

USE OF THE VIBRANT SOUNDBRIDGE MIDDLE EAR IMPLANT WITH SHORT PROCESS INCUS COUPLER FOR CHRONIC OBSTRUCTIVE INFLAMMATION OF THE EXTERNAL EAR CANAL: CASE STUDY

Contributions:

A Study design/planning
B Data collection/entry
C Data analysis/statistics
D Data interpretation
E Preparation of manuscript
F Literature analysis/search
G Funds collection

Piotr H. Skarzynski^{1,2,3AE}, Kamila Osinska^{1ABCF}, Bartłomiej Krol^{1BC}, Sandra Wawarczyk^{1BC}, Monika Matusiak^{1BCF}, Anna Ratuszniak^{1CE}, Henryk Skarzynski^{1AE}

¹ Oto-Rhino-Laryngology Surgery Clinic, World Hearing Centre, Institute of Physiology and Pathology of Hearing, Warsaw/Kajetany, Poland

² Heart Failure and Cardiac Rehabilitation Department of the Medical University of Warsaw, Poland

³ Institute of Sensory Organs, Warsaw/Kajetany, Poland

Corresponding author: Ass. Prof. Piotr H. Skarzynski, Institute of Physiology and Pathology of Hearing, Mochanckiego 10, 02-042 Warsaw, Poland,
Email: p.skarzynski@ifps.org.pl, Tel. +48 22 3560486, Fax. +48 22 3560367

Abstract

Objective: Chronic obstructive inflammation of the external ear canal after different kinds of surgeries often leads to stenosis. There are different approaches to treatment of such cases, and one solution is a middle ear implant. Here we analyze the efficacy of using the Vibrant Soundbridge middle ear implant with a new incus short process (SP) coupler in this type of case.

Materials and Methods: We present a case study of a 29-year old patient with bilateral mixed hearing loss caused by bilateral obstructive inflammation of the external ear canals. He had undergone meatoplasty with very short-lived improvement. Afterwards he qualified for middle ear implantation to restore hearing, and the Vibrant Soundbridge was implanted with a new SP coupler to which the floating mass transducer (FMT) is attached. Postoperative hearing tests included pure tone audiometry, free field audiometry, speech recognition, and APHAB questionnaire.

Results: Speech recognition after implantation improved to 100%. Pre- and postoperative bone conduction thresholds were unchanged. Vibrometry thresholds 10 months after surgery did not deteriorate. There was a decrease in global APHAB score by 61% from 2 to 10 months after implantation.

Conclusion: Application of the Vibrant Soundbridge middle ear implant can be an effective treatment in cases of hearing loss caused by obstructive inflammation of the external ear canals. The new incus SP coupler seems to be an effective method of stimulating the middle ear in mixed hearing loss.

Keywords: middle ear implant • Vibrant Soundbridge • chronic obstructive inflammation of the external ear canal • incus SP coupler • mixed hearing loss

APLICACIÓN DEL ENGANCHE DE LA RAMA CORTA DEL YUNQUE DEL IMPLANTE DEL OÍDO MEDIO VIBRANT SOUNDBRIDGE EN LA OTITIS EXTERNA CRÓNICA OBLITERANTE – DESCRIPCIÓN DEL CASO

Resumen

Introducción: La otitis externa crónica obliterante, a pesar de operaciones de reconstrucción, en muchas ocasiones lleva a la recurrencia de la estenosis. En tales situaciones, se aplican varios métodos de tratamiento de la hipoacusia, uno de los cuales son las implantaciones del oído medio. La presente descripción del caso presenta el análisis de la eficacia de la aplicación de un nuevo enganche de la rama corta del yunque del implante del oído medio Vibrant Soundbridge en la otitis externa crónica obliterante.

Material y método: La descripción del caso se refiere a un paciente de 29 años con hipoacusia mixta bilateral causada por la otitis externa crónica obliterante. El paciente tuvo una intervención quirúrgica de reconstrucción del conducto auditivo con un efecto a corto plazo. A continuación, fue calificado para la implantación del oído medio con el fin de compensar la hipoacusia. El implante Vibrant Soundbridge fue sujetado mediante un enganche nuevo de la rama corta del yunque. El análisis postoperatorio se refería a los resultados de la audiometría tonal, audiometría de campo libre y de los resultados del cuestionario APHAB.

Resultados: Se observó una mejora de la comprensión del habla hasta el 100% en el oído implantado. Los umbrales de conducción ósea pre- y postoperatorios no cambiaron. Los umbrales de vibrometría observados al cabo de 10 meses después de la cirugía seguían sin cambio. Se

registró la reducción del porcentaje de problemas globales con la comunicación tras la inserción del implante del oído medio en el cuestionario APHAB en un 61% en el período entre el segundo y el décimo mes después de la cirugía.

Conclusiones: La aplicación del implante del oído medio Vibrant Soundbridge puede ser un método efectivo de tratamiento de la hipoacusia en caso de la otitis externa crónica obliterante. El nuevo enganche de la rama corta del yunque parece ser un efectivo método de estimulación del oído medio en caso de hipoacusia mixta.

Palabras clave: implante del oído medio Vibrant Soundbridge • otitis externa crónica obliterante • enganche de la rama corta del yunque • hipoacusia mixta

ИСПОЛЬЗОВАНИЕ ЗАЦЕПА НА КОРОТКУЮ НОЖКУ НАКОВАЛЬНИ КОХЛЕАРНОГО ИМПЛАНТА VIBRANTSOUNDBRIDGE ПРИ ХРОНИЧЕСКОМ НАРУЖНОМ ОТИТЕ С ЗАРАЩЕНИЕМ – ОПИСАНИЕ СЛУЧАЯ

Абстракт

Введение: Хроническое воспаление наружного слухового прохода с заращением, несмотря на операции по реконструкции, часто вызывает повторное сужение. В данном случае используется несколько методов лечения тугоухости, одним из них являются импланты среднего уха. Настоящее описание случая представляет анализ эффективности использования нового зацепа на короткую ножку наковальни кохлеарного импланта VibrantSoundbridge при хроническом наружном отите с заращением.

Материал и методы: Описание случая касается 29-летнего пациента с двусторонней комбинированной тугоухостью вследствие воспаления наружных слуховых проходов с заращением. Пациенту была проведена операция по реконструкции слухового прохода с кратковременным эффектом. Позже он был определён на установку импланта среднего уха с целью компенсации тугоухости. VibrantSoundbridge был закреплён с помощью нового зацепа на короткую ножку наковальни. Послеоперационный анализ касался результатов тональной аудиометрии, аудиометрии в свободном звуковом поле и результатов анкеты APHAB.

Результаты: Было отмечено улучшение понимания речи даже до 100% в ухе с имплантом. До- и послеоперационные пороги костной проводимости были неизменными. Пороги виброметрии при наблюдении после 10 месяцев от операции не изменились. В анкете APHAB было отмечено уменьшение процента общих проблем с коммуникацией после установки импланта среднего уха на 61% между 2 и 10 месяцев после операции.

Выводы: Использование импланта среднего уха VibrantSoundbridge может быть эффективным методом лечения тугоухости при хроническом воспалении наружного слухового прохода с заращением. Новый зацеп на короткую ножку кажется эффективным методом стимулирования среднего уха при комбинированной тугоухости.

Ключевые слова: имплант среднего уха VibrantSoundbridge • хронический наружный отит с заращением • зацеп на короткую ножку наковальни • комбинированная тугоухость

ZASTOSOWANIE ZACZEPU NA ODNOGĘ KRÓTKĄ KOWADEŁKA IMPLANTU UCHA ŚRODKOWEGO VIBRANT SOUNDBRIDGE W PRZEWLEKŁYM ZAROSTOWYM ZAPALENIU PRZEWODU SŁUCHOWEGO ZEWNĘTRZNEGO – OPIS PRZYPADKU

Streszczenie

Wprowadzenie: Przewlekłe zarostowe zapalenie przewodu słuchowego zewnętrznego mimo operacji rekonstrukcyjnych, często prowadzi do nawrotów zwężeń. Stosowanych jest kilka metod leczenia niedosłuchu w takich przypadkach, jednym z nich są implanty ucha środkowego. Niniejszy opis przypadku przedstawia analizę skuteczności zastosowania nowego zaczepu na odnogę krótką kowadełka implantu ucha środkowego Vibrant Soundbridge w przewlekłym zarostowym zapaleniu ucha zewnętrznego.

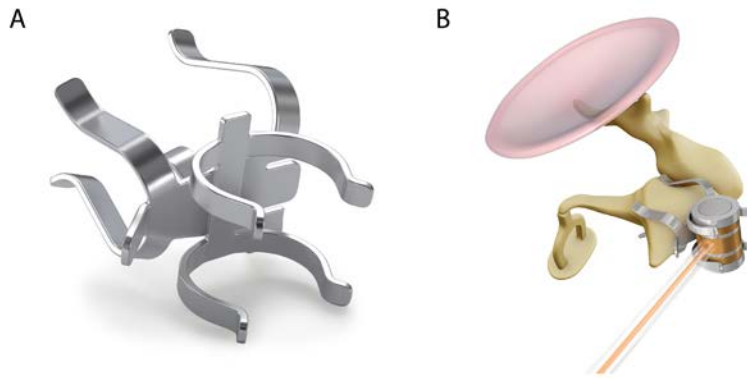
Materiał i metoda: Opis przypadku dotyczy 29-letniego pacjenta z obustronnym mieszanym niedosłuchem wskutek zarostowego zapalenia przewodów słuchowych zewnętrznych. Pacjent przeszedł operację rekonstrukcyjną przewodu słuchowego z krótkotrwałym efektem. Następnie został zakwalifikowany do wszczepienia implantu ucha środkowego w celu kompensacji niedosłuchu. Vibrant Soundbridge został zamocowany z pomocą nowego zaczepu na odnogę krótką kowadełka. Analiza pooperacyjna dotyczyła wyników audiometrii tonalnej, audiometrii wolnego pola oraz wyników kwestionariusza APHAB.

Wyniki: Zaobserwowano poprawę rozumienia mowy aż do 100% w uchu implantowanym. Przed- i pooperacyjne progi przewodnictwa kostnego były niezmiennie. Progi wibrometrii w obserwacji po 10 miesiącach od operacji nie zmieniły się. Odnotowano zmniejszenie odsetka całościowych problemów z komunikowaniem się po wszczepieniu implantu ucha środkowego w kwestionariuszu APHAB o 61% pomiędzy 2 a 10 miesiącem po operacji.

Wnioski: Zastosowanie implantu ucha środkowego Vibrant Soundbridge może być skuteczną metodą leczenia niedosłuchu w przewlekłym zarostowym zapaleniu przewodu słuchowego zewnętrznego. Nowy zaczep na odnogę krótką wydaje się być efektywną metodą stymulacji ucha środkowego w mieszanym niedosłuchu

Słowa kluczowe: implant ucha środkowego Vibrant Soundbridge • przewlekłe zarostowe zapalenie przewodu słuchowego zewnętrznego • zaczep na odnogę krótką kowadełka • mieszanym niedosłuch

Figure 1. A) Incus SP coupler. B). How the coupler, with floating mass transducer (FMT), is attached to the short process of the incus



Introduction

Acquired atresia of the external auditory canal (EAC) is a rare complication of recurrent EAC inflammation. Based on the literature, the annual incidence is estimated on the level of 0.6:10,000 inhabitants (1). There are different approaches to the symptoms depending on the clinic. Topical application of corticosteroids or tacrolimus often shows limited improvement (2,3). In many cases surgical restoration of the external ear canals gives only temporary improvement due to restenosis (4,5). This group of patients requires repeated EAC surgeries. There are reports of different techniques: transmeatal, transmastoid with postaural incision and application of skin grafts, and enlargement of the bony canal (4,6). The literature indicates up to 100% restenosis if only excision of a soft tissue plug was performed (7). Use of skin grafts results in

about 70% patent ear canals in early observation but in the longer term are unstable (7). In some cases there is a need to look for alternative methods of treating hearing loss due to acquired atresia.

Middle ear implants were initially developed for treatment of sensorineural hearing loss (SNHL). The Vibrant Soundbridge (Med-El, Innsbruck, Austria) was introduced to the market in the late 1990s. In 2007, its application was expanded to include conductive and mixed hearing loss, with several methods of cochlear stimulation via the round or oval window. The first surgery with direct round window stimulation without fascia was performed in 2007 (8), and the Vibrant Soundbridge is now the most popular active middle ear implant. It can be used in treatment of conductive, mixed, and mild-to-severe sensorineural hearing loss (9–11). The device includes an external audio processor from

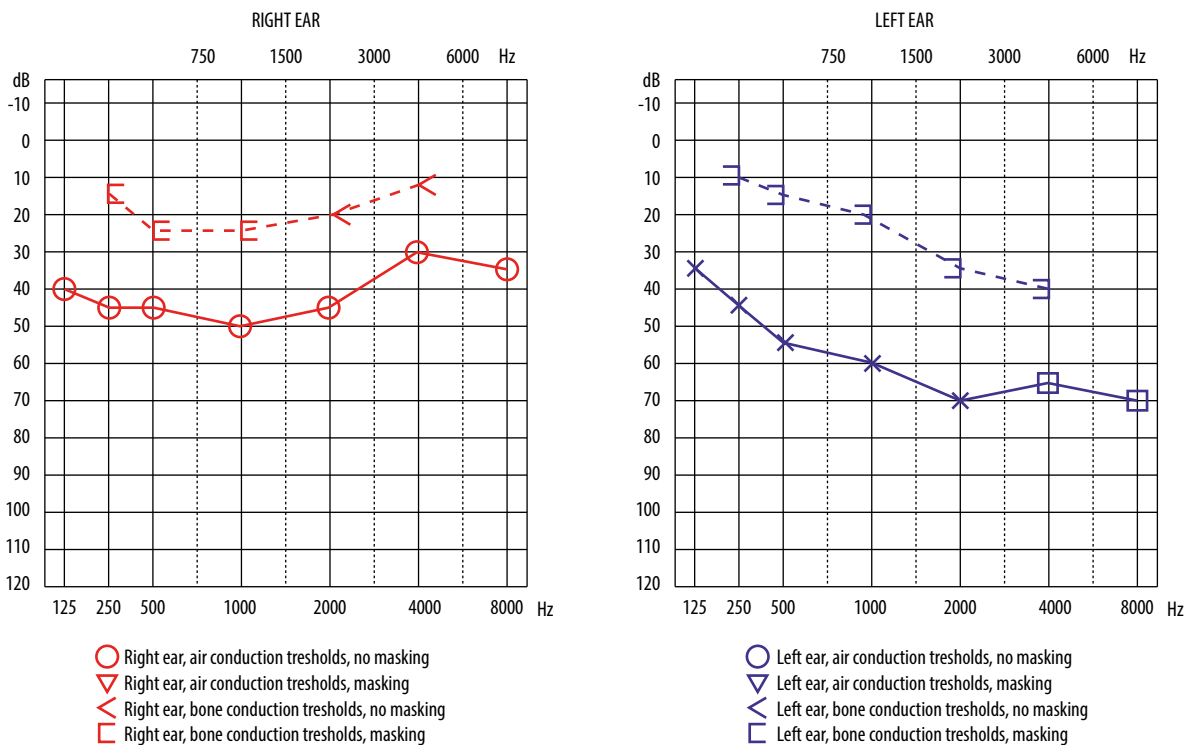


Figure 2. Pure tone audiometry before surgery

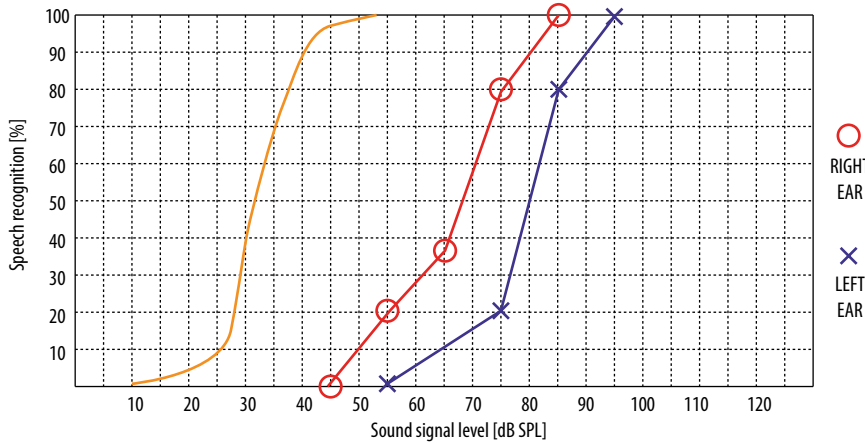


Figure 3. Speech audiometry before surgery

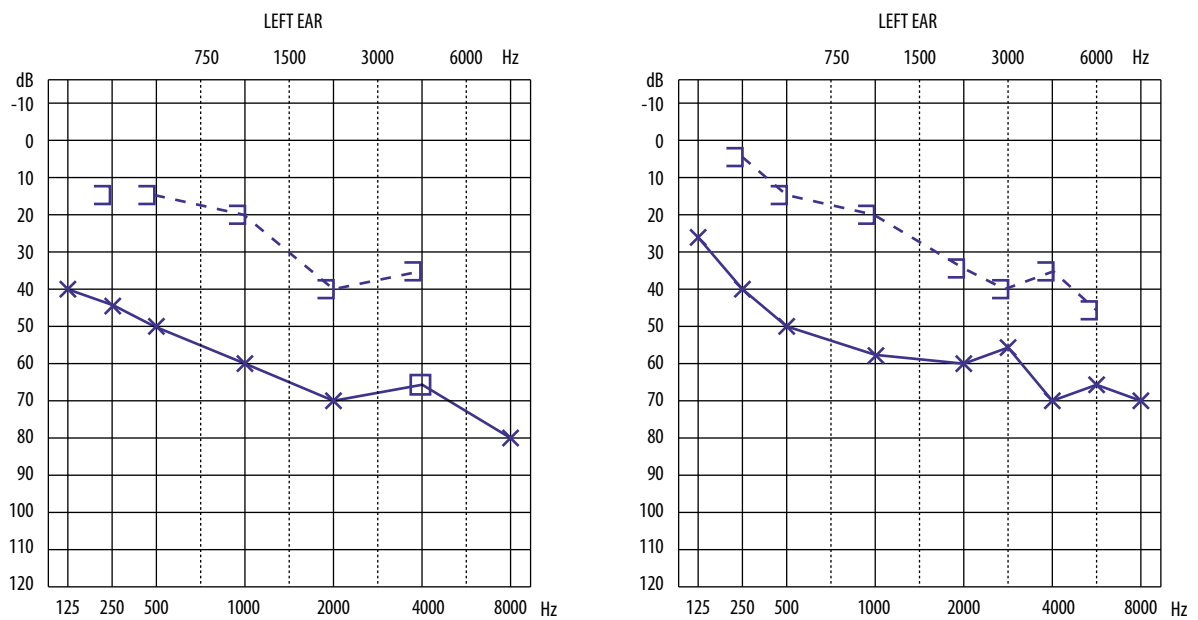


Figure 4. Pure tone audiometry after Vibrant Soundbridge implantation in the left ear 2 months after surgery (left panel) and at 10 months (right panel)

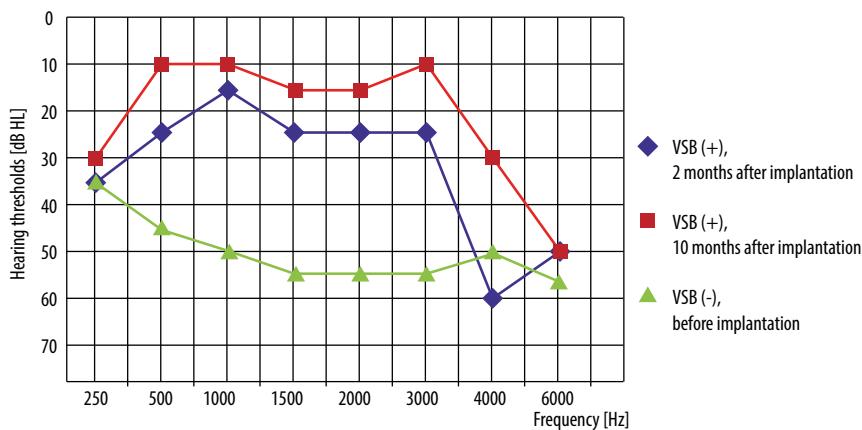


Figure 5. Free-field threshold audiometry results before VSB implantation (green) and 2 and 10 months after implantation (blue and red)

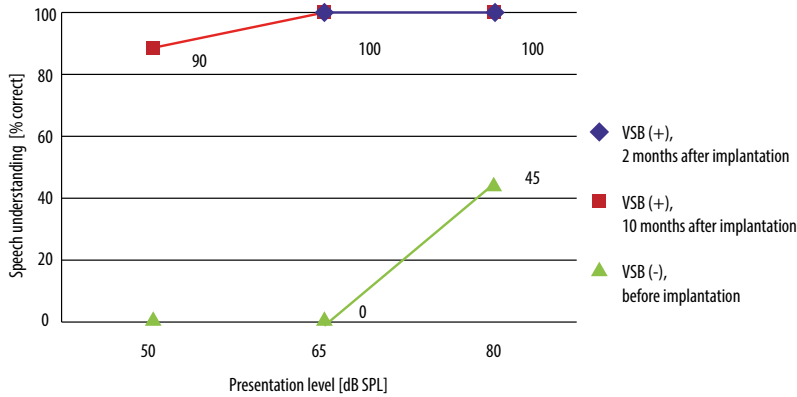


Figure 6. Free-field speech audiometry results

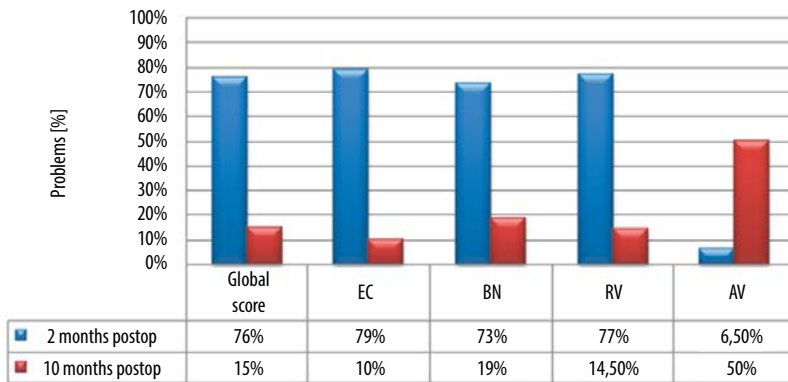


Figure 7. APHAB questionnaire results 2 and 10 months after implantation. EC = ease of communication; BN = background noise; RV = reverberation; AV = aversiveness to sounds

which the signal is transmitted to an implant receiver (11). The receiver transmits electrical signals to the demodulator and then to the floating mass transducer (FMT) in the middle ear which in turn vibrates the ossicular chain (11).

The coupling between the FMT and the ossicles is crucial, as it must transmit vibrations precisely and effectively. Until now the most commonly used coupler connected the FMT to the long process of the incus. It has also been possible to place the FMT on the round window, oval window, or to hook it to the stapes (8,12,13). Recently, a new type of coupler became available. It is a clip designed to connect with the short process (SP) of the incus and hold the FMT in place (Figure 1). Applying the coupler to the short process moves the surgical field away from the vulnerable anatomical elements, the facial nerve and chorda tympani, giving it an advantage over a standard long process coupler.

In this report we describe use of the VSB middle ear implant with a short-process coupler in a case of EAC obstruction coexisting with adhesions in the epitympanic recess. The overall aim of the study is to describe treatment of hearing loss with an active middle ear implant in case of acquired stenosis of the ear canal and the long term results of using the SP coupler in treating mixed hearing loss.

Material and Methods

Our patient was a 29 year old man with a history of bilateral progressive hearing loss since childhood caused by chronic inflammation of the external ear canals. He

had undergone 5 surgeries to restore bilateral patency of the ear canals. Improvement after each surgery was only temporary. Several attempts to use behind-the-ear (BTE) hearing aids did not bring any long-term benefits. After the last attempt to fit hearing aids the patient suffered intense chronic inflammation in both external ear canals with discharge. The patient did not accept bone conduction hearing prostheses. Pure tone audiometry results are shown in Figure 2.

During the examination we found bilateral EAC atresia in the osseous parts with a residual funnel-shaped lumen in the cartilaginous parts. As previous attempts of treating hearing loss had been unsuccessful in the long term, the patient was directed for diagnostics for middle ear implantation.

Before the middle ear implantation we tested each ear separately, using the BAHA processor on a soft band. Free field audiometry was performed with and without the BAHA. In these tests we used one loudspeaker positioned in front of the patient at the height of his ears, with active masking of the contralateral ear. Unaided and aided thresholds in the free field using warble tones were obtained at frequencies from 250 to 6000 Hz. Word recognition score was assessed with the Demenko & Pruszewicz Polish monosyllabic word test at 50, 65, and 80 dB SPL presented via a loudspeaker. The patient achieved 100% speech understanding in the right ear at 80 dB SPL; maximum speech understanding in the left ear was 85%. Computed tomography (CT) of the temporal bones showed total atresia of the left EAC and substantial atresia lesions in the right EAC. Some adhesions were also detected bilaterally in the

middle ear. Inner ears were intact and the internal auditory canals unchanged, symmetric with 6 mm diameter.

The patient was qualified to receive a Vibrant Soundbridge middle ear implant in the left ear. This decision was based on consideration of his degree of hearing loss (worse hearing thresholds in the left ear), radiological findings (total atresia of the left ear compared to substantial obstruction in the right), speech audiometry over headphones showing 100% speech discrimination bilaterally with SRT in the left ear at 80 dB SPL and in the right ear at 68 dB SPL (Figure 3), and substantial improvement of speech recognition achieved in both ears with BAHA on a soft band. The left ear was chosen as the more impaired, but with good prospects of obtaining significant improvement in hearing.

The study was part of a project accepted by the Bioethical Committee of the Institute of Physiology and Pathology of Hearing (IFPS/KB/07/2016). The study was performed in accordance with the principles of the Declaration of Helsinki.

In the surgical procedure, after detaching the skin, muscle, and the cortical part of the temporal bone we performed a limited atticotomy. It revealed a properly pneumatized mastoid process and some adhesions in the epitympanic recess. The short process and body of the incus were exposed, palpated, and found to be intact with good mobility. In the next step, the SP coupler was connected to the FMT and then attached to the short process and body of the incus. We used a VORP 503 implant with unattached FMT and an SP vibroplasty coupler. Then the mastoid was closed with spongostan and covered with a bone chip that had been harvested at the beginning of the procedure. The internal part of the implant was placed in a bony bed drilled between the temporal and parietal bones and fixed with self-drilling screws. The surgical field was closed in layers and the wound was dressed.

The perioperative course was uneventful. The patient was discharged from hospital and attended a follow-up visit 10 days later in our out-patient clinic. During that visit the wound was found to be healing well and sutures were removed. One month after surgery the Samba sound processor was activated and fitted. A check-up of the VSB settings was performed at 2 and 10 months after implantation and included pure tone audiometry, free field tests (warble-tone audiometry and speech audiometry), and APHAB.

Results

Postoperative pure tone audiometry showed that postoperative bone conduction thresholds in the left ear were unchanged compared to pre-operative tests (Figure 4).

Hearing thresholds in free field were significantly better at 2 and 10 months after the first fitting compared to preoperative. Free-field audiometry (Figure 5) performed during the follow-up tests showed a functional gain, aided compared to unaided, of up to 35 dB at 1 kHz after 2 months and 45 dB at 4 kHz after 10 months. The mean functional gain after 2 months was 19 dB; after 10 months it was 34 dB.

There was substantial improvement in speech perception after implantation. In free-field speech audiometry (Figure

6) performed 2 and 10 months after surgery, the patient achieved 100% correct answers (WRS) at 65 dB SPL.

The APHAB questionnaire was used to assess benefits from using the device. There was a substantial decrease in the incidence of hearing problems in daily life, and in environments where there were echoes or noise. Following 2 and 10 months after implantation the global APHAB score had reduced from 76% to 15% (Figure 7).

Discussion

In this case study we observed speech recognition improving to 100% in free field speech audiometry, and an improvement of up to 45 dB in free field audiometry. The APHAB score indicates improved communication in daily life and fewer hearing problems while using the device in conditions of noise or echo.

Generally, application of an SP coupler is indicated in cases of sensorineural hearing loss. Presently the data on application of this vibroplasty coupler is still limited, as it has been in use for only a short time (14,15). As reported in the temporal bone study of Schraven (15), the SP coupler gives a slight reduction in stapes velocity around 3000 Hz compared to a long process coupler. Despite this decrease, improvement in speech reception after implantation with an SP coupler is substantial; for example, Mlynski et al. (14) reported up to 80% improvement in their case study of sensorineural hearing loss.

In our case study, stable bone conduction thresholds indicate good and lasting placement, showing there is good transmission of vibrations through the incus SP coupler. The aided free field audiometry (Figure 5) shows a roll-off in thresholds from 3000 Hz to 6000 Hz. A recent report by Mlynski et al. explains this behaviour (14). Their measurements of stapes velocity show a maximum response at 1100 Hz and a substantial roll-off at low (100–1100 Hz) and high frequencies (1100–20000 Hz), leading to the conclusion that an SP coupler mainly provides gain of up to 20 dB between 700 to 1500 Hz.

The new incus SP coupler opens up new possibilities for application of the VSB middle ear implant. In our case, changed anatomical conditions, such as adhesions in the middle ear, caused us to search for an alternative method of positioning the floating mass transducer. As this study of a case of mixed hearing loss shows, SP coupling gives stable post-operative thresholds and a substantial improvement in speech perception.

This case study shows that the Vibrant Soundbridge middle ear implant, with an FMT connected to the body of the incus by an SP coupler, can be successfully used to treat mixed hearing loss.

Conclusions

The Vibrant Soundbridge implant with an SP coupler is an effective intervention in the described case and appears to be an effective method of treatment for mixed hearing loss. In particular, there can be an appreciable benefit in using the Vibrant Soundbridge in patients with bilateral chronic

inflammation and atresia of the external ear canals who despite surgical treatment have not achieved long-term hearing improvement. The Vibrant Soundbridge creates the chance for these patients to achieve a long-term hearing

improvement. However, results from a larger group of patients who have received the SP coupler are required before any general conclusions about its effectiveness in treating different types of hearing loss can be made.

References:

1. Becker BC, Tos M. Postinflammatory acquired atresia of the external auditory canal: treatment and results of surgery over 27 years. *Laryngoscope*, 1998; 108: 903–7.
2. Kesser BW. Assessment and management of chronic otitis externa. *Curr Opin Otolaryngol Head Neck Surg*, 2011; 19: 341–7.
3. Caffier PP, Harth W, Mayelzadeh B, Haupt H, Sedlmaier B. Tacrolimus: a new option in therapy-resistant chronic external otitis. *Laryngoscope*, 2007; 117: 1046–52.
4. Bajin MD, Yılmaz T, Günaydin RÖ, Kuşçu O, Sözen T, Jafarov S. Management of acquired atresia of the external auditory canal. *J Int Adv Otol*, 2015; 11: 147–50.
5. Kuczkowski J, Sierszeń W, Narożny W, Gulida G. Surgical treatment results of acquired external auditory canal atresia. *Otolaryngol Pol*, 2012; 66: 387–91.
6. Herdman RC, Wright JL. Surgical treatment of obliterative otitis externa. *Clin Otolaryngol Allied Sci*, 1990; 15: 11–14.
7. Jacobsen N, Mills R. Management of stenosis and acquired atresia of the external auditory meatus. *J Laryngol Otol*, 2006; 120: 266–71.
8. Skarzynski H, Olszewski L, Skarzynski PH, Lorens A, Piotrowska A, Porowski M, Mrowka M, Pilka A. Direct round window stimulation with the Med-El Vibrant Soundbridge: 5 years of experience using a technique without interposed fascia. *Eur Arch Otorhinolaryngol*, 2014; 271(3): 477–82.
9. Baumgartner W-D, Böheim K, Hagen R, Müller J, Lenarz T, Reiss S, et al. The Vibrant Soundbridge for conductive and mixed hearing losses: European multicenter study results. *Adv Otorhinolaryngol*, 2010; 69: 38–50.
10. Yu JKY, Tsang WSS, Wong TKC, Tong MCF. Outcome of Vibrant Soundbridge middle ear implant in Cantonese-speaking mixed hearing loss adults. *Clin Exp Otorhinolaryngol*, 2012; 5: 82–8.
11. Vibrant Soundbridge system including the Samba audio processor, the VORP 503 and the vibroplasty couplers. Med-El fact sheet. Available from: http://s3.medel.com.s3.amazonaws.com/pdf/28477_10_Factsheet%20VSB%20System%20%28english%29-8seitig_screen6.pdf
12. Luers JC, Hüttenbrink K-B, Zahnert T, Bornitz M, Beutner D. Vibroplasty for mixed and conductive hearing loss. *Otol Neurotol*, 2013; 34: 1005–1012.
13. Beleites T, Neudert M, Beutner D, Hüttenbrink K-B, Zahnert T. Experience with vibroplasty couplers at the stapes head and footplate. *Otol Neurotol*, 2011; 32: 1468–72.
14. Mlynski R, Dalhoff E, Heyd A, Wildenstein D, Rak K, Radeloff A, et al. Standardized active middle-ear implant coupling to the short incus process. *Otol Neurotol*, 2015; 36: 1390–8.
15. Schraven SP, Dalhoff E, Wildenstein D, Hagen R, Gummer AW, Mlynski R. Alternative fixation of an active middle ear implant at the short incus process. *Audiol Neurootol*, 2014; 19: 1–11.

