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# Analysis and Management of Complications in a Cohort of 1,065 Minimally Invasive Cochlear Implantations

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**Objectives:** To analyze complications associated with minimally invasive cochlear implantation by comparing data from different centers, to discuss major reasons for complications, and to refine implantation techniques to decrease them.

**Patients:** Patients who underwent cochlear implantation at our center by the same surgeon (the corresponding author of this article) from March 2006 to March 2015 were enrolled.

**Intervention:** First, a retrospective analysis of the complications associated with minimally invasive cochlear implantation at our center was performed. Second, published reports from other centers that describe complications were reviewed. Differences between complications in our cohort and other studies were evaluated.

**Main Outcome Measure:** Strategies for reducing complications were assessed and modifications in surgical protocol proposed accordingly.

**Results:** In total, 1,014 patients underwent 1,065 cochlear implantations. There were 28 complications (7 major, 21 minor) and only 2 reimplantations for the entire cohort, with no case of severe infection, flap necrosis, or device extrusion. The major complications were electrode misplacement, magnet displacement, implant failure secondary to trauma, and temporary cerebrospinal fluid leakage. The rates of major complications in our cohort were very low (0.6%) compared with those in the literature.

**Conclusion:** Preoperative surgical planning based on individual patient anatomy and employment of soft surgical techniques can minimize surgical complications. **Key Words:** Cochlear implantation—Complication—Literature review.

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Cochlear implantation (CI) has been recommended as an efficient procedure to rehabilitate hearing in patients with bilateral severe-to-profound sensorineural

hearing loss and has become a routine procedure. Approximately 324,200 people worldwide had undergone CI by December 2012 (1), and this number was estimated to grow to 550,000 by March 2016. Steadily growing numbers of CI require additional refinements and improvements of the CI technique to reduce complications and provide better outcomes under more difficult hearing conditions (1–8). Over the last decade, minimal-access CI surgery becomes popular because of the esthetic outcome and lower incidence of complications. In this study, we analyzed related complications retrospectively, reviewed the literature for large patient cohorts, and discussed possible improvements in relevant surgical steps.

## METHODS

### Patients

This study included 1,014 patients (1,065 CIs). All CIs were performed consecutively by the same surgeon (the corresponding author of this article, P.D.) from March 2006 to March 2015

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**TABLE 1.** *CI complications in this cohort*

Complication	Cases (n)	Management and Outcomes
Major	7	
Surgical-related	4	
Electrode misplacement	3	Electrode replacement with intraoperative image guidance, full insertion
Temporary cerebrospinal fluid leakage	1	Oral antibiotics 4 days, full recovery without revision
Device-related	3	
Device failure secondary to trauma	2	Ipsilateral reimplantation, no further problem
Magnet displacement	1	Magnet replacement, no further displacement
Minor	21	
Facial nerve stimulation	1	Reprogram, full recovery
Chorda tympani dysfunction	10	Untreated
Temporary facial nerve weakness	3	Conservative management, full recovery
Superficial wound infection	5	Oral antibiotics, full recovery
Hematoma	2	Local drainage and dressing, full recovery
Total	28	

CI indicates cochlear implantation.

in our department. This study was approved by the ethics committee of our institution.

The series included 963 unilateral and 51 simultaneous bilateral CIs, in 618 (61%) men and 396 (39%) women. The mean age at the initial surgery was 10 years (range, 4 mo to 74 yr). The age distribution of the patients and device brands are listed in Supplemental Table 1, <http://links.lww.com/MAO/A489>. There were 93 cases of inner ear malformation in this cohort, including 53 cases of enlarged vestibular aqueduct syndrome, 4 cases of incomplete partition (IP)-I, 15 cases of IP-II, 5 cases of IP-III, 8 cases of a common cavity, and 8 cases of cochlear hypoplasia. The mean follow-up duration was 43 months (range, 9 mo to 9 yr), with monthly examinations and mapping in the first year after CI and annual examinations and mapping thereafter. Patients who underwent primary CI surgery in outside institutions but revision surgery in our department were excluded.

### Surgical Technique

An inverted “S” incision (4.5–5 cm) was used until 2009. Since 2009, we designed a new retro-auricular linear skin incision with a 3 to 4 cm straight incision, 0.5 to 1 cm posterior to the posterior auricular sulcus. A muscle-periosteal incision was the second-layer incision; it began from the mastoid tip, extended up along the anterior boundary of the mastoid, and then turned 45 degrees superiorly and posteriorly to cut the temporal muscle. A simple mastoidectomy was performed; when the short process of the incus was exposed, the facial recess was opened cautiously and sufficiently. A bony well for the receiver/stimulator was drilled and tailored in accordance with the implant shape. Bony tie-down sutures were used for adult and pediatric subjects. The electrodes were inserted via the round window or cochleostomy, according to the cochlear implant brand. The wound was closed in three layers: the muscle periosteum layer with continuous sutures, the subcutaneous layer with interrupted sutures, and the intradermal layer with continuous sutures. A pressure dressing was used, and an intravenous antibiotic was prescribed for 3 days.

### Classification of Complications

In the absence of a generally accepted criterion for categorizing complications and device failure, we performed the literature review and defined as major those complications

resulting in life-threatening conditions, permanent disability, or needing surgical intervention. In contrast, as minor were considered those treated medically or with minor surgery. Therefore, temporary cerebrospinal fluid leaks were taken as major, because of its possible life-threatening nature, whereas injury of the chorda tympani and facial nerve paralysis without injury and complete recovery after steroid therapy as minor. Finally, device failure was considered a device-related major complication (3–6).

## RESULTS

### Complications at Our Center

In total, 28 (2.60%) complications occurred in 1,065 CIs (Table 1). We did not observe any severe infection, skin flap necrosis, or implant exposure in this cohort. There were seven (0.6%) major complications in the entire cohort. Among these, three electrode misplacements occurred in patients with ear malformations. In one patient with congenital microtia and severe malformation of the middle ear and facial nerve, the electrode was inserted into the Eustachian tube in the primary surgery and into the cochlea via a subfacial approach under intraoperative computed tomography guidance in revision. One patient had IP-I; postoperative imaging confirmed that the electrode was in the vestibule. One patient had enlarged vestibular aqueduct syndrome; postoperative imaging confirmed that the electrode was in the vestibule and superior semicircular canal. Correction of the misplaced electrodes in the cochlea was confirmed using C-arm X-ray imaging during revisions in the latter two patients. One patient with IP-III experienced transient cerebrospinal fluid leakage beginning 24 hours post-operation. Intravenous antibiotic treatment was begun and the leak resolved after 4 days without revision. One patient with magnet displacement suffered a head trauma and underwent minor surgery to replace the magnet. The only two (0.2%) reimplantations in the patient group were due to device failure, secondary to head trauma.

There were 21 minor complications; occurrences and the corresponding management are listed in Table 1.

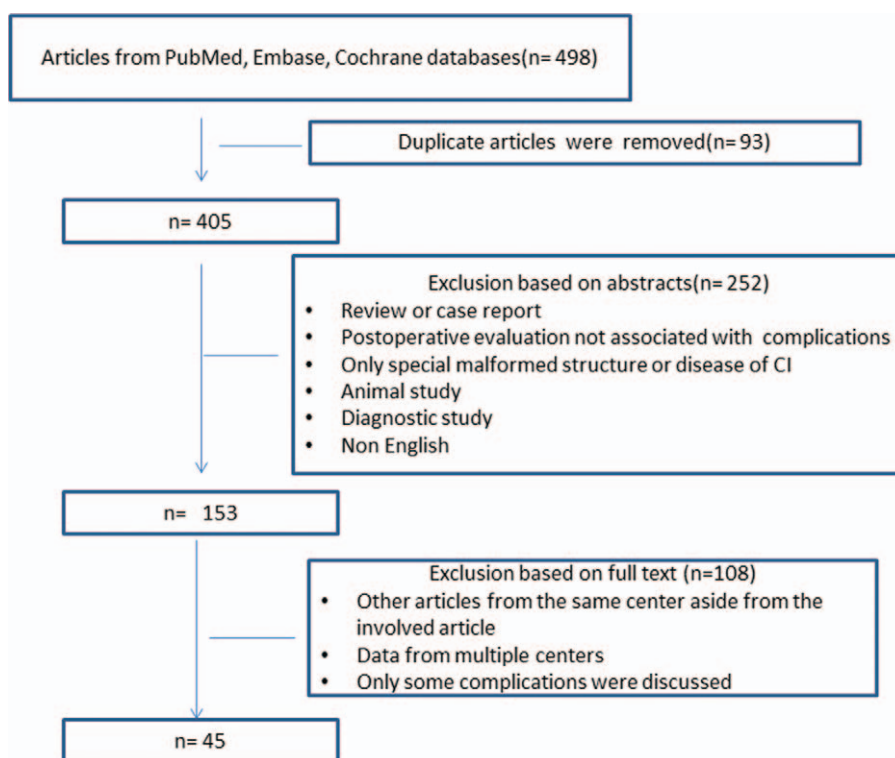


FIG. 1. Study selection criteria.

Injury of the chorda tympani was recorded by the operator via direct observation. Two patients experienced mild facial paralysis just after the surgery and one patient experienced delayed facial nerve paralysis. They all recovered completely after oral steroid therapy.

**Literature Review**

We conducted a systematic search of the PubMed, Embase, and Cochrane databases up to November 31, 2015, by combining the search terms “cochlear implant or cochlear implantation” and “complication or revision or reimplantation or explanation” in all fields. The study selection criteria are shown in Figure 1. For each study, two reviewers separately extracted standard sets of data.

We stratified studies by decade; CI complications in different periods are listed in Table 2. Before 2000, infection was the main complication. Since then, it has

shifted toward device failure. After 2010, the rate of device failure declined; this may be the result of improvements in the manufacturing process.

In total, nine articles reporting complications of CI in large cohorts of patients (more than 500) were reviewed with a total of 5,491 CI (Table 3) (3–10). Major complication rates ranged from 1.8 to 10.2%. The top three were device failure, infection, and misplaced electrodes; and were noted in 152, 51, and 29 patients, respectively. The incidence of the major complications in our cohort was significantly lower than in the total CI group from these studies.

**DISCUSSION**

The systematic literature review of 45 articles unfolded trends toward minimal access incisions since

TABLE 2. Comparison of CI complications in different decades

Period	Article	CI	Major Complications (Morbidity)											
			Device Failure	Device Infection	Device Migration	Electrodes Misplaced	Facial Paralysis With Sequel	Cholesteatomas	Hematoma	CSF Fistula	Body Reaction	Eardrum Perforation	Upgrade	Others
–2000	8	1,145	9	24	3	4	0	2	0	0	0	2	0	1
			Morbidity	0.8	2.1	0.3	0.3		0.2				0.2	
2000–2010	19	5,891	184	52	15	24	6	16	0	1	8	13	0	8
			Morbidity	3.1	0.9	0.3	0.4	0.1	0.3		0.02	0.1	0.2	
2010–	18	12,675	219	109	74	29	13	7	7	7	2	1	8	0
			Morbidity	1.7	0.9	0.6	0.2	0.1	0.06	0.06	0.06	0.02	0.01	0.06

CI indicates cochlear implantation; CSF, cerebrospinal fluid.

**TABLE 3.** Major complications at different centers

Author (yr) (Ref)	CI	Complications	Major Complications										
			Major	Minor	Device Failure	Infection	Device Migration	Electrodes Mislaced	Facial Paralysis With Sequel	Cholesteatomas	Hematoma	CSF fistula	Others
Mathieu (2007) (7)	668	47 (7.04%)	45 (6.7%)	2	35	3	3	0	0	3	0	1	0
Venail (2008) (5)	500	79 (15.8%)	51 (10.2%)	28	31	9	5	1	0	3	0	2	2
Kim (2008) (6)	720	68 (9.44%)	31 (4.3%)	37	14	4	2	4	3	1	3	0	0
Hansen (2010) (8)	505	147 (29.1%)	9 (1.8%)	138	NA	1	3	0	1	3	0	1	1
Black (2011) (9)	547	47 (8.9%)	11 (2.0%)	36	NA	0	8	3	0	0	0	0	0
Brito (2012) (4)	591	92 (15.6%)	49 (8.3%)	43	NA	14	1	12	5	6	0	2	9
Theunisse (2014) (3)	1,003	208 (20.7%)	49 (4.7%)	159	25	11	5	2	0	1	2	3	3
Olgun (2014) (10)	957	80 (8.4%)	72 (7.5%)	8	47	9	1	7	1	3	1	0	3
Total	5,491	768	316	452	152	51	28	29	10	19	5	5	18
This study	1,065	28 (2.63%)	7 (0.7%)	21	3	0	0	3	0	0	0	1	0

CI indicates cochlear implantation; CSF, cerebrospinal fluid.

2000. Multiple authors have commented that such techniques can reduce the risk of infection and flap necrosis. In fact, severe infection related to CI declined, resulting in morbidity drop from 2.1% before 2000 to 0.9% since then. In the nine articles with large patient cohorts, 51 major complications occurred because of infection, which was the major medical reason for CI reimplantations.

Importantly, no case of severe infection was noted among our 1,065 CIs. Two factors may have helped to prevent infection in our cohort: the design of the incision and fixation of the cochlear implant. We used a minimal-access skin incision and a periosteal incision with a three-layer suture method to control complications. The periosteal incision in our group was 1.5 cm anterior to the skin incision without any overlap between the two incisions. In all of our cases, the sutured muscle-periosteal flap fully covered the bony surface, mastoid cavity, and all parts of implant, creating double protection with the sutured skin layer.

In our group, the receiver/stimulator bony well was made carefully to accommodate different cochlear implants and fixation with 3/0 sutures ensured no migration of the implant. Indeed, we did not observe any device migration, flap, or intracranial complication, suggesting that our fixation technique may be one reason for our low complication rate (11,12). Other techniques, such as keeping the overhanging cortical bone in the posterior edge of the mastoid cavity to provide a hard support for the electrode cable hidden in the mastoid, helped maintain the stability of the electrodes and cables.

Electrode misplacement related to inner ear malformations was an important risk factor for major complication (Supplemental Table 2, <http://links.lww.com/MAO/A490>). The only electrode misplacements in our cohort occurred in three patients with inner ear malformations. To minimize this type of complication, 22 subsequent patients with severe ear malformations underwent operations with intraoperative computed tomography guidance. These included eight cases with

a common cavity, nine with IP-I, four with IP-III, and one with cochlear hypoplasia. Consideration was also given to selection of the most appropriate electrode type in light of each patient's anatomic variation (10).

## CONCLUSIONS

CI has been well established as a relatively safe and very effective auditory rehabilitation procedure. Progress has been made in reducing major complications by advancements in surgical technique over three decades, though inner ear malformations and device failures still represent a considerable challenge. Well-informed surgical design and careful device fixation can minimize complications related to scalp flap infections and implant device exposure, as illustrated in this large case series.

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