Output performance of the novel active transcutaneous bone conduction implant Sentio at different stimulation sites

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ABSTRACT

Objectives: The output performance of a novel semi-implantable transcutaneous bone conduction device was compared to an established percutaneous bone-anchored hearing system device using cadaver heads. The influence of actuator position, tissue growth below the actuator and mounting it on the surface or in a flattened bone bed on the performance of the implanted actuator was investigated.

Materials and Methods: The percutaneous and the new transcutaneous device were sequentially implanted at two sites in five human cadaver heads: 55 mm superior-posterior to the ear canal opening (position A) and, closer to the cochlea, about 20 mm inferior-posterior to the ear canal opening behind the pinna on the mastoid (position B). The ipsi- and contralateral cochlear promontory (CP) velocity magnitude responses to percutaneous and transcutaneous stimulation were measured using laser Doppler vibrometry. In addition, the CP vibration of the transcutaneous device placed directly on the skull bone surface was compared with the placement in a flattened bone bed at a depth of about 3 mm. Finally, the influence of placing a thin silicone interposition layer under the implanted transducer was also explored.

Results: The percutaneous device provided about an 11 dB higher average CP vibration level than the transcutaneous device at frequencies between 0.5 and 10 kHz. The ipsilateral CP vibration responses with stimulations at position B were on average 13 dB higher compared to stimulation at position A. The placement of the transcutaneous transducer at position B provided similar or higher average vibration magnitudes than the percutaneous transducer at position A. The 3 mm deep flattened bone bed had no significant effects on the output performance. Placing a thin silicone layer under the transcutaneous transducer had no significant influence on the output of the transcutaneous device.

Conclusions: Our results using the CP vibration responses show that at frequencies above 500 Hz the new transcutaneous device at position B provides similar output levels as the percutaneous device at position A. The results also indicated that neither a bone bed for the placement of the transcutaneous transducer nor a simulated tissue growth between the actuator and the bone affect the output performance of the device.

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1. Introduction

Bone conduction (BC) devices are an alternative solution for patients with conductive hearing loss (CHL) or mixed hearing loss (MHL) when conventional hearing aids and middle ear surgeries are ineffective (Snik et al., 2005). Bone anchored hearing devices (BAHD) such as the Baha systems (Cochlear bone-anchored solutions; Mölnlycke, Sweden) or the Ponto systems (Oticon Medical, Askim, Sweden), using a titanium screw implant attached to a transducer by a skin penetrating abutment are among the effective
BC devices (Lagerkvist et al., 2020). The titanium screw is usually anchored approximately 55 mm posterior–superior to the external ear canal. With certain limitations, single sided deafness (SSD) can also be treated using BAHDs, by transmitting the sound from the deaf side to the healthy contralateral side (Stenfelt, 2005). Despite the successful rehabilitation results using BAHDs (Snik et al., 2005) the lifelong daily care to keep the penetrating abutment clean, infections and loss of the implant due to accident or trauma are among the disadvantages (Lagerkvist et al., 2020; Staffors and Tjellström, 2008). In recent years, semi–implantable active transcutaneous BC devices (TBCD) that transmit the audio signal inductively across the intact skin to an implanted transducer have been used and reported to be successful (Goldstein et al., 2020; Huber et al., 2013; Reinfeldt et al., 2015). TBCDs consist of an external sound processor which picks up the sound by microphones, digitally processes the signal and transmits inductively power and the audio signal to the subcutaneous BC implant. The implanted part (transcutaneous BC implant; TBCI) consists of a receiving coil, a retention magnet to hold the external part, a demodulation circuit, and the BC transducer, as well as a fixation band and screws (Fig. 1a).

On the one hand, due to losses in the inductive link, TBCDs provide 10 to 15 dB lower output levels compared to BAHDs (Håkansson et al., 2008). On the other hand, BC stimulation closer to the cochlea provides a higher output efficiency as shown by studies using cochlear promontory vibrations measured with a laser Doppler vibrometer (LDV) as well as an accelerometer to estimate the output performance of the BC transducers (Eeg-Olofsson et al., 2008; Stenfelt and Goode, 2005). The lower output for the TBCD could be compensated by placing the BC transducer at a position closer to cochlea (Håkansson et al., 2010).

Recently, a new TBCD (Sentio system, Oticon Medical, Askim, Sweden) was developed consisting of the sound processor Sentio 1 and the implant Sentio Ti. The objective of the current study was to investigate output performance of this new TBCD and compare it with a state of the art commercially available percutaneous BAHD in human cadaveric heads. Moreover, the effect of implant location, placement of the implant in a bone bed, and tissue growth below the transducer on the output performance was investigated.

2. Material and Methods

2.1. Cadaver heads

Five fresh frozen human cadaver whole heads (10 ears) comprising four males and one female were used to measure the cochlear promontory vibrations in response to stimulations with the new TBCD (Fig. 1a) and the percutaneous BAHD (Fig. 1b). The use of whole human cadaver heads for these experiments was approved by the ethics committee of the Hannover Medical School (8151_BO_K_2018). The profile and medical history of the specimens were unknown to the authors. All heads were scanned with volume computed tomography before experiments and checked by experienced surgeons (RS, NP) to detect and exclude specimens with fractured skulls. The heads were thawed in a cooling room at +4 °C at least 24 h prior to the experiments. The cochlear promontory of both ears was exposed through the ear canal and an approximately 2x2 mm opening in the tympanic membrane. The measurements were performed sequentially on both ears on two consecutive days. At the end of the first day, the head was placed in a +4 °C cooling room overnight.

2.2. Surgical sequence and conditions

In otologic surgery, some transcutaneous BC implants require drilling of a bone bed (Eeg-Olofsson et al., 2014; Huber et al., 2013). One potential issue with the implant is the transducer protruding in the skin and soft tissue. The TBCI transducer housing has a height of approx. 5 mm and a diameter of 20 mm. Another issue is that skull bone surface is not flat and the uneven interface area between the transducer housing and the skull bone can potentially affect the BC transmission. The effect of the latter issue was investigated by drilling a ~3 mm deep bone bed and comparing the CP velocities from the TBCI transducer before and after the drilling of the bone bed. A template was used to ensure a snug fit of the transducer as well as a flat surface for the transducer-skin interface.

The bottom of the TBCI (Sentio Ti) is designed to osseointegrate. In the absence of osseointegration, a fibrous capsule could form around the implant (Anderson, 2001) and soft tissue might grow.
between the transducer housing of the TBCI and the skull bone attenuating BC sound transmission. The acoustic impedance of silicone elastomer is close to that of soft tissue (Yamamoto et al., 2009), hence a 300 μm thick silicone sheet was used to simulate potential tissue growth between the transducer housing of the TBCI and the skull bone (Palmquist et al., 2013).

The TBCI was implanted under four different conditions by placing the transducer without and with bone bed and by placing the transducer without and with the 300 μm thick silicone sheet interposed between the TBCI transducer and the skull bone. For all conditions, the ipsi- and contralateral cochlear promontory (CP) velocity measurements were performed sequentially. Here, ipsilateral means the measurements on the same side as the stimulation and contralateral means the measurements on the side opposite to the stimulation.

First, the TBCI was implanted on the skull bone surface at position A using the fixation band. The fixation band was a 1 mm thick, 6 mm wide, and 39 or 45mm long silicone coated titanium band with holes for screws in both ends (see Fig. 1). The band secures the TBCI transducer to the skull bone by two 4 mm self-tapping osseointegrating titanium bone screws (MODUS, Switzerland). After implantation of the TBCI, the ipsi- and contralateral cochlear promontory vibrations were measured and the measurements were repeated having the silicone interposition under the transducer. After conclusion of these measurements, a 4 mm long (4.5 mm diameter) implant with a 9 mm long abutment of the Ponton BAHD system (Oticon Medical, Askim, Sweden) was placed at position A using the standard guide drill and a 4 mm countersink drill (Oticon Medical, Askim, Sweden). After CP vibration measurements in response to stimulation by both implants at position A, the mastoid bone was inspected and an appropriate position (position B) about 20 mm posterior-inferior to the ear canal opening was chosen for TBCI placement. The TBCI transducer was fixed on the bone using the fixation band and CP vibrations were measured with and without the silicone interposition. After conducting the measurements with TBCI at position B, the 4 mm implant with 9 mm abutments of the BAHD system was placed at position B and again CP vibrations were measured. Finally, the TBCI was implanted at position B after creating a cylindrical 3mm deep flat bone bed at this position and the measurements were performed with and without the silicone interposition between transducer and skull bone.

2.3. Stimulation

The stimulation was provided by a Sentio 1 sound processor for the TBCD and a Ponto 3 for the BAHD. Both processors were modified to enable a direct electrical input connection. The gains were set to full-on setting according to IEC 60118-9 for MFO (OVFL90) measurements, and the microphones were turned off. The input voltage was set so that the output force level measured on a skull simulator (SKS-10, Interacoustic, Middelfart, Denmark) matches the output force (usually ±1 dB) when stimulated by 90 dB SPL acoustic pure tones (OVFL90) at frequencies between 0.1 and 10.0 kHz (Fig. 2). The stimulation signals were synthesized using a data acquisition device (NI-4431 BNC, Austin TX, National Instruments, USA) with a 24-bit analogue-to-digital converter in combination with a custom-written program in LabVIEW (National Instruments, Austin TX, USA). The stimulation signal was a stepped sine consisting of 77 logarithmically spaced sinusoids from 0.1 to 10 kHz that was supplied to the processors. A 5 mm plastic spacer was placed between the TBCD sound processor and receiver coil to simulate the patients’ skin and subcutaneous tissue in a controlled way (Ghoncheh et al., 2020). A buffer amplifier (SAI, TDT, USA) was connected between the signal generator and sound processors to provide the required current.

![Figure 2](image_url) Reference maximum vibratory output force levels on the skull simulator for the TBCD and the BAHD at 90 dB SPL input level (OVFL90).

2.4. Reference Measurement

A verification procedure using the skull simulator was performed before and after the experiments to assure that the processors and implants functioned according to the specifications. During the study, different version of the TBCD sound processors and implants were used and the force measurement on the skull simulator was used to compensate for the differences between prototypes. All measurements with the TBCD and BAHD system were normalized to the reference maximum output vibratory force levels (OVFL90) at 90 dB SPL, shown in Fig. 2.

2.5. Laser Doppler Vibrometry

The velocity responses of the cochlear promontory were measured by a laser Doppler vibrometer (LDV) (OFV 534, Polytec, Germany). The sensitivity of the system was set to 5 mm/s/V. The laser head was mounted on a surgical microscope (OPMI 1, Zeiss, Germany) with a micromanipulator to adjust the laser beam. The cochlear promontory of both ears was exposed through small (< 10% of the membrane area) triangular perforation of the tympanic membrane and small reflector tapes were placed on the CPs to improve the reflection of the laser beam. The data were sampled at 51.2 kS/s and averaged 30 to 500 times to obtain a signal-to-noise ratio (SNR) of at least 12 dB. The noise floor was estimated based on the average of six adjacent frequency bins (3 below and 3 above) to the stimulus frequency in the computed FFT (Fast Fourier Transform), with each bin representing a frequency bandwidth of 12.5 Hz. Data with SNR below 12 dB were excluded from the analysis. The laser beam was almost perpendicular to the surface of the CP.

2.6. Statistics

A paired t-test was used (ttest function, MATLAB, MathWorks Inc., Massachusetts, USA) in order to investigate significant differences (p < 0.05) between conditions at each frequency. All data from the 5 heads (10 ears) were pooled at each frequency and condition. The datasets were checked for a normal distribution (Lilliefors test, lillietest function, MATLAB) and a Holm–Bonferroni correction for multiple comparisons was applied. At most frequencies the data were normally distributed. For the data points that were not normally distributed a two-sided Wilcoxon signed rank test (signrank function, MATLAB) was used. Data visualization and analysis were performed with MATLAB.
3. Results

3.1. CP vibration: BAHD versus TBCD

The velocity levels of the ipsi- and contralateral CP vibration with the BAHD and TBCD at position A and B are shown in Fig. 3. One contralateral CP vibration measurements was excluded from the analysis due to incompletion caused by a connection failure to the sound processor.

Fig. 3a shows that at position A, the average ipsilateral CP velocity levels of the BAHD were 15 dB lower than the TBCD at frequencies below 0.5 kHz. At frequencies above 0.5 kHz, the average magnitude differences remained below 12 dB. Fig. 3b shows that the average contralateral responses with stimulation at position A were also 15 dB higher for the BAHD compared to the TBCD at frequencies below 0.5 kHz while the average differences above 0.5 kHz were approximately 9 dB. With stimulation at position A, the ipsilateral BAHD results were significantly higher than the TBCD results at most frequencies in the investigated range (Fig. 3a) while on the contralateral side (Fig. 3b) statistical significant differences were mostly limited to frequencies below 500 Hz.

With the transducers at position B, average ipsilateral CP velocity (Fig. 3c) was 13 dB better for the BAHD compared to the TBCD at frequencies below 0.5 kHz. Above 0.5 kHz, the BAHD gave 10 dB larger magnitudes than the TBCD. Average velocity responses at the contralateral CP (Fig. 3d) were similar to the ipsilateral results at frequencies below 0.5 kHz, with the BAHD magnitude being approximately 13 dB higher than the TBCD magnitude. Above 0.5 kHz, the magnitude of the BAHD was approximately 9 – 10 dB larger than that of the TBCD. The contralateral differences between the TBCD and BAHD with stimulation at position B (Fig. 3d) were mostly significant below 2.5 kHz.

The magnitude of ipsilateral responses with stimuli at positions A and B were significantly higher for the BAHD compared to the TBCD (Fig. 3a, c) at most of the tested frequencies. However, no significant difference was found with stimulation at position A and B around 800 Hz which is the resonance frequency of the TBCI transducer.

3.2. CP vibration: Position B versus Position A

The effect of placing the BC transducers closer to the cochlea was investigated by comparing ipsi- and contralateral CP vibration levels of the TBCD (without bone bed) and BAHD at position B in relation to position A (Fig. 4). In Fig. 4, the average magnitudes indicated a higher CP vibration level for stimulation at position B compared to position A for both implants. Moving the BAHD from position A to position B (closer to the cochlea), provided 13 dB higher ipsilateral velocity magnitudes at frequencies above 500 Hz. For the TBCD, the average increase in magnitude was approximately 14 dB at frequencies above 500 Hz. The differences at those frequencies were significant for both implants.

Fig. 4b shows that on the contralateral side, the average CP velocity differences between stimulation at positions A and B were less than 3 dB at frequencies below 500 Hz for both implants. At frequencies between 1 – 3 kHz, the average improvement was approximately 8 dB for the BAHD and 6 dB for the TBCD system. However, the differences were not significant.

3.3. Transcranial attenuation

The transcranial attenuation (TA) was defined as the ipsilateral CP velocity level minus the contralateral CP velocity level with stimulation at positions A or B. With stimulation by the TBCD at
Fig. 4. The relative velocity level of the ipsi- and contralateral CP responses with stimulation at position B relative to position A. (a) Average ipsilateral velocity level differences for BAHD (red) and (b) TBCD (blue). (b) Contralateral relative velocity levels for BAHD and TBCD. Solid lines represent the average and shaded areas with the same color represent standard deviations. grayscale squares (BAHD) and grayscale triangles (TBCD) in the top of the graphs represent statistically significant differences (Black ▲ ▲ p ≤ 0.001; dark Gray ▲ ▲ 0.001 < p ≤ 0.01; light gray ▲ 0.01 < p ≤ 0.05).

Fig. 5. The transcranial attenuation (TA). (a) The average TA with the BAHD stimulation at position A (black line) and B (red line); SDs are depicted by shaded ranges of corresponding color. (b) The average TA for the TBCD stimulation. Thick lines depict grand mean of TAs at position A (black dashed line, N=18) and position B (red solid line, N=36); shaded areas of corresponding color depict SD ranges.

position B, data for several conditions were available as measurements were also done after drilling the bone bed and interposition of the silicone sheet. The TA was computed for all the different conditions. One contralateral CP vibration measurement with the BAHD processor at position A was excluded due to improper sound processor placement.

Fig. 5a shows the TAs for the BAHD at positions A and B. At frequencies below 400 Hz, the average TA was approximately -2 dB for the BAHD at both stimulation positions. The average TA at position A increased from -5 dB at 500 Hz to 4 dB at 2 kHz and started to decline around 3 kHz. The TA for position A started to increase again at 6 kHz resulting in a 15 dB TA at 10 kHz while the average TA level between 2 and 10 kHz was approx. 6 dB. For the BAHD stimulation at position B, the average TA was 7 dB between 0.5 and 2 kHz and increased to become around 20 dB at frequencies above 5 kHz.

Fig. 5b shows the TA for the TBCD at positions A and B. Similar trends were observed for the TBCD as for the BAHD. In general, for frequencies above 400 Hz, stimulation at position A gave 5 to 15 dB lower TA compared to stimulation at position B.

3.5. Effect of bone bed

The influence of placing the TBCI transducer in a 3 mm bone bed with flat bottom on CP vibrations was explored. Fig. 7 shows the average difference in CP velocity levels with and without the bone bed at position B for both the ipsi- and contralateral responses. Fig. 7 also shows the influence of placing a silicone sheet between the transducer housing and the skull bone, both with and without a bone bed. Irrespective of response side or the use of silicone sheet interposition, at frequencies below 700 Hz, the average relative CP velocity magnitude difference was in the -1 to -2 dB.
Fig. 6. The relative velocity magnitude of the CP comparing without and with silicone sheet interposition between the TBCI transducer housing and the skull bone. (a) The average ipsilateral and (b) the average contralateral CP velocity level difference with the TBCD at position A. (c) The average ipsilateral and (d) the average contralateral CP velocity level difference with the TBCD at position B. Standard deviations are depicted by shaded areas (MV: mean value; SD: standard deviation; N: number of ears).

Fig. 7. The relative velocity magnitude of the CP between without and with a bone bed (BB) drilled at position B (levels without BB minus levels with BB). (a) The average ipsilateral and (b) the average contralateral CP velocity magnitude difference with the silicone sheet interposition. (c) The average ipsilateral and (d) the average contralateral CP velocity magnitude difference without silicone sheet interposition. Standard deviations are depicted by shaded areas (MV: mean value; SD: standard deviation; N: number of ears; BB: bone bed).
dB range. This indicates a minor performance benefit of placing the implant in a bone bed but none of the observed differences were statistically significant. At the transducer resonance frequency (around 1 kHz), the relative magnitudes were positive indicating a slight negative effect of placing the implant in a bone bed. Again, none of the observed differences were statistically significant. The largest differences were observed at 1.5 and 5 – 6 kHz, with approximately 5 – 7 dB improvement for having a bone bed. However, the observed differences were not statistically significant. A slight resonance shift toward lower frequencies as indicated by a steep minimum – maximum transition in Fig. 7 at 800 – 900 Hz occurred due to the implantation of TBCI in the bone bed.

4. Discussion

In this study, we measured vibration of the CP (Eeg-Olofsson et al., 2013; Stenfelt and Goode, 2005) in human cadaver heads to investigate the output performance of a new semi-implantable TBCD with different coupling modes at two different locations on the skull and compared the output level to the already established BAHD (Oticon Medical Ponto 3).

In BAHDs, the transducer is integrated into the external sound processor and the vibration of the transducer is directly and efficiently transmitted via an abutment to the bone through an osseointegrated implanted screw. In semi-implantable TBCDs, the audio signal and power are inductively transmitted to the implant, leaving the skin intact. Häkansson et al. reported that the transcutaneous BC stimulation using an inductive link provided 10 to 15 dB lower output compared to percutaneous BC devices (Häkansson et al., 2010, 2008). However, the comparison was based on the maximum force output of the devices using a skull simulator. This may only give a rough estimate since the skull simulator has been designed to determine the output of percutaneous bone anchored devices with a different attachment type compared to transcutaneous devices. Secondly, we cannot distinguish if the reported lower force output was due to losses of the wireless transmission or to lower efficiency of the transducer. In the current study also the BAHD produced 12 dB and 11 dB higher average CP velocity magnitudes than the TBCD at positions A and B, respectively (Fig. 3).

The ipsilateral CP velocity magnitudes produced by the BAHD and the TBCD at frequencies above 500 Hz at position B, located closer to the ear canal at the mastoid, were 13 and 14 dB higher than the velocity magnitudes at the standard BAHD position A posterior-superior to the ear canal. As the position closer to the ear canal proved to be more efficient, one solution to compensate for the transmission loss of the TBCD is to implant it closer to the cochlea. This is feasible as, in contrast to BAHDs, TBCDs with the receiving coil being separated from the transducer by an electrical connection allow placement of the transducer closer to the cochlea, posterior to the pinna. This means that the sound processor with the receiver coil underneath can be placed at a distance from the transducer. For this reason, we compared the output of the different devices at their suggested operating positions. Fig. 8 shows ipsilateral and contralateral velocity magnitudes of the CP in response to TBCD at position B and BAHD at the standard position A. On the ipsilateral side, placing the TBCD at position B provided 3 dB higher average velocity magnitudes across frequencies ranging from 0.5 to 10 kHz compared to BAHD at position A. By placing the TBCD at position B, we could compensate and even gain 3 dB at frequencies above 500 Hz. However, this small gain found at frequencies above 500 Hz was not statistical significant at individual frequencies. Although the optimized surgical position can compensate the loss in high frequencies a significant gap between the BAHD and TBCD remains at frequencies below 500 Hz. The advantages and trade-offs of surgical placement of TBCD emphasize again that these devices permit to adapt their use to specific audiological requirements and pathologies. However, this newly gained degree of freedom is currently not fully explored and needs further investigation.

The contralateral CP velocity was also not significantly different at frequencies above 500 Hz when comparing the TBCD at position B and the BAHD at position A. In contrast to responses on the ipsilateral side, the contralateral average CP velocity levels of the TBCD at position B showed a trend to be up to 10 dB lower than the BAHD at the standard position A for frequencies between 4 and 6 kHz. Moreover, at frequencies below 0.5 kHz, the CP velocity from the TBCD at position B was ipsilaterally up to 20 dB and contralaterally up to 17 dB lower than from the BAHD at standard position A. These differences were statistically significant.

Transcranial attenuation in this study was computed as the ipsilateral CP minus contralateral CP velocity levels. Using a comparable method, the amount of TA reported by (Stenfelt and Goode, 2005) and Eeg-Olofsson et al. (2011) for stimulation at the typical BAHD site and the mastoid position showed a similar trend (Fig. 9). At the normal BAHD position (Pos A, Fig. 9a) the average TA level was very similar. However, the average TA levels at the mastoid position were 5 to 10 dB higher at frequencies above 0.5 kHz in the current study compared to the (Stenfelt and Goode, 2005) and Eeg-Olofsson et al (2011) studies (Fig. 9b). This is likely an effect of the difference between the exact stimulation positions on the mastoid between the studies. The use of 3D composite response in the Stenfelt et al. (2005) study can also influence the computation of TA and be a source for differences between the studies in Fig. 9. In the study by Eeg-Olofsson et al., higher attenuation levels at high frequencies similar to our study were reported when the stimulation was at a position very close to the osseous labyrinth.

Our data showed that the TA was mostly independent of the transducer type but related to the stimulation site such that a position closer to the cochlea gave greater interaural separation, similar to the results in Stenfelt (2012). At frequencies above 500 Hz, the TA for the implants at position B increased with frequency with levels of up to 24 dB at the highest frequencies. This large TA at higher frequencies with TBCD at position B can be beneficial for binaural hearing with BC (Stenfelt and Zeitooni, 2013; Zeitooni et al., 2016), as it provides larger interaural separation than with stimulation at position A. Practically, another consequence is that lower contralateral masking levels would clinically be required.

The bottom of the TBCI where the transducer housing is attached to the skull bone is designed to osseointegrate (Palmquist et al., 2013). However, there is a possibility of a fibrous tissue formation under the transducer, e.g. related to excessive movement during the healing period (Anderson, 2001). In absence of osseointegration, in TBCDs the BC vibration transmission might be reduced as a result of tissue between the bottom of the transducer and the skull bone. Palmquist et al. reported a tissue encapsulation thickness of 344 ± 67.7 μm surrounding the implant (Palmquist et al., 2013). We investigated the effect of such a tissue growth underneath the BC transducer by placing a 0.3 mm thick silicone sheet under the transducer and found no significant change of promontory vibration (Fig. 6).

Transcutaneous BC implants are usually placed in a bone bed to avoid bulging of the transducer under the skin and to have a flat surface for the transducer to efficiently transfer the BC vibration to the skull bone. However, for future implant designs with even smaller heights it might become surgically feasible and easier to abstain from the creation of a bone bed. Our data suggested that placing the TBCI transducer in a bone bed did not significantly improve (Fig. 7) the output performance of the device. Therefore, our results indicate that future TBCDs with smaller heights can po-
tentially be designed for being placed directly on the bone surface. However, we did not address the clinical and surgical consequences of placing the transducer with 5 mm thickness on the bone surface under the skin and clinical investigations are needed to demonstrate clinical feasibility and safety. For the current design, the results clearly indicate that the exact depth of the bone bed and tissue growth of 0.3 mm does not affect the performance. However, a bone bed seemed to produce a resonance shift toward lower frequencies (see local maxima between 800 Hz and 900 Hz in the bone bed vs. no bone bed comparison Fig. 7) due to the change of mechanical load impedance at the interface.

Cochlear promontory vibration can be used as an estimate for BC hearing sensation (Stenfelt and Goode 2005). High correlation was previously reported between the average CP bone vibration and average BC threshold of subjects (Eeg-Olofsson et al., 2013). The same study also showed similar vibration levels for cadaver heads and live human subjects. Although commonly used and well established (Håkansson et al., 2010; Huber et al., 2013), one-dimensional CP vibration is an indirect measure of cochlear excitation. Alternatively, a more direct indicator of hearing sensation of the BC stimulation could be intracochlear pressure measurements (Borgers et al., 2019; Grossöhmichen et al., 2017; Stieger et al., 2018) or three-dimensional vibration measurements (Dobrev and Sim, 2018) that may provide more accurate estimates of output performance when off-axis vibrations dominate. For example, Zhao et al. (2021) showed that the absolute threshold error in Guinea pigs was on average 50 to 100% larger when BC hearing was estimated by CP vibration in one direction compared to an optimally obtained combination of the CP vibration in three dimensions. However, these more advanced approaches require a more sophisticated invasive surgery such as mastoidectomy or sacrificing the bony ear canal. This in turn might cause BC pathways alteration compared to a normal surgical procedure for BC hearing device recipient (Prodanovic and Stenfelt, 2020).

5. Conclusion

Our results indicate that the vibration response at the CP from the new Sentio system at a position close to the ear canal (position B) provides similar output levels as the percutaneous Ponto 3 at its normal position (position A) at frequencies above 500 Hz. Additionally, larger transcranial attenuation at higher frequencies for the TBCD at position B compared to the BAHD at position A may

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**Fig. 8.** Cochlear promontory velocity in response to TBCD (blue) stimulation at position B and BAHD (red) stimulation at position A. (a) Average ipsilateral CP responses (N=10). (b) Average contralateral CP responses (N=9). Standard deviations are depicted by shaded areas of the same color (MV: mean value; SD: standard deviation; N: number of ears). Grayscale symbols on top of the graphs represent statistical significant differences (Black ▲ p ≤ 0.001; dark Gray ▼ 0.001 < p ≤ 0.01; light gray ● 0.01 < p ≤ 0.05).

**Fig. 9.** Average transcranial attenuation (ipsilateral CP vibration minus contralateral CP vibration) incorporating results from the studies of Eeg-Olofsson et al. (2011) and Stenfelt et al. (2021). Average transcranial attenuation obtained without interposition and bone bed by the velocity responses of TBCD at (a) position A (red solid line) and (b) position B (blue solid line). The shaded area with corresponding color depicts the standard deviation in our study. Transcranial attenuation estimated from single beam LDV (black solid lines, Eeg-Olofsson et al. (2011)) and accelerometer (black dashed lines) measurements with the BC transducer at position 4 (similar to our position B) in the study from Stenfelt et al. (2005).
provide binaural hearing benefits for CHL and MHL with bilateral TBCD implantation. This is achieved without sacrificing contralateral stimulation as the output vibration level transferred from the ipsilateral side was similar for the BAHD and the TBCD at their operational positions. Similar CP vibration magnitudes for the TBCD at position B with and without bone bed suggest that neither flattening of the bone nor the depth of the bone bed affects the output level. Furthermore, the comparison of TBCD placement with and without a silicone sheet, mimicking tissue growth, implies that a thin layer of tissue growth, if it occurs, would have an insignificant effect on the BC stimulation by the TBCD.

Declaration of Competing Interests

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CRediT authorship contribution statement

Mohammad Ghoncheh: Data Analysis, Methodology, Software, measurements, writing - original draft, editing. Stefan Stenfelt: Reviewing, editing, measurements. Patrick Maas: Reviewing, Technical support, Measurements. Rolf Salcher: Surgical preparation and procedures, Reviewing. Nils Prenzler: Surgical preparation and procedures, Reviewing. Stefan Raufer: Reviewing, Measurements. Hannes Maier: Conceptualization, Methodology, Measurements, Writing, Revision, and Editing, Supervision, Funding acquisition.

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