ADHEAR device in bone conduction audiometry

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Abstract: ADHEAR is a bone conduction hearing aid that uses an adhesive skin adapter. In the current study, the use of ADHEAR as an audiometric bone stimulator was investigated in normal-hearing subjects by comparing it to the standard Radio-Ear B71. Bone conduction thresholds of 15 normal-hearing subjects (aged 21–36 years) were measured four times in a randomized order, twice with the B71 and twice with the ADHEAR. There were no significant differences in test-retest reliability between the two devices. Subjectively rated comfort was better for the ADHEAR. The development of a specific audiometric adhesive bone stimulator may be warranted.

1. Introduction
The measurement of bone conduction (BC) thresholds is an important and routine procedure in clinical audiometry. It helps to establish a diagnosis of BC hearing loss (HL). Measuring BC hearing thresholds is technically more demanding and less reliable than measuring air conduction (AC) thresholds (Carhart, 1950; Studebaker, 1962). The electro-mechanical properties of BC transducers (Frohlich et al., 2018) lead to reduced ranges of frequencies and levels compared to AC transducers. The BC transducers are also typically more difficult to place reliably than the headphones used for AC stimulation. Resulting differences in contact position and pressure have been shown to affect the test-retest variability of BC hearing thresholds (Dobrev et al., 2016).

Bone conduction HL can be treated with hearing aids that use bone vibrators (Pfiffner et al., 2011). Many different designs of such devices have been developed in past decades, some used as purely external systems, and some used transcutaneously or percutaneously with surgically implanted parts (Ellsperman et al., 2021). The ADHEAR (MED-EL Medical Electronics GmbH, Innsbruck, Austria) is a new adhesive BC hearing aid system that has recently been introduced (Dahm et al., 2018). It consists of an audio processor fixed to an adhesive adaptor with a snap coupling and is typically attached to the mastoid plane behind the ear. The clinical efficiency and usability of the ADHEAR device have been demonstrated repeatedly (Gawliczek et al., 2018; Dahm et al., 2019; Kuthubutheen et al., 2020).

We reasoned that such an adhesive BC system could be used as a BC stimulator for clinical audiometry. Possible advantages include easier and more reliable placement of the stimulator, better hygiene by way of disposable contacts only, and increased comfort due to the avoidance of pressure. Herein we report the results of a clinical study using an adapted ADHEAR system as an audiometric BC stimulator in normal-hearing subjects.

2. Methods
2.1 Subjects
Fifteen subjects were enrolled in the study (mean age 28.2 years, range 21–36 years, 9 female and 6 male). The inclusion criteria were AC hearing thresholds not exceeding 15 dB HL at frequencies from 0.25 to 4.00 kHz, normal otoscopy, and no history of otologic disease. Figure 1 shows the AC hearing thresholds of the subjects measured using standard clinical procedures in accordance with the International Organization for Standardization (ISO) ISO 8253-1(ISO, 2010).

2.2 Study devices
BC audiometry was performed with (1) a standard audiometric device (B71 bone conductor with a steel headband P3333, RadioEar, Middelfart, Denmark) and (2) an ADHEAR BC system as a bone vibrator. Both study devices were connected...
to a clinical audiometer (MIDIMATE 602, Madsen Electronics, Taastrup, Denmark), which was calibrated in accordance with standard procedures (ISO 8253-1).

Standard ADHEAR adhesive adapters of the hearing aid system were used to fix the ADHEAR audio processor on the mastoid plane behind the ear. The ADHEAR sound processor was connected to the audiometer through the external audio input via a cable and adjusted to a linear amplification with a unity gain of 32 dB (MED-EL Configuration Software, version 1.0.0, MED-EL Medical Electronics GmbH, Innsbruck, Austria). The volume control was disabled to ensure that no changes could be accidentally made.

2.3 Study protocol

The study protocol was approved by the local ethics committee of the Kanton of Zurich (KEK 2019–01793) and was conducted in accordance with the Declaration of Helsinki. All participants provided written informed consent prior to inclusion in the study. After AC pure tone audiometry established study inclusion (Fig. 1), masked BC hearing thresholds of each participant were measured four times in both ears, twice with the B71, and twice with the ADHEAR device. The sequence of ear sides and devices was randomized. After each measurement, the device was removed (including the adhesive adapter for the ADHEAR) and then placed again for the next measurement. Standard clinical procedures in accordance with ISO 8253-1 were used for threshold measurements, including measurement steps of 5 dB, selection and order of frequencies (0.25, 0.5, 1.0, 2.0, 3.0, and 4.0 kHz), and masking of the contralateral ear. Study subjects were not informed about which device belonged to the standard equipment. The frequency-dependent differences in BC hearing thresholds of the first and repeated measurements were used to characterize the test-retest reliability of the devices.

The subjects rated their subjective experience during the BC audiometry at the end of the procedure via a questionnaire. The questionnaire was structured to address procedure-related issues, and consisted of three questions used to compare the devices with a visual analogue scale of ten units (−5 much better with the ADHEAR; 0 = equal experience; +5 much better with the B71). The three questionnaire prompts were:

![Fig. 1. (A) Left and (B) right AC hearing thresholds. Data are shown as quartiles (boxes), medians (horizontal lines in boxes), mean values (black line), minimums and maximums (error bars), and with circles representing individual values.](image-url)
(Q1) How comfortable was it putting on/taking off the device?
(Q2) How was the pressure on your head?
(Q3) What is your overall device preference?

3. Results

3.1 Comparison of test-retest reliability

A total of 720 BC hearing thresholds were determined (30 ears, six frequencies, test-retest, two devices). Overall differences between the first and repeated BC audiometry for both devices are summarized in Fig. 2(A). There was no significant difference between the test-retest reliability of the devices (B71 vs ADHEAR; respective means 0.53 vs –0.14 dB, standard deviations 4.89 vs 5.80 dB, paired t-test p = 0.46). Frequency-dependent test-retest reliability is shown in Fig. 2. Data derived from all frequencies were normally distributed (D’Agostino-Pearson normality test) and there were no significant differences between the two devices at any frequency (one-way analysis of variance test with Bonferroni’s correction).

3.2 ADHEAR correction values relative to B71

We are unaware of any other trials using ADHEAR for threshold measurements or calibration data for hearing thresholds with ADHEAR. Figure 3 shows mean ADHEAR and B71 thresholds in dB HL as calibrated for B71 for both sides of the 15 subjects. Relative correction values to fit ADHEAR BC thresholds to those of the B71 are provided in Table 1. It is important to note that differences in the frequency responses of both devices in Fig. 3 are due to several factors, such as the different electro-mechanical properties of the transducers, differences in mechanical point impedances, and the different type of coupling the device to the mastoid (Chang and Stenfelt, 2019).

3.3 Subjective evaluation

No difficulties were noted during application or removal of the patches. No incidences of skin irritation occurred. Comparisons of ratings of comfort associated with ADHEAR and B71 provided by the test subjects are shown in Fig. 4. There were no significant differences (one sample Wilcoxon signed rank p = 0.904) between the two devices with respect to comfort associated with putting them on and taking them off. The first three subjects rated the comfort of putting on/off of the ADHEAR as +4. This may have been due to lack of training for the audiologist in handling the ADHEAR prior to the study.

Pressure on the head and the overall comfort associated with the ADHEAR were rated significantly (one sample Wilcoxon signed rank p < 0.001, respective p < 0.02) better than those associated with the B71.

4. Discussion

The current study investigated the principle of using a bone vibrator attached via an adhesive patch as an audiometric BC stimulator. ADHEAR was used as an adhesive vibrator, which is a BC hearing aid not specifically designed as an
audiometric bone vibrator. Features such as frequency response with resonances, energy efficiency, mass, and cosmetic aspects are optimized in the ADHEAR for the purposes of a hearing aid, not for those of a vibrator attached to an audiometer. We compared the ADHEAR hearing aid system connected to an audiometer via a cable with a standard B71 stimulator, a bone vibrator that is specifically designed as an audiometric device.

Given these pre-conditions, the non-linear frequency response of the ADHEAR with a resonance peak at 1–2 kHz was not surprising. Even so, the ADHEAR compared favorably with the B71 stimulator with respect to BC threshold measurements in normal hearing subjects. Both devices exhibited similar test-retest reliability, and the ADHEAR was rated better for overall comfort by the test-subjects. The handling of the ADHEAR device was straightforward and at least as convenient as that of the standard B71 device.

The present study suggests that several advantages may be associated with using an adhesive BC stimulator in audiometry. The skin patch is easy to place on almost any mastoid plane before the vibrator is connected. In addition, the skin patch guarantees a fix position during audiometry. Depending on the shape of the head, the standard steel headband of the B71 system can be more difficult to fit, and it is prone to displacement during the measurement procedure. The most obvious difference is the lack of pressure during testing with the adhesive connection. In the current study, the test subjects rated the placement of the two systems as equal but reported a lack of pressure and better overall comfort associated with the ADHEAR. Another advantage is the use of a disposable, single-use attachment that can provide enhanced safety and hygiene.

Notably, the current investigation was a preliminary examination using an adjusted device primarily constructed as a BC hearing aid. The lack of pressure in adhesive devices and differences in thickness or tightness of the skin over the mastoid may be associated with poorer transfer of vibration to the cochlea and reduced dynamic range, even though

| Frequency (Hz) | 250 | 500 | 1000 | 2000 | 3000 | 4000 |
|---------------|-----|-----|------|------|------|------|
| Correction (dB) | -32.2 | -32.3 | -22.9 | -11.9 | -35.1 | -36.3 |
| Standard deviation of correction (dB) | 6.6 | 8.5 | 5.1 | 4.8 | 5.0 | 4.8 |
| Lower an upper 95% | -35.8 | -37.0 | -25.8 | -14.6 | -37.9 | -39.0 |
| Confidence intervals (dB) | -28.5 | -27.7 | -20.1 | -9.3 | -32.4 | -33.7 |

Fig. 3. (A) Left and (B) right BC hearing thresholds with standard deviations for tests and retests with B71 (blue and red lines) and with ADHEAR (black lines) in dB HL as calibrated for the B71. Data are shown as solid lines (1st test), dashed lines (retest), means (circles and triangles), and standard deviations (error bars).
recent measurements in cadaver heads showed comparable promontory vibrations and surface motions of the skull when using adhesive or pressure coupling to the skin (Dobrev et al., 2021).

Further development may yield a specific audiometric adhesive stimulator with both a more linear frequency response and more power, particularly in the low and high frequency range of BC stimulation. Investigation of such a future adhesive device should include the measurement of reference equivalent threshold force levels and calibration values obtained by step sizes of less than 5 dB. We abstained from such measurements in this proof-of-concept trial with a commercial hearing aid device. In the present study, the audiometry was performed in step sizes of 5 dB increments according to ISO 8253-1:2010 (ISO, 2010), resulting in uncertainties for measuring and comparing actual hearing thresholds.

The use of adhesive attachments in clinical audiometry may result in the disadvantage of higher costs and more waste. Thus, the development of a specific disposable attachment for short-term audiometric use may be just as important. It may help to make the audiometric procedure less costly, simpler, and even more comfortable. We used the regular patch of the ADHEAR system with its snap connection as an adhesive device. As part of the limitations of using a hearing aid system as an audiometric stimulator, the patch is designed for long-term use of a few days, not for short-term use in audiology. A patch specifically developed for audiology may also help to improve other features such as the frequency response. Testing in a clinical population rather than normal-hearing subjects will be necessary to further assess the true potential of an adhesive BC stimulator in clinical audiology. In such trials, it may be wise to use an adhesive vibrator specifically designed for audiology. ADHEAR may prove to have a too limited dynamic range for testing subjects with sensorineural HL. Again, this limitation may be overcome via a new mechanical design that includes larger mass and possibly a larger connection. Cosmetic aspects or power-efficiency will not be of importance with respect to an audiometric testing device.

5. Conclusions and outlook

The results of the current study demonstrate the principal usability of an adhesive connection for bone vibrators in audiology. A vibrator system specifically designed for such use may include the advantages of easier placement with a reduced chance of displacement during examination, more comfort for both the patient and examiner, and enhanced safety and hygiene by way of single-use components. The drawbacks of such a system may include increased costs and waste because of single-use fixation components, and the possibility of skin irritation caused by the adhesive patch. The development of a specific system will be needed, as will testing in hearing-impaired subjects.

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References and links

Carhart, R. (1950). "Clinical application of bone conduction audiometry," Arch. Otolaryngol. 51, 798–808.
Chang, Y., and Stenfelt, S. (2019). “Characteristics of Bone-Conduction Devices Simulated in a Finite-Element Model of a Whole Human Head,” Trends Hear. 23, 233121651983605.
Dahm, V., Auinger, A. B., Liepins, R., Baumgartner, W. D., Riss, D., and Arnoldner, C. (2019). "A randomized cross-over trial comparing a pressure-free, adhesive to a conventional bone conduction hearing device," Otol. Neurotol. 40, 571–577.
Dahm, V., Baumgartner, W. D., Liepins, R., Arnoldner, C., and Riss, D. (2018). "First results with a new, pressure-free, adhesive bone conduction hearing aid," Otol. Neurotol. 39, 748–754.
Dobrev, I., Farahmandi, T. S., Huber, A. M., and Roosli, C. (2021). “Experimental evaluation of the adhear, a novel transcutaneous bone conduction hearing aid,” Laryngorhinootologie 100, 811–817.

Dobrev, I., Stenfelt, S., Röösli, C., Bolt, L., Pfiffner, F., Geric, R., Huber, A., and Sim, J. H. (2016). “Influence of stimulation position on the sensitivity for bone conduction hearing aids without skin penetration,” Int. J. Audiol. 55, 439–446.

Ellisperman, S. E., Nairn, E. M., and Stucken, E. Z. (2021). “Review of bone conduction hearing devices,” Audiol. Res. 11, 207–219.

Frohlich, L., Plontke, S. K., and Rahne, T. (2018). “Influence of transducer types on bone conduction hearing thresholds,” PLoS One 13, e0195233.

Gawliczek, T., Munzinger, F., Anschuetz, L., Caversaccio, M., Kompis, M., and Wimmer, W. (2018). “Unilateral and bilateral audiological benefit with an adhesively attached, noninvasive bone conduction hearing system,” Otol. Neurotol. 39, 1025–1030.

ISO (2010). ISO 8253-1:2010, Acoustics—Audiometric Test Methods—Part 1: Pure-Tone Air and Bone Conduction Audiometry (ISO, Geneva, Switzerland).

Kuthubutheen, J., Broadbent, C., Marino, R., and Tavora-Vieira, D. (2020). “The Use of a novel, nonsurgical bone conduction hearing aid system for the treatment of conductive hearing loss,” Otol. Neurotol. 41, 948–955.

Pfiffner, F., Caversaccio, M. D., and Kompis, M. (2011). “Audiological Results with Baha® in Conductive and Mixed Hearing Loss,” Adv. Otorhinolaryngol. 71, 73–83.

Studebaker, G. A. (1962). “Placement of vibrator in bone-conduction testing,” J. Speech Hear. Res. 5, 321–331.