CASE REPORT

First use of the Vibrant Soundbridge middle ear implant in Turkish patients: A Report of 2 cases

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The quality and efficacy of conventional hearing aids are limited, and those limitations often cause patients' dissatisfaction and noncompliance. Middle ear implants are a new alternative to conventional hearing aids. The Vibrant Soundbridge (VSB) is an electromagnetic middle ear implant that transforms external sounds into vibrations transmitted directly into the intact ossicular chain. Adult patients (ie, those aged at least 18 years) who have a moderate-to-severe sensorineural hearing loss and who do not benefit from traditional hearing aids because of a medical condition or a device-related problem are candidates for a VSB. Clinical studies have reported overall patient satisfaction with that device, even though the VSB does not seem to be audiometrically superior to conventional hearing aids. Patients have reported satisfaction with the more natural sound quality, lack of feedback, absence of occlusion and distortion, and improved speech discrimination against background noise provided by a VSB. We report the first 2 Turkish patients in whom a VSB was implanted, and we describe our first experience with that device.

Hearing aids are the main rehabilitation device for patients with a sensorineural hearing loss. Despite ongoing advances in conventional hearing-aid technology, some patients do not greatly benefit from a hearing aid. The quality and efficacy of conventional hearing aids are limited [1], and those limitations often result in patients' dissatisfaction and noncompliance. However, new alternatives (such as implantable middle ear hearing devices) to conventional hearing aids have been developed and are now available to patients. The Vibrant Soundbridge (VSB) (MED-EL Hearing Technology, Innsbruck, Austria) is one of those devices. The VSB was first used in Europe after its commercial release in February 1998, and it became available in the United States after its approval by the US Food and Drug Administration in August 2000 [2].

Indications for a VSB include adult age (least 18 years), a moderate-to-severe sensorineural hearing loss, and lack of benefit from a traditional hearing aid because of a medical condition or a device-related problem. The VSB consists of 2 primary components: a surgically implanted vibrating ossicular prosthesis (VORP) and an externally worn audio processor (AP). This electromagnetic device (VSB) transforms external sounds into vibrations that are transmitted directly to the intact ossicular chain.

Clinical studies have reported overall patient satisfaction with the VSB, even though it does not seem to be audiometrically superior to conventional hearing aids [2-4]. Patients have expressed satisfaction with the more natural sound quality, the lack of feedback, the absence of occlusion and distortion, and the improved speech discrimination in noise [1,4,5] that they experience when wearing a VSB. In this report, we describe the result of the first VSB implantation in Turkish patients and share our first experience with this new device.

CASE REPORTS

Case 1

A 30-year-old woman with an idiopathic bilateral moderate sensorineural hearing deficit sought hearing improvement at our institution. The results of an audiogram (Figure 1) revealed a pure tone average of 53 dB in the right ear and 55 dB in the left ear. Her speech response threshold was 60 dB in both ears. Her speech discrimination level was 40% in the right ear at 100 dB and 36% in the left ear at 100 dB. She had a type A tympanogram in both ears. For 7 years, she had been using a conventional hearing aid with which she was not satisfied because of its appearance and unnatural sound quality. A VSB was implanted in right ear without complications in this patient in April 2006. That procedure was very similar to traditional cochlear implantation except for the size and shape of the facial recess and the absence of cochleostomy. The patient received a general anesthetic, after which an extensive hair shave was performed. Using a silicone template, we placed drawings of device on the patient's scalp at the site of the VORP. The procedure was performed through a postauricular incision. After simple mastoidectomy, a posterior tympanotomy via a facial recess approach was performed. The tympanotomy was enlarged, and into the temporal bone we drilled a tunnel that served as a bed for the lead wires. Silicone templates were also used for the placement of a VORP bed that was drilled posterior to the tunnel of the lead wires. The VORP was fixed to its bed with polypropylene (Prolene) sutures. A floating mass transducer (FMT) was then passed through the facial recess and was clipped onto the long process of the incus (Figure 2). It is important to ensure that the FMT is in position parallel to the long axis of the stapes and is not in contact with the tympanic membrane, the promontorium, or the pyramidal eminence. We applied bone cement to the long process of the incus to prevent erosion of the bone. We then closed the periosteal flap with absorbable sutures and the skin with polypropylene sutures.

After her AP was programmed 2 months after surgery, the patient reported hearing a more natural quality of her own voice, and she noted improved speech discrimination in noise. She greatly appreciated the hidden AP. Two months after VSB placement, the results of a pure tone audiogram of the right ear indicated 53 dB without the device and 28 db with the implant (Figure 1). The patient thus experienced an increase of 25 db after VSB implantation.

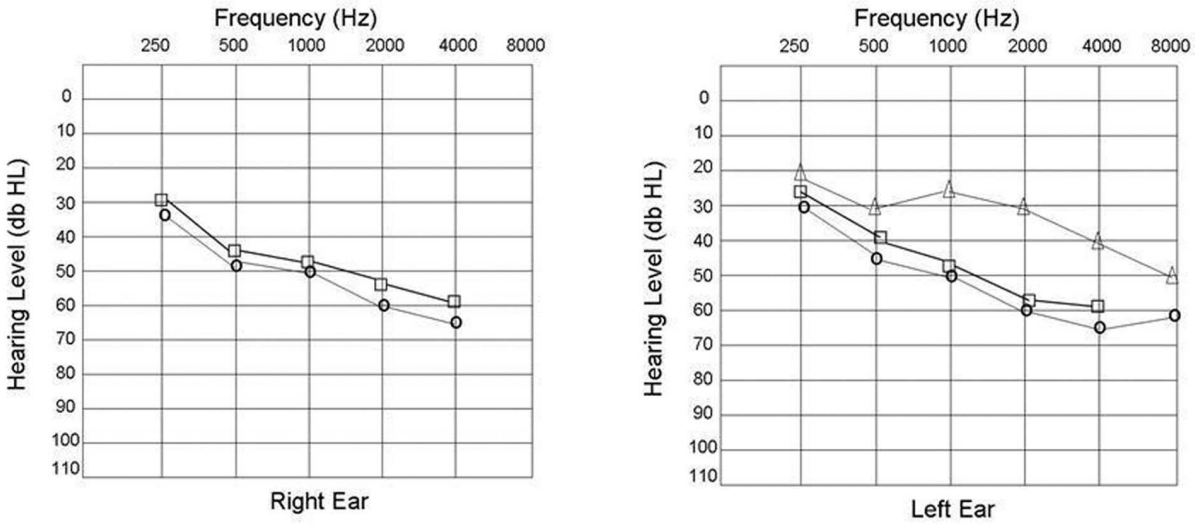

Figure-1: Left-sided and right-sided audiograms of patient 1. Preoperative (o)-pure tone average, 55 dB; (□)-bone conduction and postoperative with implant (Δ)-pure tone average, 28 dB.

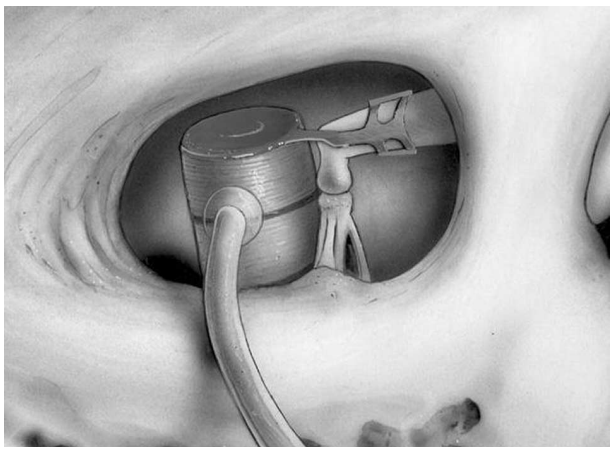

Figure-2: The floating mass transducer is clipped onto the long process of the incus.

Case 2

A 40-year-old man with a mixed-type bilateral moderate hearing deficit sought treatment at our institution. He had undergone a right-sided mastoidectomy in a hospital 5 years earlier. After that operation, a fistula developed between the mastoid cavity and the skin over the temporal bone. Three years earlier, we performed a right-sided revision mastoidectomy, closure of the fistula, and obliteration of the cavity. Two years after that surgery, we performed a modified radical mastoidectomy to treat a cholesteatoma of the left ear. The patient's results of a pure tone audiogram were 58 dB in the right ear and 73 dB in the left ear. His speech response threshold was 60 dB in the right ear and 80 dB in the left ear. His speech discrimination level was 96% in the right ear at 100 dB and 96% in the left ear at 115 dB. He had a type C tympanogram in the right ear and a type B tympanogram in the left ear. Chronic middle ear problems prevented his use of a hearing aid.

A VSB was implanted in the patient's left ear in April 2006 to ameliorate poor hearing caused by the cholesteatoma. In that surgical procedure, the FMT was to be placed on the round window because clipping the FMT to the stapes was inadvisable. However, the round window could not be opened because the ring of the round window niche revealed tympanosclerotic obliteration and hyaline degeneration, so we decided to position the FMT on the oval window. After stapedectomy and removal of the soft tissue from the oval window, a temporalis fascia was placed on the oval window to produce a medium between the FMT and the oval window. The carrier of the FMT was secured to the bone with bone cement to prevent migration.

Two months after the implantation of the VSB, the results of the patient's pure tone average audiogram in the left ear were 73 dB without the device and 53 db with the implant (Figure 3). The implantation of the VSB resulted in an increase of 20 db.

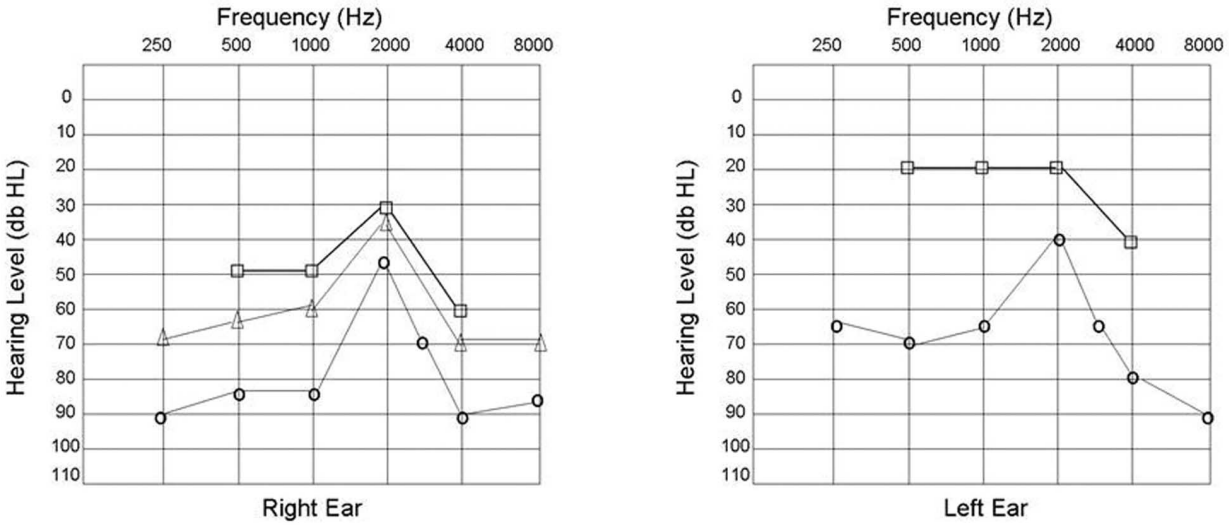

Figure-3: Left-sided and right-sided audiograms of patient 2. Preoperative (o)-pure tone average, 73 dB; (□)-bone conduction and postoperative with implant (Δ)-pure tone average, 53 dB.

DISCUSSION

Hearing disorders have been one of the most prevalent and chronic disabilities since antiquity, and efforts to cure hearing impairments are as old as human history. During the last century, great technologic advances in the treatment of auditory disorders have been made. Improvements in conventional hearing aids have occurred, and alternative methods (such as middle ear implants) of treating hearing loss have been developed. The VSB, which is an electromagnetic middle ear implant, has been available to patients for almost a decade.

The VSB is composed of 2 basic components: an internal part (the VORP; Figure 4) and an external part (the AP; Figure 5). The surgically implanted VORP consists of an internal coil, a magnet, a conductor link, and an FMT. The AP is worn externally just posterosuperior to the pinna, and it can be hidden under the hair. The AP consists of a microphone, a signal processor, telemetry electronics, a magnet, and a battery. The magnetic attraction between the magnet in the VORP and the magnet in the AP holds the AP on the head.

The signal from the AP is transferred across the skin to the internal coil and is then relayed to the FMT via the conductor link. The FMT, which is attached to the incus, converts the signal to vibrations that move the ossicles in a manner similar to that in which vibrations move the ossicles in the healthy ear canal. These vibrations are then interpreted by the brain as sound. Selection criteria for VSB implantation are shown in the Table.

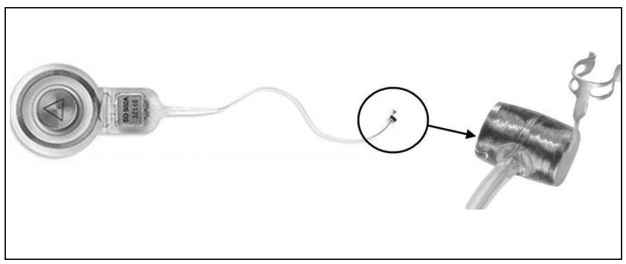

Figure-4: The vibrating ossicular prosthesis (an internal part of theVSB) contains the internal coil, a magnet, a conductor link, and the floating mass transducer.

Figure-5: The audio processor (an external part of the VSB) contains a microphone, a signal processor, telemetry electronics, a magnet, and a battery.

Table. Selection Criteria for Vibrant Soundbridge Use

Criteria for Vibrant Soundbridge Implantation
A bilateral mild-to-moderate or severe sensorineural hearing disorder.
A bilateral mixed-type hearing disorder, including congenital ossicular anomalies (Round or oval window implantation).
A unilateral sensorineural and unilateral mixed-type hearing disorder in the same patient.
Inability to use or benefit from a conventional hearing aid because of an ear canal anomaly, cosmetic issues, or a high-frequency hearing loss.
Discrimination scores greater than 50%.
Hearing loss that has been stable for 2 consecutive years and must not be progressive.
The absence of retrocochlear pathologic conditions.
Realistic expectations in a psychologically stable adult patient (ie, aged at least 18 years).

In the last 2 years, animal studies have shown that vibrating middle ear implants provide some improvement when they are used on the oval or round window. The VSB has recently been used to ameliorate mixed-type hearing loss and to improve hearing in people who have undergone mastoidectomy. Patients so treated have achieved results similar to those of standard procedures for correcting hearing loss.

The VSB is usually used in patients who have no chronic middle ear disease and who have not undergone prior middle ear surgery. Because the VSB transmits sounds by vibration, it is sometimes used through the round window. In our second patient, who had undergone prior bilateral middle ear surgery and in whom the round window was obliterated, oval window application was performed. To our knowledge, he is the second individual so treated to date.

Complications that may develop during surgery include facial nerve damage, ossicular chain damage, and injury to the chorda tympani. Postsurgical complications include facial paralysis, flap infection, healing difficulty, vertigo, a decrease in residual hearing, the development of a hematoma, and failure of the device. Because of the impact of the VSB on residual hearing and the requirement for middle ear surgery, some authors [6] have suggested that it be used only in patients intolerant to a hearing aid for reasons such as severe chronic otitis externa. However, VSB surgery has a low complication rate in the hands of a skillful surgeon, especially one who has performed cochlear implantations [2,4,7]. Factors that limit the use of a VSB include its cost, the need for surgical implantation, permanent avoidance of certain types of physical activity and contact sports, and the appearance of artifacts on magnetic resonance imaging.

Because the VSB is a novel device, its long-term effects (including those of the FMT, which may include the erosion of the ossicular chain; especially the erosion of the long process of the incus) have not yet been identified [8]. To prevent the erosion of the incus in the first patient described in this report, we applied bone cement to the area in which the FMT was clipped to the incus. We hope that the application of bone cement will prevent the mechanical effects of the FMT from eroding the incus.

Many people today do not benefit from wearing a conventional hearing aid for a medical reason (chronic external otitis, external ear aplasia, external ear skin irritation, radical mastoidectomy) or because of acoustic feedback, occlusion of the ear canal, or sound distortion. Recent studies have shown that the VSB is a suitable,

safe, and effective treatment for patients who experience moderate-to-severe sensorineural hearing loss and that patients express greater satisfaction with its use than with that of a conventional hearing aid [1-5]. According to several authors, patients appreciate the VSB because of the more natural sound quality they experience and because of improved speech discrimination in noise, the lack of feedback, and the absence of occlusion and distortion [1,4,6].

This is the preliminary report of the first 2 Turkish patients in whom a VSB was implanted (1 via standard technique and 1 by means of an oval window procedure). The VSB, which is an effective device in patients with a sensorineural hearing disorder or a mixed-type hearing problem, is especially appreciated by those who do not wear a conventional hearing aid for social, psychologic, or medical reasons. The limitations of using that device are primarily cost related. The hearing outcomes in both patients described in this report, who will be monitored long term, are promising at the time of this writing.

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