

Safe explantation of a Vibrant Soundbridge with incus short process coupler: Case report and literature review

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ABSTRACT

We describe the first reported case of explantation of a Vibrant Soundbridge (VSB) with the floating mass transducer (FMT) fixed to the incus short process that was implanted 2 years before. The patient had good hearing results on the conversational frequencies but complained about insufficient amplification of low and high frequencies, discomfort, and blurred hearing. Our team along with technical specialists from Med-El analyzed and tried to solve his problems through multiple fitting sessions, computed tomography scan (which was normal), and revision surgery to exclude displacement of the FMT and eliminate excessive fibrosis surrounding it, all without success. Finally, the patient decided to be explanted. We removed the FMT from the short process of the incus without major complications. The hearing thresholds remained globally stable, except at 250 Hz (a decrease of 10 dB). This case is the first description of FMT removal from the short process of the incus as this coupler has only been available since 4 years. We reviewed the literature to look at the reported complications of the VSB and the revision surgery rates, especially when the FMT is fixed on the incus.

Keywords: Explantation, incus short process, middle ear implant, sensorineural hearing loss, vibrant soundbridge

Introduction

The Vibrant Soundbridge (VSB) is the most frequently used active middle ear implant. It allows rehabilitation of sensorineural, mixed, or conductive hearing loss because of the floating mass transducer (FMT) that can be fixed to any vibratory structure of the middle ear. In sensorineural hearing loss (SNHL), the FMT is attached to the incus, originally the long process (LP). Since the end of 2015, a new coupler has been available, which allows the attachment of the FMT to the short process (SP) of the incus, avoiding the need for a posterior tympanoplasty and, therefore, decreasing the risk of facial nerve or chorda tympani injury and reducing the operating time (1, 2). However, this coupler is relatively recent, and long-term results are unavailable. Our case report describes a patient who was not satisfied with his VSB and chose to remove it.

Case Presentation

A 45-year-old man suffered from SNHL in the context of Alport syndrome. He had worn conventional hearing aids (HA) since his childhood; however, 10 years ago, he developed skin

problems at the level of the external auditory canal resulting in an inability to wear the HA for more than a few hours per day. He tried many different models, but the problems persisted. Finally, we suggested a VSB as his hearing was situated within the range for this implant, albeit with thresholds at the upper limits at 4,000 Hz. The preoperative computed tomography (CT) scan did not show any abnormalities of the middle or internal ear. In 2017, we successfully implanted his right ear with an incus SP coupler. Immediately after the intervention, the patient complained of a decreased subjective hearing with the sensation of having a veil in the implanted ear, despite no clinically significant changes in bone conduction (BC) thresholds (maximum 5 dB per frequency) (Figure 1). Moreover, he was disappointed with the hearing outcomes, in particular at low and high frequencies. When we compared the pure-tone audiometry with and without the VSB, we observed a significant improvement, although the gain at 250; 4,000; and 8,000 Hz was poor compared with that of his HA (Figure 2). The unaided air conduction thresholds at 4,000 Hz seemed slightly decreased compared with that of the preoperative audiogram, falling just beyond the functional gain the VSB can offer. The speech audiometry was slightly better with his HA than with

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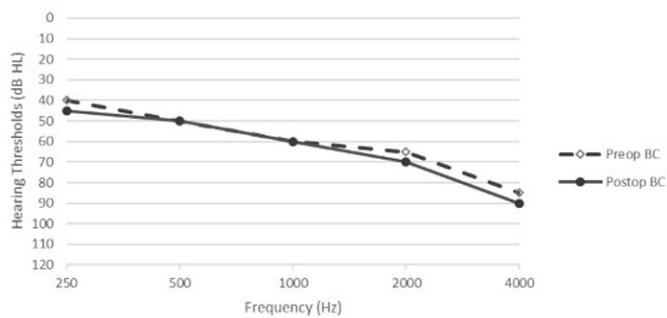


Figure 1. Right bone conduction hearing thresholds before (dashed line) and after (solid line) Vibrant Soundbridge implantation for frequencies from 250 to 4,000 Hz

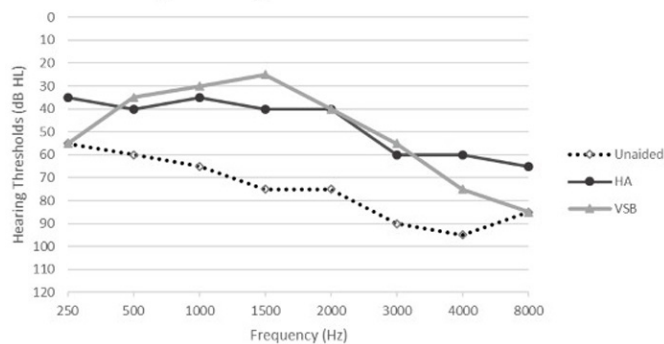


Figure 2. Comparison of unaided air-conduction hearing thresholds (broken line) with those with conventional hearing aids (black line) and with VSB (gray line) for frequencies from 250 to 4,000 Hz

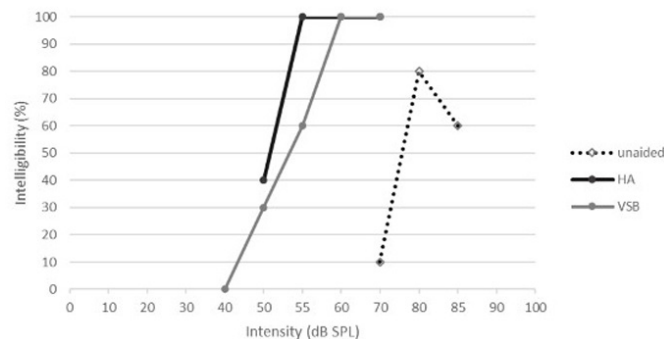


Figure 3. Comparison of Lafon disyllabic French word speech audiometry unaided (broken line) with that with conventional hearing aids (black line) and with Vibrant Soundbridge (gray line)

the VSB (Figure 3). In addition, after wearing the processor for a few hours, he started to experience a deep pain in the ear. We tried to improve the hearing results with numerous fitting

Main Points:

- The Vibrant Soundbridge incus short process coupler seems a safe and efficient alternative to the well-known incus long process coupler, but studies with larger sample size and long-term results are required.
- Our patient suffered from pain and insufficient hearing outcomes with his conventional hearing aids, without clear explanation.
- If needed, it is possible to remove the incus short process coupler without dislocation of the ossicles.

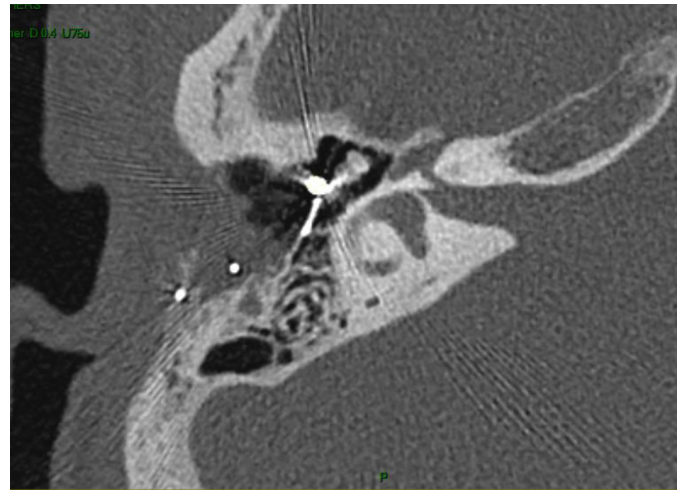


Figure 4. Axial image of the temporal computed tomography scan showing the floating mass transducer fixed to the short process of the incus of the right ear without displacement or massive fibrosis

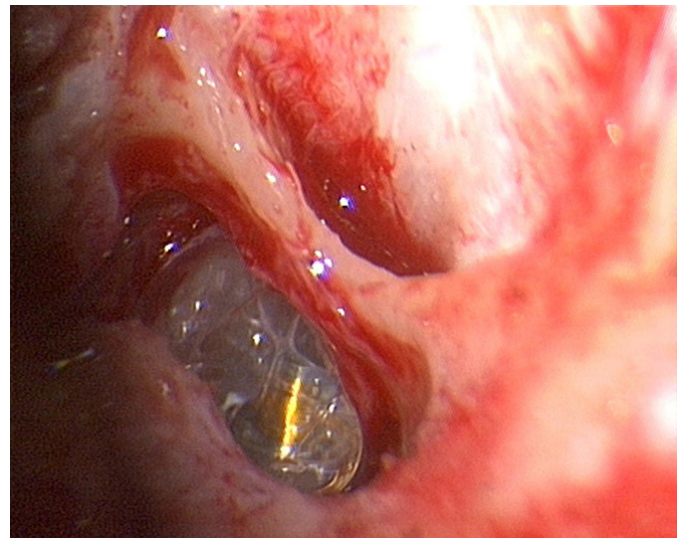


Figure 5. Operative view of the floating mass transducer fixed on the short process of the incus and surrounded by fibrous tissue (right ear)

sessions, without significant improvement. We performed a CT scan of the temporal bone, which did not show any displacement of the FMT or massive fibrotic tissue (Figure 4). We performed a surgical exploration and removed some scar tissue; however, it did not improve the audiometric results or his unpleasant sensations. Finally, the patient decided to remove the implant and gave his informed consent for the surgery. The surgical intervention took place 2 years after the implantation under general anesthesia. We opened the skin with a retro-auricular approach. We drilled the ossified bone pate in the mastoidectomy, which kept the conductor link in place. We removed fibrous tissue enclosing the FMT (Figure 5). We detached the SP coupler with the FMT from the incus by gentle back and forth movements in the axis of the incus with the help of a microforceps (video). The entire VORP (Vibrating Ossicular Prosthesis, the internal part of the VSB) was removed without any problem. Because the open mastoid could explain the "veil sensation," we reconstructed the cortical part with some cortical bone fragments of 1 mm from our tissue bank, mixed with biological glue (Tisseel, Baxter Global Head-

quarters, Deerfield, Illinois, USA). The skin was closed, and we put a compressive head bandage for 24 hours. The patient had some nausea without vertigo for a few hours after the surgery. He immediately described disappearance of the sensation of the veil on his hearing. We checked his hearing thresholds 1 and 10 days after the surgery, which revealed a decrease of BC threshold of 10 dB at 250 Hz. The other frequencies remained stable. The patient gave his informed consent for the writing and publishing of this case report.

Discussion

The middle ear VSB implant is a reliable device for SNHL and mixed or conductive hearing loss as has been shown by numerous clinical studies (3-5). Even if most authors have demonstrated that it does not significantly alter the residual hearing (less than 5 dB HL per frequency) (2, 6, 7), others have described significant worsening after 2 years, with FMT fixed on the LP (8). A recent study including 12 patients with incus SP coupler reported 2 patients with deterioration of BC thresholds of more than 10 dB on average on frequencies from 0.5 to 4 kHz (9), without explanation. More long-term data are needed about hearing preservation with the SP coupler because the high-speed drilling could theoretically cause noise trauma to the cochlea if the drill touches the ossicular chain (1).

Our patient achieved 23 dB hearing gain on average for frequencies from 250 to 4,000 Hz, which is in accordance with the published studies (3, 6, 10). However, his gain at 250; 4,000; and 8,000 Hz was poorer than what is generally described in the literature (3). He achieved slightly lower speech intelligibility in quiet with VSB than with his HA. Different authors have described similar speech gain with conventional HA or VSB in quiet (6, 8, 11) but improved speech intelligibility in noise with the VSB (7, 12-14).

The outcomes between SP and LP couplers have been compared by 2 recent studies with the 1st one showing comparable functional gain, except at 8,000 Hz where the LP coupler achieved a better gain in 36 patients (2). However, the speech gain was alike in the 2 groups. The 2nd study compared 17 patients with incus SP coupler and 25 patients with incus LP coupler (1) and showed that the recognition score for monosyllabic words was significantly higher with the SP coupler (76.1% versus 66.2%). Larger sample sizes are needed to study the gain in pure-tone and speech audiometry with the SP coupler.

When we looked at the reported rate of revision surgery for FMT fixed to the incus LP coupler, we obtained scores between 8% and 16% (3, 8, 15). Revision surgery is mostly because of migration of the FMT. To our knowledge, no studies have yet reported on FMT migration with the SP coupler. Brkic et al. (4) have recently published their long-term outcomes of 118 VSB. They used the incus LP coupler in 73 patients and SP coupler in 4 patients. Adverse events with the LP coupler were seen in 9.6% patients, and they did not report any adverse event with the incus SP coupler. They explanted 28 incus LP couplers because of medical or technical issues without any reported adverse event (for example, ossicular dislocation or hearing deterioration), and 2.5% of the patients were explanted owing to complaints of pain. This is the first reported case of explantation of a VSB with incus SP coupler, which happened without adverse effects.

In conclusion, the VSB incus SP coupler seems a good alternative to the incus LP coupler for SNHL with a contraindication to conventional HA. Indeed, the surgical approach to fix the incus SP coupler reduces the risk of facial nerve and chorda tympani injury and gives good audiometric results. However, long-term results and larger sample sizes are lacking, especially in terms of impact on residual hearing and audiometric gain per frequency. We described the first reported case of a man implanted with an SP coupler, which was finally successfully explanted owing to subjective hearing loss, insufficient hearing gain than with his HA, and pain. This case highlights the importance of using VSB in patients who are unable to wear conventional HA. If the SP coupler is to be removed later, this procedure seems safe according to our experience.

Informed Consent: Verbal informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Supervision – G.A.; Design – G.A.; Resources – G.A.; Materials – G.A.; Data Collection and/or Processing – G.A.; Analysis and/or Interpretation – G.A., D.M.; Literature Search – D.D., G.A.; Writing Manuscript – G.A.; Critical Review – D.M., H.V.

Conflict of Interest: The authors have no conflict of interest to declare.

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Video: Removal of the floating mass transducer fixed on the short process of the incus of right ear through the mastoidectomy

References

- Schraven SP, Rak K, Cebulla M, Radeloff A, Hagen R, Mlynski R. Surgical impact of coupling an active middle ear implant to short incus process. *Otol Neurotol* 2018; 39: 688-92. [\[CrossRef\]](#)
- Lee JM, Lee YH, Jung J, Kim SH, Moon IS, Choi JY. audiologic gain of incus short process vibroplasty with conventional incus long process vibroplasty: a retrospective analysis of 36 patients. *Otol Neurotol* 2017; 38: 1063-70. [\[CrossRef\]](#)
- Grégoire A, Van Damme JP, Gilain C, Bihin B, Garin P. Our auditory results using the Vibrant Soundbridge on the long process of the incus: 20 years of data. *Auris Nasus Larynx* 2018; 45: 66-72. [\[CrossRef\]](#)
- Brkic FF, Riss D, Auinger A, et al. Long-term outcome of hearing rehabilitation with an active middle ear implant. *Laryngoscope* 2019; 129: 477-81. [\[CrossRef\]](#)
- Khan A, Hillman T, Chen D. Vibrant soundbridge rehabilitation of sensorineural hearing loss. *Otolaryngol Clin North Am* 2014; 47: 927-39. [\[CrossRef\]](#)
- Luetje CM, Brackman D, Balkany TJ, et al. Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: A prospective controlled multicenter study. *Otolaryngol Head Neck Surg* 2002; 126: 97-107. [\[CrossRef\]](#)
- Frayssé B, Lavieille JP, Schmerber S, et al. A multicenter study of the Vibrant Soundbridge middle ear implant: Early clinical results and experience. *Otol Neurotol* 2001; 22: 952-61. [\[CrossRef\]](#)
- Schmuziger N, Schimmann F, Wengen D, Patscheke J, Probst R. Long-term assessment after implantation of the vibrant soundbridge device. *Otol Neurotol* 2006; 27: 183-8. [\[CrossRef\]](#)
- Rahne T, Skarzynski PH, Hagen R, et al. A retrospective European multicenter analysis of the functional outcomes after active

- middle ear implant surgery using the third generation vibroplasty couplers. *Eur Arch Otorhinolaryngol* 2021; 278: 67-75. [\[CrossRef\]](#)
10. Maier H, Hinze AL, Gerdes T, et al. Long-term results of Incus Vibroplasty in patients with moderate-to-severe Sensorineural hearing loss. *Audiol Neurotol* 2015; 20: 136-46. [\[CrossRef\]](#)
 11. Snik AFM, Cremers CWRJ. Vibrant semi-implantable hearing device with digital sound processing. *Arch Otolaryngol Head Neck Surg* 2001; 127: 1433-7. [\[CrossRef\]](#)
 12. Garin P, Debaty M, Galle C. Hearing in noise with the Vibrant Soundbridge middle-ear implant. *Cochlear Implants Int* 2005; 6(Suppl 1): 72-4. [\[CrossRef\]](#)
 13. Todt I, Seidl RO, Gross M, Ernst A. Comparison of different vibrant soundbridge audioprocessors with conventional hearing aids. *Otol Neurotol* 2002; 23: 669-73. [\[CrossRef\]](#)
 14. Truy E, Philibert B, Vesson JF, Labassi S, Collet L. Vibrant sound-bridge versus conventional hearing aid in sensorineural high-frequency hearing loss: a prospective study. *Otol Neurotol* 2008; 29: 684-7. [\[CrossRef\]](#)
 15. Schraven SP, Grohmann W, Rak K, Shehata-Dieler W, Hagen R, Mlynski R. Long-Term stability of the active middle-ear implant with floating-mass transducer technology: a single-center study. *Otol Neurotol* 2016; 37: 252-66. [\[CrossRef\]](#)