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REVIEWS

Rehabilitation of Hearing Function With Active Devices Bonebridge and Vibrant Soundbridge

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Abstract

The Bonebridge hearing aid (Med-EL, Innsbruck, Austria) is a semi-implantable hearing system with transcutaneous bone conduction that was implemented in Europe in 2012. It is indicated for patients with conductive and mixed hearing loss or unilateral profound sensorineural hearing loss, who do not obtain adequate benefits with conventional hearing aids and are not candidates for middle ear reconstructive surgery. The Bonebridge device, being an active transcutaneous bone conduction implant, can overcome the disadvantages of percutaneous bone conduction devices. The Vibrant Soundbridge hearing aid (Med-EL, Innsbruck, Austria) was implemented in Europe in 1996 as an implantable hearing device in the middle ear in patients with mild to severe sensorineural, conductive or mixed hearing loss with medical and audiological contraindications for the use of conventional hearing aids or with rapidly progressive sensorineural hearing loss.

The Bonebridge and Vibrant Soundbridge devices, used in patients with the same indication criteria, had similar audiological results – adequate hearing rehabilitation with improvement of subjective hearing (perception of silent and noisy speech, spatial hearing, hearing quality, sound localization), a significant increase in perceived quality of life and patients' satisfaction with the hearing aid (comfort, sound quality, cosmetic appearance). Because the Vibrant Soundbridge device requires the floating mass transducer to be coupled to the ossicles, round window, or oval window, this surgery carries a higher risk of inner ear injury than surgery with the Bonebridge device. The advantages of the Vibrant Soundbridge system, compared to the Bonebridge device, are the potential for greater stimulation power, especially at high frequencies, unilaterally stimulating the affected ear without influencing the contralateral ear through bone conduction.

Keywords: hearing loss, implant, bone conduction implantable hearing aid, Bonebridge, Vibrant Soundbridge

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INTRODUCTION

Hearing loss is defined as a functional deficit of hearing ability compared to a healthy person. The World Health Organization reported a prevalence of hearing loss in 2021 of about 5% (about 430 million) of the world's population and estimated an increase to 700 million people affected in 2050[1].

Patients with conductive and mixed hearing loss or unilateral profound sensorineural hearing loss, who cannot be assisted with conventional air conduction hearing devices or with limited audiological outcomes of middle ear reconstructive surgery, are usually equipped with percutaneous bone conduction devices. Of these systems, the bone-anchored hearing aid is the most used. The main disadvantages of bone-anchored hearing aids are related to the percutaneous abutment and include skin reaction, wound infection, skin growth over the abutment, and implant extrusion (up to 9.3% of cases)[1,2].

Technological advances have led to the development and implementation of electromagnetically active implantable devices. The Bonebridge hearing aid (Med-EL, Innsbruck, Austria) is a semi-implantable hearing system with transcutaneous bone conduction that was implemented in Europe in 2012. It has been designed for adult patients with conductive or mixed hearing loss and good speech discrimination, who do not obtain adequate benefits with conventional hearing aids and are not candidates for middle ear reconstructive surgery. In addition, Bonebridge being an active transcutaneous bone conduction implant can overcome the disadvantages of percutaneous bone conduction devices[1,2,3].

The Vibrant Soundbridge hearing aid (Med-EL, Innsbruck, Austria) was implemented in Europe in 1996 as an implantable hearing device in the middle ear in patients with mild to severe sensorineural, conductive or mixed hearing loss with medical and audiological contraindications for the use of conventional hearing aids or with rapidly progressive sensorineural hearing loss[4].

In the context of the above, **the purpose** of this article is the narrative synthesis of the latest data on the effectiveness of Bonebridge and Vibrant Soundbridge hearing devices.

MATERIAL AND METHODS

In order to achieve the set objective, an initial search was carried out for specialized scientific publications, identified from the *databases of PubMed, Hinari (Health Internet Work Access to Research Initiative)*, *SpringerLink, National Center of Biotechnology Information* and *Medline*. The article selection criteria included contemporary data on hearing aids by the following keywords: "hearing loss", "unilateral hearing loss", "conductive hearing loss" and "sensorineural hearing loss", used in different combinations with the words "implant", "bone conduction implantable hearing aid", "Bonebridge" and "Vibrant Soundbridge" to maximize search yield.

For the advanced selection of bibliographic sources, the following filters have been applied: full-text articles, articles in English, articles published in the period 2000-2024. After a preliminary analysis of the titles, original articles, editorials, narrative synthesis, systematic and meta-analysis articles were selected, which contained relevant information and contemporary concepts on the effectiveness of the Bonebridge and Vibrant Soundbridge hearing devices. In addition, a search was carried out in the bibliographic reference lists of the identified sources in order to highlight additional relevant publications, which were not found during the initial search in the databases.

The extracted data was systematically classified into sections, highlighting the main aspects of the contemporary vision on advances in the development and efficiency of the Bonebridge and Vibrant Soundbridge hearing devices.

In order to minimize the risk of systematic errors (bias) in the study, we carried out thorough searches in the databases to identify a maximum number of publications relevant to the purpose of the study, we evaluated only those studies that meet the validity criteria, we used reliable criteria for excluding articles from the study.

RESULTS AND DISCUSSIONS

After processing the information, identified from the *databases of PubMed, Hinari*, *SpringerLink, National Center of Biotechnology Information*, *Medline,* according to the search criteria, 165 articles were found that address the topic of advances in the development and efficiency of the Bonebridge and Vibrant Soundbridge hearing devices. After the primary analysis of the titles, 42 articles were qualified as possibly relevant for the given synthesis. After repeated review of these sources, 24 publications relevant to the intended purpose were finally selected. In the final bibliography of the paper, 24 articles were included, which were considered representative of the materials published on the topic of this synthesis article.

Although conventional bone conduction hearing aids have technically improved, there are still restrictions that prevent a satisfactory fit. Limitations may include sound distortion, irritation of the external ear canal, acoustic *feedback*, occlusion, and discomfort caused by the device's obstruction of the external ear canal. The goal of hearing device development is to maximize quality of life, hearing perception, and patient satisfaction with the hearing aid[5].

The Bonebridge **hearing aid** (Med-EL, Innsbruck, Austria) is the first active transcutaneous bone conduction implant implemented in 2012 and indicated for patients with conductive and mixed hearing loss or unilateral profound sensorineural hearing loss. Bonebridge is a semi-implantable system and consists of an external audio processor (Med-EL Amade/Samba) and a floating table transducer with bone conduction, which is surgically implanted and fixed on the temporal bone (in the transmastoid, retrosigmoid or middle fossa region) and thus stimulates the inner ear. For implantation in the mastoid cavity there must be sufficient space between the posterior wall of the external auditory canal, the middle cerebral fossa and the sigmoid sinus. Otherwise, exposure and compression of the middle cerebral fossa may be necessary. A narrow mastoid cavity, the presence of mastoid pathology, or an anterior wall down canal mastoidectomy with a radical cavity may be contraindications to this placement. On the other hand, implanting the Bonebridge in the retrosigmoid area avoids any mastoid pathology or previous surgery, exposure or compression of the sigmoid sinus. However, in patients with thin bone in this area, exposure and compression of a few millimeters of the posterior cerebral fossa may be necessary to fully implant the transducer into the occipital bone. In general, the decision of the best location for the implantation of this device is based on preoperative scanning by high-resolution computed tomography of the temporal bone. Bonebridge uses two osseointegrated screws to hold the transducer in place, one on each side of the transducer housing, positioned on the surface of the bone and anchored in the outer compact bone. In addition, in cases where the skull is not thick enough to accommodate the implant, lifting devices can be used to avoid dura mater compression. Lifting devices of different thicknesses (1-4 mm) can be positioned between the implant flanges and the surface of the skull to lift the actuator from the dura mater[1,2,3,6,7,8,9,10].

The implantation is completely subcutaneous and the skin on top of the implanted device remains intact, which offers advantages over percutaneous bone conduction implants. The implant contains a magnet that holds the external audio processor in place by means of magnetic attraction. The audio processor includes the battery, microphones and a digital signal processor, which transmits signals to the implanted part and is worn under the hair. The sound is transmitted from the audio processor to the implantable active part, where it is converted into mechanical vibrations that are applied directly to the skull bone via the bone conduction floating mass transducer. It is particularly effective in bypassing dysfunctional structures of the middle ear and transmitting sound directly to the inner ear. Due to its placement under the retroauricular skin, this device eliminates many of the inherent side effects of conventional percutaneous bone conduction systems. However, the main concern of surgery with the Bonebridge device is the large size of the implanted bone part of the device (10 mm high, 8.7 mm thick, 15.8 mm in diameter and weight about 10 g). Drilling a bone bed for an 8.7 mm thick transducer makes it very likely to expose dura mater and/or sigmoid sinus. For the experienced surgeon, the real probability of having these complications can be extremely low. In order to avoid these complications, careful preoperative planning is mandatory to select the most appropriate location for the transducer and meticulous performance of the procedure[1,2,3,6,7,8,9,10].

The surgery lasts between 30 and 60 minutes and is performed either on an outpatient or inpatient basis. Since osseointegration of the screws is not required, the processor can be activated immediately after the reduction of skin edema[7].

The implantation of the Bonebridge active bone conduction hearing aid, partially implantable, shows adequate hearing rehabilitation with an improvement in subjective hearing (perception of silent speech and noise, spatial hearing, hearing quality, sound localization), a significant increase in perceived quality of life (physical aspects, sensory perception), but also patients' satisfaction with the hearing aid.[1,2,3,11]. Thanks to the clamping screws, an optimal acoustic coupling between the floating-table transducer and the bone is achieved. Thus, some patients with a preoperative speech perception of 0% for numbers and 0% for monosyllabic words demonstrated a postoperative performance of up to 100% for both variables. Patients with the largest preoperative air-bone gap had the greatest hearing benefit[3].

Although the audio processor is in an out-of-body position, the hearing aid is evaluated as a useful tool with a positive impact on social life. Most patients subjectively benefited from the implantation of the Bonebridge device (comfort, sound quality, cosmetic appearance) and there were no significant physical or sensory limitations after implantation[1,2,3,11].

A significant improvement in tonal thresholds was observed, with an improvement in the air-bone gap. The perception of silent speech, the threshold of reception of speech in noise, and the localization of sound were significantly better after surgery than in the situation with the best care before surgery. The results of assisted speech perception were independent of the initial bone conduction thresholds and equally high (word recognition score >75%) throughout the device's indication range. The quality of life specific to hearing increased significantly after surgery. In situations relevant to daily life, hearing impairments have been almost completely restored with Bonebridge implantation in both adults and children[3,8,9,10,11].

Thus, Bonebridge not only provides a significant audiological benefit in both understanding speech in silence and in noisy environments, but also increases the self-perceived quality of life in patients suffering from mixed and conductive hearing loss. Together with a very low rate and minor nature of adverse events, it is the state-of-the-art solution for hearing rehabilitation in patients with mixed or conductive hearing loss up to a bone conduction threshold of 45 dB for 500, 1,000, 2,000 and 3,000 Hz in the ear to be implanted or, in cases of unilateral deafness, in the ear with severe to profound hearing loss and normal contralateral hearing[3,9,11].

The comparative analysis found that the Bonebridge device exhibits an effective functional gain of 7.7-12 dB and exhibits lower complication rates than conventional bone-anchored hearing aids in both subjects with mixed hearing loss and patients with unilateral sensorineural deafness. Several studies have reported a functional gain of 24 dB to 37 dB. Another relevant difference between the conventional bone-anchored hearing aid and the Bonebridge system is that the former requires osseointegration of the implant, while Bonebridge screws are not osseointegrated. Thus, the first fitting of the Bonebridge can be performed three or four weeks after surgery, since it is not necessary to wait for the osseointegration process. In addition, transcutaneous bone-anchored hearing aids usually do not require intensive hearing training after implantation and quickly provide the patient with a satisfactory hearing sensation[1,3,9,11,12].

The Vibrant Soundbridge **hearing aid** (Med-EL, Innsbruck, Austria) was developed by Geoffrey Ball, implemented in Europe in 1996 and in the United States of America in 2000 as an implantable hearing device in the middle ear in patients with mild to severe sensorineural, conductive or mixed hearing loss with medical and audiological contraindications for the use of conventional hearing aids or with rapidly progressive sensorineural hearing loss. The direct-acting active electromagnetic implantable device is suitable for both children and adults and includes an external audio processor, fixed by a magnet, from which the signal is transmitted to an implanted receiver, then to the floating-table transducer in the middle ear, which in turn directly drives the ossicular chain or round window using mechanical vibrations. The floating table transducer vibrates in a controlled way, specific to the hearing needs of each patient. Different coupling techniques (vibroplasty) have been developed. The most commonly used technique connected the floating-table transducer to the long anvil process, but it was possible to place the floating-table transducer on the round window, the oval window, the short anvil process, the ladder, or the joint of any middle ear prosthesis[4,13,14,15,16,17,18,19,20,21,22].

Ensuring an ideal attachment and positioning of the transducer remains a primary goal during surgery, and its various coupling techniques for different pathophysiological situations in the middle ear allow the Vibrant Soundbridge hearing aid to provide greater improvement in the hearing performance of affected individuals[18,19].

The development of different vibroplasty techniques aims to adapt implants to almost any pathophysiological situation in the middle ear and restore hearing by amplifying residual hearing. The method used depends on the severity of the pathology, the prognosis of improvement and the state of hearing. This has become particularly effective in patients with chronic suppurative otitis media, patients who undergo several revision surgeries to improve hearing. However, the inflammatory response of the middle ear leads to a loss of sensorineural hearing over time. Ear surgeries often involve a change in the shape and condition of the skin of the external auditory canal (skin lesions, keloid formations), which makes conventional hearing aids not always applicable. The vibroplastic implant is an alternative to improve the hearing and communication skills of these patients[18].

Since 2006 the indications of the Vibrant Soundbridge hearing aid have been expanded to include people with mild to severe conductive or mixed hearing loss, the device is now the most popular active middle ear implant. The new method was based on direct stimulation of the round window membrane with a standard floating-mass transducer (round window vibroplasty) and with a fascia interposed between the transducer and the round window membrane, bypassing chronic middle ear and outer ear infections. The supply of vibrational energy to the inner ear can be carried out with or without amplification, depending on whether the bone conductivity thresholds are normal (conductive hearing loss) or affected (mixed hearing loss). Broader indications for the use of this type of device have led to the development of alternative surgical techniques, such as direct stimulation of the round window membrane without intercalated tissue[4,13,14,15,20,23].

Evaluation of a 12-patient group with the Vibrant Soundbridge hearing aid found that assistive hearing thresholds, conversational word recognition, and quiet and noisy sentence recognition were significantly improved with no significant changes in residual cochlear hearing and without major medical and surgical complications. The subjective benefit and satisfaction with the device were good, as was the overall quality of life. The authors concluded that the amount of stimulation is sufficient to improve auditory performance and speech perception, support daily communication in a variety of situations, with no risk to residual hearing, and with few medical and surgical complications[20].

Multiple original studies and systematic reviews of the literature have confirmed that functional ear surgery, including rehabilitation with Vibrant Soundbridge of patients with severe and profound mixed hearing loss, is safe, effective and reliable in the long term – successful device acceptance and improvement of audiological performance, regardless of the coupling modality applied, lack of major complications and low rates of mild complications. Some studies have reported an average hearing function gain of 19 dB after 2 months and 34 dB after 10 months of supervision. The device also provides excellent functional gain in diseases that are difficult to treat with conventional hearing aids. It improves assisted thresholds, intelligibility of silent and noisy speech, and clear perception of conversational speech, without significant changes in auditory thresholds[5,13,14,16,19,21,22].

Direct round window stimulation without intercalated fascia is an alternative for patients with hearing loss caused by chronic otitis media and/or lack of ossicular chain, especially after modified radical mastoidectomy. In 5 years after the implantation of the Vibrant Soundbridge hearing aid, no significant complications or extrusion of the device were observed. Adverse effects (tinnitus, periodic vertigo) after surgery were rare and disappeared within 3 months of surgery. Thus, the device allows good results in a selected group of patients, although further studies in a larger population are needed to confirm long-term validity and efficacy. The lack of interposed fascia is an advantage of this method, in terms of ensuring a better coupling between the floating mass transducer and the round window by avoiding the appearance of scars and adhesions later[4].

Various authors have demonstrated the efficacy and safety of Vibrant Soundbridge over the past decades in a number of studies and it has been systematically evaluated in several review articles[13,23].

A systematic review of the literature, which evaluated 34 studies involving 294 adults and children, found that the Vibrant Soundbridge device was shown to be safe and effective compared to unassisted patients and bone conduction hearing implants, and provided greater and more consistent hearing gain compared to middle ear surgery plus conventional hearing aids. Thus, the Vibrant Soundbridge device, as an active device, offers an effective alternative for patients with various middle ear pathologies, especially with mixed hearing loss and failed previous tympanoplasties, when classic osiculoplasty with numerous variants of prostheses and different materials only partially solved the problem and did not provide sufficient functional gain. This new strategy in hearing rehabilitation has led to an improvement in the quality of hearing and quality of life. The mean value of the functional gain was 29.6 dB at 3 months, stable effect at 6 and 40 months. Few adverse events have been reported, with floating-mass transducer extrusion (6.63%) being the most common[18].

Another systematic review of the literature found that the Vibrant Soundbridge implant has proven to be a highly reliable and safe device that significantly improves the perception of speech in silence and noisy environments with high sound quality. The average functional gain value ranged from 12.5 dB to 33 dB. The Vibrant Soundbridge improved speech perception by about 30% compared to unassisted patients, and significantly more compared to conventional overhead hearing aids. In addition, it was found that the subjective benefit of the device is significant in all studies – the device is much more comfortable, with clearer sound perception and few restless events. Ultimately, implanting the Vibrant Soundbridge has proven to be an effective and cost-effective solution in terms of complication rate, cost, and justified for health care. The rate of complications related to surgery when implanting the Vibrant Soundbridge device ranges from 2% to 9%. Adverse events were generally reduced, mainly presenting with a feeling of auditory fullness (27%) or taste disturbances (9%). The failure rate of the second-generation implant was only 2.6%, compared to 14% for the first-generation Vibrant Soundbridge device[22].

However, a study that evaluated long-term outcomes with a semi-implantable mid-ear hearing aid (Vibrant Soundbridge), looked at pre- and postoperative results of audiological tests, found that satisfaction with Vibrant Soundbridge hearing aids was not superior to conventional hearing aids subjectively and audiometrically. The authors concluded that due to its impact on residual hearing and the need for middle ear implantation surgery, implantation of the Vibrant Soundbridge should be limited to patients with relevant hearing aid problems and side effects[24].

Unlike the conventional hearing aid that only offers an "acoustic amplification", the Vibrant Soundbridge offers a "direct conduction", which has the following advantages: elimination of the occlusion effect, improved sound quality of one's own voice (no occlusion effect), increased naturalness of sound quality, elimination of *feedback*, easy to hide (covered by hair), high frequencies can be amplified without creating *feedback*[17].

When the Bonebridge and Vibrant Soundbridge machines were used in patients with the same indication criteria, similar audiological results were reported. For patients with bone conduction thresholds close to the upper limit, the implantation of the Vibrant Soundbridge provided an alternative option that would also be beneficial in the event of future increases in sensorineural hearing loss. However, because the Vibrant Soundbridge requires the floating mass transducer to be coupled to the ossicles, round window, or oval window, this surgery carries a higher risk of inner ear injury than surgery with Bonebridge. The choice of implant should also take into account the fact that the Vibrant Soundbridge excludes the option of undergoing an MRI, which is possible with Bonebridge or another per- or transcutaneous bone conduction device[8].

An advantage of the Vibrant Soundbridge system is the potential for greater stimulation power, especially at high frequencies, compared to the Bonebridge device. Another advantage is unilateral stimulation of the affected ear without influencing the contralateral ear through bone conduction. Thus, directional hearing performance is better with the Vibrant Soundbridge device, as spatial indices of the interaural time difference and interaural level differences can be provided correctly by this device[3].

CONCLUSIONS

The Bonebridge hearing aid (Med-EL, Innsbruck, Austria) is a semi-implantable hearing system with transcutaneous bone conduction that was implemented in Europe in 2012. It is indicated for patients with conductive and mixed hearing loss or unilateral profound sensorineural hearing loss, who do not obtain adequate benefits with conventional hearing aids and are not candidates for middle ear reconstructive surgery. The Bonebridge device, being an active transcutaneous bone conduction implant, can overcome the disadvantages of percutaneous bone conduction devices.

The Vibrant Soundbridge hearing aid (Med-EL, Innsbruck, Austria) was implemented in Europe in 1996 as an implantable hearing device in the middle ear in patients with mild to severe sensorineural, conductive or mixed hearing loss with medical and audiological contraindications for the use of conventional hearing aids or with rapidly progressive sensorineural hearing loss.

The Bonebridge and Vibrant Soundbridge devices, used in patients with the same indication criteria, had similar audiological results – adequate hearing rehabilitation with subjective hearing improvement (perception of silent speech and noise, spatial hearing, hearing quality, sound localization), a significant increase in perceived quality of life and patients' satisfaction with the hearing aid (comfort, sound quality, cosmetic appearance).

Because the Vibrant Soundbridge device requires the floating mass transducer to be coupled to the ossicles, round window, or oval window, this surgery carries a higher risk of inner ear injury than surgery with the Bonebridge device. The advantages of the Vibrant

Soundbridge system, compared to the Bonebridge device, are the potential for greater stimulation power, especially at high frequencies, unilateral stimulation of the affected ear without influencing the contralateral ear through bone conduction.

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