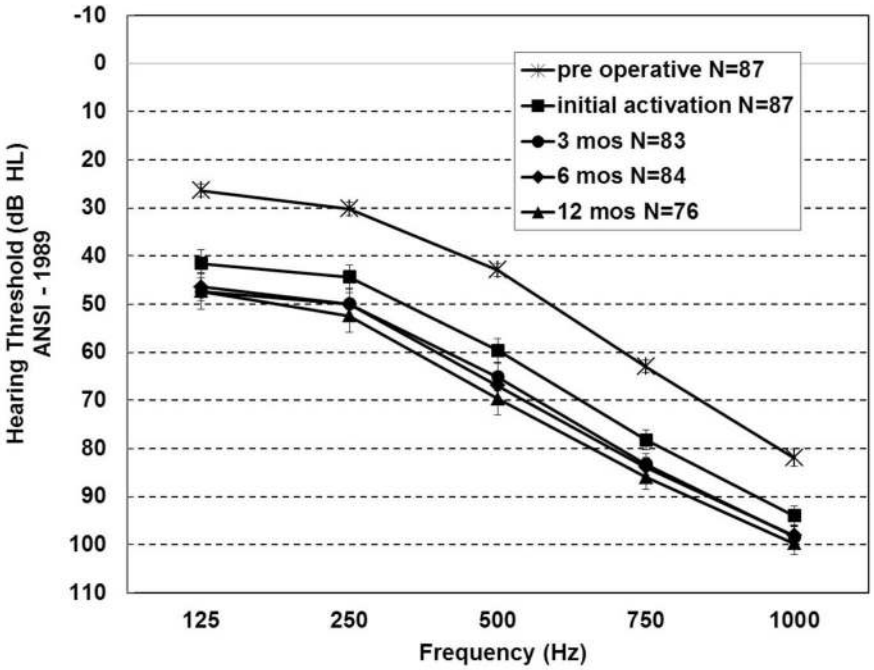

Figure 1.

Averaged unaided thresholds over the range 125 to 1000 Hz in the implanted ear shown preoperatively and post-operatively at initial activation, 3 months, 6 months, and 12 months.

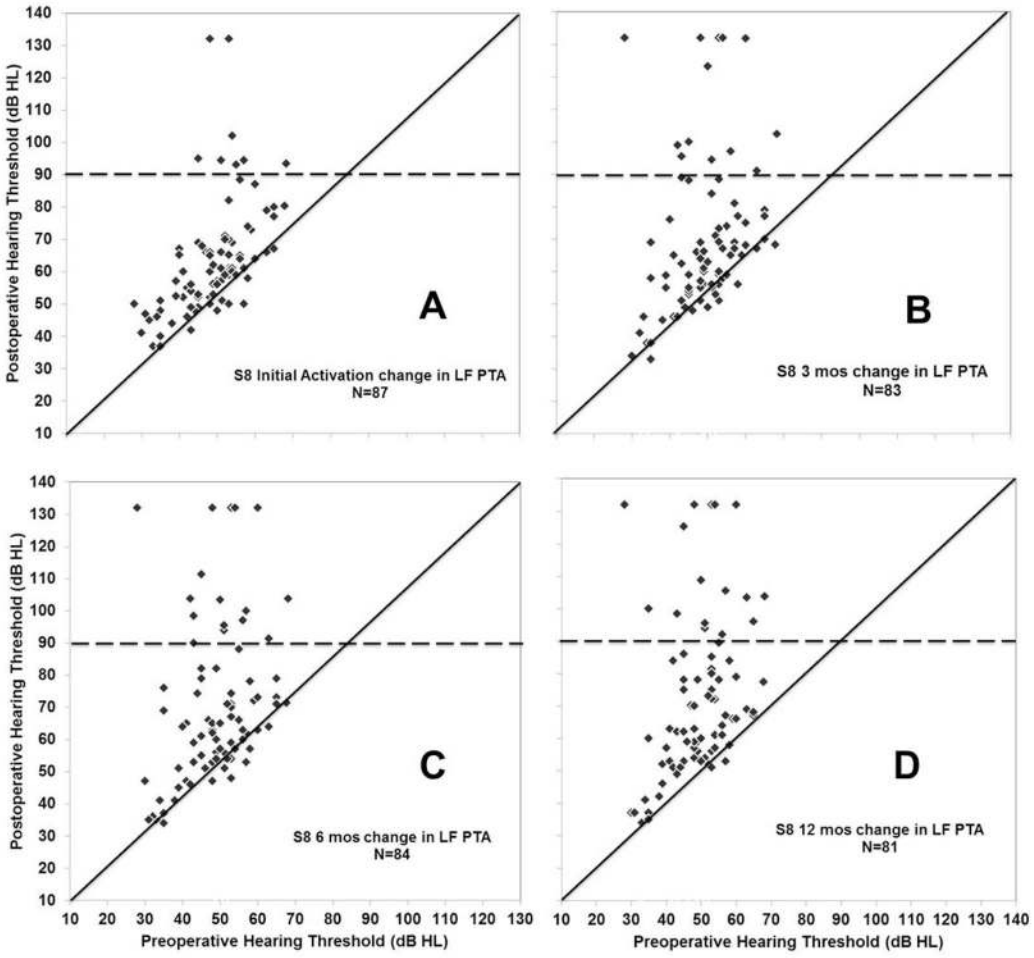

Figure 2.

Change in individual subject LFPTA at initial activation and longitudinally through 12 months post-implantation. Horizontal axis in each panel shows the pre-operative LFPTA versus post-operative LFPTA at initial activation (Panel A), three months (Panel B), six months (Panel C), and twelve months (Panel D) on the vertical axis.

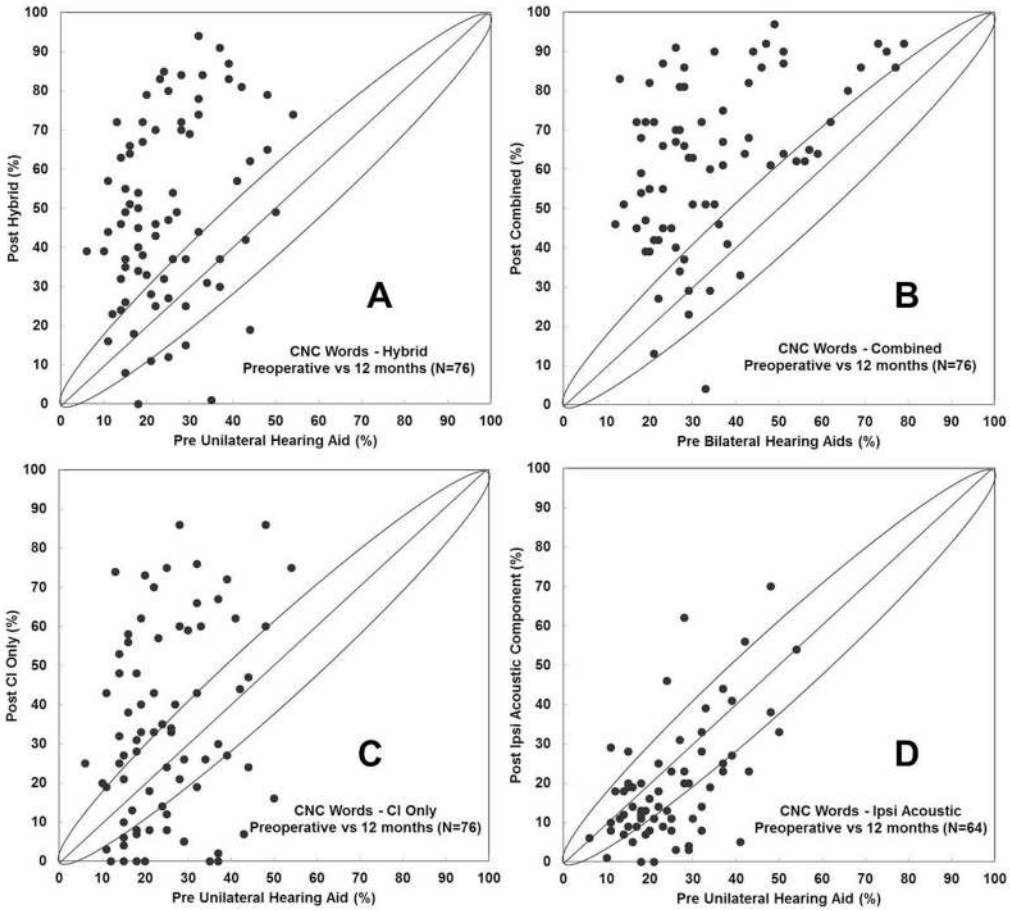

Figure 3.

Change in individual CNC word score. Horizontal axis in each panel shows the pre-operative CNC word score with hearing aid(s) versus postoperative CNC word score at 12 months in the Hybrid condition (Panel A), Combined condition (Panel B), CI only (Panel C), and Ipsilateral Acoustic (Panel D) on the vertical axis.

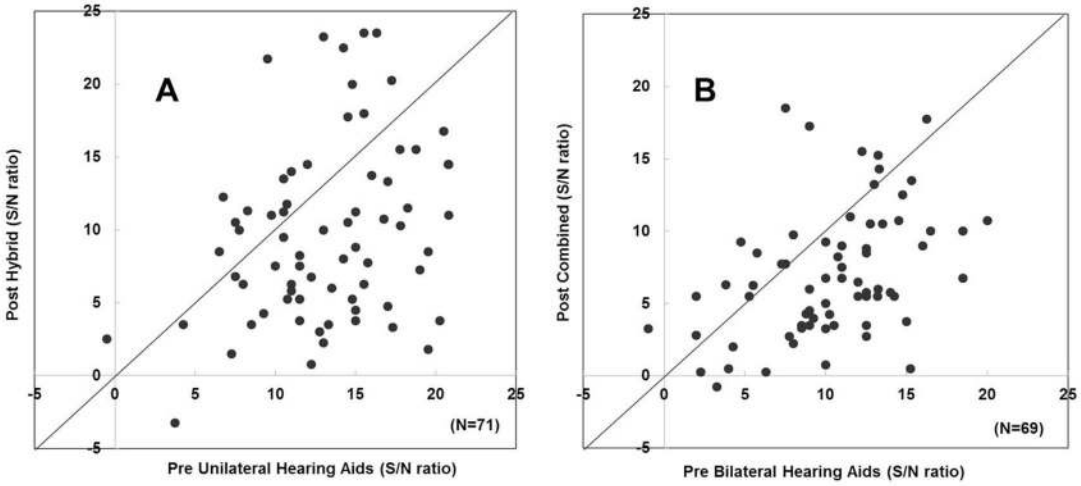

Figure 4.

Change in individual BKB-SIN in noise score. Horizontal axis in each panel shows the pre-operative BKB-SIN score with hearing aid(s) versus postoperative BKB-SIN score at 12 months in the Hybrid condition (Panel A) and Combined condition (Panel B) on the vertical axis.

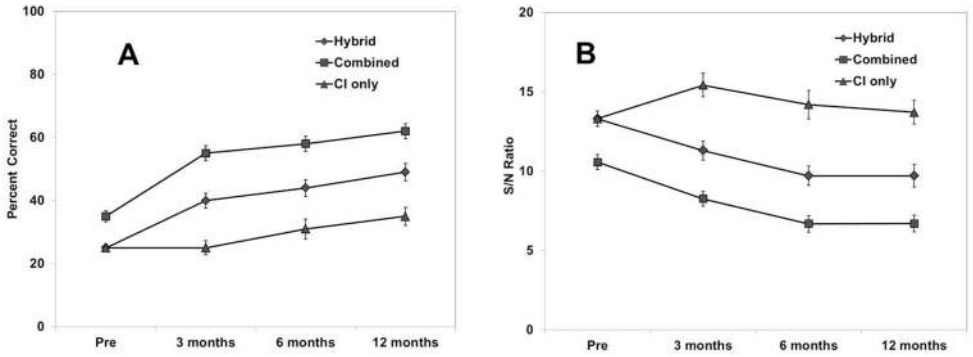

Figure 5.

Averaged speech perception results pre-operatively and postoperatively over time at 3 months, 6 months and 12 months in the Combined, Hybrid and CI only conditions for CNC words (Panel A) and BKB-SIN (Panel B).

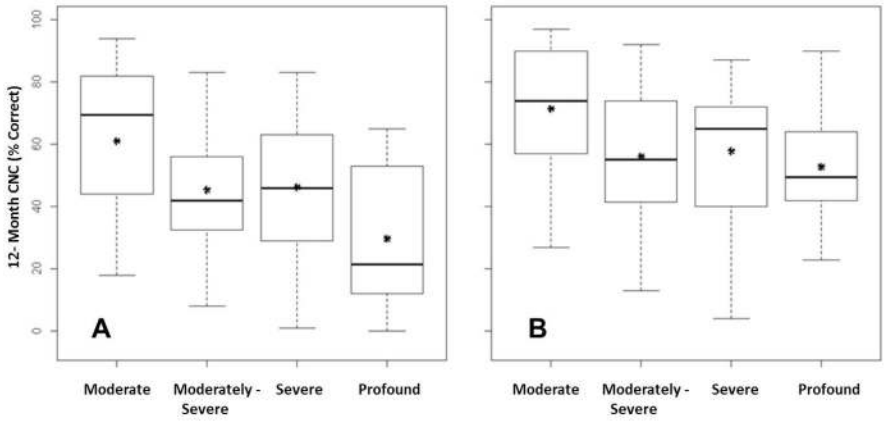

Figure 6.

The influence of LFPTA on CNC word scores at the 12 months postoperative time point. The CNC word scores are shown by amount of functional hearing in the Combined (Panel A) and the Hybrid (Panel B) conditions where the subjects' LFPTA was in the moderate, moderately-severe, or severe hearing range. The line represents the median and the "X" denotes the mean.

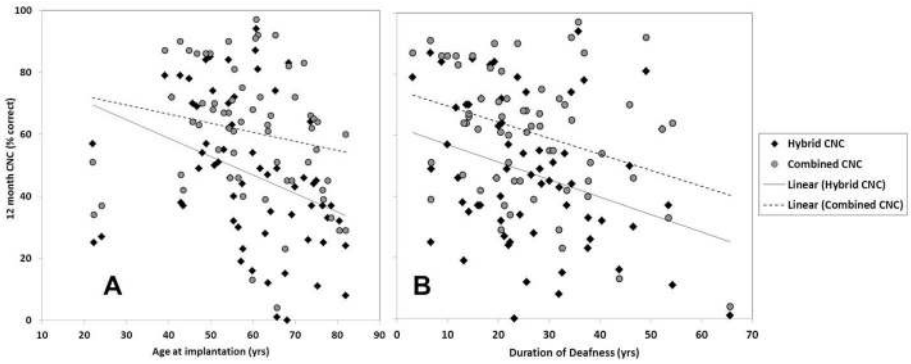

Figure 7.

The influence of age at implantation and duration of hearing loss on CNC scores at the 12 months post-operative time point. The horizontal axis in Panel A shows the age at implantation in years and the horizontal axis in Panel B shows the duration of deafness in years. In each Panel, the vertical axis represents the CNC word score, the diamonds are representative of the Hybrid condition and the circles show the Combined condition. The solid line in each Panel represents the trendline for the Hybrid condition and the dashed lined is representative of the Combined condition.

Table 1

Definitions used to classify device use and testing conditions.

Name	Definition
Acoustic Stimulation	Use of the word “acoustic” refers to sound delivered with or without amplification only.
Electric Stimulation	Use of the word “electric” refers to sound delivered via the Hybrid cochlear implant only.
Hybrid Stimulation	Use of unilateral acoustic hearing, with or without amplification, in addition to electric hearing via the Hybrid cochlear implant in the *same* ear.
Bimodal Stimulation	Use of unilateral acoustic hearing, with or without amplification, in addition to electric hearing only via the Hybrid cochlear implant in the *opposite* ear.
Combined Stimulation	Use of *bilateral* acoustic hearing, with or without amplification, in addition to electric hearing via the Hybrid cochlear implant. That is, a combination of the Hybrid and Bimodal conditions.
Ipsilateral Acoustic	Use of unilateral acoustic hearing, with amplification. That is, only acoustic hearing in the implanted ear.