Middle Ear Implants (MEI): Vibrant Soundbridge

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Mario Emilio Zernotti and Peter Grasso

Description of the Vibrant Soundbridge Middle Ear Implant

The Vibrant Soundbridge® (VSB) is a middle ear hearing implant that was first implanted in 1996 as a treatment for moderate to severe sensorineural hearing loss. In February 1998, the device was approved with the CE mark and in August 2000 by the Food and Drug Administration (FDA) as well. Thousands of patients around the world have been implanted with the VSB since 1996. Remarkable patient satisfaction and performance of the device have been reported in scientific publications and presentations. In general, patients who wear the device all day long (up to about 16 h) report a natural sound quality, high device satisfaction, and a better ability to understand speech, especially in noisy environments [1]. Since 2007 the VSB is also approved as a treatment for conductive and mixed hearing loss and in 2009 the VSB got the approval for implantation in children by the EU authorities. The VSB has also proved to be a very reliable device, with a cumulative survival rate of 98.3 % after a period of 105 months.

The system consists of an implanted part, the vibrating ossicular prosthesis (VORP) (Fig. 4.1), and an external part, the audio processor (AP) (Fig. 4.2). The AP is worn behind the ear, held by a magnet, and contains a microphone, a digital signal processor, and a battery. The VORP consists of a receiver coil, a conductor link, and the floating mass transducer (FMT) (Fig. 4.3). The FMT is 2.3 mm long; its diameter is 1.8 mm and weighs about 25 mg. The conductor link has a diameter of 0.6 mm.

M.E. Zernotti, MD, PhD (✉)
Department of Otolaryngology, Catholic University of Córdoba, Córdoba, Argentina

Director of Postgraduate Course of Specialization in Otorhinolaryngology, National University of Córdoba, Córdoba, Argentina
e-mail: mario.zernotti@gmail.com

P. Grasso, Dott
Head of clinical Support, Business Unit Vibrant, Med-El., Innsbruck, Austria

G. Mankekar (ed.), *Implantable Hearing Devices other than Cochlear Implants*,
DOI 10.1007/978-81-322-1910-1_4

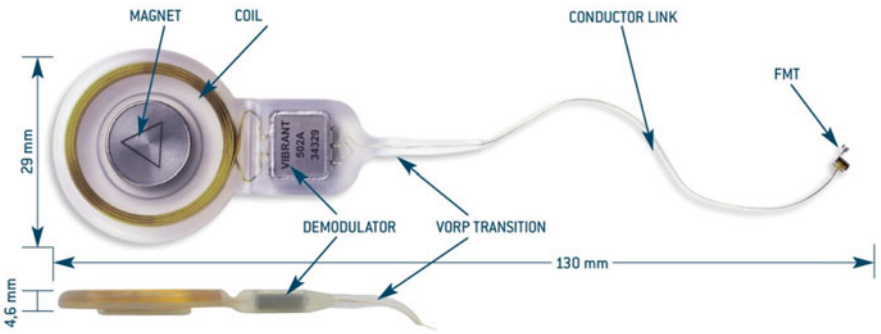

Fig. 4.1 VORP

Fig. 4.2 AP (Amadé)

The sound is picked up by the two microphones of the AP and is processed by state-of-the-art signal processing software. This information is then transmitted via amplitude modulation to the receiver coil of the VORP. Afterwards the information is demodulated into the electrical pulses that drive the vibration of the FMT.

Audiological Indications and Patient Selection

The Vibrant Soundbridge® is indicated for patients who have mild to severe hearing impairment and cannot achieve success or adequate benefit from conventional therapy.

Fig. 4.3 FMT (right)

As with all surgical procedures, the physician must fully assess the potential risks and benefits of the patient prior to the decision to implant the VSB. It is important to take the patient's complete medical history into consideration. For patients suffering from sensorineural hearing loss, the pure tone air conduction threshold levels have to be at or within the levels listed below:

Frequency (kHz)	0.5	1	1.5	2	3	4
Lower limit (dB HL)	10	10	10	15	25	40
Upper limit (dB HL)	65	75	80	80	85	85

For patients affected by conductive or mixed hearing loss, the pure tone bone conduction threshold levels should not be worse than 45 dB in the low frequencies and 65 dB in the high frequencies. See table below. A patient with sensorineural hearing loss shall be a current user of an acoustic hearing aid and should use it for at least 4 h (average) per day for at least 3 months prior to evaluation or shall not be able to wear or benefit from conventional hearing aids for medical reasons.

Frequency (kHz)	0.5	1	1.5	2	3	4
BC upper limit (dB HL)	45	50	55	65	65	–

The potential patient shall present an ear anatomy that can facilitate the positioning of the FMT in contact with a suitable vibratory structure of the ear. Different surgical techniques on how to directly stimulate the residual hearing bypassing the air-bone gap will be described in the following chapters.

Some patients may benefit more than others from a VSB. Certain conditions may preclude the selection of a VSB for a particular patient. These conditions include patients known to be intolerant of the materials used in the implant (medical grade

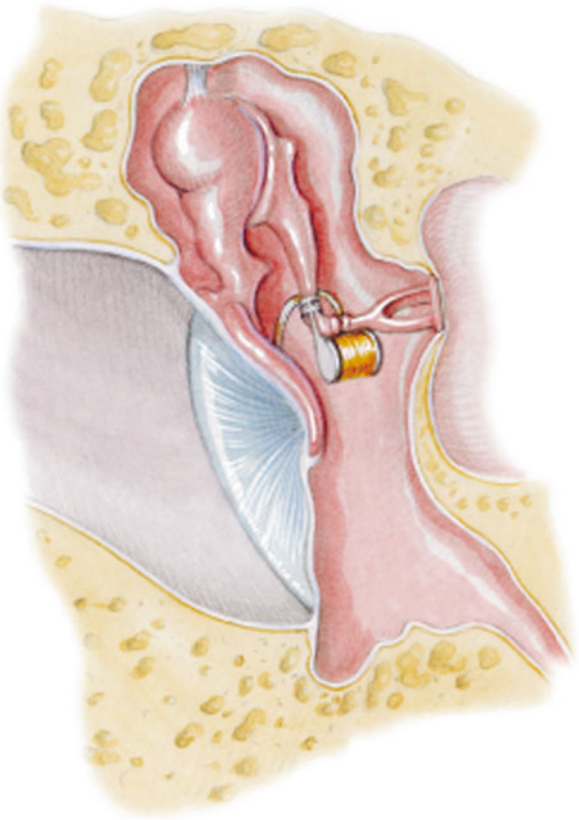

Fig. 4.4 Vibroplasty over the long process of the incus

silicone elastomer, medical grade epoxy, and titanium). It is very important to assess retrocochlear components or central auditory disorders prior to implantation, because such patients are not indicated for a middle ear implant. Special attention should also be given to patients with nonresponsive active ear infection or chronic fluid in the ear as well as to patients whose hearing loss has demonstrated an improving or decreasing fluctuation of 15 dB in either direction over a 2-year period.

Surgery

In 1996, Prof. Ugo Fish implanted the first patient with sensorineural hearing loss. This type of vibroplasty involves partial mastoidectomy with posterior tympanotomy [2]. Through this access, the FMT is introduced into the middle ear space. The FMT is attached by the titanium clip to the long process of the incus, while the VORP is located in a small bed on cortical temporal or parietal bone (Figs. 4.4 and 4.8).

Years later, Vittorio Colletti [3–5], proposed that the VSB could improve profound/severe conductive or mixed hearing via placing the FMT in the round window (Figs. 4.5 and 4.9). This milestone opened up many possibilities to place the FMT

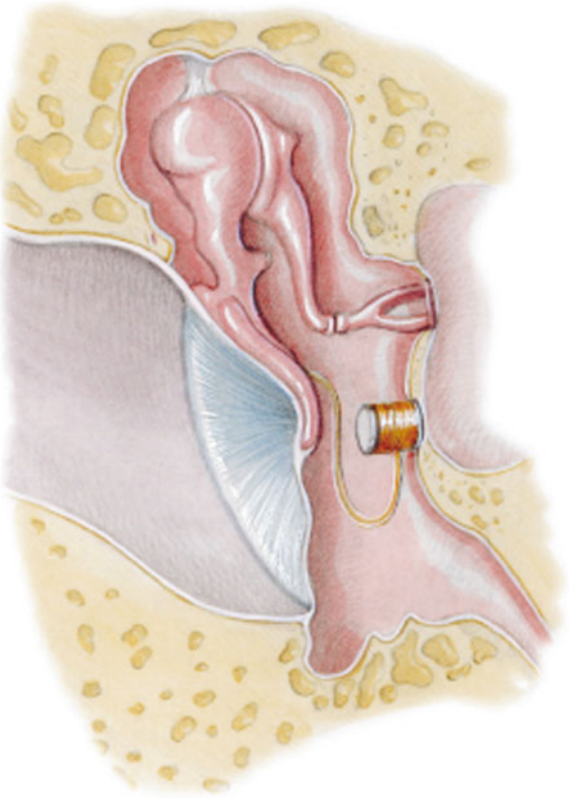

Fig. 4.5 FMT directly on the round window

into the middle ear in various positions and reflects the original idea of Geoffrey Ball – inventor of the Vibrant Soundbridge – which aimed to be able to place the FMT on any mobile structure of the middle ear. Additional accessories, the so-called couplers, also foster the flexibility during surgery, and with their help, the surgeon can place the FMT onto the head of the stapes, into the round window, and the oval window and thus avoids having to reconstruct certain middle ear structures. Thus the prosthesis can be placed on the ossicles (incus or stapes), round window, oval window, or with passive (TORP and PORP) prosthesis (Figs. 4.6 and 4.7).

Later on, Dr. Milo Beltrame from Italy classified the vibroplasty as COR (C is chain, O is oval window, and R is round window).

The original vibroplasty was developed for patients with sensorineural hearing loss who had complete and mobile ossicular chain. However, FMT placement was started in those patients who did not have the full ossicles, could fit on the head of stapes, in one of the crura or directly on the footplate. Some patients need a coupler for the perfect contact with the footplate or a stapes superstructure. These techniques are used with TORP, PORP, or couplers (see Figs. 4.6 and 4.7).

This currently widespread option is the placement directly on the round window which is based on the theory of sonoinversion by Garcia Ibanez. This theory, now proven, explains that the cochlea can be stimulated from the round window in reverse,

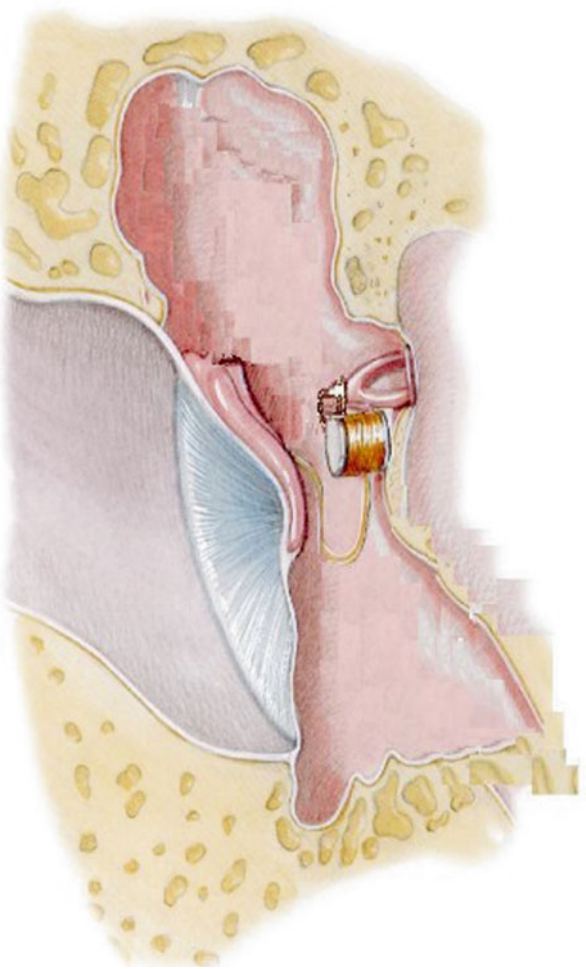

Fig. 4.6 FMT clipped on the head of the stapes

and the patient can hear normally. On this basis Colletti designed the round window technique which requires partial drilling of the overhang covering the round window membrane. The membrane is covered with a small piece of fascia or some synthetic material as pericardium to protect it, and the FMT without its clip is placed directly onto the round window membrane. A better fit is obtained by putting small pieces of cartilage in the hypotympanum to press the FMT over the round window and to prevent it from movement. Furthermore with the use of the round window coupler, a better coupling can be achieved between the surface of the membrane and the FMT [3–6] (Figs. 4.5 and 4.9). It is necessary to mention that the couplers are merely passive prostheses which allow a better coupling of the FMT, are very useful in patients with difficult anatomy, and improve the performance of the vibrating prosthesis.

Another option is the creation of the "3rd window." This is a fenestration or a cochleostomy to expose the membranous labyrinth in the promontory to place the FMT directly over the structures of the inner ear. It is a very difficult and risky technique, and the results are poorer than the results from the other options.

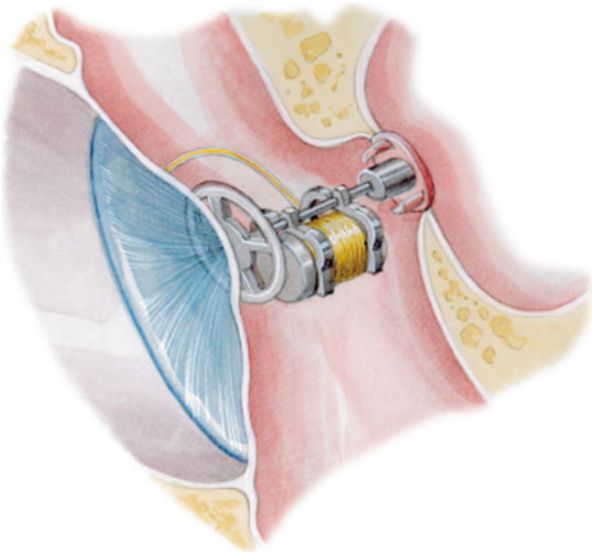

Fig. 4.7 Attached with a TORP

Approaches

As in cochlear implants, there are several approaches to place the FMT in the middle ear structures.

For Non-sensorineural hearing loss (NSHL) the facial recess approach is the most common (the most widely used also in CI). Here it should be noted that the only difference to the classical technique is that we make a generous posterior tympanotomy to allow passage of the FMT (see dimensions) and then to use the forceps when we perform the adjustment.

There are other techniques originally described for cochlear implant surgery and which can also be used for VSB implantation such as the suprameatal approach (SMA) designed by Lela Migirov and Jona Kronenberg or the endomeatal approach (EMA) described by Victor Slavutsky and Nicenboim, where a groove is carved in the bone of the external auditory canal where the cable is placed, without mastoidectomy. The groove is covered with bone pate and the skin of the EAC.

(a) Vibroplasty in sensorineural deafness
This was the original indication and technique. In this case, the FMT directly stimulates the ossicular chain. And the facial recess is used to reach the middle ear space. A wide tympanotomy is required to tighten the clip with a special forceps. The reviewed publications refer to a mean functional gain near to 30 dB [2, 7] (Fig. 4.8).

(b) Vibroplasty in Congenital Aural Atresia (CAA):
In our experience, CAA represents a challenging situation, especially due to abnormalities in the normal anatomy in the external and middle ear. Usually we performed the approach in two ways: directly through the atretic placode or through a mastoidectomy and atticotomy to reach the middle ear space.

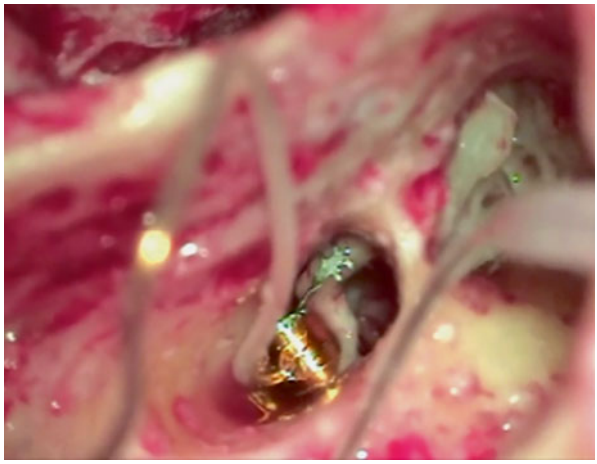

Fig. 4.8 FMT clipped on the long process of the incus

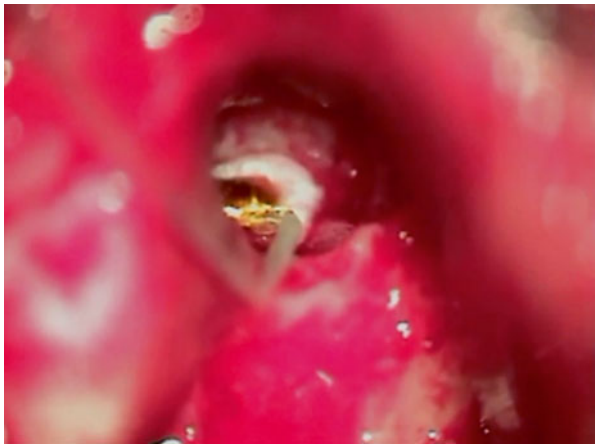

Fig. 4.9 FMT in the round window, previously covered with fascia

The ossicular chain is often malformed, especially the incus-malleus complex. In these cases, there are two possibilities for the FMT placement: into the round window or in the stapes. In the round window technique, a piece of fascia is used to cover and protect the round window membrane, and the clip is cut off. In patients where the FMT was placed on the stapes superstructure, the clip is put on a crura, while in patients with good and mobile stapes, the FMT is placed onto the head. There is a third but less effective alternative as well, when the FMT is directly placed over the footplate or, with a coupler, into the oval window. Finally, only in difficult anatomies, a fenestration is the last option which is called as the third window technique [8] and is only recommended when the anatomy of the middle ear is fully altered (a case with the facial nerve covering both windows) [9–12] (Fig. 4.9).

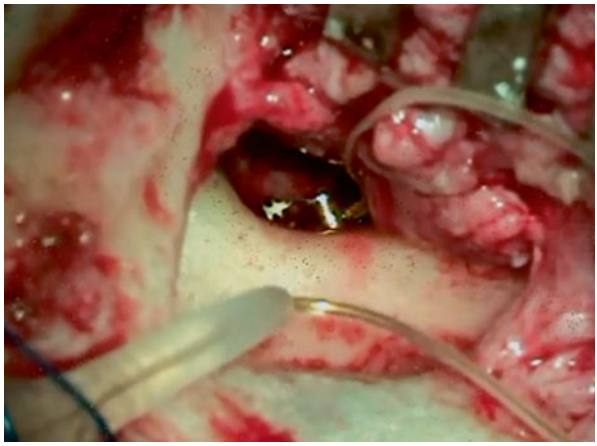

Fig. 4.10 FMT attached to the stapes in a patient with open cavity

(c) Vibroplasty in Chronic Otitis media:
In chronic otitis media, there exist and have been described numerous techniques and prostheses to restore hearing. The ossiculoplasty with many variants of prostheses (TORP, PORP) and different materials (hydroxyapatite, titanium, Teflon, steel, etc.) has only partially solved the problem. While we have established and standardized surgical techniques, functional failure often leads the patient to disappointment because the only alternative remains the conventional hearing aid. Unfortunately, in some cases of otitis media, especially for patients who have sequelae at the tympanic membrane (have perforations or tympanosclerosis) or have large open cavities, the use of conventional hearing aids is difficult and often unsatisfactory. For these patients, vibroplasty represents a good option. Streitberger [13] presented a series of patients, suffering from chronic otitis media with cholesteatoma, who have been implanted with the VSB [14–16]. The preoperative thresholds were 82.38 dB SPL, while thresholds in word recognition were 94.28 dB SPL. Three months later this group obtained audiometric thresholds of 50.63 dB SPL with vocal audio to 61.68 dB. After 6–9 months tonal audiometric thresholds were 47.89 dB SPL and the word recognition test of 53.33 dB SPL [13]. In our study we obtained an average functional gain of 35, 40, 48.7, and 45 dB for the frequencies 500, 1,000, 2,000, and 4,000 Hz, respectively [17].

In many cases, the patients presented open cavities. The implantation of VSB or even cochlear implants in this kind of cavities is really a problem. In these cases, there are two main possibilities: the first one is the obliteration of the mastoid cavity. After the placement of the FMT, in RW, or on the stapes (Fig. 4.10), an obliteration is necessary to avoid extrusion. In this technique, we cover the middle ear space with little pieces of cartilage. After that, we put a rotational muscular flap from the sternocleidomastoid muscle or the digastric muscle into the cavity. The blockage of the Eustachian tube is required. Finally, the use of abdominal fat to cover all the mastoid cavity and closing the external auditory canal is mandatory. In addition, this is an excellent technique to avoid

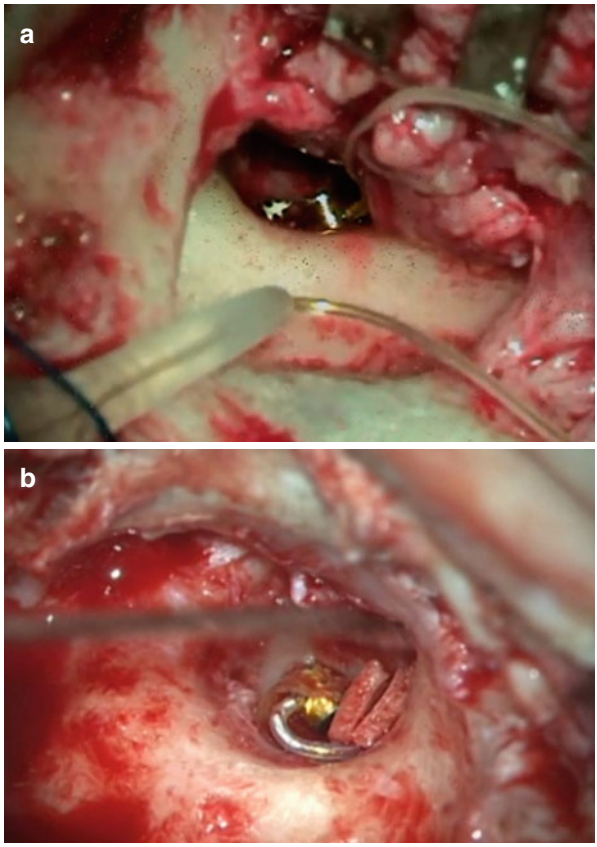

Fig. 4.11 (**a**, **b**) The subfacial approach with the FMT in front of the vertical portion of the facial nerve (Pictures courtesy Prof. Santiago Arauz)

extrusion. In many patients suffering from cholesteatoma, it is very difficult to observe and follow-up the cavity postoperatively. In case of recurrent cholesteatoma, the surgery can be very difficult.

The alternative to this approach is the so-called "subfacial approach" (Fig. 4.11a, b). In this approach, the facial nerve is "used" to anchor the cable of the VSB. A normal anatomy is required to do this technique, specially the jugular bulb should be located in a normal position. The technique consists of making a tunnel behind the third portion of facial nerve to reach the hypotympanum and penetrate the middle ear space. As seen in the figure, the cable goes from the mastoid cavity to the middle ear. The advantage of this technique is the posterior control of the cavity, because the closure of the EAC and the mastoid is not necessary. Only we need to cover the hypotympanum with cartilage to exclude the FMT from the rest of the middle ear. In the mastoid, a groove to put the cable is necessary, and it is covered with bone dust and cartilage. Finally, normal temporalis fascia is used to line the floor of the cavity. In this way one can control the residual or recurrence of cholesteatoma.

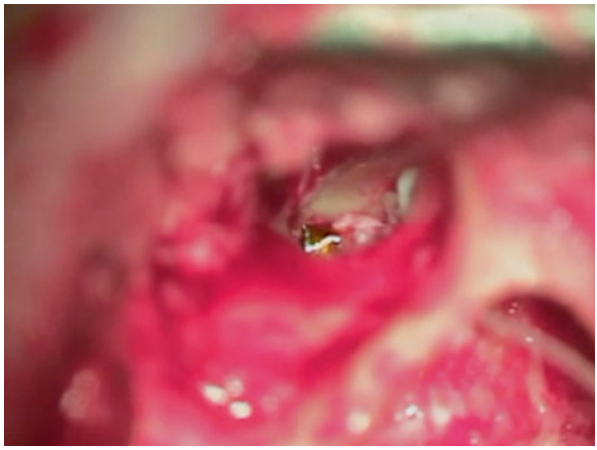

Fig. 4.12 Teflon prosthesis stapedotomy with FMT in the round window

(d) Vibroplasty in otosclerosis
Otosclerosis that produces severe mixed hearing loss means a challenge for treatment. Usually the patients need stapedectomy to improve the conductive component of the hearing loss, but even after a successful surgery, these patients need additional auditory equipment (hearing aid) to improve bone conduction already committed significantly. The VSB can be used in two different surgical techniques.

The first is stapedectomy and the simultaneous placement of the VSB on the incus, while the second alternative is the FMT placed directly into the round window, without stapedial surgery. In the latter case it is necessary to make a stapedotomy and cover it with fascia to recover the membrane's movement (Fig. 4.12).

Complications

Complications during vibroplasty are similar to the ones during cochlear implantation. While minor complications can be solved in outpatient settings, major complications can require the rehospitalization of the patient with revision surgery.

Extrusions, partial or total flap necrosis, and migration of FMT typically count as major complications.

Partial extrusions are more frequent in patients suffering from chronic otitis media with previous radical cavities (canal wall down), where some portion of the cable appears in the open cavity or in the external auditory canal. This is due to the failure to cover the cable of FMT, which in these cavities should be performed with cartilage and bone pate. The solution in these cases can be the drilling of a groove in the floor of the external auditory canal bone covered with cartilage and bone pate

or performing an obliteration surgery with closure of the external auditory canal and permanent blockage of the Eustachian tube.

The subfacial approach offers another alternative. This method anchors the cable below the facial nerve preventing it from extrusion and leaving the open cavity for inspection and cleaning.

Finally, complications can occur due to displacement of the FMT from the round window which results in the sudden loss of hearing gain. In these cases, evaluation with multislice computed tomography is mandatory to see the FMT displacement and to explore the possibilities of surgically reposition the FMT in the same place or even in another position. Temporary facial palsy, seroma, hematoma, and minor skin infections are the main minor complications.

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