Retrospective study of cochlear implantations at a single facility focusing on postoperative complications

Masako Kitano*, Hiroshi Sakaida, Kazuhiko Takeuchi

Department of Otorhinolaryngology–Head & Neck Surgery, Mie University Graduate School of Medicine, 2-174 Edobashi, Tsu, Mie 514-8507, Japan

ABSTRACT

Objective: Although cochlear implantation (CI) is a relatively safe operation, postoperative complications sometimes occur. We reviewed the frequency and severity of complications of CI at our hospital. We compared our results with previously reported complications and considered measures to improve patient outcomes.

Methods: This retrospective study examined the medical records of 70 patients who received CI between March 2005 and December 2018. We collected the following data: age at the time of the first surgery, etiology of hearing impairment, date of implantation, type of implanted devices, and complications. Surgical complications were divided by time into perioperative, early, and late, and by severity into major or minor.

Results: Records of 38 adults and 32 children were analyzed. Bilateral CI was performed in 16 patients, 8 of whom were sequential, and unilateral CI was performed in 54 patients. The total number of operations was 78 for 86 CI. Complications were observed in 15 of 78 operations (19%), and the rates of minor and major complications were 15% and 4%, respectively. Complication rates were 21% (8/39) for children and 10% (4/39) for adults. All of the perioperative and early complications were minor. There were three major complications, all of which were infections presenting with mastoiditis and subcutaneous or subperiosteal abscesses. One case required reimplantation twice because of recurrent mastoiditis and temporal abscess.

Conclusions: There was no significant difference in the incidence of complications between children and adults, but all major complications were infection in pediatric cases. Careful attention is needed to prevent postoperative infection.

© 2021 Oto-Rhino-Laryngological Society of Japan Inc. Published by Elsevier B.V. All rights reserved.

1. Introduction

Cochlear implants are among the most widespread artificial organs in the world and cochlear implantation (CI) is the only hearing acquisition method for individuals with hearing impairments for which hearing aids are ineffective. The number of CIs in Japan has been increasing year by year, most notably in children, owing to the prevalence of newborn hearing screening and genetic testing for deafness. Binaural treatment is increasing in children, thereby realizing binaural hearing. Although CI surgery is a relatively safe operation, postoperative complications sometimes occur. Several studies have reported significantly higher overall rates of complications and reimplantation in pediatric populations compared
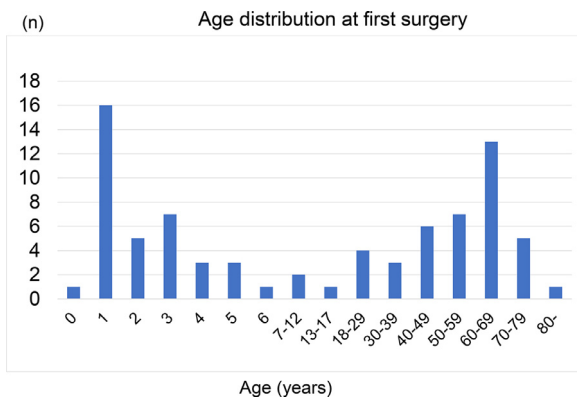
Fig. 1. Ages at the first operation in adults ($n = 38$) and children ($n = 32$) Ages ranged from 11 months to 80 years; mean age was 30.8 years.

Fig. 2. Number of operated ears by year. The number of operated ears in children has exceeded those in adults since 2014. This is because we started bilateral CI surgery for pediatric cases in 2015.

with adults [1,2]. Post-CI complications can be classified as major or minor [3].

Our objective was to review the data on complications of CI at our hospital and compare our results with previously reported complications to consider measures to improve patient outcomes.

2. Materials and methods

We retrospectively analyzed 86 CIs in 70 patients at our institution between March 2005 and December 2018.

This study was approved by the ethics committee of our institution (approval number H2019–157). All implantations were performed by specialists with over 15 years of experience performing ear surgery.

Data were extracted from a chart review, including age at the time of the first surgery, etiology of hearing impairment, date of implantation, type of implanted devices, and complications.

Surgical complications were divided according to time into perioperative complications, which occurred within 24 h after surgery, early complications, which occurred within 1 month after surgery, and late complications, which occurred more than 1 month after surgery. Complications were also divided by severity into major complications, which required surgical intervention or hospitalization, and minor complications, which required conservative treatment or a minor intervention. Descent of the receiver/stimulator was considered a minor complication.

3. Results

The reviewed cases comprised 38 adults (mean age, 54.1 years) and 32 children younger than 18 years (mean age, 3.0 years). Age at the time of the first operation ranged from 11 months to 80 years (mean, 30.8 years; Fig. 1). Causes of hearing impairment for adults and children are listed in Tables 1 and 2, respectively. We started performing CI surgery for adults in 2005 and for children in 2008. Since 2014, the number of operated ears in children has exceeded those in adults (Fig. 2). We started bilateral surgery on pediatric pa-
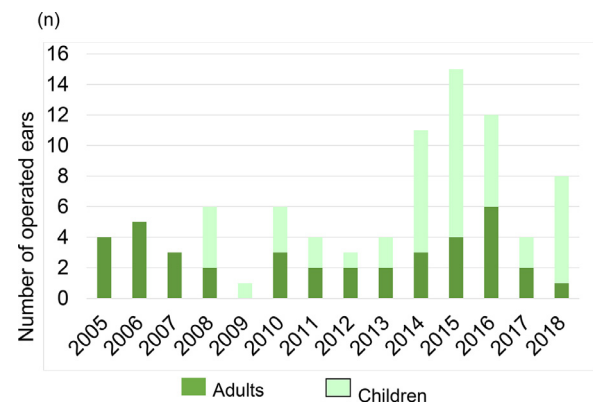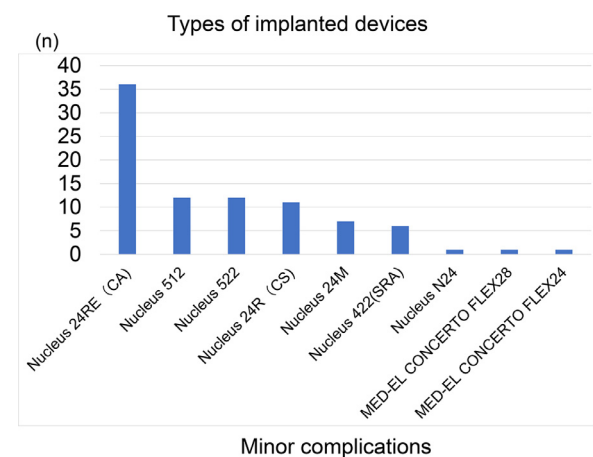
Fig. 3. Types and numbers of implanted devices.

Table 1. Causes of hearing impairment in adults.

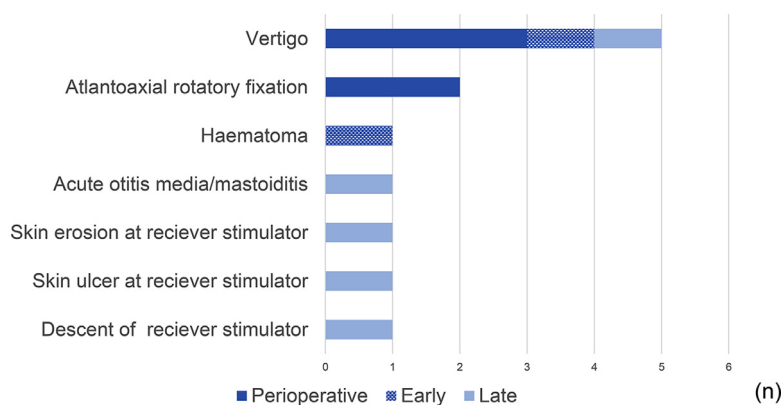| Causes	n
Mitochondrial disease	2
Leukemia	1
Acoustic trauma	1
Drug-induced	1
Otitis media	1
Congenital rubella syndrome	1
Meningitis	1
Unknown	30

tients in 2015. The types of implanted devices are shown in Fig. 3.

Of the reviewed cases, 1 adult and 15 children received bilateral CI. Of these 16 cases, half (8) were simultaneous bilateral operations, and half (8) were sequential operations.

The overall rate of complications was 19% (15/78), and the rates of minor and major complications were 15% (12/78) and 4% (3/78), respectively. The complication rates were 21% (8/39) for children and 10% (4/39) for adults, and the difference was not significant.

There were 5 cases of perioperative complications: 3 cases of vertigo and 2 cases of atlantoaxial rotatory fixation. There were 2 cases of early complications: 1 case of vertigo and 1 case of hematoma. All perioperative and early complications

Fig. 4. Minor complications. All perioperative and early complications were minor.

Table 2. Causes of hearing impairment in children.

Causes	n
Genetic mutation*	10
Congenital cytomegalovirus infection	1
Cochlear nerve deficiency	1
Unknown (congenital 17, acquired 3)	20

* Includes the following genes: *GJB2* (*n* = 6), *SLC26A4* (*n* = 3), *OTOF* (*n* = 1).

were minor (Fig. 4). There were 8 late complications, 3 of which were major.

3.1. Minor complications

There was a total of 12 minor complications. Five were cases of vertigo with nystagmus, 3 of which occurred on the day of the operation or the next day and resolved within 3 days. Their vertigo may have been the result of fenestration of the inner ear. A 1-year-old girl became unable to sit or stand up due to vertigo with lateral gaze nystagmus contralateral to the surgical side 4 days after surgery. On the day after onset of vertigo, she was admitted to the hospital for observation, and the nystagmus gradually subsided. She had a fever of 38 °C on the 6th postoperative day. On the 7th postoperative day, a rash occurred on the face, forearms, thighs, and buttocks, but not the trunk, which made the attending pediatrician suspect enterovirus infection. It was not known whether the vertigo was due to a perilymphatic fistula or associated with a viral infection. A 61-year-old female had vertigo with lateral gaze nystagmus ipsilateral to the surgical side, which occurred 2 months after surgery. Nystagmus persisted for about 3 months, and the vertigo and dizziness gradually diminished. The cause of her vertigo was not determined.

There were 2 cases of atlantoaxial rotatory fixation (AARF). One was a 5-year-old girl and the other was a 4-year-old girl. The 5-year-old girl was diagnosed as having AARF based on neck pain and diminished range of neck motion on the day after the surgery. AARF likely occurred soon after surgery in both cases. In both cases, AARF was diagnosed by an orthopedic surgeon based on the characteristic posture and typical cervical CT findings. After conservative treatment involving application of a soft cervical collar, they

were discharged to home about 1 week after surgery without any neck complaints.

Hematoma of the temporal region was found 4 days after surgery in a 51-year-old man. He recovered by puncture drainage on the 5th and 7th days after surgery.

A 58-year-old man presented with skin erosion over the surgical incision behind the ear. This was the result of a portion of the receiver stimulator extending beneath the skin incision. The skin erosion was covered with a protective hydrogel wound dressing to relieve the pressure of the receiver stimulator and speech processor. The erosion healed about 2 months later.

A 1-year-old-girl presented with a skin ulcer in the temporal region 3 weeks after starting to use the CI (13 days after CI surgery). The skin ulcer was thought to have been caused by the excessive strength of the magnet. Use of the CI was discontinued and bromelain ointment was applied to the ulcer. Her skin ulcer gradually improved and finally healed after about 6 weeks.

There was another 58-year-old man whose receiver stimulator descended from its initial position in the temporal region. Six months after implantation, he noticed his glasses touching the receiver stimulator. Because he had a pain in the posterior ear, we modified the location of the receiver stimulator.

3.2. Major complications

There were 3 major complications, all of which were infectious complications in children presenting with mastoiditis and subcutaneous or subperiosteal abscesses. There were no postoperative complications such as device failure, electrode extrusion, facial paralysis/spasm, or meningitis. There were no intraoperative complications such as facial nerve injury or bleeding requiring transfusion.

Two cases of abscess in the temporal region were improved by incision and drainage. One was a 1-year-old girl, whose abscess developed at 5 months postoperatively and the other was a 1-year-old boy whose abscess developed at 11 months postoperatively. *Hemophilus influenzae (BLPACR)* and *Streptococcus pneumonia (PSSP)* were detected in the pus of the former, whereas *PSSP* was detected in the pus of the latter.

Table 3. Time course of an intractable case.

Time after the first CI	2nd day	40th day	50th day	85th day	7 months	8 months	11 months	2 years and 8 months
Findings	Mild swelling posterior to the right ear	Acute mastoiditis and subcutaneous abscess MRSA detected	Abscess not improved	Abscess not improved	No inflammation	Abscess recurred	Abscess recurred and the implant was exposed	No inflammation
Management	Cefazolin for one day and cefditoren pivoxil for 6 days	Vancomycin for three days	Abscess incised and drained	First CI explantation	First CI reimplanation	Linezoid for a month	Second CI explantation	Second CI reimplantation

Includes the following genes: *GJB2* (n = 6), *SLC26A4* (n = 3), *OTOF* (n = 1).

Fig. 5. Findings at the second explantation. Necrosis of the scalp and reactive granulation around the device were observed.

Both cases were treated with ceftriaxone before and after incisional drainage, and the inflammation promptly subsided.

The details of a case of recurrent mastoiditis and abscess in the temporal region that required reimplantation twice is described below (Table 3).

The patient, diagnosed as severe bilateral hearing loss, had simultaneous bilateral CI surgery when he was 1 year old. On the second postoperative day, mild swelling posterior to the right ear developed.

On the 40th postoperative day, right otorrhea developed and methicillin-resistant *Staphylococcus aureus* (MRSA) was detected in the otorrhea. Diagnosed as acute mastoiditis and subcutaneous abscess, he had abscess incised and drained. The abscess recurred and the right CI was explanted 85 days after implantation.

One month after the second CI surgery, the abscess recurred and the scalp started to necrotize (Fig. 5). We performed a second explantation 4 months after the second implantation. Fortunately, he could continue using the left cochlear implant and his language development was good.

At the age of 3 years and 8 months, we performed a third CI surgery. He did not experience any severe upper respiratory symptoms during the second explantation and third implantation.

Two patients had undergone tympanoplasty prior to CI surgery, one with chronic otitis media and the other with adhesive otitis media. In another case of chronic otitis media, the ear canal was closed at the same time as the CI operation. All three cases were adults. These procedures were intended to prevent postoperative infection.

4. Discussion

We encountered a case that required reimplantation twice because of recurrent mastoiditis and subcutaneous or subperiosteal abscess. After our experience with this intractable case, we decided to evaluate CI at our facility in terms of safety and risk of complications. In addition, because the number of pediatric cases is increasing, we compared the difference in complication rate between adults and children. The results of this study revealed that all cases of infectious complications were pediatric patients.

4.1. Genetic testing

In Japan, genetic testing for 13 genes and 46 mutations associated with congenital hearing loss has been covered by medical insurance since 2012.

Furthermore, testing for 19 genes and 154 mutations has been available since 2015. Mutation of the *GJB2* gene is the most frequent cause of congenital hearing loss. Patients with *GJB2*-related deafness may have better improvement in speech performance after CI compared with those with deafness unrelated to *GJB2* [4]. It is possible that some cases of unexplained hearing loss in this study may have been hereditary, given that not all patients underwent testing for the gene responsible for hearing loss. Similarly, not all cases were tested for congenital cytomegalovirus infection.

4.2. Pediatric cochlear implant

In 2014, the Oto-Rhino-Laryngological Society of Japan reviewed the criteria for pediatric cochlear implants in

Table 4. Complications of cochlear implantation in the literature.

	Year	Number	Overall	Major	Minor
Fukatsu et al. [16]	2003	44	34%	9%	25.0%
Vinail et al. [1]	2008	500	16.0%	3.2%	5.6%
Stamatiou et al. [17]	2010	212	5.7%	4.7%	1.0%
Yamada et al. [18]	2011	72	12.5%	6.9%	5.6%
Ikeya et al. [19]	2013	366		8.7%	7.4%
Farinetti et al. [12]	2014	403	19.9%	5.0%	14.9%
Raghunandhan et al. [20]	2014	300	30.7%	10.0%	20.7%
Roa et al. [3]	2019	1027	10.2%	9.5%	0.7%
Present study	2020	78	19%	4%	15%

hearing-impaired children before and during language acquisition, after which the lower age limit for CI was lowered from 18 to 12 months, and it was decided that bilateral CI would be allowed. Hence, we have been actively performing bilateral CI surgery on pediatric cases since 2015.

Prolonged use of unilateral CI may inhibit the development of binaural processing if CIs are performed sequentially [5,6]. Simultaneous bilateral CI in children could reduce the adverse and potentially irreversible effects of auditory deprivation in early life [7]. We currently favor performing simultaneous bilateral surgery whenever possible.

4.3. Complications

Several studies have investigated complications in large case series of adult patients (Table 4). Similar incidences of postoperative complications were observed in the present study (overall, 19%; mild, 15%; severe, 4%).

In AARF, the first and second cervical vertebrae become interlocked in a rotated position and this condition is more common in children than in adults. It has been reported that AARF is associated with otologic surgery or plastic surgery involving the ear in some cases. Although AARF is a rare complication not only in CI surgery but also in other types of otologic surgery, the surgical team needs to keep the possibility of this adverse event in mind throughout the perioperative period [8]. Our current practice is to limit the degree of head rotation to 45°, which has been effective for preventing AARF.

In the case with skin ulcer, we should have realized that the magnet was too strong. Fortunately, the skin ulcer healed satisfactorily. However, if we had not noticed the skin ulcer, it might have led to flap necrosis and necessitated flap surgery. In the study of 232 implanted children, 63 (27%) had at least one episode of skin erythema at the magnet site and 2 had skin ulceration. In most cases, this resolved after reducing the magnet's field strength or by temporarily not wearing the device. Skin reactions tended to occur more often in younger children [9].

The number of CI procedures performed in children is on the rise at our institution, and we actively work to prevent AARF and skin reactions.

The case that required two reimplantation led us to reconsider the causes of complications in CI. Mild swelling at the right receiver stimulator was likely a hematoma and may have provided the breeding ground for bacterial growth. From the viewpoint of preventing infection, thorough removal of the

hematoma is desirable. Bleeding and hematoma can be suppressed by minimizing periosteal elevation. In addition, the tight pocket technique can be used to reduce the space, which results in less bleeding by minimizing the area of periosteal elevation [3].

In addition, an anti-MRSA drug was not selected at the time of the first reimplantation. The patient in this case had recurrent MRSA infections. MRSA strains have significantly higher ability to form biofilm compared with methicillin-sensitive *S. aureus* strains [10].

To prevent infection, we should thoroughly sterilize the surgical field, minimize its size, complete the operation in the shortest time possible, and use antibiotics at the appropriate timing. When infection is suspected, the principle is to remove the device except for the electrode tip, wait for the infection to heal, and perform the reimplantation in two phases, even if the device is not exposed [11].

In a report of 403 CI patients, infectious complications were observed mainly in the pediatric population and most cases were acute otitis media. The risk of infection is higher in children with CI than in children with normal hearing because the inner ear may be contaminated by cochleostomy, especially during the first months after CI [12]. In the present study, all 4 cases of infection-related complications were observed in children, 3 of which (75%) were major complications.

Otitis media ipsilateral to the implant has been reported in 50% of post-implant meningitis cases [12]. This risk has led some surgical teams to insert transtympanic ventilation tubes or perform adenoidectomy before or during CI in children with a history of acute otitis media or serous otitis media [12–14]. However, this practice is controversial because many otologists believe ventilation tubes represent a possible route for contamination of the device. Javia et al. showed that infectious complications after cochlear implantation are rarely associated with the presence of ventilation tubes, supporting the concept that ventilation tubes are generally safe in CI [15]. Accordingly, ventilation tube insertion should be considered in CI patients at risk of developing acute otitis media.

We consider that preventing postoperative infection of the cochlear implant should be a priority, especially in children at high risk of developing acute otitis media.

Conclusions

We evaluated CI-related complications at our hospital. No significant difference was found in the incidence of postop-

erative complications between adults and children, although all major complications were infection-related and occurred in children. Care must be taken to prevent postoperative infectious complications in children because of their higher risk of otitis media compared with adults.

Disclosure statement

The authors have no conflicts of interest to declare.

References

[1] Venail F, Sicard M, Piron JP, Levi A, Artieres F, Uziel A, et al. Reliability and complications of 500 consecutive cochlear implantations. Arch Otolaryngol Head Neck Surg 2008;134:1276–81.

[2] Brown KD, Connell SS, Balkany TJ, Eshraghi AE, Telischi FF, Angeli SA. Incidence and indications for revision cochlear implant surgery in adults and children. laryngoscope 2009;119:152–7.

[3] Roa H, Ahmad A, Sulumain A, Farid A. Complications of post–cochlear implantation in 1027 adults and children. Ann Saudi Med 2019;39:77–81.

[4] Fukushima K, Sugata K, Kasai N, Fukuda S, Nagayasu R, Toida N, et al. Better speech performance in cochlear implant patients with GJB2– related deafness. Int J Pediatr Otorhinolaryngol 2002;62:151–7.

[5] Gordon KA, Jiwani S, Papsin BC. What is the optimal timing for bilateral cochlear implantation in children? Cochlear Implants Int 2011;12(Suppl 2):S8–14.

[6] Jiwani S, Papsin BC, Gordon KA. Early unilateral cochlear implantation promotes mature cortical asymmetries in adolescents who are deaf. Hum Brain Mapp 2016;37:135–52.

[7] Health Quality OntarioBilateral cochlear implantation: a health technology assessment. Ont Health Technol Assess Ser 2018;18:1–139 eCollection 2018.

[8] Sakaida H, Akeda K, Sudo A, Takeuchi K. Atlantoaxial rotatory fixation as a rare complication from head positioning in otologic surgery: report of two cases in young children. Patient Safety Surg 2017;11(5). doi:10.1186/s13037-016-0116-7.

[9] James AL, Daniel SJ, Richmond L, Papsin BC. Skin breakdown over cochlear implants: prevention of a magnet site complication. J Otolaryngol Jun 2004;33:151–4.

[10] Piechota M, Kot B, Frankowska-Maciejewska A, Grużewska A, Woźniak-Kosek A. Biofilm formation by methicillin-resistant and methicillin-sensitive *Staphylococcus aureus* strains from hospitalized patients in Poland. Biomed Res Int Dec 27, 2018;2018:4657396 eCollection 2018. doi:10.1155/2018/4657396.

[11] Oyama K. Cochlear implant Q & A that you know but don't know. JOHNS Published Monthly Tokyo IGAKUSHA Ltd 2016;32(No.12):1766–7.

[12] Farinetti A, Ben Gharbia D, Mancini J, Roman S, Nicollas R, Triglia JM. Cochlear implant complications in 403 patients: comparative study of adults and children and review of the literature. Eur Ann Otorhinolaryngol Head Neck Dis Jun 2014;131:177–82.

[13] Luntz M, Teszler CB, Shpak T, Feiglin H, Farah-Sima'an A. Cochlear implantation in healthy and otitis-prone children: a prospective study. Laryngoscope 2001;111:1614–18.

[14] Luntz M, Teszler CB, Shpak T. Cochlear implantation in children with otitis media: second stage of a long-term prospective study. Int J Pediatr Otorhinolaryngol 2004;68:273–80.

[15] Javia L, Brant J, Guidi J, Rameau A, Pross S, Cohn S, et al. Infectious complications and ventilation tubes in pediatric cochlear implant recipients. Laryngoscope 2016;126(7):1671–6.

[16] Fukatsu Y, Yamasoba T, Ito K, Ishimoto S, Kaga K. Postoperative complications of cochlear implantation. Otol Jpn 2003;13:214–18.

[17] Stamatiou GA, Kyrodimos E, Sismanis A. Complications of cochlear implantation in adult. Ann Otol Rhinol Laryngol 2011;120:428–32.

[18] Yamada T, Minoda R, Miwa T, Masuda M, Kodama N, Samejima Y, et al. Postoperative complications of cochlear implantation. otologia 2011;57:283–9.

[19] Ikeya J, Kawano A, Nishiyama N, Kawaguchi S, Hagiwara A, Suzuki M. Long-term complications after cochlear implantation. Auris Nasus Larynx 2013;40:525–9.

[20] Raghunandhan S, Kameswaran M, Anand Kumar RS, Agarwal AK, Hossain MD. A study of complications and morbidity profile in cochlear implantation: the MERF experience. Indian J Otolaryngol Head Neck Surg 2014;66:161–8. doi:10.1007/s12070-011-0387-3.