## Original Study

# Assessment of Cochlear Implant Revision Surgeries in a Cohort of 802 Patients

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**Objective:** To assess the etiology, demographics, rates and outcomes of revision surgeries, and device survival rates after cochlear implantation.

Study Design: Retrospective case review.

Setting: Tertiary Otology & Neurotology center.

Patients: Cochlear implantees who received revision surgeries after implantation

**Interventions:** Any surgical intervention, performed due to device failure or the major complications of cochlear implantation.

Main Outcome Measure: Medical records of the patients who received cochlear implants (CIs) between July 2002 and March 2018 were reviewed retrospectively regarding postoperative complications. Demographic data, device survival rates, and causes of revisions were recorded.

**Results:** Totally, 924 implantations were performed in 802 patients. Eighty one (8.7%) of them underwent 102 revision surgeries. The most common causes of revision surgeries

were device failures and flap related problems which were seen in 28 and 18 patients, respectively.

Overall CI survival rate was 91.9% in a 10 years period, which remained almost stable after 10 years. Although age was not found to be related with device failure (p = 0.693), device loss rates were significantly higher in adult implantees than children (p = 0.006).

Conclusion: Device failure seems the most common cause of revision. The revision surgeries are usually safe and help to resolve the problem although flap problems are the most difficult to treat and may necessitate multiple revision surgeries. The device failure rate may reach to a plateau after 6 years. Overall CI survival rate exceeds 90% in 10 years period, and then remains stable. **Key Words:** Cochlear implant—Cochlear implant complication—Cochlear implant revision.

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Cochlear implantation is a safe procedure with a relatively low incidence of complications (1,2). In parallel to increase in the number of implantations during the last two decades and the revision surgeries has increased as well. The cumulative revision rate in cochlear implantees is estimated to be about 1% per year (3). The most common causes of revision surgeries are device failures, electrode migrations, and flap related problems (4–6). Revision surgeries are safe and the results are satisfying in most of the cases (4,5). Some of the cases may require additional surgeries after revision, even explantation of the device may be considered as an option (5).

In this study, our purpose was to assess the etiology, demographics, rates and outcomes of revision surgeries, and device survival rates after cochlear implantation.

#### MATERIALS AND METHODS

Medical records of the patients who received cochlear implants (CIs) between July 2002 and March 2018 were reviewed retrospectively, and the data related to revision CI surgeries were recorded after ethical committee approval was obtained from the university. Device failures were evaluated according to the "European Consensus Statement on Cochlear Implant Failure and Explantation" (7). Soft failures which were managed without a surgical intervention like deactivating electrodes were not included in the revision calculations. The patients who had severe inner malformations were not included in the calculations in an attempt to obtain a standardized data to figure out the device survival and revision rates in a homogenous group of patients.

There were totally 802 patients who received 924 CIs. Their ages ranged from 9 months to 87 years (mean, 14.9 yr). There were 413 (51.5%) male and 389 (48.5%) female

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patients. Both ears were implanted in equal numbers (n = 462 for each side). There were 695 patients (75.2%) younger than 18 years of age.

The implantation was unilateral in 722, bilateral sequential in 49, and bilateral simultaneous in 31 patients. The patients were implanted with the devices of four different manufacturers, which were 387 Med-El (Med-El Corporation, Innsbruck, Austria) (41.9%), 386 Cochlear (Cochlear Corporation, Lane Cove, Australia) (41.8%), 138 Advanced Bionics (Advanced Bionics Corporation, Sylmar, CA) (14.9%), and 13 Oticon (Oticon Corporation, Copenhagen, Denmark) (1.4%) devices.

All primary and revision operations were performed by the same surgical team, using the following technique; an almost 4cm retroauricular incision, mastoidectomy, posterior tympanotomy, cochleostomy or round window insertion of the electrode array, and placement of the receiver-stimulator under the subperiosteal pocket without suture fixation.

The evaluations were performed in two main categories as follows; 1) device failures and 2) complication related explantations. Device survival rates were calculated both categories.

SPSS 20.0 software program (SPSS Inc., Chicago, IL) was used for the statistical analyses. Mann–Whitney U and  $\chi^2$  tests were used to compare quantitative and ordinal variables, respectively. Kaplan–Meier test was used to construct device survival and cumulative device failure curves. In all the tests, p < 0.05 was considered statistical significance.

#### **RESULTS**

Of 802 implantees, 81 (10%) underwent 102 (8.7%) revision surgeries for one or two ears. In 42 of 102 (41.1%) revisions, a new device was implanted due to device failure, infection, or surgical trauma to the device during revision. Of 81 revision patients, 47 (58%) were men and 34 (42%) were women. The revisions were performed on the right side in 41 and left side in 40 patients. Sex and side of implantation were not associated with revision rates (p > 0.05).

The mean duration of implant use was 63.8 months (ranged from 5 to 160 mo) after the primary implantation, and the mean duration of implant use was 44.3 months (ranged from 4 to 156 mo) after revision. The mean time spent between the primary and revision surgery was 1.6 months (ranged from 1 d to 113 mo).

The rates of revision surgeries in unilateral, bilateral sequential, and bilateral simultaneous implantations were 10, 12.2, and 9.7%, respectively, and were not significantly different (p = 0.875). That is, unilateral and bilateral sequential or simultaneous implantations were not associated with revision CI surgeries.

The revision rates were 7.9 and 12.4% in children and adults, respectively, which were significantly higher in adults than children (p = 0.041).

Of 81 revised patients, 17 (2.1%) underwent more than one revision surgeries. The cause of revision had a significant impact on the number of revision surgeries as the patients who had flap related problems and

hematoma were more likely to undergo multiple revision surgeries (p < 0.001). The patients who had cerebrospinal fluid (CSF) leakage, hematoma and misinsertion needed earlier revision surgeries (p = 0.03).

The most common cause of revision surgery was device failure, which was seen in 28 (3%) cases. There were three (0.3%) soft failures and 25 (2.7%) hard failures. Thirteen (1.4%) of the hard failures were caused by trauma. In 11 patients the cause was an external head trauma. Evaluation of the explanted devices revealed an iatrogenic trauma to the electrode array presumably due to traumatic insertion in two patients. Age and sex were not found to be a risk factor for a trauma related device failure (p > 0.05). In seven cases who had Cochlear CI512 (Cochlear Corporation, Lane Cove, Australia) devices, hermeticity was the cause of failure. In five cases impedances gradually increased and all electrodes failed in time. These soft failures manifested by facial stimulation, extreme sensitivity to sound and pain. All of the failed devices were explanted and replaced with a new one simultaneously. The mean onset of device failure was  $23.7 \pm 20.4$  months.

There were 18 (1.9%) cases who underwent a revision surgery due to flap related complications. In two cases, surgical hematoma drainage was performed in the early postoperative period, but recurrent seroma formation and flap infection resulted in flap necrosis. Four patients had an abscess in the receiver-stimulator area. Despite surgical drainage and antibiotic use, skin necrosis developed in these cases. No predisposing factor could be found in seven cases of flap dehiscence. The flap dehiscence occurred over the receiver-stimulator in 11 patients, at the inferior edge of the receiver stimulator in six patients, and at the superior edge near the antenna in one patient. Swab cultures were negative in nine cases, but Staphylococcus aureus and Pseudomonas aeruginosa were isolated in two and three patients, respectively. In four cases, coagulase negative staphylococci and diphteroids were isolated. However, these flap problems could not be managed with antibiotics and rotational flaps. In 16 of 18 cases the devices were explanted, and the contralateral ear was implanted with a new device.

Flap related problems were significantly more common in Oticon devices in this series (p = 0.001). The risk for device loss was significantly higher in cases of flap problems (p < 0.001). Flap related problems were more common in adults compared with children (4.4% and 2.5%, respectively) although the difference was not statistically significant (p = 0.217). Interestingly flap related problems were more common on the left side (p = 0.046).

Migration of the electrode array or receiver stimulator occurred in 16 (1.7%) cases. In four (0.4%) of them, both the receiver stimulator and the electrode array were displaced. In two (0.2%) of them who had simultaneous bilateral implantation the displacement was seen in the initially operated side. Statistical analyses did not reveal a higher risk of migration in bilateral simultaneous

implantations compared with bilateral sequential and unilateral implantations ( $p\!=\!0.611$ ). In one of the cases who had an extensive hematoma the day after the operation, the implant was found to be displaced in the enlarged subperiosteal pocket. In another case, progressive anterior displacement of the receiver stimulator resulted in electrode array migration with subsequent decrease in the implant performance. In these cases of migration, the same device could be repositioned and the electrode array could be inserted into the cochlea during revision surgery. No suture fixation was used in these revisions except for one case who had an enlarged subperiosteal pocket.

In 12 (1.2%) cases, there was only electrode array migration. One of these cases had radical mastoidectomy cavity with cholesteatoma recurrence. The electrode was extruded into the mastoid cavity. Cholesteatoma removal and subtotal petrosectomy with blind sac closure was performed, and a new device was implanted in the same ear at the same stage. One of the patients was referred with CSF otorrhea and the electrode array was found to be completely out of the cochlea. The electrode array was reinserted, and the round window was tightly sealed with fibrous tissues. The remaining 10 (1%) cases were referred with a gradually decreasing implant performance without known predisposing factors. Complete reinsertion of the electrode array of the same device could be achieved in nine of them, and the remaining one patient received a new device in the contralateral ear due to ossification in the previously implanted cochlea.

Hematoma was another common complication and eight (0.8%) of the cases required surgical intervention. The mean surgical drainage time was 8 days. In four patients drainage was done within 3 days following the first surgery. In five patients, incision, drainage, and compressed wound dressing was performed. In three cases, a drain was used because of the excessive hematoma and two of these were operated again due to hematoma recurrence. In recurrent hematoma cases a suction drain was placed into the mastoid cavity. In one of these cases a bone bed was drilled in the skull, and the device was fixed to the bone with sutures. The devices could be preserved in all cases.

CSF leakage was seen in four (0.4%) cases. These patients had normal cochlea and large vestibular aqueduct. Perilymph gusher occurred during the surgery in all of them, and round window was tightly packed with fibrous tissues after the implant electrode was inserted into the cochlea. The mean onset of CSF leakage was 11 days (ranged from 1 to 40 d). In three patients, the round window seal was ossified while there was a fistula in the oval window. In the remaining case, the implant was completely out of the cochlea and the leakage was through the round window. In all cases fibrous tissue sealing was performed and no lumbar drainage was applied after the revision surgery. None of devices were lost in these revisions.

There was an erroneous insertion of the electrode array in four (0.4%) patients as confirmed by postoperative

radiological evaluation. Two of them had severe vertigo after the operation. The electrode array was in the superior semicircular canal in one case, and the device was completely removed as requested by the patient. The implant was found to be in the lateral canal in the second case and was successfully inserted into the cochlea in the revision surgery. The other case of cochlear ossification with a drill out procedure, the implant was explanted and implanted to the contralateral ear. In one case with otitis media with chronic effusion, there was an erroneous implantation into the hypotympanic petrous cells, and implantation into the cochlea was achieved in the revision. Postoperative x-rays are used routinely to assess the position of the electrode rather than intraoperative x-rays. In cases of suspicion of electrode misplacement, a temporal bone tomography was obtained to confirm electrode position.

One of the cases was diagnosed with a cholesteatoma at the implanted ear 9 years after the first operation. Preserving the device, a subtotal petrosectomy with blind sac closure of the ear was performed. But the cavity was infected, and the blind sac closure was broken after 6 months. The patient underwent another revision and a new device was implanted, and the patient has been using the new implant for 3 years.

Intractable vertigo occurred in one patient. Postoperative computed tomography (CT) scan of the patient was unremarkable and the hearing performance with the implant was satisfying. Medical treatments and vestibular rehabilitation failed to control the vertiginous symptoms. After 1 year of follow up, a transmastoid labyrinthectomy was performed, preserving the device in place, and symptoms resolved completely.

The revision rate made a peak around 1 year post-implantation (11.3 mo), followed by a gradual increase and reached to almost a plateau after 3 years (Fig. 1). Overall revision surgery rates were 8.2, 8.8, 8, and 30% in the patients who had Med-El, Cochlear, Advanced Bionics, and Oticon devices, respectively. Although the overall revision rates in the patients who received an Oticon implant were higher, flap related problems were the causes of statistical significance in these patients (Table 1). There was no significant relationship between implant brands and failure rates (p = 0.455) (Fig. 2).

When device survivals were taken into consideration, there were 49 devices lost during the follow up. The most common causes of device losses were device failures which were seen in 28 (57.1%) patients, and flap related problems which were seen in 16 (32.6%) patients. The device failure rate gradually increased to 3.7% in the first 6 years and then reached to a plateau (Fig. 3).

Overall CI survival rate was 91.9% in a 10 years period, which remained almost stable after 10 years (Fig. 4). Although age was not associated with device failure (p = 0.693), device loss rates were significantly higher in adult implantees than in children (p = 0.006) (Fig. 5).

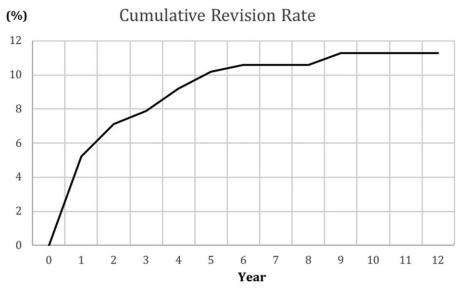


FIG. 1. Cumulative revision rates of all primary implantations.

### **DISCUSSION**

Device failure is the most common cause of revision implant surgery (3,8–10). In our series, 3% device failure rate corresponds to 34% of all revisions, which is

comparable with the literature (5,11,12). There may be hard and soft failures. The former is defined as the lack of communication between the external and internal hardware (13). Diagnosis of a soft failure is possible when

**TABLE 1.** Statistical analyses of the most common complications according to the devices.

Cause of Revision	Overall N=924		Med-El N = 387		Cochlear $N = 386$		AB N=138		Oticon N = 13		
	N	%	N	%	N	%	N	%	N	%	p Value
Device failure	28	3	16	4.1	10	2.5	2	1.4	0	0	0.455
Flap related problems	18	1.9	5	1.3	6	1.6	5	3.6	2	15.4	$0.001^{a}$
Migration	16	1.7	6	1.5	9	2.3	1	0.7	0	0	0.634
Hematoma	8	0.8	2	0.5	4	1	2	1.4	0	0	0.639
CSF leakage	4	0.4	1	0.3	3	0.8	0	0	0	0	0.574
Misinsertion	4	0.4	2	0.5	1	0.3	1	0.7	0	0	0.843

CSF indicates cerebrospinal fluid.

<sup>&</sup>lt;sup>a</sup>Indicates the statistical significance.

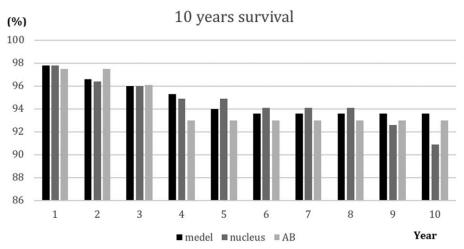


FIG. 2. Survival rates of the three most implanted CI brands, considering device failure. CI indicates cochlear implants.

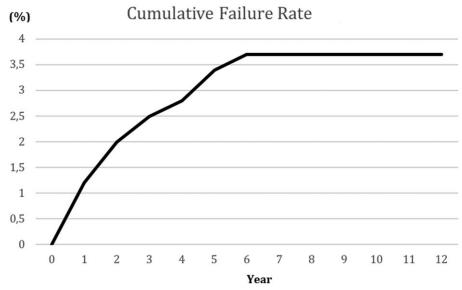


FIG. 3. Cumulative device failure rates.

hard failures and medical failures are excluded in the presence of a properly placed implant. Remission of symptoms after reimplantation with a new device also supports a previous soft failure (14). In the present study, device failure was related with a trauma in 42.8%, and the remainders were due to hard or soft failures. Hermeticity was the second most common cause of device failure (3,15). Unlike some previous studies, the overall failure rates were similar between different brands of implants (6,11,12).

Flap necrosis or dehiscence can occur due to chronic mechanical stress caused by the transmitter or infection of the implant site (16). These are the most annoying complications of cochlear implantation because solving the flap problem while preserving the device is hard to

achieve. A surgical intervention is usually required in the management (16–18). In our series, 55.5% of the patients who had flap problems required more than one revision surgeries, as the average number of revision surgeries were two (ranged from 1 to 5). Unlike the other CI complications, a flap breakdown was associated with multiple revision surgeries.

The subperiosteal pocket technique with a minimalaccess skin incision is favored because of the low postoperative flap related complication rates (1,2,19). There are various options to treat a flap breakdown. Relocation of the receiver stimulator is a simple and relatively safe way, which also allows for preservation of the device. Local and free flaps can be used as a salvage treatment for the existing device or as a prophylactic surgery during

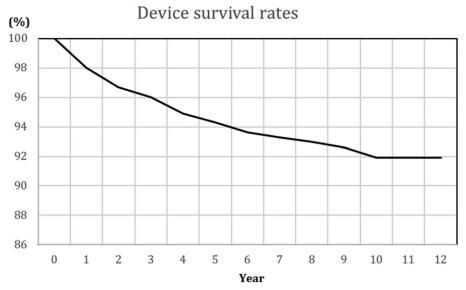


FIG. 4. Overall survival rate of the devices considering all explantations.

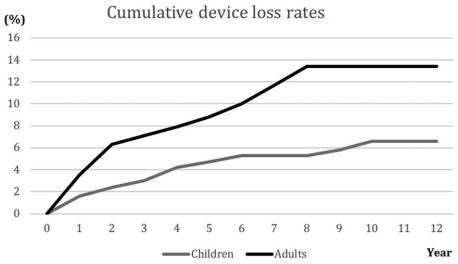


FIG. 5. Comparison of cumulative device loss rates between children and adults.

reimplantation (10,18,20–22). If cases of infection, preservation of the existing implant is usually unlikely. This may be attributed to biofilm formation on the surface of the device, which necessitates reimplantation with a new device (5,17,20,22). In our series, 88.9% of 18 devices were explanted due to infection control failure despite the use of antibiotics and local flap surgeries.

S. aureus and P. aeruginosa are the most common organisms isolated from the post-CI wound infections (18,20). In the present series, S. aureus and P. aeruginosa were isolated in two and three patients, respectively. In four cases, coagulase negative staphylococci and diphtheroids were isolated. The swab cultures were negative in nine cases, which may be due to previous use of antibiotics or presence of biofilms.

Implantation of the ears with chronic otitis media or cholesteatoma is a challenging issue because of the risk of recurrent or spreading infection. A subtotal petrosectomy combined with implantation can be performed at the same surgery or the procedures can be staged (23–25).

Both intra and extracochlear factors can play a role in device migration. Adhesions inside the mastoid cavity and increased cochlea to cortex distance due to skull growth can pull the electrode into the mastoid cavity. External factors like trauma and infection are the reasons of migration or mobilization as well (26,27). Cochlear neo-ossification can develop after postmeningitic implantation or post-CI infection. Even insertion trauma can trigger fibrosis and ossification (26). The new bone growth can push the electrode out of the cochlea. In one of our cases with electrode array migration, a reimplantation could not be performed due to cochlear ossification, and the contralateral ear was implanted.

Although stabilization of the receiver stimulator by drilling a bony well and suture fixation is recommended, a tight periosteal pocket is also effective in immobilizing the receiver stimulator (1,2,8). In our practice with

subperiostal pocket technique without fixation, receiver stimulator migration occurred only in four cases.

Hematoma can develop early after surgery or as a late complication. Head trauma is usually responsible for a late onset hematoma, but it can be seen even in cases without evident predisposing factors (16,28-30). On ultrasound assessment, hematoma appears as an anechoic collection in the first 24 hours and tends to be hyperechoic after fibrotic reorganization. Most of the hematoma cases can be managed conservatively such as aspiration and tight dressing while a surgical intervention is needed rarely. But an extensive hematoma requires surgical drainage since it can lead to flap necrosis or infection, resulting in explantation of the device (16,29). Coagulopathies and extended skin incisions correlate with high risk of hematoma formation after cochlear implantation. Minimal-access skin incision seems safe when hematoma development is considered (29).

In general, vertigo or disequilibrium, which is likely after cochlear implantation, usually recovers spontaneously. In our series, there were two cases of misinsertion into semicircular canals which manifested postoperatively by intractable peripheral vertigo. The patients who had intractable vertigo should be evaluated in terms of misdirection of the electrode.

Device survivals were associated with complications and failures. It was proposed that new generation implants are more reliable with higher survival rates when failures are considered (12). However, complication related device losses remain as a problem although the complication rates are less common with new techniques (29,31).

CIs are implanted with the expectation of lifetime use. Identifying the survival rates of different brand of devices and the risk factors for device loss will allow candidates and surgeons to make more accurate choices. In the present series survival rates did not differ between all

brands except for Oticon devices. Flap related problems, which were among the most common complications, resulted in explantation, and were the cause of the high rate of Oticon device losses. Otherwise, the failure rates of Oticon devices did not differ from the other brands. Therefore, it is not plausible to relate this brand with lower survival rates.

In conclusion, device failure seems the most common cause of revision. The revision surgeries are usually safe and help to resolve the problem although flap problems are the most difficult to treat and may necessitate multiple revision surgeries. The device failure rate may reach to a plateau after 6 years. Overall CI survival rate exceeds 90% in 10 years period, and then remains stable.

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