Otology

First experience in Italy with a new transcutaneous bone conduction implant

Prima esperienza in Italia con una nuova protesi impiantabile a conduzione ossea

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SUMMARY

Since 2011, transcutaneous bone-anchored auditory implants have been an alternative to the classic percutaneous implant (Baha) for bilateral conductive/mixed hearing loss that cannot be corrected by surgery. Recently, a new transcutaneous device has been approved for clinical use. Its internal component is made of the classic titanium Baha fixture, coupled to a 27 mm diameter subcutaneous circular magnet. The external component includes a second circular magnet 29 mm in diameter and a digital sound processor. To date, there are no reports describing the results of the application of this device. The aim of the present study is to report on the anatomical and functional results of transcutaneous Baha implantation in three patients: two adults, one with syndromic aural atresia and one with bilateral conductive hearing loss due to bilateral tympanomastoidectomy, and an 8-year-old child with non-syndromic aural atresia. No major intraoperative or post-operative complications were observed. The three patients tolerated the external magnet, with no signs of skin irritation. Functional results were good: median unaided free-field PTA (0.5-3 kHz) was 50 dB HL (range = 41-66 dB HL); with the transcutaneous Baha median PTA (0.5-3 kHz) was 27 dB HL (range = 25-30 dB HL) and median gain was 25 dB HL (range = 11-39 dB HL). Preliminary results encourage use of the device as a valuable alternative to other implantable devices in these patients. To ensure the success of treatment, several precautions are suggested including gradually increasing use during the first post-operative months to favour skin adaptation to magnet pressure. In addition to skin reactions, in a paediatric age most concerns are related to the curvature of the skull, which may induce tenting of the skin over the internal magnet.

KEY WORDS: Transcutaneous • Bone conduction implant • Baha

RIASSUNTO

Nei pazienti affetti da ipoacusia trasmissiva o mista bilaterale che non trovano indicazione in una ricostruzione chirurgica, sono state nuovamente reintrodotte protesi ad impianto osseo di tipo transcutaneo, in alternativa a quelle percutanee di uso corrente (Baha). Di recente, un nuovo dispositivo Baha transcutaneo è stato approvato per uso clinico. Esso è composto da una parte impiantabile, che consta della classica vite Baha accoppiata ad un magnete circolare sottocutaneo di 27 mm di diametro, e da una porzione esterna, costituita da un secondo magnete circolare di 29 mm e dal processore digitale del suono. Ad oggi non vi sono studi clinici che descrivano i risultati dell'applicazione del Baha transcutaneo. Il presente lavoro riporta i risultati anatomici e funzionali dell'impianto in tre pazienti operati presso l'Ospedale Pediatrico "Bambino Gesù" di Roma: due adulti, uno affetto da atresia auris sindromica ed uno da ipoacusia trasmissiva bilaterale (esiti di timpanoplastica aperta bilaterale), ed una bambina di 8 anni con atresia auris bilaterale non sindromica. Non sono state osservate complicanze intra- o post-operatorie. Tutti e tre i pazienti hanno ben tollerato il magnete esterno senza segni di irritazione cutanea. I risultati funzionali sono apparsi incoraggianti: il PTA (0.5-3 kHz) mediano con il Baha transcutaneo è di 27 dB HL (range = 25-30 dB HL) e il guadagno mediano di 25 dB HL (range = 11-39 dB HL). In considerazione di ciò, il Baha transcutaneo sembra proporsi come una valida alternativa alle protesi impiantabili a conduzione ossea nei pazienti con ipoacusia trasmissiva bilaterale. Tuttavia, affinché il trattamento abbia successo sembrano opportuni alcuni accorgimenti, come in particolare un graduale incremento nell'utilizzo del dispositivo durante i primi mesi post-operatori allo scopo di favorire l'adattamento della cute sottostante al magnete ed evitare reazioni locali. Motivo di particolare attenzione soprattutto in età pediatrica è la spiccata curvatura della teca cranica, che potrebbe causare una sporgenza dei margini del magnete sottocutaneo, determinando una maggiore sofferenza locale dei tessuti.

PAROLE CHIAVE: *Transcutaneo • Impianto a conduzione ossea • Baha*

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Introduction

For decades, bone conduction implants have been the mainstay of treatment of bilateral conductive hearing loss that cannot be corrected by otomicrosurgery. By allowing activation of the cochlea by bone vibration, they bypass the air conduction impairment and restore good quality hearing. Percutaneous implants, which imply a direct coupling of the external and the implanted component through an interrupted skin, have been highly successful

both in adult and paediatric subjects [1-6], allowing direct transmission of sound vibrations through the bone. However, related drawbacks include the need for a complete osseointegration, the risk of local infection or skin overgrowth, and poor aesthetic outcomes.

Recently, transcutaneous bone conduction implants have been available for the same indications as percutaneous devices. Compared to the latter, they are abutment-free, thus stimulating bone vibration through an intact skin thanks to the magnetic coupling between an external and an implantable component. In turn, this allows a better cosmetic result and elimination of the risk of local infection and extrusion, while maintaining good functional gain [7-9]. These are the principles that could drive the indication for such a device and the main reasons for shifting the choice from percutaneous to transcutaneous.

In 2013, a new transcutaneous bone conduction implant designed on pre-existing Baha implants obtained CE mark and Food and Drug Administration approval (www.fda.gov) for subjects aged 5 and older. The device is a non-active one, in which vibration of a "passive" implant is driven by an external mechanical transducer. The internal (implantable) component is made of a 3- or 4-mm titanium fixture of the BI300™ series and of a circular magnet (BIM400™) 27 mm in diameter and 2.4 mm in thickness, which is coupled to the fixture. The external component includes a digital multi-channel sound processor and a 29.5 mm large and 4.9 mm thick magnet, which adapts to the underlying skin thanks to a pad that is 1.5 mm thick. The external magnet can be chosen among six different strengths.

Indications are identical to those of other transcutaneous bone-conduction implants: bilateral conductive hearing loss, bilateral mixed hearing loss with bone-conduction PTA (0.5-3 kHz) ≤ 45 dB HL (up to 55 dB HL if appropriate sound processor is used) and single-sided sensorineural deafness.

The potential advantage of the transcutaneous Baha compared with other currently available passive transcutaneous implants is the possibility of conversion to a percutaneous solution in case of major local complications or special conditions in which the magnet has to be removed. At any rate, this should be considered a minor advantage, because the procedure would likely require general anaesthesia.

Possible device-related drawbacks are common to all other transcutaneous implants, i.e. skin complications due to use of a magnet that is too powerful and lower hearing gain compared with a percutaneous device.

To date, there are no published reports in the literature on the anatomical and functional outcome of transcutaneous Baha.

"Bambino Gesù" Pediatric Hospital is a tertiary care Italian centre for paediatric disease, with long-standing experience with bone-anchored hearing aids [4]. Since September 2013, the Audiology and Otology Unit of the Institution has started implanting transcutaneous Baha and is therefore the first centre in Italy and one of the first in Europe to try this device. The aim of the present study is to describe three cases, focusing on surgical procedure and anatomical and functional outcomes.

Description of clinical cases

Our methods were reviewed and approved by the Institutional Review Board and are in accordance with the ethical standards laid down in the Declaration of Helsinki. Patients or their parents gave their informed consent to inclusion in the study.

Candidates for the Baha Attract™ (Cochlear Bone-Anchored Solutions, Molnlicke, Sweden) were selected amongst patients followed in the Audiology and Otology Unit of Bambino Gesù Pediatric Hospital. Only subjects with pure bilateral conductive hearing loss were enrolled in the study. Anatomical criteria were a presumed scalp thickness of at least 5 mm (confirmed intraoperatively) and skull thickness ≥3 mm as assessed by a pre-operative high-resolution CT of the temporal bones.

The senior otosurgeon gave patients and/or their parents the possibility to choose between a percutaneous or a transcutaneous device among those commercially available.

Three patients, two adults and one 8-year-old child, were implanted. Demographic and clinical characteristics are shown in Table I. Before being implanted, patients 1 and 2 had been using an external, steel band bone-conduction hearing aid; for them Baha Attract™ implantation was the only surgical procedure of the operating session. Patient 3 had been using no hearing aid, but gave consent for implantation to be performed in the same session as left-sided canal-wall down tympanomastoidectomy, after experiencing the bone conduction by the classic Rod Test.

The surgical steps common to all patients were:

- Measurement of skin thickness by a needle gauge before local anaesthetic infiltration
- External marking of the site for the fixture and the magnet (Fig. 1), paying particular attention to distancing the site of incision at least 1.5 cm from the edge of the magnet.
- C-shaped incision approximately 5-6 cm postero-superiorly to the auricle.
- Periostium exposure and cross-shaped incision.
- Drilling and countersinking of a hole and 3 or 4 mm BI300™ fixture placement.
- Coupling of the magnet to the fixture head (Fig. 2)
- Suture of the wound and compression medication

All subjects received 3 mm fixtures because skull thickness did not allow placement of a 4 mm one. In patient 1, the internal magnet was not placed in full contact with the skull bone, due to the steeper curvature of the child calvarial bone, which caused minimal tenting of the skin

Table I. Demographic and clinical characteristics of implanted patients.

Pt	Sex	Age (yr)	Side	R-ACPTA	L-ACPTA	Aetiology	Pre-operative BCHA
1	F	8	R	58	52	Bilateral aural atresia	Steel band
2	M	22	R	69	69	Treacher-Collins syndrome	Steel band
3	M	44	L	39	45	Bilateral CWD TPL	None

L: left; R: right; ACPTA: Air-conduction pure-tone average; BCHA: conventional bone conduction hearing aid

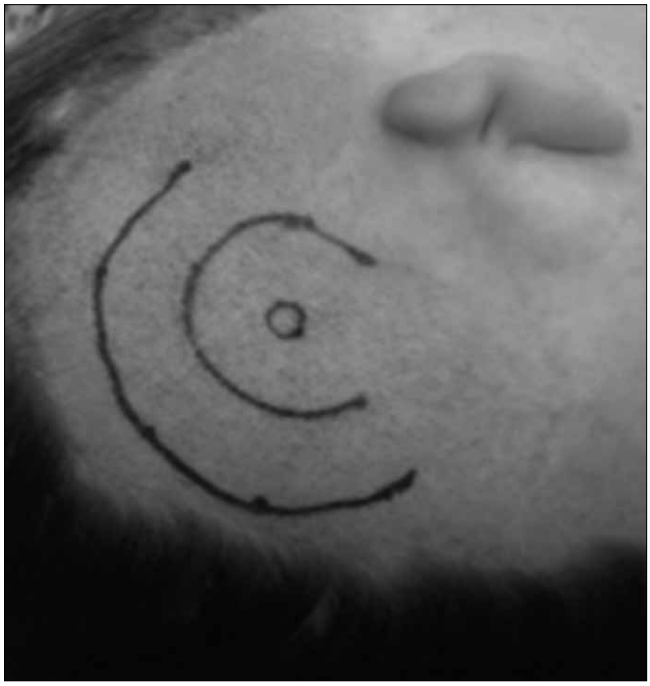

Fig. 1. Marked surgical site.

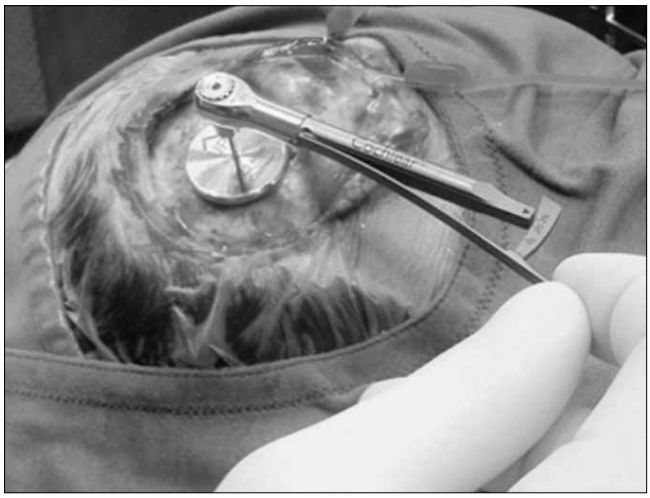

Fig. 2. Coupling and calibrated wrenching of the internal magnet to the implanted fixture.

covering the magnet. In patient 3, due to thin skull bone, drilling of two holes was necessary before a suitable place for fixture insertion could be found. One week post-operatively, patient 2 presented with mild swelling of the subcutaneous tissue above the magnet, associated with fever and flu-like symptoms, which resolved after intravenous antibiotic and corticosteroid treatment.

Patients 1 and 2 received their external Baha 4™ processor one month after surgery, whereas switch-on was precautionally planned two months after surgery in patient 3 because of the frequent ear medications that were needed after tympanomastoidectomy.

On the day of processor loading, each patient was invited to try magnets of increasing strength in the clinic, until one allowing good hearing and processor stability on the scalp at the same time was found (magnet N.1 in patient 1 and N.2 in patients 2 and 3). The Baha 4™ processor was fitted by means of the Cochlear® Baha Fitting Software™ (Cochlear Bone-Anchored Solutions AB, Mölnlycke, Sweden). Subjects were instructed to use the processor for a maximum of 4 hours a day for the first two months. They were also advised to check the skin area under the magnet daily and to suspend processor use immediately in case they should notice any redness or feel pain. Follow-up visits were planned 1 and 2 months after loading: the skin under the magnets was found intact and healthy in all subjects.

All patients reported using their processor comfortably for the recommended time with no skin hyperaemia in the area of magnet contact (Fig. 3). Functional results in the unaided condition with the external bone conduction hearing aid and with Baha Attract™ are reported for each subject in Table II: median unaided PTA was 50 dB HL, median Baha PTA was 27 dB HL and median gain with Baha was 25 dB HL. Speech recognition scores were obtained by administering lists of bysyllabic Italian words [10] in quiet. Figure 4 illustrates the mean hearing threshold in the unaided and Baha Attract-aided conditions for each frequency.

Discussion

This is the first report in the literature describing transcutaneous Baha surgery and functional outcomes. Overall, the cases presented in this study suggest that Baha Attract™ surgery is safe and that the device can be a valuable alternative to traditional percutaneous bone implants as well as other transcutaneous devices. In our patients, no skin complications were observed following fitting, differently from our recent series on Sophono™ (Sophono Inc., Boulder, CO, USA) [11] and from other studies report-

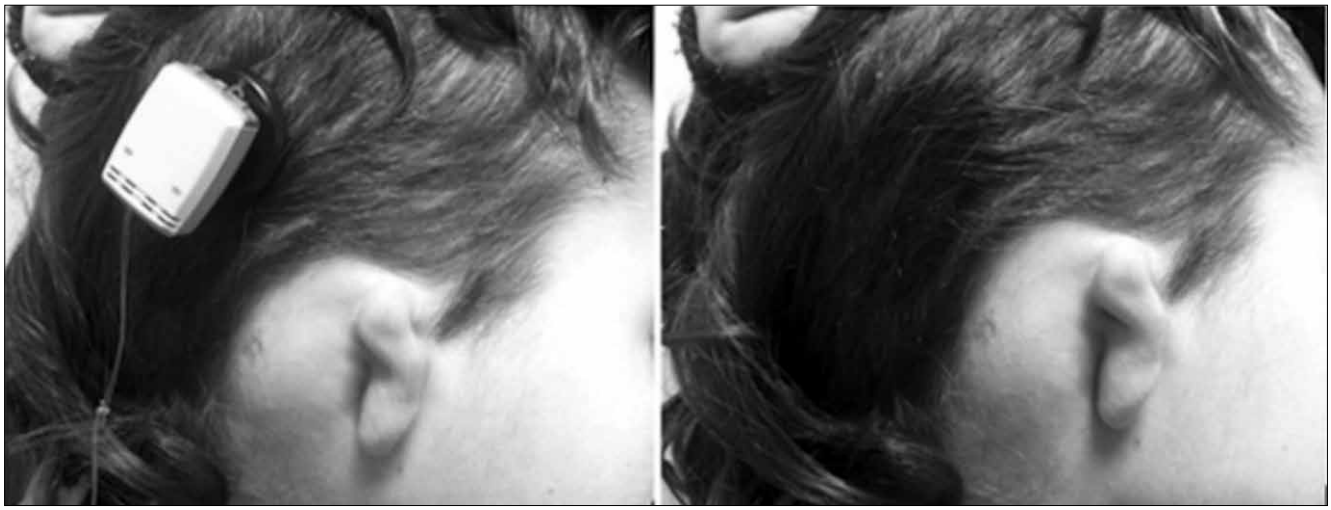

Fig. 3. Paediatric patient #1 with and without the Baha 4™ sound processor.

Table II. Functional results with transcutaneous Baha.

Pt	Unaided PTA	Unaided speech recognition	BCHA PTA	BCHA speech recogn	Baha PTA	Baha speech recognition	Baha Attract™ gain
1	50	20	40	80	25	100	25
2	66	30	48	90	27	100	39
3	41	60	-	90	30	100	11

BCHA: conventional bone conduction hearing aid; PTA: pure tone average

ing a magnet lesion rate as high as 36% [12]. Possibly, the soft pad interface under the external magnet and the skin may have favoured better pressure distribution on the underlying skin. Moreover, previous experience with transcutaneous bone conduction implants in our centre was important in choosing the right magnet and in counselling patients and parents correctly as to progressive processor use in the 2-3 months following activation.

The audiological results of our series are comparable to those obtained with other passive transcutaneous bone conduction implants [11-14]. In particular, a better gain for central frequencies (500-2000 Hz) and a smaller gain for lower (250 Hz) and higher (4000 Hz) frequencies was found, as expected. Overall, the gain appears to be 10-15 dB HL lower than what can be obtained with percutaneous implants, due to skin and soft tissue interposition. For this reason, even though our series is too small to draw any conclusions, it can be hypothesised that subjects with a moderate degree of hearing loss are expected to obtain a greater benefit from the device than patients with an unaided PTA exceeding 70 dB HL in the better ear, such as patient n. 2 in our series.

After the short follow-up of these cases, the typical advantages of passive transcutaneous implants over traditional percutaneous device appear to be confirmed. First, healed skin eliminates the risk of local infection and allows reducing the number of post-operative medications; secondly, life-long care of the peri-abutment skin is no longer required; third, the timing and level of osseointegration is less crucial with a transcutaneous implant, because of a much lower risk of extrusion, which enables it to fit in a 3 mm fixture in thin skulls.

One specific concern with Baha Attract™ relates to feasibility in very young children for two reasons: first, the thickness of the internal magnet may determine a poor

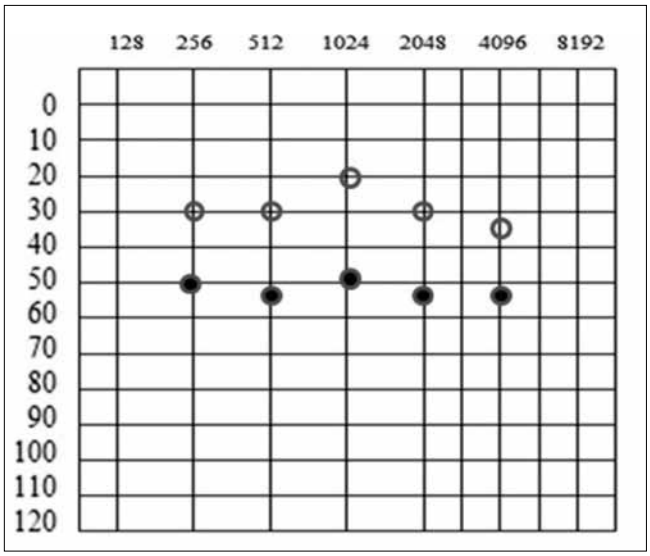

Fig. 4. Average frequency-specific PTA in unaided and Baha-aided conditions.

aesthetical outcome, owing to magnet bulging under very thin skin; second and more important, the internal magnet may not fit the highly curved skull typical of very young children or the irregular skull of syndromic subjects. More specifically, intraoperative placement of the fixture in a perfectly perpendicular plane with the skull emerged as a crucial point. If caution is not taken, there may be a significant tilting of the internal magnet causing a tenting of the skin, and secondary soft tissue injury and necrosis. Although this complication was not observed in our cases, this risk was especially evident in the paediatric case.

In conclusion, the present series shows encouraging functional results of Baha Attract™. However, whereas implantation of the device can be considered to be a safe procedure in adults, further studies are needed to eliminate concerns and demonstrate its safety in very young children.

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