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Review

ACTIVE MIDDLE EAR VIBRANT SOUNDBRIDGE SOUND IMPLANT

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SUMMARY – The Vibrant Soundbridge represents a new approach to hearing improvement in the form of active implantable middle ear hearing device. Unlike conventional acoustic hearing aids, which increase the volume of sound that goes to the eardrum, the Vibrant Soundbridge bypasses the ear canal and eardrum by directly vibrating the small bones in the middle ear. Because of its design, no portion of the device is placed in the ear canal itself. The Vibrant Soundbridge has been approved by the FDA as a safe and effective treatment option for adults with moderate to severe sensorineural, conductive or mixed hearing losses who desire an alternative to the acoustic hearing aids, for better hearing. The paper presents a review of the active middle ear implant Vibrant Soundbridge, which has been also implanted at the Department of Otorhinolaryngology and Head and Neck Surgery, Sestre milosrdnice University Hospital Center, which is the Referral Center for Cochlear Implantation and Surgery of Hearing Impairment and Deafness of the Ministry of Health, Republic of Croatia.

Key words: *Hearing; Hearing aids; Hearing loss, sensorineural; Hearing loss, mixed conductive-sensorineural; Croatia*

Introduction

Middle ear implants (MEIs) are useful for those with a purely sensorineural hearing loss. Historically, the first clinically available MEIs (by Suzuki and Yanagihara in Japan) were those with unresolveable middle ear conductive/mixed losses[1]. However, modern MEIs require a well functioning ossicular chain. MEIs have been around in one form or another since 1935 when Dr. Wilska sprinkled some iron filings onto a person's eardrum. A magnetic field was generated by a coil of wire inside an earphone and was applied to the iron filings. The subjects reported 'hearing', despite the fact there was no acoustic sound energy coming from the earphone. The magnetic field from the earphone caused the iron filings to vibrate in synchrony with the magnetic field. This vibration in turn caused the eardrum to vibrate, which allowed sound to be transduced to the inner ear in the normal fashion. Dr. Wilska's experimental device had some obvious limitations, i.e. its bulky size, the amount of energy required to transduce a sound (28,000 mA to produce 85 dB SPL) and the person had to be lying down on the bed in order to keep the iron filings correctly positioned on the tympanic membrane. Since the 1930s, a number of research teams around the world have tried to create a wearable MEI. Current MEIs can generate 85 dB with less than 3 mA.

A MEI is a hearing aid where either the receiver or the entire hearing aid is surgically inserted into the middle ear. The advantages of such an implant are twofold. First, if the ossicles can be driven directly, there may be improved sound quality, with no feedback. Second, a MEI may be completely implantable with no external components at all. Indeed, two manufacturers have now designed completely implantable middle ear devices. In addition, depending on the

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MEI, if there is no device in the ear canal, there is no insertion loss with a net boost in high-frequency sound transmission[2].

Direct drive, implantable middle ear hearing devices represent a new category of hearing devices. Rather than delivering acoustic energy into the external auditory canal (as with traditional hearing aid systems), direct drive MEI systems use mechanical vibrations delivered directly to the ossicular chain, while leaving the ear canal completely open. One major advantage of direct drive devices is the ability to provide improved sound quality to hearing impaired subjects [13]. Patient reports of improved sound quality with direct drive devices of various types have been published previously by many authors[3-5]. In a recently published report, patients using the Vibrant® Soundbridge™ MEI systems using the Floating Mass Transducer™ (FMT) have also reported improvements in overall sound quality, clearness of sound and tone, and improved sound quality with respect to their own voice[6].

Appropriate candidates for direct drive middle ear hearing devices include adults aged 18 years and older with moderate to severe sensorineural hearing loss. Candidates should have experience with traditional hearing aid fittings and should desire an alternative hearing system. Word recognition as determined under headphones should be at least 50 percent correct in the designated ear. Normal middle ear function should be apparent based on clinical history, tympanometry and observation. The patient should be counseled regarding realistic expectations. Often, patients who are interested in seeking direct drive middle ear hearing devices have experienced dissatisfaction regarding sound quality of their own voice. Despite multiple office visits to their hearing healthcare professional, these individuals are unable to produce speech sounds that sound 'normal' or comfortable to them, and they are unable to overcome this obstacle. Additionally, some of the patients who have been successful with the direct drive middle ear hearing device have experienced physical discomfort while wearing traditional hearing aids. Other commonalities across these patients include frustration with amplification secondary to multiple hearing aid repairs and multiple office visits, cerumen issues relating to occluded hearing aid receivers, and potential cerumen impaction of the external auditory canal, inability to wear traditional hearing aids due to sensitive ear canal skin, exostosis, miscellaneous physical complaints related to the presence of a foreign object in the ear canal, and the inability to overcome acoustic feedback issues with traditional amplification. Sound quality measures are difficult to grasp and quantify. Almost by definition, the word 'quality' implies a subjective measure[7-9]. There are several theoretical reasons why direct drive MEI hearing devices might indeed produce better sound quality than conventional acoustic hearing aids. The theoretical issues which might impact qualitative judgments include increased high frequency gain (more high frequency energy can be delivered *via* the Vibrant Soundbridge than would typically be anticipated using traditional hearing aid technology), improved signal coupling (bypassing the tympanic membrane, yielding a potentially more efficient high frequency sound transfer system, reduction in acoustic feedback because the signal is not acoustically delivered into the external auditory canal, less acoustic feedback is likely), no insertion loss, no occlusion effect, and reduced distortion from external auditory canal resonances because the external auditory canal is not occluded while using direct drive MEI systems[2].

The first Food and Drug Administration (FDA) approval for a direct drive MEI system was granted on August 31, 2000. The Vibrant Soundbridge was shown to be safe and effective in clinical studies[10]. A review of 81 patients, studied as part of the FDA approval process, determined that the participants could hear as well with the device as with more traditional hearing aids (FDA, 2000). Fisch *et al*. report on the results in 47 patients in their multi-center European clinical trials. They found that the Vibrant Soundbridge could be used safely to treat moderate to severe sensorineural hearing loss. Additionally, they reported that changes in pre- *versus* postoperative hearing thresholds (under headphones) were clinically nonsignificant (within 5 dB)[8]. Fraysse *et al*. have reported results in 25 patients using the Vibrant Soundbridge direct drive MEI system. Objective and subjective tools were used to determine results. Their results indicated that no significant changes were recorded concerning the status of pre-*versus* postoperative hearing thresholds. These authors have also reported significant improvements in communication across various listening situations while using the Vibrant Soundbridge, as compared to traditional (acoustic) hearing aid fittings in the majority of their patients[11].

The Vibrant Soundbridge Device

The Vibrant Soundbridge is a partially implantable hearing system for adults with mild to severe sensorineural hearing loss, as well as for persons with conductive and mixed hearing losses. It is implanted in the middle ear and mechanically vibrates the middle ear structures.

The Vibrant Soundbridge consists of two parts, an external portion and implanted portion[12].

The external portion: Audio Processor

The externally worn Audio Processor (Fig. 1) is attached to the patient's head, behind the ear, by a magnet that is attracted to a magnet within the implanted Vibrating Ossicular Prosthesis (VORP) (Fig. 2). The Audio Processor includes a microphone to pick up sound from the environment, sound processing circuitry to modify the output signal to the patient's specific requirements, a battery to power the device, and high-quality, fully digital signal processing. The Audio Processor is designed to have a battery life of approximately one week. The attractive features of the Vibrant Soundbridge are wearing comfort, as the ear canal remains completely open and the Audio Processor is nicely hidden by hair. The Vibrant Soundbridge is activated by fitting the Audio Processor[13].

Fig. 1. Audio processor of the Vibrant Soundbridge.

The implanted portion: Vibrating Ossicular Prosthesis (VORP)

The implanted part of the Vibrant Soundbridge is called the Vibrating Ossicular Prosthesis (VORP) and consists of an internal coil, a magnet to hold the Audio Processor over the implant, a demodulator, the conductor link, and the innovative technology of the Floating Mass Transducer™ (FMT™). The signal from the Audio Processor is transmitted to the VORP and transformed into mechanical vibrations by the FMT. The VORP is implanted during a surgical procedure in which the FMT is attached to a vibratory structure of the ear. When activated, the FMT vibrates in a controlled manner, specific to each patient's hearing needs, causing the structure of the ear to vibrate. It conducts a wide frequency range up to 8000 Hz. The FMT is a totally enclosed transducer that uses inertial drive to impart mechanical vibrations directly to the vibrating structure of the middle ear, i.e. the ossicles. Although small in size, the mechanical energy that the FMT imparts to the vibratory structure can be comparable to very high sound pressure levels. The FMT has been specifically designed to mimic the vibratory responses of the middle ear. It is capable of delivering mechanical stimulation to the middle ear throughout the entire speech frequency range of human ears. The FMT has two electromagnetic coils. The coils are wound around hermetically sealed titanium housing. Residing within the housing is a permanent magnet supported by a pair of springs. Electrical signal is supplied to the coils, which in turn causes the magnet and the entire transducer to vibrate. The driving force of the transducer is imparted to both the ossicular chain and the driving mass through their mutual reaction. This type of inertial drive transducer is referred to as a 'Floating Mass Transducer' or FMT. The transducer is the key component of the Vibrant Soundbridge[10,14,15].

Fig. 2. Vibrating ossicular prosthesis of the Vibrant Soundbridge.

Selection Criteria

Selection criteria are sensorineural (Fig. 3), conductive and mixed hearing losses (Fig. 4).

Sensorineural hearing loss

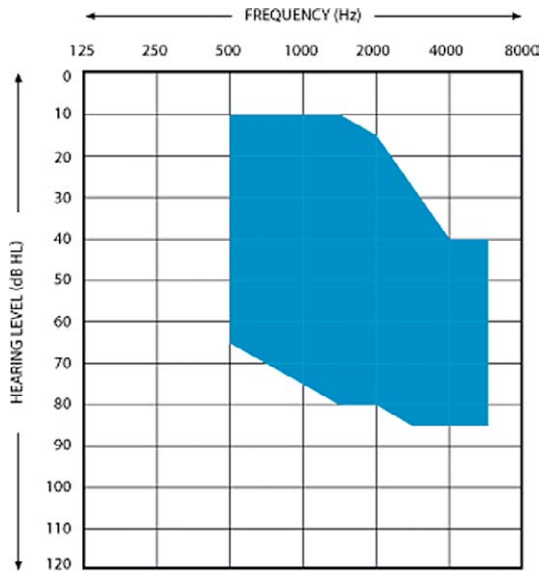

Fig. 3. Sensorineural hearing loss for the Vibrant Soundbridge implantation.

1. Air-conduction thresholds at or within the shaded region.
2. Normal middle ear function as shown by audiometric thresholds, tympanometry and acoustic reflexes.
3. Speech understanding of at least 50% on an open-set word test;
   - at the most comfortable listening level using head phones, or
   - at 65 dB SPL in the free field using hearing aid(s).
4. Stable hearing loss. Patient should be experienced with hearing aids.
5. No skin conditions preventing attachment of the Audio Processor.
6. Realistic expectations.
7. Absence of retrocochlear and central auditory disorders.
8. 18 years of age or older[16-18].

Conductive and mixed hearing losses

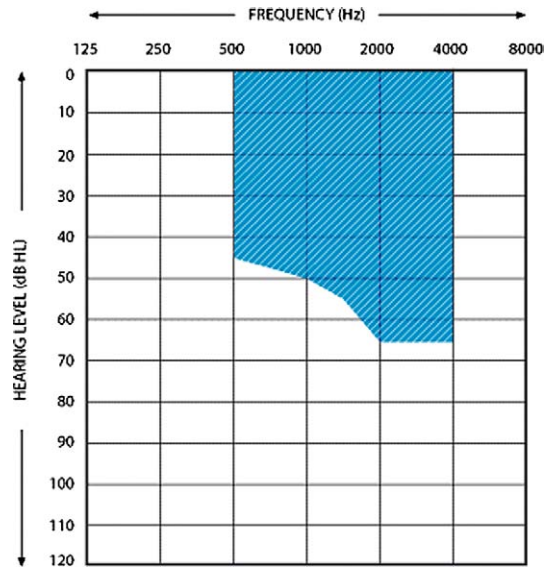

Fig. 4. Conductive and mixed hearing losses for the Vibrant Soundbridge implantation.

1. Bone-conduction thresholds at or within the shaded region.
2. Ear anatomy allows positioning of the FMT in contact with a suitable vibratory structure of the ear.
3. Absence of active middle ear infection and/or chronic fluid in the ear.
4. Stable bone conduction thresholds.
5. No skin conditions preventing attachment of the Audio Processor.
6. Realistic expectations.
7. Absence of retrocochlear and central auditory disorders.
8. 18 years of age or older[19-21].

Surgery

There are two common surgical routes to access the middle ear:

1. the facial recess route *via* mastoidectomy and posterior tympanotomy (Fig. 5), and
2. the transmeatal route *via* the ear canal. Surgeons determine which route to use from the medical status of the patient's ear. Surgeons may also combine the two. It is possible to ei-

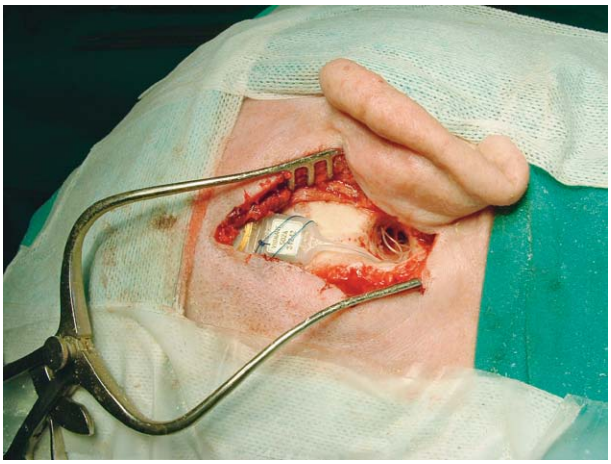

Fig. 5. Surgical implantation of the Vibrant Soundbridge via mastoidectomy and posterior tympanotomy at the Department of Otorhinolaryngology and Head and Neck Surgery, Sestre milosrdnice University Hospital Centre.

ther attach the FMT to the incus (Fig. 6)[22], or to place it in the round window niche[23].

Surgery takes about 2 to 2.5 hours and is performed either on an outpatient or inpatient basis. As with all surgical procedures, the physician must fully assess the potential risks and benefits for the patient prior to the decision to implant the Vibrant Soundbridge. The physician must exercise medical judgment and consider the patient's complete medical history. Four to eight weeks after surgery and healing, the surgeon medically evaluates the patient, and an audiologist programs the Audio Processor to activate the Vibrant Soundbridge. The patient typically wears the device for several hours a day, or all day, immediately after activation[24].

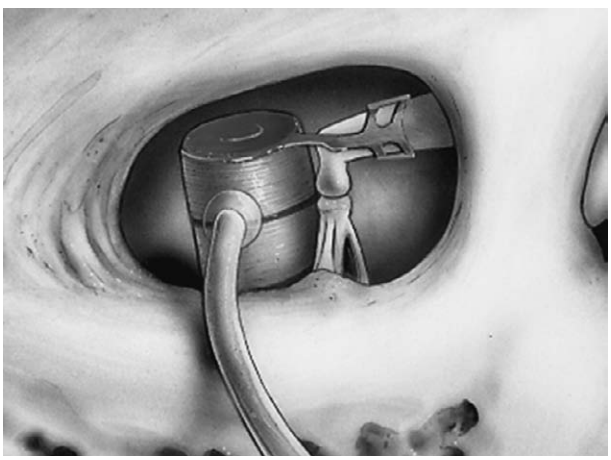

Fig. 6. Floating Mass Transducer attached to the long process of the incus with titanium clip.

Programming the Audio Processor

Because of variations in skin flap thickness, different magnet strengths are available. The Audio Processor should hold firmly onto the head without creating a pressure point. The Vibrant Soundbridge uses Siemens Connexx software along with the SYMFIT proprietary database. The software features eight channels for independent gain adjustment and four individual bands of compression. The Vibrant Soundbridge is activated when the Audio Processor is placed over the internal coil of the implant and the battery compartment door is closed. The Audio Processor has no user controls. To extend battery life, the battery door should be opened whenever the Audio Processor is not in use. This disconnects the battery from the Audio Processor and shuts off the Audio Processor. The Audio Processor is designed to have a battery life of approximately one week. This is based on an average duration of use of 16 hours a day at an average volume level. The battery life of the Audio Processor may vary depending on programmed settings, environment, and duration of use[2].

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Sažetak

AKTIVNI SLUŠNI IMPLANTAT SREDNJEGA UHA VIBRANT SOUNDBRIDGE

A. Pegan, M. Ries, J. Ajduk, V. Bedeković, M. Ivkić i *R. Trotić*

Vibrant Soundbridge (VSB) predstavlja nov pristup poboljšanju oštećenog sluha aktivnim ugradbenim uređajem za srednje uho. Taj uređaj zaobilazi zvukovod i bubnjić, za razliku od standardnih slušnih pomagala kod kojih povećani volumen zvuka ide kroz njih i izaziva direktne vibracije lanca slušnih koščica. Zahvaljujući svom dizajnu nijedan dio VSB-a nije u zvukovodu. VSB je odobrila FDA kao siguran postupak u liječenju odraslih osoba koje imaju zamjedbeno, provodno ili mješovito oštećenje sluha i koje žele čuti bolje nego sa standardnim slušnim pomagalima. Ovaj rad je pregled djelovanja aktivnog ugradbenog implantata srednjega uha VSB-a koji je ugrađen na Klinici za otorinolaringologiju i kirurgiju glave i vrata KBC-a Sestre milosrdnice, Referentnom centru Ministarstva zdravlja za kohlearnu implantaciju i kirurgiju nagluhosti i gluhoće.

Ključne riječi: *Sluh; Slušna pomagala; Sluh, gubitak, neurosenzorni; Sluh, gubitak, mješovit provodno-neurosenzorni; Hrvatska*