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Surgical Factors in Pediatric Cochlear Implantation and Their Early Effects on Electrode Activation and Functional Outcomes

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Objective: To assess the impact of surgical factors on electrode status and early communication outcomes in young children in the first 2 years of cochlear implantation.
Study Design: Prospective multicenter cohort study.
Setting: Six tertiary referral centers.
Patients: Children 5 years or younger before implantation with normal nonverbal intelligence.
Intervention: Cochlear implant operations in 209 ears of 188 children.
Main Outcome Measures: Percent active channels, auditory behavior as measured by the Infant Toddler Meaningful Auditory Integration Scale/Meaningful Auditory Integration Scale and Reynell receptive language scores.
Results: Stable insertion of the full electrode array was accomplished in 96.2% of ears. At least 75% of electrode channels were active in 88% of ears. Electrode deactivation had a significant negative effect on Infant Toddler Meaningful Auditory Integration Scale/Meaningful Auditory Integration Scale scores at 24 months but no effect on receptive language scores. Significantly fewer active electrodes were associated with a history of meningitis. Surgical complications requiring additional hospitalization and/or revision surgery occurred in 6.7% of patients but had no measurable effect on the development of auditory behavior within the first 2 years. Negative, although insignificant, associations were observed between the need for perioperative revision of the device and 1) the percent of active electrodes and 2) the receptive language level at 2-year follow-up.
Conclusion: Activation of the entire electrode array is associated with better early auditory outcomes. Decrements in the number of active electrodes and lower gains of receptive language after manipulation of the newly implanted device were not statistically significant but may be clinically relevant, underscoring the importance of surgical technique and the effective placement of the electrode array. **Key Words:** Activation—Channels—Children—Cochlear implant—Complications—Outcome.

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Multiple factors likely influence speech perception and language outcomes after early cochlear implantation (1,2). Medical, surgical, and anatomic factors may contribute to variability in these outcomes as suggested by the influence of electrode position on speech perception results in adults (3,4). Although long-term morbidity rarely results from perioperative complications (5–7), the long-term effects on device function and patient outcome are less clear. The present report examines whether optimization of surgical implantation represents an opportunity for greater implant benefit.

We considered surgery-related variables, including cochlear anatomy, cause, and complications alongside other child, environmental, and device variables to assess effects on auditory behavior and receptive language at 2 years after surgery. Our goal was to examine

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how surgical factors relate to device function and their early effects on auditory performance and verbal language comprehension.

METHODS

Study Population

The Childhood Development after Cochlear Implantation study is a multicenter prospective cohort study designed to analyze the predictive value of clinical variables as they relate to communication, behavior, and economic outcomes of cochlear implantation in young children (8). A total of 188 cochlear implant (CI) candidates aged 5 years or younger at the time of enrollment were recruited. The CI cohort underwent standard evaluation within a month before surgery and had regular follow-up evaluations after surgery according to study protocol. Peers with normal hearing (n = 97) in the same age range were recruited from 2 preschools affiliated with 2 of the clinical centers and were evaluated with the same study protocol. A detailed description of the study cohort and the protocol has been published (9). Only the CI cohort was examined in this report of the potential impact by surgical and device-related factors on the outcomes of interest. The study protocol and informed consent were approved by the institutional review boards of participating centers.

Data Collection

Auditory behavior and language comprehension were assessed within a month before cochlear implantation (baseline) and at 6-month intervals after CI activation (8,9). Auditory behavior was measured by family report using the Infant Toddler Meaningful Auditory Integration Scale (IT-MAIS) (10) and MAIS (11) administered for participants aged 1 to 3 and 4 years and older, respectively. Children were evaluated with the language measure Reynell Developmental Language Scale (12). This report focuses on auditory, language, surgical, and device outcomes collected through 24 months after surgery.

Surgical and postoperative medical questionnaires prospectively captured details of the surgical procedure and postoperative health status. Information abstracted from the medical record was used to supplement this information when necessary. Channel-specific parameters were examined from maps taken at activation and at 6, 12, and 24 months postactivation. The percentage of active electrodes was calculated relative to the maximum number of programmable electrodes. A programming questionnaire was completed by audiologists describing anomalous effects of stimulation and indications for electrode deactivation.

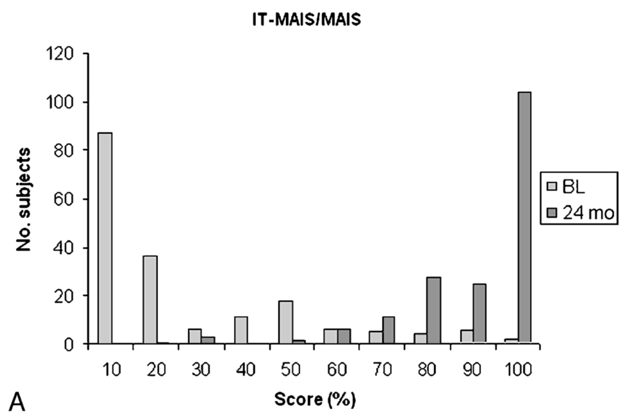
Statistical Analysis

Baseline characteristics, including demographic data, socioeconomic status, medical history, and surgical outcomes, are described as means (SD) for continuous variables and as frequency distributions for categorical variables. We tested the effect of anatomy and surgical outcome (independent variables) on the percentage of active electrodes (dependent variable) at 6, 12, and 24 months postactivation using analysis of variance. We also assessed the effects of medical history, anatomy, surgical outcomes, and percentage of active channels (independent variables) on auditory behavior (IT-MAIS/MAIS) and receptive language (dependent variables). Analysis of variance, nonparametric regression, and mixed-effect models were used to test these associations. All tests are 2-sided; a $p \leq 0.05$ is considered statistically significant.

RESULTS

Baseline Characteristics

Most children had minimal or no experience with hearing or verbal language before cochlear implantation as demonstrated by low IT-MAIS and Reynell scores (Fig. 1). The cause of hearing loss was unknown in 57% of children, whereas 28% were due to genetic causes, and 4% were due to meningitis (9) (Table 1). Hearing loss was reported to be congenital in 60% of subjects and progressive or sudden in 40%. The study cohort had a mean (SD) period of 0.22 (0.6) years with hearing, 0.8 (0.69) years with hearing loss without intervention, and 1.17 (0.99) years with hearing loss and amplification



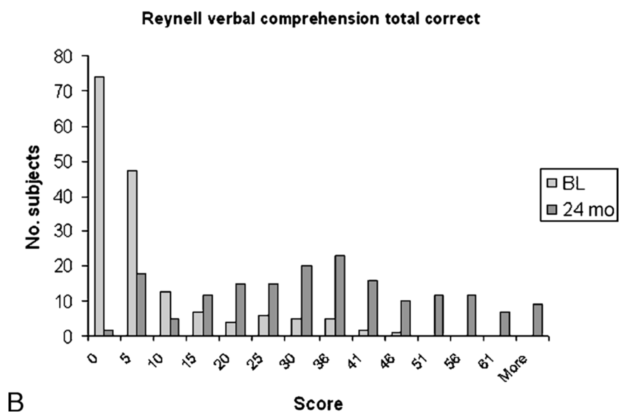


FIG. 1. Auditory and language measures performed at BL and at 24 months after activation of the device in the CI cohort. Auditory behavior measured using the IT-MAIS/MAIS (*A*) and verbal language measured using the Reynell (*B*). There is a significant increase in both measures at 24 months compared with baseline: mean gain of 64.9 for IT-MAIS/MAIS ($p < 0.0001$) and 26.3 for Reynell Developmental Language Scale measure of verbal comprehension ($p < 0.0001$) based on paired t comparisons. BL indicates baseline.

before cochlear implantation. During the study period of interest in this report, 167 children had unilateral CIs, whereas 21 had bilateral implants. Seventeen bilateral cases were placed sequentially with a mean interval of 1.2 years. The age at CI surgery, including the first ear in bilateral cases, was performed at the mean age of 2.4 (1.2) years, with most (70%) occurring before 3 years of age.

Radiologic assessment of the temporal bone with emphasis on the labyrinth was routinely conducted in all children before cochlear implantation (computed tomography, 73.4%; magnetic resonance imaging, 23.4%; computed tomography and magnetic resonance imaging, 3.2%). Anomalies of the labyrinth and/or internal auditory canal were reported in 45 (22%) ears. Cochlear dysplasia was reported in 20 (10%) ears, of which 17 had incomplete partition. Enlarged vestibular aqueduct was also reported in 20 (10%) ears.

TABLE 1. *Baseline demographic and surgical characteristics of the study population (n = 188)*

Subject characteristics	n (%)
Age at cochlear implantation (yr)	
<1	15 (8)
1–2	72 (38)
2–3	45 (24)
3–4	34 (18)
4–5	18 (10)
5–6	4 (2)
Mean age (SD)	2.4 (1.2)
Sex	
Male	90 (48)
Female	98 (52)
Cause of hearing loss	
Genetic	53 (28)
Meningitis	7 (4)
Hyperbilirubinemia	6 (3)
Prematurity	5 (3)
Other perinatal complications	4 (2)
CMV	3 (2)
Aminoglycoside exposure	2 (1)
Cause unknown	108 (57)
Hearing experience	Mean (SD)
Duration of hearing, yr	0.22 (0.6)
Duration of HL, no HA, yr	0.8 (0.69)
Duration of HL, with HA, yr	1.17 (0.99)
Surgical and device information	
Side implanted	
Left only	57 (30)
Right only	110 (59)
Bilateral (simultaneous)	4 (2)
Bilateral (sequential)	17 (8)
Device make	
Advanced Bionics Corporation	62 (30)
Cochlear Corporation	113 (54)
Med-El Corporation	34 (16)
Electrode insertion[a]	
Full (100%)	201 (96)
>75%	1 (0.5)
50–75%	3 (1)
25–50%	2 (1)
<25%	1 (0.5)
Incomplete (unspecified %)	1 (0.5)

[a]Includes 4 cases with incomplete insertion noted intraoperatively and 4 cases with incomplete insertion noted postoperatively.

CMV indicates cytomegalovirus; HL, hearing loss; HA, hearing aid.

TABLE 2. *Surgical complications in 209 ears*

Complication categories	n (%)
Wound complications[a]	8 (4)
Otitis media, implanted ear	5 (2)
Incomplete insertion of electrode channels	
Noted intraoperatively	4
Noted postoperatively	4
Persistent CSF leak	2 (1)
Dizziness	1 (0.5)
Consequences of complications	
Additional surgery	
With device reimplantation	3 (1)
With electrode manipulation	5 (2)
Without device manipulation[b]	4 (2)
Hospitalizations without surgery	
Perioperative complications	1 (0.5)
Delayed postoperative infection	1 (0.5)
Delay to activation	
Number delayed[c]	5 (2)
No. d to activation with complication (SD)	51 (44)

[a]Patients with 1 or more of the following presentations: dehiscence, infection, excessive swelling; excludes 1 case of traumatic wound infection.

[b]Includes 3 cases of ventilation tube replacement.

[c]Delay defined as >1 SD more than the mean time to activation for the cohort as a whole (34.9 ± 19.6 d).

Surgical Observations and Complications

Full array insertions were achieved in 201 (96.2%) primary operations. Four incomplete insertions were reported at surgery, of which 2 were in postmeningitis ears, 1 in an ear with Mondini dysplasia, and 1 in an otherwise normal ear. An additional 4 ears with otherwise normal anatomy were subsequently found to be not fully implanted. Of 8 implanted ears deafened by meningitis (in 7 patients), a full insertion was achieved in 6.

We observed unexpected consequences of cochlear implantation in 18 (8.6%) of 209 operations, of which wound dehiscence or infection, otitis media, and incomplete electrode insertion were the most common (Table 2). No cases of facial weakness or neurologic complications and no postoperative meningitis or mortalities occurred. Age at cochlear implantation, cause of hearing loss, and radiologic findings did not predict the occurrence of complications. Fourteen (6.7%) patients were either hospitalized (n = 2), underwent surgery (n = 7), or both (n = 5) because of perioperative complications (Table 2). Excluding 1 child with a traumatic wound infection, revision of the surgical site was performed in 10 (4.8%) subjects in response to perioperative complications. Device explantation and replacement were required in 3 of these cases, whereas adjustment of the electrode array was performed in another 3.

Surgical site complications were associated with a delay to activation (Table 2). The average time between implantation and activation for the study cohort as a whole was 34.9 ± 19.6 days. A delay in activation beyond 1 SD of this group mean occurred in 9 patients. Six of these cases were due to the need for additional surgery after surgical complications (5) and head trauma (1), whereas there were no medical or surgical explanations for delays in the other 3 cases.

Electrode Performance and Device Malfunction

Figure 2A shows an incremental increase in the number of cases with inactive electrodes within the first 2 years after initial activation. Whereas electrode activation was incomplete in 23 ears at initial programming, electrodes were turned off in an additional 15 ears at 6 months and in an additional 10 and 3 ears at 12 and 24 months, respectively (Table 3). After initial activation, additional electrodes were most frequently turned off in an attempt to optimize phoneme detection and in response to anomalies noted with electric testing (Fig. 2B).

Five (2.4%) devices were structurally defective or malfunctioned within the first 25 months of the study (Table 3). Device malfunction was diagnosed at 5 to 20 months after initial activation (mean time to malfunction, 12 mo). The time between device failure and reimplantation was 75 days for a child with a functioning contralateral device. For the remaining 3 children, the time to reimplantation ranged from 5 to 28 days (mean, 16 d), and CI use was interrupted for an average of 1.25 months (range, 1–2 mo) until a new device was reactivated.

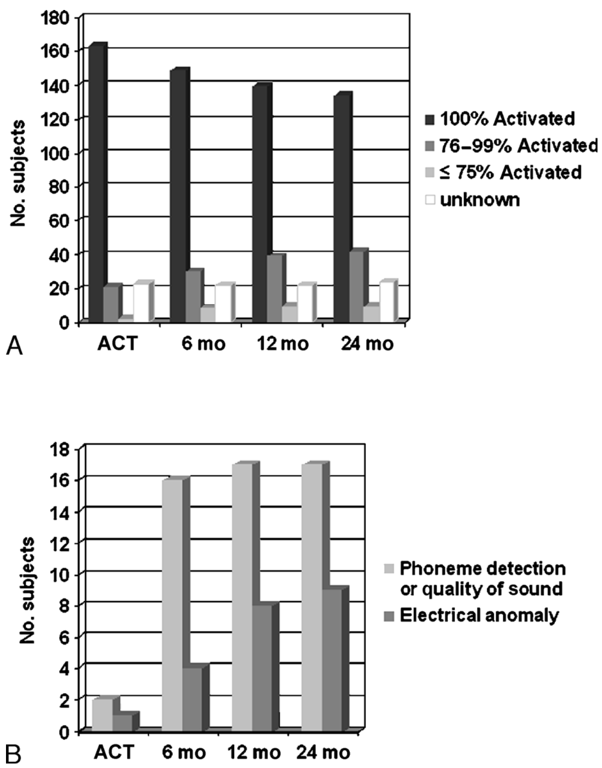


FIG. 2. Prevalence of inactive electrodes over time. *A*, There was a steady increase in the number of subjects with inactive electrodes in the first 2 years after ACT. *B*, Additional electrodes were most often deactivated because of sound quality concerns or electric anomalies. ACT indicates activation.

Predictors of Channel Activation

Reduced numbers of active channels may result from a suboptimal surgical intervention due to anatomic, pathologic, or technical factors. By treating electrode activation as the dependent variable, several host factors were evaluated for their predictive value.

There was a significantly smaller proportion of electrodes that was initially activated in children reported to have meningitis (87 versus 99%; F = 21.46; $p < 0.0001$). This difference remained stable at 12 and 24 months (88 and 87 versus 96%; both $p < 0.05$). The need for additional cochleostomy drilling in 7 ears, 5 of which had a history of meningitis, was also associated with a lower proportion of active electrodes at initial activation (85 versus 99%; F = 21.29; $p < 0.0001$). This discrepancy was smaller by 12 and unchanged at 24 months (88 and 96%, respectively; F = 3.98; $p < 0.05$). There was no significant effect of cochlear dysplasia on the number of active electrodes at initial activation or subsequent follow-up (all $p > 0.05$). Neither age at cochlear implantation, duration of hearing loss without intervention, nor the history of other etiologies (all $p > 0.05$) were found to significantly influence the proportion of electrodes activated.

Complications in general had no impact on the proportion of electrodes activated (95 compared with 96%; F = 0.39; $p = 0.53$). When additional surgical manipulation of the cochlea or device was necessary in response to a complication, however, this was associated with small and nonsignificant increases in channel deactivation in the first 2 years. Children requiring reimplantation (n = 2) because of perioperative complications (excluding 1 case of contralateral implantation) or manipulation of the electrode array (n = 5) exhibited a gradual but insignificant decline in the proportion of fully activated electrodes from 98% at activation to 96% at 6 months, 95% at 12 months, and 95% at 24 months. By comparison, in children with wound infections and otitis media that did not require manipulation of the electrode array (n = 11), electrodes were active at levels of 99, 98, 97, and 97%, on average, at corresponding time points.

Correlates of Auditory Function and Language Development

As shown in Figures 1A and B, there was significant improvement in both auditory responses as reported by parents and receptive language after 2 years with the CI ($p < 0.0001$; paired t comparison). Host, technical, and device factors were examined for their effects on differences in these scores, adjusting for age at test and age at implantation (Tables 4 and 5). There was a significant negative effect of incomplete electrode activation on IT-MAIS/MAIS scores at 24 months after adjusting for age and baseline IT-MAIS/MAIS scores. There was also a

TABLE 3. *Device complications in 209 ears*

	n (%)			
Device status	Activation	6 mo	12 mo	24 mo
Maximum possible electrodes activated, %*				
100	163 (78)	149 (71)	139 (67)	134 (64)
76–99	21 (10)	30 (14)	39 (19)	42 (20)
51–75	1 (0.5)	4 (2)	6 (3)	6 (3)
25–50	1 (0.5)	4 (2)	3 (1)	3 (1)
<25	0 (0)	0 (0)	0 (0)	0 (0)
No data	—	—	—	—
First ear	7 (3)	9 (4)	11 (5)	17 (8)
Second ear	16 (8)	13 (6)	11 (5)	7 (3)
Reasons for deactivation				
Absence of sound perception/behavioral response	0	0	2	0
Phoneme detection/quality of sound	2	16	17	17
Abnormal or absent NRI	0	1	1	1
Nonauditory stimulation	2	1	0	0
Electric anomaly	1	4	8	9
Partial insertion	2	2	3	3
Multiple reasons	0	1	2	2
High-rate processing strategy	0	0	1	1
Unspecified	16	13	14	18
Device failure requiring additional surgery				
Spontaneous failure	3 (1)	—	—	—
Pain	1 (0.5)	—	—	—
Structural defect	1 (0.5)	—	—	—
Average time to failure, mo	12 (range, 5–20)	—	—	—
Additional surgery needed				
Device failure (reimplantation)	4 (2)	—	—	—
Average time to reimplantation, d	31 (range, 5–75 d)	—	—	—
Device defect (revision)	1 (0.5)	—	—	—

*For third-generation processors, the denominator used was 20, rather than 22.
NRI indicates neural response imaging.

TABLE 4. *Difference (SE) in adjusted mean IT-MAIS/MAIS scores between presence and absence of medical, surgical, and device variables*

	Baseline (n = 188)[a]		Δ, 24 mo (n = 182)[b]	
History				
Postnatal complication	16.8 (6.2)	.008	5.4 (4.2)	NS
Meningitis	−15.2 (9.5)	NS	−2.6 (6.2)	NS
Neuropathy[c]	3.2 (8.5)	NS	3.8 (5.5)	NS
Length HL, no HA[d]	1.2 (2.5)	NS	−5.1 (1.8)	0.005
Length of HL with HA[d]	11.0 (1.7)	<0.0001	−1.8 (1.4)	NS
Cochlear dysplasia	14.7 (6.1)	0.02	−4.9 (4.1)	NS
Postoperation				
Any complications	3.9 (5.0)	NS	−0.5 (3.3)	NS
Requiring surgery	4.6 (6.5)	NS	−0.2 (4.2)	NS
Device				
Per 10% higher EA[e]	2.1 (1.9)	NS	3.6 (1.3)	0.005

[a]Adjusted for test age (i.e., age at implantation).
[b]Adjusted for test age, age at implantation, and baseline IT-MAIS/MAIS score.
[c]The auditory neuropathy group excludes 1 child with cochlear nerve deficiency.
[d]Further adjusted for each other; n = 180 at baseline, n = 174 for Δ at 24 mo.
[e]EA, electrodes activated at 12 mo follow-up; n = 178 at baseline, n = 176 for Δ at 24 mo.
HA indicates hearing aid; HL, hearing loss; IT-MAIS, Infant Toddler Meaningful Auditory Integration Scale; NS, not significant.

TABLE 5. *Difference (SE) in adjusted mean Reynell verbal comprehension scores between presence and absence of medical, surgical, and device variables*

	Baseline (n = 164)[a]		Δ, 24 mo (n = 153)[b]	
History				
Perinatal complication	0.9 (2.5)	NS	1.4 (4.1)	NS
Meningitis	−3.7 (4.1)	NS	−3.7 (6.3)	NS
Neuropathy[c]	0.2 (3.6)	NS	0.9 (5.4)	NS
Length HL, no HA[d]	0.9 (0.9)	NS	−3.4 (1.8)	NS
Length HL with HA[d]	6.0 (0.6)	<0.0001	−1.4 (1.1)	NS
Cochlear dysplasia	4.4 (2.4)	NS	3.6 (3.8)	NS
Postoperation				
Any complications	−1.9 (2.1)	NS	−3.6 (3.3)	NS
Requiring surgery	−1.5 (2.8)	NS	−5.1 (4.3)	NS
Device				
Per 10% higher EA[e]	0.5 (0.8)	NS	−0.5 (1.3)	NS

[a]Adjusted for test age (i.e., age at implantation).
[b]Adjusted for test age and age at implantation.
[c]The auditory neuropathy group excludes 1 child with cochlear nerve deficiency.
[d]Further adjusted for each other; n = 156 at baseline; n = 146 for Δ at 24 mo.
[e]EA, electrodes activated at 12 mo follow-up; n = 154 at baseline, n = 147 for Δ at 24 mo.
HL indicates hearing loss; HA, hearing aid; NA, not significant.

significant negative effect of prolonged preoperative hearing loss without amplification on IT-MAIS/MAIS scores at 24 months after adjusting for age at implantation, age at auditory behavior assessment, baseline auditory behavior scores, and length of preoperative hearing loss with amplification. Whereas an advantage in baseline IT-MAIS/MAIS scores was observed for children with perinatal complications and cochlear dysplasia, there was no significant effect of clinical history, cause, or the occurrence of surgical complications on these measures of auditory behavior at 24 months. There were no significant effects of history, surgical factors, or electrode activation on receptive language scores at baseline or 24 months (Table 5). The impact of bilateral CI on auditory and language outcomes could not be analyzed because most children had very limited experience wearing both devices by the 2-year follow-up. Meningitis, preoperative hearing loss without amplification, and the occurrence of perioperative complications all had negative effects on receptive language that did not, however, achieve statistical significance.

DISCUSSION

A satisfactory surgical outcome with cochlear implantation entails atraumatic placement of a functional device and array of electrodes that provides a robust and stable neural interface. The present report models the effect of satisfactory surgical implantation as a necessary prerequisite for maximal auditory benefit from cochlear implantation. It is evident that early auditory outcomes are influenced by the percentage of active electrodes, which is affected in turn by previous cochlear disease and the electrode-neuronal interface that is surgically developed. Although negative effects on receptive language would also be expected, none were evident at 24 months. It remains to be analyzed whether early effects on electric audition may presage a diminished trajectory of language development, which may become more evident at longer postoperative intervals. Furthermore, multiple modifiers beyond speech perception per se likely influence the development of receptive language.

Age at implantation, duration of auditory deprivation, and the presence of bilateral CIs were not confounded for the effects of electrode activation on language outcomes because they were not found to affect the proportion of electrodes activated. Incomplete activation of the electrode array has previously been found in retrospective studies to be a negative predictor of open-set speech perception 4 to 7 years after cochlear implantation (13), suggesting a long-term effect on CI benefit.

There are likely to be multiple causes for the inactivation of electrodes. Audiologic judgment in optimizing reception, device defect, and cochlear anatomy may prompt electrode deactivation. Device malfunction required revision surgery in 2.4% of implanted ears at a mean interval of 12 months after implantation, which is slightly lower than the rate reported by Maurer et al. (14) for the first year (3.6%). Whether or not an early trend of electrode deactivation is a predictor of future device failure is under prospective examination in this Childhood Development after Cochlear Implantation study.

Preexisting and surgically induced cochlear pathologic findings are likely to affect the neural interface of the cochlear prosthesis and may contribute to decrements in active electrodes. Cochlear pathologic findings associated with meningitis may, for example, explain the lower rate of complete electrode activation observed in this patient group, which corresponds to reports of altered electric properties associated with labyrinthitis ossificans (15,16). A history of electrode reinsertion or device replacement in response to a surgical complication was associated with a small increase in the likelihood of incomplete electrode activation.

These preliminary data indicate the importance of early intervention with hearing aids because longer periods without hearing aids were associated with smaller gains in auditory behavior (Table 4). Higher baseline IT-MAIS/MAIS and Reynell scores associated with longer periods of preoperative hearing aid use may reflect a greater likelihood of residual hearing and a progressive pattern of hearing loss. Likewise, the higher preoperative IT-MAIS/MAIS scores reported for children with cochlear dysplasias may be explained by a progressive pattern of hearing loss, particularly in cases with enlarged vestibular aqueducts. Children with a history of perinatal complications may undergo greater scrutiny of their auditory function during hospitalization, with a greater likelihood of early diagnosis and intervention and the preoperative development of auditory behaviors.

A high rate of complete surgical implantation of electrode arrays was achieved. Technical challenges and complications were nevertheless encountered in the hands of experienced teams of implant surgeons. Although neither permanent nor life-threatening, these complications had negative consequences for subsequent rehabilitation. Delays in activation and interrupted implant use occurred in association with device malfunction. When combined with small negative effects on electrode activation, these delays caused by perioperative complications and revision surgery manifest an unfavorable, although insignificant impact on early receptive language performance. Such trends suggest that surgical complications can impact larger communication outcomes with CIs. These observations underscore the importance of optimal surgical management as an early step in the rehabilitative experience upon which a child's auditory development depends.

This longitudinal prospective study offers a unique opportunity to identify variables that may significantly associate with outcome by capturing effects that are otherwise missed in retrospective studies. Multiple domains were assessed simultaneously to establish relationships between predictive variables. With a multicenter design, true real-world effectiveness and generalizable outcomes are better established. Shortcomings in the present study, however, include limitations in the development of a longitudinal control group and the absence of randomization. In fact, potential controls, children with advanced levels of hearing loss using amplification, often become CI candidates. With respect to differentially assigning subjects to an experimental arm, the current state of knowledge regarding the harmful effects of auditory deprivation and clinical practices related to the importance of family-based choice combine to hamper randomization.

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