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COMPARISON OF ADHESIVE AND PASSIVE TRANSCUTANEOUS BONE CONDUCTION SYSTEMS IN ATRETIC CHILDREN

María Fernanda Pedrero Escalas[1A-F], Laura Caballe[2BD], Rosa Maria Pérez Mora[1ABD], Carlos De Paula Vernetta[2BC], Luis Lassaletta Atienza[1DE], Javier Gavilan[1D-F]

[1] Otorhinolaryngology, La Paz University Hospital, Spain
[2] Otorhinolaryngology, La Fe University Hospital, Spain

Corresponding author: María Fernanda Pedrero Escalas, Otorhinolaryngology, La Paz University Hospital, Paseo de la Castellana 261, 28046, Madrid, Spain; email: mariafernanda.pedrero@salud.madrid.org

Contributions:
A Study design/planning
B Data collection/entry
C Data analysis/statistics
D Data interpretation
E Preparation of manuscript
F Literature analysis/search
G Funds collection

Abstract

Introduction: In 2017, the first adhesive bone conduction device (aBCD) was introduced. Since then, clinical studies have extensively compared adhesive bone conduction devices to conventional bone conduction systems on softbands. The aim of this study is to evaluate the audiological and subjective outcomes of patients suffering from conductive hearing loss (CHL) who used an aBCD for a trial period, comparing outcomes with their existing passive transcutaneous bone conduction implants (ptBCI), which was either the Sophono Alpha or the BAHA Attract.

Material and methods: This prospective study included 14 congenital aural atresia patients between 7 and 16 years old. Participants had been ptBCI users for at least 2 years and had bone conduction thresholds ≤ 25 dB HL. The aBCD trial was for 1 week. Average pure tone thresholds (PTA4) and word recognition scores (WRS) with disyllabic words at 65 dB SPL in quiet and in noise were measured for each device. Subjective outcomes were recorded using the aBCD mini questionnaire and the SSQ questionnaire for hearing satisfaction, which were filled in by parents.

Results: We analyzed 16 ears. The mean sound field PTA4 was 52 dB HL unaided, 27 dB HL ptBCI-aided and 29 dB HL aBCD-aided. Mean WRS in quiet was 96% with ptBCI and 95% with aBCD. In noise (+5 dB SNR) the mean WRS was 70% with ptBCI and 77% with aBCD. A questionnaire revealed easy handling and good acceptance of the aBCD.

Conclusions: In this group of patients, comparable audiological and subjective satisfaction results were achieved with a non-implantable adhesive bone conduction device. Despite differences in handling, the adhesive BCD presents itself as an alternative to transcutaneous bone conduction implants.

Key words: adhesive bone conduction • Adhear • bone conduction implant • Sophono Alpha • BAHA Attract

PORÓWNANIE PASYWNYCH PRZEZSKÓRNYCH SYSTEMÓW NA PRZEWODNICTWO KOSTNE – NAKLEJANYCH NA SKÓRĘ I NA OPASCE – U DZIECI Z ATREZJĄ

Streszczenie

Wprowadzenie: W roku 2017 wprowadzono na rynek pierwsze przezskórne urządzenie na przewodnictwo kostne (aBCD) naklejane na skórę. Od tego czasu przeprowadzono liczne badania kliniczne porównujące naklejane na skórę urządzenia na przewodnictwo kostne z konwencjonalnymi urządzeniami mocowanymi za pomocą opaski. Celem tego badania była ocena audiologicznych i subiektywnych wyników pacjentów z niedosłuchem przewodzeniowym (CHL) korzystających z aBCD przez okres próbny i porównanie z wynikami uzyskanymi przez tych pacjentów w ich własnych pasywnych przezskórnych implantach na przewodnictwo kostne (ptBCI) Sophono Alpha albo BAHA Attract.

Materiał i metody: Badanie miało charakter prospektywny. Uczestniczyło w nim 14 pacjentów z wrodzoną atrezją ucha zewnętrznego w wieku od 7 do 16 lat. Uczestnicy byli użytkownikami ptBCI przez przynajmniej 2 lata i mieli próg przewodnictwa kostnego ≤ 25 dB HL. Test aBCD trwał 1 tydzień. Dla obu urządzeń zmierzono średnie progi audiometrii tonalnej (PTA4) i wyniki rozpoznawania słów (WRS) z wyrazami dwusylabowymi na poziomie 65 dB SPL w ciszy i w szumie. Wyniki obiektywne zmierzono z użyciem mini kwestionariusza aBCD i kwestionariusza SSQ satysfakcji słuchowej wypełnianych przez rodziców.

Wyniki: Zbadaliśmy 16 uszu. Średni wynik PTA4 w wolnym polu wynosił 52 dB HL bez aparatu słuchowego, 27 dB HL w ptBCI i 29 dB HL w aBCD. Średni wynik WRS w ciszy wynosił 96% w ptBCI i 95% w aBCD. W szumie (+5 dB SNR) średni WRS wynosił 70% w ptBCI i 77% w aBCD. Kwestionariusze wykazały, że aBCD są łatwe w obsłudze i dobrze akceptowane.

Wnioski: W badanej grupie pacjentów uzyskano porównywalne wyniki audiologiczne i subiektywnej satysfakcji gdy stosowali oni nie wszczepialne urządzenie na przewodnictwo kostne naklejane na skórę. Pomimo różnic w obsłudze, aBCD naklejane na skórę jest alternatywą dla przezskórnych implantów na przewodnictwo kostne.

Słowa kluczowe: urządzenie na przewodnictwo kostne naklejane na skórę • Adhear • implant na przewodnictwo kostne • Sophono Alpha • BAHA Attract

Introduction

Patients with conductive hearing loss (CHL) have impaired sound transmission. If untreated, CHL may affect language development, education, social, and emotional development [1,2]. Surgical or non-surgical hearing devices have been developed to overcome the impaired sound transmission to the inner ear.

The surgical percutaneous bone anchored hearing aid (BAHA) was introduced in the 1980s. Later in 2001 a non-surgical softband option for the BAHA audio processor appeared on the market, especially for small children [3–5]. The main disadvantages of the softband are unstable positioning, poor esthetics, and discomfort due to constant pressure on the mastoid [3,6]. A passive transcutaneous bone conduction implant (ptBCI) was first launched in 2006 and a similar product from a different company was introduced in 2013 [7–9]. Although the ptBCI requires surgery, it overcomes some of the disadvantages of the softband device. However, for many children, surgery is contraindicated due to possible comorbidities [10] or parents wanting to avoid surgery for their children [6]. In 2017 an adhesive bone conduction device (aBCD) was introduced. Due to the pressure-free attachment of the audio processor through use of an adhesive adapter, the aBCD does not require surgery and overcomes the drawbacks of BCDs held in place by softbands or headbands that require pressure.

The aBCD consists of two parts: an adhesive adapter that is attached to the skin over the mastoid, and an audio processor that is connected directly to the adapter. The adhesive adapter is water resistant and can remain on the skin for 3 to 7 days. The audio processor has dual directional microphones, feedback suppression technology, and runs on a single P13 battery. Users can select one of four pre-arranged programs and can manually adjust the volume (**Figure 1**). Since its release, several clinical studies have evaluated the audiological performance, wearing comfort, and subjective satisfaction of the aBCD compared to conventional BCDs on softbands or headbands, both in adults and pediatric patients who have CHL. Dahm and colleagues [11] conclude that the aBCD is a valuable alternative to conventional BCDs, with significantly longer wearing time [11]. Neumann and coworkers [3] find, in children with CHL resulting from congenital aural atresia, other ear malformations, or chronically discharging ears, that there is comparable, or even slightly better, audiological performance with the aBCD compared to a conventional softband-integrated BCD. Furthermore, the aBCD overcomes many of the pressure-related limitations of softband-integrated BCDs [3].

Few studies have evaluated the performance of an aBCD compared to implantable bone conduction devices. Work by Canale and colleagues [12] studied how an aBCD could be used to predict the hearing outcome for a patient before he or she received an active bone conduction implant (aBCI). They found that there were slightly lower audiological results with the aBCD, but sufficiently close to predict the hearing outcome of an aBCI. Dahm and colleagues [11] compared the audiological performance and

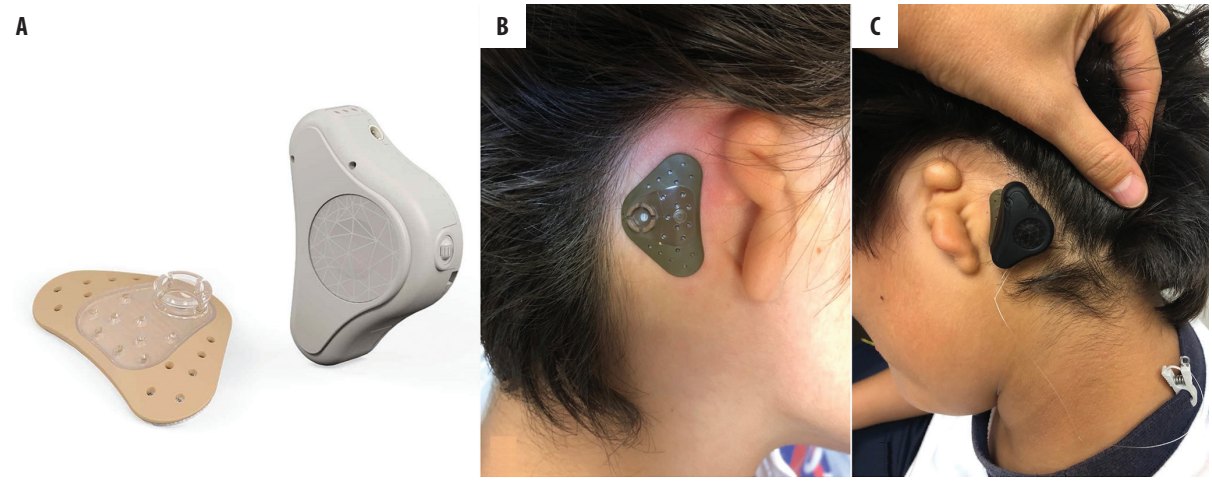

Figure 1. (**A**) Adhesive bone conduction device adapter (left) and audio processor (right). (**B**) Adhesive bone conduction device placed on the mastoid of a child with microtia and congenital aural atresia. (**C**) Same child wearing the adhesive bone conduction device, protected with a black silicone sleeve and retention clip

subjective satisfaction of an aBCI compared to an aBCD. Based on hearing-specific and general quality-of-life questionnaires, they found no significant difference in subjective outcomes between the devices, although the audiological performance could be superior with an aBCI, depending on the patient's BC threshold. A limitation of this study was that many patients have BC thresholds outside the indicative criteria for an adhesive BCD [11]. The clinical study by Skarzynski et al. (2019) tested 5 patients (16 to 65 years) with a ptBCI who had BC thresholds within aBCD indications, and found that implant users received comparable hearing benefit from the aBCD. No data evaluating differences in handling, wearing time, or subjective satisfaction were collected.

The aim of this clinical investigation is to help fill the knowledge gap by following up on the preliminary results of the Skarzynski et al. work. Using 16 patients, our aim is to evaluate the audiological performance and subjective satisfaction in patients with CHL by comparing their standard ptBCI to the new adhesive aBCD [13].

Material and methods

Between September 2020 and June 2021, two tertiary referral centers in Spain (La Paz and La Fe) recruited 14 pediatric patients who used either the BAHA Attract (Cochlear Inc., Mölnlycke, Sweden) or the Sophono Alpha 2 (Medtronic, Inc., Fridley, MN, USA). The research protocol was reviewed and approved by the ethics committee (approval IP-3413). The study was done in accordance with the Helsinki Declaration. All participant's parents gave written informed consent for the study.

Subjects

Patients who were enrolled were aged between 7 and 16 years, had unilateral or bilateral permanent conductive hearing loss (CHL), had used a ptBCI for at least 2 years, and had bone conduction thresholds ≤ 25 dB HL. They had a suitable mastoid area and skin to place the adhesive adapter.

Procedure

This prospective study used a single-subject repeated-measures design where each subject served as his or her own control. All children normally used their own ptBCI audio processor, but for this study were willing to trial the Adhear for a period of 2 weeks.

Audiometric tests were conducted in a calibrated audiometric sound-proof room. For patients with bilateral CHL, each ear was examined separately. When needed, the contralateral ear was occluded with an ear plug (1100, 3M, Berkshire, U.K.) and earmuff (Peltor, 3M, Berkshire, U.K.). A loudspeaker was positioned 1 m in front of the patient for sound field testing.

Audiometric measures were obtained over two visits. At the first, air conduction (AC) and bone conduction (BC) thresholds were recorded, and the average threshold was calculated across 0.5, 1, 2, and 4 kHz (PTA4). Sound field thresholds were measured unaided and aided with ptBCI. The word recognition score (WRS) with bisyllabic words was obtained using the validated Cardenas and Marrero test in Spanish in quiet and in noise, both unaided and aided with the ptBCI [14]. Speech was presented at 65 dB SPL, and noise either at 65 dB SPL (0 dB SNR) or 60 dB SPL (+5 dB SNR).

The validated hearing-specific Speech, Spatial, and Qualities of Hearing Scale Questionnaire, in its version for parents (SSQ for parents) was filled in by the parents for the aided condition with the ptBCI.

At the end of the first visit, the Adhear system (Med-El, Innsbruck, Austria), fitted with one program in the omnidirectional microphone setting, was handed to the patient for a 1-week trial. The user could adjust the volume control to a preferred level during the trial and performance was measured at this setting.

At the second and final visit, the sound field thresholds (in aided condition with the aBCD) and WRS in quiet and noise were measured, and the SSQ for parents was filled in. The SSQ for parents consists of 22 questions in total: 9 for the evaluation of speech perception, 5 for spatial hearing, and 8 for hearing quality. Answers range from –5 (worse performance) to +5 (improved performance) [15]. In addition, the aBCD mini questionnaire – a short version of the Adhear use-and-satisfaction questionnaire provided by the manufacturer – was handed out. The aBCD comprises 7 questions regarding device handling and was filled in by the users.

Statistical analysis

Data and statistical analysis were conducted using Excel and GraphPad Prism 6 (GraphPad Software, San Diego, CA). Non-parametric testing was used for audiological data. A Friedman test with Dunn's multiple comparison was performed with $\alpha < 0.05$. SSQ data was analyzed using the Wilcoxon test.

Results

Patients

We recruited 14 patients (11 males and 3 females) whose average age was 10 years (range 7 to 16 years). CHL was due to congenital aural atresia in all cases (12 unilateral and 2 bilateral). Only 4 patients were diagnosed with Treacher Collins Syndrome. Of these patients, 9 used the BAHA Attract implant (5 used the BAHA 5 and 4 used the BAHA 4 audio processor). There were 7 children who used the Sophono Alpha 2. Average ptBCI usage was 3.5 years (range 2 to 7 years). **Table 1** shows the details.

PTA over headphones

Of the 16 ears were tested, the mean AC PTA4 was 62.5 dB HL (±9.4) and the mean BC PTA4 was 13.5 dB HL (±7.8).

Sound field thresholds

The mean PTA4 in the unaided condition was 51.6 dB HL (±10.5); the mean PTA4 in the ptBCI-aided condition was

Table 1. Participants and their passive transcutaneous bone conduction implants (ptBCI)

Patient ID	Age in years	ptBCI usage in years	Device type	Bilateral or Unilateral	Side
1	9	2	BAHA Attract	Unilateral	L
2	11	3	BAHA Attract	Unilateral	R
3	11	2	BAHA Attract	Unilateral	R
4	10	3	BAHA Attract	Unilateral	L
5	9	3	BAHA Attract	Unilateral	L
6	10	3	BAHA Attract	Unilateral	R
7	10	2	Sophono	Unilateral	R
8	7	2	BAHA Attract	Unilateral	R
9	16	5	Sophono	Unilateral	L
10	10	4	Sophono	Unilateral	L
11	9	4	BAHA Attract	Unilateral	R
12	9	7	BAHA Attract	Unilateral	R
13L	12	5	Sophono	Bilateral	L
13R	12	5	Sophono	Bilateral	R
14L	12	5	Sophono	Bilateral	L
14R	12	5	Sophono	Bilateral	R

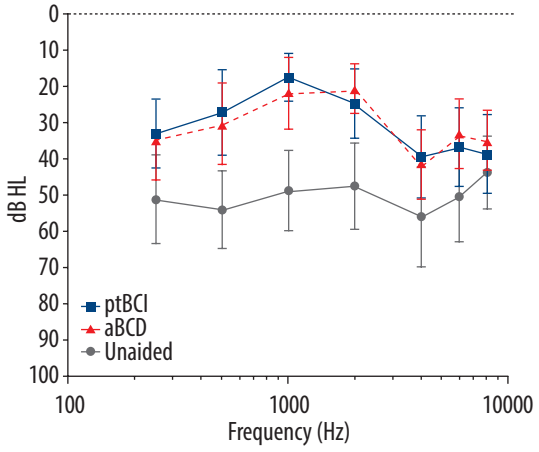

Figure 2. Sound field thresholds for 14 patients measured from 0.5 to 8 kHz in unaided conditions (grey), with passive transcutaneous bone conduction implant (blue), and with adhesive bone conduction device (red)

27.3 dB HL (±6.7) and the mean PTA4 in the aBCD-aided condition was 28.7 dB HL (±7.3). Both aided results were statistically significant compared to unaided (both $p < 0.001$). Between the aided conditions there was no significant difference. **Figure 2** shows the sound field results for each frequency under unaided and aided conditions.

WRS in quiet and noise

In the unaided condition, the mean WRS was 39.4% (±36.7). With the ptBCI, the mean WRS was 95.7% (±7.4) and with aBCD 94.6% (±6.9) at 65 dB SPL. Aided results were significantly different from unaided (ptBCI, $p = 0.0001$; aBCD, $p = 0.0023$). Between the aided conditions there was no significant difference, the devices showing similar performance (**Figure 3**).

At 0 dB SNR the mean unaided WRS was 25.4% (±30.7), while the mean ptBCI-aided WRS was 50.3% (±32.8) and the mean aBCD-aided WRS was 48.1% (±35.4). There was a significant difference between the unaided versus the ptBCI-aided ($p = 0.0311$) and aBCD-aided ($p = 0.04$) condition. There was no significant difference between the two aided conditions (**Figure 3**).

At +5 dB SNR, the WRS in the unaided condition was 30.4% (±34.0), while the mean ptBCI-aided result was 69.9% (±25.2) and the mean aBCD-aided WRS was 77.3% (±19.3). There was a significant difference found in WRS between the unaided versus the ptBCI-aided ($p = 0.008$) and aBCD-aided ($p = 0.0003$) condition. There was no significant difference between the two aided conditions (**Figure 3**).

Questionnaire outcomes

SSQ for parents

Analysis of the SSQ questionnaire for parents was done for the 3 subgroups as well as the total score, and the results are shown in **Figure 4**. In the domain of speech perception, the average score for the ptBCI was 2.9 (±1.5) while for aBCD the average score was 2.2 (±1.7). In the domain of spatial hearing the average score with the ptBCI was 2.2 (±2.1), while with the aBCD the average score was 1.6 (±1.9). Hearing quality with the ptBCI was 3.1 (±1.5) and 2.3 (±1.7) for aBCD. The total score was 2.9 (±1.5) for ptBCI and 2.1 (±1.6) for aBCD. There was no

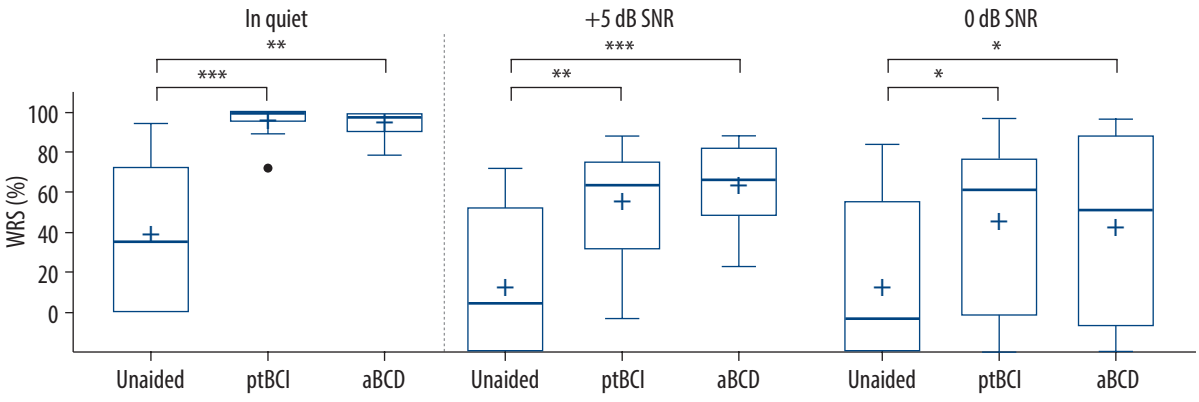

Figure 3. Word recognition scores with bisyllabic words at 65 dB SPL for 14 patients. **Left panel:** in quiet (unaided vs ptBC; $p = 0.0001$(***) and unaided vs aBCD; $p = 0.0023$(**)). **Middle panel:** in noise at +5 dB SNR (unaided vs ptBCI; $p = 0.008$(**) and unaided vs aBCD; $p = 0.0003$(***)). **Right panel:** in noise at 0 dB SNR (unaided vs ptBCI; $p = 0.0311$(**) and unaided vs aBCD; $p = 0.04$(***))

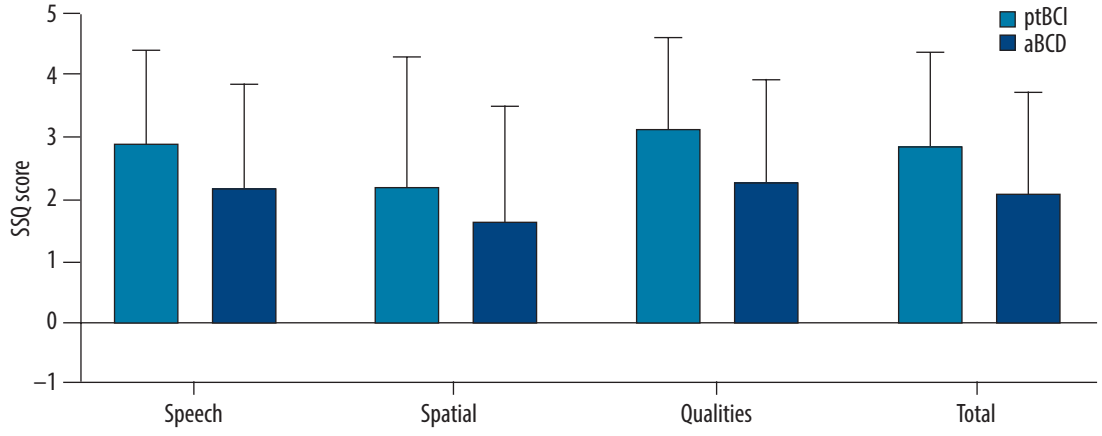

Figure 4. SSQ scores from 14 parents rating passive transcutaneous bone conduction implant (light blue) vs adhesive bone conduction device (dark blue). Subgroups are for speech perception, spatial hearing, hearing quality, and total score in the range –5 (worse performance) to +5 (better performance)

significant difference between the two aided conditions in any domain.

aBCD mini questionnaire

For the mini questionnaire the answers were analyzed in percentages, and the results are shown in **Table 2**. Users were asked "How often do you change on average the aBCD adhesive adapter?": 21% answered every day, 30% every 2 days, 21% said 2 times a week, 21% once a week, and 7% less than once a week. The average adhesive adapter wearing time was 3.7 days (±2.7). When patients were asked about how often the adhesive adapter fell off during normal use, 64% said never. Concerning the tool to help with the placement of the adhesive adapter, 53% found it useful, while 23% found it useless. When asked about the comfort of the adhesive adapter, only 7% of all participants found it to be annoying, 50% noticed the adhesive but found it didn't annoy them, 14.5% said they noticed the adapter sometimes, and 28.5% reported that they didn't notice it most of the time. Regarding the adhesive adapter placement, 57% said that help was needed and 43% placed it in one attempt. In terms of placing the audio processor onto the adhesive, only 14% of participants required help. Concerning skin problems, 43% reported minor skin irritation, referring to some redness that disappeared after removing the adhesive for a few hours; 57% reported no skin irritation.

The average wearing time for the aBCD was 10.6 (±3) hours per day, which compares to the average wearing time for the ptBCI of 9.7 (±3.5) hours per day.

Discussion

The patients in our study were between 5 and 16 years old and had a BC PTA4 of 13.5 dB HL, which conforms with the manufacturer's recommendation of ≤ 25 dB HL. Like other transcutaneous devices, the aBCD has better audiological gain in the middle frequencies (0.5–2 kHz) compared to higher frequencies (≥ 4 kHz) due to skin attenuation [4,6,8,11,16,17]. Children have thinner, softer tissue and less attenuation of vibration than adults [8]. As shown in **Figure 2**, the aided thresholds with both the ptBCI and

Table 2. Answers to questions on aBCD questionnaire ($n = 14$)

Question	Possible answers	Answers from 14 children
How many hours a day did you/your child use the ADHEAR system?	_____ hours a day	1–4 h a day, $n = 2$ 5–7 h a day, $n = 1$ ≥ 8 h a day, $n = 11$
Did the ADHEAR adhesive adapter fall off during normal usage?	☐ Never ☐ Only once ☐ Less than once a week ☐ More than once a week ☐ Every day	$n = 9$ $n = 3$ $n = 0$ $n = 1$ $n = 1$
How often did your child on average change the ADHEAR adhesive adapters?	☐ Less than once a week ☐ Once a week ☐ Twice a week ☐ Every second day ☐ Every day	$n = 1$ $n = 3$ $n = 3$ $n = 4$ $n = 3$
What is your child's experience in placing the Adhesive Adapter behind the ear?	☐ Most of the time one attempt was needed ☐ Most of the time more than one attempt was needed ☐ Help was required	$n = 5$ $n = 3$ $n = 5$
What is your child's experience in putting the audio processor back on the adhesive adapter behind the ear?	☐ Most of the time one attempt was needed ☐ Most of the time more than one attempt was needed ☐ Help was required	$n = 6$ $n = 6$ $n = 2$
Did your child notice wearing the adhesive adapter?	☐ Hardly ever, most of the time my child didn't notice it ☐ Rarely, sometimes my child didn't notice it ☐ Yes, but it does not annoy my child ☐ Yes, my child is annoyed by it	$n = 4$ $n = 2$ $n = 7$ $n = 1$
Did your child suffer from skin problems or irritation from the ADHEAR adhesive adapter?	☐ No, never ☐ Yes, a little	$n = 8$ $n = 6$
Has the tool for the placement of the adhesive adapter behind the ear been helpful?	☐ Very valuable ☐ Valuable ☐ No difference ☐ Partially valuable ☐ Not valuable	$n = 3$ $n = 4$ $n = 2$ $n = 3$ $n = 1$

aBCD in sound field are better in the middle frequencies and decrease in higher frequencies, with no statistically significant differences noted between the devices.

With both devices a clinically significant and comparable hearing threshold improvement over the unaided condition was achieved (**Figures 2** and **3**). Considering that all children had long experience with the ptBCI device (2 to 7 years), better performance was expected compared to the aBCD that was worn for only 1 week. Our results show that the patients adapted to the aBCD quickly.

Speech perception is the most challenging aspect for patients with hearing impairment, whether in quiet or noise. Previous studies with the aBCD in children and adults with CHL have demonstrated a benefit in speech understanding in quiet and noise [3,4,13,11,19]. In our study, the mean WRS in quiet with the aBCD (95%) was comparable to the findings by Neumann et al. (91%) [3] and by Zernotti et al. (92%) [9]. The results of this study show excellent word recognition in quiet with both devices (**Figure 3**).

In noise at +5 dB SNR the mean WRS was 70% with the ptBCI and 77% with the aBCD, showing a numerically better result for the aBCD. However, in the more difficult test at 0 dB SNR no such difference was present (**Figure 3**). The audiological results of our study thus confirm the findings by Skarzynski et al., where comparable results between ptBCI and aBCD were first published in 10 adult patients with pure CHL [13]. However, some authors have reported slightly poorer WRS scores with the aBCD in adult patients who have had a mastoidectomy and canal wall down surgery [11]. This may be explained by the lack of sufficient bone surface after radical mastoidectomy for sound transmission.

The dedicated aBCD questionnaire provided good information about patient satisfaction and daily utilization of the adhesive adapter. The SSQ questionnaire confirmed comparable benefit for both devices in hearing-related quality of life, although numerically better results were obtained with the ptBCI. This might be due to familiarity bias as patients were used to their own ptBCI and the aBCD was only tested for a short time (**Figure 4**).

We reported satisfaction after 1 week of aBCD use. Others have reported subjective satisfaction with the aBCD after longer periods of use (e.g. Neumann, 2 months [3] and Osborne, 1 month [10]). Adaptation to the new device seems relatively fast, with reliable and stable results reported over time.

Similar to what other authors have concluded, we suggest that since the results of our study show similar audiological

outcomes for the aBCD compared to ptBCI, the former can be used as a non-implantable alternative for hearing rehabilitation as well as for preoperative assessment of bone-conduction implants [20]. For older children it can be used as a preoperative tool before implantation of an active device to estimate their perception and expected results [12]. The adhesive BCD can also be an option for patients who require a BC hearing aid for only a short period of time, such as children who do not have sufficient skull thickness for other implant options [11,12], children with temporary CHL (e.g. previous middle ear surgery or transient ear pathology) [4], or even when surgery is contraindicated or the parents simply want to avoid it [6,7,21]. One important aspect in children with microtia and canal atresia is that the placement of the ptBCI with the osseo-integrated fixture and/or magnet transducer, must not compromise the option of auricle reconstruction in the future [10]. For such patients, the aBCD may be a valuable hearing option until patients choose to undergo pinna reconstruction.

The most challenging point in all transcutaneous systems is adequate static pressure on the skin to transmit vibrations to the cochlea, without compromising the integrity of the skin [20]. Cooper et al. in a systematic review [17] reported major complication rates in 5% of the patients (wound dehiscence, skin breakdown, or inability to use passive transcutaneous devices) and minor, self-resolving, complications in 13% (redness). Other authors provide similar results in the pediatric population, with 12–24% minor skin complications [5,20,16,22]. These are higher than those found in adults, who have thicker soft tissue [11]. To avoid these problems some authors recommend that the processor be used for less than 3 or 4 hours per day [8]. This is not an option for bilateral microtia with canal atresia, or for children that need more hours of audiological stimulation, especially at school. In this study, 43% reported some skin redness related to the adhesive adapter, although the redness resolved after leaving the skin free overnight and did not preclude normal daily use of the system. The aBCD was on average used 1 hour per day more than the ptBCI. Only 1 child (7%) was annoyed by wearing the adhesive adapter. Favoreel et al. reported no skin related problems with the aBCD in children over 8 years of age [4], whereas other authors report redness in up to 30% of patients [3]. These differences may be attributed to child age or time of daily use of the device or to climate.

In terms of overall satisfaction, half of our patients preferred the aBCD to their current hearing device. It must be emphasized that this preference was obtained after 1 week of use of the new device and more than 3 years of experience with the ptBCI. Two factors could be considered here. It could be a "new toy" effect, in which children feel more attracted to a new device compared to something they have been using for a long time. On the other hand, it could be that patients received comparable or better results with the aBDC in just a short period of time.

Other studies have also reported ease of use [23], high acceptance by children and caregivers [3,6,10], and noted positively that there is no age limitation for this aBCD [3]. In addition, the aBCD was reported to be more aesthetically attractive than the softband BCD [3,7,10,19] and easier to connect and disconnect to the adapter. Esthetic concerns are highly relevant for acceptance by teenagers [5]. Finally, MRI can be easily performed because there are no artifacts from an implanted magnet [16].

The outcomes of this study confirm and expand the first findings by Skarzynski et al. and call attention to aBCD as an available non-implantable option for children with aural atresia [13]. Perhaps ptBCIs should be reconsidered if similar or comparable results can be achieved without surgery, taking into account potential risks and cost [24]. Further studies, especially with a larger sample size, longer trial period, and cost analysis would be of value.

Conclusions

Hearing results of the adhesive bone-conduction device in children with CHL and normal BC thresholds are comparable to the results of surgically implanted passive transcutaneous bone-conduction implants – in sound field, speech in quiet, and speech in noise. The adhesive BCD is well tolerated in the pediatric population, subjective satisfaction was comparable to ptBCI treatment, and only minor skin problems with the aBCD occurred. For the studied patient group, the aBCD appears to be a viable treatment option that does not require surgery.

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Declarations

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