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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

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