Operative Techniques in Otolaryngology (2010) 21, 194-196

Operative Techniques in
Otolaryngology

Alternative placement of the floating mass transducer in implanting the MED-EL Vibrant Soundbridge

Geoffrey J. Service, MD, Joseph B. Roberson Jr, MD

From Otology, Neurotology and Skull Base Surgery, California Ear Institute, E. Palo Alto, California.

KEYWORDS
Vibrant Soundbridge;
Round window;
Placement;
Floating mass transducer

Implantable hearing devices, such as the Vibrant Soundbridge, were originally developed to be an alternative to traditional external auditory canal hearing devices. Recent modifications in surgical technique have allowed this implantable device to find a unique new niche in the treatment of mixed hearing loss. The primary design of the Vibrant Soundbridge marries a floating mass transducer to the incus to deliver mechanical energy through the native conductive mechanism. Variants to this theme have been developed to address specific issues. In this work we review the alternative placements of the floating mass transducer with different ossicular reconstruction configurations and placement at the round window.

The challenge to restore hearing to patients with hearing loss persists despite a multitude of innovative techniques. Traditional hearing devices successfully treat most patients with sensorineural and mixed hearing loss. They fall short, however, in cases in which occlusion of the external auditory canal leads to recurrent infection, epithelial irritation, discomfort, or hearing aid feedback. In other mixed-loss situations, attempts at surgical improvement of the conductive component of a mixed loss leave patients with poorly or sometimes nonaidable hearing.

Implantable hearing devices, such as the Vibrant Soundbridge (VSB; MED-EL, Durham, NC), were originally developed to be an alternative to traditional external auditory canal hearing devices. The traditional placement of the VSB attached to the incus has been shown to be as safe[1] and effective in restoring hearing for patients with sensorineural hearing loss.[2] Mosnier et al[3] demonstrates that the gains obtained at 3 months from VSB testing persist 5 to 8 years after implantation. Recent modifications in surgical technique have allowed this implantable device to find a unique new niche in the treatment of the hearing impaired. The VSB device has now been successfully used in Europe and in ongoing US clinical trials to address mixed hearing loss. Frequently, the conductive component of a mixed loss is alleviated, and a significant quantity of gain is realized to aid the sensorineural hearing loss.

The primary design of the VSB marries a floating mass transducer (FMT) to the incus to deliver mechanical energy through the native conductive mechanism. A titanium clip loosely crimped to the incus with intact stapedius tendon and stapes allows transmission of vibrational energy to the ossicular chain. Gain and function that are roughly equivalent to those of a standard hearing device have been realized by hundreds of patients. The principle advantages of the device include avoidance of the occlusion effect, the ability to leave the ear canal open in cases of intolerance of hearing device use, and its cosmetic advantage. The device has been remarkably dependable, and early concerns about incus necrosis have not proven to be a problem of any significant degree. Despite early hopes with the first VSB placement strategy, no significant difference in functional hearing in quiet or noise was realized when compared with traditional hearing devices.[4] The advent of an open-mold hearing device design removes most of the advantage in 2 of the 3 areas of the traditional VSB use.

Variants to this theme have been developed to address specific issues. In Europe, several connecting clips are

Address reprint requests and correspondence: Joseph B. Roberson Jr, MD, 1900 University Avenue Suite 101, E. Palo Alto, CA 94303
E-mail address: jbr@calear.com.

1043-1810/$ -see front matter
doi:10.1016/j.otot.2010.03.009

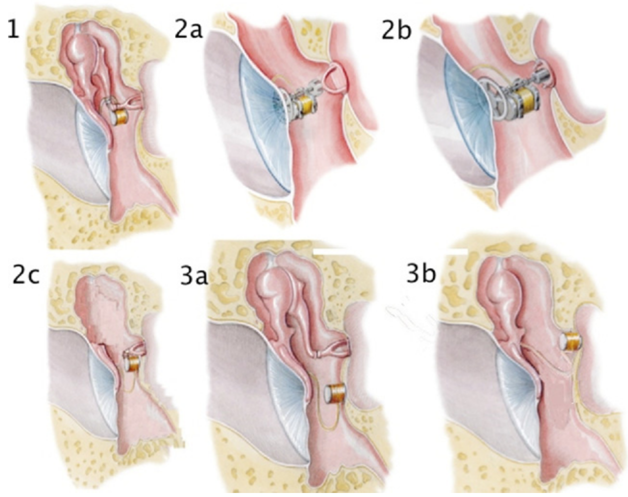

Figure 1 Classification of FMT placement. Pictorial demonstration of classification scheme of alternative placement of the VSB FMT. (1) Shows traditional placement of FMT to incus. (2a) Shows the FMT attached in a PORP configuration, and (2b) shows attachment to TORP. (3a) Demonstrates placement of the FMT at the round window, and (3b) shows placement at the oval window. Adapted from Dumont et al.[7] Images with permission from Vibrant Med-E l. (Color version of figure is available online.)

available to allow fixation of the FMT to an ossicular reconstruction prosthesis. For example, Cremers et al[5] interposed the FMT from the anterior crus to the tympanic membrane in a case of incus necrosis. Hüttenbrink et al[6] carried this further by the addition of a titanium clip to the FMT carrying it from the TM directly to the stapes footplate.

Recently, several authors have reported on placing the FMT at the round window. This has the particular advantage of treating patients in whom the ossicles are eroded or missing. Many of these patients have failed previous ossicular reconstruction attempts and have sought an alternative solution. In addition, round window placement of the FMT has been attractive in treating patients with atresia and unfavorable anatomy for external auditory canal reconstruction or with poor ossicular configuration.

A comprehensive classification system has been described by Baumgartner for all alternative placements of the FMT (Figure 1; Baumgartner WD, personal communication). Although there have been several iterations of placement of the FMT, this work will focus on the round window placement.

Round window placement

Placement of the FMT at the round window takes advantage of directly displacing intracochlear fluid in a retrograde fashion compared with the typical stimulation of the oval window. Round widow stimulation has been successfully borne out with experiments in animal models.[7] With use of the VSB, FMT placement at the round window has been shown to successfully treat mixed hearing loss and has been used in patients with atresia[8,9] as well as in patients with posterior petrosectomy.[10]

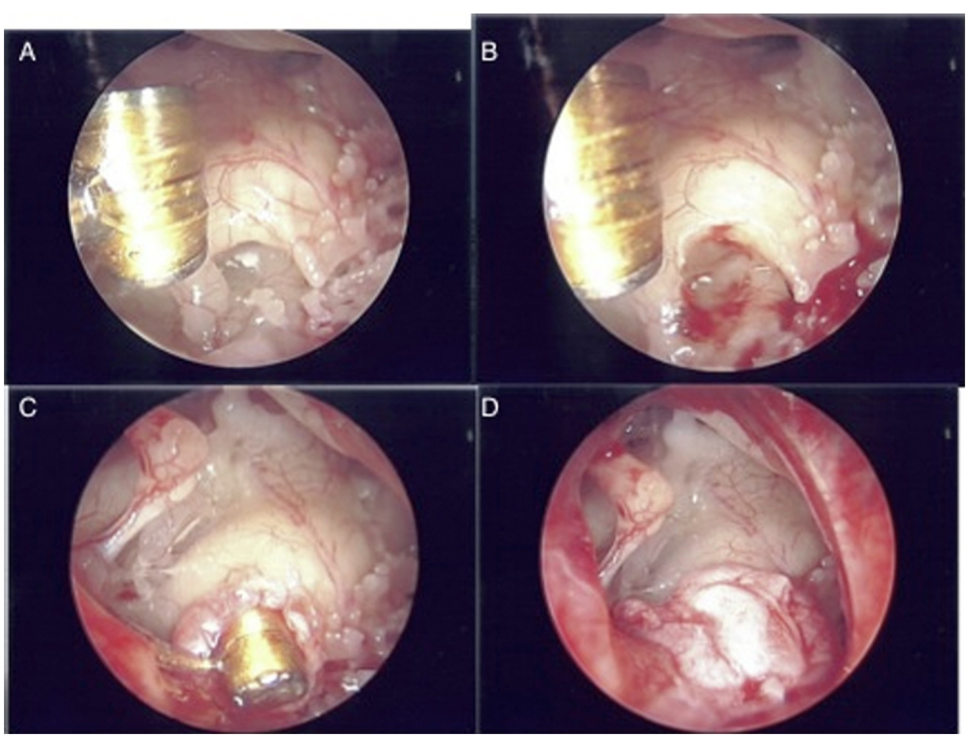

Figure 2 Placement of FMT at the round window. Placement of the FMT at the round window. (A) Showing the FMT size in relation to the round window anatomy. (B) The round window niche has been drilled to view the membrane and to accommodate the FMT. (C) The FMT is in the round window niche with an interposed piece of fascia. (D) Another piece of facia is placed over the FMT to ensure stable placement. (Color version of figure is available online.)

Indications

Round window placement has been reserved for cases in which traditional hearing devices are problematic, bone conduction devices are insufficient, and erosion or missing ossicles prevent conventional placement. Round window placement is particularly attractive in many cases of atresia with poor prognostic criteria for standard atresia repair.

Procedure

The VSB device comprises the speech processor and the vibrating ossicular prosthesis (VORP). The VORP is further composed of the FMT, a conductor link, and an internal receiver.[11] The size of the FMT is 1.4 mm in diameter by 2.1 mm in length, which correlates nicely to the round window niche. The approach is similar to a cochlear implant with a limited mastoidectomy and a wide facial recess exposure. The titanium clip for ossicular fixation is clipped off, as it is not needed. The boney lip of the round window niche is carefully drilled until the membrane is clearly visualized (Figure 2B). The FMT must have good approximation to the round window membrane to successfully transmit mechanical energy to the cochlea. Thus, an intervening layer of temporalis muscle is placed between the FMT and round window membrane and is directly visualized (Figure 2C). The speech processor is then placed in a cortical well, as is typical. A video of placement of the FMT at the round window can be found at http://calear.com/video.php.

Efficacy

Compared with total ossicular replacement prosthesis reconstruction, RW placement of the FMT the postoperative air-bone gap is significantly favorable (−19.38 dB at the round window vs 21.52 with a total ossicular replacement prosthesis). The air conduction gain was 58.31.[1] Beltrame et al [12] reported similar gains of 37.5 dB from 0.5 to 4 kHz with an SRT gain of 24 dB in quiet. This result compares well with conventional attachment of the FMT to the incus, showing gains of 18-36 dB even up to 8 years postoperatively.[3]

Pearls

As with conventional placement of the FMT onto the incus, patients with pure tone thresholds less than 15 dB may notice a "buzz" from the transducer itself. To avoid this, it is advisable to reserve VSB placement in patients with an appropriate cochlear loss. In the near future, a low circuit-noise processor will be constructed by the parent company. Also, successful placement requires interposition of tissue between the device and the round window membrane. In this way, direct coupling to the cochlear fluids is possible avoiding a thin layer of air between the FMT and the round window membrane.

Conclusions

VSB has been a successful option in restoring hearing in cases of mixed hearing loss. The device allows for creative placement of the FMT depending on the topography and function of the middle ear space. Furthermore, these alternative placements allow the device to treat a diversity of conductive and sensineural hearing losses.

References

1. Colletti V, Carner M, Colleti L: TORP vs round window implant for hearing restoration of patients with extensive ossicular chain defect. Acta Otolaryngol 129:1-4, 2009
2. Fisch U, Cremers WRJ, Lenarz T, et al: Clinical experience with the vibrant Soundbridge implant device. Otol Neurotol 22:962-972, 2001
3. Mosnier I, Sterkers O, Bouccara D, et al: Benefit of the vibrant Soundbridge device in patients implanted for 5 to 8 years. Ear Hear 29:281-284, 2008
4. Snik AF, Cremers CW: Vibrant semi-implantable hearing device with digital sound processing: Effective gain and speech perception. Arch Otolaryg Head Neck Surg 127:1433-1435, 2001
5. Cremers CW, Verhaegen VJ, Snik AF: The floating mass transducer of the vibrant soundbridge interposed between the stapes and tympanic membrane after incus necrosis. Otol Neurotol 30:76-78, 2008
6. Hüttenbrink KB, Zahnert T, Bornitz M, Beutner D: TORP Vibroplasty: A new alternative for the chronically disabled middle ear. Otol Neurotol 29:965-971, 2008
7. Dumont T, Zennaro O, Aran J, et al: Piezoelectrical, middle ear implant preserving the ossicular chain. Otolaryngol Clin North Am 28:173-187, 1995
8. Kiefer J, Arnod W, Staudemaier R: Round window stimulation with an implantable hearing aid (Soundbridge) combined with autogenous reconstruction of the auricle—A new approach. ORL J Otorhinolaryngol Relat Spec 68:378-385, 2006
9. Frenzel H, Hanke F, Beltrame M, et al: : Application of the vibrant Soundbridge to unilateral Oseous atresia cases. Laryngocsope 119: 67-74, 2009
10. Linder T, Schlegel C, DeMin N, et al: Active middle ear implants in patients undergoing subtotal petrosectomy: New application for the vibrant Soundbridge device and its implication for lateral cranium base surgery. Otol Neurotol 30:41-47, 2008
11. Miyamoto RT, Kirk KI: Cochlear implants and other implantable auditory prostheses, in Bailey BJ, Johnson JT, Newlands SD (eds): Head and Neck Surgery—Otolaryngology (ed 4). Philadelphia, Lippincott Williams & Wilkins, 2006, pp 2266-2277
12. Beltrame AM, Martini A, Prosser S, et al: Coupling the vibrant Soundbridge to cochlea round window: Auditory results in patients with mixed hearing loss. Otol Neurotol 30:194-201, 2009