The ADHEAR System – Review of clinical evidence and user satisfaction

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1. Summary

The world’s first non-implantable adhesive bone conduction system (ADHEAR) has been commercially available since August 2017. The clinical research field has shown immense interest in evaluating the performance of this new bone conduction concept. This paper summarizes the clinical outcomes with the ADHEAR hearing system approximately 2 years after its market release.

2. The ADHEAR System

The ADHEAR system is the world’s first non-implantable bone conduction device (BCD) that does not require pressure against the skin and skull. The system works by converting sounds into vibrations. These vibrations are transferred through the skin to the mastoid bone (skin-drive) and via bone conduction to the inner ear, enabling individuals with conductive hearing loss (Figure 1, A) or single-sided deafness (Figure 1, B) to hear better. The ADHEAR system consists of an adhesive adapter which is placed on the mastoid and an audio processor (AP) which is attached to this adhesive adapter (Figure 2). The adhesive adapter is a water-resistant, single use device and can remain on the skin for up to 3 to 7 days before replacement.

Other skin-drive BCDs are (1) conventional BCDs that are retained by steel spring headbands, elastic headbands (softbands) or eyeglasses and (2) passive transcutaneous BC implants (ptBCI) that are retained via magnetic force to an implanted part under the skin. Both device types exert pressure against the skin and skull.

The pressure-free adhesive concept of the ADHEAR was developed to offer a hearing solution without the pressure-associated drawbacks like pain, pressure marks, placement loss and discomfort that can often lead to shortened wearing time [2, 3].

![Figure 1: Candidacy audiogram for ADHEAR users with conductive hearing loss (A) or single-sided deafness (B). The red shaded area indicates bone conduction thresholds; the grey shaded area indicates air conduction thresholds.](image)

![Figure 2: The ADHEAR bone conduction hearing system. A. The ADHEAR audio processor and ADHEAR adhesive adapter. B. Connecting the audio processor to the adhesive adapter. C. The ADHEAR system in place behind the auricle (In addition see Figure 6).](image)
3. Clinical evidence of the ADHEAR system

3.1 Method

The electronic database PubMed (MEDLINE) was searched for clinical trials reporting any outcomes with the ADHEAR system, published between July 2018 (this was the date of the first article published on the ADHEAR hearing system [4]) and 19th October 2019. Hearing research-related abstract books were also searched for oral or poster contributions within the same timeframe. If a relevant conference contribution was identified, the corresponding author’s permission for using the content as published data was obtained. All included articles were screened for audiological (audiometric tests), subjective (questionnaires and scales) and safety-related (adverse side effects) outcomes. Whenever raw data were given, means and standard deviations were calculated. When necessary, means and standard deviations were provided by the authors upon request. Data were tabulated and analysed within the R Statistical Computing Environment [5] using the RStudio IDE [6] and the metafor package [7]. Meta-analysis was used to estimate pooled effect sizes when two or more samples (articles) were available for any specific outcome. Pooled results are reported as the mean value followed by the upper and lower 95 % confidence limits. The variability among reported outcomes (i.e. effect sizes) was analysed by means of $\tau^2$ (tau-squared) and $I^2$, where $\tau^2$ is a unitless measure for the amount of variability present, and $I^2$ is a measure of how much of the total variability (in %) can be explained by the heterogeneity among the true effects. Whenever data integrity precluded meta-analysis, outcomes were summarized in the text. In some cases (e.g., ‘adhesive adapter change interval’ and ‘audio processor wearing time per day’) data were reported as mean (min/max) or in categorical terms, and thus a simple weighted mean was calculated to account for differences in study-specific sample sizes.

3.2 Search results

Fourteen studies [4, 8-20] were identified that reported on the performance and/or safety of the ADHEAR system. Eleven research articles were published in peer-reviewed journals [4, 8-10, 14-20]. In addition, three research institutes reported on their experience with the ADHEAR at various conferences [11-13]. The published and presented data are summarized in the following sections. This resulted in data on a total of 177 subjects. 69 were under 20 years of age and 56 were children younger or equal to 12 years of age. The ADHEAR system was evaluated in subjects with conductive hearing loss (n = 141), single-sided deafness (n = 23) [4, 17] and mixed hearing loss (n = 13) [15].

3.3 The ADHEAR system in children and adults with conductive hearing loss

The main target group for the ADHEAR hearing system consists of patients with pure conductive hearing loss (CHL), with bone conduction (BC) thresholds equal to or less than 25 dB HL in the frequencies between 0.5 to 4 kHz. Eleven studies [8, 9, 11-13, 15-20] reported on mean sound field thresholds of a total of 141 subjects (143 ears) with this condition. Nine of the studies [8, 9, 11-14, 16, 18, 20] included the word recognition score (WRS) of a total of 108 subjects (110 ears). Five studies [8, 9, 13, 16, 20] reported the speech recognition threshold of 50 % speech intelligibility (SRT50) in noise using the matrix sentence test [1] of 56 subjects (56 ears).

Infobox - Meta-Analysis:

The goal of systematic literature reviews is to derive general conclusions on specific research questions, based on the aggregation of available outcomes. For quantitative data, meta-analysis is the appropriate statistical tool to summarize outcomes from multiple studies. In short, meta-analysis can quantify the overall effect, the variability among studies and the potential influence of other variables on the outcome under investigation. Figure 3, Figure 4, Figure 5, Figure 7, Figure 8, and Figure 12 graphically summarise meta-analytic results from different audiological tests and study designs. For single cohort studies (pre- vs. post), both mean aided outcomes and mean improvement were analysed. For comparative cohort studies (ADHEAR vs. alternative treatment), meta-analyses were conducted on the mean difference among aided conditions. Each figure shows outcomes of single studies (unaided and aided scores) with respective confidence limits, thus enabling an intuitive assessment of the overall variability. The actual result of meta-analyses (Random Effects Model) — pooled estimates of overall or subgroup mean effects — are highlighted in grey lines.
Table 1: Combined forest plot of meta-analyses of aided PTA4 and functional gain. Pooled effects (diamonds) are given for all studies and for two subgroups (Adults, Children) separately. Studies are ordered from lowest to highest unaided threshold. N = sample size; PTA4 = pure tone average over 0.5, 1, 2 and 4 kHz; CI = confidence interval; dB HL = decibel hearing level; RE = random effects; *data of two groups by Skarzynski et al. were combined.

Table 2: Combined forest plot of meta-analyses of aided WRS and WRS improvement. Pooled effects were summarized for all studies and for two subgroups (Adults, Children) separately. Studies were ordered from lowest to highest unaided score. N = sample size; WRS = word recognition score in % correct at 65 dB SPL; CI = confidence interval; RE = random effects; *data of two groups by Skarzynski et al. were combined.
The pooled unaided WRS score in the adult group (n = 72), was 39.0 % at 65 dB SPL (normal speech level). Using the ADHEAR, their hearing thresholds improved on average from 44.5 dB HL unaided to 26.7 dB HL aided, resulting in a mean word recognition score of 75.8 %. The speech recognition in noise improved on average by 2.7 dB SNR.

In the pediatric group (71 ears), 56 children aged between 8 months to 12 years and 13 teenagers used the ADHEAR hearing system in a study setting. The sound field threshold improved on average from 57.9 dB HL unaided to 27.6 dB HL aided. The word recognition score was evaluated in 31 children ≤12 years of age and 5 teenagers. The WRS improved on average from 27.5 % unaided to 92.8 % with the ADHEAR system.

Using a mixed effects model to analyse the impact of confounding variables age group, trial time and severity of CHL (unaided threshold) showed that users of the ADHEAR achieved the treatment target of around 30 dB HL independently of these factors. The aided sound field thresholds were comparable for children and adults. There is a large variability in functional gain (τ² = 53.2) between studies. The meta-analysis revealed a significant effect of the unaided sound field threshold on the functional gain (p = .0012) and accounted for 89.0 % of the variability in this case. This means that users with worse unaided thresholds had a higher FG than users with better unaided thresholds. Consequently, each study’s average aided result reached the treatment target with low variability (τ² = 5.2).

The WRS improvement and aided word recognition score showed high variability (τ² = 346.8 ; τ² = 261.0, respectively), largely due to the heterogeneity between the studies (I² = 94.9 % ; I² = 98.2 %, respectively). However, this could not be explained by the co-variables age, trial time or the unaided score. The aetiologies for the CHL might play a role. Studies mainly testing patients with atresia or microtia [11, 12, 18] as well as those evaluating subjects with a simulated CHL [9, 14] reported high aided scores. The aided WRS was lower in studies with a large proportion of patients with cholesteatoma or chronic otitis media [8, 13, 16, 20].

Looking at the SRT50 in noise, we found a high variability in the aided results as well as the improvement outcomes between the studies. The effect of co-variables was not analysed because of the small N in five studies.

The studies that evaluated subjective results reported high levels of user satisfaction [8, 11-13, 16, 18, 19], and the ADHEAR hearing system was rated as a valuable hearing device by 88 % of users [12, 13, 18]. For more detailed information see Chapter 3.12 Subjective satisfaction with the ADHEAR system.
3.4 The ADHEAR system compared to other skin-drive bone conduction devices

A total of seven studies [8, 9, 11, 16, 18-20] (90 subjects, 92 ears) aimed at comparing the audiological performance of the ADHEAR hearing system to other skin-drive bone conduction treatment options. Meta-analysis was performed to evaluate the mean difference of outcomes tested between treatments and revealed low variability among studies, regardless of the audiological outcome analysed (PTA4: $\tau^2 = 0.75$, $I^2 = 9.9\%$; WRS: $\tau^2 = 0.0$, $I^2 = 0.0\%$).

The following two paragraphs summarise the outcomes with the ADHEAR compared to passive transcutaneous BC implants (ptBCI) and bone conduction devices (BCD) on elastic headbands separately. The study by Sykarzynski et al. [20] is present in both subgroups, as this study evaluated two individual patient groups, comparing the ADHEAR system with the ptBCI (group A) and the BCD on an elastic headband (group B).

![Figure 7: Meta-analyses of aided sound field thresholds in direct comparative studies. Random effects meta-analysis was separately performed for studies comparing the ADHEAR with (A) passive transcutaneous bone conduction implants (ptBCI) and (B) bone conduction devices on elastic headbands. Studies were ordered from lowest to highest unaided thresholds. N = sample size; PTA4 = pure tone average over 0.5, 1, 2 and 4 kHz; CI = confidence interval; dB HL = decibel hearing level; RE = random effects; Signif. = statistical significance at $\alpha = 0.05$; ns = not significant.](image-url)
3.4.1 The ADHEAR system in passive transcutaneous bone conduction implant users

Two studies [11, 20] (19 subjects, 21 ears) assessed the audiological efficacy with the ADHEAR hearing device in experienced passive transcutaneous bone conduction implant (ptBCI) users. The study by Skarzynski et al. [20] evaluated 5 BAHA Attract 1 implant users (BAHA4 1 sound processor) with a mean age of 32 years (range: 16 – 65 years). Time since implantation was 1.9 years on average (range: 1 – 3 years). The subjects achieved a hearing threshold of 33.0 dB HL and a word recognition score of 66.0 % at 65 dB SPL with the passive implant. Without acclimatisation, the same patients fitted with an ADHEAR achieved WRS scores of 66.0 % and a hearing threshold of 32.0 dB HL.

Gavilan et al. [11] studied more users (14 children, 16 ears) with a mean age of 10 years (range: 7 – 16 years). 7 were fitted with a Sophono 2 implant and 9 with a BAHA Attract implant with either BAHA5 1 (n = 5) or BP100 1 (n = 4) audio processor. The subjects had been using their implant for on average 3.7 years (range: 2 – 7 years). The average hearing threshold was 27.2 dB HL, WRS scores in quiet were 95.7 % and WRS scores in noise were 69.9 % at 5 dB SNR and 50.3 % at 0 dB SNR. Comparable results were achieved with the non-implantable ADHEAR system after a trial period of 7 days. The average hearing threshold with the ADHEAR was 28.6 dB HL, WRS in quiet was 94.6 % and WRS in noise was 77.3 % at 5 dB SNR and 48.1 % at 0 dB SNR.

The meta-analysis revealed a pooled PTA4 of 29.7 (24.1, 35.4) dB HL with the ptBCI and 29.2 (25.9, 32.5) dB HL with the ADHEAR. The pooled WRS result was 82.7 (53.9, 111.6) % with the ptBCI and 84.1 (57.0, 111.1) % with the ADHEAR. The mean difference in each test was not significant.
comparable between the ADHEAR and the ptBCIs (see Figure 15). Participants (n = 14) were asked about which device they heard better with: 3 answered that they could hear equally well with both devices, 4 reported better results with the ptBCI and 7 stated that their hearing was better with the ADHEAR system. Both studies concluded that the ADHEAR system showed comparable audiological performance to passive BC implants and that it is a valuable treatment option for patients who are not willing to have an implant or are not suitable for implant surgery.

3.4.2 The ADHEAR system compared to BCDs on elastic headbands

Before a pressure-free solution was available, the standard non-implantable treatment for persons with pure conductive hearing loss was a BCD on either elastic (softbands) or steel spring headbands. Six studies [8, 9, 16-20] compared the audiological performance and subjective satisfaction of the ADHEAR with that of BCDs on headbands.

A total of 41 subjects had average BCD on headband-aided hearing thresholds of 27.7 (25.0, 30.4) dB HL, with a mean WRS of 81.0 (62.5, 99.5) %. With the ADHEAR, the mean hearing threshold was 27.7 (25.4, 29.9) dB HL and the WRS 81.0 (60.9, 101.0) %. In two out of six studies [18, 19] the PTA4 mean difference between the BCD on an elastic headband and the ADHEAR on an adhesive adapter was statistically significant and better for the ADHEAR system. However, the pooled and weighted mean difference calculated by the random effects model was -0.1 (-2.4, 2.2) dB HL and not significant. The mean difference in word recognition score between both devices was not significant, with a value of -2.0 (-0.5, 4.6) %.

The ADHEAR was well accepted by adults and children. The lack of pressure and the low visibility of the system compared to elastic headbands, seems to have resulted in long wearing times per day [16, 18]. For more detailed information see chapter 3.11 Usability of the adhesive concept for bone conduction and 3.12 Subjective satisfaction with the ADHEAR system.

It was long believed that pressure is an essential component of the transmission of vibration through bone conduction, but the results in studies with the ADHEAR have shown comparable audiological outcomes to those with BCDs on elastic headbands. Westerkull [10] describes how the adhesive technology of the ADHEAR system compensates for the absence of pressure, allowing comparable performance to treatments that require static force for AP retention.

3.4.3 The ADHEAR system compared to BCD on SoundArc

The SoundArc® (SA) is an encapsulated spring wire that wraps around the back of the head and sits behind and above the ears (see Figure 9). The SA was introduced in 2018 [21] as an alternative wearing option to a BCD on an elastic headband or steel spring headband. The fundamental operating principles and functional characteristics remain the same. The SA still requires pressure for its retention. Gawliczek et al. [22] report that the average force needed to lift the holding disc from the skin was even somewhat higher with the SA (1.8 N) compared to the elastic headband (1.7 N).

In two studies by Gawliczek et al. [9, 22], the ADHEAR and SA were tested by 15 subjects. The unaided threshold of 49 dB HL improved with the SA to 25 dB HL and with the ADHEAR to 22 dB HL. The average unaided WRS at 65 dB SPL was 48 %, and improved to 100 % with both systems. In conclusion, the ADHEAR provides the same audiological performance as BAHA® on SoundArc, but has the advantage of superior wearing comfort due to the lack of pressure.

3.5 The ADHEAR system compared to the BONEBRIDGE

The BONEBRIDGE® is a direct-drive bone conduction implant, which means that vibrations are directly transferred to the bone. The bone conductor is implanted into the bone, which allows the AP to be lightweight and the dampening effect of the skin is circumvented. In comparison to the ADHEAR skin-drive BCD, the BONEBRIDGE is additionally indicated for mixed hearing loss up to a BC threshold of 45 dB HL. Although the ADHEAR belongs to the device category of skin-drive BCDs and is not indicated for mixed hearing loss, Canale et al. [15] compared the audiological performance of the ADHEAR and the BONEBRIDGE in 15 patients, of which 13
were mixed hearing loss cases. The BONEBRIDGE showed numerically better results in all tests; however, the author concludes that the ADHEAR could be used as a tool to estimate the audiological benefit for patients before undergoing BONEBRIDGE implantation, especially at higher levels of acoustic stimulation.

3.6 The ADHEAR system in binaural fitting

The studies by Gawliczek et al. [9, 22] evaluated the audiological benefit of bilateral versus unilateral treatment with non-implantable bone conduction devices in 15 subjects.

Compared to the results with only one device, bilateral fitting with the ADHEAR reduced the PTA4 by 2.2 dB, improved the SRT50 in quiet by 2.7 dB and improved the SRT50 in noise by 4.3 dB SNR in the S-CL/N-D situation (see Figure 10) by compensation of the head shadow. In comparison, improvement of the SRT50 in noise was 4.1 dB SNR with BAHA5 on SA and 3.9 dB SNR with BAHA5 on an elastic headband. Looking at sound localization ability, bilateral versus unilateral fitting with the ADHEAR significantly improved the mean absolute localization error by 34.2°.

From these results, it can be concluded that the usage of an additional BC sound processor improves sound localization and speech understanding in noise in subjects with bilateral CHL.

3.7 The ADHEAR system in single-sided deafness

In individuals with single-sided deafness (SSD), the ADHEAR is placed on the deaf side, transducing sound via the skull to the contralateral cochlea. Consequently, the device does not restore binaural hearing in SSD cases, but it enhances the monaural function of the healthy cochlea by reducing the disadvantages imposed by the head shadow effect.

Two studies [4, 17] evaluated the ADHEAR in SSD with a total of 23 individuals. Mertens et al. [4] tested the ADHEAR and the CROS (contralateral routing of signals) hearing aid in 17 SSD patients. This CROS HA wirelessly transmits the sound from the unaided ear to a hearing aid in the normal hearing ear. Some patients have problems accepting a hearing aid in the normal hearing ear, which is not an issue with the ADHEAR as there is no occlusion effect. With the CROS HA, speech in noise scores significantly improved in one type of hearing situation but significantly degraded in another. Sound localisation was also found to be significantly less favourable with the CROS device. With the ADHEAR, there were no significant increases or declines in speech in noise; however, localisation skills improved significantly using the omnidirectional program. 70% of users reported the ADHEAR to be a “partially” to “very useful” aid for their condition. Since the ADHEAR is easy to implement, the authors recommend that SSD patients try the device and closely observe the benefits.

Urik et al. [17] reported on 6 SSD patients using the ADHEAR, with the users experiencing a significant average improvement in speech in noise compared to the unaided condition. A hearing-related questionnaire (SSQ) revealed significantly improved subjective satisfaction, while they
also found a positive trend on a general quality of life questionnaire (AQol-6D).

In conclusion, as a non-surgical treatment, the ADHEAR system can be a good solution for SSD patients who are unsuitable for, or who do not want to undergo cochlear implant or bone conduction implant surgery.

3.8 The ADHEAR system in temporary hearing loss

There are several occasions in which temporary conductive hearing loss (CHL) can occur: a waiting period of several months before a necessary surgery, recurrent infections of the ear (e.g. glue ear) in childhood which subside with age or a wound healing phase of several weeks during which the ear canal is blocked with tamponades.

Conventional treatment does not normally assist this CHL within the 3 to 6 weeks wound healing phase. Transient CHL could hamper work, social communication and road safety. A study by Weiss et al. [13] evaluated patients with transient CHL due to postoperative tamponade of the auditory canal.

The study (n = 10, mean age: 38) showed that, as long as the tamponade was blocking the ear canal, use of the ADHEAR significantly improved hearing by 19 dB HL and speech perception in noise by 2.7 dB SNR. In quiet the word recognition was restored from 29 % to 75 % using the ADHEAR. The ADHEAR system was well accepted and the majority of users (80 %) found it to be a “valuable” or “very valuable” aid for this purpose.

3.9 The ADHEAR system in medium-term use

In 2017, Neumann et al. [18] fitted eleven study participants with the ADHEAR, with one child subsequently receiving a VIBRANT SOUNDBRIDGE and another who returned to a BCD on an elastic headband. The remaining 9 children are still using the ADHEAR two years later. Seven of these did not accept their BCD on an elastic headband when starting the ADHEAR trial. After the trial, two children returned to the ADHEAR after an initial re-use period of their BCD on an elastic headband. Four children have been successfully wearing the adhesive BCD for 2 years now and three children for more than 1.5 years [23]. A study by Zernotti et al. [12] followed 14 children using the ADHEAR for 1 year; all children have been wearing it since the beginning. These first outcomes confirm medium term usability of the ADHEAR system.

3.10 The ADHEAR system in unilateral conductive hearing loss

In 12 studies [8, 9, 11-20] a total of 112 subjects with unilateral CHL were evaluated using the ADHEAR.

The outcomes reported in 9 of those studies [8, 11, 12, 15-20] are combined with results from subjects with bilateral CHL. Here we summarise the results from three studies [9, 13, 14] with a total of 37 subjects that focused on unilateral conductive hearing loss. Without a hearing solution these individuals achieved a hearing threshold of 43.5 dB HL; using the ADHEAR, the PTA4 improved on average to 24.2 dB HL. Due to the small sample size the effect of co-variables was not analysed.

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<tr>
<td>Gawliczek, 2018</td>
<td>15</td>
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<td>24.3 [21.7, 26.9]</td>
<td>34.3 34.8 24.6 [21.7, 27.5]</td>
</tr>
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</table>

RE model for All studies

100.0 24.2 [20.3, 28.1] 100.0 19.3 [13.5, 25.2]

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Figure 12: Combined forest plot of meta-analyses of aided PTA4 and functional gain in subjects with unilateral CHL. The pooled effect is shown by the diamond, and the width of the diamond is scaled to the respective 95% confidence interval. Studies are ordered from lowest to highest unaided thresholds. N = sample size; PTA4 = pure tone average over 0.5, 1, 2 and 4 kHz; CI = confidence interval; dB HL = decibel hearing level; RE = random effects.
3.11 Usability of the adhesive concept for bone conduction

The adhesive adapter is the main part of the ADHEAR system that allows for the positive benefits of the adhesive concept, namely: absence of pressure to the head, reliable positioning, less visibility and longer wearing times.

The length of time between changing the adhesive adapter depends on several factors such as weather conditions, the individual’s activity level and perspiration, correct handling and the patient’s general skin condition [10, 18]. The longest average intervals between adapter changes were reported by Mertens et al. [4] (n = 17, mean age: 40) and Dahm et al. [8] (n = 12, mean age: 38), who studied the ADHEAR in mostly adult subjects. The pediatric studies by Neumann et al. [18] (n = 10, mean age: 4) and Gavilan et al. [11] (n = 14, mean age: 10) report slightly shorter intervals (see Figure 13). It appears that the adhesive adapter requires less frequent changes as the patient’s age increases. Overall, the weighted mean over 98 subjects that tried the ADHEAR for periods of 1 week to 12 months is a change interval of 5 days.

It has been reported in the literature [2, 3] and widely known in the ENT field that BCDs worn on conventional elastic or steel spring headbands have limited daily wearing times due to cosmetic reasons and uncomfortable pressure. The ADHEAR adhesive concept was designed to overcome these issues by using an audio processor attachment that requires no pressure and is less visible compared to softband or headband options. The results shown in Figure 14 demonstrate that users of the ADHEAR are wearing the audio processor almost every waking hour of the day, with a weighted mean of 9.3 hours per day (n = 70). The study by Dahm et al. [16] compared the median daily wearing time in 13 users and found a statistically significant difference. The conventional BCD on a headband was used for 4 hours a day, whereas the ADHEAR AP on the adhesive adapter was used for 8 hours a day.
3.12 Subjective satisfaction with the ADHEAR system

The Speech, Spatial, and Qualities of Hearing Scale (SSQ) [24] is a questionnaire designed to measure auditory disability across a variety of domains, reflecting the reality of hearing in everyday life. Three studies (n = 31) [8, 16, 18] used this tool before (unaided) and after a study specific device trial period (aided), ranging from 2 weeks to 2 months. The total scores show statistically significant improvements between unaided and aided conditions in all three studies.

In the study by Dahm et al. [16], participants tried the ADHEAR system and a BCD on a headband for 2 weeks each. The SSQ revealed comparable improvements with both systems compared to the unaided condition in the total score and statistically significantly better results for the ADHEAR system compared to the BCD on headband in the qualities of hearing sub score.

Gavilan et al. presented results on 14 passive transcutaneous implant users with a mean implant wearing time of 3.7 years. They used the SSQ to evaluate subjective satisfaction with the ptBCI, and after a one-week trial period with the ADHEAR system. No significant difference in total SSQ score between both devices was found.

Five studies [11-13, 18, 19] with a total of 68 subjects evaluated the subjective satisfaction with the ADHEAR hearing system using the audio processor-specific ADHEAR questionnaire. Six questions and answers were reported by two studies [12, 18]. The remaining three studies [11, 13, 19] did not report all items (see Figure 16).

As the ADHEAR hearing system was developed to be less visible than headband solutions the first question evaluates the visibility of the system. Out of 23 users [12, 18] (Figure 16 a), 22 % reported that people hardly ever noticed the ADHEAR hearing system, and 26 % said the device was rarely noticed; therefore, 48 % of users felt that the ADHEAR was not noticed by other people most of the time. The remaining 52 % reported that others did notice that they were wearing a hearing device. The adhesive bone conduction concept provided by the adhesive adapter is new to the field. Three of the questions evaluate the users’ experience with this adhesive adapter.

Out of 36 users [11, 12, 18] (Figure 16 b), 78 % needed one attempt most of the time to place the adhesive adapter behind the ear, 8 % needed more than one attempt and 14 % required help. The chances that the adhesive adapter will detach from the skin increases when it is bearing weight and being subject to challenging conditions such as sweat or movement (sport or play). Out of 58 users [11, 12, 18, 19] (Figure 16 c), 43 % reported that the adhesive adapter never fell off during normal use, 31 % said this happened more than once a week and 1 child experienced this every day. Although the adhesive is biocompatible and made of hypoallergenic material, frequent removal/exchange of the adhesive may cause mechanical stress to the skin [25]. A total of 68 users [11-13, 18, 19] were asked if they encountered skin reactions while using the adhesive (Figure 16 d). 65 % reported no skin reaction at all, whereas 34 % had slight skin reaction (some redness), which
disappeared after one night of not wearing an adhesive adapter. This condition did not affect device use, with the exception of one user in this group. Another user experienced a very bothersome reaction and stopped using the adhesive adapter. However, no redness occurred when this user placed the adhesive adapter on a different skin position [18]. A total of 2 out of 68 users stopped using the adhesive concept because of a skin reaction, while the remaining 66 users were able to wear the ADHEAR every day. 41 users rated the sound quality of the device [12, 18, 19] (Figure 16 e). 56 % evaluated the sound quality as very good, 32 % as good, 10 % as acceptable; only one user considered it to be bad.

The last question asks the user if the ADHEAR system is a valuable hearing aid for their condition. From a total of 34 users, [12, 13, 18] (Figure 16 f) 88 % think the device is a very valuable or valuable hearing aid, while 6 % rated it as partially valuable and 6 % found it to be not valuable. In conclusion, the ADHEAR hearing system shows significant subjective hearing improvement as evaluated by the Speech, Spatial, and Qualities of Hearing Scale, as well as high subjective satisfaction, easy handling and a low number of complications.
4. Conclusion

Two years after the market release of the evidence about the adhesive concept of bone conduction, 14 studies [4, 8-20] have studied 177 subjects in order to answer the following research questions: Does the novel adhesive concept of bone conduction work? Is the audiological performance comparable to other treatment options? How does it perform in children, or SSD patients? Where are the limitations of this device? What is the patient’s opinion? How comfortable do the patients find the ADHEAR to be, in terms of handling and wearing?

The clinical outcomes provide evidence that the ADHEAR system is safe and effective at any age in users suffering from conductive hearing loss or single-sided deafness. The ADHEAR system represents the state-of-the-art treatment, considering the treatment options that are currently available on the market for the same intended use. The lack of pressure and the associated benefits are a clear advantage of this non-implantable hearing system. The audiological performance has proven to be comparable to devices on elastic headbands, steel spring headbands or SoundArc as well as to passive transcutaneous bone conduction implants in subjects with conductive hearing loss.

In conclusion, the ADHEAR system is a safe and comfortable application for those who cannot or do not wish to undergo surgery and want a pressure-free hearing solution for all-day hearing.

5. References

8. V. Dahm, W.D. Baumgartner, R. Liepins, C. Arnoldner, D. Riss, First Results With a New, Pressure-free, Adhesive Bone Conduction Hearing Aid, Otol Neurotol, 6 (2018) 748-754.