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Title page

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A novel bone conduction implant (BCI) – engineering aspects and preclinical studies

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Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

Acronyms and abbreviations:

AC	Air conduction
AM	Amplitude modulation
BAHA	Bone anchored hearing aid
BC	Bone conduction
BCI	Bone conduction implant
BEST	Balanced electromagnetic separation transducer
C-BEST	Capsuled BEST
DSP	Digital signal processor
Fout	Force output at Skullsimulator or at implant
HF	High frequency
ISQ	Implant stability quotient
j	Complex constant where $j^2 = -1$
LDV	Laser Doppler vibrometer
LF	Low frequency
MPO	Maximum power output
MRI	Magnetic resonance imaging
MAPP	Mastoid area, petrous part
PAL	Promontory acceleration level
Pin	Active electric power fed to transducer terminals
RFA	Resonance frequency analysis
SSD	Single sided deafness
Vin	Electric voltage at transducer terminals
VSF	Vibrant sound bridge
ω	Angular frequency in Radians per second
Z	Electric impedance at transducer terminals

Abstract

Percutaneous Bone Anchored Hearing Aids (BAHA) are today an important rehabilitation alternative for patients suffering from conductive or mixed hearing loss. Despite their success they are associated with drawbacks such as skin infections, accidental or spontaneous loss of the bone implant, and patient refusal for treatment due to stigma. A novel Bone Conduction Implant (BCI) system has been proposed as an alternative to the BAHA system because it leaves the skin intact. Such a BCI system has now been developed and the encapsulated transducer uses a non-screw attachment to a hollow recess of the lateral portion of the temporal bone. The aim of this study is to describe the basic engineering principals and some preclinical results obtained with the new BCI system. Laser Doppler vibrometer measurements on three cadaver heads show that the new BCI system produces 0-10 dB higher maximum output acceleration level at the ipsilateral promontory relative to conventional ear-level BAHA at speech frequencies. At the contralateral promontory the maximum output acceleration level was considerably lower for the BCI than for the BAHA.

Introduction

Air conduction (AC) hearing aids are generally used in the rehabilitation of patients with a hearing impairment. However, for certain ear canal and middle ear disorders (e.g. congenital malformations, chronic ear infections, draining ears, and eczema in the ear canal) AC hearing aids cannot be used or are insufficient. In such cases, a conventional bone conduction (BC) hearing aid can be provided as an alternative. In BC devices the airborne sound is converted to vibrations that are transmitted through the skin to the skull bone and then directly to the cochlea, bypassing the outer and middle ear.

In conventional BC hearing aids the plastic housing of the transducer is pressed against the soft tissues behind the ear by means either of a steel spring or softband arrangement or spectacle frames of a pair of glasses. Drawbacks with these devices are related to: (1) discomfort from the static force pressing the transducers against the skin and soft tissue over the temporal bone, (2) reduced high frequency sensitivity because of attenuation effect of the soft tissue, and (3) sound radiation from the housing causing feedback problems (Snik et al., 1995).

A new generation of BC hearing devices was introduced in the 1980's named percutaneous Bone Anchored Hearing Aids (BAHA), see Figure 1. BAHAs have become increasingly popular and are today an important treatment alternative for patients where AC devices are contraindicated (Håkansson et al., 1985; Tjellström et al., 2001; Snik et al., 2005). Today more than 40 000 patients have been operated for a BAHA (Cochlear annual report, 2008). One prerequisite for the use of a BAHA is that the patients should have adequate cochlear function or else the device will be experienced as too weak. Recently, a relatively new group of patients that are fitted with a BAHA are those having a single sided deafness (SSD). In these cases the sound from the deaf side is transmitted through the skull to the functioning cochlea on the contralateral side. The advantage of this application has to do with reducing the head shadow effect (Hol et al. 2005).

Even though very good rehabilitation results are reported with the BAHA (see for example Snik et al. 2005), there are some known associated drawbacks. One main drawback is related to the fact that the skin penetration site needs lifelong daily care. Some patients may acquire a skin reaction with persistent infection and may form granulation tissue that requires surgical revision or re-implantation. Also, the bone anchored fixture can be lost spontaneously or as a result of trauma.

Finally, there are a number of potential BAHA patients that reject a BAHA because they cannot tolerate a skin penetration implant for stigma reasons.

Figure 1: Principal design of a generic percutaneous bone anchored hearing aid (BAHA) with a microphone (Mic), battery (Bat), and a digital signal processor (DSP) that drives a bone conduction transducer attached to a skin penetrating and bone anchored implant. Often there is also an electric input socket (E) for connecting external electronic equipment.

It has been discussed that a bone conduction device with a permanently implanted transducer could improve the situation for patients with a percutaneous BAHA (Håkansson, 2000a, Stenfelt et al., 2000). It has also been argued that the expected loss of 10-15 dB from the required inductive link

across the skin would result in an output that may be deemed too low for this option to be successful. Moreover, evidence is mounting that, even for the percutaneous BAHA, there is an increased need for more power, not less. However, it has been shown in earlier studies on a dry skull and on cadaver heads that the sensitivity to bone conducted sound would increase if the excitation point approaches cochlea (Stenfelt *et al.*, 2000; Stenfelt *et al.*, 2005; Håkansson *et al.*, 2008; Eeg-Olofsson *et al.*, 2008). This phenomenon seems to be related to the fact that the excitation point moves from the thinner parietal region of the skull bone to the interior portion of the temporal bone and closer to the cochlea.

Recently, such a system named the Bone Conduction Implant (BCI) was tested in a feasibility study on one cadaver head (Håkansson *et al.*, 2008). Generally, such a system comprises an external audio processor and an implanted unit as illustrated in Figure 2. In order to keep the skin and subcutaneous tissue intact the signal is transmitted through an inductive link to the implanted transducer. The link consists of one external transmitting coil and one implanted receiving coil that are attached and aligned to each other with a permanent magnet retention system. Also illustrated in Figure 2, an amplitude modulation (AM) of the signal to a carrier frequency is needed to achieve an efficient transmission. Furthermore, both the driver and the receiver coils must be tuned to optimize the transmission through nominally 4-6 mm of non-magnetic soft tissues. The external processor also comprises microphone, analogue amplifier or digital signal processor (DSP), battery and controls. On the receiver side the modulated signal must be demodulated using a demodulation network to finally drive the implanted transducer. A new transducer type has been developed for this implantable application which is called the Balanced Electromagnetic Separation Transducer (BEST) which has been described by Håkansson (2003). The topology of the implanted circuits including the transducer is completely passive but has been found to have sufficient power efficiency for ordinary BAHA patients in a feasibility study by Håkansson *et al.* (2008). The demodulator unit is preferably placed inside the transducer casing.

The system used in the feasibility study (Håkansson *et al.*, 2008) was based on the Vibrant Sound Bridge[®] (VSB) from Vibrant Med-El and a specially designed and naked (unhoused) BEST transducer attached to a bone screw firmly anchored 15 mm deep in the temporal bone. When comparing the promontory acceleration levels measured by a laser Doppler vibrometer (LDV) through the ear canal it was found that this first version of the BCI had a similar or even higher Maximum Power Output (MPO) as compared to a Classic Baha[®] (Håkansson, *et al.*, 2008). This was a positive and partly unexpected result, as previous dry skull measurements had

underestimated the output from the BCI and indicated slightly lower values in this comparison especially below 1 kHz.

Figure 2: Principle design of a full scale BCI system. The skin penetrating implant of the percutaneous BAHA is here replaced by an amplitude modulation (AM) unit including a carrier signal generator, a driver unit connected of a transmitting coil, an implanted receiving coil and a demodulator unit connected to the implanted transducer. Permanent magnets integrated with the coils for retention of the external unit are not shown.

In the paper by Håkansson et al. 2008 it was also discussed how the implanted transducer could be installed with a safe and minimally invasive surgery. Obviously, the screw attachment and coupling used in that study on the cadaver head should not be used in live human skulls for several reasons: (1) to drill and install a screw interiorly from a bottom plane in a recess in the lateral portion of the temporal bone is associated with a high risk for facial nerve or vestibular damage, (2) the spongy quality of the bone might not give a stable and firm attachment, (3) the screw length and snap coupling creates an extra height of 8-10 mm that should be added to the height of the transducer casing resulting in a total distance of 16-20 mm into the temporal bone and (4) would most likely need a two stage surgical procedure.

One alternative approach to the direct screw approach for installation of the implanted transducer was originally proposed (Håkansson, 2000) in order to minimize the surgical risks. This approach is performed in two steps as follows; (1) the fixture was first safely installed in a bone graft from the outer bone surface; (2) then the graft with the fixture was placed in the recess of the temporal bone that was prepared using traditional methods. However, also this solution suffers from high building distance requiring 16-20 mm clearance proximal from the outer surface of the temporal bone.

In this paper a new method to attach the implanted transducer to the temporal bone is proposed that minimizes the required clearance (depth of engagement in the temporal bone) and where the surgical procedure is assumed to be minimally invasive.

It should be pointed out that a simple method for removing the implanted transducer is required, for example, if a replacement of the transducer is required or if a magnetic resonance image (MRI) investigation has to be performed. If an MRI acutely has to be performed and the transducer still is in place, there is according to preliminary tests, most likely no risk for the patient (forces were less than a couple of Newton and temperature increase was assumed negligible for a 1.5 Tesla MRI procedure) but the transducer might be broken due to demagnetizations of biasing magnets. Also, the images in the vicinity of the transducer (within 5-10 cm) will be heavily distorted. More investigations are needed to more precisely determine adverse effects when an implanted transducer is in place during a MRI investigation. However, the standard procedure will probably be that the BCI system is temporarily removed if a patient requires an MRI investigation and hence the BCI system itself and its attachment to the temporal bone must be designed for such a procedure.

Aim of study

The aim of this study is to describe (1) the basic engineering principles behind a novel BCI system, (2) a new method for its installation and attachment to the temporal bone, (3) an innovative technical improvement of the high frequency sensitivity of the implantable capsuled BEST transducer, and (4) preclinical results from this new BCI system in three cadavers. Results will be compared with commercially available BAHA systems.

BCI design aspects

Attachment of the capsuled transducer:

In contrast to a transducer for a percutaneous BAHA, an implanted transducer must be hermetically sealed preferably by using a titanium casing. In the feasibility study (Håkansson et al., 2008) the transducer was naked and attached to the skull bone via a conventional snap coupling. A capsuled transducer must naturally be of greater size than a non capsuled transducer due to the required clearance between the casing and the transducer and due to the thickness of the casing walls. Also a coupling to a bone anchored fixture will build additional height. The total height (capsuled transducer + coupling + fixture) will determine the depth of the engagement into the temporal bone. This height should be kept to a minimum because it is assumed to be correlated to the degree of invasiveness (i.e. the risk for the patient and the cost for the surgical procedure). Additionally, the casing should be easy to remove if the transducer needs to be updated or temporarily removed for a MRI investigation, preferably on outpatient basis,.

One solution can be that the casing could protrudes outside the outer bone level, but such a solution was considered less favorable from cosmetic aspects and could possibly also cause some skin reactions and feedback problems. Another solution would be to move the transducer to an epicranial position using screw fixation on the side of the transducer casing as suggested by Ball et al., 2007 and Westerkull, 2007. This was not considered as a desired solution as the sensitivity increase by exciting over or interiorly of the temporal bone as shown by Eeg-Olofsson et al. (2008) and Håkansson et al. (2008) is then reduced and there might also, as mentioned above, be cosmetic-, skin- and feedback problems associated with an epicranial (protruding) casing.

Instead, in the present study, a new solution is proposed which does not use a screw attachment (Håkansson, 2008). As shown in Figure 3, the transducer casing in titanium is pressed by a small static force towards a flat bottom plane in a recess made in the temporal bone. The transducer is fixed by a thin titanium clamping bar placed over the titanium casing and is attached to the skull by standard craniofacial screws (Stryker AB, Malmö) with diameter 1.5 mm and length 5 mm. The casing is covered by a silicon seal except in bottom contact area. As there is an intermediate elastic layer of silicon between the casing and the clamping bar, it will facilitate the generation of the static force pressing the transducer casing towards the bone in the bottom area. By this method of attachment no coupling or screw attachments are needed and the total height of the implanted transducer is kept to a minimum (approx. 8 mm). As the clamping bar is not in metallic contact

with the casing it will also prevent casing vibrations to radiate outwards through the skin and thus reducing this feedback path to the microphone. In this study no feedback problems with this novel BCI system were experienced, which in fact was present using the percutaneous BAHA models. A further advantage with the clamping bar attachment over the silicone sealing is that it protects the implanted transducer and the bone at the attachment area in the bottom plane of the recess from potential trauma that may happen from accidents.

Figure 3: The top illustration shows the transducer casing (1) attached towards the bottom surface of a recess (2) in the temporal bone by a static force F by means of a clamping bar (3) and orthopedic screws (4). The casing is covered by a silicone sealing (5) except in the direct interface between the casing and the bone where some bone dust (6) may be applied. Between the casing and the lateral bone wall some supporting fat tissue (7) may also be applied. The capsuled transducer used in this study is called the C-BEST and has the approximate dimensions of 14x14x8 mm (left picture). The complete transducer arrangement was also mounted on a dry skull (bottom picture).

It is assumed that in a living subject some bone dust from the drilling procedure can be used to smoothen the seat at the attachment area that might be rough due to exposure of air cells, see bottom hatched area in Figure 3 (top). It is anticipated that these bone cells will remodel to a smooth “bone to casing” interface over time and this process may also reduce the required level of the force F . Even if the force F is reduced over time due to plasticity and remodeling of bone tissue, the contact area may still transmit dynamic forces without distortion as the surface will be joint like. Compare, for example, the joint between the lower jaw to the skull bone, which can transmit BC sound efficiently. In the present study on three subjects no remodeling of the bone could of course take place and instead a small portion of bone cement (Simplex[®] sold by Styker AB, Malmö) was applied and assumed to improve the contact. However, in a test-retest procedure in two of the subjects, before and after the bone cement was applied, no significant difference was seen in the measured frequency response function (“Promontory acceleration output”/ “Voltage input to transducer”). This indicates that the transmission through the “bone to casing” interface may be used from the day of surgery without any loss of sensitivity. Over time the remodeling of bone in the interface zone will most probably improve the contact (make it stiffer and tighter) but, as indicated by the test-retest procedure, that might not change the acoustic transmission. If desired also some fat tissue can be placed on the sides of the transducer casing to further stabilize its position in the recess made in the temporal bone, see hatched area at sides of the casing in Figure 3 (top).

It is also anticipated that this method of using a flat and joint like attachment will offer a possibility to easily replace or remove the whole implanted unit on an outpatient basis. This is facilitated by the fact that the casing and the implanted receiving coil have as mentioned above a protective layer of medical grade silicon rubber over their surfaces except in the bottom attachment area of the transducer casing where it is in direct contact with bone. It is assumed that the flat and stiff contact between the casing and the bone tissue will not “osseointegrate” or glue to each other instead it will be a joint like attachment that will easily disengage when the casing is removed.

Transducer attachment to casing:

Obviously, the transducer should be attached to the internal side of the casing as tightly as possible to keep down the physical dimensions. Looking back on the design principals of the percutaneous BAHA, it was also considered to be of utmost importance that the direct attachment or coupling to the skull bone should be done in a way that the transmission will not suffer from any sensitivity loss or cause distortion. Moreover, it was also clear from clinical point of view that all present

BAHAs should benefit if the sensitivity and the MPO could be increased especially at higher frequencies (Hodgetts, 2009, personal communication). Therefore, the attachment of the transducer to the casing of the BCI was conducted to improve the sensitivity and the MPO at higher frequencies.

Once again looking back on the design of conventional bone conductors, the low frequency response is enhanced by the design of a resonance between the suspension spring and the counter weight mass giving a low frequency (LF) resonance or boosted sensitivity and MPO in the range of 600-900 Hz. As a consequence of this design there is a steeper sensitivity roll off below the resonance frequency. It is now proposed to use a similar design approach also at high frequency region (Håkansson, 2009). By studying the lumped parameter topology of a conventional BAHA transducer in Figure 4a the idea is that by adding the compliance C, the gain sensitivity in the high frequency range can be significantly boosted by a high frequency (HF) resonance in the 2-4 kHz range (here at 3 kHz). This behavior was verified in PSpice (OrCAD v. 9.2) simulations of the network presented in Figure 4a as shown by the frequency responses in Figure 4b. Above this resonance region the roll-off will be increased as compared with the conventional BAHA but if the resonance frequency is chosen to 3 kHz the crossing point where attenuation occurs is just below 5 kHz and hence this increased roll-off will have less consequence since it occurs beyond the frequency region where most speech information exists.

This design is implemented in the capsuled BEST and is denoted C-BEST (C for Capsuled) throughout this paper. To verify the C-BEST frequency response function, it was measured using the Skullsimulator (Håkansson, 1989) and compared with the previous naked BEST (used by Håkansson et al., 2008), Baha[®] Classic and Intenso transducers (Cochlear Bone Anchored Solutions AB, Göteborg, Sweden), see Figure 5. The C-BEST casing was pressed statically by some 4-5 Newton against the Skullsimulator attachment by use of a special adapter.

In Figure 5a it is shown that the C-BEST has a maximum boost (HF resonance) in sensitivity at 3 kHz of 17 dB starting gradually from 1 kHz and ending at just above 4 kHz when compared with the naked BEST. Above 4 kHz there is a higher roll-off with the C-BEST. When comparing the C-BEST with the Baha[®] Classic transducer it has a generally higher frequency response $[F_{out}/V_{in}]_{dB}$ for all frequencies and for frequencies around the HF resonance at 3 kHz it is also higher than the Baha[®] Intenso transducer. The resonance peak at 3 kHz for the C-BEST might be slightly lower and more damped in a real patient as indicated by the simulations (Figure 4b) due to differences in the mechanical impedances between the Skullsimulator and the human skull.

(a)

(b)

Figure 4: Lumped parameter model of the C-BEST driving a lumped parameter model of the human skull (a) and PSpice simulation $[F_{out}/V_{in}]$ in dB with and without HF network (b). The graphs from the simulations show the C-BEST with HF network attached to the mechanical load Z_{load} being either the human skull impedance (Håkansson et al., 1986) or the Skullsimulator impedance (Håkansson and Carlsson, 1989). Also a simulation of a BEST without HF network attached to the human skull impedance is included as a reference.

Figure 5: Frequency response function of the transducers: C-BEST, naked BEST, Baha[®] Classic and Baha[®] Intenso attached to a Skullsimulator. Both the linear frequency response $[F_{out}/V_{in}]_{dB}$ (a) and the frequency response related to active input power $[F_{out}^2/P_{in} (active)]_{dB}$ (b) are shown. As indicated in the simulations the peak at 3k Hz for C-BEST is probably smoother (more damped) when attached to a human skull.

To give a more complete picture of the transducers' performance, the electric input impedances Z (magnitudes and phases) at 2 kHz for the different transducers were also measured and presented in Table I.

Table I: Electrical input impedances

Transducer	Magnitude @ DC Ohm	Magnitude @ 2kHz Ohm	Phase @ 2kHz Degrees
C-BEST	14	100	75
BEST	14	100	80
Classic	28	120	55
Intenso	8	40	50

Apparently, all electrical input impedances were rather similar @ 2 kHz except for the Intenso which has a considerably lower impedance magnitude. The reason for choosing 2 kHz for this comparison is that this frequency is above the LF resonance frequency (600- 900 Hz) and below the HF resonance frequency (3 kHz) in the present transducers. It was also noted that the impedance of all BEST transducers generally have higher phase values at frequencies above 1 kHz indicating that they have less internal losses of power (Håkansson, 2003).

By using the input impedance responses the normalized mechanical power output for a given active power input (consumed power) was calculated. It is denoted $[F_{out}^2/P_{in}(\text{active})]_{dB}$ and the results are presented in Figure 5b. Here it is more clearly shown that the BEST transducers have generally higher efficiency (less Eddy current losses) at higher frequencies than the conventional BAHA transducers. It is also shown that the transducers in general are most effective around their resonance frequencies. It should be noted that the total efficiency in a hearing aid can only be determined when the power consumption of all electrical components (microphone, DSP, power amplifier) are included.

Detailed frequency responses of all impedances are presented in the Master Thesis report by Gabrielsson and Adler (2009).

Materials and Methods

This study was approved by the Regional Ethics Committee, Göteborg, Sweden.

Subjects:

Three embalmed cadavers (two females of ages 102 and 81 years and one male of age 69 years) were used. For a description of the embalming procedure, see Eeg-Olofsson *et al.* (2008). All cadavers had normal skull anatomy and there were no signs of any chronic infections or former ear surgeries. The subjects were lying horizontally on a stainless steel table with an angled head support and they had a layer of approximately 5 cm sound absorption material as a pillow.

A 4 mm titanium Baha[®] fixture was placed in each subject in the standard BAHA position i.e. in the parietal bone 55 mm posterior and slightly superior to the ear canal opening – denoted “Pos A” (see Figure 7). The Implant Stability Quotient (ISQ) was measured with resonance frequency analysis (RFA). In RFA a small sensor (magnet) is first attached (screw attachment) to the fixture. Then a non contact probe is used, that in a repetitive procedure, first is impacting a force and then immediately thereafter measuring the vibration response of the fixture. The measured response vibrations of the fixture under test have a certain resonance frequency that is related to how well the fixture is integrated to the bone. This measured resonance frequency is then automatically by the software mapped into a clinical scale from 0 to 100 called ISQ where “100” represents a very rigid osseointegration and “0” a very loose one. It was here found that all fixtures installed had an ISQ value in the range from 72-81 in all directions. These ISQ values are within the range for the implants being regarded to be rigidly attached to the skull bone. For further details of RFA and ISQ, see Osstell Mentor at <http://www.biolin.se>.

A recess was formed with the approximate dimensions 16 x 16 x 8 mm (width x length x depth) and the bottom attachment surface area is denoted “Pos B” (see Figure 7). This size of the recess gives an appropriate clearance of approximately 1 mm around the transducer casing. The transducer casing of the C-BEST was attached by using a clamping bar that was fixed by the miniature orthopedic bone screws previously mentioned. Between the transducer casing and the clamping bar two silicon tubes (outer diameter 0.7 mm) were compressed by the clamping action by the bar construction to exert the static force *F*. This static force was estimated by manually compressing the bar and found to be in the range of 1 Newton. This force was considered to be sufficient and not influencing the output force level from the transducer as the maximum signal forces generated in this application (with rigid bone contact) are significantly less than 0.1 Newton.

Sound processors:

The sound processors used in this study are shown in Figure 6 and comprised: (a) BCI, (b) Baha[®] Classic, (c) Baha[®] Intenso.

The BCI included a VSB[®] (Vibrant Med-El, Innsbruck, Austria) with factory preset gain and volume control (the VSB[®] has no external controls) and the floating mass transducer (FMT) was replaced by the C-BEST. The Baha[®] Classic had the volume control (VC) set at 2 (maximum = 3), the tone selector set to N, and the frequency control H set to “+” (minimum). In the Baha[®] Intenso the VC was set to 1.5 (maximum = 3), the program selector was set to 1, the gain control was set to 1.5 and the tone control was set to “+” (maximum). Reduced VC settings (from maximum 3) were used in the Classic and the Intenso to avoid feedback problems encountered on the cadaver heads. However, the VC setting was high enough to reach the MPO of the devices at 90 dB SPL (in some cases 100 dB SPL was used for the Intenso).

Figure 6: Pictures of BCI (left), Baha[®] Classic (middle) and Baha[®] Intenso (right).

Measurement set-up:

In Figure 7 the complete measurement set-up is shown.

Figure 7: Measurement set-up.

A LDV from Polytec (HLV-1000) was used to measure the vibration velocity of the cochlear promontory. In order to enhance the reflection of the laser beam, small reflectors were glued onto the cochlear promontories (with Loctite gel glue No 454). As shown by the setup in Figure 7, the measurement of the cochlear promontory vibration was conducted by aiming the laser beam through the ear canal. The sound pressure at the devices microphones was measured by a reference microphone (Brüel & Kjær Condenser Microphone Type 4134) connected to a power supply (Brüel & Kjær Microphone Power Supply Type 2804) and the signal was fed via a high pass 20 dB amplifier stage (lower limiting frequency 30 Hz) to the Agilent 35670A dynamic signal analyzer. Calibration of the sound pressure was done by using Brüel & Kjær Calibrator Type 4230. The output from the Agilent 35670A was fed to a loudspeaker (HECO Odeon 100) via a power amplifier (ROTEL RB-976MkII).

As the subjects were lying horizontally on a stainless steel table in a highly reverberant room (stone floor and tile walls) it was a challenge to keep the sound pressure constant at the hearing aid microphones. The sound source was a stepped sine that was swept from 100 to 10k Hz with 1/64 octave band frequency resolution. The sound pressure level was kept constant by using an “auto

level” function of the Agilent 35670A where the built-in power source changes the output level to keep the reference microphone signal constant.

The sound field pressure levels presented to the microphone of the devices attached to the cadaver head were 60, 70, and 90 dB SPL (100 dB in some subjects for the Baha® Intenso). The output signal from the LDV, which measured the promontory velocity, was fed to one of the input channels of the Agilent 35670A. Measurement data were subsequently transferred to MatLab® where the Promontory Acceleration Level (PAL) was calculated by a multiplication by $j\omega$ in the frequency domain and then presented as dB relative to 1 m/s^2 . The reason choosing acceleration instead of velocity was to facilitate comparisons with results from previous studies where accelerometers have been used. It should be noted that the final results in this study are presented as relative measures between devices and/or stimulation positions and hence they are independent of whether velocity or acceleration was chosen for the raw data.

In order to measure the sensitivity difference between stimulation at Pos A and Pos B, excluding the influence of the inductive link, the frequency response function was measured as PAL divided by the input voltage level for the different transducers. This measurement did also use a stepped sine procedure from 100 to 10k Hz. The input voltage to the transducers was 0.5 Volt rms for all frequencies in these measurements.

Summary of measurements performed:

1. PAL at ipsilateral side from acoustically driven BCI at Pos B.
2. PAL at ipsilateral side from acoustically driven Baha® Classic at Pos A.
3. PAL at ipsilateral side from acoustically driven Baha® Intenso at Pos A.
4. PAL at contralateral side from acoustically driven BCI at Pos B.
5. PAL at contralateral side from acoustically driven Baha® Classic at Pos A.
6. PAL at contralateral side from acoustically driven Baha® Intenso at Pos A.
7. PAL at ipsilateral side related to the voltage input to the BEST at Pos A.
8. PAL at ipsilateral side related to the voltage input to the C-BEST at Pos B.
9. PAL at contralateral side related to the voltage input to the BEST at Pos A.
10. PAL at contralateral side related to the voltage input to the C-BEST in Pos B.

Results

The ipsilateral promontory acceleration responses with sound field stimulation are shown in Figure 8 with the responses for the three subjects and devices separated. Each row represents one of the three subjects and the columns represent each of the devices.

Figure 8: Ipsilateral frequency response functions from subjects 1, 2, 3 for the three different devices BCI (Pos B), Baha[®] Classic (Pos A), and Baha[®] Intenso (Pos A).

In a similar way, the contralateral promontory acceleration responses with sound field stimulation for the different subjects and devices are shown in the array of responses in Figure 9.

Figure 9: Contralateral frequency response functions from subject 1, 2, 3 for the three different devices BCI (Pos B), Baha® Classic (Pos A), and Baha® Intenso (Pos A).

Figure 10 shows the ipsilateral and contralateral responses when the transducers are driven electrically: the BEST in Pos A and the C-BEST in Pos B for all three subjects.

Figure 10: Ipsilateral and contralateral frequency response functions from subject 1, 2, 3 by electrically driving the transducers BEST in Pos A and C-BEST in Pos B.

Discussion

Two types of frequency response measurements are used in the present investigations which are slightly different. One is the “acoustically” generated frequency response measurement of the devices where the linear output spectrum is measured frequency by frequency. Output spectrum is the promontory velocity (in post processing multiplied by $j\omega$ to yield acceleration) at a certain input sound pressure level to the device microphone. The other is the frequency response measurement with the transducers “electrically” driven where the output velocity is divided (normalized) by the input voltage.

The first measure is just a scalar acoustic quantity and is a measure of the real vibration output (at the promontory) of the total system (hearing aid + skull) and is not necessarily directly related to the input of the system. The system can for example be completely nonlinear like when the hearing aid is in saturation and the maximum power output (MPO) has been reached. If stimulated at a high enough input level this acoustic response will be the maximum output of the device i.e. the MPO. The MPO is a very important measure and the limiting factor for those patients with a moderate to severe sensorineural hearing loss.

The second measure assumes a linear system and tells you how much sound/vibration output the transducer - skull system will produce at the promontory at a certain electric input to the transducer. This is the frequency response of the system and referred to as the sensitivity of the system. It is measured with a naked transducer attached and gives information about the properties of the “transmission channel” that the hearing aid uses to transmit the sound to the inner ear. It can be discussed if the transducer performance should be eliminated (from calibration charts the voltage input to the transducer can be transformed to yield the force output of the transducer) in order to make the results more generic and only be dependent on the bone conduction properties. However, in this case we are interested in a particular application where the transducer has been adapted (C-BEST) and hence the transducer performance was included in the results.

Acoustic responses of the devices

When comparing the “acoustically” generated frequency responses between the different devices only the maximum power output (MPO) gives an adequate comparison of the potential capacity of the systems. At levels below the MPO the response curves in each device can be changed by amplifier settings in a multitude of ways. Therefore, only the maximum power output (MPO)

acceleration difference (BCI vs Baha[®] Classic and BCI vs Baha[®] Intenso from Fig 8 and 9) at the ipsilateral and contralateral side were calculated as the average among the subjects. The results are presented in solid lines in Figure 11. A five point moving average smoothing filter was used to make it easier to interpret the difference of the raw data in Fig 8 and 9.

These differences in acoustic response curves at MPO (average among the three subjects) indicate what will be experienced by the patients regarding maximum loudness with each device. Hence it seems from ipsilateral measurements that the BCI will be 5-10 dB stronger than the Baha[®] Classic and 0-5 dB stronger than the Baha[®] Intenso for frequencies 700-7k Hz. At the contralateral side, however, it was found that the BCI produced a considerably lower MPO than the Baha[®] Classic as well as Baha[®] Intenso.

For comparison the corresponding results from Håkansson *et al.* 2008 is plotted in Figure 11 in dashed lines. That study was based only on one subject but the results seem to be in line with the results from the present study on three subjects. There are two differences between these two studies i.e. method of transducer attachment to the skull bone (non-screw vs screw attachment) and transducer modification (C-BEST vs BEST). Most likely the improved MPO at higher frequencies in the present study is related to the HF Boost network used in the C-BEST.

Responses from the electrically driven transducers

In Figure 12 the differences in ipsilateral and contralateral responses from electrical stimulation between sites (Pos B versus Pos A) are shown. In Pos A the transducer was a BEST transducer and in Pos B the C-BEST transducer was used. This comparison shows the difference in direct bone conduction sensitivity between Pos A and Pos B including the transducer difference between C-BEST versus BEST (from Figure 5). Apparently Pos B will give a 10-20 dB higher response than Pos A on the ipsilateral side for 700-7k Hz whereas for the contralateral side responses are fairly similar except for a dip at around 600 Hz of -10 dB and a roll off above 4 kHz, both in favor for Pos A.

Similar measurements were made by Eeg-Olofsson *et al.* 2008 and their Figure 5 show the relative sensitivity between approximately same positions (their Pos 8 vs Pos 1) for a normalized force input. It seems that their result is fairly well the same except for a lower high frequency response most likely due to differences between C-BEST and BEST that boost present results in this region.

This big difference in sensitivity for the ipsilateral side seen in this study will be reduced by the loss from the inductive link of some 10-15 dB (results from our lab) when the BCI device is included but still there will additional gain in favor for the BCI over the percutaneous Baha as also was shown by the acoustic measurements (see Figure 11a).

Figure 11: Ipsilateral and contralateral average (subject 1, 2, 3) MPO difference as BCI vs Baha[®] Classic (left) and BCI vs Baha[®] Intenso (right).

In Figure 13 the difference in responses at the ipsilateral versus the contralateral promontory from stimulation at the same site, Pos A and B, are shown. This is known as the transcranial attenuation and shows the difference in ipsilateral and contralateral response from a stimulation from either Pos A or Pos B. It should be noted that these results are independent of transducer as the same transducer are used for both ipsi and contralateral responses at the two positions.

The transcranial attenuation measured is between 5 and 25 dB at frequencies from 500 to 9k Hz with stimulation at Pos B. With the stimulation at Pos A the transcranial attenuation is much lower and even slightly negative. It seems that from Pos B the transcranial attenuation at higher frequencies is more in line with results that has presented from psychoacoustic studies (Nolan et

al., 1981; Reinfeldt, 2006) which may be explained by the fact that Pos B is more directly or rigidly in contact with the cochlea.

Pos B vs Pos A

Figure 12: The difference in acceleration responses at the ipsilateral and the contralateral promontory when stimulation from Pos A (BEST) versus Pos B (C-BEST) measured at the ipsilateral and the contralateral promontory acceleration, respectively, as the average among all subjects 1, 2, and 3

Similar tests of transcranial difference based on cochlear vibrations or ear canal sound pressure measurements have been made in several other studies: in a dry skull (Stenfelt, 2000) and cadaver heads (Stenfelt, 2005) and in live humans (Reinfeldt, 2006).

Transcranial attenuation

Figure 13: The difference in responses at the ipsilateral versus contralateral promontory acceleration (the transcranial attenuation) when stimulation from Pos A (BEST) and Pos B (C-BEST), respectively, as the average among all subjects 1, 2, and 3.

General discussion

It seems from all measurements that an implantable transducer can give an increased vibration level at the ipsilateral cochlear promontory compared with existing ear level BAHAs. One remaining uncertainty is whether this improvement in vibration level also implies an improvement in hearing. Psychoacoustic investigations are on-going to address this question regarding interpretation of *in vitro* LDV responses at the promontory versus hearing perception (Eeg-Olofsson, 2009 personal communication). These investigations use subjects who have a BAHA implant but also additional implants in the mastoid region for retaining an artificial outer ear. Preliminary results from these measurements indicate that a mastoid positioned implant gives a significantly better S/N ratio than a parietal positioned BAHA implant (Eeg-Olofsson, 2009 personal communication).

The potential hearing improvements with a BCI over a BAHA should be balanced by the potential risk differences in the surgical procedures as well as long term effects. How this balance will turn out may differ between patients and future *in vivo* studies are planned to clinically evaluate the whole BCI system in this respect.

It is also clear from these investigations that a SSD patient may not benefit from a BCI system since the present BAHA system shows a better transcranial transmission to the contralateral cochlea. On the other hand, this study shows that the sound transmission will be more directed to the ipsilateral cochlea and can therefore be beneficial for patients with bilateral implantation in order to better use binaural cues. It may also be beneficial to implant the BCI on the hearing side of a SSD patient and have a microphone on the deaf side from which the signal is wirelessly transferred to the BCI. The improved high frequency response from the C-BEST with the HF-resonance may then be very useful for compensating the head shadow effect.

One important question to address is: Why do we see this huge improvement in promontory response from 700-7k Hz when the excitation position moves from Pos A (BAHA position) to Pos B (BCI position)? In previous studies on a dry skull (Stenfelt, 2000) it was shown that this improvement was present but only above 1 kHz. This might have to do with the fact that the always existing low frequency anti resonance (between skull mass and local connection compliance) is higher for the dry skull than for the cadaver skull which is heavier and also loaded by the neck and torso. There is also a difference in the mechanical impedances in the cadaver heads between Pos A and B where Pos B have a generally higher impedance (higher mechanical compliance) than Pos A (by analysis of impedance data in Figure 2 in Eeg-Olofsson, 2008). The large difference in compliance is likely the most important explanation for the higher (improved)

sensitivity when stimulating in Pos B than in Pos A (Figure 12). This can be explained by the fact that the BAHA at the current site (Pos A), in the shell-like part of the parietal bone, is by increasing frequency elastically decoupled from the petrous portion of the temporal bone where the cochlea is situated. This is generally speaking how any compliant suspension between an attachment structure (Pos A) and a rigid body (Petrous portion of the [temporal bone](#)) works. Also there is a shift in the low frequency anti resonance of the mechanical point impedances between Pos A and B which most likely manifests itself by a pronounced valley in the ipsilateral difference responses in Figure 11 at 350 Hz. This lower sensitivity with the BCI versus the BAHA occur at these very low frequencies and may hence not be a real problem but clinical tests have to be performed to investigate this further.

Finally, it is probably the higher impedance in Pos B that explains the no feedback problems was encountered with the BCI in Pos B. In other words the bone surrounding Pos A is flexing more and thus radiating more sound for a given stimulation force than in Pos B and hence the conventional BAHA devices are more prone to have feedback problems. It should be noted that the feedback problems encountered in this study were not explicitly investigated but most likely they were more pronounced here than in a real life situation because of the extremely challenging set-up where the cadaver was resting on a hard stainless steel bed etc. Also, it should be pointed out that the different reduced volume control settings used did not affect the final MPO results as that saturation level was reached in all cases.

Conclusions

Generally it was found in this study that a BCI can be a realistic alternative to a percutaneous BAHA. One obvious advantage is that no permanent skin penetration is needed. However, more investigations are required to prove that this new approach will acoustically as well as medically work at least as good as a BAHA in a clinical setting.

The following conclusions can be made from the present study on three subjects:

- The BCI had 5-10 dB higher ipsilateral MPO promontory acceleration level than the Baha[®] Classic in the frequency range 700-7k Hz.
- The BCI had approximately 0-5 dB higher ipsilateral MPO promontory acceleration level than the Baha[®] Intenso in the frequency range 700-7k Hz.
- The contralateral MPO promontory acceleration levels are generally approximately 10-15 dB lower for the BCI than for the Baha[®] Classic and Baha[®] Intenso.

- The transcranial attenuation seems to be around zero or slightly negative for Pos A whereas for Pos B it is increasing from zero at low frequencies to almost 25 dB in the high frequency range.
- The results in this study indicates that the screw attachment used in previous studies can be replaced with a flat surface attachment under a static force which has a lower profile and is relatively easy to install.
- It was shown that bone cement is not needed to create a smooth attachment surface between the bone bed and the transducer.
- It was found that the BCI did not suffer from feedback problems in this setting for the preset gain whereas neither the Baha[®] Classic nor the Baha[®] Intenso could be used at a full volume setting (volume 3) because of feedback.

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