



The First Active Transcutaneous Bone Conduction Implant in Romania-Case Report of Permanent Conductive Hearing Loss Due to Cleft Palate



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Abstract

Since the introduction of bone conduction hearing implants in 1977, quality of life of the implantees have improved substantially. The first available option were bone-anchored hearing devices, which improved sound quality, but had the major disadvantage of post-operative skin and wound infections. Therefore, new technologies seeking intact skin solution have emerged lately. The BONEBRIDGE system (MED-EL, Medical Electronics, Innsbruck, Austria) incorporates the first active bone conduction device, which especially aims to resolve abutment issues and still offers excellent audiological benefit. The successful implantation of this system in the first Romanian patient suffering from congenital lip and hard palate cleft with recurrent suppurative otitis media is presented. The authors report their experience with implantation, in terms of indications, selection assessment as well as functional results with a critical review of advantages and disadvantages in comparison with classical methods.

Introduction

Hearing implants employing bone conduction (BC) stimulation have a long tradition (since 1977) and have become a standard care for patients suffering with conductive- or mixed hearing loss who cannot benefit from the conventional hearing aids. Since their development 40 years ago, there have been many improvements in both, the surgical approach, the technology itself and the way of fixation towards intact skin solutions of bone conduction hearing systems.

Existing percutaneous bone conduction implants (BCI) provide good audiological gain but are associated with a high rate of complications. 67 studies with a total of 6168 subjects were found reporting on safety outcomes of the percutaneous BAHA Connect bone conduction system since 2012 (date of first BONEBRIDGE implantation was used for literature search (Figure 1)). Despite good audiological rehabilitation results, the abutments of the BAHA percutaneous systems are at risk of complications (75.3%), especially skin related issues like infection and skin overgrowth as high as 46,7% were found, as discussed elsewhere [1-67]. The Ponto system from Oticon Medicals slightly differs from the Baha Connect system, as it facilitates a longer abutment that does not require removal of the muscles and subcutaneous tissue. Both have similar audiological

results, as discussed by Syms [68]. Safety issues in the Ponto System were reported in twelve studies in a total of 314 subjects, as discussed elsewhere [20,30,34,35,51,59,61-73]. Also, the Ponto system due to its percutaneous nature reports a high incidence rate of complications with 44.6% out of which the majority was related to skin complications (37.3%). Thus, patients with the percutaneous kind of device need to have a commitment to life with the care of the skin where the device was placed, as discussed by Iseri [74].

In 2011 transcutaneous bone conduction implants, have become available: The Alpha Hearing System and the BAHA Attract, both conduct the sound through a titanium plate which is fixed under the skin through surgery, differing only in size and shape from each other. Despite the aesthetic and functional benefits, the devices cause skin friction generated by the powerful magnet, necessary to transfer the sound vibration to the skull efficiently, causing discomfort, vascularization difficulties and local skin irritation may lead to reduced wearing time [75]. Seventeen publications evaluating data of 210 subjects reported a 40.6% rate of safety outcomes for the Sophono Alpha 1 and Alpha 2, as discussed elsewhere [21,61,65,75-88]. The Baha Attract system reported 56.9% safety outcomes in nine studies with a total of 153 subjects, as discussed elsewhere [47,75,83,89-94].

The BONEBRIDGE works differently from the Sophono Alpha Hearing System and BAHA Attract in that the Implant generates vibrational stimulation that is directly applied to the bone ("direct drive bone conduction stimulation"). Active transcutaneous bone conduction implants have the advantage over passive implants in that the vibrating part of the device is located under the skin, directly stimulating the bone through the screws, as discussed by Sprinzl [95]. Several studies have shown that BONEBRIDGE implantation offers an improvement of hearing thresholds and speech recognition, as discussed by Sprinzl [95] and fourteen studies showed a 7.4% rate of complications, as discussed elsewhere [49,88,96-107].

All above mentioned devices and indications were carefully considered before the here presented patient decided on the BONE-

BRIDGE device. In this report, we present the first BONEBRIDGE implantation performed in Bucharest, Romania. To the best of our knowledge, there have been no previous reports of this kind of implantation.

Case Presentation

A 25-years-old Caucasian male reported permanent hearing loss in the left ear. The patient's medical history included congenital lip and hard palate cleft with recurrent suppurative otitis media in the left ear. He underwent corrective procedures at the age of 3 for cleft closure and two surgeries in the left ear for otitis media, leaving him with a permanent conductive hearing loss.

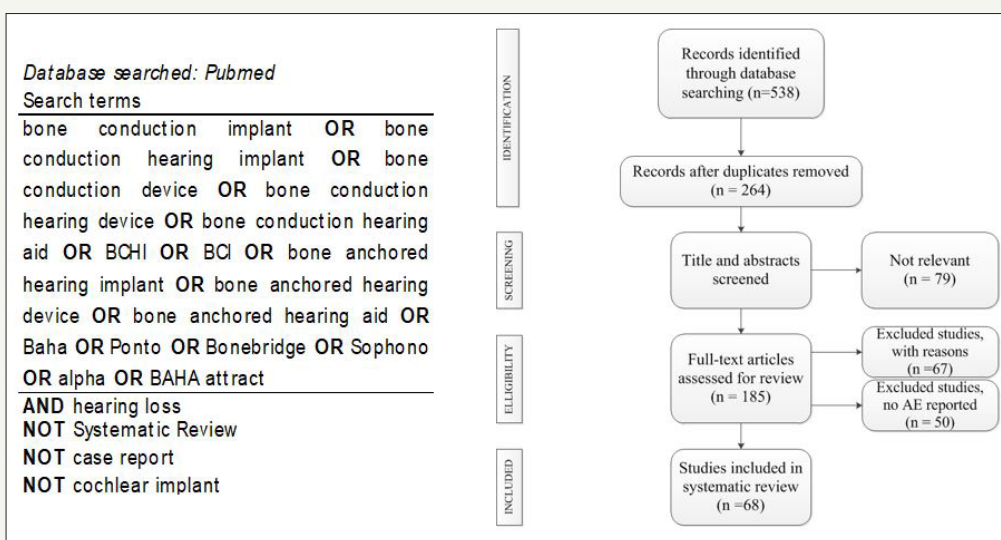


Figure 1: Search strategy used for searching PubMed databases (left) and flowchart of study selection (right).

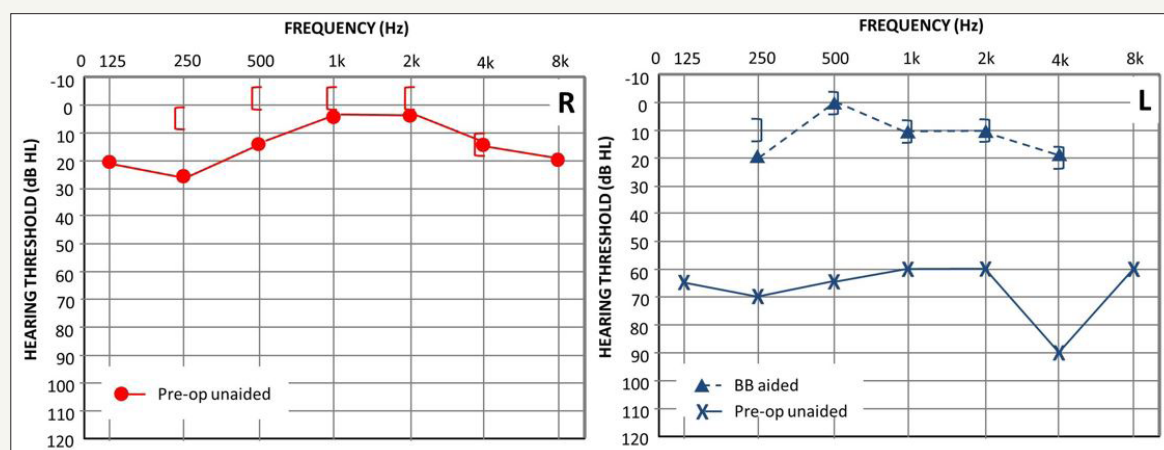


Figure 2: Pure tone audiogram: Right ear – pre-op unaided mild conductive hearing loss (red); Left ear – pre-op moderate conductive hearing loss, post-op BB-aided condition; (BB-BONEBRIDGE); [- BC masked, right ear;] - BC masked, left ear.

Examinations, otomicroscopy and audiological investigations revealed a mastoidian cavity widely communicating with the external auditory meatus in the left ear. The patient also presented a nasal septum deviation, with severe obstruction of the left na-

sal pathway. Pure tone audiometry revealed moderate conductive hearing loss and a small perforation in the right eardrum with mild conductive hearing loss (Figure 2).

Post-operative CT-scans in the left ear revealed 4mm bone dehiscence of the lateral sinus and a dense deposit in the hypo-tympanum which was in contact with the facial aqueduct (Figure 3a & 3b). The lamellar deposit in the mezzo-tympanum, attached to the promontory showed fibrous obstruction of the oval and round

windows. No density anomalies in the compact bone of the inner ear were found, presenting normal permeability of the cochlea and semi-circular canals, without dehiscence. The absence of the ossicular chain led to moderate permanent conductive hearing loss.

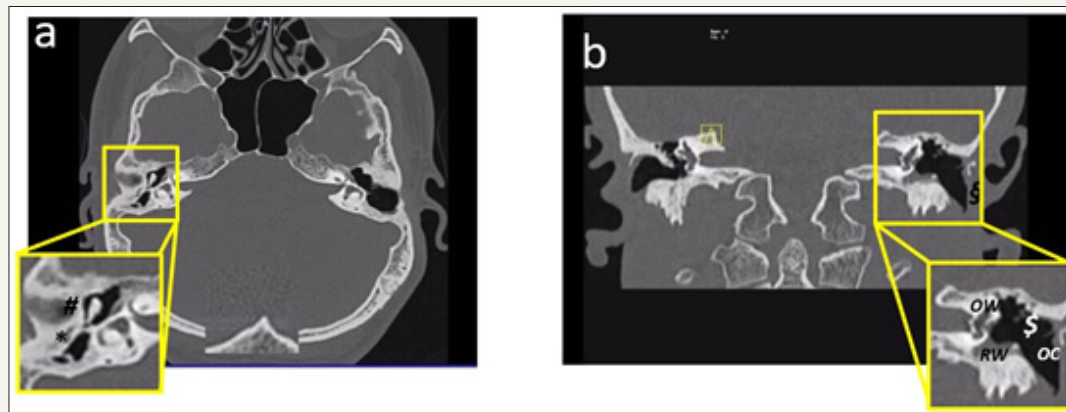


Figure 3: High-resolution computed tomography temporal bone (a) axial section and (b) coronal section

(a) Right ear (axial view)
chronic otomastoiditis
sequelae (*) thick, retracted
eardrum with perforation in
the pars tensa; (#) punctual
erosion of the long incus arm

(b) Left ear (coronal view): post-mastoidectomy status,
(\$) absence of the eardrum; (\$) dense lamellae in hypo-
and mezzo-tympanum, attached to the otic capsule,
obstructing completely the oval (OW) and round
windows (RW); complete absence of the ossicular chain
(OC)

Luckily for the patient, despite the congenital cleft and nasal septum deviation, otitis media in the right ear was not so severe and the sequelae minor—with small eardrum perforation and mild conductive hearing loss. For this reason, language development of the patient was not affected, and he therefore only opted in adult age for a solution for his left ear hearing loss. No conventional hearing aid was recommended due to the mastoid cavity communicating widely with the external acoustic meatus. Recommended treatment included nasal surgery and a bone conduction hearing implant in the left ear. The candidate objected to the alternatives of a conventional percutaneous and passive transcutaneous BCI because of the stigmatization by the visible screw and the relatively high complication rates. Secondary reason to opt for BONEBRIDGE implantation was to avoid the need for life-long screw care [1-107].

Three months after nasal surgery, improved Eustachian tube function was measured via impedancemetry and the patient was scheduled for BONEBRIDGE implantation. Surgery was performed at the Phono-Audiology and Functional ENT Surgery Institute, Bucharest, Romania, under general anaesthesia. A presigmoid transmastoid approach was used to place the internal component in the drilled cavity, after removal of the chronic inflammatory mastoid mucosa. Due to a relative high position of the sigmoid sinus, elevators were used to ensure a proper position of the bone conduction implant (BCI). This was fixated with two Titanium screws in the

normal density mastoid bone for best vibration transmission. The internal coil of the BONEBRIDGE was placed in a subperiosteal pocket. Two layers closure of the muscular and skin layers was used, with different directions of the incisions.

No intra- nor postoperative complications occurred.

At four weeks after surgery, the Samba audio processor was switched on, and hearing evaluation was performed by pure tone and speech audiometry, immediately after activation and one week later. Results were similar at the two sessions: the PTA4 resulted in an improvement of 58.8dB (pre-op unaided 68.8; post-op best aided 10dB), with complete closure of the air-bone gap (ABG) on PTA and 100%-word recognition score measured at 65dB SPL using a Romanian language multisyllables-word test in quiet (post-op best-aided condition) (Figure 2 aided condition and Figure 4b).

Discussion

Recent literature suggests that implantation with the only active transcutaneous bone conduction hearing implant, is safe and effective for treating conductive and mixed hearing loss, as discussed by Sprinzl [95]. The surgical technique for insertion is easier than that of traditional surgeries, and there is no risk of inner ear damage. Due to the intact skin solution, with the internal part of the device being fully implanted without an abutment, the risk of skin infections is minimal. Furthermore, the active vibration

without skin attenuation ensures more and better bone conduction gains than that of passive bone conduction devices [95]. The implantation of the BONEBRIDGE in this complex case due to its specific pathological condition of lip and hard palate cleft, inducing long-term dysfunction of the Eustachian tube and thus leading to

recurrent suppurative otitis media episodes, presents good long-term solution with very satisfactory outcome. Postoperative audiological evaluation showed very good pure tone thresholds, with complete closure of the ABG and also excellent speech-recognition score at 65dB SPL testing.

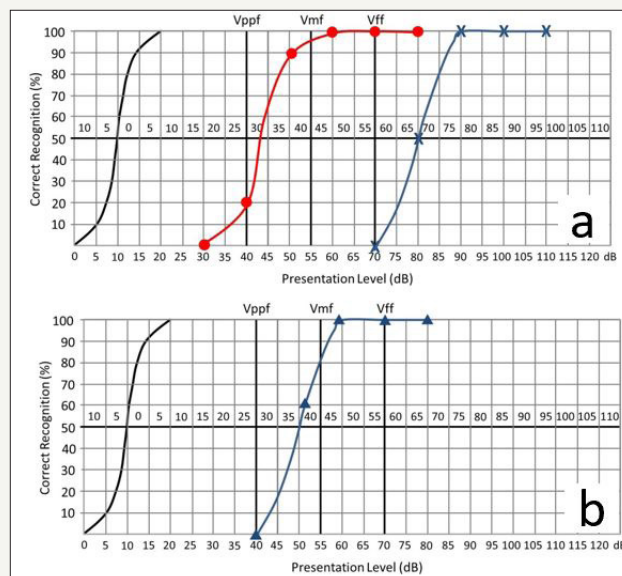


Figure 4: Word recognition score at 65dB after BONEBRIDGE implantation: (a) pre-op unaided (left and right ear (red) left ear (blue) (b) post-operative aided condition (left, operated ear); Vppf - vocal pianissimo (very soft loudness); Vmf - vocal mezzoforte (half-loud); Vff - vocal fortissimo (very loud).

Conclusion

For the treatment of conductive hearing loss with complex underlying pathologies such as lip and hard palate cleft inducing chronic otitis media, BONEBRIDGE implantation is a promising option, offering a relatively easy surgical technique, very promising audiological outcomes, and high patient satisfaction.

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