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Original Article

Cochlear implantation in 602 cases: surgical complications during 7 years of experience in a specialized institute

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Abstract

Aim
To assess the complications of cochlear implantation (CI) during our 7 years of experience since the start of the CI program in our institute.

Patients and methods
The study included 602 CI procedures performed from April 2013 to January 2020. The follow-up period ranged between 12 and 73 months. Complications were classified into perioperative, major complications requiring reimplantation, major complications not requiring reimplantation, and minor complications. Collected data were statistically analyzed.

Results
Of the 602 implantations, 509 were children. Age ranged between 1.2 and 64 years. Mean implantation age in pediatrics was 4.4 and 31.07 years in adults. A total of 76 (12.62%) complications were recorded, 49 (8.13%) in children and 27 (4.49%) in adults. Of these, 17 (2.83%) were major, 24 (3.99%) were minor, and 35 (5.81%) were perioperative complications. Five (0.83%) of the major complications required reimplantation (two cases of device failure 0.33%), and 12 did not need reimplantation. Our study's most common cause of minor complications was partial facial nerve paresis (11 patients, 1.83%).

Conclusion
Our 7 years of experience have shown that CI is a successful and safe procedure that can be performed with low major complication rates. It is important to know the possible complications and to manage them properly.

Keywords: Cochlear implantation, complication, device failure, facial palsy, reimplantation

Introduction

Cochlear implantation (CI) has been a routine procedure to rehabilitate patients with severe-to-profound sensorineural hearing loss for more than 20 years. The numbers of CI recipients are increasing substantially, so both patients and physicians need to be aware of the CI complications that can occur due to the surgical technique, foreign body implantation, or device failure [1–4].

Classification of CI complications is needed to determine the timing and magnitude of their management. Some studies classify the complications as early postoperative (≤3 months postimplantation) and late postoperative (>3 months postimplantation), while others classify as intraoperative and postoperative complications [5,6].

The most efficient classification that addresses the management plan is 'major complications' (as in the case of wound-flap necrosis, implant extrusion, meningitis, electrode misplacement, and magnet displacement) versus 'minor complications' (as in the case of chorda tympani nerve injury, facial paresis, acute otitis media, intraoperative bleeding, postoperative pain, facial nerve stimulation, dizziness, and others). Major complications can be very serious conditions requiring prolonged hospitalization and/or surgical intervention, whereas

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minor complications can be treated with conservative methods, medical treatment, and minimal surgical procedures [7].

Our institute is considered one of the biggest otolaryngological referral centers in Egypt, and it has one of the largest series of CI surgeries in the country. To the best of our knowledge, only one similar local study has been published in 2018, and it was carried out in our institute for 112 CI cases [8]. We consider this study a continuation of the previous one as we present the results of our 7 years of experience in managing CI complications at our institute for 602 implanted patients from April 2013 to January 2020. We also evaluate our experience considering reports from other centers that describe CI complications.

Patients and Methods

This study followed local laws and the Declaration of Helsinki. Our local ethics committee approved it. All patients who received CI in the Department of Otorhinolaryngology, the National Hearing and Speech Institute (Gothi), from April 2013 to January 2020, were included in this study.

Experienced surgeons operated upon all patients. The procedures were performed alternatively by six surgeons, four seniors, and two juniors. Junior surgeons had an average experience of 1 year and senior surgeons of 8 years in cochlear-implant surgery. All patients received routine vaccinations for pneumococcal (PREVNAR 13 vaccines), meningococci, and H-influenza 2 weeks before surgery.

A routine surgical procedure was used in all patients. A cortical mastoidectomy was performed, the short process of the incus was visualized, and the facial recess was detected and enlarged to approach the round-window niche. In some cases, finding the location of the round window might not be easy, and we preferred to employ the cochleostomy approach to enable electrode insertion into the cochlea. After electrode insertion, auditory nerve-response telemetry and/or neural-response telemetry were performed. Radiological imaging was used to verify electrode alignment on the first postoperative day.

Over the years, there have been some modifications to the surgical procedure. In earlier years, a C-shaped skin incision was made as of 2017; however, a lazy S-skin incision and a tunnel-pocket method were used. Moreover, the receiver–stimulator of the implant was placed in the bony bed and then fixed with 3.0 prolene sutures to both sides of the bony bed to prevent implant migration from occurring in the future; the nonfunctional and nonstimulating part of the electrode was organized into an '8' shape and then extended from the mastoid tip to the antrum. This arrangement was to prevent electrode extrusion. Consequently, the electrodes were medialized by filling the mastoid cavity with gel foam. The gel foam creates a physical barrier between the mastoid cavity and the periosteal flap.

During follow-up, complications were recorded, tabulated, and classified once detected into perioperative, major, and minor complications. During surgery, perioperative complications were mainly incidents like chorda tympani nerve injury, posterior meatal wall breeching, and perilymph gushers that required immediate intervention either intraoperatively or postoperatively.

Major complications were divided into two subgroups as those required and those that did not require reimplantation. Major complications that did not require reimplantation were cases that needed additional surgical intervention, which is accompanied by compromised function (e.g., flap necrosis, hematoma, seroma, cholesteatoma, tympanic membrane perforation, and facial paralysis). Major complications that required reimplantation were device failure (either hard or soft), foreign body reaction (e.g., flap necrosis), and misplacement or displacement problems.

The condition is considered as a minor complication when outpatient medical treatment, minimal intervention (e.g., needle aspiration), or hospital stay were needed (e.g., vertigo, minor wound infection, acute otitis media, and facial paresis).

The collected data were described in percentages for categorical data and mean ± SD for numerical data. Statistical analysis was done using SPSS, version 24 (SPSS Inc., Chicago, Illinois, USA).

Results

This study included 602 cases, the distribution of their numbers through study years is shown in Fig. 1, while their demographic data, the side implanted, approach, implanted brand, and classification of complications among them are represented in Table 1. The types and numbers of implanted electrodes in this study are detailed in Fig. 2. Congenital anomalies, difficulties, and syndromic cases represented 97 (16.12%) cases, enlarged vestibular aqueduct was the most common among them (Fig. 3).

The complications were reported in 76 (12.62%) cases during the follow-up period ranging between 12 and 73 months, perioperative complications being the most prevalent in 35 cases (46% of complications and 5.81% of all cases studied). This was followed by minor complications in 24 cases (31.6% of complications and 3.99% of all cases studied). Then major complications not requiring reimplantation in 12 cases (15.8% of complications and 1.99% of all cases studied). The least

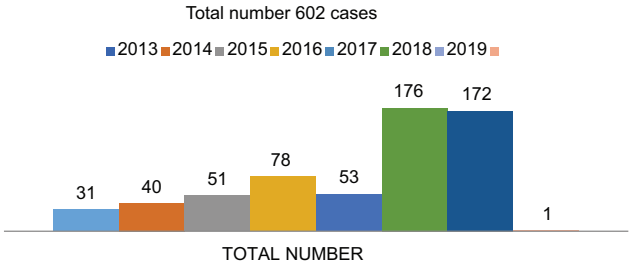

Figure 1: Number of cases implanted per year in our institute.

were major complications requiring reimplantation in five cases (6.6% of complications and 0.83% of all cases studied). We did not observe any severe infection, skin-flap necrosis, or implant exposure in this study. We observed no more than one complication in any of the cases studied.

The most common cause of major complications requiring reimplantation was the soft failure of the device in two cases. Three cases had the device explanted with revision CI in the same setting, while two cases required explantation and a staged-revision CI later (Table 2). In addition, as for major complications not requiring reimplantation (Table 3), the most common cause was major hematomas (in three cases) followed by two cases with wound infection and erosion of periosteum (Fig. 4) and two cases with facial nerve paralysis. Other causes occurred in single cases like implant magnet migration (Fig. 5), displacement of the electrode in the mastoid cavity outside the cochlea (Fig. 6), and misplacement of the electrode in the lateral semicircular canal (Fig. 7).

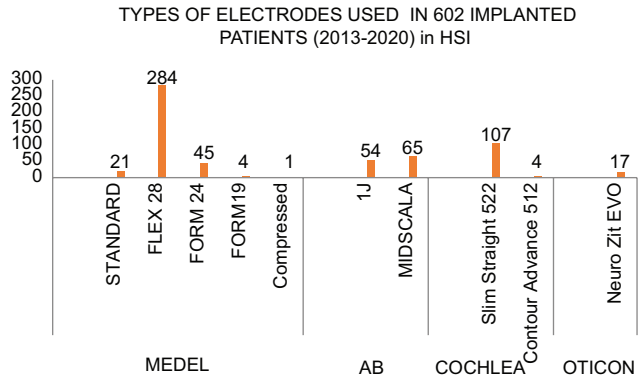

Figure 2: Type of electrode used in this study.

Table 1: Data demography and characteristic of cochlear implant patients clinically from April 2013 through January 2020 (602 cases)

	n (%)
Gender	
Male	290 (48.17)
Female	312 (51.83)
Children (<18 years)	509 (84.55)
Mean age at time of implantation	4.4±2.3
Male	243 (47.74)
Female	266 (52.26)
Adults (>18 years)	93 (15.45)
Mean age at time of implantation	31±10.5
Male	47 (50.54)
Female	46 (49.46)
Youngest age at time of implantation	1.2 years old
Oldest age at time of implantation	64 years old
Implanted side	
Right ear	555 (92.2)
Left ear	46 (7.64)
Bilateral (simultaneous) implantation	One case (right and left) (0.16)
Approach	
Round window	533 (88.54)
Cochleostomy	69 (11.46)
Implanted brand	
Nucleus (cochlea)	111 (18.44)
MED-EL	355 (58.97)
Advanced bionics	119 (19.77)
Oticon	17 (2.82)
Complications	
Major complications requiring reimplantation	5 (0.83)
Major complications not requiring reimplantation	12 (1.99)
Minor complications	24 (3.99)
Perioperative complications	35 (5.81)
Total	76 (12.62)

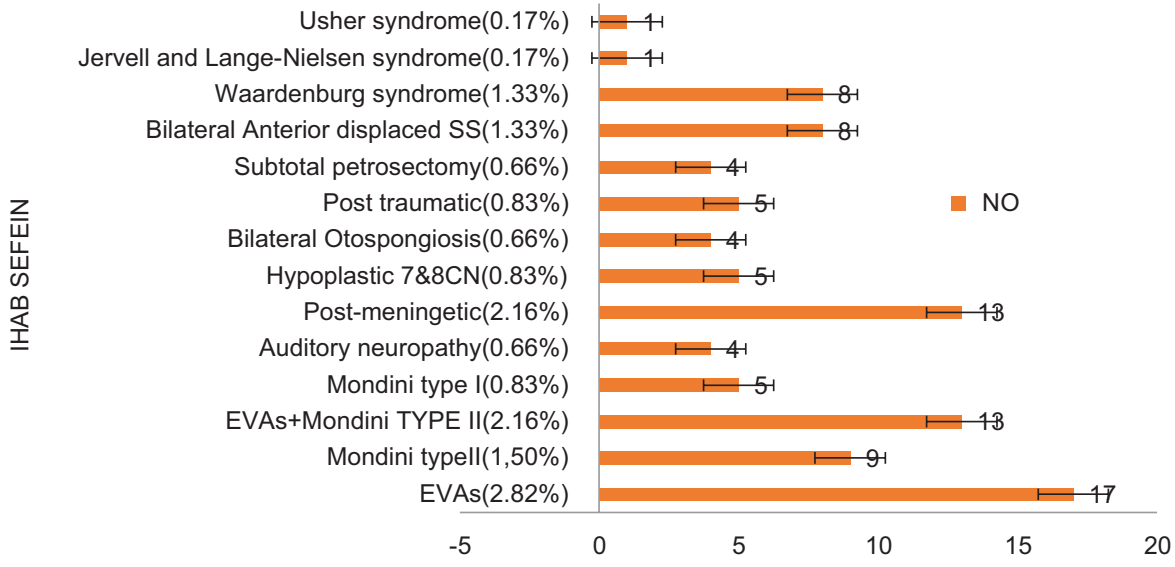

Figure 3: Congenital anomalies, difficulties, and syndromic cases of total implantations.

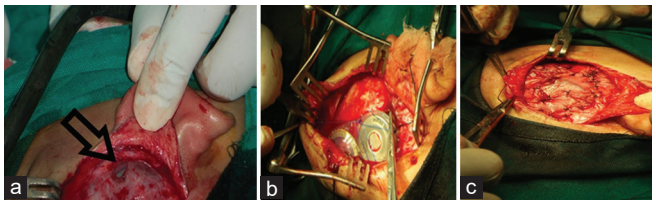

Figure 4: (a) Erosion of the periosteum over internal processor 'black outlined arrow.' (b) The muscle was mobilized in the temporal region (superiorly to the pinna), (c) repositioned flap posteroinferiorly over the implant.

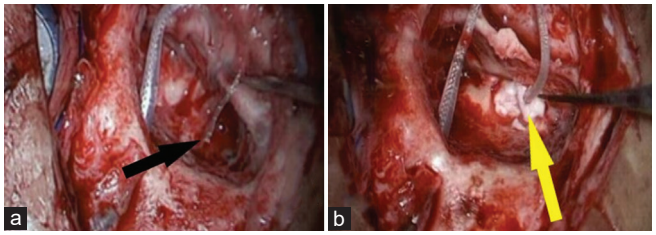

Figure 6: (a) Displacement of the electrode in the mastoid cavity outside the cochlea (black arrow). (b) Successful reimplantation of the same electrode (yellow arrow).

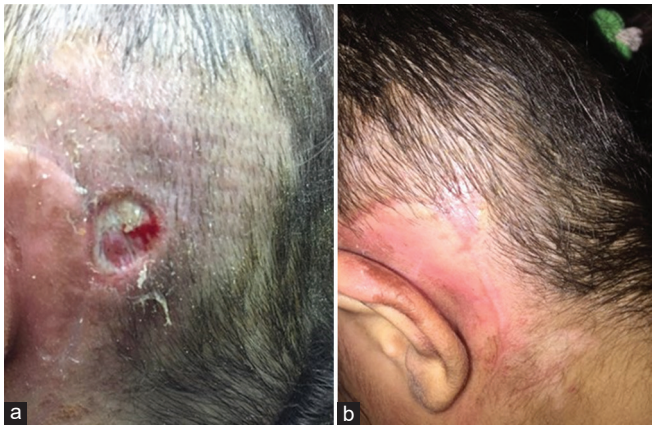

Figure 8: (a) Skin ulcer, (b) complete healing after use of Phenytoin spray for 2 weeks.

The most common cause of minor complications (Table 4) was mild facial palsy in 11 (1.83%) cases, potentially due to neural edema provoked by heat generation from burr friction in narrow posterior tympanotomies. All cases fully recovered within six months. Other causes like postoperative vertigo, tinnitus, mastoiditis, skin ulceration (Fig. 8), facial stimulation (Fig. 9), and electrode-tip rollover (Fig. 10) were of lesser rate.

The most common perioperative complication (Table 5) was the perilymph gusher in 26 (4.32%) cases, 12 of them had enlarged vestibular aqueduct, one with incomplete partition type I, and 13 with incomplete partition type II Mondini malformation. Intravenous 20% mannitol drip was used in these cases, and none required lumbar drainage. The second most common complication was chorda tympani nerve injury in six (0.99%) cases.

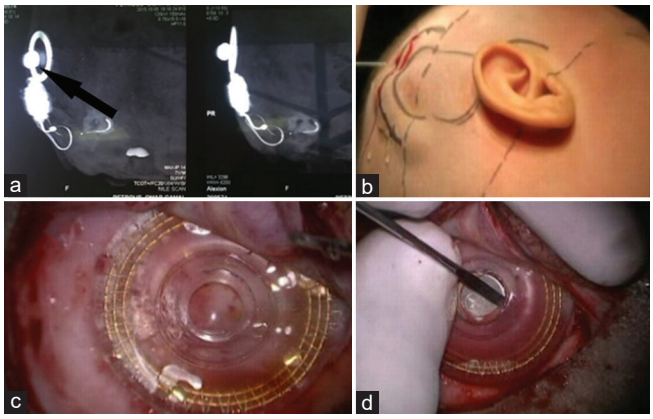

Figure 5: (a) Stenvers' view radiograph (modified) showing a tilted magnet outside of the internal coil and silicone boundary (black arrow). (b) Flap and incision design to expose the magnet. (c) Old magnet removed. (d) Reinsertion of the new magnet.

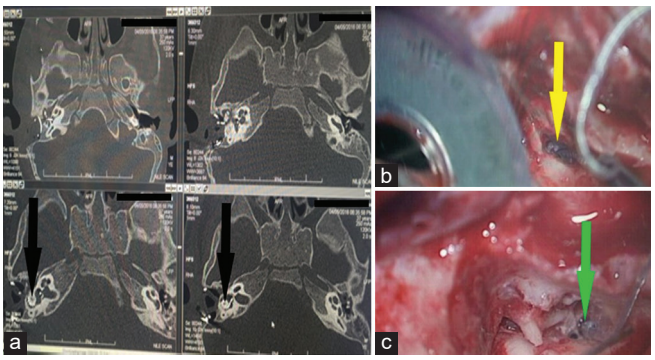

Figure 7: (a) CT revealed the LSCC electrode misplacement (black arrows). (b) Removal of the electrode from LSCC (yellow arrow). (c) Reinsertion of the same electrode using freehand technique (green arrow). CT, computed tomography; LSCC, lateral semicircular canal.

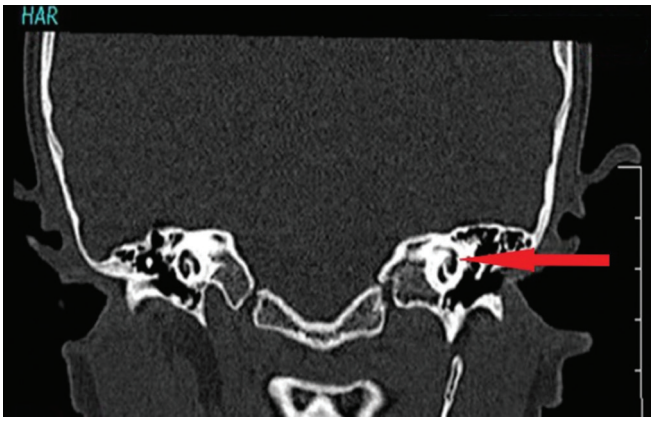

Figure 9: Coronal CT temporal bone showing the lack of bony margin and merging of the overlying facial canal and cochlea (red arrow). CT, computed tomography.

Discussion

In 7 years, the overall complication rate in 602 CIs was 12.62% (76 patients), the rate of major complications was 2.833% (17 patients), of which the major complications

Table 2: Major complications requiring reimplantation

Complications	Children [*n* (%)] [509 (84.5%)]	Adult [*n* (%)] [93 (15.5%)]	Total [*n* (%)] [602 (100%)]	Management, type of implant electrode
1. Central perforation (CSOM) - 6 month after 1st implantation	Female	0	1 (0.166)	Explantation and staged revision CI. (AB-1J electrode)
Late	0.196			
2. Seroma and pseudomonas infection after C&S-1 month after 1st operation	Female	0	1 (0.166)	Explantation and staged revision CI. (AB-mid scala electrode)
Late	0.196			
3. Hard failure following sever head trauma 1 year after 1st operation	Female			
Late	0.196	0	1 (0.166)	Explantation and revision CI in the same setting. (MEDEL-Flex 28 electrode).
4. Soft failure-1 years and 14 months after 1st operation	2 males	0	2 (0.33)	Explantation and revision CI in the same setting. (Oticon-Neuro Zit EVO)
Late	0.39			
Total number (%)	5 (0.98)	0	5 (0.83)	

Table 3: Major complications not requiring reimplantation

Complications	Children [*n* (%)] [509 (84.5%)]	Adult [*n* (%)] [93 (15.5%)]	Total [*n* (%)] [602 (100%)]	Management, type of implant and electrode
1. Implant Magnet migration 1 Year postoperative because of severe head trauma, (Late)	1 Male (0.196)	0	1 (0.166)	Repositioning of new magnet into receiver-stimulator coil (AB-1J electrode)
2. Wound infection and erosion of the periosteum 3 weeks postoperative (late)	2 Female (0.39)	0	2 (0.332)	Successfully treated with appropriate flap design and intravenous antibiotics. (1AB-MS, 1MEDEL-flex 28)
3. Displacement of the electrode in the mastoid cavity outside the cochlea six month postoperative. (late)	0	1 Male (1.075)	1 (0.166)	Reimplantation of the same electrode 6 month postoperatively (MEDEL-Flex 28)
4. Persistent pain and discomfort (migration) 6 months postoperative (late)	1 Male (0.196)	0	1 (0.166)	Drilling a sharp edge of the cavity at its anterior aspect and sutures were used to fix the same implant. AB-1J electrode
5. Mastoid abscess not responding to medical treatment five month postoperative (late)	1 Male (0.196)	0	1 (0.166)	Surgical drainage was done (MEDEL-Fle×28)
6. Misplacement of the electrode in LSCC (early)	1 Male (0.196)	0	1 (0.166)	Reimplantation of the same electrode 2 days postoperatively. (AB-Mid Scala electrode)
7. Major hematoma (postauricular swelling), on the second day postoperative. (early)	2 Male 1 Female (0.589)	0	3 (0.498)	Surgical evacuation and hemostasis on the 2nd day postoperative (local drainage and dressing), full recovery. (2MEDEL - Fle×28, 1 Cochlear-Slim straight)
8. Facial nerve paralysis. (immediate)	1 Male (0.196)	1 Male (1.075)	2 (0.332)	Decompression of the facial nerve (1 MEDEL-Flex 28, 1 cochlear-slim straight)
Total number (%)	10 (1.96)	2 (2.15)	12 (1.99)	

LSCC, lateral semicircular canal.

requiring reimplantation were five (0.830%) patients, the rate of minor complications was 3.986% (24 patients), and perioperative complications 35 (5.81%) patients. These rates were not found to contradict those reported in the literature. Nine articles reporting complications of CI in large cohorts of patients (>500) were reviewed with a total number of 6556 CI (Table 6) [9–17]. The total number of complication rates ranged from 2.63 to 29.1%. The major complication rates ranged from 0.7 to 10.2%, and also minor complication rates ranged from 0.299 to 27.32%. The incidence of the major and minor complications in our cohort was significantly lower than in the total CI group from these studies.

It seems that the decision of including some incidents like chorda tympani injury and device failure as medical complications affected the complication rates. The unclear definition of minor complications also affects the rates in different studies [15].

Regarding variations in complication rates according to age, Farinetti *et al.* [1] demonstrated that minor complication rates were significantly higher in the adult population, but there were no differences in major complication rates between the adult and pediatric populations. While among the 17 (2.82%) patients with major complications in this study, only two (0.33%) were adults. Further, among the minor

Table 4: Minor complications

Complications	Children [*n* (%)] [509 (84.5%)]	Adult [*n* (%)] [93 (15.5%)]	Total [*n* (%)] [602 (100%)]	Management, type of implant and electrode
1. Temporary facial nerve weakness early	2 Female (0.39)	3 Male 6 Female (9.67)	11 (1.83)	Conservative management-steroids/physiotherapy
2. Skin ulcer early	1 Female (0.196)	0	1 (0.17)	Medical treatment (phenytoin spray)
3. Postoperative vertigo. Early	0	2 Male 3 Female (5.38)	5 (0.83)	Tend to improve rapidly over time with medical management and vestibular rehabilitation
4. Tinnitus. Late	0	1 Male 1 Female (2.15)	2 (0.33)	Reassurance and tinnitus rehabilitation therapy
5. Mastoiditis. Late	1 Male 1 Female (0.39)	0	2 (0.33)	Conservative management-IV antibiotics
6. Facial nerve stimulation. Late	2 Male (0.39)	0	2 (0.33)	Reprogram, full recovery
7. Tip rollover of the electrode. Early	0	1 (1.08)	1 (0.17)	Electrodes that are likely to cause stimulation overlap are deactivated and thus reprogramming does not require major processing changes. (cochlear-slim straight)
Total number (%)	7 (1.38)	17 (18.27)	24 (3.99)	

Table 5: Perioperative complications

Complications	Children [*n* (%)] [509 (84.5%)]	Adult [*n* (%)] [93 (15.5%)]	Total [*n* (%)] [602 (100%)]	Management, type of implant and electrode
1. Gusher (CSF) leaks and oozing	10 Male	3 Male	26 (4.32)	IV mannitol and (RW or cochleostomy) seal
	11 Female	2 Female		7 Cases (AB Mid-scala)
	4.13%	5.38%		19 cases (MEDEL Form24)
2. Opening of scala vestibuli	1 Female	0	1 (0.17)	Corrected by opening of scala tympani in the same setting (AB-1J)
	0.2%			
4. Fenestration (injury) of ear canal	1 Female	1 Male	2 (0.33)	Repaired with tragal cartilage. (MEDEL-FLEX 28)
	0.2%	1.08%		
4. Chorda tympani nerve injury	2 Male	1 Male	6 (0.99)	Reassurance
	2 Female	1 Female		
	0.79%	2.15%		
Total	27 (5.3)	8 (8.6)	35 (5.81)	

Table 6: Cochlear implant complications at different centers

	Reference	CI {N}	Complications [*n* (%)]	Major [*n* (%)]	Minor [*n* (%)]
1	Côté *et al*. [9]	668	47 (7.04)	45 (6.7)	2 (0.299)
2	Kim *et al*. [10]	720	68 (9.44)	31 (4.3)	37 (5.13)
3	Venail *et al*. [11]	500	79 (15.8)	51 (10.2)	28 (5.6)
4	Hansen *et al*. [12]	505	147 (29.1)	9 (1.8)	138 (27.32)
5	Black [13]	547	47 (8.9)	11 (2.0)	36 (6.581)
6	Brito *et al*. [14]	591	92 (15.6)	49 (8.3)	43 (7.27)
7	Theunisse *et al*. [15]	1003	208 (20.7)	49 (4.7)	159 (15.85)
8	Olgun *et al*. [16]	957	80 (8.4)	72 (7.5)	8 (0.83)
9	Jiang *et al*. [17]	1065	28 (2.63)	7 (0.7)	21 (1.065)
	Total	6556	796 (12.14)	323 (4.93)	473 (7.21)
10	This study (at HSI)	602	76 (12.62)	17 (2.82)	24 (3.986)

complications, 24 (3.98%) temporary facial nerve weakness disorders were the most common complications in our case series in 11 (1.827%) patients, of which nine (1.5%) were adults.

Only three cases (0.49%) of soft-tissue infection were noted among our 602 CIs. Although it seems more traumatic to soft tissue, the lazy-S incision with adequate exposure of the receiver–stimulator well area did not affect the soft-tissue complication rate in this study. Davids *et al.* [18] advocated a small 25-mm postauricular incision and reported a 1.51% soft-tissue complication rate, which triples our rate. This can be explained by the nonalignment of skin and periosteal incisions, full periosteal coverage of the device, and the perfectly designed well with suture fixation.

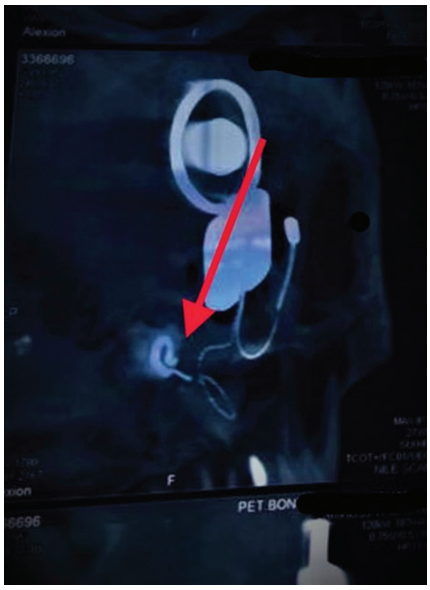

Figure 10: CT image showing tip rollover of a slim straight electrode inside the cochlea (red arrow). CT, computed tomography.

Conclusion

Our study, which reflects the results of 7 years of our experience in CI, showed that CI is a very successful and safe surgery with a limited number of serious complications that can be treated with conservative measures or mild interventions. Knowing all possible complications of CI and considering them during the surgery together with the long-term follow-up can minimize the risks of this procedure.

Acknowledgements

The paper has been read and approved by all authors.

The requirements for authorship have been met.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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