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Bilateral Cochlear Implants Using Two Electrode Lengths in Infants With Profound Deafness

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Abstract

Objective: The goal of this investigation was to determine if a short electrode in one ear and standard electrode in the contralateral ear could be an option for infants with congenital profound deafness to theoretically preserve the structures of the inner ear. Similarities in performance between ears and compared with a control group of infants implanted with bilateral standard electrodes was evaluated.

Study Design: Repeated-measure, single-subject experiment.

Setting: University of Iowa—Department of Otolaryngology.

Participants: Nine infants with congenital profound bilateral sensorineural hearing loss.

Intervention(s): Short and standard implants.

Main Outcome Measure(s): Early speech perception test (ESP), children's vowel, phonetically balanced-kindergarten (PB-K) word test, and preschool language scales-3 (PLS-3).

Results: ESP scores showed performance reaching a ceiling effect for the individual short and standard ears and bilaterally. The children's vowel and PB-K word results indicated significant (both $p < 0.001$) differences between the two ears. Bilateral comparisons to age-matched children with standard bilateral electrodes showed no significant differences ($p = 0.321$) in performance. Global language performance for six children demonstrated standard scores around 1 standard deviation (SD) of the mean. Two children showed scores below the mean, but can be attributed to inconsistent device usage. Averaged total language scores between groups showed no difference in performance ($p = 0.293$).

Conclusions: The combined use of a short electrode and standard electrode might provide an option for implantation with the goal of preserving the cochlear anatomy. However, further studies are needed to understand why some children have or do not have symmetric performance.

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Keywords

Bilateral; Cochlear implants; Pediatric; Short electrode; Simultaneous

Bilateral cochlear implantation in children with profound sensorineural hearing loss has become standard of care at many cochlear implant centers. Research demonstrates that children who have received bilateral cochlear implants show significant benefits for speech perception in quiet and in noise, music perception, and spatial acuity (see for example 1–7) (1–7). While these benefits are compelling, there is some concern that bilateral implantation might limit children from taking advantage of future advances in molecular and/or genetic treatments of the inner ear due to damage to the delicate inner ear following cochlear implantation.

Literature suggests that placement of a cochlear implant electrode array into the inner ear might cause direct trauma to cochlear structures and/or inflammation which could result in damage to the scala media, Organ of Corti, and supporting cells (8–14). Preservation of the supporting cells in the Organ of Corti might be of particular interest as there is preliminary evidence that the supporting cells of the Organ of Corti may have the capacity to be transduced into functional hair cells (15,16). Newer cochlear implants have been designed to preserve the anatomy of the inner ear as evidenced by hearing preservation of individuals with preoperative low-frequency residual hearing (see for example 17–19)(17–19). These newer devices incorporate electrodes that are often shorter in length, smaller in diameter, and involve a more flexible tip to allow for less invasive insertion into the cochlea.

In this study, nine children between the ages of 12 to 24 months of age with congenital deafness were implanted with a “short” 10-mm length electrode array (Nucleus Hybrid S12) and a “standard” Nucleus Freedom implant in the contralateral ear. This feasibility study was conducted under a special Food and Drug Administration Investigational Device Exemption study (FDA IDE; G070130). Preliminary data on this study were previously reported (20). The objective of this prospective study was to evaluate whether a short electrode on one ear and a standard electrode in the contralateral ear is a possible bilateral cochlear implant option for children with congenital profound bilateral sensorineural hearing loss. To determine this feasibility, we evaluated symmetry between ears and bilateral performance on speech perception and language tests over time. We are also interested in comparing this pediatric population with a short and standard cochlear implant with a group of congenitally deafened children implanted with bilateral standard-length cochlear implants. Because the children in this study were implanted at a young age, a variety of speech perception measures were used as the child aged and matured. A long-term goal of implanting a shorter electrode array in profound congenital deaf children was to provide auditory stimulation to the cochlea while at the same time theoretically preserving cellular structure leaving it available for possible future advances in the field of regenerative medicine.

METHOD

Participants

Nine subjects with congenital bilateral sensorineural hearing loss were recruited from our cochlear implant center to participate in this research. Ear to be implanted with the short electrode was selected based on their enrollment in the study. Five children were implanted with the short electrode on their left side and four were implanted with the short electrode on their right side. The average age at the time of implantation was 13.3 months (range: 12–16 mo; standard deviation [SD]: 1.2). Four of the subjects were men and five were women. The etiology of each subject's hearing loss was unknown. Each child's parent(s) or guardian were given adequate time to review the informed consent form and given the opportunity to ask questions regarding the informed consent and/or the study before signing the informed consent form. All of the children have pre- and post-implantation speech perception data and eight children have speech and language results.

Four of the children had one of their cochlear implant devices explanted and reimplanted with a new or different electrode. Subject S5 had his standard electrode removed at 12 months post-implantation due to an infection at the implant incision. He was reimplanted with a new standard electrode at 14 months post-implantation. He used his short electrode during this 2-month time period. Subjects S2, S3, S6 had their short electrodes removed at 57, 73, 69 months post-activation due to asymmetries in speech perception scores between ears. All three were reimplanted with a standard electrode. After analysis of the devices by Cochlear Ltd in Sydney, Australia, it was determined that S2 had a failed device. The analysis came back a soft failure for S3 and S6. The term "soft failure" is often used when the device is not performing up to expected benefits, but there is no evidence that the device is malfunctioning. Table 1 shows demographic and implant information for the target group of children in this study.

Subjects selected for this study met the following inclusion criteria:

1. Twelve to 24 months of age at the time of implantation.
2. Audiometric thresholds for frequencies 250 to 8000 Hz in the severe-to-profound hearing range bilaterally. The type of hearing loss must be categorized as sensorineural in nature.
3. English spoken as a primary language (monolingual English speaking family, where English is the primary language).
4. Minimum of a 3-month hearing aid trial.
5. Patent cochlea and normal cochlear anatomy as shown by a computed tomography (CT) or magnetic resonance imaging (MRI) scan.
6. Must be in a habilitation/educational program with an emphasis on spoken language development.
7. No known developmental disabilities or other conditions that may prevent or restrict participation in the audiological evaluations and clinical trial.

A group of children were also used as a control for comparison on speech perception and language measures to the target group. All control children fit the inclusion criteria for this study, but their parents chose to have the child simultaneously implanted with bilateral standard electrodes (Table 2 shows demographic information for the control group).

Cochlear Implant Devices

Short Electrode Array—The short electrode used in this study was the Nucleus Hybrid S12 electrode array. This electrode was developed by the University of Iowa Cochlear Implant Team and Cochlear Americas and was designed to reduce the incidence of intracochlear injury. The device is 0.2 mm × 0.4 mm in diameter and is 10 mm in length. The electrode has 10 contacts or channels distributed in the distal 5.7 mm of the array.

Standard Electrode Array—The standard electrode used in this study was the Nucleus Freedom standard electrode. This electrode array is 24 mm in length with 22 electrode contacts. This device has received FDA approval for implantation in children and adults.

PROCEDURE

Design Overview

Success of this study was measured by assessing speech perception on individual ears and bilaterally on the children implanted with a short and standard electrode. Results were also compared with age-matched children with bilateral standard electrode arrays in both ears.

Speech Perception and Speech/Language Testing

Auditory function was evaluated using the following test battery. Subjects were tested in three listening conditions: 1) short electrode only; 2) standard electrode only; and 3) short and standard electrode array, bilaterally.

Speech Perception

The Early Speech Perception (ESP). This is a closed-set test which required the identification of a spondee or monosyllable from a set of four spondees (i.e., French fry, airplane, hotdog, popcorn) or monosyllables (i.e., ball, book, bird, boat), respectively presented in quiet at 70 dB C (21). The ESP test was scored as total number of words correct.

Iowa Children's Vowel Test. This test required the identification of a monosyllabic word presented at 70 dB C from a closed-set of four words (e.g., toe, toy, tie, two) varying only in vowel content (place and height) (22). Scoring is based on the percent-correct performance at the word level.

Phonetically Balanced-Kindergarten (PB-K) words. This test requires the identification of a monosyllabic word from an open-set list of 50 words (23). The scoring was based on percent-correct performance at the word level. Three of the PB-K 50-word lists were used (list 1, 2, and 3). One PB-K list was administered at 70 dB C in each of the three listening

conditions. All lists were randomized between children and no child received two of the same lists during the same visit.

Global Language

Preschool Language Scale-3 (PLS-3): This measure is a standardized and norm-referenced receptive and expressive language measure (24). It can be administered to children ages 2 weeks to 6 years, 11 months. The PLS-3 consists of two subscales: Auditory Comprehension and Expressive Communication. For both subscales, children are evaluated through a combination of clinician observation and use of manipulatives and pictures. It provides age-based standard scores for Auditory Comprehension, Expressive Communication, and Total Language, with a score of 100 representing average performance for a typically-developing child.

RESULTS

Speech Perception

Figure 1 shows results for the ESP word test administered in quiet to all nine subjects in the target group at the post-activation test session listed under the subject ID. This was the most recent test session that these subjects were administered this test (average of 27 months post-operative, $SD = 11.5$). Most of the children performed at a ceiling level on this closed-set word test with individual ears and bilaterally. While showing results at a ceiling effect does not offer much insight into differences between ears, this was a test that could be performed by these children at a young age to allow us to assess whether or not they were getting speech understanding with their devices.

Figure 2 shows individual ear and bilateral scores for the nine subjects in the target group for the children's vowel test. S7 does not have a standard electrode ear score and S8 does not have a bilateral score. Both of these omissions are due to fatigue in testing for the child. This test was administered in quiet at the post-activation test session listed under each subject ID and includes the most recent test session that these subjects were administered the test. The average age of these nine children at the time of this testing was 47 months ($SD = 17.5$). Averaged results showed a significant difference on a paired t test ($p < 0.001$) between the ear with the short electrode (81% correct) and the ear with the standard electrode (91%) correct. There was no significant difference ($p = 0.91$) between the ear with the standard electrode and bilateral condition (92%) for the target group. Four children (S1, S2, S4, S9) demonstrated symmetry between their ears (averaged 84% short and 87% standard) and four children (S3, S5, S6, S8) showed asymmetries between their ears (averaged 79% short and 95% standard). One child (S7) did not have an individual ear score with the standard electrode. When comparing the averaged bilateral score (92%) of the target group to the averaged bilateral score of the control group (87%), there was no significant difference in bilateral scores ($p = 0.321$).

Figure 3 shows results for the PB-K word scores. Individual ear and bilateral scores for each subject in the target group as well as the averaged individual ear and bilateral scores are displayed. The post-activation test session that this test was administered is listed under

subject ID. The average age of these eight children at the time of this testing was 79 months (SD = 14.6). The averaged bilateral score is also shown for the standard bilateral control group. The average age of these eight children at the time of this testing was 62 months (SD = 14). Three of the children in the target group (S1, S5, S7) showed symmetrical performance between ears (averaged 85% short and 91% standard) and five of the children (S2, S3, S6, S8, S9) showed asymmetries (averaged 45% short and 90% standard) in performance between ears. One child (S4) has never been administered the PB-K test due to lack of speech and language development, most likely due to early intermittent use. This child is only able to be assessed using closed-set tests. Averaged individual ear scores for the target group showed significant paired t test ($p < 0.001$) differences between the ear with the short electrode (60%) and the ear with the standard-length electrode (91%), but no significant difference ($p = 0.12$) between standard-length electrode and the bilateral condition for this group. Averaged individual ear (right = green bar; left = orange bar) and bilateral scores for the control group showed no significant ($p = 0.08$) differences (individual ears each 77% and bilateral 82%). Interestingly, when comparing the averaged bilateral score of the target group (94%) to the averaged bilateral score of the control group (82%), there was no significant difference in scores ($p = 0.16$).

Three of the children (S2, S3, S6) in Figure 3 with asymmetries had the short electrode explanted and reimplanted with a standard-length electrode. Figure 4 displays individual ear and bilateral scores for these three subjects in the target group following explantation and reimplantation. The individual ear that was explanted and reimplanted is denoted using the hashed bar. The scores for the explanted and reimplanted ear showed an averaged improvement of 47%. Following this, there was no significant difference between their individual ears ($p = 0.37$).

PB-K scores are shown over time for children in the target group in Figure 5. In each of the panels, months post-activation are shown on the horizontal axis and percent correct is shown on the vertical axis. In Panel A, we show scores over time for the ear with the short electrode for the three children (S2, S3, S6) that had their short electrode explanted and were reimplanted with a standard electrode. The solid line indicates when they were using their short electrode whereas the dashed line demonstrates performance after they were explanted and reimplanted with a standard electrode. Each of these children showed an almost immediate improvement in performance. In Panel B, we show scores over time for the children who were not explanted and reimplanted. One child (S1) has shown stable high performance over time with the short electrode. Interestingly, for four children (S5, S7, S8, S9) in Panel B who had asymmetry between ears, scores have shown improvement over time. Three of the children (S7, S8, S9) did not demonstrate improvement in PBK words scores until after 72 months post-implantation with the short electrode. The three children in Panel A who had their short electrode device explanted and were reimplanted with a standard electrode had this surgical procedure either before or at 72 months post-implantation. In Panel C, scores over time for the ear with the standard electrode show stable performance over time for all of the children.

Global Language

Figure 6 shows the results for the PLS-3 for children in the target group and in the control group at 48 months post-activation and with a chronological age of 5 years. Expressive, receptive, and total language standard scores are shown for each child in the target group (with the exception of S8). S8 did not have a language score at 48 months post-activation. Averaged scores are shown for the target group and for the control group. Individual scores for five children in the target group (S1, S2, S5, S6, and S7) show expressive, receptive, and total language standard scores that are within 1 SD of the mean for this test. One child (S9) shows standard scores that are slightly below 1 SD of the mean. Two children (S3, S4) show standard scores that are well below the mean. These two children have not had consistent use of their devices over time. The children in the target group achieved averaged standard scores of 87, 83, and 84 on expressive, receptive, and total language, respectively ($SD = 19.5, 23, \text{ and } 23.1$). The children in the control group achieved averaged standard scores of 77, 80, and 77 on expressive, receptive, and total language, respectively ($SD = 7.4$). In the simultaneous bilateral comparison group, the average standard score was 83.57 ($SD = 17.1, 21, \text{ and } 19$) indicating consistent performance between the two groups.

CONCLUSION

The purpose of this prospective clinical trial was to evaluate a possible alternative to bilateral standard-length cochlear implantation in infants with bilateral profound congenital deafness with the goal of potentially preserving inner ear cellular structure for future medical interventions. This feasibility study was designed to test the hypothesis that an ear with a short hearing preservation electrode (Nucleus Hybrid S12) would perform similarly to an ear with a standard electrode.

In our preliminary publication on this subject population in 2010 (20), we felt that even though the depth of insertion differed between the two ears for these children at a young age, speech recognition performance appeared to be similar between ears. This assertion was based partially upon parent-report questionnaires that documented auditory and language growth. Secondly, as children were able to perform behavioral speech perception tests, our early results for two of the children using the ESP test demonstrated outcomes between ears that suggested similarities. Furthermore, the bilateral results of these two children also resembled that of our control population with bilateral standard-length electrodes.

In this follow-up manuscript, we were able to complete the ESP test on all of the children in the target group. We were not able to determine differences between ears for the participants as scores were at a ceiling level for this test. Nonetheless, it was exciting to see that both ears were showing speech perception progress. As we moved through our protocol of tests based upon the age of child, we started to see small deviations appear between ears for some of the participants when using the children's vowel test. While this test is also closed-set, it requires the child to distinguish differences in words based upon the vowel. Yet, the bilateral score for the target group demonstrated no significant difference when compared with the control group.

As we began to administer tests which utilized open-set, rather than closed set paradigms, more asymmetries between ears for some of the children was evident. Some children presented with patterns between ears where the performance with the ear with the shorter electrode was inferior. Others, however, were demonstrating patterns that were consistent with our hypothesis, in that the ears were performing similarly.

Expressive, receptive, and total language outcomes for the target group at 48 months post-activation demonstrated that five of the children were within 1 standard deviation of the norms for this test. Three of the children performed below 1 standard deviation of the norm. Two of the children (S3 and S4) who had low performance did not have consistently use either cochlear implant due lack of compliance and family dynamics. The third child (S9) scored only slightly below 1 standard deviation. When comparing the results overall between the target and control group, the average performance between the two groups was the same. It is also important to point out that reported language outcomes were assessed before any of the children having their shorter electrode devices explanted for asymmetric speech perception performance. Of the children who demonstrated asymmetric speech perception outcomes (S2, S3, S6, S8, and S9), only S3 and S9 had total language scores below 1 standard deviation.

Three of the children (S2, S3, and S6) with asymmetric speech perception scores had their short electrode cochlear implant removed and were reimplanted with a standard electrode. Each of these children received significant improvements in their scores following reimplantation. This finding supports the hypothesis that a longer electrode might indeed be needed for early and adequate speech understanding. Given that we were able to explant and reimplant with a longer electrode after several years of stimulation with a shorter electrode does coincide with the notion that marginal damage is being done to the inner ear with electrodes implanted in a more basal region of the cochlea. This was also seen in a case study where an adult with hearing preservation was implanted with a 10 mm electrode that was later explanted due to a device failure and reimplanted with a 16 mm electrode. Following implantation and explantation, the patient maintained substantial low-frequency hearing (25).

Three children whom also had asymmetric results at one point in time between ears, but chose not to have their device removed showed improvements in performance longitudinally after several years of use. While we do not promote these children should have to wait several years to have symmetrical performance between ears, we do find this trend in performance interesting. Perhaps these results are consistent with research in adults with preserved low-frequency hearing using the Nucleus Hybrid S12 cochlear implant, where the place-pitch sensations between ears shifts by as much as two octaves over time with consistent use (26). Furthermore, it was also shown that the changes in pitch perception were found to be dependent on the patients' experience with the frequency presented to the electrode by the cochlear implant speech processor (27). Thus, if there is sufficient nerve survival in the base of the cochlea, the child might be able to adapt to the abnormal place–frequency map between ears resulting in improvement in speech perception outcomes for the ear with the shorter electrode over time.

While enrollment and study outcomes for this study is complete, we are following a group of children with the same inclusion criteria of this study who were implanted with a Nucleus Hybrid L24 (16 mm electrode length) on one ear and Nucleus Freedom cochlear implant on the contralateral ear. It will be interesting to determine if these children present with similar patterns of performance to the children in this study or if the additional length of the L24 electrode compared with the S12 electrode used in this study will reveal different patterns.

In conclusion, we have not been able to determine the nature of why some children in the target group perform similarly between ears early while others take longer to adapt to the shorter electrode. It is important to remember that bilateral speech perception and language outcomes for the target group was not statistically different from that of the control group of age-matched children implanted with standard bilateral cochlear implants. Additionally, some variability can be expected in performance between outcomes of all infants implanted with a cochlear implant due to consistency of auditory/oral learning in a habilitation/educational program. The variability of these results in a small sample size does not allow us to draw strong conclusions. It is interesting that some children adapt more quickly than others to a shorter electrode. The fact that the auditory nerve and central auditory system continues to demonstrate plasticity and adaptability over time is encouraging. The new group of subjects now implanted with the L24 and standard electrode might add clarity. Furthermore, implementing tests that will better assess bilateral benefit (e.g., localization and speech perception in complex listening situations) will help us understand similarities or perhaps limitations of implanting two different lengths of electrodes on opposite ears. We will continue to follow both groups to determine future outcomes as the children age.

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FIG. 1.

Early speech perception test (ESP) results are shown for nine children implanted with a short and a standard cochlear implant on contralateral ears. Individual scores using the short electrode only, standard electrode only, and bilaterally are shown for each child. Averaged results for the short electrode only, standard electrode only, and bilaterally are also shown. Averaged scores are shown with ± 1 standard error bars.

FIG. 2.

Children's vowel test results are shown for the nine children implanted with a short and a standard cochlear implant on contralateral ears. Individual scores using the short electrode only, standard electrode only, and bilaterally are shown for each child. S7 does not have testing using the standard electrode only and S8 does not have testing in the bilateral condition both due to time constraints. Averaged results for the short electrode only, standard electrode only, and bilaterally are also shown. Averaged scores are shown with ± 1 standard error bars.

FIG. 3.

Phonetically balanced-kindergarten (PB-K) test results are shown for eight children implanted with a short and a standard cochlear implant on contralateral ears. Individual and averaged scores using the short electrode only, standard electrode only, and bilaterally are shown. S4 does not have outcome results on this test due to restricted language and speech production development. The set of three bars on the far right show averaged individual ear and bilateral PB-K scores for children implanted with bilateral standard cochlear implants. Averaged scores are shown with ± 1 standard error bars.

FIG. 4.

Phonetically balanced-kindergarten (PB-K) test results are shown for the three children who had the short electrode explanted and were reimplanted with a standard electrode. Individual scores using the reimplanted ear only, contralateral standard electrode array only, and bilaterally are shown.

FIG. 5.

Phonetically balanced-kindergarten (PB-K) test results are shown over time with months post-activation on the horizontal axis and percent correct is on the vertical axis. In Panel *A*, we show the scores over time for three children who had their short electrode explanted and were reimplanted with a standard electrode. The solid lines are scores using the short electrode and the dashed lines are following explantation and reimplantation with a standard electrode. In Panel *B*, we show scores over time with the short electrode ear for children who were not explanted. In Panel *C*, we show scores over time for the contralateral standard electrode ear.

FIG. 6.

Individual and averaged receptive, expressive, and total language standard scores for the Preschool Language Scale-3 (PLS-3) are shown at 48 months post-activation for children implanted with a short and a standard cochlear implant on contralateral ears. Averaged receptive, expressive, and total language standard scores at 48 months post-activation are also shown for children implanted with bilateral standard cochlear implants. Averaged scores are shown with ± 1 standard error bars.

TABLE 1.

Short and standard electrode subject demographic information

Subject	Gender (M = Male; F = Female)	Device (L = Left; R = Right)	Age at Implantation (mo)	Age at Explantation/ Reimplantation (mo)	Ear Explanted (L = Left; R = Right)	Device Reimplanted
S1	M	L = S12 R = Freedom	14			
S2	M	L = Freedom R = S12	14	71/71	R	Freedom
S3	F	L = S12 R = Freedom	13	86/86	L	Freedom
S4	F	L = Freedom R = S12	13			
S5	M	L = S12 R = Freedom	16	28/30	R	Freedom
S6	F	L = Freedom R = S12	13	82/82	R	Freedom
S7	F	L = S12 R = Freedom	13			
S8	F	L = Freedom R = S12	13			
S9	M	L = S12 R = Freedom	13			

TABLE 2.

Bilateral standard electrode control group demographic information

Subject	Gender (M = Male; F = Female)	Age at Implantation (mo)	Outcome
B1	F	15	PBK
B2	M	16	V
B3	M	11	PBK
B4	M	14	PLS
B5	F	13	PBK, V
B6	M	14	PBK, V, PLS
B7	F	18	PBK
B8	F	13	PBK
B9	M	13	PBK, V, PLS
B10	F	13	PBK
B11	M	13	PBK
B12	F	13	PBK
B13	M	13	PBK, V
B14	M	13	PBK, V, PLS
B15	F	13	PLS
B16	F	13	PBK
B17	F	13	PBK, V, PLS
B18	F	13	PBK, V, PLS
B19	M	13	PBK, V, PLS
B20	M	13	PBK, V

ESP indicates early speech perception; PB-K, phonetically balanced-kindergarten word test; PLS, Preschool Language Scale; V, children's vowel test.