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Direct bone conduction stimulation: Ipsilateral effect of different transducer attachments in active transcutaneous devices

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ABSTRACT

Active transcutaneous bone conduction devices, where the transducer is implanted, are used for rehabilitation of hearing impaired patients by directly stimulating the skull bone. The transducer and the way it is attached to the bone play a central role in the design of such devices. The actual effect of varying the contact to bone has not been addressed yet. The aim of this study is therefore to compare how different attachment methods of the transducer to the bone for direct stimulation affect the ear canal sound pressure and vibration transmission to the ipsilateral cochlea.

Three different attachments to the bone were tested: (A) via a flat small-sized surface, (B) via a flat wide surface and (C) via two separated screws. Measurements were done on four human heads on both sides. The attachments were compared in terms of induced cochlear promontory velocity, measured by a laser Doppler vibrometer, and ear canal sound pressure, measured by a low noise microphone. A swept sine stimulus was used in the frequency range 0.1–10 kHz.

On an average level, the attachment method seems to affect the transmission mainly at frequencies above 5 kHz. Furthermore, the results suggest that a smaller contact surface might perform better in terms of transmission of vibrations at mid and high frequencies. However, when considering the whole frequency range, average results from the different attachment techniques are comparable.

1. Introduction

Hearing rehabilitation for patients with conductive or mixed hearing loss can effectively be achieved with bone conduction devices (BCDs), transmitting vibrations directly to the cochlea via the skull bone. In active transcutaneous BCDs the transducer is implanted directly on the skull bone. There are multiple ways of attaching and securing the transducer and its casing to the bone, and the possible influence of different attachments on vibration transmission is unknown at present.

In fact, although the phenomenon of bone conduction (BC) hearing has been widely studied since the beginning of the 20th century, it is still not fully understood. Previous studies have demonstrated that the basilar membrane is stimulated in the same way regardless of the originating pathway, resulting in air conducted (AC) and BC components of sound being indistinguishable at the basilar membrane level (Adelman et al., 2012; Stenfelt and Goode, 2005a; v. Békésy, 1960). In normal-hearing individuals subjected to external sound stimulation, the AC component is predominant, whereas the BC component becomes significant for example in the perception of one's own voice (Reinfeldt et al., 2010; v. Békésy, 1949). The main advantage of BCDs over conventional AC devices is that BCDs rely on the stimulation and transmission of vibrations through the skull directly to the cochleae, bypassing the external and the middle ear, where the cause of hearing loss might be located. Vibrations that are transmitted through the skull result in vibration of both cochleae with an intensity level dependent on the stimulation position among other factors. Changes in vibrational level at the cochlea, as well as in the ear canal sound pressure, have been shown to correlate to changes in hearing

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perception (Eeg-Olofsson et al., 2013; Reinfeldt et al., 2013): an increased vibrational response appears to result in an increased hearing sensation. In other words, by measuring vibration velocity on the cochlear promontory and sound pressure level in the ear canals, it is possible to extract partial information about the quality of rehabilitation in terms of improved hearing sensation.

Vibrations reaching the cochleae are determined by the original electrical signal fed to the transducer in combination with the characteristics of BC transmission to the cochlea: a high amplitude signal transferred in an inefficient way could result in a weaker response than the one evoked by a low amplitude signal transferred in an efficient way. There are a number of reasons why it is desirable to keep the input signal amplitude as low as possible for a given hearing sensation, among which the most important are a longer battery life, lower risk to fall into feedback problems and the possibility of having a smaller and more easily implantable transducer. The focus in this study is BC vibration transmission, which appears to be a convenient approach to improve the BCD design. In other words, developers should search for an efficient way to convey vibrations so that the level of the stimulus reaching the cochleae is as high as possible given a certain input signal intensity. However, such optimization needs knowledge of the dynamical properties of the skull and transmission patterns. This generates a need for a deeper understanding of the relation between the stimulation condition at the transducer attachment level and the vibrational response at the cochlear level.

When referring to a stimulation condition, several characteristics can be addressed. For example, the transducer can be positioned at varying distance from the ear canal, it can be in contact with the skin or with the bone directly, it can be kept in place by a soft band or rigidly implanted on the skull. Furthermore, during an implant design process, several factors are to be taken into account, such as ease of implantation and possible future explantation, robustness of the contact and long term osseointegration, and anatomical limitations to the implant size. The focus of this study is limited to addressing the way the transducer is attached to the bone when the device is implanted directly on the skull.

BCDs where the vibrations are applied directly on the skull bone are referred to as direct-drive BCDs, as opposed to skin-drive BCDs, where the stimulation is given through the skin (Reinfeldt et al., 2015). Within the group of direct-drive BCDs currently implemented, different stimulation methods can be identified. In the percutaneous bone anchored hearing aid (BAHA), the first developed direct-drive BCD and still today's most widespread model, the vibrations are transmitted via a screw rigidly anchored in the skull bone. The screw has a diameter of 4.5 mm and can be regarded as a single point stimulation. Active transcutaneous BCDs, where the whole transducer is implanted under the skin, act instead with either a multiple screw stimulation or a flat-surface contact. A double point contact is found in the Bonebridge™ from MED-EL (Innsbruck, Austria), where the casing containing the transducer is kept in place by a rigid bar anchored at the two ends with screws of 2 mm diameter, 4 mm length and a circular arm surface of 5 mm in width. In the recently developed bone conduction implant (BCI), the contact is instead achieved by placing the transducer in a shallow recess of the mastoid portion of the temporal bone with its flat surface of 6 mm in diameter in direct contact with the bone (Håkansson et al., 2010).

Although these solutions are already used in practice, the influence of the attachment type on the efficiency and the quality of the transmitted vibrations has not been investigated so far. Nevertheless, other aspects have been previously studied by applying a stimulus to the skull via a bone vibrator and measuring the resulting movement (acceleration or velocity) at the cochlear promontory, using accelerometers and Laser Doppler Vibrometer (LDV). The most important findings from such studies are: (1) the transmission of vibrations is linear for normal BC hearing levels and frequencies (Håkansson et al., 1996), (2) the efficacy of a stimulation increases when the input is applied closer to the cochlea, with the transmission evaluated in terms of vibration level on the cochlear promontory (Eeg-Olofsson et al., 2008; Stenfelt and Goode, 2005b), and (3) the transcranial attenuation, i.e. the quotient between ipsilateral and contralateral cochlear response, is frequency dependent and is generally higher in the high frequency range and with a stimulation position close to the ipsilateral cochlea (Stenfelt, 2012).

All the aforementioned studies were conducted with a single point stimulation technique (screw), and did not provide information about the influence of different attachments. The overall aim of this study is to investigate the effect of transducer attachment on the transmission of vibrations to further increase the knowledge of dynamical properties of the human skull. Such knowledge can be usefully applied in the field of BC hearing rehabilitation to design and improve BCDs in order to achieve an optimal transmission of vibrations to the skull without the need of increasing the input power.

More specifically, the following research questions are addressed in this study:

(1) How does a separated twin screw attachment affect the BC vibration transmission compared to a flat surface?
(2) What is the effect of increasing the size of the contact surface?

2. Material and methods

The study was approved by the Regional Ethics Committee.

The complete test setup is illustrated in Fig. 1 and consists of the following parts: human subject, transducer with adaptor (to apply the stimulus), signal generator and analyzer (to drive the transducer and receive the recorded data), LDV (measuring the cochlear promontory velocity), video to USB converter (to couple the built-in camera of LDV with the computer), microphone (to measure sound pressure level in the ear canal) and laptop (to save and analyze data).

2.1. Subjects

Measurements were performed on four human cadaver heads severed from the body. The heads were frozen after decease and defrosted two and a half days prior to the measurements. During the measurements, the heads were kept in a resting position on a soft doughnut-shaped pillow, with the purpose of preventing unwanted rolling movement as well as to vibrationally decouple the head from the underlying surface. At visual inspection, no traces of previous surgery were found in the hearing organ. During the measurements, however, fractures were surprisingly noticed on 3 of 8 sides. The cause was hypothesized to be a post-mortem mechanical trauma as no external sign of impact was seen. Data analysis was performed to investigate whether such injuries could have significantly affected the results, but no trends were found when comparing the intact five sides with the fractured three sides. The effect of such injuries on the collected ipsilateral data are therefore considered negligible. The measurement sequence was additionally tested on one side of a dry skull to further verify the utilized methods.

Details about the heads are found in Table 1.

2.2. Stimulation

Vibrations were transmitted to the skull bone by direct-drive

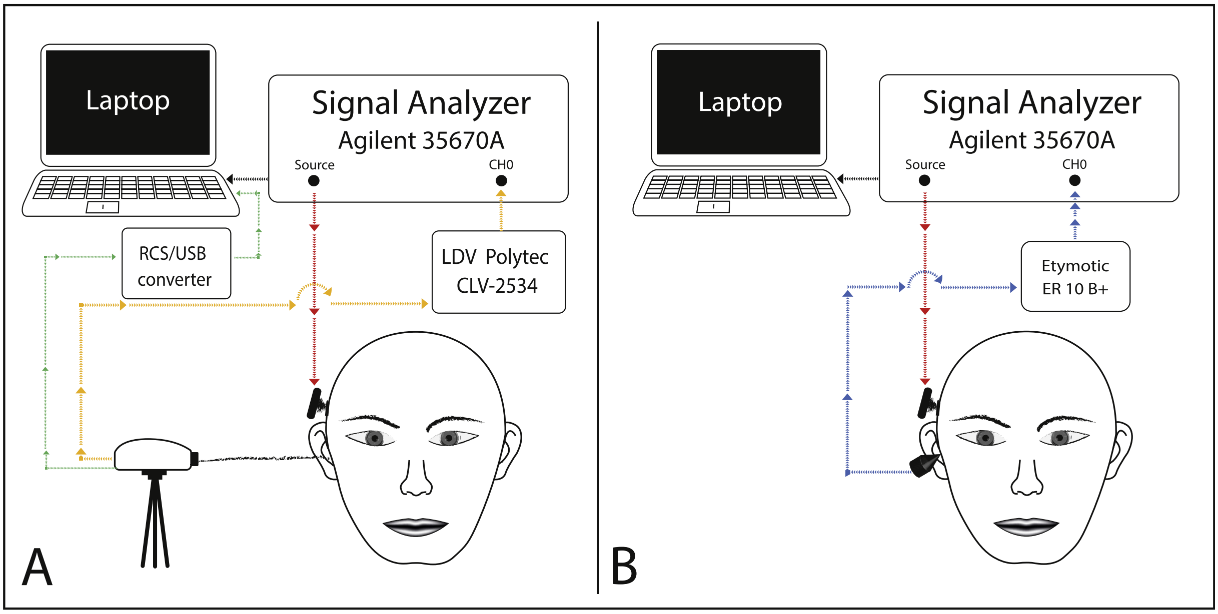


Fig. 1. Measurement setup. Schematic setup for measurement of cochlear promontory velocity and sound pressure level in the ear canal (A and B, respectively) during bone stimulation. (A) The signal analyzer produces the stimulus (red path) and collects the measured data from the laser Doppler vibrometer (yellow path). A built-in video connection (green path) is used to monitor more precisely the position of the laser beam on the reflector glued on the cochlear promontory. (B) The signal analyzer generates the stimulus signal (red path) and collects the measured data from the low noise microphone (blue path) positioned inside the ipsilateral ear canal. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

Table 1
Details about the study subjects. F = female, M = male, yrs = years.

Subject ID	Gender	Age (yrs)	Circumference (cm)
1	F	74	52
2	F	50	54
3	M	78	54
4	F	90	53

stimulation. Three dummy implants were produced to obtain different typologies of contact with the bone: (A) small-sized flat surface, (B) extended flat surface and (C) bar with double screw contact separated by 21 mm. Representations of the three adaptors are shown in Table 2, where complete technical specifications are also given.

The following surgical protocol was followed for each implantation side: (I) A recess was drilled in the mastoid part of the temporal bone, centered 18–26 mm behind the ear canal. The recess had a diameter of approximately 22 mm and depth of 3 mm, with variations due to anatomical differences between subjects. (II) Adaptor A was implanted in the center of the recess, secured with a pliable 3-arms band screwed on the surrounding bone. (III) Adaptor A was substituted with adaptor B, implanted in the center of the recess and secured with the pliable band in the same way as adaptor A. (IV) Adaptor B was removed and adaptor C was implanted with the bar secured via two screws on the border of the recess. Fig. 2 shows how the three adaptors were positioned with respect to the ear canal in a schematic side view of a human head. Table 3 summarizes the details of the positioning of each adaptor with individual variations between subjects mainly caused by anatomical characteristics.

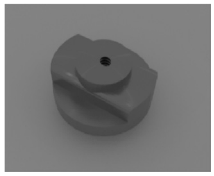
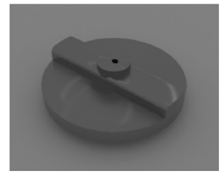
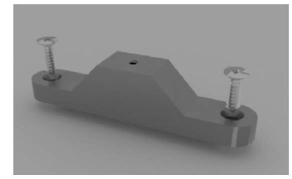
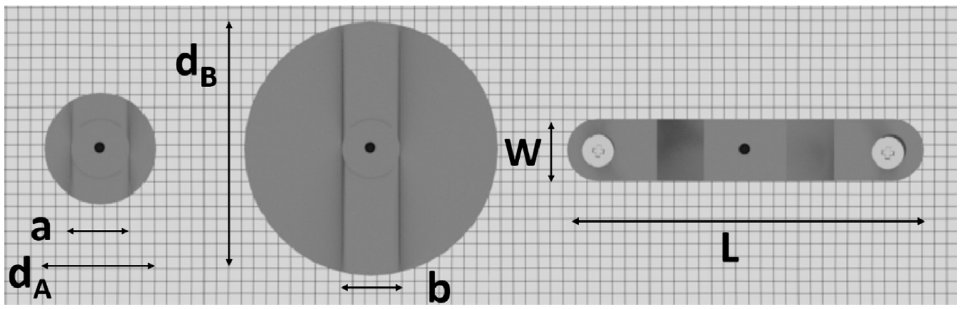
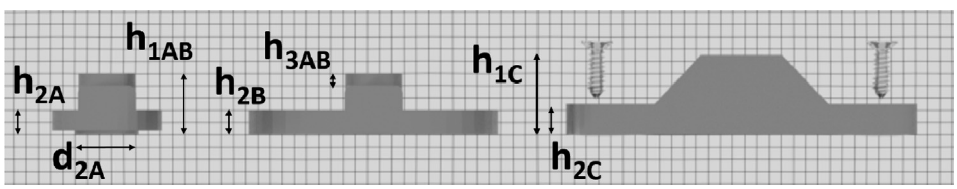
In order to ensure good adherence to the bone surface, clay material was squeezed to a very thin layer between the flat surface of adaptors A and B and the bone bed. This highly deformable and non-compliant material secures full contact over the whole surface without modifying the vibration characteristics of the stimulus. This method of attachment was verified in separate measurements on a dry skull and is assumed to replicate an osseointegrated surface in a real head where the surface will be either in direct bone contact or in contact via incompressible viscous tissues filling up potential air cells in the contact area.

The vibrations were generated by a balanced electromagnetic separation transducer (BEST) (Håkansson, 2003) calibrated on the Skull Simulator TU-1000 (Nobelpharma, Göteborg, Sweden) to obtain the output force level (Håkansson and Carlsson, 1989). The driving stimulus, a swept sine over the frequency range 0.1–10 kHz with fixed voltage amplitude, was generated by the signal analyzer Agilent 35670A (Agilent Technologies, Inc., CA, USA). The transducer was coupled to each of the three adaptors through an M2-thread screw in the center of the adaptors providing a rigid attachment. In all cases, the direction of the stimulation was approximately perpendicular to the skull bone surface.

2.3. Sound pressure level

Ear canal sound pressure level (ECSP) was measured with a low noise ER-10B + microphone system (Etymotic Research, Inc., Elk Grove Village, IL, USA). The frequency response of the microphone was measured in an anechoic chamber B&K 4222 (Brüel and Kjaer, Nærum, Denmark) and its sensitivity was determined using a GRAS Type 42AB sound level calibrator (G.R.A.S. Sound & Vibration, Holte, Denmark). In order to have a good sealing of the ear canal and to minimize external noise interference, a microphone-holding conical plug was inserted, sealed and secured with expanding polyurethane foam Sika Boom S All Seasons (Sika Sverige AB, Spånga, Sweden) applied 30 min before the measurements to guarantee sufficiently long drying time. The polyurethane foam kept the holding plug in place during the whole measurement session, ensuring a low variability between subsequent measurements when the microphone had to be removed to allow for LDV measurements through the ear canal. Background noise level was measured at the beginning of the measurement session to verify

Table 2
Technical specifications of the adaptors utilized to convey vibrations to the skull bone.

Adaptor ID	A	B	C
Weight	0.8 g	3.1 g	1.3 g
Material	Dural Aluminium, Density: 2800kg/m^3		
3D model			
Top view			
Side view			
Dimensions	$d_A = 9$ mm $a = 5$ mm $d_{2A} = 6$ mm $h_{1AB} = 6$ mm $h_{2A} = 2.3$ mm $h_{3AB} = 1$ mm	$d_B = 20.5$ mm $b = 5$ mm $h_{1AB} = 6$ mm $h_{2B} = 2$ mm $h_{3AB} = 1$ mm	$W = 5$ mm $L = 29$ mm $h_{1C} = 6.5$ mm $h_{2C} = 2.5$ mm

the quality of the acquired signal. Test-retest variability measurements were performed on one randomly selected subject to assess the robustness of measurements against contingent external factors, reset of the measurement setup and reset of the stimulation setup. The sound pressure level is presented as a frequency response expressed in dB rel 20 μPa/N, i.e. it was normalized for 1 N input stimulation level.

2.4. Cochlear vibration

The velocity of the cochlea was measured with the LDV CLV-2534 (Polytech, Waldbronn, Germany) pointed directly at the cochlear promontory. In order for the laser beam to reach the promontory, it was necessary to remove the tympanic membrane, the malleus and the incus, and to glue a small reflector together with small glass spheres on the promontory. Measurements with laser and microphone were alternated according to a randomized order, which was possible due to the fact that the reflectors could be reached by the laser beam through the opening in the microphone cone plug. Furthermore, background noise level was recorded at the beginning of the measurement session. Test-retest verifications were carried out in the same way as for the sound pressure level measurements. Velocities were measured with an accuracy of 5 (mm/s)/V and are presented as frequency responses expressed in dB rel (1 mm/s)/N.

2.5. Data analysis

Results were analyzed in relative terms, meaning that the difference between values measured at separate stimulation occasions were taken into account rather than the actual absolute values. This is to make the comparison more straightforward while avoiding calibration problems and large inter-subject variability. A statistical analysis was conducted for the differences between all attachments, both in terms of cochlear velocity and ECSP.

Two sides from the same head were considered as two independent measurements, leading to statistics based on data from 8 subjects (where each side of a head counts as one subject).

In the investigation of the statistical significance of the differences, it was first assumed that the underlying statistical process is normally distributed. The confidence interval (CI) method was then used over the p-value method because it gives more comprehensive information about the reliability of the estimates and the estimation method. A confidence interval consists in a range of values that contains the true value of the unknown parameter estimated from the data with a certain confidence level which is complementary to the level of significance: a 95% confidence interval reflects a 5% significance level. When a 95% CI is calculated for a difference, e.g. between two means, the difference between the two groups is statistically significant at that level if the interval does not include 0.

Test-retest variability was estimated from four repeated measurements with LDV and four with microphone. The standard deviation of the test-retest measurements, quantifying the within subject variability, was graphically compared to the standard deviation of the analyzed differences between adaptors, namely A vs B, A vs C and B vs C. Furthermore, an intraclass correlation

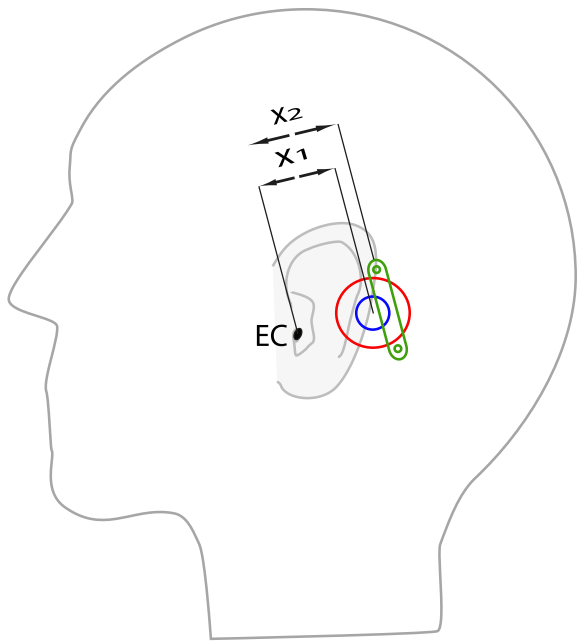


Fig. 2. Adaptors location. Illustrative side-view of a human head where the locations of the adaptors are indicated. EC = ear canal; x_1 = distance from ear canal to flat surface center, 18–26 mm; x_2 = distance from ear canal to bar center, 22–26 mm (see Table 3 for individual details). The three adaptors are outlined in three different colors: blue = adaptor A (small-sized flat surface), red = adaptor B (flat wide surface), green = adaptor C (bar with double screw fastening). (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

coefficient (ICC) was calculated as an index of reliability of measurements. ICCs are useful statistics for measuring homogeneity when larger sets of measurements are organized in groups. The calculated ICC is a quantification of how strongly the data in the same group tend to resemble each other. Regardless of how different the values are from one group to the other, i.e. between different frequencies in this case, the four measurements belonging to the same group are expected to be highly similar as they represent the same quantity measured on the same subject under identical experimental conditions. Several different types of ICCs are defined, but their value is in practice very similar in most cases (Lexell and Downham, 2005). The ICC that was utilized here is the one appointed by McGraw and Wong (1996) as the most appropriate indicator of absolute agreement among several repeated measurements where there is only one source of variation (frequency). This index is defined as

$$ICC = \frac{\sigma_b^2}{\sigma_b^2 + \sigma_w^2}$$

where σ_b^2 and σ_w^2 are the between-groups and within-group variance, respectively. Formulas for the definition and the estimator are found in (McGraw and Wong, 1996, Table 4).

The interpretation of the ICC value is not universally agreed on, but a generally followed classification is the one originally proposed by Fleiss (1986), where values above 0.75 are associated to “excellent reliability” and values between 0.4 and 0.75 indicate “fair to good” reliability.

Data handling and statistical analysis were performed with MatLab (MathWorks Inc, Massachusetts, USA).

3. Results

3.1. Differences between adaptors

In Fig. 3, measurements of cochlear promontory velocity and ECSP are shown for adaptor A. As seen in the plot, the variability between different subjects is high, with differences up to 35.5 dB in velocity at 6.9 kHz and 37.6 dB in ECSP at 830 Hz for adaptor A. Results for adaptors B and C are not displayed as they are analogous, with maximal inter subject variability at frequencies around 1 kHz. The background noise illustrated in the figure is calculated as the average of four repeated measurements. A signal to noise ratio (SNR) highly above 20 dB was achieved in the great majority of LDV measurements, but a lower SNR tendency was found at higher frequencies, with SNR between 10 and 20 dB above 6.2 kHz. Six data points for subject 2L with adaptor A were recorded with SNR smaller than 10 dB at frequencies above 9.5 kHz, with an absolute minimum of 5.9 dB. The SNR for microphone measurements was constantly above 20 dB, with the exception of one data point: adaptor B, subject 2L at 100 Hz had a SNR of 18.6 dB.

To distinguish the relatively small differences between the attachments with high inter-subject variability, average differential measurements are shown in the next plots rather than single absolute values, and the differences are expressed in decibel.

In Fig. 4, the results are presented for the adaptors compared pairwise. The results are shown as a relative difference, where 0 dB indicates identical results in the two cases, positive values correspond to a higher quantity measured for the first adaptor compared to the second one, and the other way around for negative values. Significantly different results (where the CI does not include 0 dB level) are found mainly at high frequencies, between 5 and 7 kHz when comparing adaptor A with B (Fig. 4a – in ECSP measurements) and B with C (Fig. 4c – both in LDV and ECSP measurements). For adaptors A and C such a significant difference is only found around 2 kHz when measuring with the LDV.

Measurements performed with LDV (upper row) and with microphone (lower row) appear to mainly agree for the comparison between A and B, especially for frequencies above 1 kHz, where the average difference is mostly positive. Despite these general similarities in high frequency trends, significant differences are found at different frequency bins. When looking at lower frequencies, LDV

Table 3
Position details for the implanted adaptors. The variability in the positioning is mainly caused by anatomical differences between subjects. R = right, L = left. Subjects where a fracture was detected after the measurements are marked with (*).

		Ear canal – flat surface center (mm)	Depth (mm)	Ear canal – bar center (mm)
Head 1	L (*)	18	3	25
	R	18	3	23
Head 2	L	25	2	22
	R (*)	21	2	23
Head 3	L	21	3.8	25
	R	26	3.6	24.2
Head 4	L	20	3.3	26
	R (*)	18	2	22

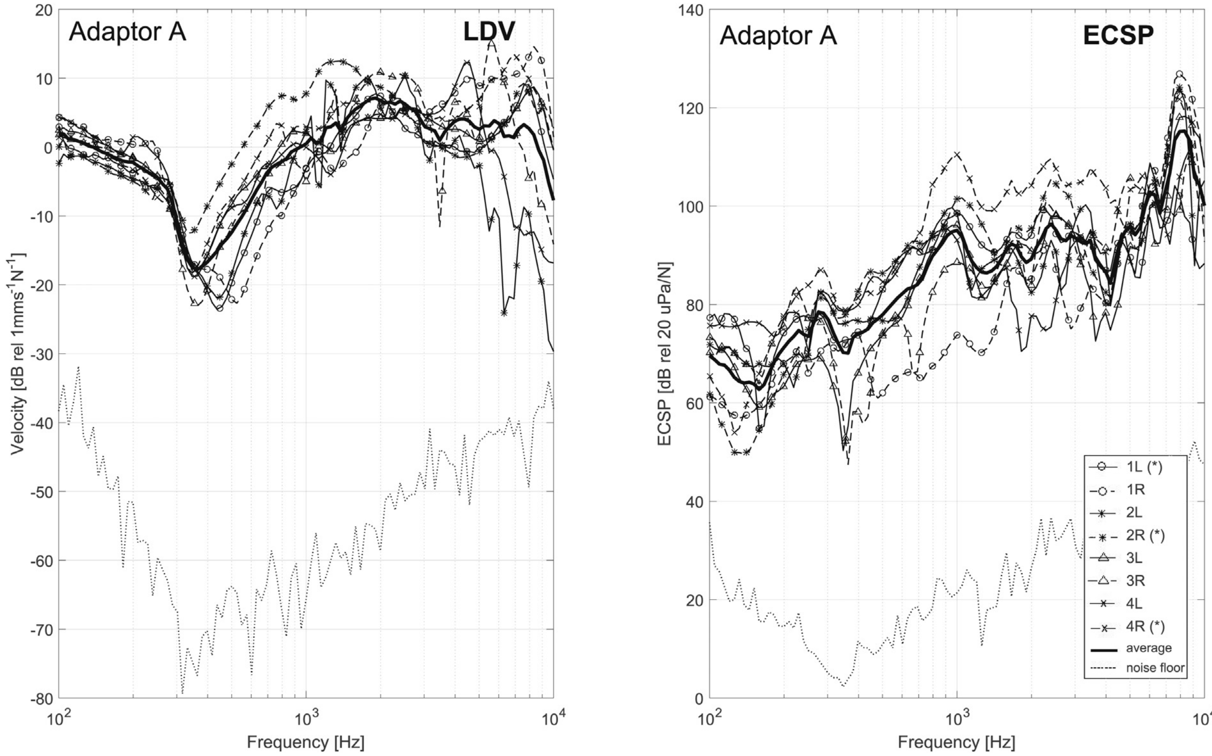


Fig. 3. Inter-subject data variability. Ipsilateral cochlear promontory velocity measured by the LDV and ECSP measured by the microphone at stimulation through adaptor A, i.e. small-sized flat surface implanted 18–26 mm behind the ear canal in a 3 mm deep recess. LDV = laser Doppler vibrometer, ECSP = Ear canal sound pressure. Results from the 8 subjects are plotted individually (thin lines with markers) together with the mean value (thick lines). Subjects where a fracture was detected after the measurements are marked with (*) in the legend. R = right, L = left. The noise floor (thin dotted line) is obtained by averaging four repeated measurements.

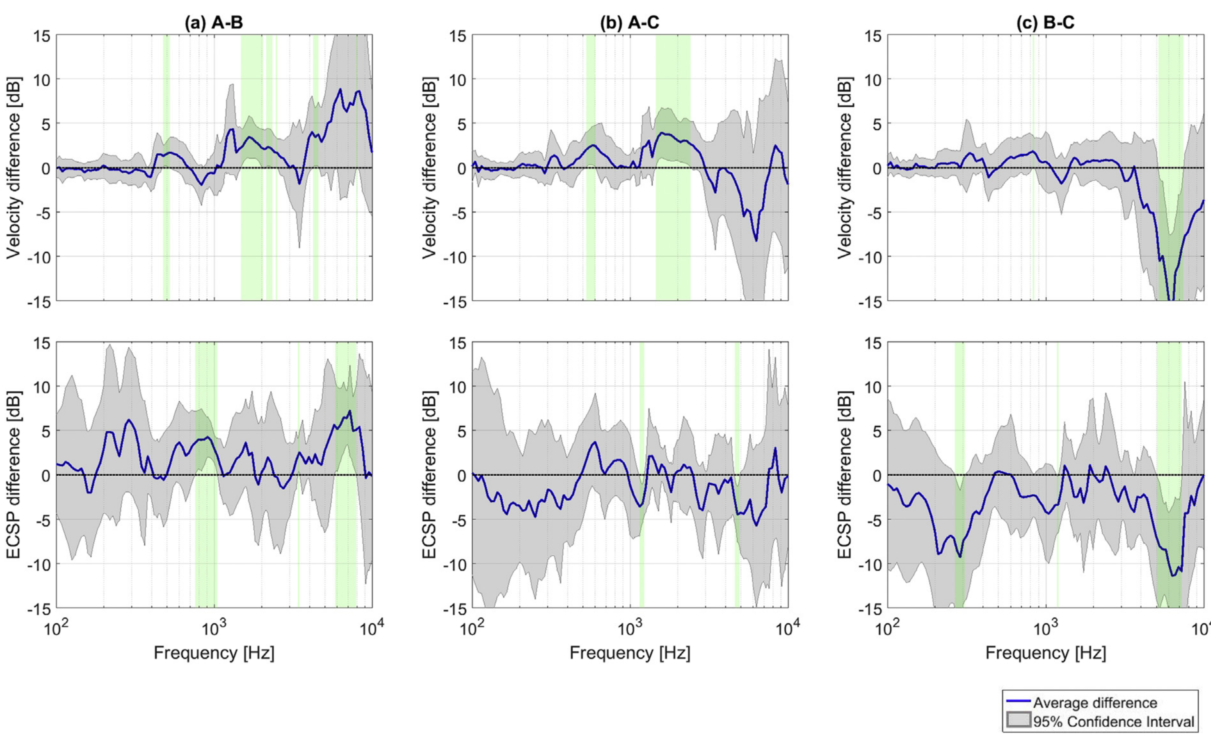


Fig. 4. Average differences between adaptors. Average difference in LDV measurement of velocity at cochlear promontory (top row) and ECSP (bottom row) for (a) adaptor A minus B, (b) A minus C and (c) B minus C. The zero line is marked with a dotted line. 95% confidence interval (CI) is shown as a shaded grey area and significant differences are highlighted with green colored background. LDV = laser Doppler vibrometer, ECSP = ear canal sound pressure, CI = confidence interval (of the average estimate). (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

measurements show less variation between adaptors than ECSP measurements do, thus making the comparison more complex. Between B and C, the difference is mainly negative in both LDV and ECSP values above 1 kHz, while the same complexity as in the previous comparison is found at lower frequencies. In the comparison between adaptor A and C (middle column, Fig. 4b), instead, the two measured quantities are not in complete agreement with each other and the alternation of positive and negative values varies to a greater extent over the whole frequency range. A common feature that is found among all the LDV results (cochlear velocity) at frequencies below 500 Hz is that they show very low variability between subjects and between adaptors, and have a standard deviation significantly smaller than that found at higher frequencies. ECSP results, instead, present the same amount of variability at all the investigated frequencies, i.e. ECSP has a notably higher variability than the LDV results at low frequencies. This trend is in line with findings from previous studies and is further addressed in the discussion.

A box plot of the collected data at selected frequencies is shown in Fig. 5. Boxplots are useful to graphically show the distribution of the dataset and visually verify its normality: too many outliers could indicate a non-Gaussian distribution of the measured data and the position of the median gives an indication about the skewness of the distribution. From Fig. 5 a very limited number of outliers is seen, with maximum one data point per dataset, indicating that the assumption of normal distribution is not to be rejected. This provides a good basis for the statistical analysis of the data, which is based on the assumption of a normally distributed underlying statistical process. The differences that are found significant according to the statistical analysis are marked with a bar and a green asterisk.

3.2. Test-retest variability

Test-retest variability is presented in Fig. 6 as a comparison of standard deviations (SD). As seen in the lower panel, the test-retest SD for measurements with microphone was very low (dark green area), with maximum SD of approximately 7 dB around 250 Hz and 9000 Hz, abundantly lower than the SD of the differences between adaptors (other colored areas). Measurements with LDV (upper panel) showed a higher degree of variation, with an increasing SD for higher frequencies. However, the SD of the test-retest is consistently smaller than the SD of the measured differences throughout the frequency range.

The ICC for LDV was calculated to 0.9476 with 95% CI [0.939; 0.955] and 0.984 for microphone measurements with 95% CI [0.982; 0.987]. Both indicate, according to Fleiss' classification, a very good level of reliability of the measurements.

4. Discussion

In the present study, the effect of the BC transducer attachment on the vibration transmission characteristics to the ipsilateral side was investigated. Application of the results can be done in the field of BC hearing rehabilitation, where hearing implants have been developed to transmit vibrations to the cochlea through a direct bone stimulation from an implanted transducer.

The reliability of the collected data was investigated through repeated test-retest measurements. Measured data are considered reliable if they show a sufficiently high degree of stability and adequate levels of variability (Lexell and Downham, 2005). The variability level can be said adequate if the uncertainty coming from the measurement setup is such that the measurement noise does not prevent the detection of clinically relevant differences. Although this is an extremely important aspect in experimental studies, test-retest investigations have seldom been reported and analyzed in previous studies. Variability of measurements of ECSP has been reported in a study by Reinfeldt et al. (2014) to be between 4 and 12 dB for frequencies from 125 to 8000 Hz. The lower variability, thus higher repeatability and reproducibility, achieved in the present study can probably be attributed to the fact that cadaveric subjects allow for more stable measurement conditions. On the other hand, the measurements with LDV resulted less robust to test-retest variation. However, low repeatability in LDV measurements from BC stimulus was found also in a study by Röösli et al. (2012), where the authors hypothesize this to be a potential factor contributing to the high inter-subject variability.

One potential source of variation in LDV measurements is the use of a single point measurement technique. Due to their one dimensional nature, LDV measurements are sensitive to directionality. This could affect the collected data, especially at high frequency, where the skull movement is a complex combination of wave transmissions in all three spatial directions. A slight change in the laser beam positioning might therefore cause two consecutive measurements to represent two different spatial components of the vibrational movement, thus increasing the test retest variability. A possible improvement in this regard would be to use a three dimensional LDV, or to scan a small surface instead of a single point. On the other hand, the cochlear responses measured in three dimensions with accelerometers were found to be normally within 5–10 dB in previous studies (Stenfelt and Goode, 2005b), which makes it hard to appoint the choice of direction as the sole cause of variation. Another possible source of variation in LDV measurement may be the effect of external factors. In fact, while the microphone is placed in the ear canal i.e. attached to the head itself, the laser beam comes from an instrument that is external to the measurand (the head): the two parts may therefore be subjected to different micro-motions contributing to the final measured values.

The analysis of test-retest variance suggests that there is room for improvement in the design of LDV measurements, while it also highlights the need for further investigation of the repeatability issue. However, despite the relatively great degree of variation, the calculated ICCs show very high scores both for microphone and LDV measurements, giving confidence on the actual reliability of the presented data.

All the presented data were obtained with measurements on human cadaver heads. Objective measurements were performed under the assumption that an increase in such output quantities would result in an increased hearing sensation in living subjects.

The legitimacy of extending the findings from measurements on cadaver heads to (I) full body subjects, and (II) further to living subjects, is supported by previous studies. Regarding the first point, several vibrational studies have been previously performed on heads severed from the body assuming that such a condition does not have a substantial impact on the results. In a study by Stenfelt and Goode (2005b) the authors support their assumption with a publication by Stalnaker and Fogle (1971) where the junction between head and neck was shown to have an influence only for frequencies below 400 Hz.

The relation between a cadaver and a living human body is a more complex issue to address when considering hearing mechanisms. Cochlear response in healthy subjects stimulated by BC is induced in several ways complementing direct skull bone vibration, as initially hypothesized by Békésy (1954). Cerebrospinal fluid (CSF) and soft tissues among others are considered to play a role, even though the exact mechanisms and relative importance of each pathway are still uncertain (Stenfelt and Goode, 2005a). In a cadaver, all such additional pathways might not be activated and the measured cochlear movement and ECSP might suffer from this. However, there is no evidence showing a predominant role of

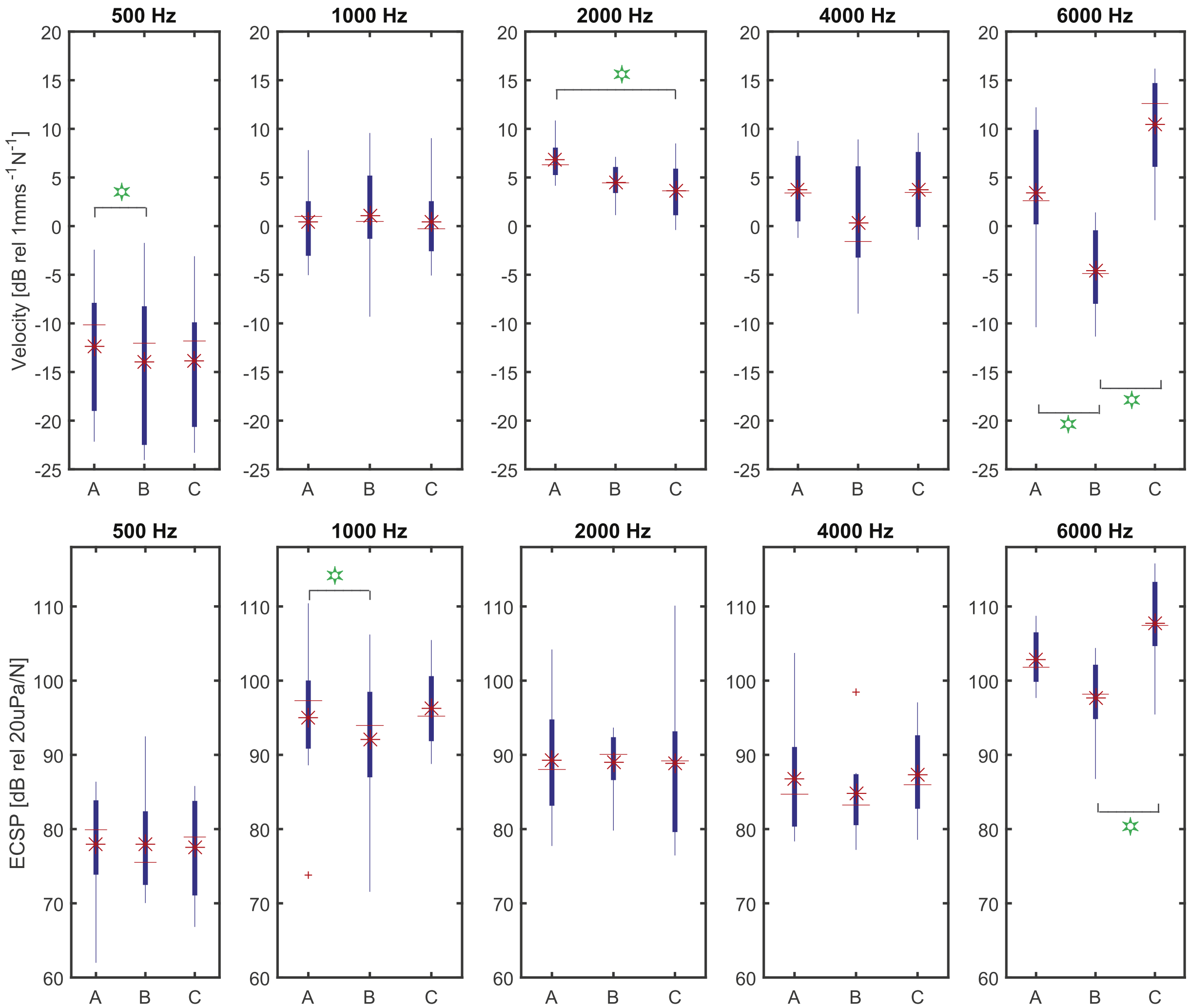


Fig. 5. Data boxplots. Box plot of the LDV measurements (cochlear promontory velocity, top row) and the microphone measurements (ECSP, bottom row) for the three adaptors at selected frequencies (0.5, 1, 2, 4 and 6 kHz). Median values are indicated by the red line, mean values by the red star, 25th and 75th percentiles are included in the boxes and whiskers mark maximum and minimum value (excluding outliers). Potential outliers are marked with a red cross. Data points are classified as outliers if their value lies above (or below) 3/2 times the upper (or lower) quartile, corresponding to a coverage of approximately 99.3% if the data follows a normal distribution. LDV = laser Doppler vibrometer, ECSP = ear canal sound pressure. Bars with green stars indicate the differences that are found significant according to the statistical analysis. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

neither of these alternative components in evoking the cochlear response. Measurements of cochlear promontory velocity and ECSP performed on cadavers are thus considered to be well representative for living subjects.

Cochlear vibrations and ECSP are good alternatives when the research method, as in the current study, cannot be applied in living subjects. Such objective measurements, even though having some limitations, can give valuable information in the design of hearing implants. This is based on the important assumption that cochlear vibration velocity, as well as ECSP, can be used as a measure of relative BC sound perception. In other words, the underlying condition is that an increase in the measured quantity would result in an increased hearing perception, thus in a more satisfactory rehabilitation effect. Such a correlation has been investigated in a number of studies.

Eeg-Olofsson et al. (2013) measured the vibration of the cochlear promontory under direct BC stimulation in living subjects with a middle ear common cavity. BC pure tone hearing thresholds were measured in the same patients. The two measurements showed a common trend and the conclusion was that relative BC hearing sensation in living humans can be reasonably estimated by measuring the relative cochlear vibration response. This correlation, however, was found only at a group level and not individually for each subject. Vibrational and hearing thresholds combined measurements on living subjects were performed also in a study by Reinfeldt et al. (2014), where the conclusion from the study from Eeg-Olofsson et al. (2013) was confirmed.

Concerning the correlation between ECSP and subjective BC hearing thresholds, recent studies by Reinfeldt et al. (2013, 2014) established the direct connection between variations in ECSP and perception during BC stimulation for varying stimulation positions. Nevertheless, it should be noted that those studies were performed on normal hearing subjects with intact tympanic membrane and middle ear, and with conventional transcutaneous stimulation. The altered anatomy of parts of the hearing organ could have an impact on the ECSP, but the authors believe that with the current measurement setup, the observed variation in ECSP is still a valid indicator of shifts in BC sensitivity. This is mainly because the results are presented in relative terms with the microphone being kept in the exact same position during all measurements, ensuring thus that any variation in ECSP level was due to stimulation rather than measurement setup.

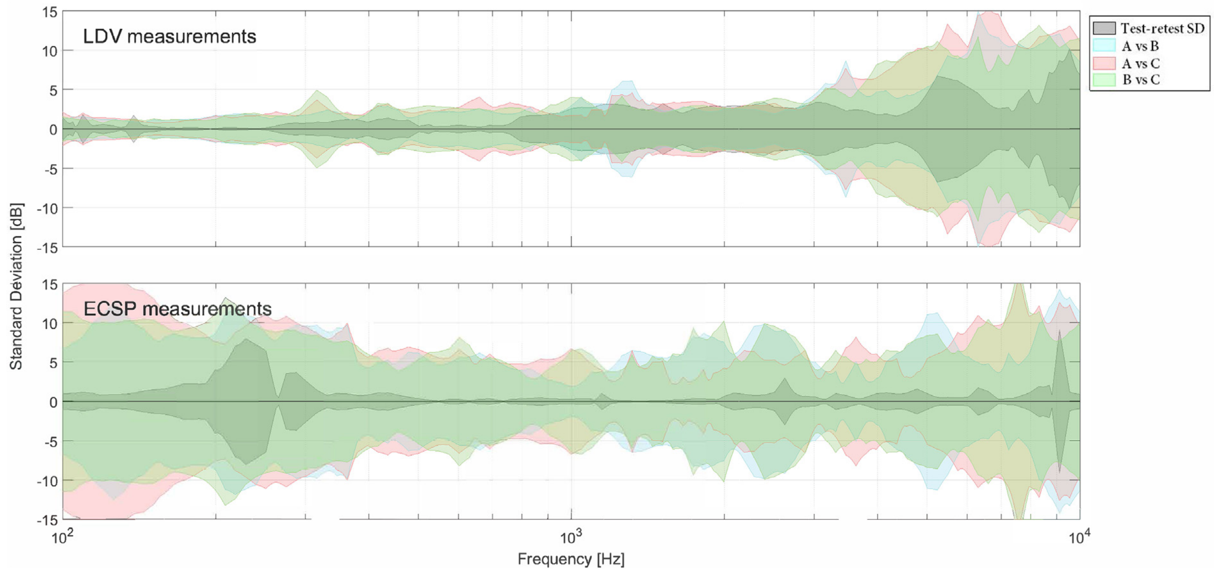


Fig. 6. Test-retest vs between adaptors variability. Shaded plot of the standard deviation (SD) in test-retest measurements compared to the SD of differences between adaptors for LDV measurements (top panel) and microphone measurements (bottom panel). The smaller the shaded area, the lesser the variability in the measurements. LDV = Laser Doppler Vibrometer, ECSP = ear canal sound pressure level.

Both quantities are assumed to be representative for hearing sensitivity estimation and agreement is therefore expected between observations with both techniques. This was the case in most regions, except in the comparison between adaptors A and C. Furthermore, the difference detected in the ECSP compared to cochlear velocity at low frequencies is up to 9 dB higher. This trend is in line with the results from the study by Reinfeldt et al. (2014), where the LDV was not able to detect a threshold shift below 500 Hz which was detected both with tone audiometry and ECSP when comparing BC stimulation at the BAHA position and the BCI position (closer to the cochlea). One possible explanation to this lower sensitivity could be that the beam of the LDV can only measure the promontory velocity in one direction, while ECSP is a three-dimensional measurement. However, a contradictory finding is that the promontory vibration velocity measured with a laser beam perpendicular to the head is either similar or dominating compared to other directions (Stenfelt and Goode, 2005b). This would imply that the essential vibration of the cochlea is captured by only measuring the perpendicular direction. These discrepancies emphasize that BC sound transmission on the human skull is not completely understood.

In the present study, relative difference in ECSP between 100 and 500 Hz is in the range of 5–10 dB between different adaptors, while cochlear velocity shifts are within 2–3 dB range for the same frequency window. The higher difference in ECSP between adaptors is however accompanied by a seemingly higher intra subject variability, which prevents the detection of statistically significant differences. The trend at low frequencies seems nevertheless analogous to the one seen at high frequencies: adaptor A gives generally higher ECSP than B, and adaptors A and B give generally lower ECSP than C.

LDV measurements for adaptor A were found to be significantly different from both B and C in narrow frequency bands around 500 Hz and 600 Hz, as seen in Fig. 4a and b, respectively. The CI in these cases is less than 0.5 dB above the zero line, indicating that the estimated mean difference could hardly be distinguishable from zero. By visual inspection of the LDV data distribution at this same frequency (Fig. 5, top left corner), it can be confirmed that the average and median values for adaptor A are slightly above the ones for adaptors B and C, but the data is generally spread over the same range of values in all three cases. On the other hand, the microphone measurements seem to confirm this finding, thus suggesting a superiority of adaptor A in the range 500–600 Hz. It is nevertheless essential to reduce the CI width in order to be able to draw more secure conclusions from both measurement techniques.

Additional factors other than transmission efficiency have to be considered when designing or choosing a specific transducer and its attachment method. Although transmission of vibrations is a key aspect, equally important are qualities related to the implantation procedure itself. For example, the surgical procedure should be as easy and risk-free as possible, which is an advantage for all patients including children where the anatomy in the surgical field can be demanding. Furthermore the attachment method might be chosen with consideration to the possibility of a future explantation. Several factors could in fact lead to the necessity of removing an implant, such as the need to perform magnetic resonance imaging scans, a failure of the implant or the wish to install an updated version with greatly improved performance: in this case a flat contact surface might be preferable to a more solid osseointegrated screw attachment that would be harder to remove. Moreover, BC transducers have different shapes and sizes that can limit different possible positions for implanting the BCD, which in turn could affect hearing rehabilitation.

5. Conclusions

Three attachment typologies have been tested for direct BC stimulation: (A) small-sized flat surface, (B) extended flat surface and (C) separated twin screw attachment of a bar at its two end portions. The effect of different contact to the bone was evaluated in terms of sound pressure level in the ear canal (ECSP) and cochlear promontory velocity (LDV measurements).

It was found that the differences between attachments were generally small and within ±5 dB except at higher frequencies, where increasing the size of the contact surface (adaptor B) led to generally lower transmission sensitivity, measured by both LDV and ECSP, compared to the small-sized flat surface (A) and the screw attachment (C).

In a planned future study with intact cadaver heads also the transcranial attenuation and other transmission properties such as phase velocity and transmission delay will be investigated.

Conflicts of interest

The co-authors Bo Håkansson, Sabine Reinfeldt and Måns Eeg-Olofsson, act as consultants for Oticon Medical. The remaining authors report no declaration of interest.

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Contribution from each author

a. Rigato, Cristina: contributed to the design of the study, performed measurements and main data analysis and wrote most of the report.
b. Reinfeldt, Sabine: contributed to the design of the study, performed measurements, and provided support in the interpretation of the results and in the writing process.
c. Håkansson, Bo: contributed to the design of the study, performed measurements, and provided support in the interpretation of the results and in the writing process.
d. Fredén Jansson, Karl-Johan: performed measurements, and provided support in the data handling and writing process.
e. Renvall, Erik: participated to the preparation of the study, performed surgeries on the subjects, and provided support in the writing process.
f. Eeg-Olofsson, Måns: contributed to the design of the study, performed surgeries on the subjects, and provided support in the interpretation of the results and in the writing process.

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