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To cite this article: Koenraad S. Rhebergen (2022) Extended high-frequency bone conduction audiometry Calibration of bone conductor transducers in the conventional and extended high-frequency range, *International Journal of Audiology*, 62:2, 182-191, DOI: [10.1080/14992027.2022.2034059](https://doi.org/10.1080/14992027.2022.2034059)

To link to this article: <https://doi.org/10.1080/14992027.2022.2034059>



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ORIGINAL ARTICLE



Extended high-frequency bone conduction audiometry Calibration of bone conductor transducers in the conventional and extended high-frequency range

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ABSTRACT

Objective: To monitor ototoxicity, air conduction (AC) extended high frequency (EHF) thresholds can be measured up to 16 kHz. However, conductive hearing loss might influence these results. This is unfortunate because the EHF thresholds are important to follow the impact of ototoxic medication during therapy. Therefore a suitable bone conduction (BC) transducer and norm values for EHF BC measurements are needed.

Design: In this study three different BC transducers were used: the B71 (Radioear), the KH70 (Präcitrone), and the KLH96 (Westra). Hearing thresholds were measured from 0.125 to 16 kHz using AC transducers (Telephonics TDH39, Sennheiser HDA200), and BC thresholds from 0.25 to 8 kHz with the B71, and from 0.25 to 16 kHz with the KLH96 and KH70.

Study sample: 60 ears of 30 normal hearing subjects were measured.

Results: The KLH96 showed the highest output for the high frequencies, and distortion measurements were similar to the KH70. The results show that EHF measurements are possible using the KLH96 and KH70 bone conductors.

Conclusion: EHF BC measurements are reliable when using the KLH96 and KH70 bone conductors. The extended force sensitivity of the used artificial mastoid should be determined for a proper EHF BC calibration.

ARTICLE HISTORY

Received 25 June 2021
Revised 14 January 2022
Accepted 20 January 2022



KEYWORDS


Calibration bone conductors; extended high-frequency audiometry; 'false' air-bone gap at 4kHz; Bone conduction thresholds between 250Hz and 16kHz

Introduction

The treatment of cancer often includes platinum chemotherapeutics and other free-radical inducing therapies which can cause ototoxicity in up to 60–70 percent of patients at frequencies of 8 kHz and above (e.g. Brooks and Knight 2018). Initially, the hair cells at the base of the cochlea, where the high-frequency sounds are encoded, are damaged. Clinically this is seen as a bilateral symmetrical loss of hearing that begins in the high frequencies and progresses to lower frequencies with increased cumulative doses. Monitoring hearing during platinum therapy is important to inform treatment management, since in some treatment regimens it is possible to decrease the dose of cisplatin to avoid further hearing loss. Monitoring for ototoxicity can be obtained by hearing threshold measurements using air conduction (AC) transducers or bone conduction (BC) transducers. Generally, BC thresholds are measured for frequencies up to 4 kHz while AC thresholds are measured for much higher frequencies up to 16 kHz. For ototoxicity monitoring the hearing thresholds for higher frequencies are of interest. Unfortunately, monitoring the hearing of patients treated with these types of chemotherapeutics can often be hindered by middle ear dysfunction, causing conductive hearing loss due to the weakening of

the immune system. As a result, the AC extended high-frequency (EHF) thresholds are elevated (e.g. Sharma, Munjal, and Panda 2012; Cordeiro et al. 2018; Li et al., 2020). Cordeiro et al. 2018 followed a group of patients for up to 180 days after the first episode of otitis media. The initially elevated EHF thresholds were mostly reduced but a part of the elevated EHF thresholds was still present after 180 days. In their study, the EHF thresholds were only measured with an AC headphone. The results suggested that the elevated thresholds after an episode of otitis media were at least partially due to EHF conductive hearing loss and that there might still be an air-bone gap present after 180 days. This diagnostic problem may be avoided if monitoring of high-frequency (i.e. > 4 kHz) pure-tone hearing thresholds could be done using BC transducers. The search for a suitable EHF bone conductor is of particular importance at the University Medical Centre Utrecht (UMCU). The Audiological department of the Children's Hospital (Wilhelmina Children's Hospital, WKZ) of the UMCU is responsible for the monitoring and revalidation of hearing in cancer patients under the care of the Princess Máxima Centre for Paediatric Oncology. This centre provides acute treatment to more than 500 children per year with specific types of cancer from all around the Netherlands. Improving the diagnostics of monitoring for ototoxicity during

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 Supplemental data for this article can be accessed online at <https://doi.org/10.1080/14992027.2022.2034059>.

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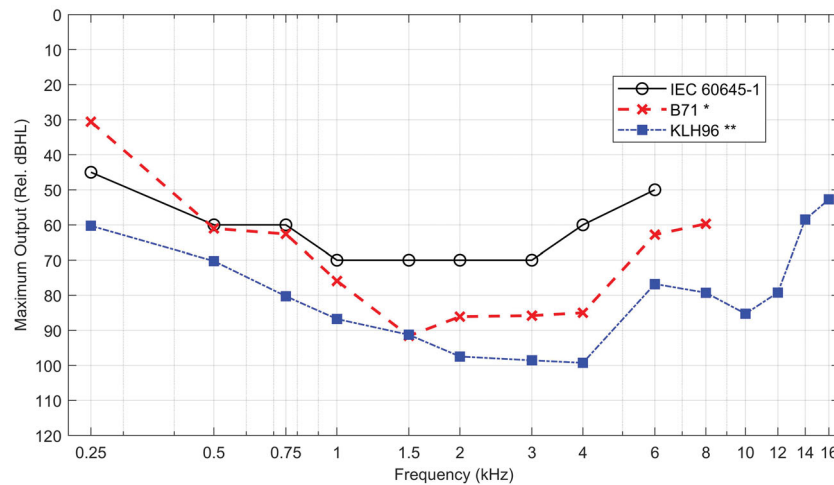


Figure 1. The minimum hearing level required for a bone conductor according to the IEC 60645-1 (circles with solid black line). The maximum output level in dB HL that can be generated by the B71* (dashed red line with crosses) and the KLH96** (dashed-dotted blue line with squares). *data taken from Jansson et al. (2015); **data taken from Westra, manufacture of the KLH96.

platinum therapy will inform treatment management and in some treatment regimens may decrease the dose of cisplatin to avoid further hearing loss. Therefore it is important to investigate the feasibility of high-frequency BC thresholds up to 16 kHz.

The widespread B71 BC transducer (Radioear) and its successor the B81 (Radioear) are generally only used for pure tone threshold measurements no higher than 4 kHz. BC standards thresholds are available for frequencies up to 8 kHz (ANSI S3.6 and ISO 389-3). However, there is some debate about the accuracy of the ISO standard for 4 and 8 kHz frequency (e.g. Margolis, Eikelboom, and Swanepoel 2019). In addition, the frequency response of most BC transducers in the past (i.e. Radioear B71 & B72, Oticon A 20, and the Bosch BKH 10) are characterised by steep resonance peaks and sharp drops at frequencies higher than 8 kHz (Richter and Frank 1985). Therefore a search for types of BC transducers and their frequency specifications was needed. This yielded two types of potential candidate transducers; the discontinued KH70 (Präcitronic) and the KLH96 (Westra). The KH70 BC transducer has been used for the development of the ISO 389-3 norm for hearing levels between 0.25 and 8 kHz (Richter and Brinkmann 1981). Additionally, several studies have investigated this transducer to determine hearing thresholds for higher frequencies (e.g. Richter and Frank 1985; Hallmo, Sundby, and Mair 1994). Unfortunately, this device is no longer manufactured as of 2006. No peer-reviewed literature was found about the KLH96 BC transducer, but the frequency specifications supplied by the manufacturer met the requirements.

This study investigates the specifications and characteristics of the B71, KH70, and KLH96 BC transducers and test measure BC thresholds for frequencies up to 16 kHz. The B71 transducer is included as a standard at frequencies up to 8 kHz, while the KH70 serves as a reference for the higher frequencies up to 16 kHz. The new B81 (not used in this study) has a higher output for frequencies below 1.5 kHz and less distortion up to 1 kHz compared to the B71 (Jansson et al. 2015). However, like the B71, the frequency response of the B81 is limited to frequencies up to 8 kHz. To limit BC measurements only the B71 reference bone vibrator was used in this study. The BC thresholds were compared with AC thresholds for frequencies between 0.25 kHz and 8 kHz obtained with a TDH39 headphone and frequencies between 8 and 16 kHz with an HDA200 headphone. For both

AC transducers RETSPL (Reference Equivalent Sound Pressure Level) values are available in a standard (ISO 389-3; ISO 389-5; ANSI S3.6). To assess the reproducibility of the measurement, the measurements with the KLH96 transducers were performed twice on the right ear, with repositioning of the transducer between measurement sessions.

Materials and methods

Transducers

In this section a description of the transducers is given. The two air conduction (AC) headphones and their calibration are briefly described below. As suggested by the ISO389-9 the observed AC thresholds are used as a reference for the bone conductor (BC) measurements. The specifications and calibration of the three BC transducers are described in more detail in the section *Bone Conduction transducers*.

Air conduction transducers

In this study two types of AC headphones are used: the TDH-39 (Telephonics, USA) and the Sennheiser HDA 200 headphones (Sennheiser electronic GmbH and Co, Germany). The TDH39 is a supra-aural headphone suitable for pure tone audiometry up to 8 kHz. The HDA200 is a circumaural headphone suitable for EHF audiometry up to 16 kHz. The TDH39 headphone was calibrated with a Bruel & Kjaer 4153 artificial ear (IEC 60318-1 coupler) according to the ISO 389-1 and ANSI S3.6 for frequencies between 0.125 and 8 kHz. The HDA200 headphone was calibrated with a Bruel & Kjaer 4153 artificial ear with the flat plate (IEC 60318-1 + Type 1 adapter) according to the ISO 389-5 and ANSI S3.6 for extended high frequencies between 8 and 16 kHz. The Sennheiser HDA200 is out of production. Recently the Radioear DD450 headphone was made available which is designed to replicate the characteristics of the HDA200 (Smull, Madsen, and Margolis 2019) and has the same RETSPL values (ANSI S3.6-2018).

Bone conduction transducers

Three different BC transducers are used: the B71 (Radioear, Middlefart, Denmark), the discontinued KH70 (Präcitronic,

Table 1. The used frequency dependent Force Sensitivity values (dB) with a static load of 5.4 N relative to the value at 1 kHz (re 1 V/N). The values between 0.25 and 8 kHz are taken from the calibration certificate of our Bruel & Kjaer 4930 artificial mastoid (serial number 2548208) and between 10 and 16 kHz from our lab results. The values between 10 and 16 kHz at the bottom are taken from Richter and Frank (1985, Figure 1).

Frequency (Hz)	250	500	750	1000	1500	2000	3000	4000	6000	8000	10000	12500	14000	16000
Present study	-1.0	-1.0	-0.5	0.0	1.0	1.8	1.7	-4.0	-10	-10	-8.5	-5.5	-2.4	17.2
Richter and Frank (1985)	-	-	-	-	-	-	-	-	-	-11	-10	-9	-7	-4

Dresden, Germany), and the KLH96 (Westra, Meitingen, Germany) respectively.

Supplementary data Figure 1 shows a picture of the three bone conductors to give an impression of their sizes. Name and manufacturer as well as dimensions (length x width x height), contact area and electric impedance are stated in Supplementary data Table 1. Each of the transducers has a circular contact surface of approximately 1.75 cm^2 (± 0.25) and should be used with a static force of $5.4 \pm 0.5 \text{ N}$ as in accordance with the standard (ANSI S3.6-2018; IEC 60645-11, 2017).

Calibration of the bone conduction transducers

The BC transducers were calibrated according to the ANSI S3.6-2018 with a Bruel & Kjaer 4930 artificial mastoid with a static force of $5.4 \text{ N} \pm 0.5$. The output of the artificial mastoid was measured in dB using a Bruel & Kjaer sound level metre (type 2250). The voltage level was converted to the corresponding force level in dB relative to $1 \mu\text{N}$ using the correction factor of the used artificial mastoid (122.6 mV/N) and the frequency-dependent force sensitivity. The IEC 60318-6 standard for calibration of the Bruel & Kjaer 4930 artificial mastoid only provides a description up to 8 kHz. Therefore, the force sensitivity values between 0.25 and 8 kHz were taken from the recent calibration certificate of our Bruel & Kjaer 4930 artificial mastoid (serial number 2548208). The values between 10 and 16 kHz were measured with aid of a Bruel & Kjaer type 8000 impedance head and a Bruel & Kjaer type 4810 mini shaker according to the IEC 60318-6 and Bruel & Kjaer type 4930 and type 3505 manual (for more details on this measure the reader is referred to Richter and Frank 1985). The measurements were repeated 4 times after repositioning the impedance head and mini shaker on the centre of the rubber pad of the artificial mastoid. The 5 measurements between 0.25 and 16 kHz were nearly the same. The average measurement values for 0.25 kHz up to 8 kHz were virtually the same compared to the calibration certificate. Therefore it was assumed that the measurements up to 16 kHz are valid. Other extended BC studies (e.g. Frank and Ragland 1987; McDermott et al. 1991 and Hallmo, Sundby, and Mair 1994) assumed that the force sensitivity values between 10 and 16 kHz measured by Richter and Frank (1985) could be used to transform the dB voltage level into force levels. Table 1 shows the frequency-dependent force sensitivity levels used in this study and the values used by Richter and Frank (1985) and others. On the Bruel & Kjaer 4930 artificial mastoid used in this study and the Richter & Frank study, the differences between the measurements up to about 12 kHz are small, but at 12.5, 14, and 16 kHz there is a clear difference that may have a large impact on the calibration of the BC if the Richter & Frank values were used. Like Richter & Frank, a sharp decay above 16 kHz down to 18 kHz was observed (see for more details Supplementary data Figure 2). According to Bruel & Kjaer, the resonance frequency of the type 8000 impedance head lies at 80 kHz. Therefore frequency response up to 20 kHz is assumed to be linear. The frequency response of the type 4810 mini shaker is linear up to 18 kHz. As a result, the measured force sensitivity values up to

16 kHz are most likely related to the properties of the type 4930 artificial mastoid (i.e. the rubber pad on the coupling surface for the bone vibrators).

Values were available (ISO 389-3) for frequencies from 0.25 kHz up to 8 kHz RETVFL (Reference Equivalent Threshold Vibratory Force Level), and therefore the force levels could be converted into hearing levels (HL) for these frequencies. For any measurement frequencies above 8 kHz, the calibration was done in force levels (dB $1 \mu\text{N/V}$).

Table 2 shows the average BC threshold levels in force levels (dB $1 \mu\text{N/V}$) between 8 and 16 kHz reported by Richter and Brinkmann 1981; Richter and Frank 1985; Frank and Ragland 1987; McDermott et al. 1991 and Hallmo, Sundby, and Mair 1994 observed in young normal-hearing listeners measured with the KH70 bone conductor. In the same table, the weighted mean values are shown to account for the different number of ears per study. The differences between the mean and weighted mean are very small and are likely not clinically significant. There was no peer-reviewed paper found with BC threshold measured with the KLH96 bone conductor. The manufacturer Westra Electronics GmbH provided us with a technical calibration report by Physikalisch-Technische Bundesanstalt (PTB Report 1997) with EHF thresholds between 8 and 16 kHz in 17 ears obtained with a KLH96. This PTB report does not mention the RETVFL values below 8 kHz nor the repeatability of the thresholds.

The drawback of the KH70 bone conductor was that the maximum output level in the EHF range was limited to about 55 dBHL at 8 kHz down to 30 dBHL at 16 kHz (Richter and Frank 1985). Therefore the KH70 is suitable for conventional BC audiometry up to 8 kHz but reaches its limits with listeners with mild hearing loss as well as older listeners (age >30 years, e.g. Hallmo, Sundby, and Mair 1994). The dashed line in Figure 1 shows the maximum output level relative to the hearing levels (dB HL) for the B71 bone conductor. This data was taken from Jansson et al. 2015. The dashed-dotted line with square symbols represents the maximum output values according to the specifications of the manufacture of the KLH96. The values up to 8 kHz are related to the RETVFL values of the ISO389-3. Values between 10 and 16 kHz are related to the average RETVFL value from the literature (see Table 2). The solid line shows the minimum hearing level required according to the IEC 60645-1. The B71 is not in compliance with the norm at 0.25 kHz. The KLH96 and the new B81 (not displayed in Figure 1) are in agreement with the norm (for details about the B81 the reader is referred to Jansson et al. 2015). If it is assumed that the RETVFL values of Table 2 are similar for the KLH96, then its maximum output in the extended high frequencies up to 16 kHz has more headroom than the discontinued KH70 (55 vs 30 dBHL).

Frequency response characterisation

The frequency response for all three transducers coupled on the Bruel & Kjaer 4930 artificial mastoid was measured using a white noise signal. Measurements were performed with an input level of 1 Vrms. Post-processing frequency analysis with a fast Fourier transform (FFT) function was used to determine the frequency

Table 2. Mean, and weighted mean extended high frequency bone conduction threshold levels observed in normal hearing listeners measured with a KH70 bone conductor. These values (dB re. 1 μ N/V) are reported by the authors below.

Study	Ears	Age (years)	Gender	Frequency (kHz)							
				8	9	10	11	12.5	14	16	
Richter and Brinkmann 1981	50	18–30	Both	39.5							
Richter and Frank 1985	16	18–23	Both	36		36		41.6	47.4	54.8	
Frank and Ragland 1987	30	19–27	Both	36.8		34.4		39.1	46.2	53.6	
McDermott et al. 1990	28	21–49	Both	35.2	37.9	38.6	40	42.9			
McDermott et al. 1991	95	11–49	Both	35.3	36.6	38.2	38.6	39			
Hallmo, Sundby, and Mair 1994	54	18–24	Male	37	42	39	38	39	48	59	
Hallmo, Sundby, and Mair 1994	56	18–24	Female	42	42	39	43	39	43	59	
Total ears	329			329	233	279	233	279	156	156	
Mean RETVFL (dB)				37.4	39.6	37.5	39.9	40.1	46.2	56.6	
Weighted mean RETVFL (dB)				37.5	39.3	38.0	39.7	39.6	45.8	57.5	

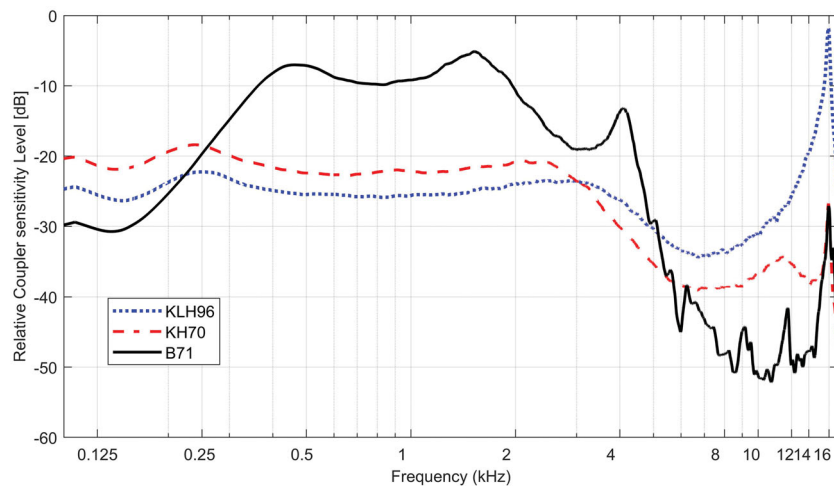


Figure 2. The relative frequency response of the B71, KLH96 and KH70 bone conductor with an input level of 1Vrms.

spectrum of the measured signals. Figure 2 shows the relative frequency response of the three bone conductors used in this study.

Total harmonic distortion

The total harmonic distortion (THD) at all octave frequencies between 0.125 and 4 kHz (for the B71) or between 0.125 and 16 kHz (for the KH70 and KLH96) was measured according to the IEC 60268-3 (see Supplementary data Figure 2). For more details readers are encouraged to read a study by Jansson et al. 2015. Only the THD up to 4 kHz are shown in Supplementary data Figure 3 because the B71 is not suitable for pure tone audiometry above 4 kHz due to its steep frequency response above 4 kHz (see Figure 2). The THD of the KH70 and KLH96 are negligible between 0.125 and 16 kHz measured at an input level of 1Vrms.

Test subject measurements

The study protocol, informed consent forms, questionnaires, and information sheets were submitted to the Ethical Review Board of the UMCU and written approval was given for the study (SL/mb/18/032366).

Participants

In total 30 test subjects were included (13 male and 17 female) with a mean age of 25.3 years (SD = 2.4, Range = 18–29).

Subjects were excluded if they had a history of ear infections and other ear problems, middle ear surgery, or abnormal tympanometry results.

Measurement procedure

At the start of the procedure, the informed consent form was taken along with a questionnaire about the test subjects' hearing. Subsequently, the measurements were performed in an audiometric cabin that meets the desired background noise levels stated in (ISO8253-1).

First, hearing level thresholds at all octave frequencies from 0.125 to 8 kHz were measured using the TDH 39 headphones and the B71 bone transducer. The test ear was uncovered during BC testing. For each measurement frequency, pure tone thresholds were obtained via the pure tone audiometry protocol as described by the ISO (ISO8253-1), with an adjusted step size of 2 dB up and 4 dB down to gain more accuracy. The contralateral ear was masked using narrow-band noise via a TDH-39 headphone. A minimum of 30 dB HL of narrow-band noise was used up to 8 kHz. For the lowest measured frequencies (0.25 and 0.5 kHz), the noise level was increased to 50 dB HL to account for a possible occlusion effect of about 20 dB (Dean and Martin 2000). Next, a middle ear immittance measurement was performed using a Madsen Zodiac or an Interacoustics AT235 tympanometer. To proceed to the third step, AC hearing thresholds level of each ear were not allowed to exceed 20 dB at any measurement point in the range from 0.125 to 8 kHz and

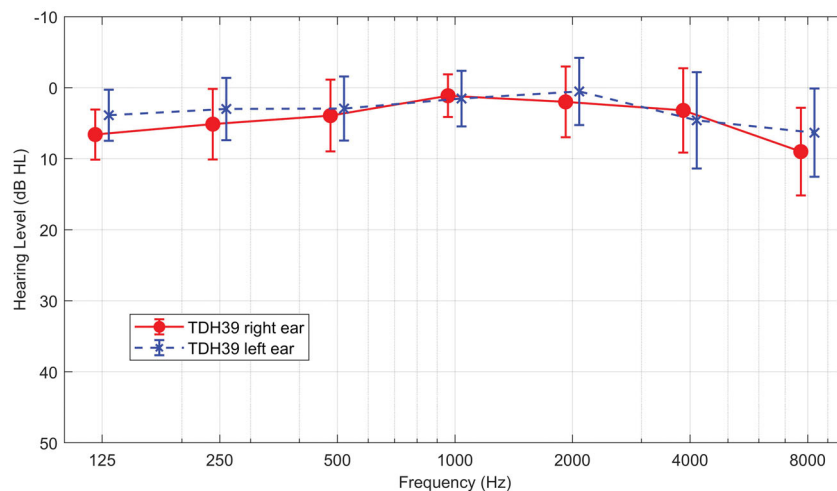


Figure 3. Mean Air Conduction Hearing Levels (dB HL) measured with the TDH39 headphone of the left ear (dashed blue line with cross symbols) and the right ear (solid red line with circle symbols) for pure tones between 0.125 and 8 kHz. Error bars indicate the standard deviation.

tympanometry results would have indicated a normal function of the middle ear (type A). Then the remaining measurements for the study were performed. The HDA200 headphones were used to determine the AC hearing thresholds at 8, 10, 12.5, 14 and 16 kHz. All three BC transducers were used to measure the octave frequencies between 0.25 and 8 kHz. Additionally, the KH70 and KLH96 were used to measure the pure tone hearing thresholds at 10 kHz, 12.5 kHz, 14 kHz, and 16 kHz. Pure tone hearing levels from 0.25 kHz up to 8 kHz were measured in the standard audiometry module of a Decos Audiometer. Additionally, the pure tone hearing levels from 8 kHz up to 16 kHz were measured in the EHF audiometry module of a Decos Audiometer, meaning the 8 kHz threshold was measured twice. The influence of the transducer placement was investigated by repositioning the KLH96 transducer on the right side of the subject's head and comparing the test and retest pure tone thresholds from 0.25 to 16 kHz.

Statistics

The measured AC and BC thresholds were summarised in terms of means and standard deviations. A repeated-measures ANOVA was used to determine the significance of differences between means of the different transducers. Furthermore, the post Hoc Bonferroni was used to examine the differences between the measured frequency thresholds within a transducer. A *t*-test was used to compare the average BC thresholds found in the literature and the observed BC thresholds in this study.

Results

Pure tone audiometry (up to 8 kHz)

Figure 3 shows the mean AC hearing levels between 0.125 and 8 kHz measured with the TDH39 headphone at the left and right ear. All subjects had hearing levels better than 20 dBHL. The MANOVA test showed no significant differences between the two ears except for the 0.125 kHz ($p < 0.05$). Both ears show (insignificant) higher thresholds at the middle frequencies compared to the low and high frequencies.

Figure 4 shows the mean BC hearing levels of both ears combined between 0.25 and 8 kHz measured with the B71, KH70, and KLH96 bone conductors. The MANOVA test showed no

significant differences between the two ears ($p > 0.05$) and a significant difference between frequencies ($p < 0.05$). There were no significant interactions. Bonferroni Post-Hoc analysis showed no differences between the bone conductors between 0.5 and 2 kHz. At 250 Hz there was a significant difference between the KH70 and both other two BC transducers, and no differences between the B71 and KLH96. At 4 and 8 kHz all three BC transducers were significantly different ($p < 0.05$).

Figure 5 shows the mean air-bone gaps of both ears combined between 0.25 and 8 kHz measured with the B71, KH70, and KLH96 bone conductor relative to the AC thresholds (i.e. TDH39). The MANOVA test showed significant differences between the AC thresholds and the BC thresholds. Bonferroni Post-Hoc analysis showed significant differences between the TDH39 and all three BC transducers at 4 and 8 kHz. At 4 kHz the average measured air-bone gap for the B71, KLH96 and KH70 was 13.3 dB (SD: 9.3), 9.3 dB (SD: 6.6) and 6.3 dB (SD: 6.2) respectively. At 8 kHz the average measured air-bone gap for the B71, KLH96 and KH70 was 3.0 dB (SD: 6.5), 8.3 dB (SD: 7.9) and 15.5 dB (SD: 8.5) respectively.

Extended high-frequency audiometry (8–16 kHz)

Figure 6 shows the mean EHF AC hearing levels (dB HL) measured in all ears ($n = 60$).

Although all subjects had normal hearing levels measured with the TDH39 headphone between 0.125 and 8 kHz, one ear had a threshold of 20 dBHL at 8 kHz measured with the HDA200 headphone (i.e. ≥ 20 dBHL). At higher frequencies (i.e. 10, 12.5, 14, and 16 kHz) 57, 56, 53, and 46 ears respectively had normal hearing thresholds. Because the HDA200 serves as a reference for the EHF bone conductors only the normal ears (i.e. < 20 dBHL) were used for further analysis. The ANOVA Analyses showed no significant differences between both ears ($p > 0.05$) and a significant difference between frequencies ($p < 0.05$). There were no significant interactions. Bonferroni Post-Hoc analysis showed significant differences between 14 and 16 kHz. The frequencies 8 up to 14 kHz were not significantly different ($p > 0.05$).

Figure 7 shows the mean EHF BC thresholds (dB FL) measured with the KH70 and the KLH96 bone conductor of both ears combined between 8 and 16 kHz. At 16 kHz 5 ears were unable to hear a signal with the KH70 bone conductor. Because

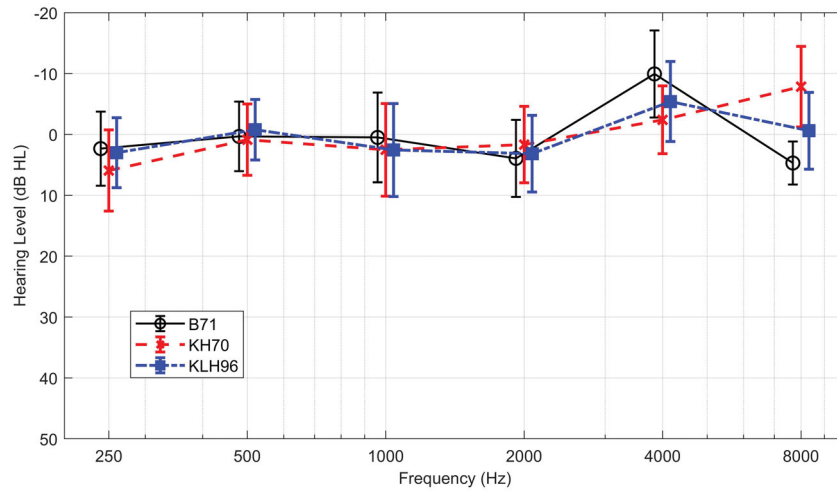


Figure 4. Mean Bone Conduction Hearing Levels (dB HL) measured with the B71(circles), KH70 (red crosses), and KLH96 (blue filled squares) bone conductor with both ears ($n = 60$) between 0.125 and 8 kHz. Error bars indicate the standard deviation.

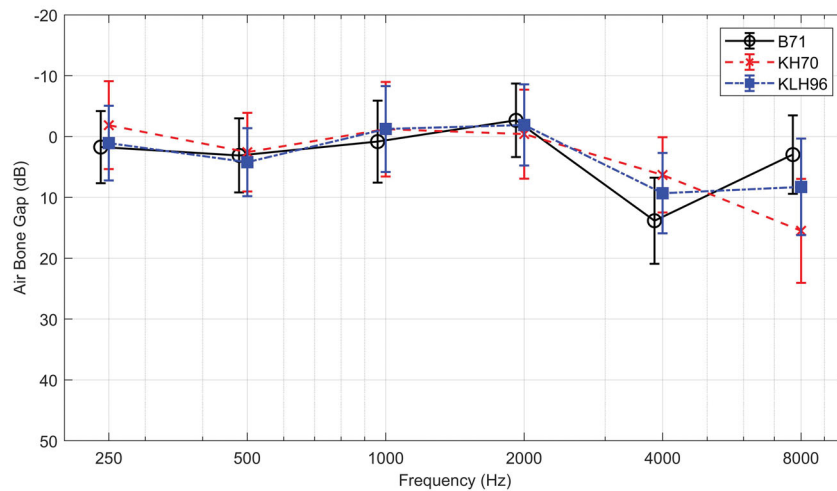


Figure 5. Mean Air Bone gaps between the TDH39 headphone and the B71(circles), KH70 (red crosses), and KLH96 (blue filled squares) bone conductor. Error bars indicate the standard deviation.

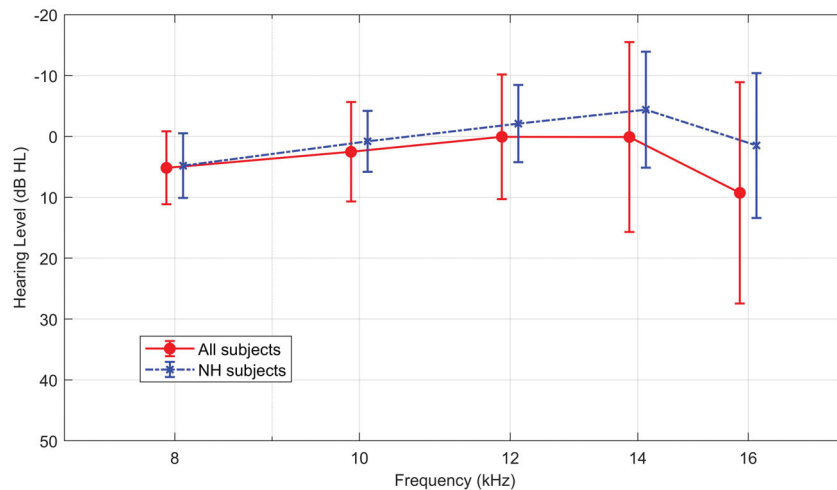


Figure 6. The red solid line with circles symbols represents the mean extended high-frequency Air Conduction Hearing Levels (dB HL) measured in all subjects (60 ears) with the HDA200 headphone of both ears combined between 8 and 16 kHz. The dashed blue line with cross symbols represents the mean NH data (hearing levels <20 dBHL) at 8, 10, 12.5, 14, and 16 kHz based on 59, 57, 56, 53, and 46 ears, respectively. Error bars indicate the standard deviation.

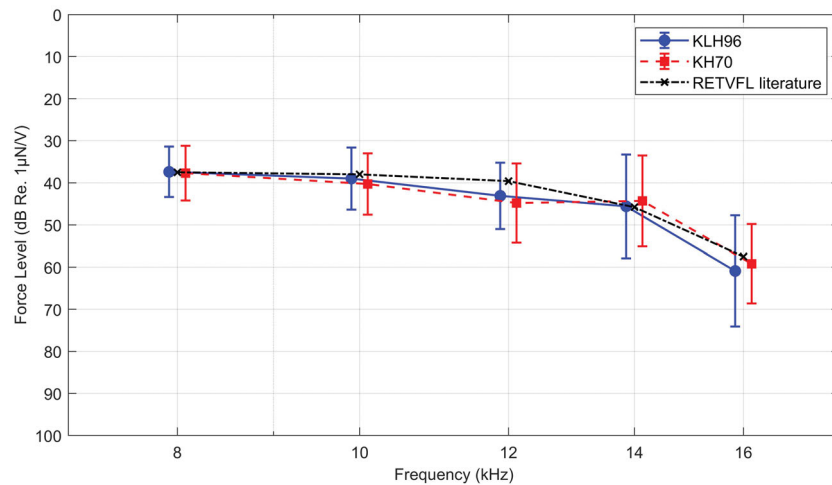


Figure 7. Mean extended high-frequency Bone Conduction Hearing Levels (dB FL) measured with the KH70 (red dashed line) and the KLH96 (blue dashed-dotted line) bone conductor between 8 and 16 kHz. Symbols denote the bone conductor type. The black dashed-dotted line with triangle symbols represents the average RETVFL values from the literature (see also Table 3). Error bars indicate the standard deviation.

the KH70 has a limited range of about 30 dB at 16 kHz (Richter and Frank 1985) it was not possible to increase the force level of the KH70 above 90 dBFL. Therefore these 5 ears were excluded for further analysis at 16 kHz. As expected, the mean force level increased at higher frequencies. The thresholds between 8 and 16 kHz of both bone conductors seem to be closely related to the average RETVFL from the literature. The Repeated Measures Analyses showed no significant differences between both bone conductors ($p > 0.05$) nor between both ears ($p > 0.05$). There was a significant difference between observed frequencies ($p < 0.05$) but no interactions. Because the EHF BC thresholds are expressed in force levels and there is no norm to transform these values to hearing levels we cannot draw a conclusion based on these differences. If it is assumed that the average RETVFL values from the literature (Table 2) are valid it is possible to analyse the observed thresholds of the KH70 and KLH96 bone conductor with a one-sample t -test relative to these RETVFL values as a function of frequency. The differences between the RETVFL values and the observed thresholds between 8 and 16 kHz were not significant ($p > 0.05$). When comparing the results to the RETVFL values mentioned in the PTB report in 1997 (see Table 3) the differences increased for both bone conductors (see Table 3). Furthermore, all frequencies are significantly different from the RETVFL values determined by the PTB ($p < 0.001$).

A paired t -test for all frequencies between both bone conductors showed a small but insignificant difference at 8, 10, 12.5, 14, and 16 kHz. Table 3 shows the mean differences (KLH96 - KH70 thresholds), standard deviation, p -value, and the number of ears.

Supplementary data Figure 4 shows the mean test-retest differences measured with the KLH96 bone conductor of the right ear between 0.25 and 16 kHz. Both MANOVA tests for frequencies between 0.25 and 8 kHz (in dB HL) and frequencies between 8 kHz and 16 kHz (in dB FL) showed no significant differences between frequency ($p > 0.05$) and test-retest ($p > 0.05$).

Discussion

Bone conduction thresholds between 0.25 and 8 kHz

In this paper, the BC thresholds in the conventional range (0.25-8 kHz) and EHF range (8-16 kHz) were examined. First, the observed hearing levels between the B71, KH70, and KLH96 bone conductors for the tone audiometric octave frequencies

Table 3. The three upper rows show the mean thresholds in normal hearing ears as a function of frequency measured with a HDA200 headphone (dBHL), a KH70 bone conductor and a KLH96 bone conductor (dB FL).

Frequency (kHz)	8	10	12.5	14	16
HDA200					
Mean (dBHL)	4.8	0.8	-2.1	-4.4	1.5
SD	5.3	5.0	6.3	9.5	11.9
Ears	59	56	56	53	46
KH70					
Mean (dB FL)	37.7	40.3	44.8	44.3	59.2
SD	6.5	7.3	9.4	10.8	9.4
Ears	59	57	56	53	41
KLH96					
Mean (dB FL)	37.4	39.0	43.1	45.6	60.9
SD	6	7.4	7.9	12.3	13.2
Ears	59	57	56	53	46
RETVFL KH70 (Table 2)					
Mean (dB FL)	37.5	38.0	39.6	45.8	57.5
Ears	329	279	279	156	156
RETVFL KLH96 (PTB 1997)					
Mean (dB FL)	32.5	36.5	32.5	41	44.5
Ears	17	17	17	17	17
RETVFL KH70 - KLH96					
Delta (dB)	0.1	-1	-3.5	0.2	-3.4
RETVFL KLH96 - KLH96					
Delta (dB)	-4.9	-2.5	-10.6	-4.6	-16.4
RETVFL KH70 - KH70					
Delta (dB)	-0.2	-2.3	-5.2	1.5	-1.7
RETVFL KLH96 - KH70					
Delta (dB)	-5.2	-3.8	-12.3	-3.3	-14.7

The fifth and sixth row shows the mean RETVFL (dB FL) values from the literature and a PTB Report (1997). The lower four rows show the mean differences between the bone conductors and the mean RETVFL values from the literature and the PTB report.

between 0.25 and 8 kHz are discussed. No differences were found between 0.5 and 2 kHz but at 4 and 8 kHz these 3 transducers differ significantly from each other. Furthermore, the observed threshold at 0.25 kHz with the KH70 was significantly higher than the observed threshold with the B71 and KLH96 transducer. The latter had no significant effect on the measured air-bone gap between the TDH39 headphone and the BC thresholds. However, at 4 kHz the measured air-bone gaps were between 6.3 dB and 13.3 dB and at 8 kHz between 3.0 dB and 15.5 dB. The results of the B71 at 4 kHz are in line with the literature (e.g. Frank and Holmes 1981; Lightfoot and Hughes 1993; Margolis and Moore 2011; Margolis et al. 2013; Rao et al. 2020). In the

past, there was a concern that acoustic radiation from the bone conductor could contaminate BC threshold measurements (Margolis et al. 2013) but the literature is not conclusive. Margolis et al. (2013) summarised the results in a review of the literature and concluded that the effect of acoustic radiation observed with a B71 BC transducer is between 0 and 5 dB. This small effect is not significant in clinical practice. However, an air-bone gap >10 dB might have clinical consequences. The origins of the observed air-bone gaps at 4 kHz may be more related to the RETVFL value calibrated on a specific artificial mastoid. The original standard that provided RETVFL values is based on the Beltone 5A artificial mastoid (ANSI S3.13:1972; Margolis and Popelka 2014). This artificial mastoid went out of production in the early seventies. The next RETVFL standard (ANSI S3.26:1981) was based on the B&K4930 artificial mastoid and this device became the default in the ANSI and ISO standard. Since then the 'false' air-bone gap at 4 kHz has still been present in clinical practice. It is known that the coupler properties of the B&K4930 have changed at the end of 1975 (Dirks et al. 1979; Richter and Brinkmann 1981). This suggests that the artificial mastoid used in the normative studies of these standards might have other coupler properties than the currently used B&K4930 for BC calibrations. Dirks et al. 1979 showed that the differences in output levels between different B&K4930 couplers could be as large as 10 dB. The newly designed rubber pad shows more consistent results between different B&K4930 couplers. It is unclear how well the differences between the couplers remain the same after the rubber pads have been replaced. Furthermore, the temperature of the B&K4930 has a large effect on impedance and force sensitivity (e.g. Frank and Richter 1985; Dowson and McNeill 1992). It is recommended to calibrate the BC transducer at a temperature of 23 °C. The influence of temperature on the output of the B&K4930 is greatest around 4 kHz (Frank and Richter 1985). The output is about 6.6 dB higher at 17 °C than at 29 °C. In daily practice, the BC device would probably not be calibrated under these strict norms. Whether the upper effects are the reason for the observed air-bone gap is still speculative. The results of Margolis et al. (2013), Margolis, Eikelboom, and Swanepoel (2019), and the present study suggest that the RETVFL for the B71 at 4 kHz should be adjusted by about -14 dB to obtain an air-bone gap of 0 dB. Still, the RETVFL value of 4 kHz is unchanged since the introduction standard (Margolis, Eikelboom, and Swanepoel 2019). The recent Amendment 1 (2020) of the ISO389-3:2016 suggests that the RETVFL value at 4 kHz should be corrected: 'ISO/TC 43/WG 1 has recognised that some studies [Margolis, Eikelboom, and Swanepoel 2019] indicate that the reference value for bone conduction at 4 kHz needs to be corrected. However, there are no sufficient independent sets of data available to provide a reliable new value.' Additionally, the results of the present study suggest that there should be different RETVFL values for the different BC transducers. This is in line with the results of Fröhlich, Plontke, and Rahne 2018 who observed different RETVFL values between the B71, B81 and the KH70 bone conductors, and Frank, Byrne, and Richards 1988 who observed different RETVFL values between the B71 and the KH70. The influence of the headbands on the observed differences between the bone conductors is unlikely. The coupling force was controlled by the standard headbands (P333 and the KH70 headband). These headbands are specially designed to couple the bone conductor to the head with a static force of $5.4\text{ N} \pm 0.5\text{ N}$. There might be some differences between subjects due to head size. However, this effect should be similar (within subjects) across transducers.

Since all subjects were tested with the same transducers this effect should have been observed (Fröhlich, Plontke, and Rahne 2018). It is more likely that the observed differences are related to the different electro-acoustic properties of the different BC transducers (Fröhlich, Plontke, and Rahne 2018). The harmonic distortion of the B71 is greatest at 0.25 kHz and even falls outside the restrictions of the IEC 60645-1 norm. The results of bone conduction RETVFL studies of the last 10 years suggest that the ISO/TC 43/WG 1 should re-examine the data in which the ISO 389-3 is based (246 ears from three studies between 1979 and 1981) as well as more recent RETVFL studies with different bone conductors.

Bone conduction thresholds between 8 up to 16 kHz

This section discusses the EHF BC thresholds between 8 and 16 kHz obtained with the Westra KLH96 and the discontinued Präcitrone KH70. The observed thresholds between 8 and 16 kHz of both transducers and the mean RETVFL data from the literature are similar. The PTB Report (1997) on measured thresholds with a KLH96 bone conductor reported lower RETVFL values compared to this study and the RETVFL values for the literature (Table 3). Utz Richter and Thomas Fedtke (2020), both involved in calibration studies at the PTB, think that the differences between the BC threshold results between this study, the literature, and the 1997 PTB report above 8 kHz might be due to the production years of the used B&K4930 couplers. It might be possible that the rubber pad on the coupling surface for the bone vibrators has changed in the last 35 years. Distortion likely has no effect on the observed threshold since both bone conduction transducers have negligible THD between 0.25 and 16 kHz. The frequency response of the KLH96 and KH70 on the B&K4930 coupler showed a large peak at 16 kHz (Supplementary data Figure 2). Both measurements in this study are similar to the Westra documentation of the KLH96. The differences could be related to other factors. The force sensitivity of the B&K4930 might have an impact on the observed differences. The IEC 60318-6 standard for calibration of an artificial mastoid provides only a description up to 8 kHz. The force sensitivity values between 0.25 and 8 kHz were taken from the recent calibration certificate of our B&K 4930 artificial mastoid. Unfortunately, calibration firms don't measure force sensitivity values outside the IEC 60318-6 range (i.e. >8 kHz). The values between 10 and 16 kHz are our own measurements. Frank and Ragland 1987; McDermott et al. 1991 and Hallmo, Sundby, and Mair 1994 assumed that values from Richter and Frank (1985) could be used to transform the dB voltage level into force levels. Their EHF results are more or less the same. However, if the same force sensitivity values were used for this study the findings would not resemble these results. Therefore it would be better if the IEC 60318-6 norm provided room for EHF measurements so calibration firms can calibrate the artificial mastoid beyond the current norm. To date, one has to rely on data from the literature or measure these values themselves. The latter is highly recommended but generally not always possible due to lack of calibration equipment or technical skills. However, it seems wise to use B&K4930 type-dependent force sensitive data to account for calibration errors in the EHF range.

The repeatability of thresholds between 250 Hz and 16 kHz was tested by repositioning the KLH96 on the right side of the subject's head. The average difference between the test and retest was not significant. This is in line with the study of Frank and Ragland (1987) and McDermott et al. 1991. Furthermore, the increased standard deviation at higher frequencies is in agreement with other bone conduction studies (e.g. Richter and Frank

1985; Frank and Ragland 1987; McDermott et al. 1991; Hallmo, Sundby, and Mair 1994). The latter is also seen in EHF measurements with an AC transducer in the present and other studies (see review Rodríguez Valiente et al. 2014). Therefore the EHF BC measurement should be considered as a reliable alternative if patients suffer from middle ear problems when their hearing is monitored for ototoxicity. Unfortunately, the KH70 bone conductor has been discontinued since 2006. However, the relatively unknown KLH96 bone conductor is suitable for this task. Furthermore, the KL96 has a higher output at higher frequencies and is smaller than the KH70, and is thus more practical for daily clinical use.

This study was primarily designed to compare the obtained RETVFL values in normal-hearing listeners between the KLH96 and the KH70 bone conductor for the EHF range. In addition, the conventional range between 0.25 up to 4 kHz and also 8 kHz was measured with a B71 bone conductor serving as a reference for the norm (i.e. ANSI S3.6-2018; ISO 389-33, 2016). The new B81 was not used as a reference because the RETVLF values of the B71 and B81 are the same and not expected to be significantly different for the conventional range (e.g. Fröhlich, Plontke, and Rahne 2018). In future BC studies, one may consider using the new B81 bone conductor instead of the B71 because of the limitations of the B71 (higher THD at 0.25 kHz and less maximum output), particularly when measuring in hearing-impaired listeners at higher hearing levels. In this study, only normal hearing subjects were measured. Therefore no conclusions can be made on how well the KLH96 would perform in hearing-impaired listeners in the clinic. The BC measurements for the EHF range with the KH70 and KLH96 were similar to each other and the literature (i.e. Figure 7; Table 3). Therefore these obtained thresholds could serve as a reference for EHF RETVFL values. Still, one should use these values with care because the normal hearing test group consists of listeners between 18-29 years of age. For RETVFL values the ISO 389-9 suggests the normal hearing reference group should be in an age range of 18-25 years. Nevertheless, the included normal hearing ears (59 at 8 kHz up to 46 at 16 kHz) had normal hearing AC thresholds according to the ISO389-5. When excluding ears with an age >25 years the obtained thresholds between 8 and 16 kHz are similar (38.5 (7.4), 39.4 (8.7), 43.5 (7.4), 42.9 (13.3), and 57.3 (11.8) dBFL, for 31, 30, 30, 28 and 23 ears, respectively). How well the KLH96 bone conductor can be used for EHF measurements in clinical practice with hearing-impaired listeners is left for further research.

To my knowledge, there are no commercial audiometers available at present that are suitable for EHF BC measurements alongside AC measurements. Manufacturers should consider expanding the EHF measurement module with an option for a bone conductor transducer. With access to a bone conductor in the EHF measurement module clinics would have the opportunity to monitor the hearing in patients with otitis media who are treated with ototoxic medication or follow the long-term effects of chronic otitis media on EHF hearing. Otherwise, one needs a dedicated audiometer for EHF BC measurements. It would be unfortunate if this type of audiometry measurement remains in the domain of research and cannot find its way to daily clinical practice.

Conclusion

The results of this study suggest that it is reliable to perform BC hearing threshold measurements in normal-hearing listeners

above 4 kHz up to 16 kHz using the Westra KLH96. The uncertainty of the measurement increases with increasing frequency, resulting in a larger measurement error. These results are comparable to AC hearing measurements for the higher frequencies.

Contrary to the B71 is the THD at 0.25 kHz of the KLH96 like the B81 within the specifications of the IEC 60645-1. Therefore the KLH96 can be used properly for clinical use between 0.25 and 8 kHz.

Like AC transducers, BC transducer dependent RETVFL values seem to be needed to calibrate the audiometer properly to obtain valid BC hearing thresholds.

This study confirms the 'false' air-bone gap at 4 kHz as observed in recent BC calibration studies.

The extended force sensitivity of the used B&K4930 artificial mastoid should be determined for a proper EHF calibration of a BC.

Acknowledgments

Dr. Kimmy Snel-Smit was involved in the experimental setup, recruiting subjects, retrieving data, and presenting the preliminary results of this study. Dr. Utz Richter and Dr. ing. Thomas Fedtke are acknowledged for the discussion we had related to the calibration and the force sensitivity measurements of the B&K 4930 artificial mastoid. Ir. Sander Ubbink and Dr. ir. Emile de Kleine of the UMCG are acknowledged for loaning us a B&K8000 impedance head. Hans Versluis is acknowledged for his textual comments. Siwa A. Versnel is acknowledged for proofreading and textual editing of the final version of this paper. Prof. dr. Robert H. Margolis, the anonymous reviewer, and the Editor-in-Chief Prof. dr. De Wet Swanepoel are acknowledged for their detailed and constructive comments.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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