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OTOLOGY

Electrode migration after cochlear implant surgery: more common than expected?

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Abstract The overall complication rate of cochlear implant surgery is low and so-called electrode failures (electrode migration, misplacement, etc.,) account for only a minority of all complications. The aim of this study was to explore the prevalence of electrode migration as the cause for increased impedance values and non-auditory stimulation in the basal channels. Within the scope of a quality control process, the cochlear implant database of the Kuopio University Hospital (Finland) was reviewed. Patients with gradual elevation of impedance values and/or non-auditory stimulation of the basal electrode channels were re-examined and cone-beam computed tomography was administered. There were 162 cochlear implant recipients and 201 implanted devices registered in the database. A total of 18 patients (18 devices) were identified having significantly increased impedance values or non-auditory stimulation of the basal electrodes. Cone-beam computed tomography revealed extra-cochlear electrodes in 12 of these patients due to the migration of the electrode array. All extruded electrodes were lateral wall electrodes, i.e., straight electrode arrays (Cochlear CI422 and Med-El devices). The most common feature of electrode migration was the gradual increase of the impedance values in the basal electrodes, even though telemetry could also be unsuspicious. Electrode migration after cochlear implant surgery may be more common than previously reported. At surgery, special attention should be paid to the reliable fixation of the electrode array. This study underlines the importance of postoperative imaging after cochlear implant surgery.

Keywords Cochlear implants · Electrode migration · Cone-beam computed tomography · Impedances

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Introduction

During the past decades, cochlear implants (CI) have become a standard treatment for both children and adults with severe to profound bilateral sensorineural hearing impairment. The rapid technological developments of CI systems and the growing clinical experience have led to constantly better hearing outcomes and, therefore, to an extension of the indication criteria. The annual numbers of cochlear implantations are thus rising worldwide. Cochlear implantation is generally considered a relatively safe procedure with a low rate of major complications.

The rate of revision surgery is reported to vary from 3 to 10 % of all CI surgeries and is more common in pediatric implantees [1–3]. Cochlear implantation failures can be categorized into three groups: hard failure, soft failure, and medical complications. The so-called hard failures or device failures are the most common reason for revision surgery. Soft failure is a working diagnosis, in which the device passes the manufacture's integrity test but patients experience non-auditory aversive symptoms, intermittent function, and a deterioration of the speech intelligibility. These symptoms usually resolve with device explantation and subsequent reimplantation [4]. Medical complications are often wound- or flap-related issues usually in conjunction with infection, which may in worst cases require the explantation of the device.

Electrode migration out of the cochlea accounts for only a minority of revision surgeries and is reported to vary from 1 to 15 % of all revision cases [1, 5–10]. Currently the underlying mechanisms for electrode migration are poorly understood. It is reported to be more common in children, in whom new bone formation and mastoid growth are thought to be responsible for electrode extrusions [6, 10]. Head trauma and intracochlear fibrosis or ossification may also lead to an extrusion of the electrode out of the cochlea. Different surgical techniques have been developed to reduce the risk of electrode migration [9–13].

During the rehabilitation with CIs, it is quite common that active electrode channels have to be removed from the stimulation map over the time [14, 15]. The main reasons for switched off channels include high impedances, shortcuts, open-circuits, non-auditory percept or non-auditory stimulation, such as facial nerve stimulation. When an increasing number of channels has to be switched off, electrode failure may be present which usually precedes device failure [15].

In the everyday clinical practice, however, most often the basal electrodes are affected by high impedances and/or non-auditory percept, which may require their removal from the stimulation map. The deactivation of those single channels is often categorized as for programming reasons and often does not entail any further investigations [16].

With the introduction of flat-panel or cone-beam computed tomography (CBCT) more accurate imaging of the post-operative electrode placement has become possible with low-dose radiation exposure. Detailed postoperative imaging provides important information about the electrode location, insertion depth, and scalar localization. Knowledge about the electrode localization is important because it bears implications for the programming strategies. Adequate postoperative imaging serves also as a measure for the quality of insertion and as a reference for the future, if problems emerge [17, 18]. Whereas computed tomography is still considered gold standard for temporal bone imaging, the metallic artifacts caused by the electrode may significantly limit its application in postoperative imaging after CI surgery. Image fusion techniques combined with statistical predictions of the intracochlear anatomy provide the most accurate estimation of electrode placement also for the apical parts of the cochlea [19]. In the clinical setting, however, CBCT offers adequate image quality with minimal electrode artifact so that accurate estimations of the electrode position with respect to insertion depth and the insertion angle are possible [20].

The aim of this study was to explore the prevalence of electrode migration as the reason for telemetry abnormalities or non-auditory percept/stimulation in the basal electrodes.

Patients and methods

A total of 162 patients (201 ears) were registered in the CI database of the Kuopio University Hospital from 01.01.2002 to 30.06.2014. 68 patients (74 ears) were implanted with Med-El™ (Med-El, Innsbruck, Austria) and 94 patients with Cochlear™ (Cochlear Ltd., Sydney, Australia) devices (63 ears implanted with Slim Straight™ arrays (CI422) and 64 ears implanted with Contour Advance™ arrays). Within the scope of a quality control process, the database with the corresponding medical records was reviewed. All patients with elevated impedance values (impedance increase $\geq$75 % from the average baseline after 1 month of activation) or non-auditory percept/sensations on the basal electrodes underwent new clinical examinations including device measurements with re-programming. New follow-up CBCT examinations were obtained to review the sustained accurate electrode placement.

The clinical examination included the determination of the threshold-levels (0.25–8 kHz) of the CI and speech audiometry (Finnish word test in quiet). Device measurements and re-programming were done with the Cochlear Custom Sound™ 4.1 and the Med-El Maestro™ 3.0 software, respectively. The basal electrodes (Cochlear: electrodes 18–22; Med-El: electrodes 9–12) were specifically tested for non-auditory stimulation such as pain sensation or facial stimulation at different current levels. The CBCT scans were performed on a ProMax 3D Max scanner (Planmeca™ Oy, Helsinki, Finland) using following parameters: 50 × 55 mm FoV, 96 kV, 7, 1 mA. Actual scanning time according to this protocol was 15 s. The authors (AD, MW, AL) reviewed the scans individually.

The number of extra-cochlear electrodes was counted in each patient, on the basis of follow-up CBCT. Electrodes, situated at the level of the round window, were categorized as extracochlear, since electrodes at this position do not provide adequate stimulation or accurate pitch perception so that they mostly have to be removed from the stimulation map.

All patients in whom a full insertion of the array was not initially achieved at surgery were excluded. In these patients the presence of the extra-cochlear electrodes had been taken into consideration at activation and programming of the sound processor. Excluded were also patients in whom an adequate immediate post-operative imaging had not been obtained at surgery or had not been available for review.

Results

In all, there were 18 patients fulfilling the inclusion criteria (i.e., increase of the impedances and/or non-auditory percept in the basal channels). In 15 patients, we observed a gradual increase in the impedance values after the activation of the device, which eventually led to the deactivation of one or more channels. Figure 1 shows a screenshot of the Custom Sound™ 4.1 software, which illustrates typical pattern of the gradual elevation of the basal impedance values. In three patients, the impedance values remained unsuspicious, but non-auditory sensation such as facial stimulation and pain sensation at stimulation were present. According to our clinical protocol, we obtained a follow-up CBCT in all of these 18 patients.

Twelve patients were found having a partly migrated electrode array on CBCT. Figures 2 and 3 show two CBCT images as examples. Five patients were implanted with the Cochlear Slim Straight array (CI422) and seven patients were implanted with Med-El arrays of different lengths (24, 28, and 31 mm). Thus, all extruded electrodes were straight arrays (i.e., lateral wall electrode). The number of electrodes outside the cochlea varied from two to six electrodes for the Slim Straight array (median 5) and from one to three electrodes for the Med-El devices (median 2). The most common feature indicating the process of electrode migration was a gradual increase of the impedance values in the basal electrodes, which was observed in nine of the twelve patients (75 %). In the remaining three patients (25 %) telemetry was inconspicuous but non-auditory sensations were present at the stimulation on some of the extra-cochlear electrodes. The time from first activation until the appearance of the impedance abnormalities varied from one to seventeen months (mean 7 months). There was no prior history of head trauma in any patient. Patients with unilateral CI noticed the gradual deterioration of the speech recognition quite clearly. Also three patients with bimodal stimulation were alerted by the decrease of speech recognition. However, most of the bimodal users did not subjectively experience any decrease in their speech recognition capacity. We recommended revision surgery for eight patients based on their age, the number of extracochlear electrodes, insertion depth angle, and speech recognition. Patient demographics and the clinical features are shown in Table 1.

All patients were operated on by the authors (A.D., H.L., H.V.), with the standardized surgical procedure of cortical mastoidectomy, followed by posterior tympanotomy. In seven patients surgery was done according the principles for hearing and structure preservation and array insertion was performed through the round window membrane, as described earlier [21]. In the remaining five patients the electrode was inserted through a cochleostomy. The fixation of the lead wire was performed according to the recommendations provided by the manufactures. In detail, the electrode's lead wire was fixated with temporal muscle fascia, fibrin glue and Spongostan™ (Ferrosan Medical Devices, Denmark) at the insertion site as well as in the

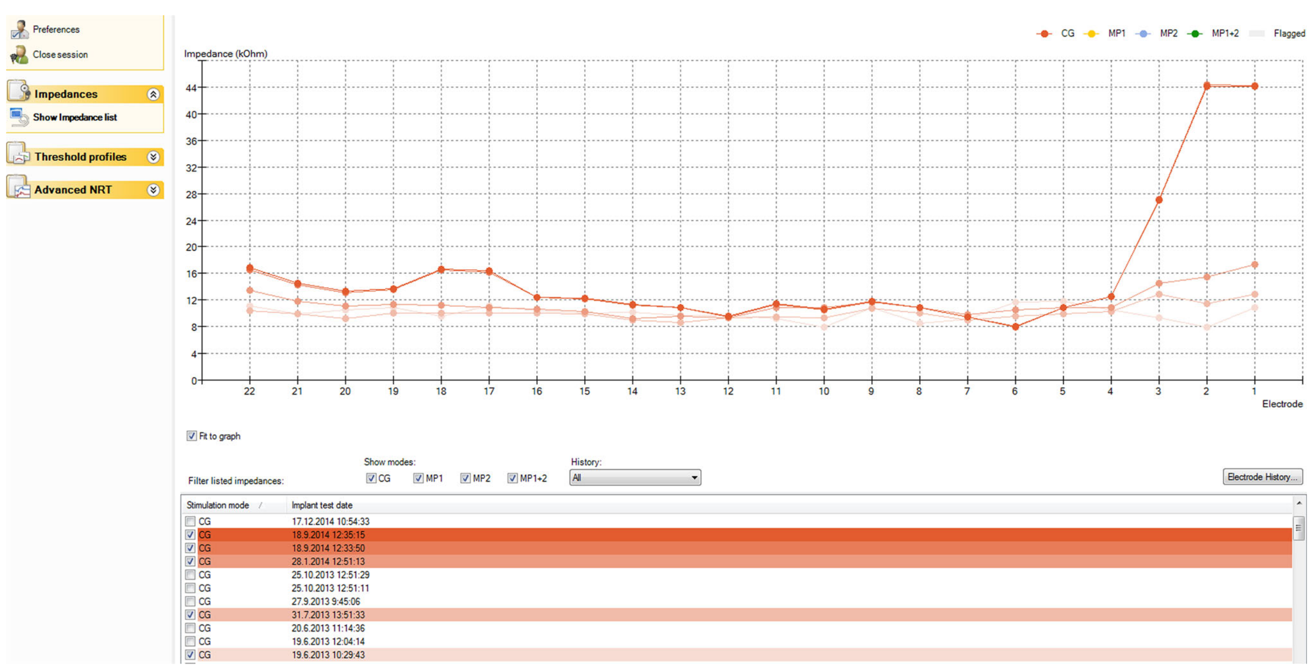

Fig. 1 Example (patient #2) of the increase of the impedance values within 15 months after activation as observed with Cochlear Custom Sound™ software. Please note that electrodes 4 and 5 have normal impedances, despite being extra-cochlear

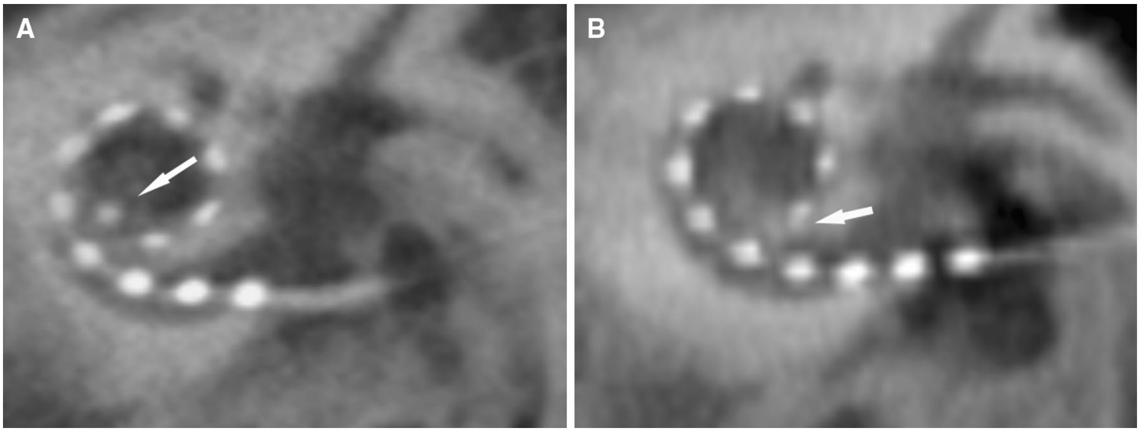

Fig. 2 **a** Immediate post-operative CBCT scan of a Med-EL™ Flex [24] array and full insertion with an insertion angle of 495°. **b** The follow-up scan shows the partly extruded array with a 360° insertion angle. Two electrodes are extra-cochlear. The *arrow points* at the tip of the electrode (patient 4)

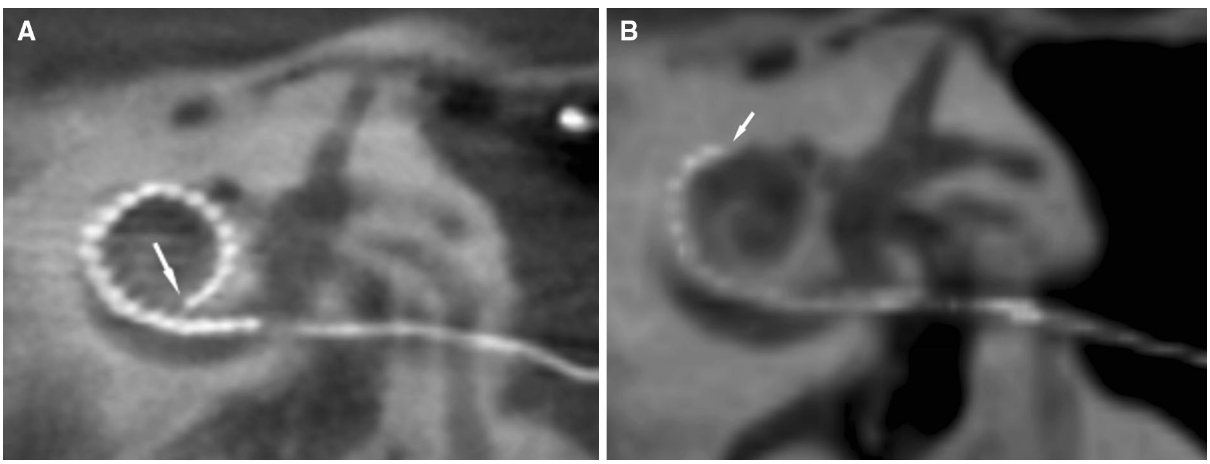

Fig. 3 **a** The immediate post-operative CBCT scan shows a fully inserted Cochlear™ Slim Straight array (CI422) with an insertion angle of 390°. **b** The follow-up scan shows a substantially retracted electrode with six extra-cochlear electrodes and an insertion angle of 210°. The arrow points to the tip of the electrode (patient 3)

facial recess. Additional fixation of the electrode was done with bone paté and fibrin glue inside the mastoid cavity. In four patients additional fixation of the lead wire was done with bone cement. Full electrode insertion was achieved in all patients and electrode placement was controlled immediately after surgery by CBCT imaging or plain radiographs in Stenvers projection in eight and four patients, respectively.

Discussion

In previous studies electrode-related failures such as electrode misplacement and electrode migration or extrusion were found to be very rare [3, 6–9]. So-called channel failures, however, are quite common during follow-up and programming of the sound processor. Mostly the basal channels are involved and often need to be switched off the stimulation map [14, 16]. For example, high basal impedances may develop as a result of incomplete insertion of the array and have to be switched off at activation of the sound processor. However, basal channel impedances may also increase over time despite complete insertion. The commonly held belief that fibrosis at the insertion site is growing slowly into the cochlea may be responsible for the gradual increase of the impedances [22, 23]. Speech recognition performance is usually maintained when only single channels are affected (i.e., switched off). Therefore, it often does not entail any further investigations in the clinical routine [16]. Special awareness is required for the detection of electrode migration. At our institution CBCT imaging in low-dose radiation setting is readily

Table 1 Patient demographics and clinical features

	Age (years)/gender	Device	Hearing	Insertion	Insertion depth at surgery	Post-operative imaging	Symptoms and signs	Impedance increase (months)[α]	Number of extra-cochlear electrodes	Scheduled for revision surgery
1	3/F	Cochlear CI422	Bilateral CI	RW	Full (23 mm)	CBCT	Impedance abnormality	11	6	Yes
2	10/M	Cochlear CI422	Bimodal & EAS	RW	Full (22 mm)	CBCT	Non-auditory sensations (pain)	No increase	5	Yes
3	9/F	Cochlear CI422	Bimodal & EAS	RW	Full (23 mm)	CBCT	Impedance abnormality, deterioration of performance	16	6	Yes
4	12/F	Cochlear CI422	Bilateral CI	RW	Full (22 mm)	CBCT	Non-auditory sensations (pain)	No increase	2	Yes
5	34/F	Cochlear CI422	Unilateral CI	RW	Full (23 mm)	CBCT	Facial nerve stimulation, deterioration of performance	No increase	5	Yes
6	48/F	MED-EL FLEX^{24}	Unilateral CI	C	Full (24 mm)	CBCT	Impedance abnormality, deterioration of performance	5	2	Yes
7	51/F	MED-EL FLEX^{Soft}	Bimodal	C	Full (31 mm)	X-ray	Impedance abnormality, deterioration of performance	2	2	Yes
8	55/F	MED-EL FLEX^{Soft}	Bimodal	RW	Full (31 mm)	CBCT	Impedance abnormality	8	3	No
9	58/F	MED-EL Standard	Bimodal	C	Full (31 mm)	X-ray	Impedance abnormality, deterioration of performance	1	3	Yes
10	58/M	MED-EL FLEX^{24}	Bimodal & EAS	C	Full (24 mm)	X-ray	Impedance abnormality	17	1	No
11	65/M	MED-EL FLEX^{Soft}	Bimodal	C	Full (31 mm)	X-ray	Impedance abnormality	5	1	No
12	71/F	MED-EL FLEX^{28}	Bimodal	RW	Full (28 mm)	CBCT	Impedance abnormality	5	2	No

RW Round window insertion, *C* cochleostomy, *bimodal* cochlear implant + hearing aid, *EAS* electric-acoustic stimulation with a CI

[α] Impedance increase $\geq$ 75 % from average baseline after activation (months from operation)

administered to rule out electrode migration in patients with impedance abnormalities or non-auditory sensations in the basal channels.

Schow et al. analyzed electrode failure in 322 implanted CIs and found that 54 % had one or more electrodes turned off because of impedance abnormalities (i.e., open or short circuit, high impedances), poor auditory sensation or non-auditory stimulation. The deactivated electrodes were mostly located in the basal part of the array, and with elevated impedance values compared to the neighboring enabled electrodes. They concluded that the high impedances were most likely the result of the deactivation itself, since impedances of unstimulated electrodes tend to increase over time. However, their study did not include any radiographic analysis so that incomplete insertion or electrode migration as the reason for the abnormalities in the basal channels was not considered [16]. In pediatric CI patients, electrode failure or switched off channels were observed in 52 of 264 devices (20 %), again mostly at the basal part [14]. In our study, we obtained a CBCT of every patient with basal channel abnormalities. The exclusion of all patients with incomplete electrode insertion and/or unavailable adequate immediate postoperative imaging helped us to gather reliable data on possible electrode movement over time.

In temporal bone studies significant inflammatory response with scar formation and fibrosis after cochlear implantation were observed [24]. Fibrosis may vary from only minimal scarring at the round window area to widespread scar formation extending into the cochlea. Accordingly, at CI revision surgeries scar formation and fibrosis of different degree are often present [3]. Postoperative fibrous tissue growth is also assumed to be one explanation for the increase of electrode impedances after cochlear implantation [22, 23]. In our series, sustained electrode localization was confirmed by CBCT in six patients. Since no dislocation or migration of electrode was found in these patients, we suspect that fibrous tissue formation in combination with absent stimuli (due to disabled channels) may have been responsible for the elevated impedances. The clinical features were almost indistinguishable from those of patients with extruded arrays. Mostly insufficient auditory stimulation of these channels was present and non-auditory sensations usually occurred at higher current levels.

The most common feature of electrode extrusion was the gradual increase of impedances, although it should be noted that in three cases telemetry remained unsuspicious. Additionally, in most patients with bimodal stimulation or bilateral CI the gradual deterioration of speech recognition was subjectively difficult to notice. The gradual increase of impedances indicates that migration of the electrode has occurred slowly over several months. Therefore, sufficiently sensitive speech-audiometric tests should be administered regularly to adequately monitor the performance of the CI recipients. Unfortunately, prior to the year 2015 no speech in noise test had been available for the Finnish language in order to document the speech recognition in noise of these patients. However, two unilateral users and two bimodal users were alerted by the gradual decline of their speech recognition (see Table 1). According to the MAUDE database (Manufacturer and User Facility Device Experience) change in sound and poor performance were the most common symptoms of electrode migration. In these patients, however, the electrode extrusions were more severe, i.e., with a substantial amount of extracochlear electrodes [9].

The underlying mechanisms for electrode migration are yet not completely known. In pediatric patients, extrusion might occur when there is new bone formation inside the mastoid cavity in conjunction with the growth of the skull, which may retract the electrode out of the cochlea. A slightly higher incidence of straight electrode extrusions has been noted as compared to so-called perimodiolar or curved electrodes [3, 10]. Indeed, also in our study all cases of electrode migration were observed in patients implanted with a straight array. Design-wise the precurved electrodes are practically self-retained inside the cochlea, and the pretension may resist pulling forces of the lead wire to some extent. Straight arrays, on the contrary, may exert forces to the outer wall of the cochlea due to the inherent tendency to spring back into its original straight position. These spring forces are the higher the stiffer the electrode and may, therefore, promote the extrusion. Also scar shrinkage or drying of fibrin glue could exert adverse forces on the electrode's lead wire. Additionally, in pediatric cases new bone formation inside the mastoid cavity is considered a risk factor for the extrusion, as described previously [3]. In earlier studies, intracochlear fibrosis and ossification were considered a risk factor for electrode migration [3, 7]. In our study, however, seven patients underwent hearing preservation cochlear implantation. Hearing preservation, as defined as postoperative change of $PTA_{(0.125–1kHz)} \leq 30\ dB_{(HL)}$, was achieved in all of these patients so that intact inner ear structures were maintained. Therefore, it is very unlikely that intracochlear fibrosis or ossification would have caused the extrusion in these patients. On the contrary, it can be speculated whether preserved inner ear structures, with their fluid-filled scalae, may even facilitate the extrusion. Straight arrays of the latest generation, designed for hearing preservation surgery, are very thin and require minimal insertion forces. This also means that the reduced intracochlear friction makes these electrodes more prone for extrusion. Therefore, special attention to the fixation of the lead wire may be required with these arrays.

From our results it is obvious that the fixating of the electrode lead wire was insufficient or failed. We secured the electrode at the site of insertion with temporal fascia and fibrin glue as well as in the facial recess and in the mastoid cavity with bone paté and fibrin glue. We ceased the application of bone cement for securing the lead wire in 2009, as manufactures advised against its general use in CI surgery. In four patients bone cement was used, which did not prevent the extrusion. Different surgical techniques were previously described for the fixating the electrode, e.g., fixation of the electrode wire into a drilled grove between the facial nerve and the chorda tympani, the use of titanium clips and the split-bridge technique [9, 12, 13]. The application of these techniques may lower the risk of electrode extrusion. We now altered our surgical technique in such a way that we curl the lead wire into the mastoid before the insertion to make sure that the lead wire will not exert any adverse forces once inserted. We additionally now use a small amount of bone paté and fibrin glue to fix the electrode in the facial recess.

Electrode migration can sometimes be addressed with reprogramming without compromising the performances when only few channels are involved. However, revision surgery is generally indicated when a concomitant decline of the speech intelligibility is present [5, 7, 9]. Depending on the medical history, revision surgery may require the explantation of the old device with subsequent implantation of a new one. It is, therefore, associated with additional surgical risks for the patients as well as considerable additional health-care expenses. Revision surgery in which only the electrode is re-positioned (i.e., deeper re-insertion) may also be a viable alternative. It, however, bears the risk of inducing inflammation or even infection into the cochlea in case of a colonization of the electrode with bacterial biofilm [25]. Possible presence of a bacterial biofilm should be considered especially in pediatric cases, in which middle ear infections are common. Therefore, replacement of the device is warranted in all children having tympanostomy tubes or in whom middle ear infection cannot be ruled out with certainty.

Whether a partly extruded electrode requires revision surgery depends on the number of switched off electrodes as well as on the performance of the patient. In pediatric cases, however, revision should always be readily considered for optimal rehabilitation and speech development. Since the neural auditory pathways are still developing, adequate electrode placement is of special importance in children. Therefore, a sufficient insertion depth angle is required to stimulate as much neural tissue as possible and to provide adequate cochlear coverage. Considering that the future success of the intellectual and occupational career (kindergarten, school, studies, etc.) of these children may substantially be facilitated by an optimal performance of their CIs, we readily advise in favor of revision surgery in pediatric cases. Additionally, revision surgery was recommended for four adult CI recipients due to the deterioration of their speech recognition performance. In three patients sequential implantation of the other ear was performed first and revision surgery will be performed as soon as they perform adequately well with the new CI ear.

With a prevalence of 6.0 % electrode migration is the most common complication of CI surgery at our institute. In two other studies, electrode migration was found to be uncommon but still comprised the second leading cause of revision surgery after device failure [7, 9]. Our exceptionally high rate of electrode migration may be partly explained by our systematic application of CBCT during follow-up of our CI recipients. Our CBCT protocol for the assessment of electrode placement is optimized for low-dose radiation exposure so that imaging can be safely done whenever electrode problems arise. Due to the somewhat longer scanning time for CBCT compared to conventional CT scanning, head movements are the most common factor for diminished scan quality. Still, we prefer CBCT for temporal bone imaging in our pediatric patients because of the substantially lower radiation dose. Furthermore, we were able to scan successfully children as young as 5 years of age without anesthesia or sedation. Before the implementation of CBCT at our institute, basal channel abnormalities did not necessarily entail any further investigation, when only few channels were involved.

Conclusion

Electrode migration may be more common than previously reported. It appears that the common techniques of electrode fixation may not be sufficiently reliable and special attention should be paid to the fixation of straight electrode arrays in particular. In the postoperative follow-up, awareness is required in patients with telemetry abnormalities or non-auditory sensations in the basal electrodes. With the introduction of CBCT accurate assessment of intracochlear electrode placement with low radiation exposure has become possible and should be considered in every patient with basal electrode failure(s). This study underlines the importance of systematic postoperative imaging after CI surgery.

Compliance with the ethical standards

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

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