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The Hybrid cochlear implant: A review

Erika A. Woodson^{1,*}, Lina A.J. Reiss^{2,*}, Christopher W. Turner^{1,2}, Kate Gfeller^{1,2,3}, and Bruce J. Gantz¹

¹Department of Otolaryngology—Head and Neck Surgery, University of Iowa Hospitals and Clinics, Iowa City, IA, USA

²Department of Communication Sciences and Disorders, University of Iowa Hospitals and Clinics, Iowa City, IA, USA

³School of Music, Iowa City, IA, USA

Abstract

The Hybrid S or “short-electrode” cochlear implant was developed to treat patients with a severe-profound hearing loss limited to the high frequencies. The short-electrode is implanted into just the base or high-frequency region of the cochlea, with the goal of preserving residual low-frequency hearing. As a result, electric stimulation can be combined with acoustic stimulation in the same ear (and the opposite ear); this is one instance of “acoustic plus electric” (A+E) stimulation. In this paper, we will review the latest findings from the first two stages of the clinical trial for the Hybrid concept in the United States. Generally, we will review surgical techniques, clinical trial criteria, residual hearing preservation, improvements in speech perception in quiet, and predictive factors for patient benefit. We will also discuss the significant benefit of A+E stimulation for speech perception in noise and musical measures of melody and instrument recognition, as well as valuable insights into central auditory nervous system plasticity gained from the use of a very short electrode array.

Background

In most cases of mild, moderate, or even severe hearing loss (HL), the auditory receptors are damaged, but hearing aids (HA) can still provide enough amplification for individuals to understand speech. However, for cases of severe to profound HL, HAs often fail to provide improvement in speech recognition [3,4].

Cochlear implantation is now a well-established and efficacious means of restoring verbal communications skills to post-lingually deafened adults with severe to profound HL. They are among the most successful neural prostheses, with improved speech recognition in quiet for the majority of cochlear implant recipients; however, speech recognition in noise and enjoyment of music has remained poor.

Corresponding Author: Bruce J. Gantz, Department of Otolaryngology—Head and Neck Surgery, University of Iowa Hospitals and Clinics, 200 Hawkins Dr, Iowa City IA 52242 USA, Bruce-gantz@uiowa.edu.

*These authors contributed equally to this article.

One overlooked segment of the hearing impaired population is individuals with a steeply sloping high-frequency (HF) HL (Fig. 1A), which is a common pattern of adult sensorineural HL. The pattern of relative preservation of low-frequency (LF) hearing with a down-sloping progressive HF HL may be seen in familial HL, presbycusis, ototoxicity, and noise-induced HL. Patients lose word understanding because consonants are heard in the HFs. These patients do not benefit fully from amplification because of the severity of the HF HL [5], but do not qualify for a standard cochlear implant because of the usable residual LF hearing. Since cochlear implants are typically implanted fully into the cochlea, the implantation process often destroys remaining auditory structures and thus the residual acoustic hearing.

Development of the Hybrid S or “short-electrode” cochlear implant, began at University of Iowa in cooperation with Cochlear Corporation to specifically treat this patient population in 1996 [1,2]. An FDA Feasibility Clinical Trial with the Hybrid S implant was initiated in 1999. Instead of a full-length cochlear implant, a shorter version is implanted into the basal cochlea, using “soft surgery” techniques to preserve the architecture of the apical cochlea. As a result, the residual apical structures and associated LF hearing can be preserved. This allows for a bimodal mode of listening: LF information provided acoustically via a HA, and HF information provided electrically through the implant. The Hybrid device is thus one implementation of the concept of “acoustic plus electric” (A+E) stimulation, in which the acoustic and electric components are provided to the same ear. A+E strategies are also being employed in Europe, with a modified technique but standard electrode length [6,7,8,9]. In this paper, we will limit our scope to reviewing the latest findings from the first two stages of clinical trial for the Hybrid S device in the United States.

The initial questions asked were: 1) Can residual hair cell function for acoustic hearing be preserved following implantation of the “short” cochlear implant? 2) Can patients successfully integrate acoustically and electrically transmitted speech cues for improved speech recognition? This paper presents the results of the Iowa/Nucleus Hybrid Implant phase I and II clinical trials, and reviews our expanding appreciation of the benefits and limitations of electroacoustic processing as well as the plasticity of our auditory system.

Methods

Overview of Hybrid clinical trial

In the initial Feasibility study, patients were implanted with two versions of a cochlear implant based on the Nucleus CI-24 implant (Cochlear Corporation). The first design consisted of a $6 \times 0.2 \times 0.4$ mm electrode with six channels. The second design increased the length of the electrode to 10 mm with the active electrodes at the distal 6 mm.

The initial single-site feasibility study was then followed by a multicenter FDA-controlled clinical trial. Based on the initial data, the 10-mm device was selected for the clinical trial. For Phase I, the study was expanded to 9 investigational sites and 25 more subjects were implanted with the 10-mm, Nucleus 24-based receiver and stimulator (CI24M). For Phase II, the study was expanded to a total of 16 sites and 58 subjects were implanted with the same

10-mm array, but paired instead with a Nucleus Freedom-based receiver and stimulator (CI24RE) (Hybrid S8).

Subjects

Patients receiving the Hybrid cochlear implantation were post-lingually deafened adults with < 60 dB HL below 500 Hz and > 80 dB HL above 2000 Hz. The specific required hearing profile is shown in Figure 1 (light gray for Phase I; dark gray for expanded profile range under Phase II). Additional inclusion criteria in Phase I were Consonant-Nucleus-Consonant (CNC) monosyllabic word recognitions scores of 10–50% in the worse hearing ear and <60% in the better hearing ear. In Phase II, these criteria were broadened to 10–60% in the worse ear and <80% in the better ear.

Preoperative audiometric evaluation included pure tone audiometry and CNC scores. Daily bilateral HA use was a prerequisite for implantation. At initial evaluation, HA checks, or fittings if the patient had not previously used amplification, were performed to ensure optimal fit. All patients underwent at least two weeks of optimally-fitted daily bilateral HA use prior to establishing preoperative speech discrimination scores, as well as implantation.

Surgical technique

Our surgical technique of soft insertion has been detailed in multiple publications [10,11]. The most important tenets are given below:

1. Completion of exposure, bony work, and soft tissue work before completing the cochleostomy. This includes drilling the well for the electronic package, harvesting and constructing a temporalis fascia washer. The facial recess or posterior tympanotomy must be opened to allow complete visualization of the round window. The overhanging niche of the round window must be removed using a diamond burr completely exposing the entire round window membrane. These steps minimize the open cochlea's exposure to blood and bone dust.
2. Minimally-traumatic cochleostomy. A strategy similar to that used to perform a "drill-out" stapedectomy should be employed. The cochleostomy must be placed approximately 1 mm anterior and inferior to the floor attachment of the round window membrane. The promontory of the cochlea in this portion can be more than 1 mm thick. It is suggested that the promontory be saucerized in this region with a 1 mm diamond burr. Placement of the cochleostomy is in the anterior-inferior position to the round window membrane avoids damage to the scala media and spiral ligament. The burr should not enter the scala tympani. The endosteum is opened with a 0.2 mm footplate hook. The smallest cochleostomy needed to insert the implant is made (0.5–0.7 mm). No suctioning of perilymph is permitted.
3. Minimally-traumatic insertion. Short lapse of time between opening the cochlea and insertion is emphasized. The electrode is stabilized with a suture at the lateral tegmen mastoid cortex prior to insertion into the cochlea. Actual insertion of the electrode is slow (30–45 seconds) to minimize intracochlear trauma.

Programming of processor and HA

All patients' processors were programmed with a standard ACE strategy (with 6 of 6 peaks, so essentially CIS).

During the initial feasibility study, each patient was provided with a range of MAP frequency allocations to wear every day and so empirically chose their preferred frequency allocation. During the multicenter clinical trial (Phases I and II), each patient was provided with a single default MAP frequency allocation that was selected to complement the frequencies available from that patient's residual hearing. Since patients eligible for the study typically had a residual hearing cutoff around 1000 Hz, typical MAP frequency allocations would be either 688–7938 Hz or 1063–7938 Hz.

Patients in the initial feasibility study and Phase I of the clinical trial used either the SPRINT, SPEAR, or Esprit processors, but eventually upgraded to the Freedom processor by the current date. Patients in the second stage of the trial were provided with the Freedom processor at initial activation.

Most, but not all, patients wore HAs in both the implanted ear and non-implant ear. Typically, the HAs in both ears were programmed to complement the frequency range provided by the implant, with a high-pass cutoff matching the low-pass cutoff of the implant frequency allocation range. A few subjects did not use one or both HAs either because they had near-normal LF hearing, or because they had very little residual hearing and relied on the implant alone.

Approval and institutional review

The University of Iowa Human Subjects Investigational Review Board (IRB) approved the Hybrid electrode investigation. Likewise, the individual institutional IRBs at each of the participating implantation centers approved the investigation at each phase of the study. The Food and Drug Administration (FDA) approved the Iowa/Cochlear Hybrid Implant for a phase II multi-center trial. The Hybrid S8 investigation was conducted under FDA feasibility IDE # G990155.

Results

The initial feasibility study included 3 patients at UI implanted with the original 6mm-length Hybrid electrode, and 4 implanted with the 10 mm Hybrid S8 (S8). The multi-center Phase I included 25 subjects implanted with the S8. Fifty-eight subjects at multiple institutions were implanted with the S8. A total of 87 patients received the 10 mm S8 electrode. There were 11 phase II withdrawals prior to completion of the study. Fourteen patients were reimplanted with a standard-length electrode (N=2 from the initial 6mm feasibility trial, and N=12 from phase I/II). Three patients received a contralateral standard electrode after Hybrid implantation due to progressive sensorineural loss in the contralateral ear.

Hearing preservation

The overall residual hearing preservation results for the multicenter study are shown in Figs. 2A and 2B. Overall, 79/87 (91%) of patients had good preservation of residual hearing,

performing within 30 dB of their preoperative low-frequency (125–750 Hz) thresholds (LFT) at initial activation (Fig. 2A). The mean LFT shift was 14.6 dB at one month post-surgery, and 41/87 (47%) had average LFT within 10 dB of baseline. Two patients (2%) experienced total HL within one month of surgery. Some patients experienced a delayed increase in their sensorineural loss. 61/81 (75%) subjects maintained LFT within 30 dB of their preoperative PTA by the end of the trial (Fig. 2B; 1 to 5 years post-activation for all included subjects). The total number of patients losing all residual hearing is 8/81 (10%).

Speech recognition in quiet

Gantz and Turner reported the results from the initial single-site Feasibility study begun in 1999 at the University of Iowa [1,2]. A variety of maps were provided to the subjects, and the most successful MAPs were those that presented speech from 1000–8000 Hz, or 2000–8000 Hz. In all subjects, comparison of pre-operative and post-operative acoustic-only scores showed that speech recognition with the acoustic hearing was preserved post-implantation, along with the residual hearing.

Larger performance improvements were seen for patients with the 10-mm array than for patients with the 6-mm array. Subjects with the 6-mm array showed on average only a 10% improvement in consonant recognition scores under the Hybrid condition (implant plus HA in the implant ear). In contrast, subjects with the 10-mm array showed an average 40% improvement in consonant recognition scores. The 10-mm subjects also showed larger improvements in understanding of monosyllabic words (preoperatively ranging from 20–43% and postoperatively ranging from 83–90%) and sentence recognition (100% postoperatively) under both the combined (implant plus HA in both ears) and the Hybrid conditions. The greater success of the 10-mm over the 6-mm array may be explained by the larger tonotopic mismatch for the 6-mm array, as a similar effect was seen in simulations of cochlear implant listening with various amounts of tonotopic mismatch [1]. Alternatively, the 6-mm array may not extend deeply enough into the cochlea to successfully stimulate surviving nerve fibers or spiral ganglion neurons.

Also noted in this initial study was the strong effect of duration of implant experience on the A+E benefit; all four 10-mm patients took at least 10 months to fully adapt to the Hybrid device and maximize their speech recognition benefit.

Gantz et al. [11] described the speech perception results for 19 subjects, mostly from Phase I, who had at least 9 months of experience with the 10-mm array. 15/19 subjects demonstrated a significant benefit in monosyllabic word recognition under the combined condition postoperatively compared to the bilateral HA condition preoperatively. One interesting observation was that 2 of the 4 individuals that did not show significant benefit had long durations of HF HL (>40 years). The effect of implant experience was strong again in this larger subject pool, with substantial improvements often seen between 3 and 12 months, and between 12 and 24 months for some subjects.

Reiss et al. showed that some individuals, when tested on consonant recognition, performed surprisingly well with just the electric (implant) stimulation (E-only), i.e. without any added

acoustic information [12]. In fact, Hybrid patients as a group performed as well as long-electrode users when tested on consonant discrimination under E-only conditions.

More recent results from Gantz et al. indicate that the majority of subjects implanted in the multicenter clinical trial to date have benefited from the device [13]. Out of a total of 87 subjects, 61 subjects with 9–12 months of experience had been tested on CNC word recognition and BKB_SIN tests. Improvement in either word score or speech reception threshold was observed in 45/61 (74%). Improvement in both scores was observed in 29/61 (48%). However, 14/61 (23%) of subjects had either no improvement or significantly diminished performance on both CNCs and SRTs after 9–12 months of use as compared to their preoperative baseline; therefore, it is important to isolate the relevant preoperative factors that determine whether a patient will benefit from a Hybrid device (described in next section).

It should be noted that there was no correlation of benefit with the amount of residual hearing remaining in the implant ear; this may be due in part to the ability of some Hybrid patients to obtain significant benefit from electric stimulation alone.

Predictive Factors for Success

A variety of potential predictors were subject to a multiple regression analysis via AIC model selection [13]. Preoperative CNC scores ($\beta=0.52$, $p<0.01$) and duration of deafness ($\beta=-0.46$, $p<0.02$) were both shown to be significant predictors of post-implantation performance. A model considering all implanted subjects that included both of these variables explained 23% of variance (R^2). This was the best-fit model, compared with other predictor variables such as age at implantation or age at onset of deafness. When the poor performers ($N=14$), were considered separately from good performers ($N=45$), 91% of the variance in performance was attributable to pre-operative CNC scores plus duration of deafness.

Speech Recognition in Background Talkers

Turner et al. also showed results for recognition of spondee (two-syllable words) in the presence of two background talkers [14]. The level of the target words was held constant and background was varied adaptively to find the signal-to-noise ratio (SNR) eliciting 50% correct performance. A lower SNR is a better score because it means that the patient can understand speech in more adverse noise conditions. Note that the use of two-syllable words makes this test an easier test than most tests of speech recognition in noise; therefore, it specifically measures the ability to resist the detrimental effects of background noise without depending on speech recognition abilities for more difficult sounds in quiet.

This test was conducted in normal-hearing, hearing-impaired, long-electrode, and Hybrid subjects tested at Iowa; the group results are compared in Fig. 3. The normal-hearing subjects performed the best at the lowest SNRs, followed by hearing-impaired subjects (grouped by severity of HL), and the Hybrid patients. Long-electrode patients performed the worst, with an average positive SNR required to understand the spondee words. The Hybrid group had a significant advantage over the long-electrode group of 4–5 dB on average [11,15,13]. However, it should be noted that some individual Hybrid subjects were able to

perform the task at 15–20 dB lower SNRs than the best long-electrode subjects, and thus showing the impressive potential benefits of preserving residual acoustic hearing.

These results point to the acoustic hearing as the main contribution to this advantage. When performance levels were compared within subjects under E-only, Hybrid, combined, and A-only conditions, performance was generally similar for all conditions utilizing acoustic hearing, but much worse for the E-only condition. Further, the benefit of acoustic hearing was seen regardless of whether the acoustic hearing was from the implant or non-implant ear [16, 17, Reiss et al., unpublished].

The benefit of acoustic hearing does not seem to be correlated with degree of HL, up to severe levels, as long as the hearing is aided [15,16]. In cases of profound or near-total HL after implantation with the Hybrid, the benefit is lost, most likely because A+E stimulation in these cases is really E-only stimulation [13].

Music Perception

Hybrid subjects were also compared with normal-hearing listeners and long-electrode subjects on the recognition of familiar musical melodies as well as recognition of musical instruments (Gfeller et al., 2006). Familiar melody recognition was tested under two conditions: melodies with sung lyrics and melodies played by instruments without lyrics. With lyrics, the Hybrid group showed no significant difference in melody recognition scores from the normal-hearing group with average scores around 70%, and performed significantly better than the long-electrode group (average scores around 30%). Without lyrics, all three groups were significantly different, with the normal hearing group performing the best, the Hybrid group performing in between, and the long-electrode group performing the worst. It is likely that the recognition of melodies without lyrics was assisted by the availability of preserved low-frequency pitch information, information that is not transmitted through conventional signal processing. On the test of instrument recognition, accuracy depended on the frequency range of the instruments being played, as the Hybrids were significantly worse than the normal-hearing group only for the medium and HF categories, and not for the LF category. These two test results suggest that the preserved LF residual hearing made an important contribution for these two musical tasks of melody recognition and musical instrument recognition in the Hybrid group.

Pitch Perception

Previous experiments on pitch perception through a cochlear implant have found pitch estimates to be lower than predicted based on the cochlear location of the electrodes [19,20]. Recent work with Hybrid patients has suggested a compelling possible explanation for this discrepancy [21,12]. In these patients, the electric pitch perceived through a single electrode in the Hybrid device against an objective reference – the acoustic hearing in the non-implanted ear. These pitch measurements was followed in each subject over time, that is, at various times from hookup to as long as 5 years of implant use.

This study led to a surprising finding: the pitch perception changed with implant experience in several subjects, in some cases by more than 2 octaves. The pitch could become higher, lower, or oscillate over time, but generally the trend was for high pitches to drop, low

pitches to rise, and pitches in an intermediate range to remain the same. Initial data suggests that the pattern of changes may be determined in part by the severe tonotopic mismatch between the original sound frequencies and the cochlear place of stimulation introduced by the speech processor MAP, and the changes in perceived pitch may in fact be driven by this tonotopic mismatch [12]. Specifically, for the Hybrid device, the theoretical cochlear place of stimulation for the six Hybrid electrodes should be in the range of 4000–9000 Hz, even if the possibility of stimulation of nerve at the spiral ganglion instead of at the Organ of Corti is accounted for [22,23]. Compare this to the typical speech processor allocation of environmental sounds from 688–7938 Hz or 1063–7938 Hz to these six electrodes. This is a consequence of the standard practice of programming MAPs to provide the sound frequencies that the patient is missing, regardless of the cochlear place-frequencies that are actually stimulated by the implant. However, despite the severe tonotopic mismatch, there was no significant difference in speech recognition scores between a mismatched and matched allocation [15]. Presumably, the loss of usable low- and mid-frequency speech information with a more-normal HF allocation balances out any advantage of more closely matching sound frequency to cochlear place of stimulation. This is reflected in the patients' preferences for the broader MAP despite the tonotopic mismatch that is introduced. In the words of one patient, a matched 3000–8000 Hz MAP was “great for listening to bird calls but that was about it” (personal communication).

Conclusions

The clinical trial results have shown that 1) residual hearing can be preserved with a short-electrode cochlear implant and soft surgery approach to implantation; and 2) Hybrid patients do very well with combined A+E stimulation--comparable to long-electrode patients in quiet, and often better in background noise and in musical tasks such as melody and musical instrument recognition that require more refined spectral information.

Overall, many patients who have received the Hybrid report high satisfaction with the device (unpublished). This study has shown a clear benefit of A+E hearing over E-only hearing for speech in noise and music appreciation. Further, the benefit of the residual acoustic hearing does not depend strongly on the amount of residual hearing preserved [15]. Residual acoustic hearing has also been shown to aid speech recognition with the implant in noise even when it is useless for speech recognition in a quiet, A-only hearing setting [24].

In addition, some unexpectedly valuable insights have been gained from the use of a short-electrode implant. First, patients are readily able to adapt to a severe tonotopic mismatch of speech processor frequency information to the cochlear place of stimulation, in contrast to early studies that suggested that correct allocation of place-frequency information was important for speech understanding [25,26]. These results suggest that experience with tonotopic mismatch is important for giving patients time to adapt, consistent with more recent studies [27,28].

Second, Hybrid patients still perform very well with E-only hearing, even if residual hearing is lost. This is surprising, considering that there are only 6 electrodes in a very narrow region of the cochlear base. Implantation of the full length of the cochlea therefore may not be

necessary for full benefit (even for long-electrode patients) given our subjects' ability to adapt to tonotopic mismatches over time.

Third, the Hybrid device, with the introduction of a very large tonotopic mismatch, has demonstrated that cochlear implant pitch perception can change with experience. In fact, the large tonotopic mismatch may drive the pitch changes. This finding implies that peripheral attributes, such as nerve survival or electrode position, do not completely account for pitch perception. Pitch perception is plastic and may be adaptable with experience. This may not be as applicable to older patients, however, as they seem less able to adapt to the Hybrid device. Central plasticity and the ability to adapt to tonotopic mismatch may depend on age, as well as duration of deafness.

There are other potential advantages of preserving residual hearing in both the implant and non-implant ears that have not yet been studied; these include the availability of binaural acoustic inputs for spatial localization and speech recognition in the presence of background talkers from multiple locations. Therefore, surgeons should consider attempting to preserve residual hearing in all cochlear implantations, including long-electrode devices, regardless of the amount of residual hearing preserved.

Finally, even though the Hybrid device can be considered a success in the majority of patients, a consistent 10% of patients eventually lost all residual hearing. This rate of HL occurred at different points along the clinical trial, suggesting that this adverse effect is not an issue of a learning curve in the device insertion. The finding that the implant did not negatively impact initial A-only speech recognition suggests that the presence of the electrode array in the cochlea did not alter residual inner hair cell function or interfere with the biomechanics of the apical organ of Corti [1,2]. However, the postoperative HL is asymmetric with the natural progressive sensorineural hearing loss in the contralateral ear and thus is likely stemming from the surgery or the device itself. It is unclear why this happens, why loss of residual hearing also has a subacute or even fluctuant course, or if there are any common elements between those subjects who lost their hearing. The problem of delayed hearing loss after initial preservation needs to be studied further.

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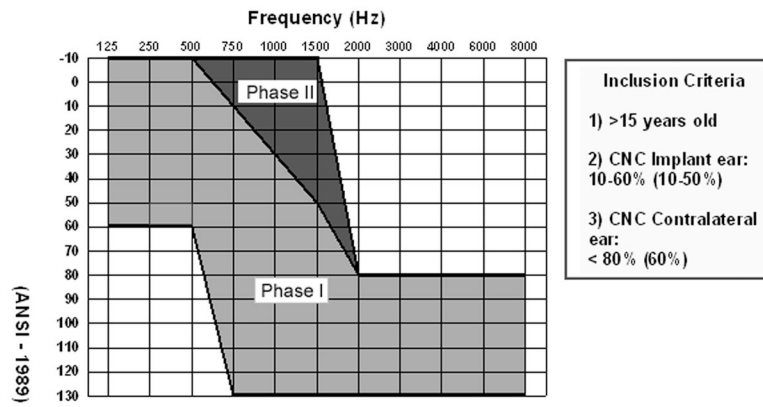


Figure 1.

Iowa/Nucleus clinical trial audiometric and other inclusion criteria (see box). Light gray shows the Phase I audiometric range, and dark gray shows additional audiometric range appended in Phase II. Speech inclusion criteria for Phase II are shown with Phase I criteria in parentheses.

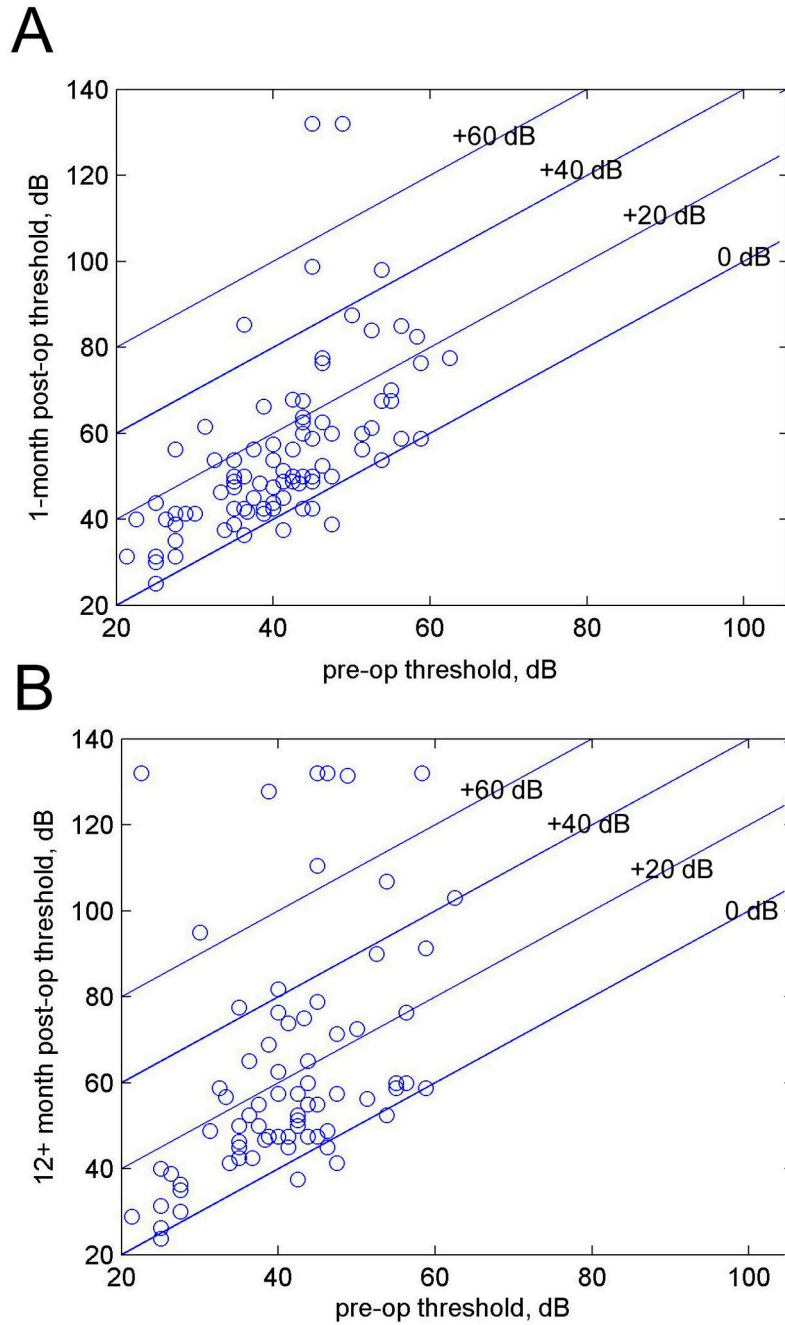


Figure 2. Postoperative hearing preservation results for subjects in multicenter clinical trial. **A.** Low-frequency threshold shifts (averaged over 125–750 Hz) in the implant ear as a function of preoperative hearing threshold for all subjects in the multicenter clinical trial at one month post-implantation (initial activation). **B.** Long-term threshold shifts at least 12-months after implantation. Plotted as in B.

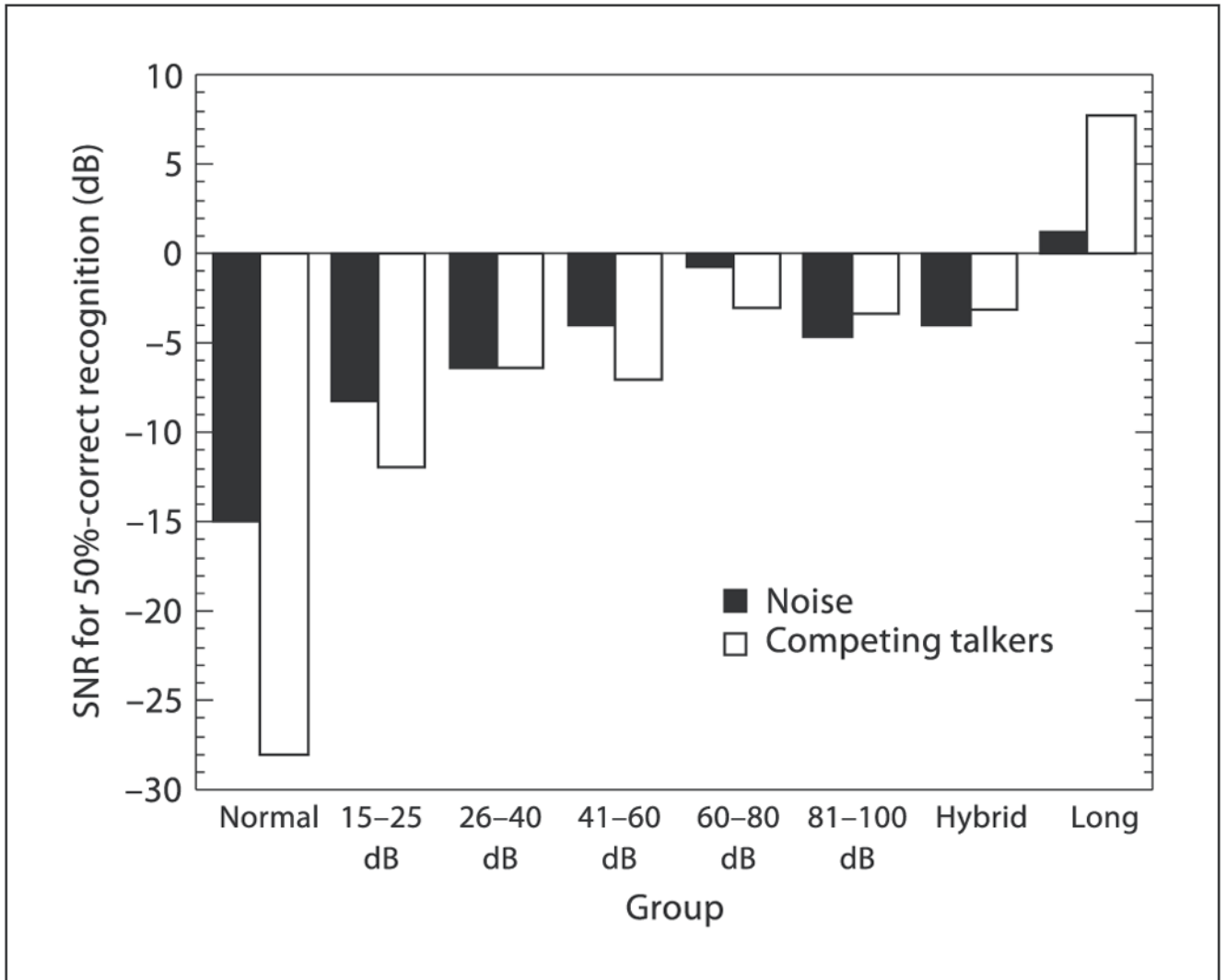


Figure 3.

Comparison of speech in noise for Hybrid patients, long-electrode patients, hearing-impaired patients, and normal-hearing subjects. The values shown are signal-to-noise ratios (in dB) for 50% correct recognition of spondee words in competing backgrounds of steady noise (black bars) or competing talkers (white bars). Subjects are sorted according to degree of hearing loss (average of 500, 1000, and 2000 Hz) and also if they are listening through a traditional long-electrode cochlear implant or Hybrid cochlear implant. Figure reprinted with permission (Gantz et al. *Audiol Neurotol*; 2006; 11 (suppl 1):63–68) courtesy of S Karger AG, Basel.