

## Original Investigation



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# Clinical Outcomes Following Revision Cochlear Implantation: A Single-Center Experience

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### Abstract

**Objective:** Cochlear implant surgery enables individuals with severe hearing loss to regain auditory function. With the increasing number of implant recipients, complications have become more common, leading to a greater need for revision procedures. This study aimed to analyze and assess the underlying causes of revision surgeries performed in our clinic.

**Methods:** This retrospective study reviewed 1,800 patients who underwent cochlear implantation in our clinic. Of these, 118 patients who required revision operations were included in the analysis. Causes of revision, observed complications, and demographic profiles of the patients were studied.

**Results:** No significant differences were found in age, gender, implantation side, presence of inner ear anomalies, or etiology between patients with and without complications ( $p>0.05$ ). Complications were observed in 22.9% of female patients ( $n=11$ ) and 8.6% of male patients ( $n=6$ ). The cochlear implant brand, failure type (soft or hard), and revision indication were not statistically related to complication status ( $p>0.05$ ). Although not significant, complication rates were higher among patients who required revision due to device malfunction or cholesteatoma.

**Conclusion:** Revision cochlear implantation should be considered in patients presenting with symptoms such as hearing deterioration, tinnitus, pain or swelling at the implant site, redness, delayed wound healing, or atypical facial sensations. This study summarizes our clinical experience and highlights the primary causes leading to revision cochlear implantation.

**Keywords:** Cochlear implant, revision surgery, complications, device failure, postoperative outcomes

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## Introduction

Cochlear implants have significantly improved the quality of life for individuals with profound or severe hearing loss by restoring auditory perception. These devices stimulate the spiral ganglion cells through electrical signals, offering an effective rehabilitation method for both congenital and acquired hearing loss. Since its initial clinical use in the 1980s, cochlear implant technology has evolved rapidly, leading to wider global application. As the number of implant recipients continues to rise, the occurrence of complications and the necessity for revision surgeries have also increased (1).

In cochlear implant surgery, the need for revision arises due to malfunctions of the device, infections, displacement of the device, or complications related to the surgery. The need for revision is indicated by clinical conditions such as device performance failure, skin redness, pain, ulcerative lesions, and extruded electrodes (2). Previous reports indicate an overall rate of device removal or revision surgery between 4% and 10% for different

clinical series (3-5). The presented study aims to share our institutional experience with revision cochlear implant operations, analyze their causes and outcomes, and compare our findings with current literature. Through this evaluation, we hope to contribute to the optimization of surgical strategies and patient management protocols in future clinical practice.

## Methods

### Study Design and Patients

This retrospective study included 118 patients who underwent revision cochlear implant surgery among 1,800 cochlear implant recipients operated on in our clinic between January 1999 and July 2023. All primary surgeries were performed at our clinic by surgeons with comparable experience. Patients who had previously received cochlear implantation at our center and subsequently required surgical revision due to any complications were included in the study. Primary implant cases, cases where complications were resolved using non-surgical methods, and primary implant cases performed at an external center with revision performed at our center were excluded.

### Preoperative Evaluation

Before surgery, all patients were assessed by a multidisciplinary team consisting of an audiologist, an audiometrist, a speech and language therapist, and an otorhinolaryngologist. Surgical indications were determined after consensus within this team. The decision for revision surgery was made based on the medical history of the cases, findings from periodic physical examinations, radiological imaging, and audiological examination results. Skin lesions that cannot be treated with non-surgical procedures, mastoid cavities, and middle ear pathologies requiring surgery, dislodged electrodes, physically damaged devices, and intermittent or continuous device malfunction are criteria used when deciding on revision.

### Hard Failure and Soft Failure

The reasons constituting indications for revision surgery were evaluated under two general headings: hard failure and soft failure.

Hard failure refers to a situation where the implant does not function due to hardware-related issues that can be objectively proven. In other words, there is a physical or electronic malfunction in the implant's internal components, and this malfunction can be definitively demonstrated through telemetry tests. Electrode breakage, extrusion of the electrode from its position, internal component failure, and short circuits in the electrode channels are examples of such situations (1).

Soft failure refers to a condition in which the cochlear implant appears to function appropriately on technical evaluation, yet clinical findings raise suspicion of device malfunction after exclusion of other causes. Soft failures manifest as decreased auditory performance, distorted or altered perception of sounds, slowed or stunted language development in children (1).

### Surgical Technique

In revision surgery, the procedure begins with an incision following the primary incision. Fibrotic structures in the mastoid cavity are meticulously cleaned. The facial nerve is identified. The electrode is separated from the receiver. First, the receiver is removed. If present, fibrotic tissues in the implant bed and subperiosteal pocket are cleaned. The subperiosteal pocket and bed for the implant are prepared again. If an infectious process is ongoing in the surgical area, the electrode is left in the cochlea and reimplantation is postponed to a second session. However, if there is no infection and the mastoid cavity is confirmed to be clean, the electrode is removed from the cochlea during the same session, and a new device is reimplanted. The surgery is concluded with intraoperative telemetry.

### Statistical Analysis

Demographic data, initial implant characteristics, revision indications, interval between first implantation and revision, cochlear implant brands, and postoperative management were reviewed.

Statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Categorical variables were expressed as numbers and percentages, while continuous variables were summarized as mean, standard deviation, median, minimum, and maximum values. Normal distribution of continuous data was checked using skewness and kurtosis (acceptable range  $\pm 1.96$ ). Since age and time-to-revision did not meet normality assumptions, appropriate non-parametric tests were applied. Comparisons of complication status across demographic and clinical characteristics, etiology, implant brands, and revision causes were performed using the chi-square test. The independent samples t-test was used for comparing continuous variables (age and revision duration) between groups. A p-value  $<0.05$  was considered statistically significant.

The study protocol was reviewed and approved by the University of Health Sciences Türkiye, İzmir Bozyaka Training and Research Hospital Ethics Committee in 2023 (approval no: 2023/136, date: 06.09.2023).

## Results

### Demographic Characteristics

Out of 1,800 cochlear implant recipients, 118 underwent revision surgery and were included in this analysis. Of the patients who underwent revision surgery, 27.1% (n=32) were 4 years old or younger, 41.5% (n=49) were between 4 and 18 years old, and 31.4% (n=37) were adults. The mean age was 17.82 years (range 1-75 years).

Table 1 summarizes the descriptive characteristics. Of the patients, 40.7% (n=48) were female and 59.3% (n=70) were male. The right ear was implanted in 61% (n=72), the left ear in 38.1% (n=45), and bilateral implantation was performed in one case (0.8%). Inner ear malformation was detected in 7 patients (5.9%), including Mondini deformity, wide vestibular aqueduct, incomplete partition type 2, and cochlear ossification (Table 1).

### Etiological Findings

Etiological evaluation revealed that the cause of hearing loss was unknown in 44.1% (n=52) of the patients. Among those with identified causes, consanguineous marriage was the most frequent (8.5%), followed by hereditary (6.8%) and febrile illnesses (6.8%). Other less frequent etiologies included progressive loss (4.2%), meningitis (3.4%), otitis media (5.1%), genetic causes (2.5%), ototoxicity (2.5%), and prematurity (2.5%) (Table 2).

### Implant Brands, Revision Reasons, and Postoperative Complications

The implant brand distribution was as follows: Advanced Bionics 11.8% (n=14), MED-EL 63.5% (n=75), and cochlear 24.5% (n=29). This difference between brands was parallel

to primary surgeries. The implant brands mentioned were those used in primary surgeries. The same brands were used in revision surgeries, taking the primary surgeries into account.

Among device manufacturers, MED-EL implants were most frequently used (63.5%), followed by cochlear and Advanced Bionics. In our study, the brands used in 1,800 primary surgeries retrospectively screened were distributed as follows: MED-EL 61.6% (n=1,110), Cochlear 28.4% (n=512), and Advanced Bionics 9.8% (n=178).

The revision rates per brand were MED-EL at 6.8%, cochlear at 5.6%, and Advanced Bionics at 7.8%. The need for revision was more common with Advanced Bionics, while it was relatively less common with cochlear brand implants.

Revision indications were mainly device failure (hard failure: 77 patients; soft failure: 17 patients). Other causes included chronic otitis media (16), infection (2), flap necrosis (3), skin dehiscence (1), and electrode malposition (Figures 1 and 2). Hematoma is also a common complication after cochlear implant surgery, but at our clinic, hematoma management is performed using non-surgical procedures. There has been no case at our clinic where revision cochlear implant surgery was performed due to hematoma. The most common indications were device-related problems. Patient-related problems were encountered less frequently (Table 2).

Postoperative complications occurred in 14.4% (n=17) of the revision group, consisting primarily of hematoma, infection, or skin breakdown. The mean time interval between primary implantation and revision was 5.51±5.09 years (range: 0-19 years). The earliest revision was due to flap necrosis, while the longest interval was observed in a case with chronic otitis media (Table 3).

**Table 1.** Descriptive characteristics of patients who underwent cochlear implantation

Features	n	%	
Gender	Female	48	40.7
	Male	70	59.3
Age	Pediatric (18 years or under)	81	68.6
	Adult (over 18 years)	37	31.4
Side	Right	72	61.0
	Left	45	38.1
	Both sides	1	0.8
Inner ear anomaly-damage	None	111	94.1
	There is	7	5.9
		Mean±SD (min-max)	
Age	17.82±18.80; 11 (1-75)		

SD: Standard deviation, n: Sample size

**Table 2.** Findings regarding the etiologies of patients who underwent cochlear implantation

Features	n	%	
Etiology	Unknown	52	44.1
	Consanguineous marriage	10	8.5
	Hereditary	8	6.8
	Progressive	5	4.2
	Meningitis	4	3.4
	Otitis media	6	5.1
	Feverish illness	8	6.8
	Genetic	3	2.5
	Ototoxicity	3	2.5
	Prematurity	3	2.5
Other	16	13.6	

**Table 3.** Findings regarding cochlear implant brands, reason for revision and postoperative complications of patients who underwent cochlear implantation

Variables		n	%
Cochlear implant brand	AB	14	11.8
	Medel	75	63.5
	Cochlear	29	24.5
Soft/hard failure	Soft failure	17	
	Hard failure	77	
Reason for revision	Hard failure	77	
	Soft failure	17	
	Infection	2	
	Chronic otitis media	16	
	Flap necrosis	3	
	Skin dehiscence	1	
Postoperative complications	Electrode malposition	2	
	None	101	85.6
Time until revision (years)	Yes (hematoma, skin dehiscence, infection)	17	14.4
	5.51±5.09; 3.42 (0-19)		

**Complication Distribution by Demographic and Clinical Factors**

No statistically significant differences were found in the distribution of gender, age, implant side, inner ear anomaly, or etiology between patients with and without postoperative complications (p>0.05). However, a higher, though non-significant, complication rate was observed among female patients (22.9%) compared to males (8.6%) (Table 4).

Analysis stratified by implant brand, soft/hard failure status, and revision cause revealed no statistically significant differences (p>0.05). However, complication rates were higher in patients with Advanced Bionics implants, soft failures, and chronic otitis media as the underlying indication for revision.

**Table 4.** Characteristics of patients who underwent cochlear implantation and distribution of complications according to etiology

Features		No complications (n=101)		Complications (n=17)		p
		n	%	n	%	
Gender	Female	37	77.1	11	22.9	0.056
	Male	64	91.4	6	8.6	
Age	Pediatric	70	86.4	11	13.6	0.924
	Adult	31	83.8	6	16.2	
Side	Right	60	83.3	12	16.7	0.650
	Left	40	88.9	5	11.1	
	Both sides	1	100.0	0	0.0	
Inner ear anomaly-damage	No	95	85.6	16	14.4	1.000
	Yes	6	85.7	1	14.3	
Etiology	Unknown	45	86.5	7	13.5	0.952
	Consanguineous marriage	9	90.0	1	10.0	
	Hereditary	6	75.0	2	25.0	
	Progressive	4	80.0	1	20.0	
	Meningitis	4	100.0	0	0.0	
	Otitis media	5	83.3	1	16.7	
	Feverish illness	7	87.5	1	12.5	
	Genetic	3	100.0	0	0.0	
	Ototoxicity	2	66.7	1	33.3	
	Prematurity	3	100.0	0	0.0	
Other	13	81.3	3	18.8		
		Mean±SD (min-max)		Mean±SD (min-max)		p
Age		17.68±18.64 11 (1-75)		18.65±20.28 12 (1-75)		0.840

SD: Standard deviation



**Figure 1.** Flap necrosis



**Figure 2.** Electrode malposition, implant electrode in external auditory canal

## Discussion

The first report of cochlear implant revision surgery was published by House (6) in 1976. Cochlear implantation, which restores hearing through direct electrical stimulation of the cochlear nerve, has become a widely accepted surgical treatment for severe sensorineural hearing loss (7). As the use of these devices has expanded, complications and subsequent revision surgeries have been reported more frequently. According to published data, the overall rate of implant removal ranges from 4% to 10% (3-5). Revision indications are commonly categorized as hard failures, soft failures, or medical/surgical causes. Hard failure represents confirmed hardware malfunction verified by device integrity testing, whereas soft failure refers to unexplained performance decline despite an apparently functional implant (8). Additional causes include wound infection, migration of device components, or electrode-related problems (9). In most series, device failure accounts for nearly half of all revision cases (10,11).

In the presented study, device-related causes represented 79.6% of all revision indications, aligning with previous literature. Chronic otitis media and related inflammatory

processes contributed to 13.5% of the cases, while a smaller subset involved tissue or flap complications. Flap necrosis presents a particular surgical challenge, and some authors recommend contralateral reimplantation as a preferred option when feasible (12). The predominant reason for revision in our cohort was device failure, consistent with prior reports.

In our study, revision rates by brand were 6.8% for MED-EL, 5.6% for cochlear, and 7.8% for Advanced Bionics. We found that the likelihood of revision is higher in Advanced Bionics brand implants, while the risk of revision is lower in cochlear brand implants compared to other brands. A study comparing brands showed that MED-EL had the highest revision rate (5.9%), followed by Advanced Bionics (5.3%) and cochlear (4.7%) (13). In another study, Advanced Bionics had the highest revision rate (6.2%), while cochlear and MED-EL devices had revision rates of 5.3% and 2.6%, respectively (14).

Children require revision surgery more than adults. A comparative study between adults and children found that the need for revision was greater in children than in adults (15). Studies have shown that revision rates are higher in the pediatric population compared to the adult population as a result of increased surgical complications and greater exposure of the implanted internal unit to trauma (16). When considering this situation in children specifically, we professionals should explain to their families the importance of protecting them from head trauma and providing a suitable environment for this purpose by giving them detailed information.

The postoperative complication rate of 14.4% found in our study is comparable to those described in earlier large-scale series (17,18). One of the complications mentioned arose due to a malfunction of the implant's internal component, while the other complications were hematoma and wound site infections (18). Various complications such as seroma, hematoma, infection, gusher, misplacement of the electrode, facial nerve palsy, and vertigo may occur after cochlear implantation (19). In our study, 16 of the 17 cases that developed complications were treated with non-surgical conservative methods. Reimplantation was performed in a case where device failure occurred. In various studies in literature, we see that conservative approaches, as applied in our center, are mostly used in the management of complications (20).

Management of complications may range from non-invasive device reprogramming to complete reimplantation, reflecting both the technological adaptability of cochlear implant systems and the necessity for individualized patient follow-up. The mean interval between implantation and revision (5.51 years) demonstrates that while modern implants are durable, long-term vigilance is essential (21,22).

Overall, our results are comparable with previously reported revision and complication rates (23,24). Certain discrepancies such as the low number of meningitis-related cases, may indicate advances in device safety features and refined surgical techniques (25). A slightly higher complication rate among female patients was noted; however, this finding was not statistically significant and may be influenced by biological or anatomical differences that warrant further investigation. Additionally, soft failure cases exhibited somewhat higher complication frequencies than hard failures, likely due to diagnostic uncertainty and challenges in determining the precise etiology of device malfunction.

In summary, the continuous advancement of cochlear implantation technology and the improvement of perioperative protocols are essential for minimizing complications and improving long-term outcomes. The findings of this study emphasize the importance of comprehensive follow-up and multidisciplinary management based on collaboration in maintaining the functional success of cochlear implants.

## Conclusion

Although continuous advancements in cochlear implant design and surgical methods have improved safety and outcomes, the risk of complications and the need for revision procedures persist. Meticulous preoperative assessment, careful surgical technique, and structured postoperative monitoring remain key factors in preventing complications. Sustained collaboration between surgeons, audiologists, and rehabilitation specialists is essential to ensure long-term implant performance and patient satisfaction.

## Ethics

**Ethics Committee Approval:** The study protocol was reviewed and approved by the University of Health Sciences Türkiye, İzmir Bozyaka Training and Research Hospital Ethics Committee in 2023 (approval no: 2023/136, date: 06.09.2023).

**Informed Consent:** Informed consent was obtained from all adult participants and from the parents or legal guardians of pediatric participants for inclusion in the study and the use of anonymized clinical data.

## Footnotes

### Authorship Contributions

Surgical and Medical Practices: A.D., Concept: C.K., Design: H.B.Y., Data Collection and/or Processing: E.A., Analysis or Interpretation: A.D., Literature Search: C.K., Writing: C.K.

**Conflict of Interest:** The authors declare that they have no conflict of interest.

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## Main Points

- This study presents our clinical experience regarding revision cochlear implant surgeries.
- Revision-related complications are complex and should be managed by experienced surgeons.
- Postoperative cochlear implant failures can be classified as soft or hard failures, and awareness of these distinctions is crucial for clinical management.

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