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Original Article

Bone Conduction Threshold Measurements in Patients with Bone Conduction Devices: A Comparison of Available Methods

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BACKGROUND: The semi-implantable bone conduction devices connect the skull to the hearing device by means of an implant. This implant affords us 3 possible methods for conducting bone conduction evaluation, which may produce a different result for the same patient, and comparisons of results from different centers may therefore be interpreted incorrectly. Thus, the authors attempt to quantify the audiometric differences between the obtained auditory results and to check whether the results of standard pure tone audiometry could be replaced with the results obtained by alternative measurement methods.

METHODS: Measurements were conducted in a group of 53 adult patients implanted with bone conduction devices in 3 modes: bone conduction-direct, when the bone conduction device itself is used to assess the audiometric threshold; bone conduction-pure tone audiometry with audiometric oscillator placed over mastoid aside of an implant; and bone conduction-indirect with oscillator placed on an implant.

RESULTS: The analysis revealed differences between obtained results, which can reach up to 21.48 dB with a mean of 10 dB across all frequencies. The lowest values, regardless of the type of implant connection ("magnetic"; "snap"), were recorded for bone conduction-indirect mode whereas the highest mean all-frequency thresholds were recorded in the mode defined as bone conduction-direct.

CONCLUSION: The method that provides the most comparable thresholds is when the oscillator is positioned on the mastoid, aside from an implant. It should be the method of choice for any hearing evaluation in patients fitted with bone conduction devices, because of standardized equipment and the availability of preoperative data obtained with the same method.

KEYWORDS: Bone conduction, pure tone audiometry, bone conduction devices, hearing loss, hearing rehabilitation

INTRODUCTION

Within the wide range of hearing devices used for hearing rehabilitation, bone conduction devices (BCDs) are used to prosthesize conductive and mixed hearing losses as well as unilateral deafness in selected clinical situations.[1] Bone conduction devices encompass different systems that can be subdivided into non-implantable, that is, conventional BCDs (such as sound processor attached to spectacles) and semi-implantable, where part of the BCD system is implanted—integrated with the skull. This last group of devices can subsequently be subdivided with respect to the sound delivery pathway into "direct-drive systems," where the sound is transmitted to the cochlea through the direct connection of the oscillator to the skull, and "skin-drive systems," where the vibrations are delivered to the cochlea through the intact skin.[2] In order to evaluate the extent of primary hearing loss prior to implantation or its progression over time after implantation, a set of different audiological tests is available, and pure tone audiometry (PTA) with air and bone conduction threshold evaluation is the basic standard.

The semi-implantable systems described above connect the skull to the hearing device by means of an implant. The fact of this implant affords us three possible methods for conducting bone conduction (BC) evaluation (aside from the basic standard of air

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conduction [AC] evaluation [i.e. PTA]). The possible BC measurement options include BC evaluation using the BCD itself to assess the BC threshold; the basic standard of BC evaluation with an audiometric oscillator placed over the mastoid; and BC using an audiometric oscillator placed in the mastoid region, either in physical contact with the skin-penetrating abutment attached to the implant or, in the case of BCDs with magnetic connection, "over" the implant (i.e., in physical contact with the intact skin covering the magnet).

There is potential for each of these three methods to produce a different result for the same patient, and comparisons of results from different centers may therefore be interpreted incorrectly. This is particularly the case in the event that the clinician does not have access to information with which to interpret differences in results stemming from the method used.

With that in mind, the authors attempt to quantify the audiometric differences between the auditory results obtained during BC clinical testing in the three available options that use PTA with oscillator and a BCD in combination with dedicated hardware and software for measurements. The second goal was to suggest the best BC evaluation option for monitoring auditory thresholds in patients fitted with BCDs, and thus the option that should be considered best clinical practice when evaluating BC thresholds in BCD recipients.

MATERIAL AND METHODS

Study Design

This study compares the results of audiological measurements (of BC thresholds) in a group of adult patients implanted with BCDs. The study refers to a clinical situation where in an outpatient setting (not a specialized implant center) clinicians should pay attention to the method of conducting the test and to the interpretation of the obtained results in relation to the method of hearing assessment used.

Measurements were conducted in three modes, depending on the oscillator position (over the implant, or over the bone) and its type (oscillator integrated into the BCD, or audiometric oscillator). The modes are defined as (1) BC-direct, when the BCD itself, which is connected to the implant, is used to assess the BC threshold; (2) BC-PTA, when the audiometric oscillator is placed over the bone of the mastoid process; and (3) BC-indirect—when the audiometric oscillator is placed on the abutment (in patients with skin-penetrating devices) or on the skin covering the magnet (in patients with magnetic connection systems).

All tests were performed during a single session for each patient. Prior to the planned investigation and analysis of audiological measurements in patients implanted with BCDs, we have consulted the project with the local Bioethical Commission by the University. We have received the approval to conduct the analysis, as the audiological evaluation is an integral part of the routine follow-up. The decision of the Bioethical Commission was presented in the decision letter 392/20, stating that the Ethics Committee of Poznan University of Medical Science deemed this study to be exempt to obtain written consent from each participant. Verbal informed consent was obtained from the participants who agreed to take part in the study.

In BC-PTA and BC-indirect mode, the tones were generated by a standard clinical diagnostic audiometer Madsen Midimate 622 (GN Otometrics A/S, Taastrup, Denmark) in a soundproof booth and delivered to the patient via audiometric oscillator. In BC-direct mode, Genie Medical software (Genie Software & Accounting Solutions, Denistone, Australia) and BAHA fitting software v.5.4 (Cochlear Americas, Lone Tree, CO, USA) were used to connect to the BCD and to conduct the measurement. The BC thresholds were obtained for the frequencies 0.5, 1, 2, and 4 kHz, stored, and subsequently analyzed. The results were compared for the whole study cohort, as well as for subgroups determined by connection type and named "snap" (skin-penetrating BDS) and "magnetic."

Variables, such as age, gender, or type of hearing loss (conductive or mixed), the type of implant and device used, were irrelevant for the study because each patient was self-controlled. The results for each type of BC measurement refer to exactly the same individual.

Patient Characteristics

Out of 511 patients implanted with BCDs in the clinical database, n = 53 randomly selected adult patients were included in the study. The studies were performed on patients who had been operated on in recent years and who regularly come for a check-up.

Patients with single-sided deafness were not included in the study due to contralateral placement of the BCD in relation to the hearing ear. All selected patients successfully underwent BCD implantation. The procedure was performed according to internationally accepted patient selection criteria—both clinical and audiological. There were 18 males (33.97%) and 35 females (66.03%), with mean age 55.71 yo (min. 19 yo., max. 77 yo) and mean BMI score 26.67 (min. 14.56, max. 38.30). Otological indications for BCD implantation were defined as chronic otitis media (n = 43; 81.13%), malformation (n = 7; 13.21%), and otosclerosis (n = 3; 5.66%), whereas audiological indications were defined as mixed hearing loss (n = 41; 77.35%) and conductive hearing loss (n = 12; 22.65%). Connection type: "snap" (n = 26; 49.06%) *versus* "magnetic" (n = 27; 50.94%); device model used for patient treatment: Ponto® (Oticon Medical), n = 16 (30.19%) and Baha® (Cochlear Ltd), n = 37 (69.81%).

Statistical Analysis

Statistical analysis was performed using Statistica 13.3 software (TIBCO Software Inc., Palo Alto, CA, USA). The significance level of 0.05 was adopted for the interpretation of all calculations. Normal distribution tests and the Mauchley sphericity test were performed. Data were analyzed by ANOVA on a repeated measures design with Huynh–Feldt correction. Then, due to the obtained *P*-value <.05, the results were further analyzed post hoc using the conservative Scheffe test.

RESULTS

The bone conduction thresholds averaged across all measured frequencies were from lowest to highest: 25.09 dB for BC-indirect mode of measurement, 30.14 dB for BC-PTA, and 35.09 dB for BC-direct. The difference between the highest and lowest of these threshold values is 10.00 dB. The differences between mean thresholds for the three modes were statistically significant at $P < .001$ (Figure 1).

A detailed comparison of the results for single frequencies obtained from different measurement modes revealed that BC-direct vs

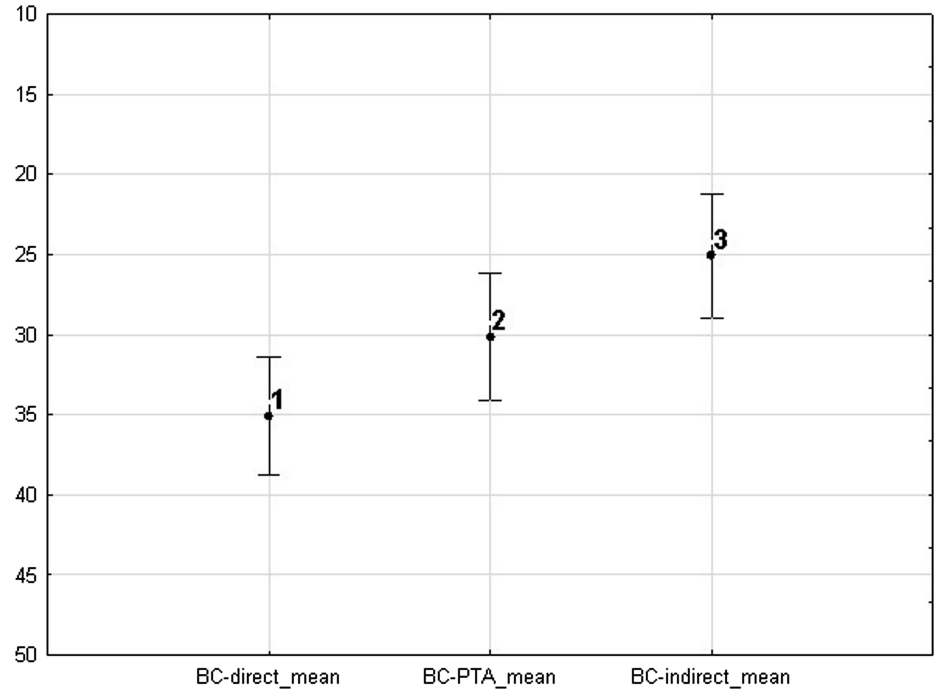

Figure 1. Results of BC threshold measurements obtained in 3 modes, calculated as a mean of measured frequencies, for the whole study group. *P*-value: 1-2—$P < .001$; 2-3—$P < .001$; 1-3—$P < .001$.

BC-indirect—differences were statistically significant for all measured frequencies—BC-PTA vs BC-direct—differences were statistically significant for all measured frequencies except 2 kHz, where there was a 1.33 dB difference ($P = .539$) (mean values 37.92 dB for BC-PTA and 39.25 dB for BC-direct)—and BC-PTA vs BC-indirect—differences were statistically significant for all measured frequencies except 4 kHz, with a difference of 3.12 dB (mean values 32.93 dB for BC-PTA and 29.81 dB for BC-indirect) ($P = .107$) (Figure 2 and Table 1).

Within the subgroups by connection type, the lowest BC thresholds averaged across all frequencies in both the "magnetic" subgroup and the "snap" subgroup were recorded for BC-indirect mode (23.24 dB and 27.02 dB, respectively). Meanwhile, the highest mean all-frequency thresholds—again, both in the "magnetic" and "snap" subgroups—were recorded in BC-direct mode (36.67 and 33.46 dB, respectively) (Figure 3). The number of measurements at 0.5, 1, 2, and 4 kHz in the "snap" and "magnetic" subgroups were insufficient to perform the ANOVA test for calculating *P* values using the same statistical tests as those used for the whole cohort. Detailed differences calculated for single frequencies are provided in Tables 2 and 3.

DISCUSSION

Regardless of the method of hearing rehabilitation, type of device, or surgical technique, the hearing loss in BCD recipients may change over the years—mainly worsening due to numerous factors, including disease, age, and environmental influence. This can usually be observed as a slow, progressive process or less frequently as a more dynamic phenomenon (e.g., sudden hearing loss). In such cases, a hearing evaluation should be performed as soon as possible to evaluate the type and extent of hearing deterioration, in order to implement the proper treatment. Moreover, measurements should be repeatable and comparable between different centers to avoid misinterpretation of results.

In the current study, we compare the BC threshold results obtained in three optional modes of examination related to oscillator type (built-in BCD, and audiometric oscillator) and oscillator position on the mastoid bone.

The overall analysis revealed that there are differences between results obtained in different modes, and these can reach up to 21.48 dB (i.e. BC-direct *vs* BC-indirect for 4 kHz), with a mean of 10 dB across all frequencies. The BC-indirect mode gave the lowest threshold results out of all tested modes in the whole study cohort (25.09 dB), whereas BC-direct gave the highest thresholds in the whole cohort (35.09 dB). The BC-PTA mode gave results in between the other two modes, with a mean threshold of 30.14 dB across all frequencies.

BC-indirect results gave lower BC threshold results than did BC-direct and BC-PTA measurement results in both the "snap" and "magnetic" subgroups (i.e. regardless of audiometric oscillator position "on" or "over" the implant). However, the results differ between the subgroups. The differences between BC-direct (higher values) and BC-indirect (lower values) were 6.44 dB for "snap" and 13.43 dB for "magnetic." Similarly, there were differences between BC-PTA results and BC-indirect results (6.06 dB in "snap" and 4.07 dB in "magnetic"). The BC-PTA and BC-direct results differed by only 0.38 dB in the "snap" subgroup, and by 9.36 dB in the "magnetic" subgroup.

With respect to the measurement modes, BC-PTA, with the oscillator over the bone of the mastoid process, has a number of benefits. First, the results can be compared against preoperative measurements to identify differences between current hearing acuity and pre-operative values and thereby to indicate potential changes in thresholds. Second, measuring conditions are the same for patients with different types of BCDs. Lastly, audiometers are calibrated and thus comparable. Any differences in measurement results may be related to

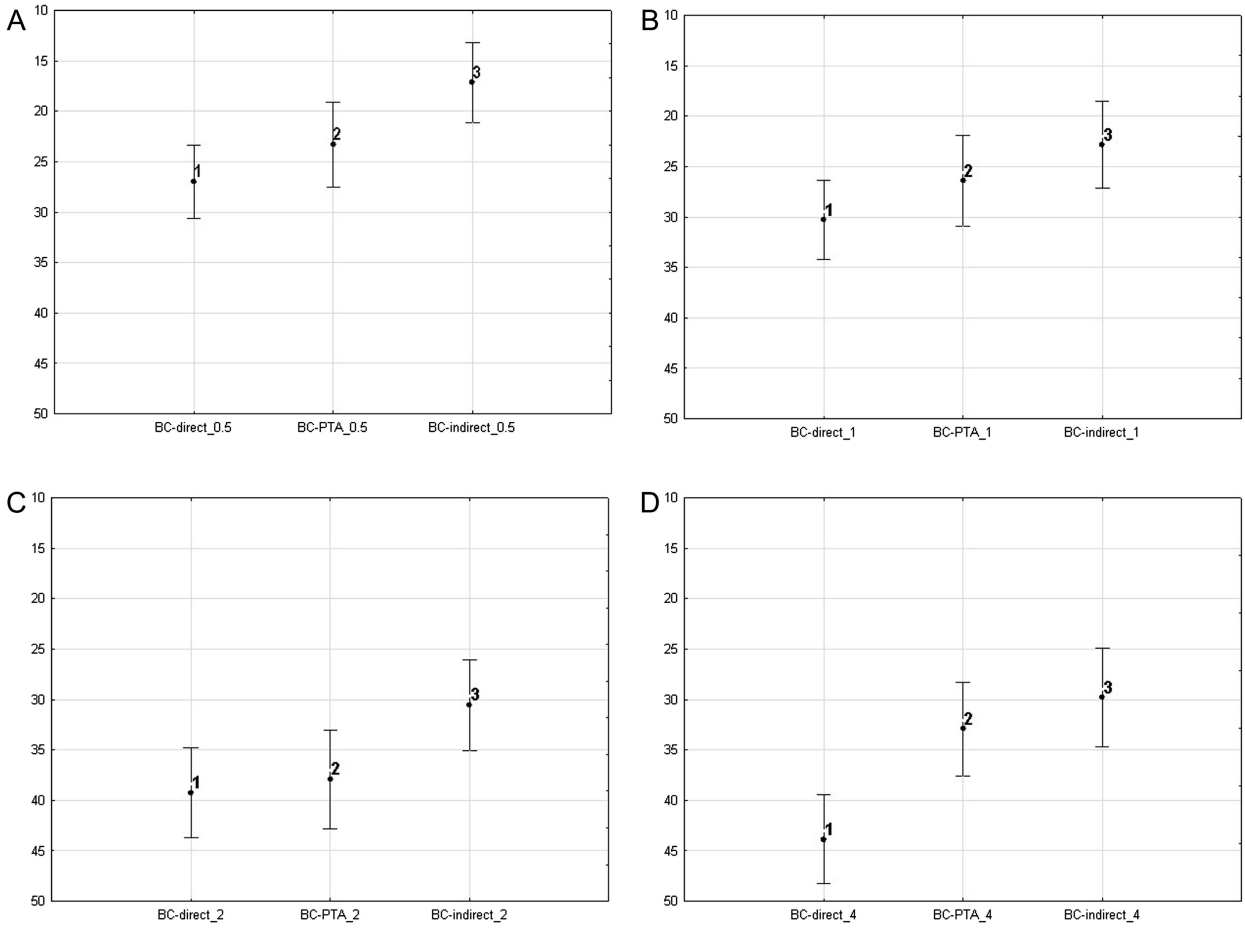

Figure 2. (A-D). Results of BC threshold measurements obtained for each tested frequency in 3 modes, for the whole study group (A: 500 Hz, B: 1000 Hz, C: 2000 Hz, D: 4000 Hz). *P*-value: (A) 1-2—*P* = .003; 2-3:—*P* < .001; 1-3—*P* < .001. (B) 1-2—*P* < .001; 2-3—*P* = .001; 1-3—*P* < .001. (C) 1-2—*P* = .54; 2-3—*P* < .001; 1-3—*P* < .001. (D) 1-2—*P* < .001; 2-3—*P* = .11; 1-3—*P* < .001.

Table 1. Summary of the Measurement Results for the Whole Study Group

Variable	N	Mean	Median	Minimum	Maximum	Lower Quartile	Upper Quartile	Standard deviation
BC[1]-direct_0.5	53	26.98	25	0	60	20	35	13.28
BC-direct_1	53	30.28	30	0	60	20	40	14.36
BC-direct_2	53	39.25	40	10	70	30	50	16.18
BC-direct_4	53	43.87	45	5	70	35	55	15.98
BC-direct_mean	**53**	**35.09**	**35**	**6.25**	**62.5**	**27.5**	**43.75**	**13.42**
BC-PTA[2]_0.5	53	23.3	20	−5	55	10	35	15.16
BC-PTA_1	53	26.42	20	−10	55	15	40	16.36
BC-PTA_2	53	37.92	40	5	80	25	50	17.85
BC-PTA_4	53	32.92	35	0	70	20	45	16.85
BC-PTA_mean	**53**	**30.14**	**28.75**	**1.25**	**55**	**20**	**42.5**	**14.36**
BC-indirect_0.5	53	17.17	15	−10	45	10	25	14.4
BC-indirect_1	53	22.83	20	−10	50	15	40	15.49
BC-indirect_2	53	30.57	30	0	55	20	45	16.46
BC-indirect_4	53	29.81	30	−5	60	15	45	17.87
BC-indirect_mean	**53**	**25.09**	**22.5**	**−1.25**	**51.25**	**15**	**35**	**14.02**

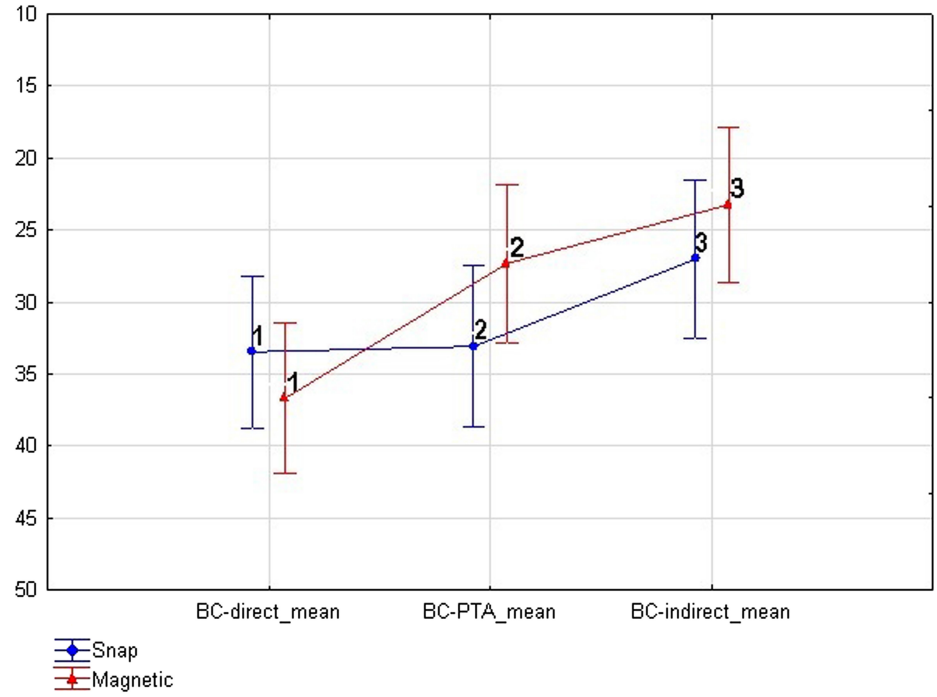

Figure 3. Results of BC threshold measurements obtained in 3 modes, calculated as a mean of measured frequencies, in subgroups of cases with different types of connection: "snap" and "magnetic." *P*-value: Snap: 1-2—*P* = .88; 2-3—*P* < .001; 1-3—*P* < .001. Magnetic: 1-2—*P* < .001; 2-3—*P* = .02; 1-3—*P* < .001.

the exact position of the oscillator on the mastoid bone.[3,4] During the examination, in patients fitted with a BCD, the oscillator should be positioned with no contact with the abutment of any skin-penetrating system or metal disc placed under the intact skin. In some cases, this may require shifting the oscillator further back and down on the mastoid, thus potentially affecting the BC results.

The next mode—BC-direct—was designed to improve the outcomes of a BCD fitting and to improve pre-operative counseling and has the benefits of the sound being amplified by the BCD itself.[5] Therefore, the BC-direct mode of measurement is essential when preparing the device for the patient. It is the most stable and repeatable method of measurement with respect to the position and attachment to the

Table 2. Summary of the Measurement Results for the "Magnetic" and "Snap" Subgroups

Type of Connection	Measurement	N	Mean	Median	Minimum	Maximum	Lower Quartile	Upper Quartile	Standard Deviation
"Magnetic" connection	BC[1]-direct_mean	27	36.67	35.00	13.75	58.75	30.00	43.75	10.48
	BC-PTA[2]_mean	27	27.31	27.50	1.25	47.50	17.50	38.75	12.08
	BC-indirect_mean	27	23.24	20.00	−1.25	43.75	15.00	32.50	11.70
"Snap" connection	BC-direct_mean	26	33.46	33.75	6.25	62.50	22.50	47.50	15.96
	BC-PTA_mean	26	33.08	32.50	3.75	55.00	25.00	47.50	16.12
	BC-indirect_mean	26	27.02	27.50	0.00	51.25	15.00	40.00	16.09

Table 3. The Differences between Measurements in 3 Modes, for All Measured Frequencies in Both Subgroups with Different Types of Connection.

	Measurement		BC-direct_mean	BC-PTA_mean	BC-indirect_mean
"Magnetic" connection		(dB[3])	**36.67**	**27.31**	23.24
	BC-direct_mean	**36.67**	—	**−9.35 (*P* < .001)**	−13.43 (*P* < .001)
	BC-PTA_mean	**27.31**	**9.36 (*P* < .001)**	—	−4.07 (*P* = .02)
	BC-indirect_mean	**23.24**	**13.43 (*P* < .001)**	**4.07 (*P* = .02)**	—
"Snap" connection		(dB)	**33.46**	**33.08**	27.02
	BC-direct_mean	**33.46**	**x**	**−0.38 (*P* = .88)**	−6.44 (*P* < .001)
	BC-PTA_mean	**33.08**	**0.38 (*P* = .88)**	**x**	−6.06 (*P* < .001)
	BC-indirect_mean	**27.02**	**6.44 (*P* < .001)**	**6.06 (.001)**	—

BC: bone conduction; dB: decibel; PTA: pure tone audiometry.

skull.[6] However, any change in the registered threshold should be considered relative, as it can be compared only to previous results conducted with the same device. Furthermore, variables in BC-direct measurements related to the processor attachment ("snap" and "magnetic") and technology (type of processor, manufacturer) may interfere with measuring outcomes.

In BC-indirect mode the audiometric oscillator is positioned "on" or "over" the implant, depending on the connection type ("snap" *vs* "magnetic"). In this mode, the oscillator is held in place by a testband, which gives firm compression onto the skull. Depending on the BCD type, this compression in BC-indirect mode is against either the penetrating abutment or the skin covering the implant with a flat metal alloy disc under it. This can be responsible for differences between the results of measurements from different modes and different subgroups. This is especially true in the "snap" subgroup, where the stable connection of the audiometric oscillator to the abutment may be an issue, leading to the loss of vibration intensity.

The calculated differences between results when the audiometric oscillator was positioned on the abutment *vs* BC-direct was 6.44 dB. Aside from connection stability, the difference in the outcomes may be related to technical differences between oscillators and their calibration (audiometric *vs* BCD).

Contrary to skin-penetrating implants, sound transmission through intact skin and subcutaneous tissue can cause sound attenuation when performing BC measurements.[7-9] It has been proved that sound energy transmitted to the skull is diminished by the damping effect of the skin and subcutaneous soft tissue. This damping effect increases as frequency increases, although skin thickness has not been shown to have any influence between 250 and 4000 Hz.[10] However, in the tested subgroups, the method by which the audiometric oscillator was connected to the implant and BCD—also connected to the implant—influenced the results of measurement. Comparison of BC-direct thresholds in the "magnetic" subgroup against BC-indirect thresholds with an audiometric oscillator over the implant revealed a difference of 13.43 dB. In such a test configuration, one of the differences may be related to the technical specifications of oscillators and another to the degree of pressure against the subcutaneous implant. BC-direct utilizes a magnet, holding the processor in place, whereas with BC-indirect there is a metal band (test band) holding the audiometric oscillator over the implant. The results of a study by Hodgestts et al suggested that test band tension does not adversely affect hearing results.[11] Nonetheless, to investigate the role of compression in the current study, our calculations in the "magnetic" subgroup should be corrected by the strength of the magnet, which was not evaluated.

There are limitations of the study which should be highlighted. Firstl, the study group was subdivided with respect to the connection type of BCD (magnetic and snap groups). These physical differences in the connection between the implant and processor may interfere with the audiology results between tested modes. Moreover, patients in subgroups were of different clinical and demographic origins, i.e., not homogenous in terms of age and sex which may cause bias in comparison. Thus the results from the two subgroups (magnetic and snap) obtained with different modes should be evaluated separately—they must not be compared to each other. Second, the strength magnet (clinical situation within the magnetic subgroup) was not taken into consideration when evaluating the results. Introducing another parameter (i.e., magnet size) would bring additional variables, difficult for statistical interpretation in this size of the study group. Nevertheless, magnet strength should always be recorded and discussed when evaluating audiological results as the potential modifier, especially in the BC-direct mode of measurement. Similar physical aspects refer to the oscillator and to the degree of pressure against the subcutaneous implant. The pressure of the metal alloy band that holds on the oscillator against the skull was not measured. However, our goal was to point out the existing differences in testing modes and to sensitize clinicians that the method matters. Lastly, the audiology results were obtained with BCDs from two different manufacturers. Authors, deliberately ignore the issues of manufacturers, concentrating on the method of assessing hearing (BC) with the various available methods. Even though this may be an area of interest for further study, no comparison was performed in this matter.

Differences between BC-thresholds obtained in three optional modes are confirmed.

The BC-direct mode of measurements produced the highest average thresholds, and these should be corrected whenever they are being compared against audiograms generated by other modes, especially in cases of suspected hearing deterioration. Differences in measurement modes are even more visible in the "magnetic" connection subgroup of BCD users, where results not only depend on the processor but may also rely on the strength of coupling between processor and implant. BC-indirect leaves space for potential errors due to the positioning of the oscillator on the protruding abutment (the "snap" group), thus making this mode of measurement technically difficult. The BC-PTA mode of measurement, though still challenging in terms of the oscillator position (not touching the implantable part of the bone conduction system), is the method that provides the most comparable thresholds; this comparability is due to the equipment being calibrated and the availability of pre-operative data conducted with the same mode. Therefore, BC-PTA should be the method of choice for a hearing evaluation, in order for physicians with and without access to specialized audiological equipment to be able to compare results more reliably. The results of alternative methods of measuring hearing, while obtainable, should not be used as a substitute as they can vary considerably.

Ethics Committee Approval: This study was approved by Ethics committee of Poznan University of Medical Sciences, Poland (Approval No: 392/20, Date: 2000).

Informed Consent: Verbal informed consent was obtained from the participants who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

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