Overview over Different Systems


Partially Implantable Bone Conduction Hearing Aids without a Percutaneous Abutment (Otomag): Technique and Preliminary Clinical Results

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Abstract

Introduction: Patients with air-bone gaps who cannot be corrected successfully by tympanoplasty or with mixed hearing loss may be treated with bone conduction hearing aids. Their disadvantages are the obvious external fixation components or the biological and psychosocial problems of open implants. We have developed new partially implantable bone conduction hearing aid without a percutaneous abutment and have been using them clinically for 4 years. The principle of these bone conduction hearing aids is a magnetic coupling and acoustic transmission between implanted and external magnets. The goal of this study was to evaluate clinical and audiological results. Methods: Magnets are implanted into shallow bone beds in a one step procedure. The skin above the magnets is also reduced to a thickness of 4–5 mm, which reduces the attenuation to less than 10 dB compared to direct bone stimulation. Over 100 patients have been implanted in the last 5 years. Results: Except for temporary pressure marks in 4%, which healed after careful shimming of the external base plate, there were no other complications. Discussion: The holding strength of the external components is equivalent to partially implantable hearing aids and cochlea implants and the hearing improvement is similar to other bone conduction hearing aids. We have found the comfort and safety of this system is significantly improved compared to conventional or percutaneous bone conduction hearing aids.

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Patients with air-bone gaps that cannot be corrected successfully by tympanoplasty or with mixed hearing loss may be treated with bone conduction hearing aids (BCHA). Three options have been used clinically to transmit the sound into the bone; two of them are still available.

1 Conventional BCHA: In conventional BCHA, a vibrator is pressed onto the skin above the mastoid with a headband or an elastic arch [1]. The sound energy is transmitted through the skin into the bone and from there on – almost without any further attenuation – into the cochlea. Their disadvantages are the pressure applied to the skin and the conspicuousness of the external components.

2 Bone-anchored hearing aids (Baha): Baha have been used clinically since 30 years [2–4]. The Baha allows a direct sound conduction via an abutment, which is fixed to the temporal bone and perforates the skin. The Baha disadvantages
are the biological and psychosocial problems of the percutaneous abutment with the risk of inflammation and injuries and the necessity of more than one operation [5, 6].

3 Partially implantable bone conduction hearing aids with electromagnetic energy transmission (Audiant): To avoid the disadvantages of open implants, an electromagnetic induction technique with an implanted vibrator has been used for some time. Although vibrations could really be transmitted into the skull, its amplification was too low, and its energy consumption was much too high for routine clinical use [7, 8]. This system is not available any more.

Due to the mentioned disadvantages, there was a need to optimize bone conduction hearing systems. The goals of this project were to develop (1) a new partially implantable bone conduction hearing system without a percutaneous abutment, (2) the surgical technique for its implantation, (3) its postoperative adjustment, and (4) the clinical introduction of this system.

Material and Methods

The Partially Implantable Bone Conduction Hearing Device
The principle of these new bone conduction hearing devices is the magnetic coupling between implanted and external magnets [9]. To reduce the magnetic perturbations of the vibrator and provide rotational stability, a magnetic circle with 4 high-strength magnets is constructed (fig. 1). The implantable twin magnets are made out of samarium-cobalt encapsulated in a titanium case with little arms like bone plates to fix the implant with screws (fig. 2).

The external twin magnets have a similar geometry as the implanted ones. They are embedded into an acrylic base plate, which is firmly connected with the vibrator.

The vibrator is controlled by a fully digital, 4-channel processor with 16 frequency bands, adaptive noise reduction and 5 adjustable notch filters. The omnidirectional microphone, battery (type 675, operating time ca. 630 h), chip and vibrator (280–5,400 Hz) are built in an acrylic housing in the standard version (Otomag). For special requirements, the microphone can be placed outside of this housing or exchanged to a directional microphone.

In addition to an air-bone gap, patients with a mixed hearing loss (with an up to 40-dB sensorineural component) as well as single-sided deafness patients may be treated with this device.
Surgical Technique
The twin magnets can be implanted under general or local anesthesia. A curved incision approximately 7 cm behind and above (superior and posterior) the external ear canal is performed all the way down to the bone. After exposure of an area of about 30 × 15 mm, the implant is positioned 6 cm away from the external ear canal and the bone marked with a pen (fig. 3a). Then, shallow bone beds are drilled out with a depth of at least 2.6 mm for the magnets (fig. 3b). The implant is then placed into these bone beds (fig. 3c) and fixed with mini-screws (e.g. diameter 1.5 mm; Martin; fig. 3d).

Finally, the skin above the magnets is thinned out to a thickness of 4–5 mm, which reduces the relatively high attenuation in conventional BCHA to less than 10 dB compared to direct bone stimulation. To measure the skin thickness, a fork-like instrument (Grosse; fig. 3e) has been constructed. The incision is closed with fast resorbable sutures which do not need to be removed in the hair-bearing area. A small pressure bandage is applied for one day.

Patients
After approval by the local ethics committee (Ruhr-Universität Bochum, AZ: 2589 from 04.10.2005) the first implantation was performed on the 31.01.2006. Since then, implantations in >100 patients have been performed. Most of them had a conductive hearing loss due to congenital auricular atresia. These were patients with severe middle ear malformations that could not be corrected by tympanoplasty [10–12].

Before implantation, all patients tried bone conduction amplification via a bite block analogue to the procedure before Baha implantation.

All patients (and in minors also their parents) were informed extensively about this study as well as the alternatives of conventional BCHA and Baha. In addition, they were informed that MRI is not allowed as long as the magnets are in place. Alternatively, they could have CT or a temporary explantation of the magnets possibly under local anesthesia.

Fitting of the Hearing Aids
After one month, the external base plate with the counter magnets is adjusted and the hearing aids fitted individually with the Optifit software similar to other digital hearing aids.

Results

Clinical Follow-Up
No complications related to the implantation were observed. All wounds healed uneventfully.

In some cases, slight pressure marks occurred, which healed after careful shimming and slight force reduction of the base plates. The hearing aids are very inconspicuous (fig. 4).

The clinical and audiological follow-up is ongoing. Detailed, but preliminary results of 12 patients (8 unilateral, 4 bilateral) showed an average skin thickness over the implants of 3.8 ± 0.5 mm and a holding strength of the base plates chosen by the patients of 0.8 ± 0.4 N.

The average hearing gain in free field pure tone audiogram was 31.2 ± 8.1 dB and the suprathreshold speech perception at 65 dB in free field increased from 12.9 without to 72.1% with the hearing device.

Discussion

BCHA may be indicated in the following situations: (1) Severe air bone gap or combined hearing loss. BCHA are especially necessary in situations where tympanoplasty is not successful in the long-term, like in severe middle ear malformation with unfavorable anatomic conditions [10] or chronic sclerosing otitis. (2) Single-sided deafness (SSD). In SSD, BCHA are an alternative to CROSS systems [13, 14]. (3) Sensorineural hearing loss which cannot be treated with conventional hearing aids. Problems with the ‘classic’ air conduction hearing aid can occur in chronic external otitis, wet external ear canals from inside due to otorrhea, from outside due to perspiration, rain (e.g. in gardeners) or other difficult environmental conditions (e.g. cooks). (4) Psychological aspects. BCHA worn behind the ear in the hair-bearing area are less visible.

As mentioned before, there are two different bone conduction systems on the market:

- Conventional BCHA with a vibrator, which is pressed onto the retroauricular skin by a headband or a similar device.
- BCHA which transmit the sound through a percutaneous abutment into the bone.
Fig. 3. Implantation of the magnets. a Markings for the position of the implantable magnet on the mastoid. b Bone beds with a depth of at least 2.6 mm for the magnets. c Twin magnet in place. d Twin magnet fixed with 4 bone micro-screws. e Device to measure the skin thickness; 5 mm (top) and 3 mm (bottom). f Intraoperative measurement of the skin thickness.
Both systems have the disadvantages mentioned above. Here, we present a new principle of a BCHA. It is partially implantable, fixed to the head by magnets and transmits the sound through the intact, but slightly thinned out skin into the bone.

After a variety of lab tests and approval of the local ethics committee, the first implantation was performed on the 31.01.2006. Since then, >100 implantations have been done without any intraoperative or postoperative complications.

The wearing comfort of this new system is very good. The patient does not need a headband or an abutment. Instead, the implants, scars and external components are hidden under the skin by hair. No hair or hair follicles have to be removed. If the patients take their hearing processors off, they can do all physical activities as before. There is no increased risk for injury, whether for themselves or their sports partner.

For daily life activities, the holding strength is sufficient. It is basically the same as for the external components of cochlear implants that have been in use for decades. In addition, the base plates can be changed by the patient himself easily so that he or she can wear stronger ones for sport activities and weaker ones for quiescent situations.

The sound processors have to be fitted in the more or less typical way. Its digital processor and the software allow for multiple individualized adjustments. The sound attenuation caused by the intact, thinned skin as measured in the previous lab test is less than 10 dB compared to direct bone coupling as in Baha. This can be compensated for easily in the majority of patients with only minor sensorineural hearing loss in addition to an air-bone gap.

According to our experiences up to now, this system can be characterized by the following aspects: (1) only one, relatively easy and fast operation, (2) no wound healing or pressure complications, (3) no biological or psychological problems related to percutaneous abutments, (4) no external pressure by a headband, (5) good wearing

Fig. 4. Patient (after first step of ongoing auricular reconstruction) with his magnetically fixed BCHA with (a) without (b) external device in place.
comfort, (6) a hearing gain, which is comparable to the other BCHA.

Therefore, we think that patients who need BCHA should be informed about this option as a third choice beside conventional BCHA and Baha.

**Disclosure Statement**

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