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Outcomes of Adolescents with a Short Electrode Cochlear Implant with Preserved Residual Hearing

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Introduction

The Nucleus Hybrid L24 cochlear implant system allows individuals with steeply sloping hearing losses an alternative to traditional cochlear implantation. These devices incorporate a cochlear implant that has a shorter electrode array compared to a traditional cochlear implant. Previous studies indicate that Hybrid devices result in better hearing preservation than other traditional longer-array devices¹. Clinical trial studies combining unilateral acoustic and electrical hearing demonstrate that listeners are able to obtain improved speech perception abilities from the integration of low-frequency acoustic hearing with high-frequency electrical stimulation^{2–5}. In fact, research suggests that individuals with steeply sloping hearing losses may benefit more from short electrode implantation than longer electrode cochlear implants^{6,7} due to the temporal cues available through the preserved low-frequency acoustic hearing. It might even be beneficial to preserve low-frequency hearing during cochlear implantation when the individual's thresholds are in the severe range before implantation⁸.

Few studies have reported on implantation of children with significant residual hearing, as current FDA criteria require children to have bilateral profound hearing loss. In one study, 18 children with some level functional low-frequency hearing were implanted with a standard electrode array with full insertion⁹. The authors defined functional hearing as at least one threshold better than or equal to 75 dB HL for 250, 500, or 1000 Hz. Following surgery, 9/18 (50.0%) maintained functional residual hearing for at least one frequency. There was no report of speech perception abilities or whether or not these children utilized the preserved acoustic hearing.

The purpose of the current study is to determine whether or not adolescents with bilateral residual low-frequency hearing in the moderate-to-severe range can develop improved speech perception and language skills by combining their residual acoustic hearing with electrical processing through the Cochlear® Nucleus™ Hybrid L24 Implant (L24).

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Furthermore, do these children/adolescents with preserved low-frequency hearing maintain sound localization abilities?

It is important to note that this study differs from the current FDA approved indications for the Cochlear® Nucleus™ Hybrid L24 Implant. The L24 device is not FDA approved for use in individuals younger than 18 years of age. Thus, in order to conduct this study, we sought out approval through a FDA Investigational Device Exemption (IDE). Additionally, the low-frequency hearing in the subjects described in this study was poorer than for those in the multi-center clinical trial² and for the indications FDA approved for the Cochlear® Nucleus™ Hybrid L24 Implant. Specifically, we are investigating children and adolescents with post-lingual deafness with a pure-tone average (PTA) between 60–90 dB HL between 125–1500 Hz and profound loss at higher frequencies. We believe that they have sufficient residual hearing to benefit from low-frequency hearing preservation and electrical stimulation for improved speech perception in noise and localization. The benefit of Cochlear® Nucleus™ Hybrid L24 Implant will be evaluated by measuring speech perception, language and localization abilities.

Methods

This study is being conducted as a repeated-measure, single-subject experiment. The University of Iowa was approved to complete this study through a Single-Site IDE. The study was also approved by the University of Iowa Institutional Review Board.

Subjects

Five adolescents who had a sensorineural hearing loss with a pure-tone average (PTA) between 60–90 dB HL between 125–1500 Hz and profound loss at higher frequencies were enrolled in our study. Per inclusion criteria, each subject presented with a Phonetically Balanced Kindergarten (PB-K) monosyllabic word score¹⁰ between 0–50% in the ear to be implanted and up to 60% understanding in the contralateral ear in the best-aided condition. Each subject used English as their primary spoken language. Additionally, at the time of implantation, subjects were enrolled in a habilitation/educational program with an emphasis on spoken language development. All subjects were required to have used appropriately fit bilateral hearing aids for at least 30 days prior to study enrollment. All subjects were implanted with the Nucleus Hybrid L24 cochlear implant in the poorer ear as determined by the PB-K score. Demographic information in regards to hearing history is detailed in Table 1.

Nucleus Hybrid L24 Cochlear Implant Device Description

The Nucleus Hybrid L24 cochlear implant incorporates an electrode array designed to preserve residual hearing. The Nucleus Hybrid L24 array has 22 electrodes spread over 16 mm and an anticipated insertion depth of 16 mm. The resultant insertion angle is about 280–300° in the scala tympani. The device was implanted through a minimally traumatic cochleostomy. Following the surgical procedure, each subject was prescribed an oral prednisone 1mg/kg once a day for 7 days. Each child was also given this same prednisone regime the day before activation and continued it for 7 days.

Audiological Assessment for Candidacy

The degree of hearing loss was determined by unaided and aided audiometric thresholds using insert earphones. Testing, for both ears included the following:

- Unaided Air Conduction thresholds at 125 thru 8000 Hz, including interoctaves;
- Aided Air and Bone conduction thresholds at 125 thru 4000 Hz, including interoctaves;

The PB-K word recognition test (Haskins, 1949) in quiet (at 60 dB A) was administered in aided conditions (right hearing aid alone and left hearing aid alone) to determine if a candidate meets the speech perception criteria. The non-test ear was plugged for all test conditions. The PB-K test has multiple 50-word lists. The test was scored as total number of words correct. Testing was accomplished using appropriately fit hearing aids in the ear to be implanted only and bilaterally at 60 dBA.

Pre- and Post-Operative Testing

Speech Perception and Localization Testing—Two lists of Consonant-Nucleus-Consonant monosyllabic words¹¹ in quiet were administered at 60 dBA in the right and left ear only and bilateral test conditions pre-operatively and in the combined (bilateral hearing aids and Hybrid L24) and hybrid (hearing aid and Hybrid L24 on the same ear) test conditions post-operatively at 4, 8, 12, and 24 months. Care was taken to plug the contralateral or ipsilateral ear, or provide contralateral masking when testing individual ears.

A multiple loudspeaker Everyday Sounds Localization Test¹² at 60 dBA using 16 different sound items was also administered pre-operatively in the bilateral condition and post-operatively in the combined condition at 12 and 24 months. Localization performance will be determined by calculating the Average Root Mean Square (RMS)-error in degrees.

Speech Language Testing—Goldman Fristoe Test of Articulation – 2 (GFTA-2)¹³, Woodcock Reading Mastery Test (WRMT)¹⁴, and Comprehensive Assessment of Spoken Language (CASL)¹⁵ tests were administered pre- and post-operatively at 12 and 24 months with bilateral hearing aids pre-operatively and in the combined condition post-operatively.

The GFTA-2 is a standardized, norm-based articulation measure that samples spontaneous sound production. Subjects responded to picture plates and verbal cues from the examiner with single words that tested consonant accuracy in the initial, medial, and final positions.

The WRMT is a standardized, norm-referenced measure of literacy skills. Reading comprehension abilities was assessed by the Passage Comprehension subtest. The WRMT Passage Comprehension subtest uses a cloze procedure in which the participants read a short passage and orally provide a missing word.

The CASL is a standardized, norm-referenced measure of oral language skills. The test is composed of core battery of measures which represents different aspects of language categories (semantics, syntax, and pragmatics). For the purposes of the current manuscript,

the CASL Core Language composite score is utilized, which is a combination of scores from age-appropriate subtests.

Device Fitting

Electric—The participants were initially fit with the Nucleus Freedom for Hybrid sound processor speech processor using a behind-the-ear (BTE) controller. Once the Nucleus 6 for Hybrid Sound Processor was FDA approved, subjects were converted to this processor. Threshold (T) and comfort (C) values were measured for 5 electrodes and then values were interpolated across the remaining electrodes. Four basal electrodes are disabled, per company recommendation.

Acoustic—The acoustic component of the Hybrid sound processor was appropriately fit using DSL to assess the degree to which real-ear targets were met for each subject. The basic programming approach was to assign frequency channels to the Hybrid electrode array that supplement the acoustic sensitivity. In other words, the frequency assignment of the electrical stimulation began at the frequency where acoustic hearing is no longer useful. For this purpose, hearing thresholds greater than 80 dB HL was considered not useful from an amplification perspective and not aidable acoustically.

Audiologic Follow-up

Audiological Testing—During the first month after activation, subjects were seen on a weekly basis to measure unaided residual acoustic hearing at 125 thru 8000 Hz. If more than a 10 dB downward PTA shift was identified, oral prednisone 1mg/kg once a day for 7 days was prescribed. Additional audiologic follow-up occurred at intervals of 4, 8, 12, and 24 months.

Hearing Aid Verification—A hearing aid check was completed by the clinician to verify that the contralateral hearing aid and the acoustic component of the Hybrid sound processor for the implanted ear were functional prior to aided testing. If any significant change of more than 10 dB (for the better or worse) at two or more (i.e., < 90 dB HL) frequencies in unaided thresholds was noted, the amplification fitting(s) was re-evaluated and adjustments were made.

Results

Hearing preservation

The surgical implantation of the Hybrid L24 electrode resulted in hearing preservation in all five subjects. Evaluation of individual change in the low-frequency pure-tone average (LFPTA) at initial activation in comparison to their preoperative LFPTA shown in Figure 1 indicated that all maintained functional hearing. 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 Hz¹⁶. The average loss of PTA at initial activation was 5.6 dB HL, which is considerably lower than the average loss of PTA for the Adult Hybrid S8 clinical trial study (14.8 dB HL)¹⁶.

In Figure 2, we show the individual thresholds over the range 125 to 1500 Hz in the implanted ear both preoperatively (Panel A) and post-operatively (Panel B) at the subjects' most recent appointment (24 months for Subjects 1–4 and 12 months for Subject 5). Hearing for Subjects 3, 4 and 5 were stable over time, whereas hearing thresholds for Subjects 1 and 2 shifted. When we look at the hearing of these two subjects over the first year after activation, the shift in hearing for Subject 1 (Panel C) occurred between 3 and 6 months post-activation. The subject was given a week-long oral steroid treatment with some return in hearing by 8 months. For Subject 2 (Panel D), the hearing loss occurred between surgery and initial activation with stable hearing over time following that time point. Subject 2 was currently taking prednisone when the hearing loss was determined as per protocol.

Speech Perception

In Figure 3, the individual scores preoperatively with a hearing aid(s) and postoperatively over time are shown in the Combined condition (Panel A), Hybrid condition (Panel B), and CI-Only (Panel C) on CNC words in quiet. Using a binomial confidence interval, we evaluated improvement in the CNC word score post-operatively versus preoperatively. In the Combined and Hybrid conditions, all subjects showed significant improvements by 4 months post-implantation, with exception of Subject 2 in the Combined condition, who showed a significant improvement by 8 months post-implantation. Subject 1 showed the greatest change in speech perception with a 63% improvement in the Combined condition. Subject 2 showed the smallest change in speech perception with a 22% improvement in the Combined condition. Subject 2 has not worn her cochlear implant device as consistently as the other 4 subjects. She focuses on a total communication approach; however, more focus has been on the sign language aspect over the hearing. Subject 5 has shown a consistent decline in the Hybrid condition over time. Via parent report, the subject is not consistently wearing her device. However, after some recent programming changes, she said that the sound is much better and she intends to wear it.

In the CI-only condition (Panel C), the CI is programmed with the electric low-frequency cut-off the same as it is in the hybrid condition. Subject 1 and 3 show significant electric-only benefit over time compared to their pre-op scores with a hearing aid. Because these subjects have much more severe residual low-frequency hearing, their electric cut-off is much lower. When you compare CI-only results to the Hybrid results in Panel B, there is very little change in performance. Their scores demonstrate amazing results with a short electrode CI with minimal acoustic hearing. Regardless, both subjects like the additional sound quality of the acoustic component and continue to its utilization. Subject 4 and 5 have much better low-frequency hearing preservation than subjects 1–3 and their testing is with a low-frequency cut-off that is much higher than the other subjects with more severe low-frequency hearing. When comparing their CI-only results to their results in the hybrid condition, you see an improvement based on the addition of the low-frequency acoustic information.

In Figure 4, CNC word scores are shown for a group of Bimodal adolescents between the ages of 5–15 at the time of testing who were implanted with a standard electrode in one ear and maintain a hearing aid on their contralateral ear. The Bimodal subjects had an average

of 74 months (SE=16) of CI experience at the time of testing. In addition, scores for our adolescents who received the Hybrid L24 device are also shown along with averaged data for both groups of subjects. The averaged data for both groups appear similar.

Localization

Figure 5 displays individual data for each subject for the Localization test shown in RMS Error in Degrees. Panel A compares pre-operative performance with bilateral hearing aids to post-operative results in the Combined condition. In this test, a lower score is indicative of better performance. All subjects scored better than 40 RMS Error in Degrees pre- and post-operatively (as indicated by the dashed line), which is the cutoff for chance performance. Thus, any localization score below 40 degrees shows that the subject has some localization ability. All subjects in this study scored better than chance performance both pre- and post-operatively. Data points on the diagonal line indicate that there was no change in localization performance pre- to post-operatively. Two (Subject 1 and Subject 5) of the five subjects have scores along the diagonal line. Subject 4 has better localization abilities post-operatively and Subjects 2 and 3 have poorer localization abilities post-operatively. In Panel B, post-operative LFPTA is used to determine if the amount of LF hearing is affecting the localization performance. Because of the limited amount of data, analysis is only speculative at this point; however, the trend suggests that the amount of LF hearing could be indicative of localization performance.

Articulation

Figure 6, Panel A, displays individual data for the GFTA-2 using standard scores. We utilized the 90% confidence intervals provided in the GFTA-2 test manual to determine whether or not there was change between the pre-operative and 24 month post-operative visit for four participants (Subjects 1 through 4) and 12-month post-operative visit for Subject 5. Three participants showed no significant change between visits (i.e., post-operative scores were within the confidence intervals of the pre-operative score). One participant (Subject 5) showed a significant improvement in articulation between the pre-operative and 12-month post-operative visit, with a change in standard score from 49 to 62 (the pre-operative confidence interval was 46 to 62). One participant (Subject 1) showed a significant decline in articulation between the pre-operative and 24-month post-operative visit, with a change in standard score from 102 to 84 (the pre-operative confidence interval was 96 to 108). It is unclear why Subject's 1 performance declined post-operatively. At the most recent visit (36 months post-operatively), it had improved to a standard score of 94, suggesting that this subject is demonstrating variability over time in speech production skills.

Global expressive and receptive language

Figure 6, Panel B, displays individual data for the CASL Core Language using the composite standard scores. We utilized the 90% confidence intervals provided in the CASL manual to determine whether or not there was change between the pre-operative and 12 month post-operative visit (the most recent visit in which all subjects contributed data on the CASL). Subject 2 was excluded because she was not tested at the 12 month visit. Three of the subjects showed no significant change between visits (i.e., post-operative scores were

within the confidence intervals of the pre-operative score). One participant (Subject 5) showed a significant improvement in global language scores, with a change in standard score from 82 to 90 (the pre-operative confidence interval was 77 to 87).

Literacy

Figure 6, Panel C, displays individual data for each subject for the WRMT Passage Comprehension scores: We utilized the standard error of measurement (SEM) scores provided in the test manual, which are consistent with the confidence intervals provided on the other measures for determining significant change over time. The standard error of measurement was ± 4 for all subjects. Data are included for four subjects at the pre-operative visit and the 24-month post-operative visit; Subject 5 has not yet been tested post-operatively on the WRMT. Two of the subjects (Subjects 1 and 2) showed significant improvements on the Passage Comprehension subtest. Subject 1 showed an improvement in standard scores from 99 to 111 and Subject 2 showed an improvement from 73 to 88. Subject 3 showed no change in performance over time (standard score of 95 at both visits). Subject 4 showed a significant decline in performance from the pre-operative to the 24 month post-operative visit, with a change in score from 93 to 87. The post-operative score was still within the average range of performance for the normative sample of the test, but it is not clear why the subject's score decreased over time.

Discussion

The purpose of this study was to evaluate the benefit of a Hybrid cochlear implant in children or adolescents with moderate-to-severe low-frequency hearing losses. Speech perception results showed that all five of the subjects in this study have benefited from the combined electrical and acoustic processing. This benefit averaged 38% correct in the Combined condition and 35% in the Hybrid condition on word scores in quiet.

All adolescents in this study maintained functional residual hearing preservation in the low-frequency region of the cochlea. Overall shift in the low-frequency PTA (125–1500 Hz) at initial activation was 5.8 dB HL and 9.2 dB HL at the most recent visit. While all of the subjects at their most recent visit continue to utilize an acoustic component to amplify hearing in the low-frequency region, the subjects (Subjects 1–3) with more severe hearing losses preoperatively have fewer low frequencies with functional hearing post-operatively. Specifically, Subject 1's pre-operative PTA was 83 dB HL, 69 dB HL for Subject 2, and 89 dB HL for Subject 3. Subjects 4 and 5 had better pre-operative PTAs of 63 and 60 dB HL, respectively. Subjects 1 and 3 are receiving acoustic amplification at 125 and 250 Hz and Subject 2 is receiving acoustic amplification at 125 Hz. Subjects 4 and 5 are receiving acoustic amplification through 750 Hz. Thus, the less residual hearing a subject has pre-operatively, the less functional hearing the subject will likely have post-operatively. However, it is remarkable that there is preservation of hearing even in those with minimal pre-operative hearing and all have maintained that hearing for 12–24 months post-implantation.

It is interesting to note that the speech perception data suggests that the amount of preserved residual hearing does not necessarily predict the speech perception benefit. Both Subjects 1

and 3 have low-frequency PTAs of 85 dB HL and 93 dB HL, respectively. These subjects have shown the best scores in speech perception with the Hybrid L24 cochlear implant. Additionally, Subject 1 and 3 have the biggest improvements of 63% and 53% in the Combined condition and 60% and 58% improvements in the Hybrid conditions, respectively. While Subjects 4 and 5 both started out with slightly higher scores initially, their scores are significantly poorer than subjects 1 and 3 post-operatively in the Combined condition and for Subject 5 only in the Hybrid condition. These results are consistent with those found in the Hybrid S8 Clinical Trial where it was found that as long as subjects maintained at least a severe LFPTA, there was significant improvement in speech understanding¹⁶.

The localization results in this study showed that all subjects have localization abilities post-operatively. These results are important because individuals with bimodal hearing (a cochlear implant and a hearing aid in opposite ears) who do not have hearing preservation on the implanted ear do not have good localization abilities¹². Furthermore, localization results for subjects with hearing preservation in the implanted ear have indicated that when subjects utilized either a Combined or bilateral hearing aid condition, subjects are able to determine sound directionality¹⁷. However, when these same subjects were tested in the Hybrid or Bimodal (the acoustic component on the implanted ear was disabled) conditions, scores were significantly poorer and above chance performance.

In the current study, the degree of low-frequency residual hearing appears to be indicative of localization acuity. However, because we only have data from 5 individuals, we are not able to conclude this finding. Nevertheless, results from other studies have indicated that symmetry in residual hearing between the two ears can affect the Interaural Timing Cues used for localization in individuals with preserved residual hearing¹⁸. Because some of the subjects in our study lost some residual hearing in their implanted ear, results from the Gifford study would support the localization outcomes in this study, suggesting that the amount of low-frequency hearing on the implanted ear could influence the subject's localization acuity.

Although the primary purpose of the Hybrid device is to improve speech perception performance, it is also important to monitor speech production and language abilities in this group of adolescents. In general, two participants (Subjects 3 and 4) demonstrated stable speech production and language scores between pre-operative and post-operative visits. Subject 1 showed a decrease in his standard score on the articulation measures, based on the confidence intervals of the standardized tests, but maintained performance on language measures and improved in reading. Subject 5 was the only subject to show significant improvement in both speech production and language from the pre-operative to post-operative visits. Unfortunately, the current results can only be presented descriptively due to the small number of subjects, making it difficult to formulate any conclusions regarding functional speech, language, and literacy outcomes. Through the use of a Hybrid cochlear implant, the goal is that these children would be able to simultaneously take advantage of electric stimulation and their natural acoustic hearing to improve their performance over time. Additional prospective longitudinal research is needed to determine if that goal can be met.

Conclusion

All of the subjects have benefitted from the combined electric and acoustic processing for speech perception abilities. Additionally, all of the subjects have some amount of preserved functional residual hearing in the implanted ear and have maintained this hearing for up to two years. The results from this study suggest that it could be worthwhile to consider acoustic and electric hearing in the adolescent population that have some low-frequency residual hearing and are struggling with hearing aids.

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Figure 1.

Change in individual subject low-frequency pure-tone average (LFPTA; 125–1500 Hz) at initial activation. Horizontal axis shows the pre-operative LFPTA versus post-operative LFPTA at initial activation on the vertical axis.

Figure 2. Individual thresholds over the range 125 to 1500 Hz in the implanted ear preoperatively (Panel A) and post-operatively (Panel B) at the subjects' most recent visit. Hearing thresholds over time through 12 months post-operatively are shown for Subject 1 (Panel C) and Subject 2 (Panel D).

Figure 3.

Individual CNC word perception performance pre-operatively and post-operatively over time at 4, 8, 12, and 24 months in the Combined (Panel A), Hybrid (Panel B), and CI-only (Panel C) conditions.

Figure 4.

Individual CNC word perception performance for a group of adolescents with a standard electrode on one ear and a hearing aid on the contralateral ear (Standard Bimodal) and a group of adolescents with a Hybrid L24 who were tested in the combined condition. Averaged results are shown for the Standard Bimodal group (BM) and the Hybrid L24 (L24) group is shown to the right of the dashed vertical line.

Figure 5.

Panel A shows change in localization performance using RMS Error in Degrees. The horizontal axis shows the pre-operative localization score with bilateral hearing aids versus post-operatively at the subjects' most recent visit in the Combined condition shown on the vertical axis. Diagonal line represents no change in performance. Panel B shows the influence of low-frequency pure-tone average (LFPTA; 125–1500 Hz) on localization performance at the subjects' most recent visit. The LFPTA is shown on the horizontal axis and the RMS Error in Degrees localization performance is shown on the vertical axis. Dashed line in both panels show the chance performance cut-off.

Figure 6. Individual data for the GFTA-2 (Panel A), CASL (Panel B), and WRMT Passage test (Panel C) are shown pre-operatively and post-operatively using standard scores.

Table 1

Subject demographic information.

Subject	Gender	Age at Implantation (years)	Age hearing loss was identified (years)	Age hearing aid first fit (years)	Etiology	Ear Implanted
1	Male	11	Birth	.5	Unknown	Left
2	Female	12	Unknown (adopted)	2.25	Unknown	Left
3	Female	12	.5	1.5	Unknown	Right
4	Female	13	4	4	Unknown	Left
5	Female	15	Birth	2.5	Unknown	Left