ORIGINAL ARTICLE

Low Pediatric Cochlear Implant Failure Rate

Contributing Factors in Large-Volume Practice

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Objective: To evaluate the rate of cochlear implant (CI) failure and CI reimplantation (CIri) in our population of children receiving implants by means of a technique that includes device fixation with suture to cortical bone.

Design: Retrospective analysis from January 1990 to June 2010.

Setting: Tertiary pediatric hospital.

Patients: A total of 971 devices were provided to 738 children (5575 implant-years).

Interventions: Cochlear implant explants and CIri.

Main Outcome Measures: Surgical findings at CIri were assessed by device model. The Pediatric Ranked Order Speech Perception score and the Phonetically Balanced Kindergarten score were used to make comparisons of hearing ability before and after CIri.

Results: Thirty-four patients have undergone CIri in our pediatric center during the past 20 years. Excluding 7 of these patients who received their initial implant at other centers, our rate of CIri was 2.9%. Mean (SD) time to device failure was 61 (43) months. A disproportionately high number of patients (7 of 35 [20%]) requiring CIri had meningitis before implantation. After CIri, children maintained or improved their best speech performance measured before device failure, with only 2 children showing a significant reduction in speech perception after CIri.

Conclusions: A very low rate of failure occurs in children who receive CI devices, and several factors may account for this low rate. Children who develop meningitis before CI appear to be at an increased risk of device failure.

Arch Otolaryngol Head Neck Surg. 2011;137(12):1190-1196

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MULTICHANNEL COCHLEAR implantation (CI) has become significantly more refined since the first implantation was performed almost 40 years ago.[1] There are now 200 000 implanted devices worldwide, and nearly 1000 CIs have been inserted at The Hospital for Sick Children, Toronto, Ontario, Canada, during the past 20 years, with an increasing proportion of patients who have been wearing their devices for longer than the 10-year period covered by warranty of device manufacturers. Not all CIs survive for long periods of use, and surgical replacement will potentially become the most common complication experienced by patients who undergo implantation. Devices currently fail as a result of what has been termed *hard* or *soft* device failure. Hard failures have been defined as a fault of the CI hardware such that it provides immediate, insufficient auditory input to the patient.[2] Soft failures are suspected when the CI user shows progressive deterioration of hearing skills but there are no clear deficits in CI device function.[2] Other patients experience problems with the surgical site, which sometimes also requires CI reimplantation (CIri) because of skin flap compromise, electrode misplacement, and device extrusion; this is a separate topic and has been reviewed carefully.[3]

Adult CIri necessary because of device failure occurs in 4% to 13% of recipients.[4,5] Some authors[6,7] have suggested that this rate is consistently lower than that in the pediatric population, but recent reviews[8,9] summarizing CIri in children reported rates of 6% to 13%.

The purpose of the present study was to evaluate the rate of CIri in our population of children. Patients at our center received implants with the use of a standardized technique,[10,11] predominantly by

a single surgeon (B.C.P.), and all initial devices were from a single CI manufacturer (Cochlear Ltd).

METHODS

After we obtained research ethics board approval, the medical records of children who had received CIs at The Hospital for Sick Children between 1990 and June 2010 were reviewed. Demographic data including children's age at the initial surgical procedure, type of initial and reimplanted device, time to device failure, operative reports, and speech and language outcomes before and after reimplantation were collected and are described herein. In addition, the manufacturer's technical device reports were reviewed.

SURGICAL TECHNIQUE

Until 2002, the approach to CI was through a postauricular incision extended up into the scalp.[10] Two hundred patients received implants with this technique. Since 2002, all procedures have been completed through a hairline incision of 3 cm or less, positioned so as to not cross the device or electrode arrays at any point.[11] The same approaches were used for CIri during these periods.

OUTCOME MEASURES

The reason for CIri was categorized as sudden device failure, progressive device failure, or failure due to infection or soft-tissue complications. This was ascertained through review of medical records and audiologic assessment notes in addition to discussion with the CI program audiologists, program administrators, and surgeons. Device failure was defined in accordance with the criteria of the European consensus meeting of June 2005.[12] Signs of hard or soft device failure were noted according to the 2005 Cochlear Implant Soft Failures Consensus Development Conference Statement.[2] The speech perception battery included a parental questionnaire (Meaningful Auditory Integration Scale), closed-set tests (Word Intelligibility by Picture Identification and Early Speech Perception), and open-set tests (Glendonald Auditory Screening Procedure and the Phonetically Balanced Kindergarten [PBK]). More recently developed open-set tests included the Multisyllabic Lexical Neighborhood Test and the Lexical Neighborhood Test. Specific tests were used in individual children according to their age and abilities to provide the required responses. The results of these tests can be combined using the Pediatric Ranked Order Speech Perception (PROSPER) score. The PROSPER score was created to integrate all available speech perception outcomes results into one score that could be followed over time because of the typical change in speech perception tests used as children age and acquire oral speech and language.[13] For this study, the PROSPER score was used to make comparisons of hearing ability before and after CIri. Because the ceiling of PROSPER scores is reached when PBK accuracy exceeds 50%, we also analyzed PBK scores in children who were able to complete this test.

STATISTICAL ANALYSES

Time to device failure in months and cumulative failure by device type and manufacturer investigation report were estimated using Kaplan-Meier methods. Paired *t* testing was used to determine differences in the 3 groups of patients after CIri: improvement in PROSPER score, same score, or decline in score. A χ^2 test was used to compare the proportion of patients with meningitis in our overall population with that in our CIri population.

Table 1. Demographics

Characteristic	No. (%)
CIs requiring reimplantation	35 (100)
Sex	
Male	23 (66)
Female	12 (34)
Prelingual onset of hearing loss	35 (100)
Age at initial implantation, median (range), mo	33 (10-193)
Right-sided implant	25 (71)
Original implant performed at another center	7 (20)
Age at CIri, median (range), mo	84 (27-220)
Time between initial CI and CIri, median (range), mo	46 (13-154)
Model difference between first and second device	20 (57)
Source of deafness	
Congenital, unknown	13 (37)
Congenital, genetic	11 (31)
Meningitis	7 (20)
Mondini deformity	3 (9)
Other cochleovestibular anomaly	1 (3)

Abbreviations: CI, cochlear implant; CIri, cochlear reimplantation.

RESULTS

In the 20-year period reviewed, 971 devices were provided to 738 children in our program. No child has experienced a simultaneous failure of bilateral CIs; thus, our results are reported in devices over a denominator of total devices implanted at our institution. One child required more than 1 CIri in the same ear and therefore represents 2 independent units of data. **Table 1** gives demographic data describing the 35 devices that were reimplanted in 34 children. The median (SD) age at initial implantation in this group was 33 (33) months. Seventeen of the children monitored in our program received the initial CI at another program. Of these 17 children, 7 required CIri; 3 had the initial procedure performed at other Canadian CI centers, 2 were conducted in the United States, and 2 were performed in other countries. In reviewing all devices implanted in our institution, only 1 patient that we are aware of had a failed device reimplanted elsewhere; this child was included in our data set. This child received the CI at our center because of a wait-time issue at her home center. Because she was not from our province, she was followed up elsewhere; when a CIri was required, it was done at the child's home center. The median (SD) time between initial CI and CIri in the 35 children we included in our analyses was 46 (43) months, with a range of 13 to 154 months. Twenty children (57%) requiring CIri received a different device model at reimplantation; the device in one of these children was from a different manufacturer.

A variety of causes of deafness of the CIri group were noted (Table 1). Seven children (20%) requiring CIri had deafness resulting from bacterial meningitis prior to implantation. Using our CI program database, we identified 429 children with a documented cause for their hearing loss; 36 patients (8%) had meningitis listed, which is significantly lower than that in our CIri population ($P=.01$).

Of the 971 devices implanted at our institution, the model type, number implanted, and number experienc-

Table 2. Time to Failure by Device

Device	Total CIs Performed at HSC	Implanted Since	Explanted and Reimplanted, No. (%)	Time to Failure, Mean (SD), mo	Device-Specific Survival, %	
					5 y	10 y
All implants	**971**	January 1990	**35** (100)	61 (43)	98.1	97.1
Cochlear Ltd CI22M	69	January 1990	12 (34)	93 (46)	95.5	86.4
Cochlear Ltd CI24M	104	October 1997	6 (17)	55 (41)	96.2	95.2
Cochlear Ltd CI24R (CA)	119	April 2003	3 (9)	29 (8)	97.5	NA
Cochlear Ltd CI24R (CS)	169	April 2000	6 (17)	53 (35)	98.2	97.1
Cochlear Ltd CI24RE (CA)	449	April 2004	5 (14)	32 (22)	98.9	NA
Cochlear Ltd CI24RE (ST)	29	August 2000	1 (3)	29 (0)	96.6	NA
Cochlear Ltd nucleus CI513	32	March 2009	0	NA	NA	NA
Advanced Bionics	0	NA	2 (6)	55 (54)	NA	NA

Abbreviations: CI, cochlear implant; HSC, Hospital for Sick Children; NA, not applicable.

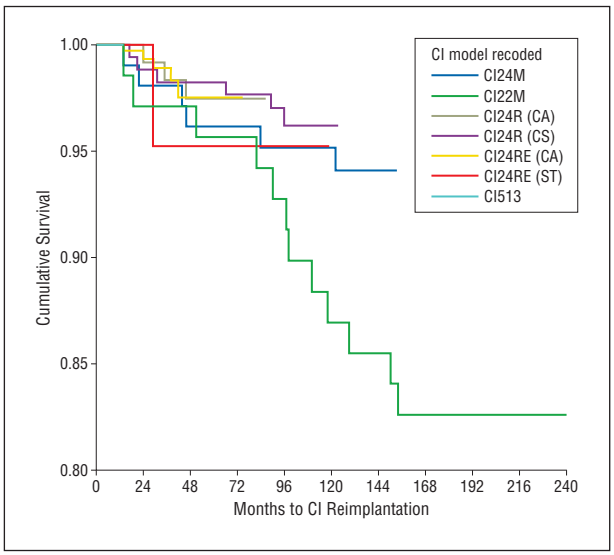

Figure 1. Device survival vs time shown with Kaplan-Meier curves. CI indicates cochlear implant.

ing failure are provided in **Table 2**. Mean (SD) follow-up for our patients was 68.5 (49.8) months. There was a total 5575 implant-years for all devices implanted and monitored at our center. This number was calculated with the length of use for the date of CI procedure to July 1, 2010, or to the patient's 18th birthday, as we do not have accurate follow-up on our patients beyond graduation from our program. **Figure 1** plots the survival of each type of CI using a Kaplan-Meier curve and shows that the earliest device (green), the CI22M, has had the largest rate of failure.

After meeting with the CI program audiologists, program administrators, and surgeons and after reviewing audiologic assessment notes, we were able to confidently place patients in one of 3 categories: 14 had sudden device failures, 16 had progressive device failures, and 5 failed owing to infection or soft-tissue causes unrelated to device function. Using the manufacturer's reports and clinical data, we determined that 13 were hard failures and 12 were soft failures; 5 could not be reliably allocated to either type of failure, and 5 devices were reimplanted because of infection or soft-tissue concerns. Of the 5 patients who required CIri for soft-tissue concerns, only 1 child (20%) had the initial implant procedure performed at another center.

Surgical notes were available for 26 of 35 CIris. Review of these documented observations indicated that bony regrowth had occurred in the facial recess in 5 cases (19%) and over the ball electrode in 13 cases (50%); 2 of these 13 children were deaf as a result of meningitis before the initial CI. Redrilling of the cochleostomy site was noted in 5 children (19%), 2 of whom had lost their hearing as a result of meningitis. Regrowth of cortical bone over the mastoid was noted in 22 children (85%); 4 of these children had meningitis as the source of their hearing loss. For the patient who underwent CIri twice, the initial device failure was related to trauma, a hard failure of the device. Subsequently, the reimplanted device failed several years later. At the time of the operation, there was significant ossification in the basal turn, and only a partial insertion could be achieved. In another child, the circumferential banded electrodes of the CI24M device were incorporated so tightly with fibrous tissue that the array was stretched almost to the breaking point prior to final explantation. In this case, CIri was uneventful.

The PROSPER score was created to integrate all available speech perception outcome results into a single score that could be monitored to remedy the problem of a large amount of incomplete data in pediatric populations. The score, which ranges from 0 to 34, has been tested in this population and was designed by preparing a hierarchy of the individual speech perception tests (**Figure 2**).[13]

PROSPER scores either improved (n=10) or remained stable (n=11) after CIri (Figure 2). Many of these children already had excellent speech perception scores and thus had PROSPER scores reaching or approaching the maximum value of 34. Of the 4 children who showed a decline in their PROSPER scores after CIri, 2 had only a minor decrease of 1 or 2 PROSPER points. Paired *t* testing did not reveal any significant differences in the 3 groups in the time from original CI to CIri, age at original CI, and age at CIri, although there appeared to be a trend toward shorter time after CIri to achieve the score reported in the group that had a decline in the PROSPER score. Two patients showed decreases in PROSPER score, both of whom received CIri for progressive hearing loss. In one of these cases, data after CIri were limited to a single test completed 1 month postoperatively, as this patient

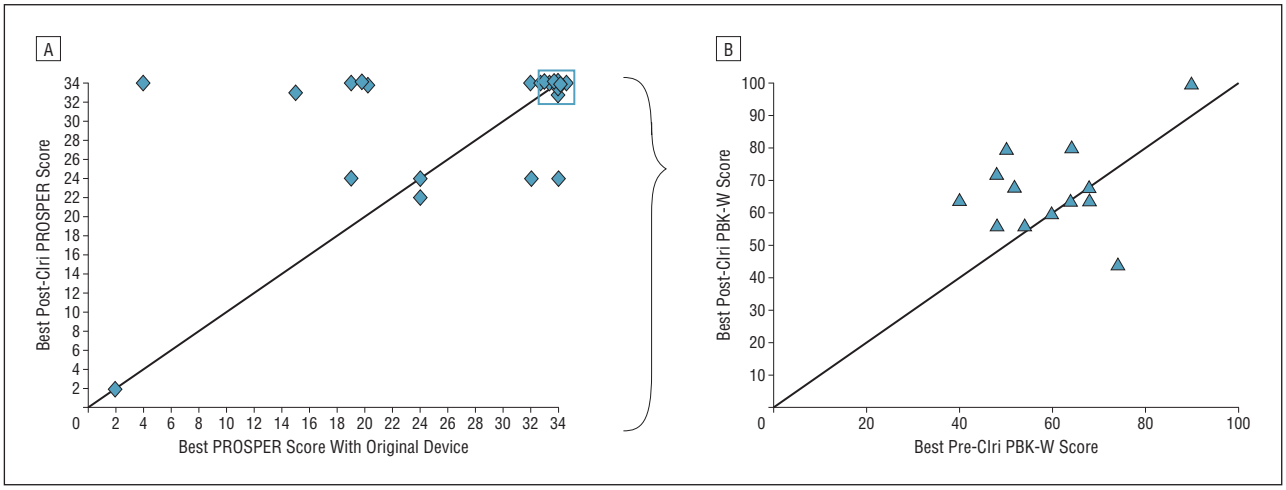

Figure 2. Pediatric Ranked Order Speech Perception (PROSPER) and Phonetically Balanced Kindergarten-Word (PBK-W) scores for a subset of PROSPER scores before and after cochlear implant reimplantation (CIri). A, The PROSPER scores after CIri (n=25) were gathered at a median of 11 months, with a mean (SD) of 13.8 (12.5) months. The solid line indicates the 1:1 relationship between PROSPER scores before and after CIri. Data points above the solid line indicate hearing improvement after CIri, those on the line show no change, and those below the line show a decline. The box indicates a cluster of 13 patients with high PROSPER scores (33 or 34). B, In a separate analysis, the best pre- vs post-CIri PBK-W scores for 33 or 34 PROSPER scores were determined in the 13 patients included in the cluster.

graduated from our program at the age of 18 years. The other patient continues to report improvement in speech perception but has yet to be reassessed.

COMMENT

RATE OF CIri IN OUR COHORT

Thirty-five patients have undergone CIri in our pediatric center during the past 20 years. Excluding 7 of these patients, who received their initial CI at other centers, our rate of reimplantation is 2.9% (28 of 971). This is a slightly lower rate than in previous reports. The adult literature suggests a rate of CIri ranging from 4% to 13%.[4,5] Although some authors[6,7] have suggested that this rate is lower than that in the pediatric population, the CIri rate in children in other reports ranges from 4% to 15.4%.[7-9,14-18] Of these pediatric series,[7-9,14-18] surgical technique is not described except in 3 reports[8,14,18] that do not state whether suture fixation was used. Fixation of the receiver-stimulator to the skull has been recommended[11] to prevent micromovement or migration of the device and subsequent fracture of the delicate wires in the array. Alexander et al[18] saw no association between any of the 3 increasingly less-involved fixation methods they used and mode of failure in a series of 320 devices monitored for a median of 26 months. We would suggest that the period of follow-up was too short, the numbers of children receiving each type of fixation method were too low, and the overall failure rate (4%) was too high to make any firm conclusions about the relationship between device fixation and device failure.

The present study was not designed to assess a causal relationship between this low failure rate and related factors. However, our program, like others,[8,9] uses a suture fixation technique. In addition, the vast majority of our devices were from one manufacturer and were implanted by a single surgeon using the same technique and with significantly high volumes. These factors may have contributed to our low failure rate, but further studies are required to assess whether a particular technique leads to lower failure rates.

The relationship between nonfixation of the receiver-stimulator and failure appears to be a strong one in our program, albeit likely as a result of our own possibly skewed experience. In the first 65 patients operated on using the 2.8-cm incision, 2 of 5 children in whom no suture fixation was used or fixation was lost developed complications that threatened the device.[11] Subsequently, a failed device included in the current series was loosely tied to the skull surface, but the receiver-stimulator (CI24RE) pedestal was not recessed, allowing demonstrable rotational movement of the device. This child had undergone primary CI at another program. These rare cases of failure are especially interesting in that fixation was inadequate and seems causally related to the observed complications. Nonetheless, we acknowledge that, despite suture fixation, other programs[17-19] have published higher failure rates and that failure rates are multifactorial.

THE RISK OF CIri AFTER MENINGITIS

In our series, 7 of 35 children (20%) requiring CIri had bacterial meningitis as the source of their hearing loss. At our institution, meningitis as an etiologic factor accounts for 8% of all patients with CI. The failure rate in children with meningitis far exceeds that in children whose deafness resulted from other causes. Our data are consistent with those of previous reports on the higher incidence of CIri in children whose deafness was caused by meningitis. Lassig et al[17] reported that 10 of 30 children (33%) requiring CIri were deaf as a result of meningitis, Parisier et al[19] reported this incidence to be 13 of 25 children (52%), and Fayad et al[16] reported the incidence to be 5 of 28 children (18%).

SURGICAL FINDINGS IN CIri

Our surgical findings revealed that the majority of the children requiring reimplantation (22 of 26 [85%]) have bony regrowth after CI. Five children (19%) had bone in the facial recess that had to be drilled away during the reimplant procedure. While our operative report review suggests that only 50% of children requiring CIri had bone regrowth over the ball electrode, this occurred in almost every case and is often a very difficult part of the reimplantation procedure. Five children (19%) required redrilling of their cochleostomy sites, 1 child (4%) had bone growth around the round window, and 7 children (27%) had fibrous tissue around the cochleostomy site. These findings suggest an inflammatory process and even osteogenesis around the cochlea. These findings were not particularly associated with our subgroup of patients with a history of meningitis. This is consistent with Parisier et al,[19] who reported the presence of ossification within the scala tympani following initial CI implantation in 52% of the children who later required reimplantation, regardless of the original cause of deafness or the type of implant used. The formation of bony growth near the cochleostomy can make reimplantation difficult. Indeed, reimplantation was nearly aborted in one case owing to the difficulty of the reinsertion, and in another case, we met with significant difficulty because of device electrode incorporation into thick fibrous tissue.

RATES OF REIMPLANTATION SPECIFIC TO CI DEVICE

The literature suggests that the rates of reimplantation appear to be CI device-dependent. The Johns Hopkins group[9] showed that 68%, 26%, and 2% of their CIris were performed on individuals receiving Advanced Bionics devices, Cochlear Ltd devices, and Med-EL devices, respectively, but that these companies manufactured 50%, 48%, and 2% of the devices at their center, respectively. A study by Gosepath et al[15] showed that Med-EL devices had a 16.2% revision rate and Cochlear Ltd devices had a 4.2% revision rate. Buchman et al[5] reported that significantly fewer Med-EL devices had to be removed compared with Cochlear Ltd and Advanced Bionics devices ($P < .003$). However, the authors noted that Cochlear Ltd devices were used for significantly longer durations before reimplantation.

In our series of Cochlear Ltd device users, we were able to more carefully assess the survival of particular device generations of one manufacturer. The earliest CI22M device had the lowest cumulative survival but is also the device with the longest follow-up and the longest mean time to failure. Nonetheless, despite implanting these devices in only 69 patients, 12 have failed to date. The continued and late failures seen with the CI22M device raise questions about the possibility of late failures for any CI device. We found that, at this time, the CI24RE (CA) shows the best survival and failure rate (after the CI513) but also has one of the shortest times to failure. Because the CI24RE (CA) has been used since 2004, we only have a moderate 6-year follow-up period for children who received this as their initial implant. The CI513 is a new device, and we have limited follow-up with it as well. Cochlear implantation is a relatively new medical intervention, and long-term follow-up, reimplantations, and audiologic outcomes gathered across 30 years have yet to be assessed.

AUDIOLOGIC OUTCOMES OF CIri

Several studies[7,9,16] have reported audiologic outcomes comparing pre- and post-CIri speech perception. These studies have consistently shown that most patients maintained or improved their best preoperative level of performance. Similarly, 44% of our patients returned to their best preoperative PROSPER score and 40% showed continued improvement in speech perception (as expected) after CIri. There were 4 children whose speech perception scores did not return to baseline within 1 to10 months. However, 2 of these 4 children had only a 1- or 2-point change in the PROSPER score. One of these children had a moderate change in the PBK word score after CIri, causing only a single point decrease in PROSPER score, and the other had a 2-point decrease, with a PROSPER score in the mid-20s. Therefore, only 2 of 34 children (6%) showed meaningful reduction in speech perception after CIri, one of whom received only a single postoperative assessment 1 month after graduating from our program at the age of 18 years; on anecdotal reports, the other child continues to improve (follow-up speech perception testing has not yet been done). Our data appear to be in contrast to those of an early report,[20] which emphasized that up to 30% of individuals may not reach their preoperative speech perception after CIri. In general, current literature[7,9,16] suggests a more optimistic audiologic outcome of CIri.

TYPES OF CI FAILURES

Device failure is defined as when the device characteristics fall outside the manufacturer's specification and/or result in a loss of clinical benefit.[12] This definition excludes devices that are believed to be functioning normally but need to be removed for medical reasons, such as infection or biological failure. Further classification into soft or hard failure is defined by guidelines of the 2005 Cochlear Implant Soft Failures Consensus Development Conference Statement.[2] According to those guidelines, a *hard failure* refers to measurable hardware abnormalities and *soft failure* refers to declining performance, aversive auditory and nonauditory symptoms, or intermittent function but with maintained communication between external and internal components. An important limitation of this classification is that the manufacturer's examination of the explanted device can identify a hard fault that was not detectable in vivo. Allocation to hard or soft groups is thus skewed by availability of the manufacturer's assessment and integrity of the device following surgical removal when the device is often injured or disassembled in the removal effort. We found difficulty in accurately defining failure by these characteristics and prefer to define device failure instead by its clinical presentation as sudden, progressive, or the result of soft-tissue causes.

The children who experienced sudden device failure had mechanical problems with the CI that were caused by trauma in some cases. After CIri, these children performed at or above their best pre-CIri PROSPER score. Five patients required reimplantation for soft-tissue concerns or infection, and these children similarly performed at or above their best pre-CIri PROSPER score because the devices were functioning when explanted. It is the gradual malfunction group that has the most notable findings. We found that the PROSPER score in some of these children improved to pre-CIri levels after reimplantation, but that others did not. We consider that the decreased speech perception in some patients within this subgroup may be the result of a physiological failure, such as an inability of the neural pathway to withstand long-term electrical stimulation. If so, CIri in this subgroup may not resolve the decrease in speech perception. A rapid decline in speech perception has been shown[9] to be a stronger predictor of successful outcome (100%) after reimplantation than chronic underperformance (57%) among children with suspected device failure, suggesting that speech perception in patients with sudden failure is more likely to improve after CIri. A subgroup of patients with gradual decline may have soft failure and improve to pre-CIri levels after reimplantation, and another subgroup with gradual decline may have physiological failure and may not improve with reimplantation. The effect of a physiological failure in response to CI would be profoundly negative for a patient and demand considerable support with alternative communicative strategies. Despite our relatively long experience, this outcome fortunately remains rare.

CLINICAL EXPERIENCE ACCRUED IN THIS SERIES OF CI FAILURES

A failed CI is a devastating event for the child and family. Device failure following implantation at a young age is, unfortunately, inevitable. The burden is therefore on the implanting surgeon and device manufacturers to ensure that implants are inserted into cochleae as delicately as possible because we have little idea how many times we can successfully replace the intracochlear electrode array in individuals who receive their initial implant in infancy. Based on the experience accrued at our institution, we, like others, have observed a few consistent facts.

There is limited information showing that a delicate preparation of the cochleostomy and electrode array demonstrably improves speech and language outcome; however, our program has shown[21] improved behavioral and electrophysiological performance with careful insertion technique, probably because we have entered the scala tympani and stayed within it throughout the insertion, more commonly using a careful, advanced off-stylet technique. Despite these improvements in outcome, we adhere to careful cochleostomy and insertion technique primarily because we believe that this portion of the initial implantation has the greatest effect on CIri. We routinely see tissue within the cochlea at reimplantation, but we remain unsure how far apically it might extend. The caliber of the tract is strongly dependent on the diameter of the explanted array, and we reimplant with arrays of the same diameter in all cases. The course that the intracochlear array must travel during reimplantation also is strongly dependent on the course taken by the explanted electrode. Early in our series, when we were using straight electrodes, small kinks were occasionally visible on the postoperative radiograph; we believe that, in time, these will likely be surrounded by intracochlear soft tissue. This will make threading a flexible, thin replacement electrode exceptionally difficult because the inertial forces it must overcome increase with intracochlear distance. At the second explant/reimplant in one child (one for hard failure, one for soft failure), the electrode could not be fully inserted and a simultaneous contralateral full insertion was performed.

Characteristics of the electrode array also have a large effect on explantation and reimplantation. Older straight arrays with circumferential banded electrodes often become trapped in the intracochlear soft tissue and within the bony cochleostomy, which is hard to modify with the electrode in place. In one child in this series, a considerable amount of force was required to remove the electrode and, as we prepared to "drill out" the electrode and the cochlea, the electrode suddenly pulled out, allowing an uneventful reimplantation. In contrast, we have found that precurved electrodes easily pull out and allow fairly straightforward reimplantation, usually with the stylet in place throughout the insertion. Postoperatively, the course of the electrodes is similar in such cases, leading us to suspect that the path taken by a reimplanted electrode is largely determined by the position of the exiting electrode. As attractive as thinner electrode designs might be, complete knowledge of the intracochlear response to electrode arrays must be understood before we are confident that the potential diminution in intracochlear reaction outweighs the potential difficulties our successors may encounter when the infant who receives a CI today requires a third or fourth electrode replacement at some distant time. A modular cochlear implant with a semipermanent detachable implanted array would be a possible way to diminish the risks of being unable to reimplant the cochlea several times in the course of a lifetime.

In conclusion, we found a very low rate of CI failure in a pediatric implant series and several related factors that may account for this low rate. Children who develop meningitis before CI appear to be at an increased risk of device failure. Most patients maintain or improve their best preoperative level of speech perception after CIri, but patients with gradual device failure have less chance of good hearing recovery.

Submitted for Publication: February 27, 2011; final revision received June 7, 2011; accepted August 2, 2011.
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Author Contributions: Drs Eskander, Gordon, Kadhim, Cushing, and Papsin had full access to all the data in the study and take responsibility for the integrity of

the data and the accuracy of the data analysis. *Study concept and design:* Eskander, Gordon, Papaioannou, and Papsin. *Acquisition of data:* Eskander, Kadhim, and Papaioannou. *Analysis and interpretation of data:* Eskander, Gordon, Papaioannou, Cushing, James, and Papsin. *Drafting of the manuscript:* Eskander, Gordon, and Kadhim. *Critical revision of the manuscript for important intellectual content:* Eskander, Gordon, Papaioannou, Cushing, James, and Papsin. *Statistical analysis:* Eskander and Gordon. *Obtained funding:* Papsin. *Administrative, technical, and material support:* Gordon, Papaioannou, and Papsin. *Study supervision:* Gordon, Cushing, James, and Papsin.

Financial Disclosure: Dr Papsin is a member of the speaker's bureau, Cochlear Americas Corporation.

Previous Presentation: This study was presented at the 2011 American Society of Pediatric Otolaryngology meeting; April 29, 2011; Chicago, Illinois.

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