Int. Adv. Otol. 2012; 8:(2) 244-252

ORIGINAL ARTICLE

Complications and Their Management Following Pediatric Cochlear Implantations

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Objective: The purpose of this study is to retrospectively review the complications of cochlear implantation in pediatric patients.

Materials and Methods: The study included 344 pediatric patients (younger than 18 years of age) who had undergone cochlear implantation surgery between September 2005 and May 2010. The patients were regularly monitored, with a mean follow-up period of 31 months (ranging from 9 to 66 months). All of the operations were performed by the same surgeon (YG).

Results: 13 major (3.8%) and 12 minor (3.5%) complications were observed. Major complications included local flap failure (3 patients), soft device failure (2 patients), magnet displacement following head trauma (2 patients), electrode displacement to vestibule (1 patient), reference electrode migration to dura mater with facial paralysis (1 patient), electrode extrusion from the external ear canal (1 patient), hard device failure after trauma (1 patient), electrode breaking into the mastoid cavity (1 patient) and bleeding from the sigmoid sinus during the operation (1 patient). The implants were removed from 8 of the patients (2.3%) and re-implanted in all of them (2.3%). Minor complications included vestibular symptoms (4 patients), seroma formation (3 patients), recurrent acute otitis media(3 patients), hematoma following head trauma (1 patient), and seizure (1 patient).

Conclusion: Power of the study is that all the operations were performed by a single surgeon and sample patients group was homogenous. When compared with the other methods reported, 3.8% major and 3.49% minor complication rates were lower than expected. These complications should be kept in mind during the CI surgery and the surgeon should be work to avoid them and be familiar with them enough to treat them.

Submitted : 4 February 2012 *Accepted : 3 May 2012*

Introduction

In the last quarter of the 20th century, cochlear implantation (CI) marked an era in the rehabilitation of profound and severe hearing loss. Along with the advancement in implant technology and surgical experience, as patients benefited from implantation, CI has gradually gained widespread acceptance all around the world. Although the number and severity of complications were reduced with growing surgical experience, rare and new complications were encountered with increasing numbers of implantation. Obviously, elimination of complications has become a major objective for each surgeon.

The aim of this study is to present the complications of 344 consecutive pediatric cases of CI. Complications occurring during the follow-up were systematically reviewed and their treatments reported.

Materials and Methods

Three hundred and forty-four pediatric patients who had CI surgery from September 2005 to June 2010 were included in the study. All of the operations were performed by the same surgeon (YG) in two different medical centers. Demographic data of the patients, etiology of the hearing loss, the time of occurrence of complications and the necessity of revision surgery

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were recorded. The patients who were referred from another center in order to undergo revision surgery were not included in the study.

Beginning in September 2005, CI was initially performed via the standard surgical technique, which involved mastoidectomy, posterior tympanotomy and drilling of the calvarium for the receiver package. Since July 2008, stabilization of the internal receiver stimulator (IRS) was achieved by applying the subperiosteal temporal pocket technique without drilling the calvarium[1] . Unilateral CI was performed on all of the patients. Unless a restrictive inner ear anomaly was present, the CI was implanted on the side the patient used his/her hand.

Complications were defined as "major" when they resulted in failure of the implant, revision surgery and/or re-implantation. "Minor complications" were defined as those not necessitating re-operation. Even in cases where surgical intervention was needed, the implant was not threatened during the minor complications.

Results

Three hundred and forty-four pediatric (190 male, 154 female) patients, from 11 months to 17 years of age (mean age 3.5±2.8 years, mean±SD) were included the study. The follow up period ranged from 9 to 66 months (mean 31±14 months, mean±SD). Prelingual hearing loss was observed in 331 patients, whereas only 13 patients were diagnosed with postlingual hearing loss. While CI was performed via subperiosteal temporal pocket technique in 178 of the patients, the standard technique was applied for 166 patients. Four different cochlear implant brands were utilized in the study. Clarion device (Advanced Bionics Corporation, Valencia, California) was used in 116 of the patients, Nucleus (Cochlear Limited, Lane Cove, Australia) in 114 patients, Digisonic (Neurelec, Vallauris, France) in 60 and MedEl (Innsbruck, Austria) was used for the remaining 54 (Table 1).

Table 1. Patients' demographics

	No of patients (%)
Gender	
Male	190 (55.2%)
Female	154 (44.8%)
Type of hearing loss	
Pre-lingual	332 (96.2.5%)
Post-lingual	13 (3.8%)
Etiology of the hearing loss	
Congenital	313 (90.98%)
Viral infectious	13(3.78%)
Meningitis	9 (2.62%)
Progressive	6(1.74%)
Trauma	1(0.29%)
Metabolic	1(0.29%)
Sudden hearing loss	1(0.29%)
Surgical Technique	
Subperiosteal Temporal Pocket Technique	178 (51.7%)
Standard Technique	166 (48.3%)
Brand of device	
Nucleus	114 (33.1%)
MedEl	54 (15.7%)
Clarion	116(33.7%)
Digisonic	60 (17.4%)

The majority of the patients were diagnosed as having non-syndromic, congenital sensory-neural hearing loss (90.1%). The remaining known etiologies of hearing loss were viral infection (3.8%), meningitis (2.6%), progressive hearing loss (1.7%), trauma (0.3%), metabolic disease (0.3%) and sudden hearing loss (0.3%).

Complications occurred in 25 of the patients (7.3%), 13 of them were major complications (3.8%) and 12 were minor (3.5%). An intra-operative complication was seen in 1 patient while the others were postoperative.

Nine out of 13 major complications were observed in the standard technique group, whereas only 4 major complications developed in the sub-periostal temporal pocket technique group. All of the local flap failures were observed in the standard technique. In two of the patients, magnet displacement was observed; one of them was re-operated with the standard technique and the other with sub-periostal temporal pocket technique.

Major complications

Major complications developed in 13 patients (3.8%). These were: local flap failure (3 patients), magnet displacement following head trauma (2 patients), soft device failure (2 patients), electrode misplacement to vestibule (1 patient), reference electrode migration to dura mater with late facial paralysis (1 patient), electrode extrusion from external ear canal (1 patient), electrode breaking in the mastoid cavity (1 patient), hard device failure after trauma (1 patient) and sigmoid sinus bleeding (1 patient). In 8 of the patients the implants were explanted (2.3%) and in all of them, a re-implantation was performed (2.3%) (Table 2).

Table 2. Major complications

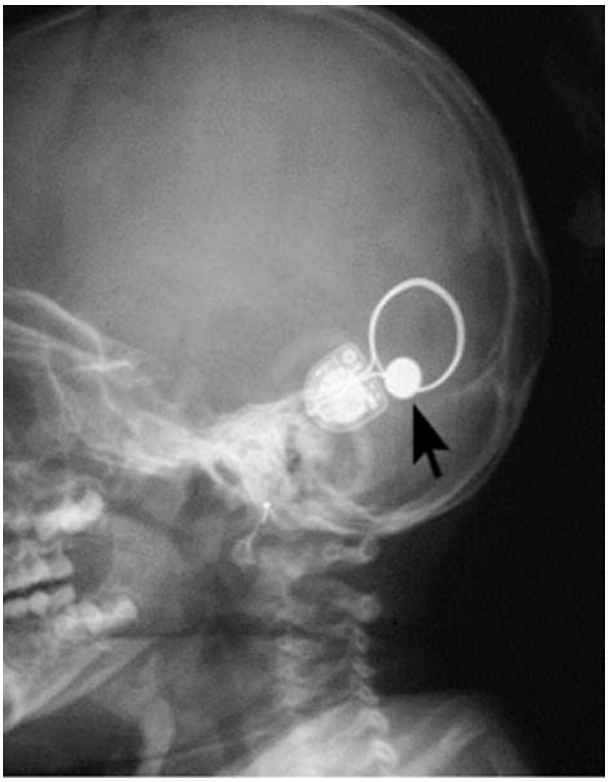
Complication	Complication time after CI	No of patients	Brand of implant	Management strategy
Magnet displacement	6 m, 1 m	2	Nucleus, Nucleus	Magnets were replaced without changing the implants
Electrode misplacement	–	1	Clarion	Electrode was inserted to cochlea through the new cochleostmy without changing implants
Soft device failure	2 m, 13 m	2	Nucleus Med-El	Changed the implants
Local flap failure	6 m, 6 m, 2 y	3	Nucleus, Nucleus, Digisonic	The implants were removed in all patients; a new implant was fitted on the opposite site in one patient; the implants were fitted on the same ear in other two patients.
Electrode cable extrusion to ear canal	1 y	1	Nucleus	Defect of the ear canal was repaired with an auricular cartilage graft.
Electrode cable break	6 m	1	Nucleus	Changed the implant
References electrode migration to dura mater with facial paralysis	3 y	1	Digisonic	The implant was changed a new one.
Aberrant sigmoid sinus bleeding	Intraoperative	1	Med-El	The operation was postponed. Three months later the implant fitted on the opposite ear.
Hard device failure	1 y	1		Changed the implant
Total		**13**		

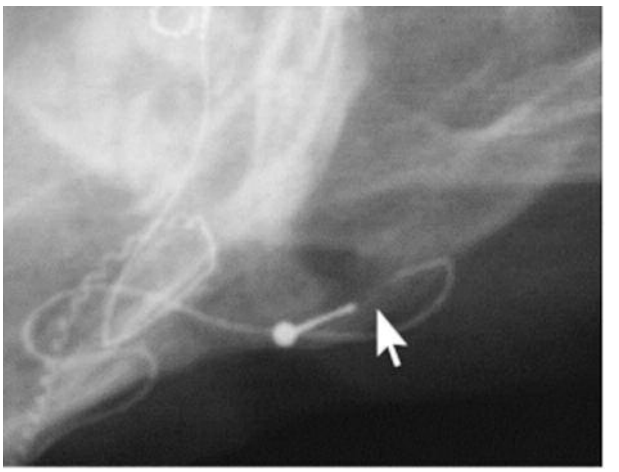
Local flap failure occurred in 3 patients. The implants were removed in all patients; a new implant was fitted on the opposite site in all of them. The first patient had a genetic skin disease, such as ichthyosis (Figure 1a, 1b). In the second month after the implantation, an inflammation occurred on the skin covering the implant. Despite appropriate medical therapy, exposition of the implant could not be avoided, and in the sixth month after the implantation, the implant was removed and re-implantation was performed. In the second case, 6 months following the CI, a local skin reaction developed and the implant was extruded. After four unsuccessful revision surgeries, the implant was eventually explanted and re-implantation was performed on the same ear at the following 5 months (Figure 2). The last patient had local skin reaction 2 years after the CI operation, the implant was also explanted and re-implantation was performed on

opposite side. All the patients use their devices without problem.

Magnet displacement occurred in 2 patients after they suffered traumas to the head. Lateral cranial x-ray revealed that the magnets were displaced and that the tip of the reference electrode was broken (Figure 1a, 1b). In the revision surgery, the magnets were replaced to original positions in both patients without implants failure (Figure 1c).

Electrode misplacement occurred in a single patient. The electrode was inserted into the cochlea through the round window. However, the patient did not benefit from the implantation. A computed tomography (CT) scan showed that the electrode had been inserted into the vestibule (Figure 2). The electrode was taken out from the round window and inserted through the new cochleostomy window without implant failure.





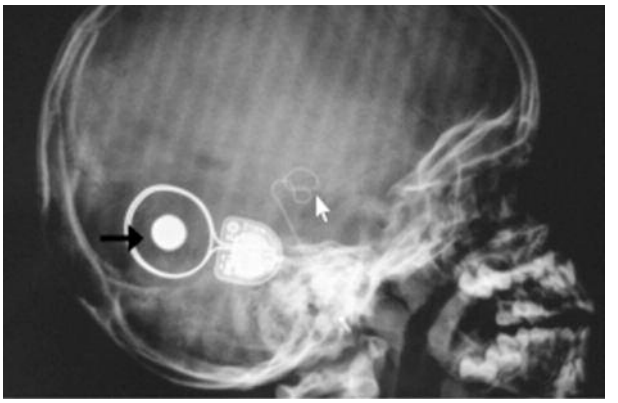


Figure 1. a) Lateral cranial x- ray after head trauma shows displaced magnet (black arrow), **b)** x-ray shows breaking the tip of the reference electrode (white arrow), **c)** Postoperative x-ray shows exposed wire of the reference electrode by peeling its insulator cover (white arrow) and fixed the magnet (black arrow)

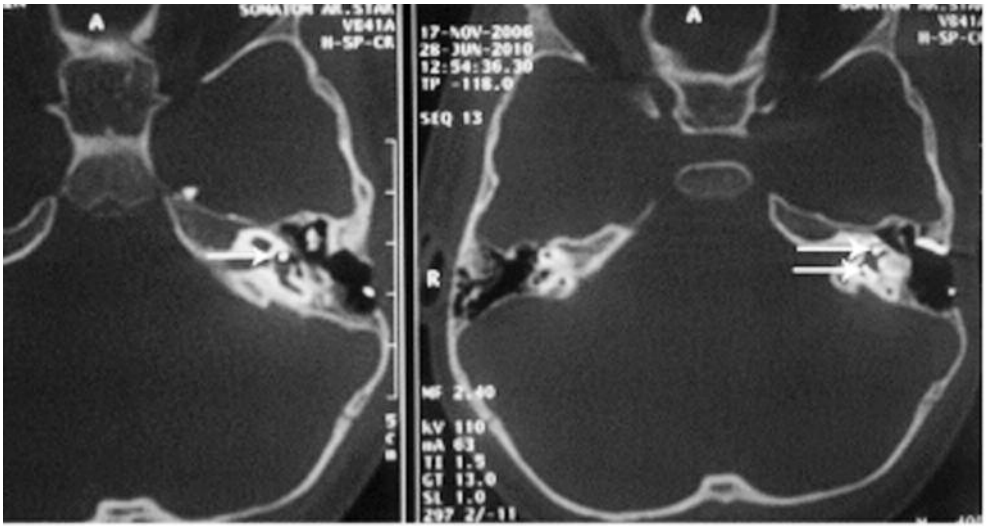


Figure 2. Axial plane computed tomography revealed misplacement of the electrode in the vestibule (white arrows).

Reference electrode migration to dura mater with facial paralysis occurred in a single patient. Three years after the CI, complete facial paralysis and vertigo occurred and did not improve despite medical treatment. Coronal and axial plane CT revealed that the reference electrode had migrated to dura mater (Figure 3a, 3b). Re-implantation was performed on the opposite ear. At 8th months following the revision

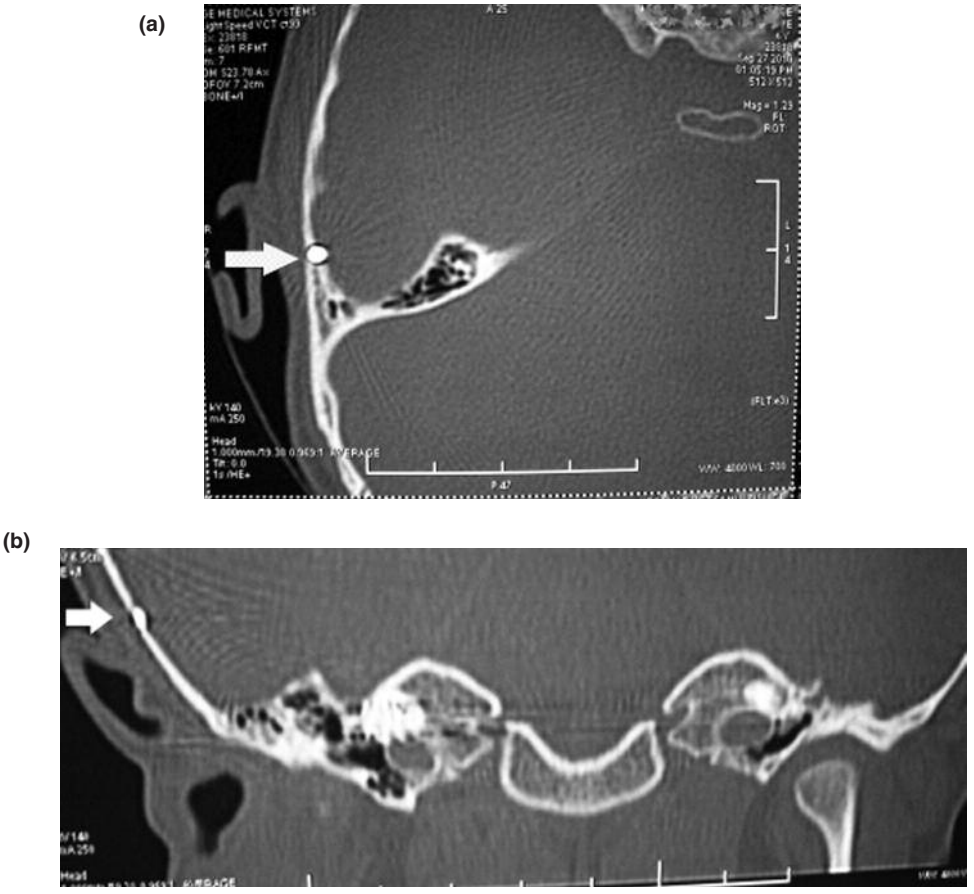


Figure 3. Computed tomography shows migration the reference electrode to dura mater, **a)** Axial plane (white arrow), **b)** Coronal plane (white arrow)

surgery the facial paralysis has improved as House Brackmann (HB) grade 2.

Electrode cable extrusion from the external ear canal defect occurred in one patient. The external ear canal defect was reconstructed with an auricular cartilage graft.

Breaking of the electrode cable in the mastoid cavity occurred in a single patient at the 6 months following the implantation. Radiological examination demonstrated that the electrode was broken in the mastoid cavity. Re-implantation was performed.

Profuse bleeding from an aberrantly located sigmoid sinus occurred in a 3 year old female patient just following the retroauricular skin incision. The operation was terminated and the opposite site was implanted 3 months later.

Minor Complications

There were 12 minor complications (3.49 %) which did not require revision (Table 3).

Table 3. Minor complications

Complication	No of patients	Management strategy
Seroma	3	Conservative treatment
Hematoma	1	Conservative treatment.
Vestibular symptoms	4	Medical treatment
Seizure	1	Medical treatment
Recurrent acute otitis media	3	Medical treatment
Total	**12**	

In 3 cases, postoperative seroma developed and in one case, a post-traumatic hematoma was observed one year after the surgery. All of these complications recovered without any surgical intervention.

In 4 cases, some vestibular symptoms emerged following implantation. In 2 of them, symptoms occurred immediately after the surgery; in one case at the 6th month and in the last case at the 2nd year of the surgery. In all cases medical therapy relieved the symptoms.

In another case, recurrent seizures appeared at the postoperative second year. Detailed neurological examinations and electrophysiological tests could not establish the definitive etiology. Fortunately with proper medical therapy, the patient ceased to have seizures.

In 3 cases, recurrent acute otitis media was observed; all of the cases responded to medical therapy and no surgical intervention was required.

Discussion

Cochlear implantation is generally a safe surgical procedure and has low complication rates. Anatomic variations, inner ear abnormalities, surgical technique and surgeon's experience are vital factors that affect the probability of complications. After the surgery, complications may still be encountered despite pre-awareness of anatomical differences, adequate preoperative evaluation, meticulous surgical technique and proper postoperative care. In the English literature, the rate of major complications is between 2.3-12.33%, with a minor complication rate of 4.4-16%[2-8] . Our overall complication rate was 6.4%, with minor complications accounting for 3.5%; major complications 2.9%.

Our re-implantation rate (2.3%) was also lower compared with in those of the literature (3.08-7.2%)[2,4,7] . Hardware/software failure was reported as the most common reason for re-implantation surgery[4,6,9-11]. Kim et al. reported that device failure was observed in 12 out of 720 patients as the most common complication of their series. The interval between the initial implantation and device failure was 28.2 months (range from 2 months to 5.4 years), and the majority occurred in the first 24 months after the surgery[6]. Sorrentino et al reported 7.6 years of mean

time for device failure in children[9]. In our series, soft and hard device failure was observed in 3 patients (0.87%). This low ratio could be attributed to the improvement in the device technology [12] as well as the comparatively short follow-up period, since in this study, our maximal follow up period was 5 years.

Magnet displacement is a rare complication. It was reported following head trauma and in the presence of a magnetic field interaction like that of a magnetic resonance imaging device [2,6,13-18]. In parallel with the literature, all of our magnet displacement cases were observed with implants including a removable magnet. The removable magnet was deliberately designed so that it could be extracted in case of an operation involving magnetic field interaction such as MRI. However, this design gave rise to the magnet's being easily displaced after a head trauma or entering a magnetic field. Indeed, the magnet displacement of our 2 patients occurred after minor head traumas. In our opinion, the implant with removable magnet should be redesigned to prevent coincidental magnet displacement.

Electrode misplacement is an extremely rare complication of CI. The tip of the electrode may turn in to the vestibule due to abnormalities of the cochlear basal turn, inappropriate cochleostomy and soft electrode tip[19]. Postoperative X-ray may not be suitable for the definitive diagnosis. If vertigo occurs following the implant usage, electrode misplacement should be kept in mind. Migration to the vestibule was firstly reported from Pau et al.[20]. Similarly other authors reported several cases with vestibular misplacement of the electrode [6,9,19]. On the other hand, cochlear-carotid interval varies widely between patients. The potential risk of carotid canal injury should be kept in mind in CI.[21] In our case, the patient didn't benefit from the surgery, so we performed a temporal bone CT and the electrode displacement to the vestibule was seen in the examination. Interestingly the patient had no vertigo. During the revision surgery a new cochleostomy was performed and the electrode was inserted there. Up to date, the hearing of the patient is well.

Dural migration of the reference electrode is an extremely rare condition and was firstly reported from Arnolder et al.[22]. Late facial paralysis may be seen following the cochlear implantation surgery [23,24]. Manipulations near the facial nerve and its branches may cause late facial paralysis due to viral reactivation. In our case, the reason of the paralysis was considered to be viral reactivation after surgery. Facial paralysis was treated with steroid and improved to HB 2 following 9th month of the paralysis.

Local flap failure may be the result of underlying skin problems such as psoriasis or wound healing difficulties like diabetes mellitus. Other factors that have been cited as causative factors include the type of incision used, the amount of tissue handling occurring during the procedure, revascularization of tissues due to excessive use of diathermy and the presence of biofilm, which are now thought to be responsible for many infective complications[25]. A large skin incision disrupting blood supply to the flap, overuse of electro cautery, local infection and biofilm formation may also cause late flap necrosis. Black et al, reported that they had no major complication with using small C incision, whereas Gerard et al, showed that classical retroauricular incision had fewer major wound complications than "C shaped incision".[26,27] The rate of local flap failure was the most common major complication and was reported as 1.55-3.3% .[2-4] On the contrary Kim et al. found fewer flap necrosis rate than the other authors, only three out of 720 patients (0.41%)[6]. The flap necrosis was the most requiring revision surgery in our series, but its rate was relatively less (0.87%). The wound infection can be reduced with a standard prophylactic antibiotic regime [28]. We routinely used a single dose of cefuroxime axetil intravenously during the operation, and postoperatively as well.

Nevertheless, in our opinion, surgical technique is the ultimate factor in prevention of local flap failure. Indeed, no local flap necrosis was observed in the sub-periosteal temporal pocket technique group, where only a small sub-periosteal pocket sized for the IRS was created on the temporal bone, and no drilling or suturing of the IRS was required. Because this

technique does not require a large post-auricular skin incision, the vascular supply of the flap does not deteriorate.

The electrode exposure from tympanic membrane was rarely reported in the literature [29,30]. Kim et al. reported in his series consisting of 720 patients, two cases, who had open mastoid cavity, of electrode guide exposure [6]. In our case, the electrode guide was extruded from the external ear canal in the first year after the surgery. We thought that during the first operation, an unnoticed bone defect of the external ear canal had caused the electrode extrusion to develop. In conclusion, in order to exclude a possible iatrogenic bony defect, the external ear canal should be inspected at the end of the CI surgery.

Unexpected bleeding from an aberrantly localized sigmoid sinus occurred in one patient. The bleeding began immediately after the skin incision. When considered retrospectively, it was evident that this abnormality had been overlooked during the evaluation of pre-operative imaging.

Complications that did not require revision were classified as minor complications. In the literature, the rate of minor complications was reported as 4.4-16%[2,4,6-8] . In our series, the rate of minor complications was 3.49%, which was also less than that reported in literature. All of the minor complications such as vertigo, seroma formation and recurrent acute otitis media were improved with medical treatment. Especially recurrent acute otitis media in patients with anatomic abnormalities can give rise to meningitis.[31]

Conclusion

Power of the study is that all the operations were performed by a single surgeon and sample patients group was homogenous. In our patient group, overall complication rate was less than that of the literature; however, rare complications such as magnet displacement, electrode misplacement, late facial paralysis and reference electrode migration to the dura mater appeared. On the other hand, the low soft device failure rate in our study can be attributed to the progress in the device technology. The complication rate of cochlear implantation may be decreased with a careful preoperative evaluation, delicate surgical technique and appropriate postoperative follow-up. These complications should be kept in mind during the CI surgery and the surgeon should be work to avoid them and be familiar with them enough to treat them.

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