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Complications after round window vibroplasty

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Abstract

Purpose To evaluate the complication rate in adult subjects with open cavities that were implanted with the Vibrant Soundbridge implant, using the round window (RW) vibroplasty procedure.

Methods From 2009 to 2014, 21 adult subjects with mixed hearing loss, all with sequel from open tympanoplasty surgery, underwent RW vibroplasty (RW-VPL). Surgical complications were recorded and a standard minimal approach was used as a basis for all the cases that needed revision.

Results The mean follow-up was 42 months (range 12–76). Complications occurred in nearly half of the cases and included: cable extrusion (23.8%), hardware failure (14.3%), profound hearing loss (9.5%), and inadequate RW coupling (9.5%). A minimal endaural approach (MEA) was used in the majority of the cases (86.7%), while the extended endaural approach was adopted for those patients requiring explantation with or without replacement (14.3%).

Conclusions RW-VPL can be considered a possible option for the rehabilitation of auditory impairment derived from an open tympanoplasty procedure due to cholesteatoma. The procedure may lead to minor/major complications that may require a surgical revision. By adopting an MEA, it has been possible to manage all the situations in which functionality of the device is worth being preserved.

Keywords Open tympanoplasty · Round window coupling · Active middle ear implant · Mixed hearing loss · Revision surgery

Introduction

Partially and fully implantable active middle ear implants (AMEI) are increasingly used for the auditory restoration of hearing loss due to middle ear pathology or surgery. These devices operate with a direct connection between an actuator and a coupled middle ear structure by delivering an electromechanical vibratory stimulation. In this regard, depending on the anatomical structure coupled to the device's actuator, one may distinguish the incus vibroplasty (I-VPL), the oval window vibroplasty (OW-VPL), and the round window vibroplasty (RW-VPL) [1]. Several clinical reports have highlighted the efficacy of the RW-VPL for providing favourable auditory results. This is especially true in the case of severe mixed hearing loss, when the mean bone conductive threshold is beyond 40–45 dB and, therefore, the application of a bone conductive implant (BCI) could theoretically prove to be inadequate [2–5]. Likewise, at our Implanting Clinic, the RW-VPL has become the standard of care for those patients who have undergone an open tympanoplasty procedure with a clean and long-standing epithelialised and dry cavity, and show a mixed hearing loss with a measurable BC threshold worse than 40 dB. The personal, favourable functional results have already been reported in a study that aimed to correlate the auditory outcome with the coupling accuracy of the actuator to the RW, as analysed by cone-beam CT scan imaging [6]. However, in some cases, these positive outcomes were obtained after resolution of complications that demanded a surgical revision.

The aim of the present report is to discuss the RW-VPL cases that needed to be revised and to describe the surgical solution adopted for each complication, with final comments that would shed some light on the best-practice procedure to apply in both primary and revision surgeries.

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Materials and methods

Twenty-one adults, 10 men and 11 women, from 55 to 73 years old underwent RW-VPL from 2009 to 2014. They were all presenting functional sequels from an open tympanoplasty procedure due to middle ear cholesteatoma performed several years before; they all had a long-standing good anatomical outcome but a poor auditory function that could not be recovered by conventional air-conduction hearing aid, owing to the surgically created enlarged meatal opening. Among the surgical steps, particular care was taken to protect the cable inside the cavity, owing to its relevant length in the 502 Vibrant SoundBridge (R) (MedEl, Innsbruck, Austria) model that was used for all the cases. This was systematically achieved by creating a bony semi-channel running in the peripheral, inferior portions of the mastoidectomy cavity and by covering it with wax or autologous bone pâté, surmounted by different layers of fascia or similar tissue.

A certain number of complications were encountered, and some occurred in the same patient: delayed, total hearing loss, in two subjects; miscoupling (as revealed by insufficient amplification at device's activation time), in two subjects; cable exposure, in five subjects; and hardware failure, in three subjects.

All these adverse events required a surgical solution that consisted of a minimal endaural approach (MEA) performed under local or general anaesthesia, eventually modified according to each case. This MEA approach was performed by incising the external auditory canal up to the lateral aspect, allowing preparation of two flaps that were kept apart via a small self-retaining retractor, and achieving an adequate visualisation of the surgical field (Fig. 1). Then, according to the complication that needed to be solved, different technical variants were adopted.

In the two cases that needed explantation due to the sudden hearing loss and in the two cases in which a hardware failure occurred, the incision was extended more superiorly than in the other cases, to allow grasping with clamp forceps and removing the internal component of the device (antenna and demodulator) together with the actuator. In the two subjects in whom the device stopped functioning, a power BC implant was simultaneously implanted. In the two cases that showed a limited amplification at activation of the device, an actuator displacement was hypothesised to have occurred during the post-operative healing period, prompting us to plan a revision to reach the round window (RW) niche level. Once this area was exposed, the actuator was identified, temporarily displaced, and then repositioned after further enlargement of the RW edges. At this time, the patients—under local anaesthesia—could give a subjective positive evaluation of the improved auditory function.

In four of the five cases in which the cable exposure was found, the same MEA was performed, while, in one of them who also displayed a concomitant profound hearing loss, the extended endaural approach was needed for the complete removal of the device. After thoroughly elevating the mastoid skin flap, the cable was isolated up to the last part ending with the FMT in the middle ear, anterior to the facial recess region (Fig. 1). A large and tailored piece of autologous (tragal) or heterologous cartilage was then positioned to fit in the mastoidectomy cavity, assuring the complete covering of the exposed cable (Fig. 1).

Results

In 12 (57%) out of the 21 operated subjects, complications of different severity were encountered and described in detail below (Table 1).

Sudden hearing loss (two subjects)

One subject has shown total loss of hearing in the operated ear at activation (delayed, short term). This had presumably occurred during the post-operative course, without

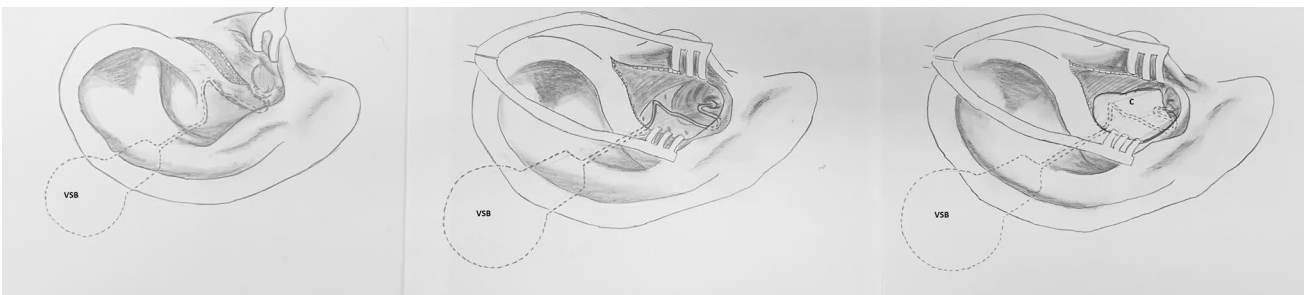

Fig. 1 Artist's drawing of the minimal endaural approach (MEA). The incision includes the skin of the external auditory canal (left), allowing to raise two flaps to be held by a self-retaining retractor (center). After elevation of the skin covering the cavity at the level of the cable extrusion, enough space is created to place a cartilage sheet to cover and protect it (right)

Table 1 Demographics of the sample study

Pt	RW-VSB Complicated subjects						
	Age at first surgery	Gender	Date of primary surgery	Side	Complication	Onset of complication (months after surgery)	Approach/anaesthesia
FO-RI	65	F	3/09	L	Cable exposure	25	MEA/local
DC-FR	70	M	7/09	R	Miscoupling	1	MEA/local
GI-MT	51	F	12/09	R	Cable exposure	12	MEA/local
RI-GA	69	F	5/10	R	Cable exposure	34	MEA/local
AB-FR	38	F	8/11	R	Device failure	30	EEA/general
VI-IR	57	F	4/12	L	Cable exposure	32	MEA/local
FA-MA	58	M	5/12	R	Device failure	30	EEA/general
FE-AN	64	F	4/13	R	Device failure	28	EEA/general
PR-BA	66	F	11/13	R	Sudden deafness + cable exposure	18	EEA/general
DG-MI	68	M	4/14	R	Miscoupling	1	MEA/local
CH-UM	58	M	6/14	R	Sudden deafness	1	MEA/local

M male, *F* female, *L* left, *R* right

any concomitant, associated inner ear symptom (tinnitus, vertigo). After an unsuccessful course of systemic steroids, it was decided to proceed with the explantation. The other subject has had an excellent auditory outcome for about 2 years, up to when, during a routine visit, exposure of the cable was evidenced inside the mastoid cavity. A revision was, therefore, needed, after which the patient experienced some imbalance, hearing deterioration (delayed, long term) and ear drainage, which were precluding the patient from wearing the device, and, thus, the decision to explant it.

Insufficient amplification at activation (two subjects)

In both subjects, approximately 6 weeks after surgery, at the first activation, an insufficient auditory improvement was found, both with conventional audiometric tests (free-field pure tone and speech audiometry) and at the Vibrogram software (Medel, Innsbruck, Austria) plot. It was, therefore, decided to revise the RW coupling and this improved the performances in both cases.

Cable exposure (five cases)

One of these cases is already included in one of the previous categories, as long-term delayed, profound sudden deafness. A third case showed an arrest of the device functioning 2.5 years after surgery, which was considered to be related to the cavity problem. He was not reporting any ear discharge, while the oto-microscopic examination revealed the exposure of the cable that appeared also surrounded by compact wax. When tested with the Quick-Check® device, no activity was found. The actuator, which was found to be well integrated at the round window niche level, together with the entire, intact implant, was then removed and replaced by a new one (503 model) that provided a good functional outcome when reactivated the day after the surgical revision. In this case, the cable in the mastoid cavity was entirely covered by a large piece of heterologous cartilage and fascia. The other two cases showed a similar picture, but, despite the cable exposure, the implant was still functioning well. In both cases, the MEA was used and, after isolating and lifting the skin lining of the mastoid region, a large, tailored piece of heterologous cartilage was positioned for cable protection.

In all the revised cases where the cartilage protection has been adopted, no signs of cable extrusion were further observed after a mean 1.6 years of follow-up (min 1–max 2.2).

Hardware failure (three cases)

This occurred at a certain distance from the implantation. In two cases, it was decided to replace the AMEI with a power BC implant, while, in the third subject, a new VSB device was positioned.

Discussion

The functional efficacy of a semi-implantable AMEI coupled to the RWM for the rehabilitation of mixed hearing loss due to sequels from an open tympanoplasty procedure is indisputable. In fact, these subjects, especially when the contralateral ear is not normal, are in the need of an auditory aid that cannot be provided by a conventional air-conductive hearing aid, which are often unsuitable due to the widely enlarged meatal entrance (meatoplasty). In theory, up to certain levels of BC threshold, an alternative rehabilitative role can be played by either percutaneous or transcutaneous BC implants, whose application surgery is also easier, faster, and less invasive than that for an AMEI. However, it is common to observe that most of the subjects with a long-standing open cavity may show a progressive deterioration of the BC threshold, reaching values beyond the indication range advised for a BC implant, from 45 dB onward. This is why, under these circumstances, an AMEI directly coupled to a middle ear structure, such as the RW membrane, could represent a practicable option. The personal experience with the RW-VPL has allowed us to both confirm this assumption and also notice that some complications may actually occur as was previously reported [7, 8]; however, they can normally be resolved with a minimally invasive procedure. The experience gathered with our RW-VPL implanted group has also allowed us to pinpoint some interesting remarks that, in our opinion, are worth being shared and discussed.

The first point regards the functional control of the device and the stability of the actuator, the latter being essential to guaranteeing an optimal amplification from a device that, with this type of coupling, i.e., to the RW membrane, is not provided with a fixation point. In regard to the coupling stability of the actuator to the RW, there is a general agreement that the major role is played by the surgeon's skill and experience, since the actuator lies at the end of a flexible cable and, as earlier mentioned, has no fixation system. Intra-operatively, one may check the appropriate placement by evoking the movement of the assemblage actuator/RW membrane through the stapes or the stapes footplate (window play effect) or, better, by performing an electrocochleographic recording [9]. Unfortunately, at the present time, the latter objective procedure has not been standardised and its use remains sporadic and mostly related to the individual surgeon's attitude. The inferior support and the pre-tensional stabilisation with cartilage and fascia would then contribute to avoid minimal displacements during the healing period and at a later stage.

In the present experience though numerically limited, there have been two cases in which the device was not giving enough gain at activation, so that a post-operative displacement was hypothesised and urged a surgical revision. The MEA, in these cases, proved to be very appropriate, and it allowed access to the round window region with a minimally invasive procedure under local anaesthesia. It is also worth mentioning that it was possible to ascertain during the revision that, after only 1 month (the time lapse before activation of the device), all the assemblage composed by actuator, fascia tissue, and cartilage was compact and stable at the coupling region site (RW membrane).

In two cases, a sudden hearing loss was experienced. This complication, already reported by Böheim et al. [8], at least in our series seems to be strictly related to the surgical procedure, being primary in one case and after a revision in the other case. Interestingly, in the first case, no other sign or symptom of inner ear involvement was present, while the second patient did experience balance problems in addition to the hearing problem.

At least in our hands, the most frequent cause for a surgical revision was the cable exposure, as shown in 23.8% of the cases. The same finding had already been reported by Lassaletta et al. [3] to occur in 33.3% of their patients, for whom different solutions were adopted: blind-sac closure of the external auditory canal (one case), simple observation (two cases), and nonuse of the device (one case). It would be likely to assume that, other than simply being a foreign body in a formerly infected ear, the excess length of the cable wire could play a crucial role for such a complication to occur, especially in the first generation of the device that was implanted in nearly all the cases of the present study. Moreover, in the majority of the cases, the implant cable showed extrusion only in the long term, from 12 to 34 months after surgery. It is also important to underline that for this reason, during the primary implanting surgeries, particular care has always been taken to create, in the mastoidectomy cavity, a shallow semi-channel meant to help keeping the cable in place. At the time of the primary surgery, no cartilage shield was used for further protection. It seems plausible that the presence of a persisting open cavity could run the risk of cable dehiscence and/or exposure, in the long term, probably due to the post-operative abnormal turnover of the cavity-covering skin. Therefore, for the revision cases of our study sample, an alternative surgical refinement was used and implied the placement of a custom-tailored, 2-mm-thick cartilage sheet over the area of the exposed cable. At short-term observation, this surgical refinement was effective in avoiding relapse of cable extrusion. In this regard, an alternative procedure that can also be directly applied during the primary implanting procedure could be represented by the blind-sac closure of the external auditory meatus (EAM), followed by abdominal fat obliteration of the middle ear, usually carried out during a subtotal petrosectomy (STP) for aggressive or recurrent cholesteatoma [3, 7, 10, 11]. It

would, therefore, be logical to assume that the adoption of this surgical variant would have avoided the most frequent complication observed in this study sample, i.e., the device cable's exposure.

It is possible to conclude that, although representing an efficient rehabilitative solution in cases with mixed hearing loss and a poor BC threshold exiting from a long-standing dry, open tympanoplasty technique, the application of an AMEI on the RW is not exempt from possible complications that, as shown in the present personal series, may require a surgical revision. This can, however, be performed through a minimally invasive procedure that may enable a stable and long-lasting result in the majority (over 90%) of the cases.

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