Reliability and Complications of 500 Consecutive Cochlear Implantations

Frederic Venail, MD; Marielle Sicard, AuD; Jean Pierre Piron, PhD; Ann Levi, MA; Francoise Artieres, MD; Alain Uziel, MD, PhD; Michel Mondain, MD, PhD

Objectives: To assess device failures as well as early postoperative, late postoperative, and medical complications occurring after cochlear implantation and to discuss their causes and treatments.

Study Design: Retrospective study of 500 consecutive cochlear implantations.

Setting: Tertiary referral center.

Patients: All patients receiving cochlear implants at our institution between 1989 and 2006.

Main Outcome Measures: All complications and treatments were systematically reviewed with a maximum follow-up of 18 years. The number of reimplantations was calculated according to follow-up duration to determine the cochlear implant survival rate. Specific risks of reimplantation were calculated for groups with differing durations of implantation.

Results: The overall rate of complications was 16.0% (79 of 500), with minor complications accounting for 5.6%; major complications, 3.2%; and reimplantations, 7.2%. Reasons for revision surgery were device failure, infection, trauma, and “soft device failure” (failure despite normal results from integrity testing). Revision surgery was performed in 51 of the 500 cases (10.2%), and other complications were managed medically (28 of 500; 5.6%). The rate of hard and soft device failures was 6% (30 of 500). Seventy-two percent of reimplantations occurred within 5 years. The risk of severe infection (eventually requiring explantation) was 1.4% (7 of 500). There was 1 case of transient facial palsy following surgery (0.2%), and the incidence of postsurgical meningitis was 0.

Conclusions: Cochlear implantation is a safe technique with a relatively low complication rate; however, certain complications may require specific attention to prevent or correct them.


Cochlear implantation is a relatively safe procedure.1-4 However, complications occur associated with the surgical approach, the implantation of a foreign body, or with the failure of the implanted device. Since the number of cochlear implantations has increased dramatically during the last decade, it is important that both patients and practitioners be aware of the potential complications.

The rate of complications and/or reimplantation also has a direct economic impact. Considerable data are available concerning surgical and medical complications,1-3 but many studies fail to provide long-term data regarding surgical complications, device failures, or specific medical complications such as facial palsy, tinnitus, or vertigo. Articles describing such complications in a large sample of patients with extensive follow-up data are rare, and equally sparse are those articles comparing results between adult and pediatric populations.

The present study addresses the first 500 consecutive cochlear implantations in adults and children performed between June 1989 and December 2006 in our department. Complications occurring during follow-up were systematically reviewed, and their treatments reported. Complications were classified according to their management: cochlear reimplantation, other revision surgery, medical treatment, or electrode deactivation. The cochlear implant life expectancy was calculated as the survival rate by duration of follow-up.

METHODS

POPULATION

This study was approved by the ethical committee of our institution. A retrospective analysis of 500 consecutive cochlear implantations between June 1989 and December 2006 was performed. Of these, only 1 adult patient had bilateral cochlear implants. The population comprised 178 adult patients and 322 patients younger than 18 years at the time of implantation. The demographics of the population are summarized in Table 1. All patients were examined annually, with the exception of 1 child who was lost to follow-up after returning to his home country. Ten adults died from causes unrelated to cochlear im-

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plantation. Four patients underwent implantation without reimplantation. Eleven patients (5 adults and 6 children) were non-users of cochlear implants at the time of this study. Seven of these patients did not respond well to implantation, although the devices performed properly.

Age at the time of initial surgery ranged from 10 months to 80.8 years (mean age, 21.3 years; median, 7.8 years). Sixty six percent of patients had the implant placed in their right ear, 34% in the left. Devices implanted at the initial surgery were Nucleus CI12 (n=121), Nucleus CI24M (n=73), Nucleus CI24ST (n=23), Nucleus CI24CS (n=92), Nucleus CI24CA (n=52), Nucleus CI24RE (n=40), Nucleus CI11 + 10 (n=2), Clarion 1.2 (n=22), Clarion CI (n=24), Clarion HP90K (n=38), MXM Digisonic (n=10) and Med-E1 Combi 40+ (n=3). All Nucleus devices were manufactured by Cochlear Corp, Lane Cove, Australia; all Clarion devices were manufactured by Advanced Bionics, Sylmar, California; the Digisonic device was manufactured by Meurelec Corp, Vallauris, France; and the Med-E1 device was manufactured by Med-E1 Corp, Innsbruck, Austria.

Patients were seen for monthly follow-up visits during the first year after implantation, every 3 months during the second year, and annually thereafter. The average duration of follow-up was 6.89 years (median follow-up, 5.96 years; range, 0.8-17.8 years) (Figure 1).

OUTCOME MEASUREMENTS

All complications were reviewed and classified into 3 types according to the European Consensus Statement on Cochlear Implant Failures and Explanation: (1) cochlear reimplantation; (2) other revision surgery; or (3) medical treatment or electrode deactivation.

Major complications were considered those that were life threatening or required surgery (including implantation), whereas minor complications were those that could be treated medically. Bhatia et al categorized the following as major complications: death; meningitis; surgery without reimplantation (large scalp necrosis, severe infection, electrode extraction, eardrum perforation, receiver repositioning, and cholesteatoma); and tinnitus, facial stimulation, and pain that could not be alleviated by electrode deactivation. Minor complications were transient facial palsy; scalp hematoma; infections that resolved without recourse to surgery; and tinnitus, facial stimulation, and pain that could be relieved by electrode deactivation.

Criteria for device failure included abnormal implant performance and failed integrity test despite a correct electrode position verified by radiography. Cases of “soft device failure” in which the results of integrity testing appeared normal were considered either a performance decrement (if the problem could only be rectified by reimplantation) or a medical problem (if reimplantation and electrode deactivation were ineffective).

Explanted devices were sent to the manufacturer for analysis of the specific cause of failure. The causes included impact failure, breach of the hermetic seal, electronic failure, defective electrode array, and unknown causes. The number and the causes of reimplantations were analyzed according to follow-up duration. The number of functional implants was calculated and compared with the total number of cochlear implantations performed for a specific duration of follow-up to produce the device survival rate for each follow-up interval. Subsequently the number of functional implants was compared with the total number of cochlear implants over all to determine the cumulative survival rate. The number of complications was analyzed as a function of the device model.

RESULTS

Analyzing the combined causes of complications occurring after cochlear implantation, we found that the overall rate of complication was 16% (79 of 500) in the total population, 15% in children, and 18% in adults. Specifically, the rate of minor and major complications was 5.6% and 3.2%, respectively, and the rate of reimplantations was 7.2%.

COMPLICATIONS REQUIRING COCHLEAR REIMPLANTATION

Cochlear reimplantation was performed in 36 cases (7.2% of patients) (Table 2). The most common cause of reimplantation was device failure, which occurred in 30 cases (83%).

An examination of the specific reasons for device failure revealed that electronic failure was involved in 13 cases (43%), failure of the hermetic seal in 4 cases (13%), a defective electrode array in 4 cases (13%), impact failure in 3 cases (10%), and unknown causes in 6 cases (20%). Interestingly, 4 devices failed shortly after minor head traumas (1 electrode array failure, 1 impact failure, and 2 failures of unknown cause), and 3 children displayed retroauricular pain as the primary manifestation of device failure. The pain was relieved after reimplantation. However, the rate of device failure did not differ between the adult and the pediatric population. All reimplantations prompted by original device failures were performed on the ipsilateral side and caused complications in only 1 adult, for whom only a partial insertion was achieved. Fifteen of 30 patients received a device upgrade at the time of reimplantation. Speech discrimination performance levels (open-set phonetically based kin-
dertten [PBK] monosyllabic word scores) 6 months after reimplantation were comparable with those usually observed after an initial implantation (35 of 36) with the exception of the 1 patient for whom the electrode had been only partially inserted. The length of time from the date of initial implantation to implantation of the second device and the specific rates of device failure according to type of cochlear implant are shown in Figure 2.

A decrease in performance was observed in 2 postlingually deafened adults. The first had a history of meningitis and a totally ossified cochlea. This patient originally received a Nucleus CI10 + 11 implant (PBK word score, 20% with the implant) and on reimplantation received a Nucleus auditory brainstem implant (ABI). The other patient, who had neurofibromatosis type 2 (PBK word score, 60% with the implant), demonstrated a decline in performance 11 years after the initial implantation and so received a Nucleus ABI on reimplantation. Two years after the reimplantations, both patients could detect environmental sounds but were unable to discriminate speech without lipreading (PBK word score, 0%).

Infections unresponsive to intensive medical treatment and requiring reimplantation occurred in 3 cases (0.6%). All reimplantations were performed on the contralateral side approximately 1 to 3 months after the infection had cleared. All of these infections were a result of skin flap breakdown and subsequent exposure of the receiver through the skin. None of these patients experienced complications after reimplantation. The rate of skin-related infection was similar in the adult and pediatric populations.

REVISION SURGERY WITHOUT REIMPLANTATION

Revision surgery without cochlear reimplantation was performed in 15 patients (3%). The occurrence of revision surgery was slightly higher in children (Table 3). Explantation without subsequent reimplantation was necessary in 4 cases of infection: 1 adult who had many medical problems; 2 children with low speech perception scores before infection and who refused to receive a second implant; and 1 child who still derived some benefit from a conventional hearing aid on the nonimplanted side. In all 4 cases, infection was related to a skin disease that could not be resolved by drainage, receiver relocation, antiseptic irrigation, and intravenous antibiotics.

In 2 children with acute mastoiditis, infection was a complication of acute otitis media (Streptococcus pneumoniae). Both cases were successfully treated by surgical drainage of the pus and intensive antibiotic treatment (follow-up duration, 12 years and 4 years).

Three cases of cholesteatoma were observed. One child presented 4 years after the initial surgery with an acquired cholesteatoma caused by skin migration through a canal wall defect related to electrode fixation with Dacron (Invista Inc, Wichita, Kansas) to the canal wall. (This external canal wall Dacron ligation technique was used only in the first 30 implant procedures in our series. In subsequent Nucleus CI122 and CI124 implantations, the electrode array was secured to the buttress with nonresorbable sutures.) Two adults also presented with a recurrent cholesteatoma following previous cholestea-

<table>
<thead>
<tr>
<th>Table 2. Complications Requiring Reimplantationa</th>
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<tbody>
<tr>
<td><strong>Reasons for Reimplantation</strong></td>
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<tr>
<td>Infection requiring contralateral reimplantation—skin infection</td>
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<tr>
<td>Device failure</td>
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<tr>
<td>Electronics</td>
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<tr>
<td>Electrode array problem</td>
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<tr>
<td>Hermetic seal failure</td>
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<tr>
<td>Impact failure</td>
</tr>
<tr>
<td>Unknown cause</td>
</tr>
<tr>
<td>Electrode shifting—upgrading device during the same surgery</td>
</tr>
<tr>
<td>Performance decrement requiring ABI</td>
</tr>
<tr>
<td>Totally ossified cochlea, meningitis</td>
</tr>
<tr>
<td>Patient with NF2</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Abbreviations: ABI, auditory brainstem implant; NF2, neurofibromatosis type 2.

a All data are reported as number (percentage) of patients within the column category.

<table>
<thead>
<tr>
<th>Table 3. Indications for Revision Surgery Without Cochlear Reimplantationa</th>
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<tbody>
<tr>
<td><strong>Surgical Indication</strong></td>
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<tr>
<td>Infection with explantation without reimplantation—skin infection</td>
</tr>
<tr>
<td>Infection requiring surgical drainage—consequences of acute otitis media</td>
</tr>
<tr>
<td>Cholesteatoma</td>
</tr>
<tr>
<td>Magnet displacement</td>
</tr>
<tr>
<td>Receiver displacement</td>
</tr>
<tr>
<td>Vestibular insertion—early surgical correction</td>
</tr>
<tr>
<td>Electrode shifting—surgery for securing the electrode array around the buttress</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

a All data are reported as number (percentage) of patients within the column category.
toma removal surgery. These 3 patients were successfully treated with revision surgery (with follow-up of 13, 4, and 2 years, respectively).

Receiver repositioning was performed on 2 children and 1 adult to correct receiver displacement, which occurred despite measures taken to secure the device. In all 3 cases, regardless of the type of incision used (minimal posterior skin or enlarged endaural approach), the receiver was fastened in its bony bed using a nonresorbable monofilament suture. In both children, previously operated on through a minimal posterior skin incision, receiver displacement occurred relatively quickly, within 3 to 6 months after surgery. With the adult patient, receiver displacement occurred 12 years after the initial implantation had been performed through an enlarged endaural approach. No further displacement was observed after repositioning surgery in all cases. One child had a magnet migration requiring revision surgery following minor head trauma.

One case of electrode shifting was observed 3 years after implantation in a young child who received a straight electrode implant. This was corrected by surgically repositioning the electrode into the cochleostomy and fastening the electrode array at the buttress with a suture. One case of erroneous vestibular positioning during surgery occurred with a Clarion 1.2 device. No cochlear anomaly had been observed on preoperative magnetic resonance imaging, and the patient displayed no vestibular adverse effects after the first procedure. The diagnosis was made by postoperative radiography, and corrective surgery was performed the next day with no apparent complications.

EARLY POSTOPERATIVE COMPLICATIONS

Early postoperative complications occurred in only 3 cases (0.6% of patients, all children) (Table 4). These included 1 case of scalp hematoma (0.2%), 1 case of transient facial palsy (0.2%), and 1 case of atlantoaxial subluxation (0.2%). All cases were treated successfully with conservative medical treatment. The case of transient facial palsy (House Brackmann grade IV) occurred as a consequence of abnormal facial nerve warming in its mastoid segment during posterior tympanotomy drilling. Full recovery was achieved within 15 days after treatment with general corticosteroids.

MEDICAL COMPLICATIONS

In our series, 25 cases of medical complications occurred and were treated (5%) (Table 4). These included 7 cases of persistent vertigo or unsteadiness (1.4%), 6 cases of facial stimulation (1.2%), 3 cases of physical discomfort (0.6%), 4 cases of debilitating tinnitus (0.8%), and 5 cases of otitis media (1%) identified during follow-up visits.

Vertigo or unsteadiness lasting more than 2 weeks postoperatively was observed in 7 cases: normal computed tomographic scan in 5 cases; Mondini dysplasia in 1 case; and common cavity in 1 case. In all children, the vertigo resolved after 1 month. In adults, some degree of unsteadiness persisted even after a vestibular rehabilitation program. Six patients displayed facial stimulation, which was successfully alleviated through deactivation of between 1 and 5 electrodes. Facial, neck, or retroauricular pain was observed in 3 cases. As with facial stimulation, this pain was eliminated through electrode deactivation. Implantation provoked debilitating tinnitus in 4 patients. Neither medical treatment nor receiver deactivation could alleviate the tinnitus in these cases. Otitis media cases were managed conservatively with systemic oral antibiotics.

IMPLANT SURVIVAL RATES

We studied the distribution of reimplantations and revision procedures according to follow-up duration (Figure 2) and found that 24% of reimplantations due to device failure or infection occurred before 2.5 years, and 72% of them before the fifth year of implantation. All reimplantations prompted by medical and surgical reasons occurred within 4 years. The longer the follow-up, the smaller the number of reimplantations, most of which were related to device failure.

In addition, we analyzed the number of functioning implants by the duration of follow-up to assess the reliability of each device (Figure 3). For the Nucleus devices, these rates increased and remained stable until the 9- to 12-year follow-up interval, when a slight decrease was observed for the Nucleus CI22 device. For the Clarion devices, the reliability of Clarion 1.2 and Clarion CII was lower than the new generation of Clarion device (HF90).

Cochlear implantation is a surgical procedure performed routinely in numerous centers around the world. Expanding the criteria for cochlear implantation leads to a significant increase in the number of patients using such devices. It is now important to evaluate the efficiency and the safety of such procedures to improve them and to reduce the incidence of complications.

In our series, the overall rate of complication was 16% during a maximum follow-up period of 18 years. The rate of major complications (3.6%) was lower than that found in previous studies (18.3% and 11.8% excluding device failures3). However, if we include device failure as a major complication, this rate becomes comparable (13.8%) to that described elsewhere.4 4 Moreover, our rate of re-

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**Table 4. Complications Encountered in the Study Population**

<table>
<thead>
<tr>
<th>Complication</th>
<th>Adults (n=178)</th>
<th>Children (n=322)</th>
<th>Total (N=500)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early surgical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facial palsy</td>
<td>0</td>
<td>1 (0.3)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Scalp hematoma</td>
<td>0</td>
<td>1 (0.3)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Atlantoaxial subluxation</td>
<td>0</td>
<td>1 (0.3)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Medical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vertigo and/or unsteadiness</td>
<td>4 (2.3)</td>
<td>3 (0.9)</td>
<td>7 (1.4)</td>
</tr>
<tr>
<td>Facial stimulation</td>
<td>4 (2.3)</td>
<td>2 (0.6)</td>
<td>6 (1.2)</td>
</tr>
<tr>
<td>Pain</td>
<td>3 (1.7)</td>
<td>0</td>
<td>3 (0.6)</td>
</tr>
<tr>
<td>Tinnitus</td>
<td>4 (2.3)</td>
<td>0</td>
<td>4 (0.8)</td>
</tr>
<tr>
<td>Otitis media</td>
<td>0</td>
<td>5 (1.6)</td>
<td>5 (1.0)</td>
</tr>
<tr>
<td>Total</td>
<td>15 (8.4)</td>
<td>13 (4.0)</td>
<td>28 (5.6)</td>
</tr>
</tbody>
</table>

*All data are reported as number (percentage) of patients within the column category.*
implantation is similar (7.2%; 36 of 500) to those observed in other studies.6

ANALYSIS OF REIMPLANTATIONS

The most common reason for reimplantation is device failure (30 of 36 reimplantations). The rate of device failure in our survey was in accordance with that found in the literature.9,13 If we look more specifically at the number of reimplantations by follow-up duration, we can see that most reimplantations occurred within 5 years of implantation (72%). According to Maurer et al,11 who reported the longest duration of follow-up, reimplantations were mainly observed in the initial years after the initial implantation. Receiver leakage, short circuits in the electrode array, and current leakage are common problems in early reimplantations, while unknown causes of device failure and progressive dysfunction of the electrode array are common in late reimplantation, as has been reported elsewhere.2

As shown in Figure 3, cochlear implant reliability appears to improve with more recent devices, such as the Nucleus CI2412 or Clarion HF90K model, although long-term follow-up will be mandatory before any definite conclusions can be drawn. In our series, as in others,9 reimplantation was a reliable and safe procedure: only 1 complication occurred among the 30 procedures performed. In most patients, speech perception was similar after cochlear reimplantation, as has been reported elsewhere.4,13 This was not the case with ABI reimplantation. None of the patients achieved open-set word recognition with the ABI device without lipreading, but they were able to detect environmental sounds, as is frequently observed in patients wearing ABI devices. Results from the

ABI devices did not differ between patients with and without NF2 (cochlear ossification) contrary to the findings of a previous report by Colletti.14

SURGICAL COMPLICATIONS

Infection is a major concern in cochlear implant surgery. The overall rate of infections reported in the literature ranges from 1.7% to 16.6%.15,16 In our survey, the rate of infection was 1.8%. When the infection was a complication of acute otitis media, medical and surgical treatments were successful. On the other hand, explanation was always performed in cases of skin flap infection, even after intensive medical or surgical treatment. Skin-related problems caused by infection, hematoma, or other abnormality were encountered using either a small postauricular incision or an enlarged endaural surgical approach. No cases of meningitis were observed in our series, and the incidence is also very low elsewhere.17 All of our patients who received their implants after 2000 were vaccinated against Haemophilus influenzae and S pneumoniae.

Displacement of the receiver occurred in 3 of 500 cases (0.6%). As reported elsewhere, displacement was a consequence of minor head traumas.6,13 Repositioning the receiver firmly in its seat is usually sufficient to prevent further displacement. One additional complication, also following minor head trauma (also as described elsewhere), was a case of magnet displacement observed in a young girl. Misdirected implantation occurred in 1 case: even if uncommon, this potential misrouting highlights the usefulness of postoperative and preoperative radiography to provide early correction.19

Other surgical complications related to cochlear implantation were cholesteatoma, facial palsy, and atlantoaxial subluxation (occurring in 3 patients, 1 patient, and 1 patient, respectively, of 500 cases). Cholesteatomas developed 4, 5, and 8 years after cochlear implantation. In our series, cholesteatoma occurred later than in other reports.6 Facial palsy remains a rare and transient complication of cochlear implantation (1 of 500; 0.002% in our series; 0.33%6 and 2.22%17 in other studies). As demonstrated elsewhere, facial palsy is usually of late onset and moderate, implying that the underlying cause is an inflammatory and edematous mechanism rather than direct trauma during drilling.6 Finally, 1 case of atlantoaxial subluxation occurred in a 2-year-old girl after surgery. This complication is the first to be reported in this type of surgery (1 of 428 pediatric cases; 0.23% in our series), although it has been previously reported with other otoplastic procedures20 and is a direct consequence of excessive rotation of the head during the procedure. The surgeon must be aware of these types of complications and handle the child’s head carefully during the procedure.

MEDICAL COMPLICATIONS

Pain (cephalalgia, shocks, burning, itching, and retroauricular pain), facial nerve stimulation, and vertigo were experienced by some patients. The physical discomfort resolved in 5 cases after electrode deactivation, and only 2 patients required reimplantation to eliminate it. Pain seems to be the consequence of device malfunction because no
residual discomfort could be observed after proper technical management. Similarly, facial nerve stimulation (1.2% in our series, 1%-14.9% in others\textsuperscript{21,22}) was alleviated by electrode deactivation,\textsuperscript{21} except in 1 case in which abnormal facial nerve stimulation could not be eliminated even after reimplantation. Vertigo presented a different problem. Indeed, immediate postoperative vertigo or unsteadiness is a common adverse effect of cochlear implantation.\textsuperscript{23} Filipo et al\textsuperscript{24} reported a mild form of postoperative vertigo episodes in 12% of patients.\textsuperscript{24} However, recurrent vertigo or unsteadiness appeared less frequently in our survey. In our experience, these types of vestibular dysfunction are often misdiagnosed and should be always investigated after surgery, especially in children. As with vertigo, the underlying cause of tinnitus following cochlear implantation is still unknown. While some patients have been cured of their tinnitus after implantation, as described previously,\textsuperscript{25} in our experience, debilitating tinnitus occurred in 4 of 428 patients (0.93%), and their conditions did not improve after electrode deactivation. None of these patients had demonstrated any symptoms preoperatively.

**COMPLICATIONS IN THE PEDIATRIC VS ADULT POPULATION**

Interestingly the rate of complications as a whole was not significantly different between the adult and pediatric populations in this survey. Some authors have reported higher rates of complications in children.\textsuperscript{1} However, we observed a different distribution of complication rates between the pediatric and adult groups. Specifically, the rates of device failure, magnet displacement, and postoperative oitis media tended to be greater in the pediatric group.

In conclusion, cochlear implantation is an effective and reliable procedure to restore auditory sensation in profoundly deafened patients. The results of this survey spanning a 17-year period confirm the improved device reliability of more recent generations of cochlear implants. Despite this improvement, however, revision surgery may eventually be required to solve certain technological, mechanical, and infection problems. Soft and hard device failures are observed in about 6% of cases, and while the rate of complication is similar between the pediatric and adult population, the distribution of specific complications differs between these groups. Patients and practitioners should be aware that one or more reimplantations may occur during a lifetime. Nevertheless, reimplantation remains a safe, effective, and accepted procedure allowing for technological upgrading.

Submitted for Publication: August 24, 2007; final revision received March 12, 2008; accepted March 16, 2008.

**Correspondence:** Frederic Venail, MD, Department of Otorhinolaryngology, University Hospital Gui de Chauliac, 80 Avenue Augustin Fliche, 34295 Montpellier, France (f-venail@chu-montpellier.fr).

**Author Contributions:** Dr Venail had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Venail and Mondain. Acquisition of data: Venail, Sicard, Piron, Arteries, Uziel, and Mondain. Analysis and interpretation of data: Venail, Levi, Arteries, and Mondain. Drafting of the manuscript: Venail and Levi. Critical revision of the manuscript for important intellectual content: Sicard, Piron, Levi, Arteries, Uziel, and Mondain. Statistical analysis: Venail. Administrative, technical, and material support: Sicard, Piron, Levi, Arteries, and Uziel. Study supervision: Venail and Mondain.

**Financial Disclosure:** None reported.

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