


# Retrospective analysis of surgical complications in 216 consecutive cochlear implantation series

## Ardışık 216 koklear implantasyon serisinde cerrahi komplikasyonların retrospektif analizi

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### Abstract

**Background:** The aim of this study is to determine the intraoperative and postoperative early and late period complications in children and adults age group patients, who underwent cochlear implantation in a University Hospital, and to discuss their causes and treatment.

**Methods:** The study is a retrospective study consisting of 216 consecutive cases, including 192 children and 24 adults, who were diagnosed with bilateral severe and profound sensorineural hearing loss (SNHL) and who underwent cochlear implantation between 2014 and 2018, in the Department of Otolaryngology at the tertiary University Hospital. Intraoperative and postoperative early and late period complications and treatments of the cases are evaluated.

**Results:** Total complication rate was found to be 19.4% (n: 42). 17.1% (n: 37) of this rate was minor complications and 2.3% (n: 5) was major complications. Seroma-induced edema of the wound area was the most common complication (n = 12, 5.5%). In general, infections were also found to be common complications (n = 9, 4.1%). Intraoperatively, perilymphatic gusher was found in 4 cases; bleeding in 1 case; iatrogenic tympanic membrane perforation in 1 case and meatus posterior wall injury in 2 cases. 6 cases had vertigo and one case had tinnitus. After surgery; temporary facial paralysis was detected in 2 cases, abnormal facial nerve stimulation was detected in 1 case and transient chorda tympani syndrome was detected in 1 case. In 2 cases, the device was removed due to severe flap and mastoid infection. The implanted internal part was removed in 1 patient due to electrode position which could not be placed in the cochlea.

**Conclusion:** Cochlear implantation surgery is a safe technique in which the majority of minor surgical complications can be managed with conservative measures or minimal interventions, with relatively low rates of serious complications in the presented population. As the learning curve progresses, complications decrease. The examination of the complication rates occurring in different centers improves learning curve of surgeon and the attention to be given to surgery.

**Keywords:** Sensorineural, Hearing loss, Surgical treatment, Cochlear implantation, Complication.

### Öz.

**Amaç:** Bu çalışmanın amacı, bir Üniversite Hastanesinde koklear implantasyon uygulanan çocuk ve yetişkin yaş grubundaki hastalarda, intraoperatif ve postoperatif erken ve geç dönem komplikasyonları belirlemek ve bunların nedenlerini ve tedavilerini tartışmaktır.

**Materyal ve metod:** Çalışma, üçüncü basamak Üniversite Hastanesi Kulak Burun Boğaz Hastalıkları Bölümünde 2014 ile 2018 tarihleri arasında bilateral ileri ve çok ileri sensörinöral işitme kaybı (SNHL) tanısı konan ve koklear implant uygulanan, 192 çocuk ve 24 yetişkin olmak üzere toplam 216 ardışık olgunun dahil edildiği retrospektif bir araştırmadır. Olguların intraoperatif ve postoperatif erken ve geç dönem komplikasyonları ve tedavileri değerlendirilmiştir.

**Bulgular:** Toplam komplikasyon oranları % 19.4 (n: 42) olarak saptandı. Bu oranın % 17.1'i (n:37) minör komplikasyonlar ve % 2.3 (n:5) majör komplikasyonlardı. Yara bölgesinin seromaya bağlı ödemi en sık saptanan komplikasyon idi (n=12, %5.5). Genel olarak enfeksiyonlar da sık görülen komplikasyonlar olarak saptandı (n=9, %4.1). İntraoperatif olarak 4 olguda perilenf gusher; 1 olguda kanama; 1 olguda iatrojenik timpanik membran perforasyonu; 2 olguda dış kulak yolu travması saptandı. 6 olguda vertigo; 1 olguda tinnitus saptandı. Ameliyat sonrası 2 olguda geçici fasiyal parezi; 1 olguda anormal fasiyal sinir uyarımı; 1 olguda geçici korda timpani sendromu saptandı. 2 olguda şiddetli flep ve mastoid enfeksiyonu nedeniyle cihaz çıkartıldı. Kokleaya yerleşemeyen elektrot pozisyonu nedeniyle 1 hastada implante edilen iç parça çıkartıldı. **Sonuç:** Koklear implantasyon cerrahisi, sunulan popülasyonda nispeten, ciddi komplikasyon oranının düşük olduğu, minör cerrahi komplikasyonların çoğunluğunun konservatif önlemlerle veya minimal müdahaleler ile yönetilebildiği güvenli bir tekniktir. Öğrenme eğrisi zamanı ilerledikçe komplikasyonlarda azalmaktadır. Farklı merkezlerde ortaya çıkan komplikasyon oranlarının incelenmesi, cerrahinin daha dikkatli yapılmasını ve cerrahin öğrenme eğrisini geliştirir.

**Anahtar kelimeler:** Sensörinöral, İşitme kaybı, Cerrahi tedavi, Koklear implantasyon, Komplikasyon.

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## Introduction

The cochlear implantation (CI) system is a safe and effective method that is successfully applied all over the world for the rehabilitation of adults and children, who have bilateral severe and profound sensorineural hearing loss (SNHL) and who do not benefit from amplification successfully (1,2). Although safe, in this surgical procedure, minor and major complications may occur associated with intraoperative and postoperative complications or used devices (3-18). The first articles describing the surgical complications associated with cochlear implantation were published by Cohen in 1991 and Hoffman in 1993 (3, 4). However, in the literature, the complication rates vary considerably, partly due to differences in the definition of complications and partly due to variables in the reporting of complications (3, 18). Increasing number of reports on this issue worldwide will contribute to the formation of consensus.

The main objective of this study was to analyze the minor and major complications associated with 216 consecutive cochlear implantation surgery and devices applied in children and adult's population between 2014 and 2018, and to compare these results with the data in the literature.

## Material and Methods

In the Department of Otolaryngology at the tertiary University Hospital, between 2014 and 2018, a total of 191 patients (167 children and 24 adults) who were diagnosed with severe and profound sensorineural hearing loss and 216 consecutive cochlear implantations were retrospectively reviewed by a systematic database research. Permission was obtained from the local ethics committee of the university (02.08.2018 / 08-02). Procedures were performed in accordance with the Helsinki Declaration.

The study group included a total of 191 patients and 216 consecutive cochlear implantations with 167 pediatric cases (83 males (49.7%) and 84 females (50.3%)) at the time of implantation, with a mean age of 43.68 months (Range: 9 to 35 months) and 24 adults (12 males (50%) and 12 female (50%)) with a mean age of 34.75 years (Range: 35 to 65 years). Bilateral cochlear implantation was performed on 25 patients in a single session. In the children, 130 cases had prelingual hearing loss (77.9%), 37 cases had postlingual hearing loss (22.1%), and adults had 100% postlingual hearing loss. The mean follow-up duration between surgery and file review for both adult and pediatric groups was 27 months. Clinical and demographic features are presented in Table 1.

Preoperatively, meningococcal and haemophilus influenza vaccines were administered to all cases. Postauricular minimal incision, mastoidectomy, posterior tympanotomy

and round window approach were performed in the surgery. Posterior tympanotomy could not be performed in two cases and the electrodes were inserted through transcanal-mastoid cavity.

### Complication definition

Complications in cochlear implantation application can be defined as the development of any pathological event in the intraoperative and postoperative period, without the time limit, whether directly related to surgical technique or cochlear implantation system (10). Complications can be classified as minor or major complications.

**1- Minor complications:** Complications that can lead to prolongation of hospitalization time or post-operative outpatient treatment and that can be treated spontaneously or by simple medical treatment or by small surgical procedures are defined as minor complications. These are the complications such as transient peripheral facial nerve paralysis, facial stimulation, chorda tympani nerve trauma, external ear canal posterior wall damage, tympanic membrane trauma, tinnitus, vertigo, scalp hematoma, seroma, minor skin infections etc. which are treatable often with minimal conservative methods without referring to surgery (6, 11).

**2- Major complications:** Complications leading to a serious medical conditions such as meningitis and mastoiditis; complications requiring additional major surgical interventions such as large scalp necrosis, cholesteatoma, retraction pocket, permanent tympanic membrane perforation; complications that may cause permanent disorders such as permanent facial paralysis; and complications such as device malfunctioning and electrode shifting leading to permanent implant dysfunction can be defined as major complications (6, 11).

We classified the complications in this study as; 1- Intraoperative: complications occurring during surgery and within 24 hours after surgery, 1.a-minor and 1.b-major. 2- Early postoperative: complications occurring 24 hours after the surgery and within 1 week, 2.a-minor and 2.b-major. 3-Late postoperative: complications occurring after 1 week, 3.a-minor and 3.b-major.

In this study, we evaluated the complication rates according to ratio of the total number of implantations. As bilateral implantations and re-implantations could not be considered, we did not use the calculation based on the number of patients.

### Statistical analysis

The collected data were analyzed using descriptive statistical studies with SPSS application for Windows-based systems.

**Results**

In the 216 implant series included in this study; a total of 18% (n = 39/216) complications were detected in children out of which 15.7% (n = 34/216) were minor complications and 2.3% (n = 5/216) were major complications, and a total of 1.4% (n = 3/216) complications were detected in adult patients which included 1.4% (n = 3/216) minor complications and 0.0% (n = 0 cases) major complications. In this series, the total complication rate was 19.4%

(n = 42/216) out of which 17.1% (n = 37/216) were minor complications and 2.3% (n = 5/216) were major complications. All complications are shown in Table 2.

In the examinations of preoperative computerized tomography (CT) and magnetic resonance imaging (MRI); cases with dilated cochlear aqueduct, internal ear anomaly such as Mondini malformation and cochlear ossification were evaluated as high complication risk expected cases such as perilymphatic gusher, abnormal anatomical localization and electrode insertion problems.

**Table 1:** Demographic characteristics of the patients implanted between 2014 and 2018.

Variables	Children (n:192)	Adults (n:24)
Age	43.68 months	34.75 years
Gender(Male/Female)	83/84	12/12
Type of hearing loss		
Prelingual	130	0
Perilingual	0	0
Postlingual	37	24
Side implanted(Right/Left)	87/80	13/11
Type of implantation(Unilateral/bilateral)	167/25	24/0

**Table 2.** Complications in 216 consecutive cochlear implantations.

Complication occurrence	Intraoperative (n= 7)				Early postoperative(n= 30)				Late postoperative (n = 5)			
	Minor(n=7)		Major(n=0)		Minor(n=25)		Major(n=5)		Minor(n=5)		Major(n=0)	
Complication degree	P	A	P	A	P	A	P	A	P	A	P	A
Pediatric (n = 192) (P)												
Adults (n = 24) (A)												
Wound infection					2		2					
Wound swelling/seroma					12							
Bleeding/haematoma/oedema	1								1			
Tympanic membrane/annulus injury	1											
Meatus posterior wall injury	2											
Vertigo/dizziness					4	2						
AOM										3		
Mastoiditis								2				
Tinnitus						1						
Transient facial palsy					2							
Facial stimulation									1			
Transient chorda tympani syndrome					1							
Perilymph leakage	3				1							
Electrode wrong poz.								1				

**Complications**

**1- Intraoperative complications:**

**1.a-Minor complications**

Severe gusher (1.8%, n = 4/216) was detected intraoperatively in 4 children with internal ear anomalies. In two of these cases, besides severe gusher, the abnormal high

course of the facial nerve was also noticed. Posterior tympanotomy could not be performed in these cases and the electrode was inserted through the external ear canal and no problems were encountered in the postoperative period.

In one pediatric patient with inner ear anomaly, sigmoid

sinus-based bleeding in the anterior region was detected (0.4%, n = 1/2016). Iatrogenic tympanic membrane perforation was detected in one pediatric case without annulus injury (0.4%, n = 1/216). In two pediatric cases, trauma was detected in the posterior wall of the external ear canal depending on its type during the posterior tympanotomy procedure (0.8%, n = 2/216).

### **1.b-Major complications**

In our series, an incorrect placement of the electrode was found in 1 pediatric case (0.4%, n = 1/216). In one case with incomplete partition type III (IP-III), a shift to internal acoustic canal was detected and the implant was removed. Severe vertigo was detected in pediatric patient with incomplete partition type III (IP-III).

### **2-Early postoperative complications:**

#### **2.a-Minor complications**

In the early postoperative period, 12 pediatric cases had surgical wound edema due to seroma (5.5%, n = 12/216). Skin flap-related mild wound infection was found in 2 cases (0.8%, n = 2/216). Vertigo was detected in 4 pediatric and in 2 adult cases (2.7%, n = 6/216). Tinnitus was detected in 1 adult case (0.4%, n = 1/216). In 2 pediatric cases, transient facial nerve paralysis was detected on the 7th day in postoperative period (0.8%, n = 2/216). Taste disorder was reported in 1 pediatric case (0.4%, n = 1/216).

The rate of severe pain was very low in the cases. Mild to moderate pain was easily taken under control using pain-killers.

#### **2.b-Major complications**

Ipsilateral infectious complications of the implant were observed in two pediatric cases with mastoiditis. In these cases, necrosis and opening were detected in the skin flap and the incision line. The implant was removed in both cases.

### **3- Late postoperative complications:**

#### **3.a-Minor complications**

In the first 2 months after implantation, 3 cases of acute suppurative otitis media (AOM) were found which are infectious complications (1.3%, n = 3/216). In 1 case, hematoma was detected 2 years after the surgery due to trauma to the head (0.4%, n = 1/216).

#### **3.b- Major complications**

During the follow-up period, no device malfunction and other major complications resulted in permanent implant dysfunction in any of the cases.

## **Discussion**

With the extension of indications and successful outcomes, the cochlear implantation system has become a surgical procedure in many centers around the world. The increasing use of this technology has made its complications interesting too. The total complication rates have decreased to 9% in recent years which were reported to

be around 39% in the first publications (3, 4, 10, 11). The spread of cochlear implantation surgery training programs and the ease of access to information have made positive contributions to the learning curve time. In addition, innovations in implant technologies and advances in surgical techniques have been effective in reducing the rate of complications (10, 11). Despite all these positive developments, complications related to surgical procedures and the devices can be seen. In cochlear implantation procedure, which brings heavy burdens to countries' health economics, the addition of complications further increases this burden. Although the incidence of complication in cochlear implantation applications is low, they should be recognized and treated quickly.

One of the first articles to describe complications in cochlear implantation applications was published by Cohen in 1991 (3). In a series consisting of 459 cases, complications were reported in 55 cases (11.8%). The most frequently reported complications were; skin flap necrosis, wound infections, incorrect electrode placement responsible for abnormal nerve stimulation, and transient facial nerve paralysis. In 1993, Hoffman reported the rate of major complications as 7.4% and total complication rate as 12.2% in 4969 implant series (4). In the literature; the rate of complications in different studies are reported as minor complications with 11.8-18% and major complications with 3.2-8% (8, 11-13). Similar results were obtained in our series with minor complications with 17.1% and major complications with 2.3%. It was found that as the learning curve time progressed, the complication rates decreased.

Especially in patients with inner ear anomalies, perilymphatic leakage (gusher) is likely to be seen. Perilymphatic leakage, which is reported to be 1- 2.2% in the literature, was found to be 1.8% in 4 pediatric cases in our series (5, 8, 14). Perilymphatic leakage was stopped intraoperatively, in 3 cases without any problems with fat tissue and muscle tissue. In one patient, postoperative continued until the 12th day. A complete recovery was achieved, without a need for lumbar drainage, with conservative measures such as prophylaxis with high dose antibiotics and head elevation. No gusher was found in any of the patients whose CT and MRI examinations were normal. Specifically designed devices for patients with a high probability of perilymphatic leakage in new implant technologies, make it easier for surgeons to solve this problem.

While skeletonizing anterior sigmoid sinus with bipolar cautery in a pediatric patient with an inner ear anomaly, bleeding was observed. Bleeding was stopped with pressure and no postoperative problems occurred. Bleeding between 0.4% and 1.1% has been reported in the literature (7, 8). In cochlear implant application, coagulation disorder and insufficient bleeding control are the most

important causes of hematoma.

Iatrogenic tympanic membrane perforation was detected in one pediatric case without annulus injury. This rate is reported to be 2.6% in the literature (17). No problem was observed in the case that was repaired with temporal muscle fascia intraoperatively, in the postoperative period. No tympanic membrane perforation, adhesion, retraction pouch and cholesteatoma which require additional surgical intervention, were detected in the outpatient follow-up. In two pediatric cases, trauma was detected in the posterior wall of the external ear canal during the posterior tympanotomy procedure (0.8%- 2/216). This rate is reported as 2.6% in the literature [17]. This fenestration was repaired with bone cement. In these cases, granulation tissue and cholesteatoma did not develop at postoperative follow-up.

The most commonly seen complication in our study group was related to skin flap; edema of the wound area caused by seroma. All patients were treated successfully with conservative methods using pressure dressing and intravenous antibiotics and did not lead to implant loss. No hematoma was detected in any patient in early period. In one case, hematoma occurred 2 years after surgery due to trauma to the head. The patient was treated completely with antibiotic, aspiration and pressure dressings. There was no loss of function related to implant. The complication rate associated with the flap reported in the literature varies between 0.06% and 10% (11, 13). During surgery, damage to the periosteum in periosteal elevation and inability to repair it during the closure phase may cause edema in the wound area. As the learning curve time progresses, performing periosteal elevation carefully, decreases this complication.

One of the most commonly seen groups of postoperative complications is infections. In various studies reported in the literature, total infection rates vary from 1.7% to 16.6%, depending on the type of infections included such as skin infections, meningitis, labyrinthitis, acute otitis media and mastoiditis (7, 8, 10). In our series, local skin infection was seen in 2 children. These cases were treated without any problems with systemic antibiotic treatment and repeated wound dressings. There wasn't any improvement in two cases despite surgical revision and medical care. In these patients; necrosis, mastoiditis and middle ear infection occurred in the flap. These patients underwent myringotomy and intravenous antibiotic treatment in the hospital. Bacteriological examination revealed methicillin-sensitive *S. aureus* in one case. In these cases, necrosis occurred in the skin flap and there was an opening in the incision line and the implant was removed. The development of acute suppurative otitis media, serous otitis media or mastoiditis tables is important as it may cause serious conditions such as implant extrusion, implant failure or meningitis. In 3 patients, acute suppurative

otitis media developed at the postoperative 2nd and 3rd months. 2 patients were hospitalized, and were completely healed by the 3rd generation cephalosporin parenteral mg / kg treatment. These 3 cases were completely healed without any need for myringotomy and culture. None of these AOM cases were complicated by meningitis. After implant, ipsilateral localized otitis media have been shown in 50% of meningitis cases related to implant (10, 11). In our series, no cases of meningitis were found, and the incidence is also quite low in the literature (8-10). As the learning curve time progressed, making the incision small reduced the rate of skin complications.

Complications related to facial nerve are a rare but rather annoying complication of cochlear implant surgery. It should be kept in mind that the facial nerve may follow an abnormal course especially in patients who have internal and middle ear anomalies. The incidence of transient peripheral facial nerve paralysis after cochlear implant surgery, has been reported as 0.4% to 0.71% in the literature (5, 15, 16). In our series too, two patients had late facial paralysis. A combined steroid was administered with antiviral drugs, and the entire facial nerve functions returned to normal. As the learning curve time progresses, the frequency of complications associated with the facial nerve decreases.

In pediatric cases of this study, vestibular complications and tinnitus rates were lower than adult cases. These low rates can be attributed to the difficulty of children in expressing their complaints and the difficulty of the health care team to examine these symptoms. However, the results should be interpreted carefully, as these complications are probably ignored in the child population. Vestibular complications developed in 4 pediatric cases and 2 adult cases. The rate in the literature is reported as 2.4% (7). Vestibular complications may occur more frequently in the adult age group, and this may be associated with some causes such as loss of perilymph, aging of vestibular organs and decreased blood flow. Tinnitus was detected in 1 adult case. And the rate in literature is approximately 0.8% (7).

Transient chorda tympani syndrome was detected in one child. During the follow-up period, it was found that the electrodes recovered spontaneously without the need for deactivation. The rates of transient chorda tympani syndrome have been reported as 5.7% to 30.8% in the literature (17). In our series, no permanent chorda tympani syndrome was detected in any of the cases. None of the cases had any cut or damage on the chorda tympani nerve. In the literature, the rate of persistent chorda tympani syndrome has been reported to be around 1.6% (17).

Facial nerve stimulation was detected in one case. This condition, which could cause significant discomfort by limiting the use of the implant, was solved by disabling the

relevant electrodes. In the literature, the rate of facial nerve stimulation is reported to be between 1% and 14.9% (18).

In our series, electrode was found to be incorrectly placed in one case. In one case with incomplete partition type III (IP-III), the shift to internal acoustic canal was detected and the implant was removed. Severe vertigo developed in the patient with incomplete partition type III (IP-III). Following removal of the device, vertigo completely disappeared in this patient. The disruption of the internal part associated with the cochlear implant dysfunction is the most common cause for reimplantation. Kandogan T et al. (5) reported a rate of 9.69% and Venail et al. (10) reported a 7.2% rate of complications due to a technological problem affecting the implant. In this study, no implant failure was detected in any case in the series due to disruption of the internal part.

Meningitis, persistent eardrum perforation, persistent peripheral facial paralysis, tympanic retraction pocket and cholesteatoma, excessive / continuous bleeding, electrode insertion problems and electrode damage, dural trauma and death related to implantation were not detected in any case in our series.

There are some points that limit this study. A retrospective file review may not necessarily be accurate due to the fact that not all the complications after surgery are routinely recorded and assessed in the outpatient follow-up. While major complications are recorded more consistently, minor complications can generally be underestimated by both patients and the medical team. This is a possible limitation in our study.

### Conclusion

The cochlear implantation system is a safe surgical technique that is effective in the rehabilitation of bilateral advanced and very advanced sensorineural hearing loss and can prevent complications if the risk factors are examined carefully. Generally, in all complication groups the complication rates decrease as the learning curve time progresses. This study confirms this information with 17.1% minor complication rate and 2.3% major complication rate and 19.4% total complication rate. The examination of the complication rates occurring in different centers improves the attention to be given to surgery and the surgeon's learning curve.

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