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Bilateral Cochlear Implants in Infants: A New Approach—Nucleus Hybrid S12 Project

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Abstract

Objective—The purpose of this feasibility study was to evaluate whether the use of a shorter-length cochlear implant (10 mm) on one ear and a standard electrode (24 mm) on the contralateral ear is a viable bilateral option for children with profound bilateral sensorineural hearing loss. A secondary purpose of this study was to determine whether the ear with the shorter-length electrode performs similarly to the standard-length electrode. Our goal was to provide an option of electrical stimulation that theoretically might preserve the structures of the scala media and organ of Corti.

Study Design—The study is being conducted as a repeated-measure, single-subject experiment.

Setting—University of Iowa—Department of Otolaryngology.

Patients—Eight pediatric patients with profound bilateral sensorineural hearing loss between the ages of 12 and 24 months.

Interventions—Nucleus Hybrid S12 10-mm electrode and a Nucleus Freedom implant in the contralateral ear.

Main Outcome Measures—The Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) parent questionnaire, Early Speech Perception, Glendonald Auditory Screening Procedure word test, and Children's Vowel tests will be used to evaluate speech perception and the Minnesota Child Development Inventory and Preschool Language Scales 3 test will be used to evaluate language growth.

Results—Preliminary results for 8 children have been collected before and after the operation using the IT-MAIS. All 3 children showed incremental improvements in their IT-MAIS scores overtime. Early Speech Perception, Glendonald Auditory Screening Procedure word test, and Children's Vowel word perception results indicated no difference between the individual ears for the 2 children tested. Performance compared with age-matched children implanted with standard bilateral cochlear implants showed similar results to the children implanted with Nucleus Hybrid S12 10-mm electrode and a Nucleus Freedom implant in contralateral ears.

Conclusion—The use of a shorter-length cochlear implant on one ear and a standard-length electrode on the contralateral ear might provide a viable option for bilateral cochlear implantation in children with bilateral profound sensorineural hearing loss. Further study of this patient population will be continued.

Keywords

Bilateral cochlear implants; Cochlear implants; Hybrid; Pediatric

Bilateral cochlear implantation in children with profound sensorineural hearing loss has become routine. Research studying the benefits of bilateral cochlear implantation over unilateral implantation in children and adults has indicated improved speech perception in quiet and noise, sound localization, and sound quality (see, e.g., (1-4)).

Although the potential benefits of binaural listening using 2 cochlear implants are compelling, there is some concern that bilateral implantation might limit children from taking advantage of future advances of molecular and/or genetic treatments of the inner ear. Placement of standard-length cochlear implant electrode arrays more than 20 mm into the scala tympani usually results in significant damage to the scala media, organ of Corti, and supporting cells. Preservation of the supporting cells in the organ of Corti might be of particular interest because these cells have been shown to be the progenitors of hair cells in birds and other animals. There is preliminary evidence that the supporting cells of the organ of Corti may be reactivated to regenerate hair cells (5,6). On the contrary, if an ear is not implanted and experiences a prolonged period of deprivation, it might not be able to take advantage of new treatments for deafness as they are developed. In addition, deprived central auditory pathways (particularly those that support binaural hearing) might result in immature or abnormally developed auditory systems (7).

In an attempt to preserve the organ of Corti and supporting cells, a 10-mm-length electrode array with an insertion limited to the basal turn of the cochlea (called the Nucleus Hybrid S12) was implanted in one ear of children who are congenitally deaf. Although the Nucleus Hybrid S12 electrode array is the same electrode array currently under investigation by the U.S. Food and Drug Administration (FDA) to preserve residual hearing in adults (8), the long-term goal of using the electrode array in this study is to theoretically attempt to preserve cellular structure rather than hearing. Using a 10-mm electrode array instead of a longer 24-mm array might allow for the ear to be stimulated during the first few years of life and result in less damage to the structures of the scala media and organ of Corti. It is hypothesized that by using the Nucleus Hybrid S12 electrode, the region of the cochlea that is apical to the electrode will be preserved, leaving it available for possible future advances in regenerative medicine. However, we recognize that we will not be able to determine whether the Hybrid S12 preserved the organ of Corti distal to the electrode until imaging or other measures allows this type of resolution. Studies in adults using the Nucleus Hybrid S12 implant demonstrate that, when an electrode is limited to the basal turn of the cochlea, acoustic speech perception can be preserved in most patients (8), suggesting little or no damage to the organ of Corti's residual hair cells. Some patients lose some acoustic hearing during the initial stimulation phase with the Hybrid implant. It is not known whether the cause of this loss is a reaction to the implant or some toxic effect of electrical charge on the hair cells that results in this loss. Even with the possible loss of hair cell function in some patients, the supporting cells of the organ of Corti might still be intact. In addition, animal studies support the concept that scala media preservation can be accomplished by limiting placement of an electrode to the lower basal turn of the cochlea (9, 10).

The purpose of this feasibility study is to evaluate whether the Nucleus Hybrid S12 in one ear and a Nucleus Freedom implant in the contralateral ear is a viable bilateral option for children with profound bilateral sensorineural hearing loss. A secondary purpose of this study is to determine whether the ear with the shorter-length electrode performs similarly to the standard-length electrode. Some adult patients with this shorter electrode achieve very high levels of

speech recognition using electric-only stimulation, despite the fact that the entire speech spectrum is presented to a narrow region of the cochlea (11). Success with the short Hybrid electrode has been shown to be greater in those patients with shorter durations of hearing loss and younger age (8,12). Thus, children might benefit the most from this device. We are also interested in comparing the pediatric population with 1 Nucleus Hybrid S12 and 1 Nucleus Freedom on contralateral ears to pediatric patients with bilateral standard-length cochlear implants. Our goal was to provide an option of electrical stimulation that theoretically might preserve the structures of the scala media and organ of Corti.

This study is being performed under a special FDA Investigational Device Exemption (IDE; G070130/S001). Ten patients between the ages of 12 and 24 months will be implanted using the Nucleus Hybrid S12 implant in one ear and a standard Nucleus Freedom implant in the contralateral ear. We recognize that this small number of patients may not afford us enough statistical power to adequately answer all questions associated with using an Nucleus Hybrid S12 and a Nucleus Freedom electrode array in contralateral ears in pediatric patients who have bilaterally severe to profound hearing loss. However, it might provide some preliminary guidance as we assess whether 1) a shorter-length cochlear implant and a longerlength cochlear implant on the opposite ear is a viable option to provide useful bilateral hearing and 2) the Nucleus Hybrid S12 can provide similar speech perception results as the ear with the Nucleus Freedom cochlear implants. Preliminary data on 8 children who have data up to at least 24 months after implantation will be shown in this report.

METHODS

Subjects

As of March 2010, 8 patients with bilateral sensorineural hearing loss have received contralateral Nucleus Hybrid S12 and Nucleus Freedom cochlear implants under this IDE. Four children have been implanted with the 10-mm electrode array on their left ear and 4 have been implanted with the 10-mm electrode array on their right ear. The patients' age ranged from 12 to 16 months (SD, 1.3 mo) at the time of implantation. Three of the patients are boys and 5 are girls. The cause of each patient's hearing loss is unknown. Each child's parent(s) or guardian were given adequate time to review the informed consent form and were given the opportunity to ask questions about the informed consent and/or the study before signing the informed consent form.

Two children have preimplantation and postimplantation speech perception data and 8 children have speech and language results. Two of the children have results through 24 months, 1 child has results at 12 months after implantation, and all others have data at less than 1 year of cochlear implant experience. Because of the age of the children, not all children have data on all speech perception tests.

Patients selected for this study met the following inclusion and exclusion criteria.

Criteria for inclusion:

1. Aged 12 to 24 months at the time of implantation.
2. Audiometric thresholds for frequencies 250 to 8,000 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. Willingness to comply with all study requirements.

5. Minimum of 3 months of hearing aid trial.
6. Patent cochlea and normal cochlear anatomy as shown by a computed tomographic or a magnetic resonance imaging scan.
7. Must be in a habilitation/educational program with an emphasis on spoken language development.

Criteria for exclusion:

1. Medical or psychological conditions that contraindicate undergoing surgery.
2. Ossification or any other cochlear anomaly that might prevent complete insertion of the electrode array.
3. Developmental disabilities or other conditions that may prevent or restrict participation in the audiological evaluations and clinical trial.
4. Hearing loss of neural or central origin.
5. Unrealistic expectations on the part of the candidate's family, regarding the possible benefits, risks, and limitations that are inherent to the surgical procedure(s) and prosthetic devices.
6. Unwillingness or inability of the candidate to comply with all investigational requirements.
7. Active and/or recurrent middle ear infection.

Cochlear Implant Devices

Nucleus Hybrid S12 Electrode Array—The Nucleus Hybrid S12 electrode array 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.

Nucleus Freedom Standard Electrode Array—The Nucleus Freedom standard electrode array is 24 mm in length with 22 electrode contacts.

PROCEDURE

Design Overview

Success of this study will be measured by assessing speech perception on individual ears and bilaterally and on speech and language development. We will compare these preliminary results with age-matched children with bilateral standard electrode arrays in both ears (demographics on these children are shown in Table 1).

Preoperative Audiological Assessment—The degree of hearing loss was determined by a combination of electrophysiological and behavioral tests including auditory brainstem response, steady-state evoked potential, otoacoustic emission, and behavioral audiometry. Audiological assessment included unaided and aided audiometric thresholds, tympanometry measures, and otoscopic inspection. Unaided pure-tone air-conduction audiometric thresholds were obtained bilaterally using insert earphones and behavioral techniques appropriate for the child's age and overall developmental level (visual reinforcement audiometry and/or behavioral observation audiometry techniques). Bone-conduction testing was also completed using a bone oscillator and the previously mentioned techniques, when possible. Aided audiometric threshold testing was obtained using narrowband noise for each ear individually.

in the sound field. In addition, the audiometric techniques listed were used to obtain these thresholds with the speakers positioned at 45 degrees azimuth relative to the participant's head. Unaided audiometric threshold results are reported in Table 2.

Fitting of Hearing Aids—Lack of benefit from appropriately fit hearing aids were determined by the lack of progress in the development of simple auditory skills as defined by aided behavioral thresholds, Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) (13) and parental and/or educator reports. Hearing aid use was determined by parental and educator reports.

All patients were fit with bilateral behind-the-ear hearing aids and were asked to use the devices for at least a 3-month trial period before determination of candidacy. All audiometric criteria were met with the patients using appropriately fitted hearing aids.

Surgical Procedure—Bilateral simultaneous cochlear implantation has been described (14). Nucleus Freedom array is always placed first, and the skin incision is closed. The surgical procedure for the Nucleus Hybrid S12 is similar to that previously described for hearing preservation (15). Soft surgery techniques were used on both arrays, and the cochleostomy was made in a similar position for both devices. Creation of the cochleostomy requires exposure of the round window, removal of bone anterior and inferior to the round window membrane, control of bleeding, and creation of a 0.5-mm cochleostomy, exposing the endosteum only. The endosteum is opened with a 0.2-mm hook. No suctioning of perilymph is allowed. The devices are then advanced slowly into the cochlea. The Nucleus Hybrid S12 implant was inserted 10 mm into the scala tympani, and the Nucleus Freedom array was inserted 24 mm into the scala tympani using the advance-off stylet technique.

Device Activation—After surgical implantation of the device and an adequate healing period, the implants were activated (usually 4 wk after surgery). The participants were fit with Freedom speech processors using a behind-the-ear controller or body-worn controller. Impedance telemetry results using common ground and monopolar (MP1, MP2, and MP1 + 2) stimulation modes were also recorded to monitor the device for possible degradation of function and/or damage to neural elements. Threshold and comfort levels were measured for approximately 3 to 5 electrodes for both devices.

The process of adjusting the speech processor programs was done several times during the first year for each patient. Behavioral observation audiometry, visual reinforcement audiometry, and conditioned play audiometry techniques were used to determine electrical threshold levels for the electrodes in the patient's program. Electrophysiological data (neural response telemetry and auto neural response telemetry) were used to verify levels obtained behaviorally or in those instances when behavioral information was limited. Electrical comfort levels were set conservatively on initial programs to ensure a comfortable listening level for the child. Levels were increased gradually at home and over several programming sessions scheduled at 2 weeks, 1 month, and 2 months after activation because it is not unusual for threshold and comfort levels to change during the initial postactivation period. The Nucleus Freedom standard implant is programmed using the ACE strategy, 1,200-Hz processing rate, MP1 + 2 grounding configuration, 25- μ second pulse width, and 8 maxima. The Nucleus Hybrid S12 array is programmed using the same parameters as the Nucleus Freedom standard implant except 10 maxima are used instead of 8.

Speech Perception and Speech/Language Testing

Auditory function was evaluated using the following test battery.

Parent Questionnaires

1. The IT-MAIS (13). This is a parent questionnaire that consists of 10 questions regarding a young infant or toddler's auditory behavior (e.g., "Does the child spontaneously respond to his/her name in quiet with auditory cues?"). Each question was scored on a 5-point scale: 0 = never, 1 = rarely, 2 = occasionally, 3 = frequently, and 4 = always. This questionnaire was used to assess the progress the child was making with his/her amplification when more formalized speech perception tests were not age-appropriate.
2. Minnesota Child Development Inventory (MCDI) (16). The MCDI is a parent report inventory that assesses developmental milestones from 6 months to 6 years. Parents indicated if behaviors do or do not apply to their child by circling "yes" or "no" on designated forms. The Expressive Language and Comprehension–Conceptual subscales were included in the present analysis. The Expressive Language subscale examined global expressive language and the Comprehension–Conceptual subscale examined global receptive language. The MCDI yields age-equivalent scores. We calculated language quotient (LQ) scores by dividing the age-equivalent scores by the child's chronological age to control for language differences across participants as a function of age. Language quotient scores that equal 1.0 indicate language performance consistent with what is expected for an individual's chronological age. Language quotient scores below 1.0 indicate delayed language performance, relative to chronological age, and LQ scores above 1.0 indicate language performance that is advanced relative to chronological age.

It is important to note that these outcome measures are subjective in nature and are highly dependent on the parent's perception of their child's progress. However, these questionnaires are widely used tools in our field to evaluate parent report on growth or change in their child's speech, language, and auditory development before objective responses can be obtained.

Speech Perception

1. The Early Speech Perception (ESP) (17). This is a closed-set test that required the identification of a spondee or monosyllable from a set of 4 spondees (i.e., French fry, airplane, hotdog, popcorn) or monosyllables (i.e., ball, book, bird, boat), respectively presented in quiet at 70 dBC. The ESP test was scored as total number of words correct. Subjects were tested in 3 listening conditions: 1) Nucleus Hybrid S12 only, 2) Nucleus Freedom standard electrode array only, and 3) Nucleus Hybrid S12 and Nucleus Freedom standard electrode array, bilaterally.
2. The Glendonald Auditory Screening Procedure Word Test (GASP) (18). This is an open-set test that contains 12 single-syllable and 12 multisyllable words. The child was tested in the bilateral and unilateral listening conditions and was administered in a livevoice mode. The child was asked to repeat the words presented by the clinician. The test was scored as total number of words correct. Subjects were tested in 3 listening conditions: 1) Nucleus Hybrid S12 only, 2) Nucleus Freedom standard electrode array only, and 3) Nucleus Hybrid S12 and Nucleus Freedom standard electrode array, bilaterally.
3. Iowa Children's Vowel Test (19). This test required the identification of a monosyllabic word from a closed-set of 4 words (e.g., toe, toy, tie, two) varying only in vowel content (place and height). Subjects were tested in 3 listening conditions: 1) Nucleus Hybrid S12 only, 2) Nucleus Freedom standard electrode array only, and 3) Nucleus Hybrid S12 and Nucleus Freedom standard electrode array, bilaterally at 70 dB C.

Speech and Language

1. Preschool Language Scale 3 (PLS-3) (20). This measure is a standardized and norm-referenced receptive and expressive language measure. It can be administered to children ages 2 weeks to 6 years 11 months. The PLS-3 consists of 2 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

Parent Questionnaires

Results of the IT-MAIS have been collected before and after operation on all 8 Nucleus Hybrid S12 cochlear implant and Nucleus Freedom cochlear implant patients enrolled in our study. Figure 1 show results for the 8 children tested on the IT-MAIS before operation and at their most recent test session. Mean postimplantation results were 66% (SD, 28.7) with all children showing improvements in their scores averaging 55% (range, 15%–88%; SD, 25.4%). Mean length of CI experience is 10.5 months (SD, 8.7 mo). A mean result of 85% (SD, 8.81%) is also shown for 4 children implanted with simultaneous bilateral standard cochlear implants. Mean length of CI experience of these 4 children at the time of this testing was 10 months (SD, 1.63 mo). Parent report showed that most of the children implanted with the contralateral Nucleus Hybrid S12 and Nucleus Freedom cochlear implants were performing similarly to the children implanted with bilateral standard cochlear implants. Three of the children (IA/NU-10/10-04, IA/NU-10/10-06, and IA/NU-10/10-08) implanted with the Nucleus Hybrid S12 and Nucleus Freedom cochlear implants showed scores notably below the average of the children with the standard bilateral cochlear implants. However, these children have only 4 months of cochlear implant experience at the time of this testing.

Eight patients with the Nucleus Hybrid S12 cochlear implant and Nucleus Freedom device have participated in speech and language testing. Figure 2A shows results for the MCDI LQs on the expressive language subscale at their most recent test session. An MCDI quotient of 1.0 indicates that the child is performing at age-appropriate levels. On average, the children in this study achieved expressive LQs of 0.87 (SD, 0.14). Seven children implanted with simultaneous bilateral standard cochlear implants at 12 months after operation achieved a mean LQ of 0.92 (SD, 0.13), which is similar to the results for the children implanted with the contralateral Nucleus Hybrid S12 and Nucleus Freedom cochlear implants.

Figure 2B shows results for MCDI LQs on the comprehension-conceptual subscale for children with the Nucleus Hybrid S12 cochlear implant and Nucleus Freedom device at their most recent test session. Mean postimplantation result was 0.84 (SD, 0.11). Mean results for the 7 children implanted with simultaneous bilateral standard cochlear implants showed similar results at 12 months after operation (mean, 0.94; SD, 0.38) to the children implanted with the contralateral Nucleus Hybrid S12 and Nucleus Freedom cochlear implants.

Speech Perception

Figure 3 shows results for the ESP word test administered in quiet to Patients IA/NU-10/10-01 and IA/NU-10/10-02 at their 12-month postoperative test session. This is the first age that these patients were age-appropriate for this test. The performance of each device (short and long electrodes) tested separately in these patients was similarly very high. Patient IA/NU-10/10-01 scored 100% individually with both the S12 and Freedom devices and 96% bilaterally. Patient IA/NU-10/10-02 scored 92% with the Nucleus Hybrid S12 device alone,

88% with the Freedom device alone, and 88% bilaterally. Testing was attempted at 12 months with Patient IA/NU-10/10-03; however, the child was not able to tolerate testing at this time. A mean result of 84% (SD, 16.48%) is also shown for 6 children implanted with simultaneous bilateral standard cochlear implants. Mean age of these 6 children at the time of this testing was 19 months (SD, 4.51 mo). The results again showed that the bilateral group implanted with the contralateral Nucleus Hybrid S12 and Nucleus Freedom cochlear implants performed similarly to the children implanted with bilateral standard cochlear implants.

Figure 4A shows results for the GASP word test F4 administered in quiet to Patients IA/NU-10/10-01 and IA/NU-10/10-02 at their 18-month postoperative test session. This is the first age that these patients were age-appropriate for this test. Patient IA/NU-10/10-01 scored 79% individually with the S12 and 83% individually with the Freedom device and 83% bilaterally. Patient IA/NU-10/10-02 scored 96% with the Nucleus Hybrid S12 device alone, 88% with the Freedom device alone, and 92% bilaterally.

Figure 4B shows results for the Children's Vowel Test administered in quiet to Patients IA/NU-10/10-01 and IA/NU-10/10-02 at their 24-month postoperative test session. This is the first age that these patients were age-appropriate for this test. Patient IA/NU-10/10-01 scored 88% individually with both the S12 and Freedom devices and 92% bilaterally. Patient IA/NU-10/10-02 scored 80% with the Nucleus Hybrid S12 device alone, 98% with the Freedom device alone, and 80% bilaterally.

Speech and Language

Figure 5 shows the results for the PLS-3. Total lan- F5 guage standard scores are reported. Children with the contralateral Nucleus Hybrid S12 and Nucleus Freedom cochlear implants achieved standard scores of 80.88, on average (SD, 7.4). In the simultaneous bilateral comparison group, the average standard score was 83.57 (SD, 18.71), indicating consistent performance between the 2 groups.

CONCLUSION

Bilateral cochlear implantation is becoming a routine method of auditory habilitation for children with profound sensorineural hearing loss. However, the standard-length cochlear implant might restrict children from taking advantage of future advances in molecular and/or genetic treatments of the inner ear as the placement usually results in significant damage to the scala media, organ of Corti, and supporting cells. This could be especially important because recent research studying hair cell regeneration in birds and other animals indicates that the preservation of the supporting cells in the organ of Corti might be very important progenitors. Theoretically, one way to preserve the organ of Corti and supporting cells might be to use a shorter-length cochlear implant array (e.g., Nucleus Hybrid S12 cochlear implant) into the ear of congenitally deafened children.

The purpose of this study was to evaluate whether implanting the Nucleus Hybrid S12 in one ear and a Nucleus Freedom implant in the contralateral ear is a feasible option of bilateral stimulation for pediatric patients who have bilateral severe to profound hearing loss. Although the depth of insertion certainly differs considerably between the 2 ears for children with 1 Nucleus Hybrid S12 and 1 Nucleus Freedom internal device, speech recognition performance seems to be similarly high in both ears. Considering that the entire speech spectrum is presented to a very restricted cochlear region in the ears with the Hybrid device, considerable discrepancies in the place-frequency mapping between ears seems to be well tolerated in these young patients. In adults using the Nucleus Hybrid S12 cochlear implant, place-pitch sensations have been shown to shift by as much as 2 octaves over time (21), and it was also shown that the resulting 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 (22). These data led to the conclusion that delivering a speech frequency spectrum to 10 electrodes in the basal region could provide a sufficient range of pitch perception for speech understanding. In addition, some adults that are long-term users of the Hybrid 10-mm implant (>4 yr) demonstrate excellent speech recognition in the electric (cochlear implant) only condition. It would seem that if there were sufficient nerve survival in the base of the cochlea and the patient is able to adapt to a quite abnormal place-frequency map in the cochlea that the shorter electrode can provide good speech recognition. In children with congenital deafness, it is likely that a near normal neural environment is present and along with a central auditory system with good potential for plasticity can be particularly successful with a short Hybrid device.

To date, 8 children have been implanted, and up to a total of 10 children will be implanted, with the Nucleus Hybrid S12 in one ear and a Nucleus Freedom implant under this FDA-IDE. Because of age restrictions with the children implanted thus far, we have collected postoperative speech perception data on 2 children and speech and language data on all 8 children. Preliminary speech perception data on these children showed that speech perception seems similar between the Nucleus Hybrid S12 and Nucleus Freedom devices. Furthermore, performance compared with age-matched children implanted with standard bilateral cochlear implants showed that the bilateral group implanted with the contralateral Nucleus Hybrid S12 and Nucleus Freedom cochlear implants showed trends in performance on parent report measures, as well as standardized speech perception and language measures, similar to the children implanted with standard bilateral cochlear implants. Some variability, however, can be expected in performance between the 2 groups of bilaterally implanted children depending on what emphasis is placed on auditory/ oral learning in a habilitation/educational program. Although an emphasis on spoken language development was considered an inclusionary criterion in this study, it was not necessarily controlled for in the children implanted with standard bilateral cochlear implants.

These preliminary results support the continued study of the use of a shorter-length cochlear implant on one ear and a standard-length electrode on the contralateral ear in children with bilateral profound sensorineural hearing loss. Because the children implanted in this study were between the ages of 12 and 24 months at the time of implantation, outcomes regarding the success of this study will continue to become clearer as the child ages and their speech perception and language skills develop.

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FIG. 1.

In the first 8 sets of bars from the left, individual parent questionnaire responses for the IT-MAIS are shown for children implanted with the Nucleus Hybrid S12 and Nucleus Freedom cochlear implants on contralateral ears. Scores are shown before operation and for the most recent postoperative session (the postoperative session is shown on the *x* axis along with their patient number). A "0" was indicated for preoperative scores of 0%. The *bar* on the far right shows averaged IT-MAIS responses for 4 children implanted with bilateral standard cochlear implants. Mean scores are shown with ± 1 SE bars.

FIG. 2.

A, In the first 8 bars from the left, individual LQs on the expressive language subscale for the MCDI are shown for the most recent postoperative session for children implanted with the Nucleus Hybrid S12 and Nucleus Freedom cochlear implants on contralateral ears. The 2 bars on the far right shows averaged LQs for 8 children with the Nucleus Hybrid S12 and Nucleus Freedom cochlear implants on contralateral ears and 7 children implanted with bilateral standard cochlear implants. Mean scores are shown with ± 1 SE bars. Language quotient scores were calculated by dividing the age-equivalent scores by the child's chronological age. B, In the first 8 bars from the left, individual LQs on the comprehension-conceptual subscale for the MCDI are shown for the most recent postoperative session for

children implanted with the Nucleus Hybrid S12 and Nucleus Freedom cochlear implants on contralateral ears. The 2 *bars* on the far right show averaged LQs for 8 children with the Nucleus Hybrid S12 and Nucleus Freedom cochlear implants on contralateral ears and 7 children implanted with bilateral standard cochlear implants. Mean scores are shown with ± 1 *SE bars*. Language quotient scores were calculated by dividing the age-equivalent scores by the child's chronological age.

FIG. 3.

In the first 2 sets of *bars* from the left, individual word scores for the ESP test are shown for 2 children implanted with the Nucleus Hybrid S12 and Nucleus Freedom cochlear implants on contralateral ears. Scores are shown using the Nucleus Hybrid S12 only, Nucleus Freedom standard electrode array only, and bilaterally. The *bar* on the far right shows averaged ESP scores for 6 children implanted with bilateral standard cochlear implants. Mean scores are shown with ± 1 *SE bars*.

FIG. 4.

A, Individual word scores for GASP word test are shown for 2 children implanted with the Nucleus Hybrid S12 and Nucleus Freedom cochlear implants on contralateral ears. Scores are shown with the Nucleus Hybrid S12 only, Nucleus Freedom standard electrode array only, and bilaterally. B, Individual word scores for the Children's Vowel Test are shown for 2 children implanted with the Nucleus Hybrid S12 and Nucleus Freedom cochlear implants on contralateral ears. Scores are shown with the Nucleus Hybrid S12 only, Nucleus Freedom standard electrode array only, and bilaterally.

FIG. 5.

In the first 8 *bars* from the left, individual total language standard scores for the PLS-3 are shown for the most recent postoperative session for children implanted with the Nucleus Hybrid S12 and Nucleus Freedom cochlear implants on contralateral ears. The 2 *bars* on the far right show averaged standard scores for 8 children with the Nucleus Hybrid S12 and Nucleus Freedom cochlear implants on contralateral ears and 7 children implanted with bilateral standard cochlear implants. Mean scores are shown with ± 1 *SE bars*.

TABLE 1

Bilateral standard electrode patients' demographic information

Patient	Sex	Device	Age at implantation (mo)	Test results included in this study
BL-01	M	L = Freedom	15	ESP
		R = Freedom		MCDI
				PLS-3
BL-02	M	L = Freedom	16	IT-MAIS
		R = Freedom		MCDI
				PLS-3
BL-03	M	L = Freedom	11	IT-MAIS
		R = Freedom		ESP
				MCDI
BL-04	M	L = Freedom	14	PLS-3
		R = Freedom		ESP
				MCDI
BL-05	F	L = Freedom	13	PLS-3
		R = Freedom		IT-MAIS
				ESP
BL-06	F	L = Freedom	14	MCDI
		R = Freedom		PLS-3
				ESP
BL-07	M	L = Freedom	18	MCDI
		R = Freedom		PLS-3
				ESP
BL-08	F	L = Freedom	13	IT-MAIS
		R = Freedom		MCDI
				PLS-3

F indicates female; L, left; M, male; R, right.

Left and right unaided air-conduction thresholds for children implanted with contralateral Nucleus Hybrid S12 and Nucleus Freedom cochlear implants

TABLE 2

Patient	Ear	250 Hz	500 Hz	1,000 Hz	2,000 Hz	3,000 Hz	4,000 Hz	6,000 Hz	8,000 Hz
IA/NU-10/10-01	Right	NR	NR	NR	NR	NR	NR	NR	NR
	Left	110	NR	NR	NR	NR	115	115	NR
IA/NU-10/10-02	Right	NR	NR	110	NR	DNT	NR	NR	NR
	Left	NR	NR	110	NR	DNT	NR	NR	NR
IA/NU-10/10-03	Right	NR	NR	NR	NR	DNT	NR	DNT	NR
	Left	105	NR	NR	NR	DNT	NR	DNT	NR
IA/NU-10/10-04	Right	NR	NR	NR	NR	DNT	NR	DNT	NR
	Left	NR	NR	105	115	DNT	115	DNT	NR
IA/NU-10/10-05	Right	NR	NR	NR	NR	DNT	NR	DNT	NR
	Left	NR	NR	NR	NR	DNT	NR	DNT	NR
IA/NU-10/10-06	Right	NR	NR	NR	NR	DNT	NR	DNT	NR
	Left	NR	NR	NR	NR	DNT	NR	DNT	NR
IA/NU-10/10-07	Right	70	80	80	85	DNT	100	DNT	NR
	Left	70	80	75	NR	DNT	NR	DNT	NR
IA/NU-10/10-08	Right	95	NR	NR	NR	DNT	NR	DNT	DNT
	Left	NR	NR	NR	NR	DNT	NR	DNT	DNT

DNT indicates did not test; NR, no response.