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Long-Term Outcomes of Cochlear Implantation in Patients With High-Frequency Hearing Loss

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Abstract

Objective: To demonstrate the long-term benefits of implantation in patients with high-frequency sensorineural hearing loss, this report provides 5-year follow-up on a group of implant recipients who were subjects of the Cochlear™ Nucleus® Hybrid™ L24 Implant System pivotal clinical study.

Methods: The results of three related clinical studies were compiled to provide outcome data after 1, 3, and 5 years of implant use in a group of subjects who presented with preoperative high-frequency hearing loss and were implanted with a Nucleus Hybrid L24 (Cochlear Ltd., Sydney, Australia) cochlear implant. A subset of the 50 adult subjects (N532) who participated in the Hybrid L24 pivotal Investigational Device Exemption (IDE) completed comprehensive evaluations at 12 months postactivation, 3 years postactivation, and then as part of a postapproval study at 5 years postactivation. Testing included audiometric, speech perception, and subjective satisfaction measures.

Results: Mean unilateral speech perception performance was significantly improved at all postoperative intervals compared to preoperative best-aided results and has remained stable to 5 years postactivation. Ninety-four percent of subjects had measurable hearing, and 72% continued to use electric-acoustic stimulation in the implanted ear after 5 years of implant use. Subjective satisfaction results support objective performance improvements.

Conclusion: Results demonstrate long-term success of patients with high-frequency hearing loss following Hybrid L24 (Cochlear) cochlear implantation. Benefits include speech perception abilities significantly better than those in the preoperative best-aided condition, with additional benefit in those using electric-acoustic stimulation in the implanted ear.

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Relevant studies were registered on ClinicalTrials.gov under trial registration numbers (primary FDA clinical trial) and (postapproval study).

Keywords

Electric-acoustic stimulation; cochlear implant; high-frequency sensorineural hearing loss; hybrid cochlear implant; hearing preservation; long-term outcomes

INTRODUCTION

Over 35 years of cochlear implant experience has proven that use of an electrical signal to replace the function of a damaged cochlea can provide both audibility and improved speech understanding in quiet and in noise.[1–3] However, those with significant residual low-frequency (LF) hearing and a precipitously sloping high-frequency (HF) hearing loss have previously been left untreated. Their LF hearing was too good to be a candidate for a traditional cochlear implant, but their HF hearing was too poor to benefit from the use of hearing aids.

The benefits of using electrical stimulation with acoustic hearing (E+A) in the same, implanted, ear are well established and include improved speech understanding in quiet and in noise, overall natural sound and music quality, and better localization.[4–12] Advances in cochlear implant design have led to arrays, like that of the Nucleus® Hybrid™ L24 (Cochlear Ltd., Sydney, Australia) cochlear implant, intended to stimulate the poorer high-frequency basal region of the cochlea while preserving the low-frequency apical region.

In 2007, Cochlear Americas (Centennial, CO) initiated a multicenter clinical trial to study the Nucleus Hybrid L24 Implant System (Cochlear) in adults with LF hearing and severe/profound HF sensorineural hearing loss (SNHL). The 6-month evaluation served as the primary safety and efficacy endpoint for the study, and these data were presented to the United States Food and Drug Administration (FDA) and an ear, nose, and throat device panel for review. These data were previously reported by Roland et al.[13]

Data presented herein expand beyond 6 months to present outcomes collected in related studies in the same cohort at 12 months, 3 years, and 5 years postactivation. Consistent test measures included consonant-nucleus-consonant (CNC) monosyllabic words[14] in quiet, audiometric thresholds, and a self-assessed satisfaction questionnaire.

MATERIALS AND METHODS

All subjects met the study inclusion criteria and were at least 18 years of age at the time of implantation. The implanted ear exhibited severe HF SNHL (≥ 75 decibels hearing level [dB HL] averaged over 2,000, 3,000, and 4,000 Hz) with residual LF hearing ≤ 60 dB HL at 500 Hz and below. Aided CNC word scores were 10% to 60% in the ear to be implanted and up to 80% in the contralateral ear. Individuals with a duration of severe/profound hearing loss > 30 years and/or onset of hearing loss before 2 years of age were not included. Study participants gave written informed consent under protocols approved by the FDA and applicable institutional review boards.

Study subjects who completed all requirements for the pivotal Investigational Device Exemption (IDE) study were considered for participation in the postapproval study, and 32 (64%) enrolled. Of the 18 who did not participate, six were explanted and reimplanted with a long electrode array during the pivotal study; two discontinued for unrelated medical reasons; two withdrew for other reasons; four declined the invitation to continue follow-up evaluations; and four who chose not to participate in the postapproval study due to clinic and staffing resources were followed at IDE study sites.

Table I provides summary demographic information for the 32 subjects for whom data were collected at each of the three intervals (12 months, 3 years, and 5 years postactivation). The mean age at implantation was 62.3 years, ranging from 23.0 to 86.2 years. Additional information, including onset and etiology of hearing loss and preoperative degree of LF hearing, are provided.

Twelve Months

Unaided air- and bone-conduction thresholds were measured using the Hughson and Westlake[15] audiometric technique. Preoperatively, speech perception was measured with hearing aids verified to meet National Acoustic Laboratories (Sydney, Australia) prescriptive targets.[16] Postoperatively, speech perception was assessed in both the best unilateral (hybrid: use of acoustic and electric hearing, or electric: via the implant—alone in the implanted ear) and best bilateral (combined: acoustic hearing in both ears, in addition to electric hearing in the implant ear; or bimodal: electric hearing alone in the implant ear, with acoustic hearing in the contralateral ear) conditions. The Speech, Spatial, and Qualities of Hearing Questionnaire (SSQ)[17] was implemented as a self-assessment measure of subjective satisfaction and benefit.

Three Years/Investigational Device Exemption Upgrade Amendment

Three-year postactivation audiometric data for each ear were gathered from semiannual evaluations through the IDE study or through data collected as part of the 2013 Cochlear-initiated Nucleus 6 (N6) Sound Processor Upgrade Amendment to the IDE protocol. The N6 (Cochlear) was programmed with existing fitting parameters, in addition to new signal processing algorithms including Signal-to-Noise Ratio Noise Reduction (aka SNR-NR), Wind Noise Reduction (aka WNR), and an automatic scene classifier called SCAN. Tests included audiometric hearing thresholds; CNC words in quiet; and the SSQ.

Five Years

The Hybrid Extended Duration Postapproval Study was initiated after FDA approval of the L24 implant to follow pivotal IDE subjects until each reached at least 5 years postactivation. At each visit, subjects completed evaluations, including audiometric thresholds, speech perception testing, and the SSQ.

Statistical Methods

Repeated-measures analysis of variance (RM-ANOVA) was employed to compare baseline and follow-up study outcomes for threshold, speech perception, and self-assessment. In the

event that the assumption of normality was not met (i.e., $P < 0.05$ from a Shapiro-Wilk test of normality), ranked data were used in the repeated-measures analyses.

RESULTS

Audiometric Thresholds

Audiometric air-conduction thresholds were measured using insert earphones. For the purpose of calculating average thresholds, a "no response" was assigned a value corresponding to maximum audiometric limits as follows: 95 dB HL at 125 Hz, 105 dB HL at 500 Hz, and 120 dB HL at frequencies at and above 750 Hz. In the IDE study, *residual hearing* was defined using a five-frequency (125–1000 Hz) LF pure-tone average (LF PTA). *Functional residual hearing* was defined as a five-frequency LF PTA ≤ 90 dB HL (consistent with the definition used in the pivotal trial, described by Roland et al.,[13] which related LF PTA and speech perception outcomes). *Measurable hearing* was defined by any measurable threshold within that frequency range. *Total loss* was defined as no measurable thresholds at the limits of the audiometric equipment. Using these historical definitions, 72% of subjects had functional hearing; 94% had measurable hearing; and 6% had a total loss at 5 years postactivation.

More recent research[18,19] has suggested that the use of acoustic information at and below 500 Hz is sufficient for providing the benefits of E+A stimulation described above. Table II provides a summary of residual hearing using a three-frequency LF PTA at 125 to 500 Hz, with the same 90 dB HL cutoff. At 5 years postactivation, 87.5% of subjects had functional residual hearing over this range of LF hearing.

Mean Low-Frequency Thresholds

Mean pre- and postactivation LF thresholds (125–500 Hz) over time along with individual thresholds at 5 years are shown in Figure 1 and Figure 2, respectively. Friedman RM-ANOVA on ranks (SigmaPlot version 12) tests were applied to test for significance of the changes observed over time for each test frequency because the distribution of thresholds did not meet a test of normality (Shapiro-Wilk $P < 0.05$). ANOVA results indicated a significant effect of test interval for each frequency. Follow-up multiple comparisons using the Tukey test indicated that only pre- to postoperative differences were significant (all $P < 0.001$). Mean changes from pre-operative to 6 months were significant ($P < 0.001$), but changes 6 months through 5 years postactivation were not statistically different ($P > 0.05$).

Mean three-frequency LF PTA thresholds over time for the ipsilateral and contralateral ears are shown in Figure 3. There appears to be a similar trend of change in hearing over time in both ears after the initial drop in the ipsilateral ear following implantation.

Acoustic Component Use

The acoustic component specifications for the N6 processor (Cochlear) allow for amplification of thresholds up to 90 dB HL. Clinicians were encouraged to evaluate the clinical utility of acoustic information and make recommendations based on additional factors, including aided sound-field or real-ear verification as well as patient preference. At

12 months postactivation, 27 of 32 (84%) used the acoustic component; 26 of 32 (81%) used it at 3 years; and 23 of 32 (72%) used it at 5 years postactivation.

Speech Perception Outcomes

Consonant-Nucleus-Consonant Words in Quiet.—Speech perception was measured using CNC words in quiet in the best unilateral and bilateral conditions. Figure 4 provides mean outcomes through 5 years postactivation. Friedman RM-ANOVA on ranks was used to test for differences in mean scores overtime because the assumption of normality was not met ($P < 0.05$ from a Shapiro-Wilk test of normality) for both unilateral and bilateral listening conditions. Follow-up paired comparisons were made using the Tukey Test. The RM-ANOVA indicated that there were significant differences across test intervals. Paired comparisons indicated postactivation performance in the unilateral and bilateral conditions was significantly improved over the preoperative condition for each postactivation interval ($P < 0.001$ for all comparisons). However, the mean scores were not significantly different after 12 months postactivation, indicating that performance reached asymptote by 12 months and remained stable through 5 years postactivation.

Figure 5 shows individual pre- to postactivation changes in unilateral (left) and bilateral (right) CNC word scores at 5 years. By 5 years postactivation, 30 of 32 (94%) showed the same or better performance over the preoperative condition, whereas two subjects (6%) showed a decline relative to preoperative performance. In the bilateral condition, 31 of 32 (97%) showed the same or better performance at 5 years, whereas one showed a decline relative to preoperative performance.

The single subject who showed a decline at 5 years was implanted at the age of 62.4 years, had an overall duration of hearing loss of 52.4 years, and had an etiology of noise exposure. The subject showed initial improvement over preoperative performance that remained stable through the 3-year evaluation, although a decline in five-frequency LF PTA of 28 dB ipsilaterally and 15 dB contralaterally was noted. Upon testing at 5 years, hearing thresholds in the implanted ear had decreased by an additional 10 dB and 5 dB contralaterally. The subject was reportedly unaware of any changes in hearing or speech perception with stable overall satisfaction. Although hearing thresholds appear to have declined in both ears, it is not clear why speech perception decreased given the subject reported not noticing any changes in hearing status.

Subjective Satisfaction

The SSQ is a validated measure of self-perceived disability across three different areas. This tool was given to each study participant preoperatively, at 6 and 12 months postactivation in the IDE study, at the time of the 2013N6 Upgrade, and at 5 years postactivation. Results in Figure 6 show average ratings for each subscale along with a total score. Subjective ratings significantly improved from preoperative to any postactivation interval and remained stable across postactivation intervals.

DISCUSSION

FDA approval of the Nucleus Hybrid L24 cochlear implant (Cochlear) provided a necessary treatment option by bringing a new device to a population that previously had been underserved. That is, people with ski-slope hearing loss traditionally had too much low-to-mid frequency hearing to be considered for a cochlear implant but HF hearing too poor to receive benefit from hearing aids. Hybrid L24 candidacy is based on aided CNC word recognition of 10% to 60% in the ear to be implanted, with the contralateral ear equal or better (but not more than 80% correct). These expanded criteria allow individuals with normal LF hearing to moderate LF hearing loss and some word recognition to become potential candidates. In contrast, traditional cochlear implant candidacy is determined based on best-aided sentence recognition scores (≤ 50% on the ear to be implanted and ≤ 60% in the best aided condition).

Preservation of residual hearing allows use of ipsilateral E+A stimulation in order to provide audibility across the speech spectrum, with LF information delivered acoustically and HF information critical to improved speech understanding coded electrically. The acoustic signal gives additional spectral information, as well as temporal fine structure not available in the electric signal that is important for music and voice pitch perception. Low-frequency vowel and consonant cues help a listener distinguish different talkers and segregate speech from noise.[8] A number of studies[21–24] demonstrated that, in complicated listening situations, having preserved acoustic hearing in the implanted ear in addition to the acoustic hearing in the contralateral ear significantly improved speech understanding.

Hearing preservation is an indirect measure of preservation of cochlear structures. Soft surgery techniques intended to limit trauma to the cochlea have become standard of care. In addition, many current cochlear implant electrode arrays have been designed to preserve the delicate cochlear structures, with the ultimate goal of preserving residual hearing. In fact, research shows that residual hearing after cochlear implant surgery may be preserved when using various electrode arrays.[25–30] Lenarz et al.[31] reported group median hearing preservation data for 66 Hybrid L24 (Cochlear) subjects at initial activation and 61 subjects at 12 months postactivation. Low-frequency thresholds (125, 250, 500 Hz) were maintained within ≤ 30 dB at initial activation for 89% of subjects, with 1-year data showing some additional decrease in low-frequency hearing. At 500 Hz, 61% of subjects showed increases ≤ 10 dB, and 89% showed increases ≤ 30 dB. These proportions decreased to 43% ≤ 10 dB and 74% ≤ 30 dB at the 1-year evaluation. The median LF thresholds reported here for 125 to 500 Hz at all three postoperative test intervals are similar to Lenarz et al.[31] findings, suggesting stability of residual hearing. In summary, technology and surgical procedures have evolved such that preservation of LF hearing thresholds can and should be a goal of implant surgery, regardless of implant type or electrode length.

Gantz et al.[18] recently reported that residual hearing could be preserved up to 15 years after Hybrid S8/S12 (Cochlear) device activation and up to 7 years in the case of Hybrid L24 (Cochlear). These authors examined results in subjects with the S8, S12, and L24 electrode arrays (S8 and S12 are 10-mm electrode arrays, relative to the 16-mm L24 array) and documented functional hearing in 83%, 92%, and 86% of subjects, respectively, at the most

recent evaluation. Seven subjects who lost residual hearing continued to use the implanted device, electric-only, along with a hearing aid in the contralateral ear. Average bilateral CNC word scores in quiet were statistically similar in these seven subjects (i.e., using electric only in one ear with LF acoustic hearing contralaterally) to Hybrid (Cochlear) subjects able to use electric stimulation with LF acoustic hearing in both ears. Further, the average word recognition scores for the same seven subjects was no different to a group of traditional implant subjects using an implant in conjunction with a contralateral hearing aid. Although Gantz et al.[18] noted that the acoustic contribution of the ipsilateral ear appears to be important, it is not necessarily the case that outcomes for those who do not maintain functional acoustic hearing in the implanted ear warrant revision surgery.

Data reported here demonstrate functional residual hearing in 87.5% of subjects, up to and including the 5-year postactivation evaluation. Of those who did not retain functional hearing at 5 years, four subjects dropped below 90 dB HL prior to the 6-month evaluation, with one subject experiencing a total loss of hearing. However, one subject who was below 90 dB at 6 months had thresholds that recovered approximately 10 dB after 6 months, falling back into the functional category. This change likely reflects the standard test–retest variability of audiometric threshold testing.

Cochlear's programming software prescribes a combination of acoustic and electric information based on the postoperative audiogram in the implanted ear. In the most recent update to the programming software, acoustic amplification is applied for frequencies with unaided thresholds up to 90 dB HL. Electrical stimulation is assigned to any channel in which thresholds are poorer than 70 dB HL. Parameters within the programming software may be adjusted to change the cutoff frequencies for acoustic and electric stimulation, and any overlap between the two, to optimize audibility and accommodate subjective sound-quality preference. In the clinical studies described herein, use of the acoustic component was not required per protocol; therefore, fitting was at the discretion of the programming clinician based on patient performance and preference. All subjects who used the acoustic component had three-frequency LF PTAs ≤ 84 dB HL. Of the nine subjects who did not use the acoustic component, four had a three-frequency LF PTA < 90 dB HL (40, 75, 81.67, and 85 dB HL). Use of the acoustic component appears to be generally applicable in patients with average LF thresholds of a severe degree or better; however, in some cases it may be driven by individual preference.

Although residual hearing is of interest, the primary goal of the intervention is to improve performance over the preoperative condition. These data confirm that average CNC word recognition results show significant postoperative improvements and remain stable after 5 years. Review of literature documenting outcomes with traditional electrode arrays show variable results. Balkany et al.[32] (2007) reported a mean 6-month unilateral CNC word score of 57% correct. Runge et al.[2] reported a mean 12-month unilateral CNC word score of 52.9% in a group of 38 postlingually deafened adults with a traditional long electrode array. Cusumano et al.[33] completed a retrospective review of outcomes in pre- and postlingually deafened adults. For the 102 postlingually deafened adults, the mean 12-month CNC word score was 57.6%. They reported further that performance continued to increase over time, with a mean of 70.4% at 5 years.

Testing using sentences in noise may be the best approach currently available in a clinical setting to simulate performance in real-world environments. Arizona Biomedical Institute at Arizona State University (AzBio) sentences[34] at a + 5 dB signal-to-noise ratio were used at all preoperative and postactivation intervals to test speech understanding in noise. Although variability in test parameters over time make mean changes in performance for this cohort impossible to directly compare, the majority of subjects (29 of 32, 91%) performed the same or better on sentences in noise after having received the intervention. Five-year mean performance was not significantly different than 12 months, and both showed significant improvement over preoperative performance. It would be of interest to compare results on sentences in noise with this group of L24 recipients using E+A stimulation to a group of traditional long electrode array users of electric-only stimulation given the established benefits of E+A for hearing in noise. This is suggested as a need for future investigation.

Subjective satisfaction results showed significant improvement following implantation when compared to the preoperative bilateral hearing aid condition. Although there were no statistically significant differences among the postactivation intervals, a trend toward decreased satisfaction following the 12-month interval appeared. Given that the next interval tested was at the time of acute adjustment to a new sound processor, the human factor of adapting to something unfamiliar may be, at least in part, related.

Patient-related factors such as age at implantation, duration and stability of SNHL, sex, and noise exposure should be considered when selecting appropriate candidates in order to maximize hearing preservation outcomes.[13,35,36] Our data suggest that increasing age and longer duration of hearing loss have trends toward negative correlations with hearing preservation and speech perception outcomes, consistent with that seen in traditional cochlear implants.[37,38] Further investigation is warranted in this population.

CONCLUSION

Results demonstrate that the Nucleus L24 Hybrid System (Cochlear) remains an effective treatment for people with severe HF hearing loss after 5 years of device use. Measurable hearing was achieved and maintained in 94% of subjects after 5 years of implant use. Most (87.5%) had functional LF residual hearing that could be aided with the N6 (Cochlear) sound processor with acoustic component. Speech perception in quiet improved significantly over preoperative performance and has remained stable at least to 5 years postactivation. Subjective satisfaction results are consistent with objective outcomes.

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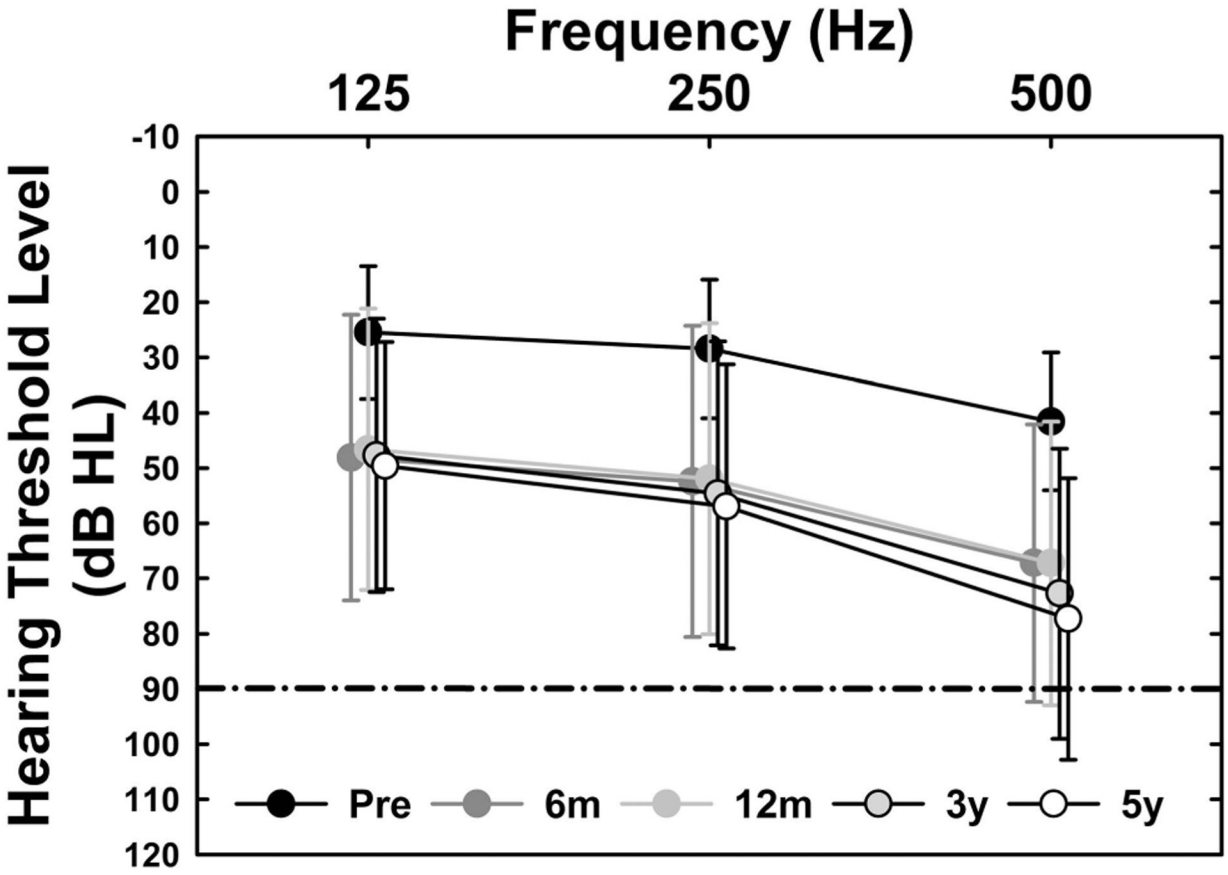

Fig. 1.

Mean preoperative versus postactivation thresholds (125–500 Hz) over time (N = 32). Error bars ± 1 standard deviation of the mean. Error bars for intermediate intervals were similar in magnitude to 5 years and hidden for clarification. Data points dithered for clarification. dB HL = decibels hearing level.

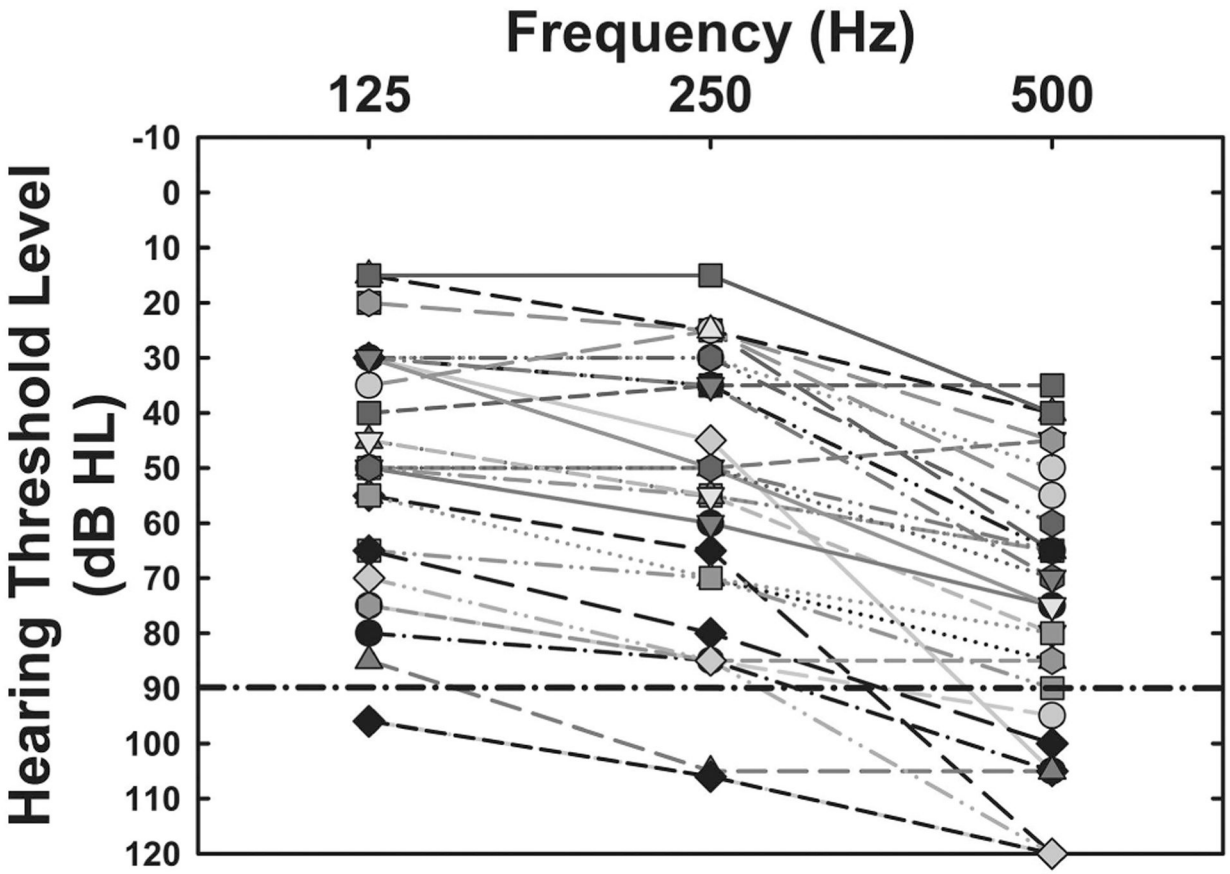

Fig. 2.

Individual low-frequency thresholds (125–500 Hz), 5 years postactivation (N = 32). dB HL = decibels hearing level.

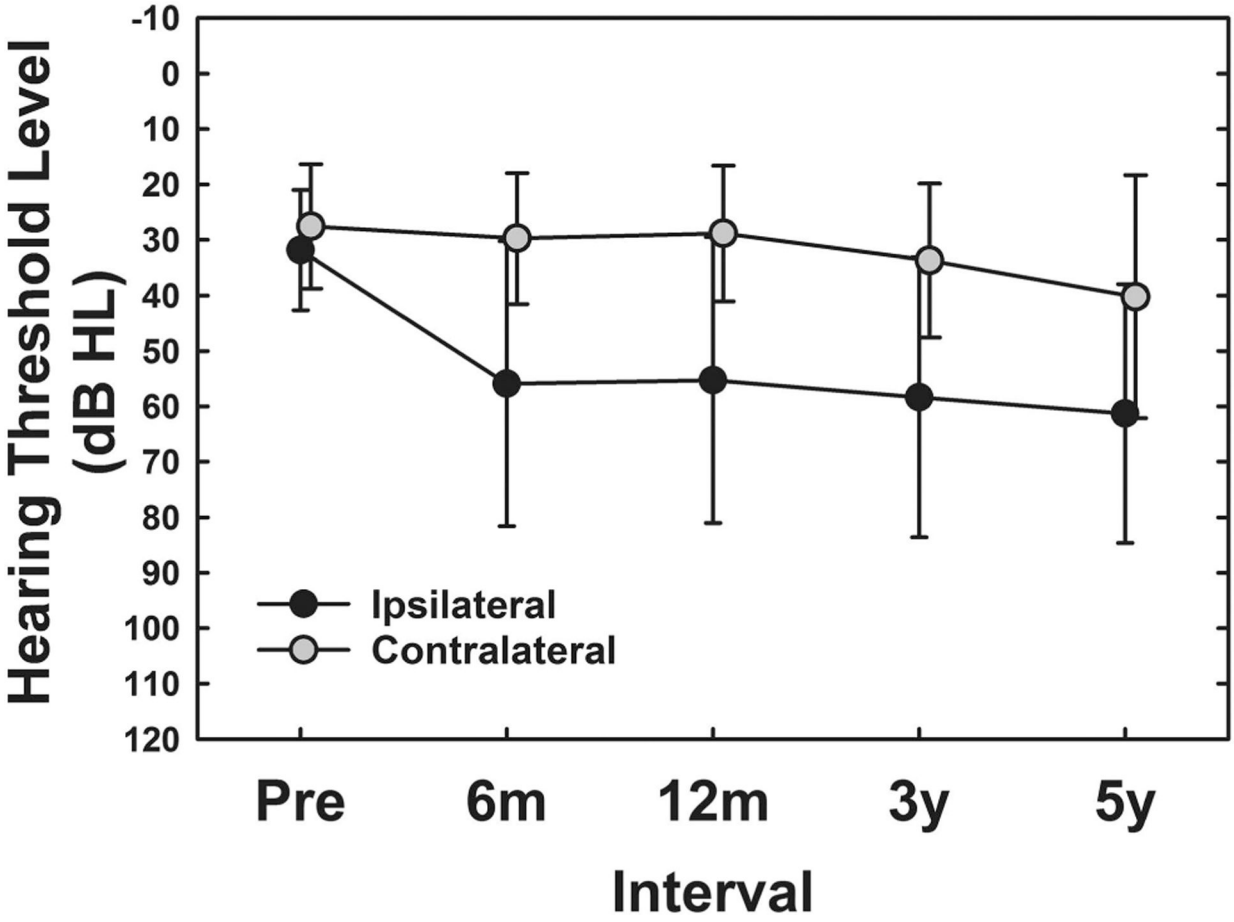

Fig. 3.

Mean ipsilateral and contralateral three-frequency low-frequency pure-tone average (125, 250, and 500 Hz) over time (N = 32). Error bars ± 1 standard deviation of the mean. Data points dithered for clarification.

dB HL = decibels hearing level.

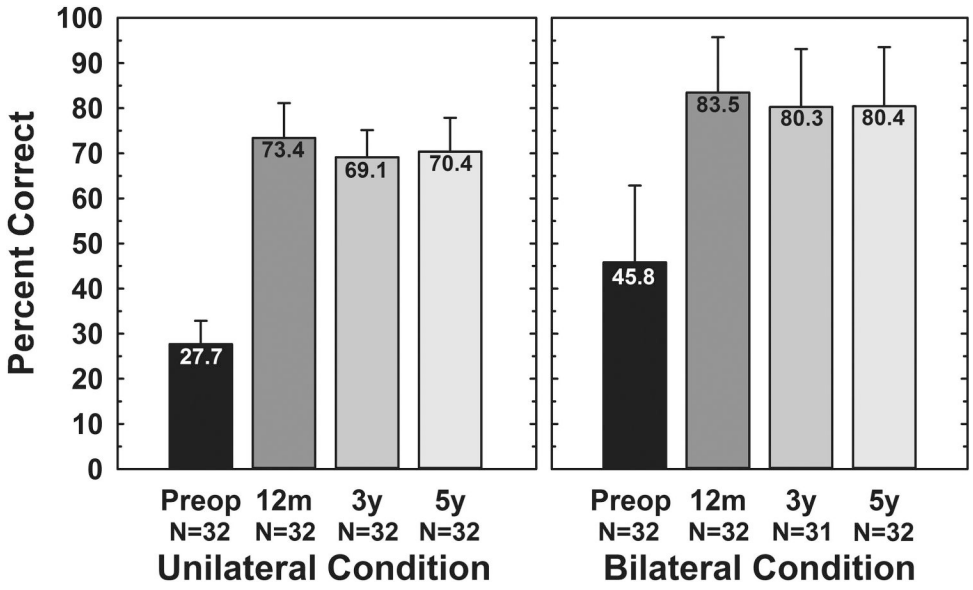

Fig. 4.

Mean consonant-nucleus-consonant word recognition over time. Error bars indicate +1 standard deviation.

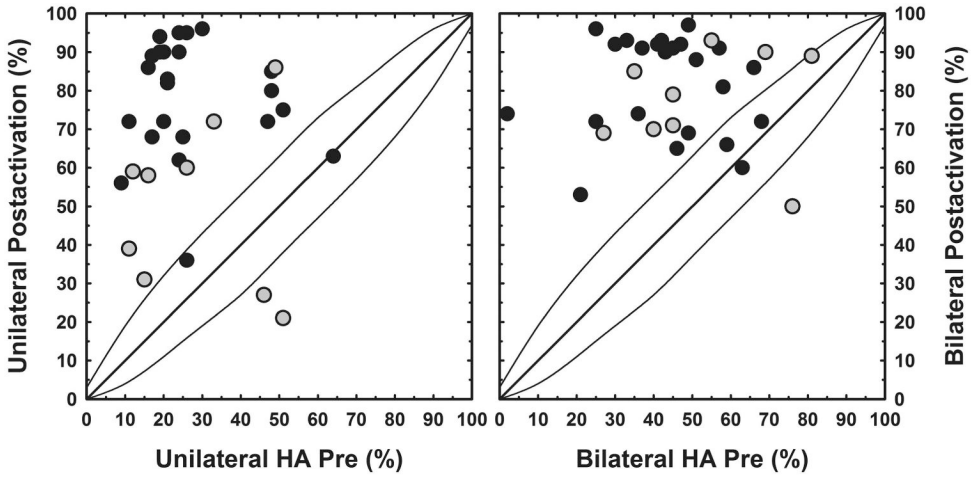

Fig. 5.

Individual pre- to postoperative unilateral and bilateral consonant-nucleus-consonant word scores (N = 32). Black data points indicate subjects using ipsilateral acoustic plus electric stimulation, gray points indicate subjects using ipsilateral electric stimulation alone (with a hearing aid contralaterally). Curved lines enclose 95% confidence intervals based on the Thornton and Raffin (1978) binomial model.[20]

HA = hearing aid.

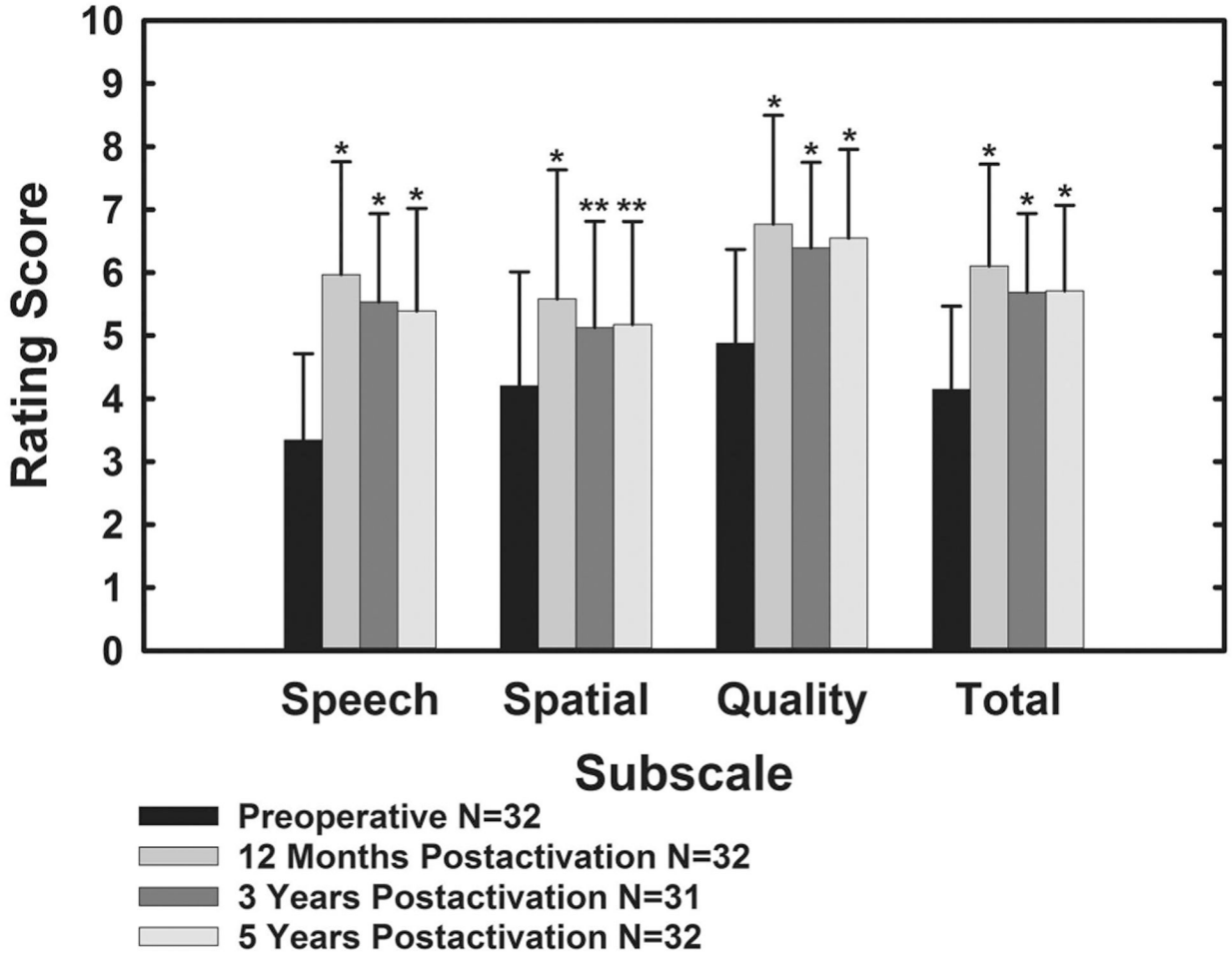

Fig. 6.

Mean ratings for the Speech, Spatial, and Qualities of Hearing Scale over time. Error bars + 1 standard deviation of the mean.

*Significant pre-to-post differences, $P < 0.001$; ** = $P < 0.02$.

TABLE I.

Subject Demographic and Baseline Characteristics (N = 32)

	Mean±SD (min, max)
Age at cochlear implantation in years	62.3±16.2 (23.0, 86.2)
Duration of overall hearing loss in years	26.5±12.1 (3.4,52.4)
Duration of severe/profound high-frequency sensorineural hearing loss in years	13.6 ±7.2 (1.6, 30.1)
	Number
Gender	
Male	15
Female	17
Onset of hearing loss	
Sudden	1
Progressive	31
Etiology of hearing loss	
Unknown	15
Noise exposure	9
Autoimmune	1
Familial	6
Fever	1
Preoperative PTA* for implanted ear	
Normal (0–25 dB HL)	0
Mild (26–40 dB HL)	9
Moderate (41–55 dB HL)	16
Moderate-to-severe (56–70 dB HL)	7

*PTA of thresholds at 125, 250, 500, 750, and 1,000 Hz.

dB HL = decibels hearing level; max = maximum; min = minimum; PTA = pure-tone average; SD = standard deviation.

TABLE II.

Residual Hearing Status (LF PTA*) as Percentage of Subjects (N = 32) With Functional (≤ 90 dB HL) and Nonfunctional Hearing (> 90 dB HL)

	6 Months Postactivation	12 Months Postactivation	3 Years Postactivation	5 Years Postactivation
≤ 90 dB HL	84.4%	87.5%	87.5%	87.5%
> 90dB HL	15.6%	12.5%	12.5%	12.5%

* LF PTA thresholds at 125, 250, and 500 Hz.

dB HL = decibels hearing level; LF PTA = low-frequency pure-tone average; SD = standard deviation.