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Otology

Revision cochlear implant surgery for clinical reasons

La chirurgia di revisione dell'impianto cocleare eseguita per problemi medici

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SUMMARY

Objective. To report the authors' experience in a series of patients treated with cochlear implant (CI) revision surgery due to medical problems.

Methods. Revision CI surgeries performed in a tertiary referral centre for medical reasons not related to skin conditions were reviewed; patients were included if device removal was required.

Results. 17 cochlear implant patients were reviewed. The main reasons requiring revision surgery with device removal were: retraction pocket/iatrogenic cholesteatoma (6/17), chronic otitis (3/17), extrusion in previous canal wall down procedures (2/17) or in previous subtotal petrosectomy (2/17), misplacement/partial array insertion (2/17) and residual petrous bone cholesteatoma (2/17). In all cases surgery was performed through a subtotal petrosectomy. Cochlear fibrosis/ossification of the basal turn was found in 5 cases and uncovered mastoid portion of the facial nerve in 3 patients. The only complication was an abdominal seroma. A positive difference was observed between the number of active electrodes and comfort levels before and after revision surgery.

Conclusions. In CI revision surgeries performed for medical reasons, subtotal petrosectomy offers invaluable advantages and should be considered as first choice during surgical planning.

KEY WORDS: revision surgery, cochlear implant, subtotal petrosectomy, ear surgery

RIASSUNTO

Obiettivo. *Scopo dello studio è stato quello di riportare l'esperienza degli Autori su una serie di pazienti sottoposti a chirurgia di revisione dell'impianto cocleare (IC) per problemi medici.*

Metodi. *Valutazione retrospettiva dei pazienti sottoposti a chirurgia di revisione con rimozione dell'IC in un Centro di riferimento.*

Risultati. *Sono stati esaminati 17 pazienti. Le indicazioni all'intervento di espianto e revisione sono state: tasche di retrazione/colesteatoma iatrogeno (6/17), otite cronica (3/17), estrusione del cavo/ricevitore-stimolatore da cavità di mastoidectomia aperta (2/17) o in petrosectomia subtotale (2/17), malposizionamento/inserzione parziale dell'array (2/17), colesteatoma della rocca residua (2/17). In tutti i casi è stata eseguita una petrosectomia subtotale. Riscontri intraoperatori addizionali sono stati: fibrosi/ossificazione del giro basale della coclea in 5 casi e porzione mastoidea del nervo facciale scoperta in 3. È stata osservata una differenza positiva tra il numero di elettrodi attivi prima e dopo la revisione. Unica complicanza è stato un sieroma addominale.*

Conclusioni. *Nella chirurgia di revisione dell'impianto cocleare la petrosectomia subtotale rappresenta una tecnica sicura ed efficace, da considerare come prima opzione terapeutica.*

PAROLE CHIAVE: *chirurgia di revisione, impianto cocleare, petrosectomia subtotale, otochirurgia*

Introduction

Global failure rate has been used in major cochlear implant (CI) centers as a tool to ascertain device survival from both primary and revision surgery [1]. Medical conditions determining the need for revision CI surgery are mainly related to

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cutaneous problems at the site of the receiver/stimulator and can often be managed while preserving device integrity [2].
Besides skin conditions, there have been few published cases of other medical problems requiring revision surgery with device removal [3,4]; surgery in these conditions may present difficulties and even preclude the possibility of re-implantation.
The aim of this study was to report the authors' experience in a series of patients who needed CI revision surgery with device removal and a subsequent re-implantation attempt.

Materials and methods

Charts of patients who underwent revision CI surgery between January 2015 and November 2019 in a tertiary referral University Hospital Otorhinolaryngology and Otoneurosurgery Department, were retrospectively reviewed. Patients were included if: 1) revision surgery was performed for medical reasons not related to skin conditions and 2) device removal was required. For each case, reason for removal, time interval between first and revision surgery, previous procedures, operative findings and complications were analysed. Number of active electrodes and mean comfort levels (C-levels) measured in current units before and after revision surgery, were evaluated as well.

Results

Seventeen patients were included, 5 males and 12 females; 13 patients were older than 18 years at the time of the study. Mean age was 45.64 years (range 5-78 years). Some patients have been reported in previous publications: patients 1, 2, 4, 6, 7, 8, 9, 10, 11, 14, 15 in a 2020 case series [5] and patient 5 in a 2011 case report [6] (Tab. I). All patients underwent temporal bone CT scan before revision surgery.
Different brands of CI were involved: Cochlear (Cochlear Company, Sydney, Australia) in 8 cases, Oticon Medical (Oticon, Vallauris, France) in 8 cases and MedEl (MedEl, Innsbruck, Austria) in 1 case.
Three cases (17.65%) had received primary surgery at authors' Institution and 13 elsewhere (82.35%). Four of the adult patients had already undergone at least 1 revision surgery.
The mean time interval between previous surgery and revision was 94.9 months (ranging from 2 to 264 months).
Revision surgery was always performed through a subtotal petrosectomy (SP); 5 patients had already been treated through a SP during first surgery.
Table I shows demographics and clinical conditions leading to revision surgery.
There were 2 cases of connecting cable and/or array extrusion in previous canal wall down (CWD) mastoidectomy

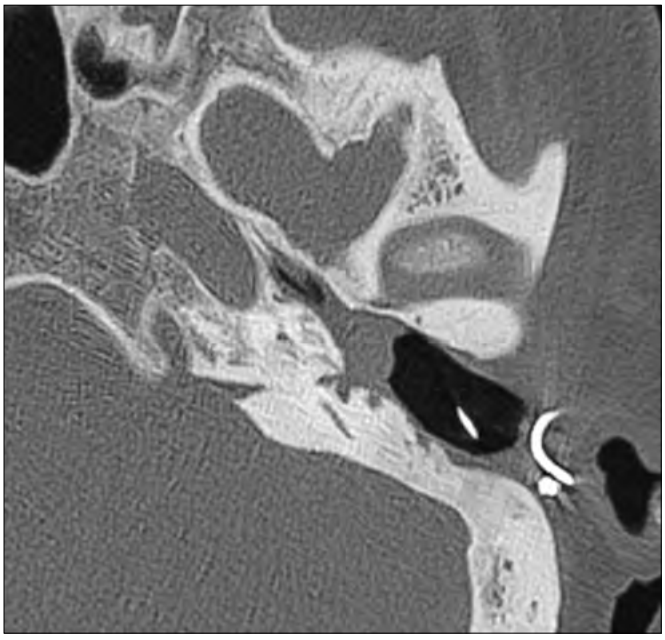

Figure 1. Axial high-resolution CT scan, left ear. Patient 14. The cochlear implant array/connecting cable can be seen in the lateral portion of the cavity. A mass of soft tissue density fills the middle ear cavity and ossification of the cochlear lumen is evident.

(# 12 and 14); in 1 (# 14), the extrusion was the result of an in-office cleaning of the cavity (Fig. 1).
Retroauricular extrusion of the connecting cable/receiver-stimulator occurred in 2 cases previously treated with a SP (# 6 and 16). In both patients device exposure led to infection of the surgical cavity with breakdown of the closure of the external auditory canal (EAC) in one.
Five cases of erosion of the posterior wall of EAC were included: in 2 patients it resulted in extrusion of connecting cable (# 2 and 8), while in 3 it progressed to an iatrogenic cholesteatoma (# 1, 9 and 13). An additional cholesteatoma through a marginal perforation occurred in one case (# 4).
Two cases were treated for residual petrous bone cholesteatoma (# 5 and 17). One patient showed a misplaced array into the petrous carotid canal (# 15), while another (# 10) had only 11 functioning electrodes due to intraoperative cerebrospinal fluid (CSF) leak.
In 3 cases revision surgery was performed for chronic otitis media (# 3, 7 and 11); one of these had already undergone miringoplasty with a reperforation (# 7).

Preoperative device functionality

In 6 cases the device was not functioning at the time of revision surgery; 2 had complete extrusion of the array from the cochlear lumen (# 14 and 16).
Eleven implants were explanted while the CI was still functional; some showed reduction of performance and/or incre-

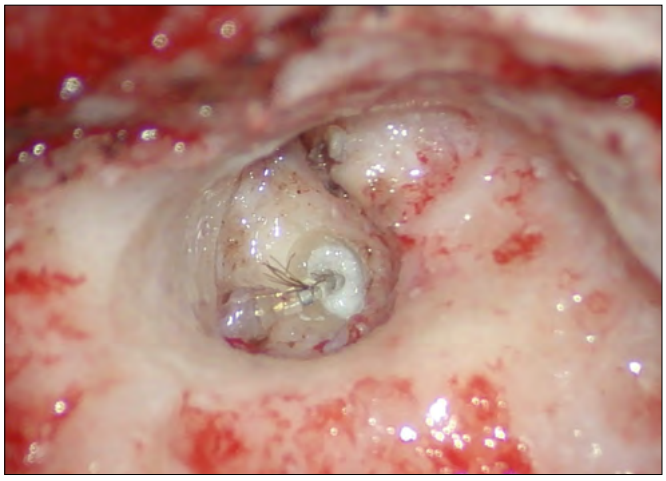

Figure 2. Intraoperative picture, left ear, surgical position. Patient 13. The cochlear implant array has been sectioned near the round window. Fibrosis and ossification can be seen surrounding the array; multiple manoeuvers were performed with fraying of the array to achieve removal.

ment of stimulation levels at the last controls before revision. Due to the clinical problems, only 3 patients were daily implant users before final revision surgery (# 1, 2 and 8).

Intraoperative findings

Cochlear fibrosis/ossification requiring additional drilling of the basal turn was found in 5 cases (29.4%) (Fig. 2), while the mastoid portion of the facial nerve was uncovered in 3 (17.6%).

Re-implantation was not possible due to extended cochlear ossification in 1 case (# 16) and to subtotal cochlear drilling to achieve total removal of residual petrous bone cholesteatoma in another (# 17).

Postoperative device functionality

A new device was inserted in 15 patients. During first fitting all the electrodes were active, except for 2 cases (# 9 and 11). One patient, despite full re-insertion, did not show any hearing sensation (# 7).

In 9 cases, it was possible to insert more active electrodes into the cochlear lumen than in the preoperative setting. In 4 patients, the number of electrodes remained the same while in one decreased.

Evaluation of C-levels was performed in 13 patients for which data were available both before and after revision surgery; mean C-levels were reduced in 10 cases.

Complications and follow-up

No major complications were reported; a subcutaneous abdominal seroma was drained in the office before activation in one case (# 8).

Mean follow-up time was 39.82 months (range 16-64 months); 15 patients have been followed using CT, while in the 2 cases of petrous bone cholesteatoma MRI was performed after magnet removal. At last follow-up, 13 patients were actively using the implant.

Discussion

Many causes for CI revision surgery are reported in the literature and most studies involve patients operated and followed in a single Institution and deal with soft/hard device failure and overall implant survival time [7-9].

Revision surgery for clinical reason may represent a challenge even for the most experienced surgeons [4-10]. Identification of causative factors is of paramount importance; in the present series most medical complications requiring revision can be considered secondary to preventable faults occurred during the primary surgery or to inaccurate selection of the approach.

Some surgical steps should be kept in mind when performing a revision CI surgery. While revision procedures for hard and soft CI failure is usually performed through the standard transmastoid approach, revision surgery for medical complications may be far more complex and often require a SP. Advantages of the latter technique include unimpeded access to the promontory, better identification of anatomical landmarks such as carotid canal, jugular bulb and facial nerve, and comfortable access to the round window. In adjunct, isolation of the surgical cavity from the external environment allows easy handling of CSF leak when required, as in patient 10 in this series [5,11]. When performing a cochlear implantation in the context of a SP, the receiver-stimulator should be positioned in a more posterior and superior position. The lack of the bony support of the EAC inevitably leads to a retroauricular retraction [5] with a higher risk of extrusion of the connecting cable/receiver-stimulator in this area.

Selection and management of the array may be a critical point in revision surgeries. The previous array is kept in place until the last steps of the procedure and should be removed just after positioning of the new receiver-stimulator. The old connecting cable is usually cut as soon as possible at the level of the posterior tympanotomy in order to avoid unintentional early array extraction from the cochlear lumen. This reduces the risk of contamination of the inner ear (especially in presence of active infection) and prevents the entrance of blood and/or bone dust. At the same time, the presence of the array avoids collapse of the fibrotic reactive tissue that grows around the array itself. In case of difficult array removal, this manoeuver should be completed before opening the new device. Whenever the surgeon is not sure of the patency of the cochlear lumen, the preliminary use of a dummy electrode is advisable. The new array size

Table I. Patient demographics, clinical data and electrophysiological values.

Patient n.	Gender	Age at revision (years)	Time interval between first and revision surgery (months)	Causes for CI revision surgery						First surgery in Parma	Active infections	Previous revision	CI brand	Follow-up (months)	N. of active electrodes before revision	N. of active electrodes after revision	Mean comfort level pre-revision	Mean comfort level post-revision
				Extrusion in previous CWD	Extrusion in previous SP	Misplacement/ partial insertion	Chronic otitis	Retraction pocket/latrogenic cholesteatoma	Residual PBC									
1^	F	78	48					x			x	No	Cochlear	53	21/22 U	22/22˚ U	144.5	124.75˚
2^	F	8	84					x		x	x	No	Cochlear	39	22/22 U	22/22 U	187.25	143.75°
3	F	16	156				x					No	Cochlear	16	0 NU	22/22˚ U	130	150.75
4^	F	63	157					x				No	Oticon	62	20/20 NU	20/20 U	44	23.25˚
5§	M	71	96						x			No	Oticon	51	20/20 NU	20/20 U	37	26.5˚
6^	F	48	122		x					x	x	Yes	Cochlear	55	20/22 NU	22/22˚ U	200.5	147.5˚
7^	M	17	204				x				x	No	Cochlear	26	0/22 NU	0/22 (full insertion) NU	-	-
8^	F	31	264					x				No	Cochlear	30	10/22 U	22/22˚ U	184	116.25˚
9^	M	73	84					x			x	No	Oticon	60	18/20 NU	15/20 NU	92.5	45.3˚
10^	F	5	48			x				x		No	Cochlear	25	11/22 NU	22/22˚ U	204.25	172.5˚
11^	F	66	20				x					Yes	Oticon	32	10/15 NU	16/20˚ U	32.5	53.5
12	F	51	60	x							x	No	Medel	21	12/12 NU	12/12 U	28.5	20.45˚
13	F	14	84					x			x	No	Oticon	16	17/20 NU	20/20˚ U	36.75	29.5˚
14^	M	57	85	x							x	No	Oticon	64	0 NU	20/20˚ U		
15^	F	71	2			x						No	Oticon	55	0/20 NU	20/20˚ U		
16	F	64	84		x						x	Yes	Oticon	40	0/20 NU	NR		
17	M	43	16						x		x	Yes	Cochlear	32	0/22 NU	NR		
Mean (min-max)	45.64 (5-78)	94.94 (2-264)		39.82 (16-64)														

^: patients already published (reference 5); § patient already published (reference 6) ˚: patients in which more active electrodes were inserted during revision surgery; °: patients in which C-levels were reduced after revision surgery. U/NU (user/non user). CI: cochlear implant; CWD: canal wall down; SP: subtotal petrosectomy; PBC: petrous bone cholesteatoma

should be similar to the previous one, as adoption of longer or larger arrays could impede complete insertion due to the presence of the peri-electrode fibrous capsule. Thin atraumatic arrays are not the first option in most of the revision surgery. Whenever possible the authors prefer stiffer arrays, with Oticon ZTI and Cochlear 512 and 612 the most frequently adopted. Use of the same CI brand is also advised, if not in presence of selective implant problems and/or specific wishes of the patient, in order to maintain the same stimulation modality.

Causes for revision surgery

Based on this series, six main causes for revision surgery were identified:

1. Chronic Otitis. Cochlear implants candidates with a history of chronic otitis media require special attention when planning primary surgery [12]. Recurrence of the chronic otitis exposes the patient to infective risk and device malfunction that can lead to revision procedures [4]. SP is suggested by the Authors in presence of a tympanic perforation accompanied by device malfunctioning, as in

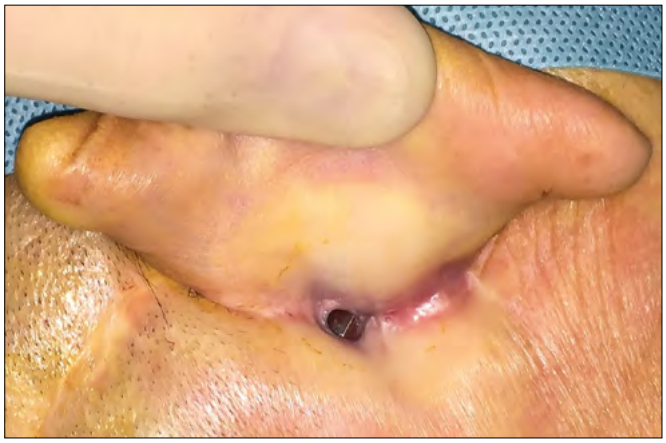

Figure 3. Preoperative picture, right ear, surgical position. Patient 16. Retraction with extrusion of the connecting cable in the retroauricular region after subtotal petrosectomy.

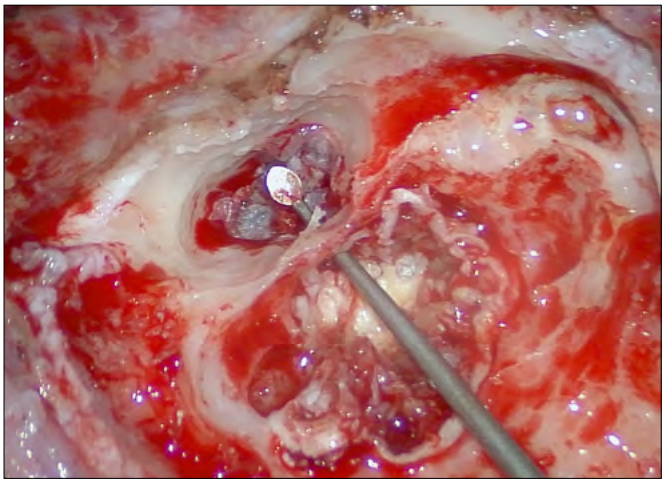

Figure 4. Intraoperative picture, left ear, surgical position. Patient 13. Erosion of the posterior external auditory canal wall can be appreciated with skin debris and cholesteatoma filling the previously performed mastoidectomy cavity.

all 3 cases of the series. Two had a history of otorrhoea since before the first CI (one had already undergone a tympanoplasty), while in another a myringoplasty after CI resulted in a reperforation.

2. Connecting cable extrusion in previous CWD. Positioning of a CI in a canal wall down mastoidectomy should be avoided for the high risk of cable extrusion (patient 12 and 14), as in the 2 cases in the series. SP is strongly recommended during the primary surgery.
3. Retroauricular extrusion in SP. A higher and more posterior positioning of the receiver-stimulator in SP is of utmost importance in order to avoid retroauricular extrusion of the connecting cable/receiver-stimulator in the "danger zone" represented by the unavoidable post-surgical retraction area. In 2 of 3 SP patients, this was considered as the causative problem for the revision (Fig. 3). One of the authors (MF) experienced an additional case at the beginning of his experience (unpublished data).
4. Retraction/cholesteatoma. Iatrogenic cholesteatoma has been reported as a rare complication after cochlear implantation [2,15]. This condition is probably induced by a combination of over-drilling of the medial portion of the posterior wall of the EAC during primary surgery and of subsequent pressure exerted by the connecting cable. Development of a retraction pocket which, in turn, may lead to cable extrusion and/or cholesteatoma formation, may require years; the 6 cases in this series (2 retraction pockets with connecting cable extrusion and 4 cholesteatomas) were revisioned after 4 to 27 years (Fig. 4). Simple retraction without extrusion does not represent an indication for immediate revision, but frequent otoscopic and electrophysiologic follow-ups are required as the skin of the EAC progressively envelops the connecting-cable and may pull the array out of the cochlear lumen, as in patient n. 8. Three additional patients (not included in the study) with the connecting cable visible behind the EAC skin are presently conservatively managed at authors' Institution.
5. Residual cholesteatoma. Residual skin debris in an inaccessible cavity represents the main drawback of SP [16]. In presence of a CI, residual cholesteatoma is difficult to be detected, due to the large artifact observed in the diffusion weighted imaging (DWI) sequences of MRI. The 2 cases included in the series were both originally affected by petrous bone cholesteatomas. While in the first case it was possible to re-implant a new device, in the second case complete cholesteatoma removal required subtotal cochlear drilling. When positioning a CI in a cholesteatoma patient the risk of a residual lesion should always be considered, and prolonged follow-up is mandatory. In doubtful cases, a staged strategy may be kept in consideration and must be balanced with the delay in hearing rehabilitation [17].
6. Array misplacement/partial insertion. Extracochlear array positioning have been reported with the hypotympanic air cells and the semicircular canals as the most frequent locations [18]. Violation of the cochlear lumen require immediate surgical revision as intracochlear inflammatory reaction may lead to fibrosis and ossification. This occurred in 1 otosclerosis case (patient n. 15), in which the array, after entering the cochlear lumen, followed a false route entering the carotid canal. The patient was sent for consultation after 2 months and basal turn drill-out was required due to a severe cochlear ossification. Violation of the carotid canal may be managed

with or without removal of the malpositioned array [19-21]. In patient 15, the tip of the array was cut and left in place in order to reduce the risk of a vascular complication [21]. Possible array misplacement strongly support the necessity of a postoperative radiological control, at least in the unusual CI cases [22].

Additional considerations can be discussed when planning surgery in particular situations.

Active infection

Ten patients showed active infection at the moment of revision surgery, and in 2 cases had been active for more than 2 years. Bacterial infection in the context of a CI is particularly dangerous for the risk of meningitis or intracranical abscess [23]. In this series, additional consequences of active infection were also identified: 2 cases of focal ossification at the level of the cochleostomy required circumferential drilling around the old array to allow removal; 1 ossification of the basal turn requiring a promontorial drill-out; 1 complete extrusion of the array from the cochlea with a massive ossification that precluded re-implantation, 1 complete erosion of the modiolus (in spite of a successful reinsertion of the array the patient did not experience any auditory sensation) [24]. These data support the concept that middle ear infection in presence of a CI must be treated as an emergency; even without intracranial complications, consequences of infection may preclude re-implantation in the same ear (2 cases) [4]. The option of staged surgery may also be considered [25].

Surgical revision of subtotal petrosectomy

Five patients required a revision of the pre-existent SP. The failure of the first surgery was due to incomplete disease removal in 2 cases (residual petrous bone cholesteatomas) and inaccurate execution of the primary surgery in the others. Incomplete exenteration of mastoid air cells, infection of the mastoid cavity and anterior positioning of the device were identified as the major causes of failure.

Even if in the authors' opinion the SP may offer a multiplicity of advantages in non-standard cases of cochlear implantation, the surgical technique should be perfectly mastered to avoid failures.

Unpredicted intraoperative findings

In the present series 5 cases of cochlear ossification and 3 facial nerve dehiscences were encountered. Prolonged middle ear infection may represent a factor in developing of a severe ossification that can also preclude re-implantation. Cochlear ossification may also be related to infection, surgical trauma, or foreign body reaction [2]. When facing this situation, delicate traction should be applied to the old array, in order to avoid breaking part of the latter into the cochlea. Circular drilling around the previous array was necessary in 2 patients; in this situation SP allows a complete control of the promontory if compared to a standard approach. Facial nerve dehiscence at the level of the mastoid portion is relatively common (17.6% in the present series), but usually does not represent a problem if facial stimulation does not occur. In one case the contact between the connecting cable and the completely uncovered mastoid portion of the nerve had produced a temporary facial nerve palsy (recovered after corticosteroid therapy before re-implantation).

Electrophysiological results

Revision surgery does not guarantee anatomical or functional success. Positioning of a new array may be impossible or not advisable (# 16 and 17 in this series). Even complete re-insertion may result in absence of auditory sensation (# 7).

In the literature, the number of active electrodes after re-implantations is usually higher, but the data mainly refer to revision for technical failure [10]. In the authors' series, it was possible to observe more active electrodes than in the preoperative setting in 9 cases, while the same number was maintained in 4 patients; only 1 patient had a fewer numbers of functioning electrodes after revision (# 9). The mean value of C-level decreased postoperatively in 10 over 13 patients. This was probably justified by the improvements in performances of the new electrodes and to the better distribution of electrical stimuli in cases with larger number of post-revision active electrodes. Positioning of arrays in pristine cochlear areas may also contribute to lower C-level values in cases where the basal turn was drilled.

Complications and follow-up

One subcutaneous seroma in the site of abdominal fat harvesting was recorded in the series. The short mean follow-up time of 39.82 months (range 16-64 months) does not allow to exclude problems in the future, such as development of entrapment cholesteatoma. In CI patients, diffusion weighted MRI sequences are disturbed by the artifact and distortion produced by the implant even after magnet removal. Two different follow-up strategies may be adopted: 1) serial CT scan, comparing direct and indirect signs such as progressive enlargement of hypodense round masses in the context of fat filled cavity or appearance of new bony erosions (this allowed detection of lesion in 1 of reported patient) (Figs. 5A, B) and 2) using standard T1 and T2 MRI sequences that produce a smaller artifact. MRI preceded by removal of the magnet under local anesthesia is usually reserved to adult

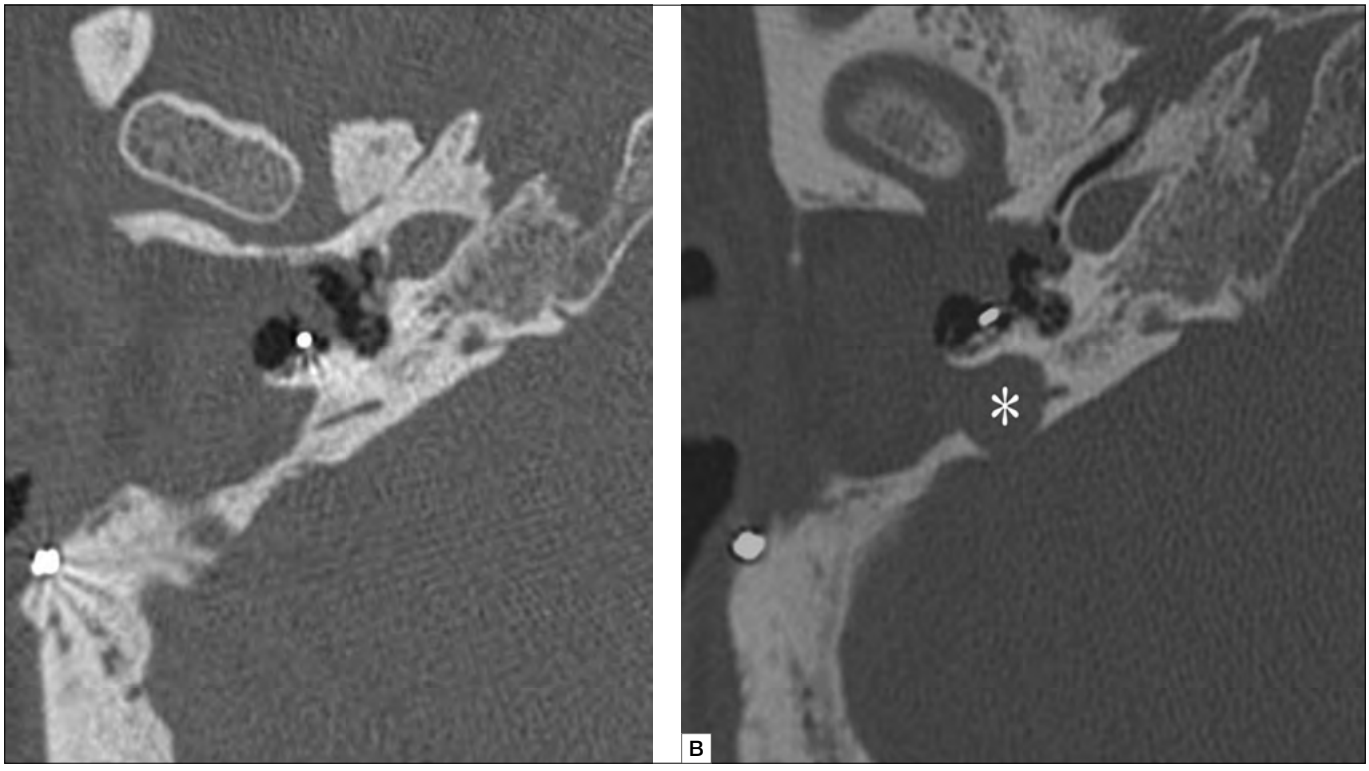

Figure 5. Axial high resolution CT scan, right ear. Patient 5. (**A**) postoperative scan few months after primary surgery; (**B**) four years later a round mass with new bone erosion (asterisk) is evident in the same section. Revision surgery confirmed residual cholesteatoma.

patients with high-risk of residual disease and was adopted in the 2 patients with petrous bone cholesteatoma.

Conclusions

Revision CI surgery may offer the patient a good chance to achieve performances similar or even better than the pre-operative one. The risk/benefit ratio should always be carefully considered as revisions may hide adjunctive difficulties that can preclude re-implantation. Middle ear infection should be considered as an emergency; in addition to the risk of intracranial contamination, prolonged infection can stimulate an inflammatory reaction in the inner ear. Cochlear lumen violation without array placement during first surgery should also be considered a rapidly evolving situation with the risk of severe ossification. In the majority of complex revision cases, SP offers invaluable advantages and should be considered as first choice during surgical planning.

Conflict of interest statement

The authors declare no conflict of interest.

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Author contributions

MF: concept; MF, FDL: design; MF: supervision; FC, MF, FDL: resource; MF, FDL, MG, EP: materials; FC, FDL, MF: analysis and/or interpretation; FC, MG: literature search; FDL, FC, MF: writing; MF, FDL: critical reviews.

Ethical consideration

This study was approved by the Institutional Ethics Committee (University Hospital of Parma) (Approval number 12015). The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki. No animals were involved. Written informed consent was obtained from each patient for study participation and data publication.

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