Methods and Preliminary Outcomes of Pediatric Auditory Brainstem Implantation

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Abstract

Objective: The objective was to provide information about methods used and preliminary outcomes for pediatric ABI (auditory brainstem implant).

Study Design: An analysis of outcome was performed in children who received an ABI.

Methods: Twelve children received a MED-EL ABI system. Progress in audition and language was monitored through parental reports, questionnaires, profiles, and closed-set tests.

Results: The median number of active electrodes was 9 of 12. Seven of 12 users consistently respond to sound, and 5 of 12 do not. Highest performers can recognize words in small sets and have begun to use some words.

Conclusion: Auditory brainstem implants appear to be beneficial for some pediatric patients who cannot benefit from traditional cochlear implant surgery. Benefits in the short term can be recognition of environmental sounds, recognition of some words and very commonly used phrases, and the beginning use of words. Although some of our ABI users demonstrate no response to sound, they do want to wear their sound processors all waking hours. The cause of lack of response may be related to the second intervention, which might have led to displacement of the electrode array, or presence of additional handicaps or syndromes. However, the results are less than optimal. The relatively short postoperative follow-up duration is a considered weakness of this study.

An auditory brain stem implant (ABI) is indicated in some cases of inner ear malformation and ossification, temporal bone fractures with cochlear nerve avulsion, otosclerosis with gross cochlear destruction, and intractable facial nerve stimulation with a cochlear implant (CI) or in patients who have had their cochlear nerves cut as a result of removal of pontocerebellar tumors.[1-4]

Promising outcomes obtained from nontumor adult ABI users have recently encouraged hearing implant teams to try and support children who cannot benefit from a CI, with an ABI.[4-6] Some promising results have been reported but auditory outcomes remain highly variable.[7-9] It has been suggested that an ABI leads to auditory perception in most cases but the potential for development of oral language depends on age at intervention, presence or absence of any additional disability and other established factors for CI such as parental involvement.[4] An ABI may enhance lip reading and some users are able to identify words and sentences without lip reading.[10-15]

Our purpose is to provide information on intra- and post-operative objective measures, fitting methods, and the characteristics of ABI audio processor programs and to present preliminary outcomes based on our experience with pediatric ABI users.

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Table 1. Clinical Data of the Patients.

No.	Ear	Implant	Age at first fit, mo	Length of ABI use, mo	Diagnosis	Complication
1	R	PULSAR	64	27	Cochlea aplasia	—
2	R	CI placed prior to ABI PULSAR	65	44	Cleft lip and palate, common cavity	—
3	R	PULSAR	46	28	Incomplete partition, common cavity	CSF leak
4	L	PULSAR	76	19	Cochlea aplasia	CSF leak
5	R	PULSAR	33	25	Cochlea aplasia	CSF leak
6	R	PULSAR	45	12	Muenke syndrome, cochlear nerve hypoplasia, internal auditory canal absent	—
7	R	PULSAR	45	16	Cochlea aplasia	—
8	R	CONCERTO	68	7	Cochlea aplasia	—
9	R	CONCERTO	42	7	Cochlea aplasia	CSF Leak
10	R	CONCERTO	37	5	CN aplasia	—
11	R	CONCERTO	26	4	Bilateral Michel deformity	—
12	R	Attempt made to insert CI prior to ABI CONCERTO	38	4	Ossified cochlea, meningitis at 9 m	—

Abbreviations: ABI, auditory brainstem implant; CI, cochlear implant; CN, cochlear nerve; CSF, cerebrospinal fluid.

Materials and Methods

Demographics

From March 2007 to September 2012, 12 children with profound prelingual hearing loss received a MED-EL ABI (Table 1). The study was approved by the local ethical committee of the university. The mean age of children at first fit was 49 months (range, 26-76 months). The mean length of ABI use at time of this report was 18 months (range, 4-44 months).

Five of 12 users have additional problems such as attention-deficit/hyperactivity disorder (ADHD), slight cerebral palsy, and motor delay. Two other children have syndromes; a 3.5-year-old girl with Muenke syndrome (cleft lip and palate, coronal craniosinostozis, and bilateral sensorineural hearing loss) and a 6-year-old girl with Arnold Chiari type 1 syndrome. The remaining ABI users have no apparent additional impairment.

One of 12 ABI users (patient 2) with incomplete cochlear partition had a CI prior to ABI. There was a cochlear nerve deficiency as well. The previous trial of CI was performed considering the presence of some auditory fibers, which might have traversed inside the facial or vestibular nerve. Both ears were implanted sequentially with CIs. However, this child had no auditory percepts with his CIs. In the second case (patient 3) with common cavity we performed a promontory electric auditory brain stem responses (EABR; which may have false negative results according to current knowledge) to assess the presence of some auditory nerve fibers. Since the EABR test result was negative, we performed an ABI without a trial of CI.

In another child with an ossified cochlea (patient 12) following meningitis at 9 months of age, an attempt was made to place a CI but the electrode could not be inserted.

Surgery

A standard retrosigmoid approach with a 3×3 cm craniotomy was made. After incising the dura and retracting the cerebellum, the foramen Luschka was found between the root of the ninth nerve and choroid plexus, and the ABI electrode was placed in the foramen Luschka.

Intraoperative Objective Measures

Intraoperative EABRs were measured using the MED-EL ABI surgical placement system. This is a 4-contact-placing electrode to optimize positioning of the ABI electrode paddle and detect undesired stimulation of adjacent cranial nerves. By means of this 4 contact placing test electrode, the surgeon can find the best site to place the actual ABI electrode. Once the electrode was placed, before closing up, a full telemetry measurement was carried out.

Audio Processor Programs

The initial fitting was performed 6 to 8 weeks after hospital discharge in an operating room (OR) with cardiac monitoring.

Charge level on each active electrode was increased (in 6% increments) from 0 to a charge level slightly above the charge level used for telemetry (6.10 qu for MED-EL PULSAR and CONCERTO implants). If no adverse reaction was observed telemetry was then performed to verify appropriate channel function and facilitate calculation of compliance indicators in the Maestro fitting software. Charge was then slowly raised on each electrode up to 30 qu unless the ABI user showed signs of the signal being

perceived as loud (eg, presence of eye blink (auro-palpebral reflex [APR]) or of the signal causing discomfort (eg, throat tickle). If there was no response and no side effect, the process of slowly increasing charge on each electrode up to, for example, 60 qu was repeated and the processor was activated. An attempt was made to increase charge level on all active electrodes until a response or side effect was observed, this was performed to eradicate the need to fit the child in the OR in the future. Later in the day, in a standard room, the children were provided with 4 programs with increasing charge levels. Even if the patient had not shown any response at maximum charge levels in the OR (approximately 203 qu), programs with lower charge levels (eg, maximum comfort levels of 30,40, 50, 60 qu) were provided. Users were seen initially on a monthly, then a 2- to 3-month basis for 2 years, which is more frequent than CI patients who are generally seen 4 times in the first year, twice in the second year, and then annually.

Follow-up Fitting Procedures

Play audiometry techniques were used to establish threshold (THR) levels. Maximum comfort levels (MCL) were set by closely observing the child for signs that a stimulus was perceived as loud, for example, presence of APR or immediate reaction to a stimulus, or MCL was set just below a charge level that elicited a side effect. Electrodes with some dynamic range (a difference between THR and MCL) were kept active. Electrodes with no or extremely limited dynamic range were deactivated.

All ABI users use high-definition, continuous, interleaved sampling (HDCIS) coding strategy with a frequency range of 250-8500 Hz. If the number of active electrodes was substantially reduced then the frequency range was narrowed; for example, users with fewer than 8 active electrodes use a frequency range of 250-7000 Hz and users with fewer than 6 active electrodes a frequency range of 250-5500 Hz.

Postoperative Objective Measures

Attempts were made to elicit electrically elicited stapedius reflexes (ESRs) from responsive ABI users. Attempts were also made to record EABRs postoperatively both from responding and nonresponding ABI users. Aided cortical assessment (ACA) was attempted on the 1 ABI user using relatively low charge levels (high charge introduces artifacts preventing cortical assessment). The Fonix HEARLab System (Frye, Tigard, USA), which collects cortical auditory evoked potentials to speech sounds with low, mid, and high frequency emphasis presented within the 55-75 dB range was used. ACA provides objective information on

detection of conversational level speech and requires only minimum cooperation from the child.

Performance With an ABI

If the ABI user was responding to sound, according to their age and ability, tools from the MED-EL LittleEARS and EARS test batteries were used to assess their auditory development: the LittlEARS Auditory Questionnaire (LEAQ); the listening profile (LIP); and the closed set monosyllabic, trochee, polysyllabic (MTP) test. A category of auditory performance (CAP) score was awarded at each assessment, and attempts were made to measure implant sound field thresholds.

Results

Surgery

In the operation of the patient with Arnold Chiari syndrome, identification of the foramen Luschka was a problem because of herniation of the brainstem through the foramen magnum. Cerebrospinal fluid (CSF) leak was the most common complication seen in 4 patients. This was treated with a ventriculoperitoneal shunt. No permanent neurologic or other type of deficit was observed as a result of surgery.[6,11,16]

Intraoperative Objective Measures

EABR data are available for 11 of 12 ABI users (Table 2). Four users showed no response (NR), 6 users had responses, and typically waves III and V could be visualized. Recordings could not be made for 1 user due to artifacts. Two of 4 users with NR intraoperatively on EABR could hear with their ABIs. Four of 6 users with intraoperative EABRs could hear with their ABIs, 2 could not.

Audio Processor Programs

Three of 12 ABI users responded to electrical signals sent via the fitting software and implant on at least 1 electrode at initial stimulation. Four of 12 users able to perform to visual cues did not respond to any signals at initial fitting, these 4 users continued to have NR to electrical signals at follow-up fitting sessions. Five of 12 users (younger children) were not able to perform even to visual cues during initial fitting; however, 2 of them showed definite responses to sound, for example, an APR on some electrodes. Four of these 5 users went on to respond to electrical signals at follow-up fitting sessions.

Side effects were only recorded for 3 ABI users and these were present only on some electrodes. Side effects observed were irritation of the throat (coughing, swallowing),

Table 2. Electrophysiologic Findings of the Patients.

No.	No active electrodes (of 12)	Intraop EABR	Charge range, qu (mean)	Rate pps	Postop objective measure
1	8	No response	97-152 (111)	464	ACA & EABR—not measurable due to artifact
2	5	No response	112-230 (158)	662	
3	9		181	310	EABR—NR
4	9	No response	226	288	EABR- NR
5	10	No response	125-215 (165)	349	EABR & ESRT—NR
6	11	Recordings could not be made due to artifacts	142	335	ACA & EABR—not measurable due to artifact
7	8	Responses	66-213 (126)	489	ESRT—NR
8	8	Good responses	106-232 (135)	480	EABR—response ESRT—NR
9	12	Responses	187	484	EABR—NR
10	12	Responses with small amplitude	150 -206 (189)	235	ESRT—NR
11	12	Responses with small amplitude	130	353	EABR—NR
12	9	Responses with minimal amplitude	36 - 72 (54)	958	ACA response to M G T at 65 dB SPL EABR & ESRT—NR

Abbreviations: ACA, aided cortical assessment; EABR, electric auditory brain stem response; ESRT, electric stapedius reflex threshold; NR, no response; SPL, sound threshold level.

discomfort in shoulder and chest, and discomfort around the roof of the mouth.

All electrodes for all ABI users were assigned OK status at initial fitting. This means current can flow effectively across the electrode and confirms electrode functioning. Two users had 1 high impedance (HI) electrode, 1 user had 2 HI electrodes, and 1 user had 2 HI and 2 sets of short circuited electrodes at later fittings. The mean impedance value for all ABI users over 12 electrodes at their latest to date fitting session is 4.01 kOhms and ground path impedance (GP) is 1.24 kOhms. To date the mean MCL for these ABI users is 150 qu, ranging from 54 to 226 qu. Their number of active electrodes ranges from 5 to 12. The median number is 9, and 8 of 12 uses 9 or more electrodes. Their mean rate is 625 pps ranging from 235 to 1319 pps (Table 2).

Postoperative Objective Measures

To date, ESR measures have been attempted on 4 ABI users who appear to perceive stimulation at MCL as loud. Even at levels eliciting an APR no ESR has been recordable. EABR measures have been performed on 8 ABI users; recordings could not be made due to artifacts for 2 users, no wave forms could be recorded for 5 users—4 of whom did not respond to sound with their ABIs; 1 user had clear recordable wave forms and could detect sound with her ABI (Table 2).

ACA could only be performed on 1 ABI user whose MCLs were set at charge levels similar to those typically used by CI users. At both 6 weeks and 7 weeks hearing age this user had responses to speech tokens /M/, /G/, and /T/ at 65 dB SPL with delayed P1 latencies.

Performance With an ABI

Category 1. Users who wear their audio processor all day long, do not report device problems and do not consistently respond to any sound including stimuli presented through the fitting software. Five of 12 ABI users from our study fit into this category, they have CAP scores of 0 equating with no environmental sound awareness (Table 3, Figure 1). Their mean age at implantation and length of ABI experience is 47 and 14 months, respectively.

Category 2. Users who wear their audio processor all day long, report device problems, respond consistently to sound including stimuli presented through the fitting software. All can detect medium loud Ling sounds (1 child has difficulty detecting /s/) and their names in a structured situation. Four users can sustain attention enabling sound field implant THRs to be measured. Response to sound in daily living varies. CAP scores vary from 1 to 5 (Table 3, Figure 1). A CAP score of 1 equates with awareness of environmental sounds, and a CAP score of 5 with recognition of frequently used phrases without lip reading. Two users with ADHD only respond to loud noises and repeated name calls. The other 5 users experiment with sound, listen to their own voices and have begun to vocalize more. They have begun to recognize some environmental sounds like music, the telephone, and

Table 3. Auditory Perception and Developmental Findings of Patients.

No.	Response to DIB	Response to sound in a structured situation; Implant sound field thresholds: (ABI THR) Hearing level: dB HL, frequency: KHz	Response to sound in daily living and CAP score	Additional problems
1	Yes	Detection of medium loud a, e, u, s, sh, name	Responds to very loud sounds; CAP-0	Attention deficit
2	Yes	Detection of medium loud, a, e, u, sh, name LIP 18/42 ABI THR: 40-500, 35-1, 35-4	Turns to name Uses 2-3 special names Imitates words Recognizes music and telephone CAP-	Attention deficit, cleft lip and palate
3	No	NR	No. CAP-0	No
4	No	NR	No. CAP-0	Arnold Chiari syndrome
5	Yes	Detection of medium loud a, e, u, loud sh, name LEAQ 9/35 expected score 27-33	Turns to loud repeated call, music, and doorbell Slightly increased vocalizations Uses a few words Makes prompted single-word imitations CAP-1	No
6	No	NR	No. CAP-0	Muenke syndrome
7	Yes	Detection of medium loud a e, u, sh, s, name Recognition of 5/6 Ling sounds LIP 35/42 MTP 6 score 12/18 ABI THR: 40-500, 40-1, 50-2, 50-4	Turns to name Recognizes doorbell and music Uses some words CAP-5	Vacant gazing
8	Yes	Detection of medium loud a, e, u, sh, s, name Recognizes a, u, sh MTP 6 score 15/18 ABI THR: 35-250, 35-500, 50-1, 35-2, 45-4, 45-6	Experimenting with sounds Turns to name even in noise Moves to music Imitates some words Uses some words CAP-4	No
9	No	NR	No. CAP-0	Motor delay
10	Yes	Detection of medium loud a, e, u, sh, s, name LEAQ 9/35 expected score 5-15	Responds to loud sounds and name Listens to own voice Can imitate some words when prompted Beginning to use some words spontaneously CAP-1	No
11	No	NR	No. CAP-0	General developmental delay
12	Yes	Detection of medium loud a, e, u, sh, s, name ABI THR: 65-250, 45-500, 50-1, 50-2, 40-4	Responds to music and name Vocalizes more Beginning to use some words spontaneously CAP-4	No

Abbreviations: ABI, auditory brainstem implant; CAP, category of auditory performance; DIB, diagnostic interface box; HL, hearing level; LEAQ, LittlEARS Auditory Questionnaire; LIP, listening profile; NR, no response; MTP, monosyllabic, trochee, polysyllabic test; THR, threshold.

the doorbell. They are beginning to imitate sounds and words and use some words spontaneously. The LEAQ validated on hearing children aged 0-24 months has been used to monitor auditory progress in 3 of these younger ABI users.[17] Two users' scores fall within the expected range for their hearing ages, the other user, with 2 years ABI experience, although showing progress scores well below the minimum expected score showing auditory behavior similar to that of a hearing child of 4 months of age. To date the highest achievement is 83% on LIP, 83% on MTP 6, and a CAP score of 5. Seven of 12 ABI users from this cohort fit into category 2. Their mean age at implantation and length of ABI experience is 50 and 18 months, respectively (Table 3).

Discussion

Children with EABR recordings intraoperatively typically hear with their audio processors; however, 2 children in this
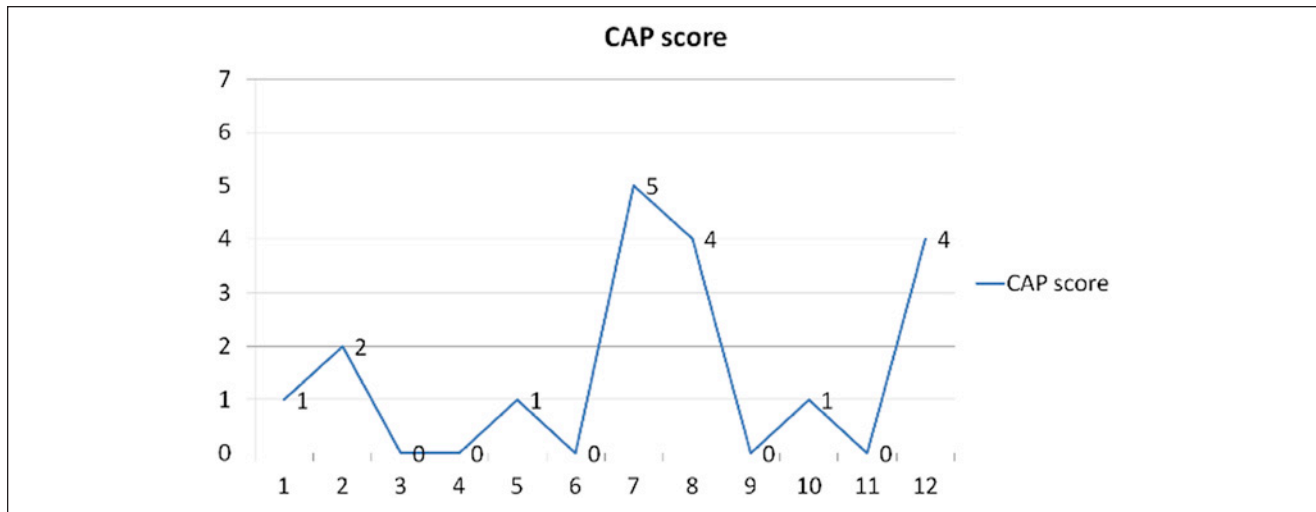
Figure 1. Graph showing category of auditory performance (CAP) achieved at last assessment by each auditory brainstem implant (ABI) user.

cohort did not. Since the children with postoperative CSF leaks went through a second surgical procedure, it is possible that this procedure caused the electrode array to migrate resulting in no reaction to sound. Although complication rates in ABI candidates have been reported to be comparable to complication rates related to CI surgery, in our pediatric series we did experience CSF leak in 4 out of 12 children making this the most common postoperative problem.[6,16]

Two children with no clear intraoperative EABR recordings went on to hear sound. This may result from 2 factors. First, artifacts prohibiting EABR testing; an ABI surgery should be carried out only in an OR that does not have electrical interference leading to artifacts preventing adequate recording of EABRs. Second, in the presence of a large foramen Luschka, the contact between the electrode and cochlear nuclei is loose intraoperatively. Although packing the electrode with soft tissues like fat, fascia or muscle against the cochlear nucleus may lead to obtaining EABR recordings, this is not the rule in all pediatric cases. In instances where EABRs cannot be recorded if the surgeon is sure that the electrode paddle is correctly positioned in the foramen Luschka, the surgeon may go ahead and place the electrode. In these patients, after surgery, the electrode comes into better contact with the nuclei due to pressure created by the cerebellum, and it may be possible to record EABRs postoperatively.

Impedances for ABI users (mean 1.24 kOhms) are usually lower than impedances recorded for CI users, mostly because the contact area per channel is larger on ABIs than on CIs. Emergence of a small number of HI electrodes overtime for some users is probably caused by deteriorating contact with the cochlear nucleus. A mean MCL for the ABI

users of 150 qu is significantly higher than a mean MCL of 44 qu for CI users with abnormal cochleae and a mean MCL of 23 qu for CI users with normal cochleae. Higher charge levels are achieved through lengthening the pulse phase duration, which slows down processing and thereby detracts from the quality of sound transmitted to the ABI user.

Postoperative EABRs, although a very positive indicator, do not give precise or detailed information for setting MCL or THR levels. Furthermore, it is not recommended to use stimulation pulse durations longer than 60 μs during EABR measures as this introduces artifacts. As most ABI users in this cohort require very high charge levels to hear, stimulation at 60 μs × 1200 cu is unlikely to elicit a response; this is probably why 6 of 8 of the postoperative EABR measures resulted in no response.

Three ABI users in this cohort had definite side effects. One young boy clutched his shoulder at charge levels above 10 qu on several electrodes during his first few fitting sessions. Over a short time period, 6 to 7 weeks, this child began to not feel discomfort, and his MCLs could be raised significantly. This child can hear with his ABI and has responses on ACA at 65 dB SPL. If children can overcome side effects through plasticity allowing widening of the dynamic range between THR and MCL, this would be a positive indicator for pediatric ABI.[12]

CI under 30 months leads to clear benefit in speech production and vocabulary acquisition.[18,19] The mean age at implantation of the children in this cohort was 49 months diminishing the possible benefit from ABI because of loss of brain plasticity due to age. The ABI users in this cohort had a mean length of ABI use of just 18 months. This is a short length of time for users to make noticeable progress in spoken language acquisition. As shown in Table 1, just over

half of the ABI users had additional problems to deafness or had syndromes (7 of 12). Five of 12 ABI users apparently had no other impairments except for congenital profound to total deafness rendering them unable to benefit from acoustic amplification prior to implantation with an ABI.

In children with ABI, progress in audition and oral language appears to be limited, variable, and unpredictable. In our cohort of patients, Arnold Chiari syndrome may be considered a contraindication to ABI, as it creates surgical challenges in terms of proper localization of the foramen of Luschka, and this patient demonstrated lack of postoperative sound awareness. Neuropsychiatric problems such cognitive impairment limit the benefits of ABI. The signal provided by the ABI is poorer than that provided by a CI due to high charge requirements limiting loudness of sounds and slowing down processing. Listening to and learning from a degraded signal is difficult and will be especially so for children with additional problems such as mild cognitive delay, poor attention and insufficient support. Pediatric ABI users may require a longer time than pediatric CI users to develop listening skills.[20,21]

Cochlear implant users implanted before 24 months of age develop auditory skills, as measured on the LEAQ, at a similar rate to hearing children.[22] The LEAQ was used to monitor auditory skills of 3 ABI users in this cohort.[23] According to LEAQ normative data 2 ABI users scored appropriately when hearing age was substituted for chronological age but 1 ABI user scored well below the critical level indicated for her hearing age, demonstrating slow progress in audition. Normative data for the EARS test battery show that CI users implanted at the age of 3 to 4 and 4 to 5 years of age score 82% and 90%, respectively, on the LIP and 72% and 80%, respectively, on MTP 6 at 6 months post–switch on. Only a few ABI users in our cohort were able to score on these tests at 15 to 18 months post–switch on. The median CAP score of ABI users who can hear is 2 equating with ability to detect speech sounds. CAP scores varying from 1 to 4 or 5 are similar to results reported by other researchers.[7] Colletti and Zoccante[7] report a mean CAP score of 4; however, the follow-up time in that study ranged from 6 months to 6 years and the study included children up to the age of 16 years. The follow-up time for this study is much shorter and the children younger. All responding ABI users were able to cooperate for a LING detection sound test. The hearing levels obtained for these children demonstrate that ABI users do have access to most speech sounds when presented close to the child in quiet surroundings.

Conclusion

Auditory brainstem implants appear to be beneficial for some pediatric patients who cannot benefit from traditional CI surgery. Benefits in the short term can be recognition of environmental sounds, recognition of some words and very commonly used phrases, and the beginning use of words. Although some of our ABI users demonstrate no response to sound, they do want to wear their sound processors all waking hours. The cause of lack of response may be related to the second intervention, which might have led to displacement of the electrode array, or presence of additional handicaps or syndromes. However, the results are less than optimal. The relatively short postoperative follow-up duration is considered a weakness of this study.

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