Summary

The ADHEAR System is a new non-invasive adhesive bone conduction system for the treatment of conductive hearing loss and single-sided deafness in subjects of any age. The ADHEAR System includes a bone conduction audio processor that is retained on the head with an adhesive adapter that is placed behind the auricle. The ADHEAR System represents a new type of technology and offers several advantages compared to other systems that are available for the treatment of conductive hearing loss or single-sided deafness. Bench-tests and audiologic evaluations in normal hearing subjects showed that the audio processor of the ADHEAR has similar performance features to comparative devices, from a technical and user point of view. However, no pressure is needed to transfer the vibrations to the inner ear as required by other non-implantable bone conduction devices e.g. a softband. Its ease of application due to the adhesive adapter, does not compromise the clinical performance of the ADHEAR System. Initial clinical data show that the ADHEAR System represents an excellent option for the treatment of conductive hearing loss or single-sided deafness in children and adults.

The ADHEAR System

The ADHEAR System consists of an adhesive adapter which is placed behind the auricle and a bone conduction audio processor being attached to the adapter (Figure 1). The audio processor is retained on the head using the ADHEAR Adhesive Adapter which is placed over the mastoid area behind the auricle. The ADHEAR bone conduction system is based on a new technology, developed by Otorix AB, Askim, Sweden. In 2015, MED-EL acquired the technology and since then continues with the development of the system. The ADHEAR bone conduction hearing system received its first CE mark on December 9, 2016 and has been commercially available since August 2017.

Figure 1. 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 (See next page).
The ADHEAR functions by connecting the two components of the system together – the audio processor and the adhesive adapter. The system as a whole works by converting sound into vibrations, which are relayed through the skin to the mastoid bone. Sound is transmitted via bone conduction to the inner ear, providing a hearing impression in patients with conductive hearing loss or single-sided deafness.

The audio processor has dual microphones and signal processing technologies and is powered by a single P13 battery. The audio processor’s push button allows users to switch between 4 pre-defined programs. Users can adjust the volume by using the small wheel on the side of the audio processor. A cable can also be connected to the audio processor and linked to devices such as mobile phones or mp3 players.

The adhesive adapter is for single use only and is water resistant, which means it can remain on the skin for 3 – 7 days. However, if retention of the adhesive adapter to the skin is reduced, a new one should be applied. After placing the adhesive adapter in the correct position behind the auricle the audio processor can be connected to the adhesive adapter via the snap connector (Figure 1). The adhesive adapter is currently available in two colours: beige or brown. The adhesive adapter is intended to be used on intact, healthy skin. No skin condition that contraindicates application of an adhesive behind the auricle should be present.

Target groups for the ADHEAR system

The ADHEAR System is intended to treat patients with conductive hearing loss or single-sided deafness via bone conduction. Individuals who have a conductive hearing loss have an impaired ability of transmitting sound through their outer and/or middle ears to the inner ear, but the inner ear function itself is not affected. In cases of conductive hearing loss, the ADHEAR can improve hearing by transforming the sound signal into vibrations, bypassing the external and middle ear and transferring the signal directly to the inner ear via bone conduction.

Those who have single-sided deafness have one perfectly normal ear while the other ear suffers from a profound hearing loss. This hearing impairment leads to a head shadow effect meaning that sounds coming from the non-hearing side are affected by a frequency specific attenuation towards the other ear as the head causes an acoustic shadow. Patients with single-sided deafness have great difficulty in hearing in noisy situations, to localize sounds well, and report problems when trying to communicate in everyday situations. In single-sided deafness, the ADHEAR reduces the head-shadow effect, i.e., sounds coming from the non-hearing side will be heard on the hearing side by placing the ADHEAR System on the deaf side. Via bone conduction, sounds are transmitted via vibration to the other hearing inner ear.

As a non-invasive, non-implantable and low risk active medical device the ADHEAR System is highly comparable to other bone conduction solutions, which are offered to treat patients with conductive hearing loss or single-
sided deafness via bone conduction. The ADHEAR is the first system that is retained on the head with an adhesive component thus omitting the pressure that is required by other systems e.g. bone conduction headbands to transmit vibrations through the skin. It also offers a more aesthetically pleasing solution.

Pre-clinical performance testing

MED-EL conducted bench testing and evaluations in normal hearing subjects to ensure that the ADHEAR System performs as intended.

Performance evaluation on a skull simulator

The adhesive concept of the ADHEAR System provides a new working principle in bone conducted sound by avoiding pressure being applied onto the skull. The audio processor was coupled directly to a skull simulator which simulated the mechanical properties of the skull bone (Figure 3). The outcome measures can be found in the standard “IEC 60118-9:1985 Hearing aids. Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output.”

For the ADHEAR audio processor the output force level frequency response for an input sound pressure level of 90 dB SPL (OFL90) and an input sound pressure level of 60 dB SPL (OFL60) were determined according to IEC 60118-9:1985. The audio processor is picking up a 90 dB SPL or 60 dB SPL input sound pressure level and transforms it into vibrations. The vibratory output of the audio processor is measured in force level (dB µN). The gain setting in this measurement was full on gain. The Peak OFL at 90 dB SPL was 124 dB rel 1 µN (Figure 4A). The peak OFL at 60 dB SPL was 120 dB rel 1 µN (Figure 4B).

The OFL90 value of the ADHEAR Audio Processor was comparable to that of other bone conduction audio processors that may be used on a softband (Table 1).

Table 1. Non-implantable bone conduction hearing aids. All devices included offer noise reduction and wide band dynamic range compression. Technical data were measured on a skull simulator (1), on an artificial mastoid according to IEC60318-6 (2), or the measurement method was not further specified (3). Data of comparator devices were extracted from publicly available fact sheets.

<table>
<thead>
<tr>
<th>DEVICE</th>
<th>MANUFACTURER</th>
<th>FREQUENCY RANGE</th>
<th>PEAK OFL AT 90 dB SPL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ponto Plus</td>
<td>Oticon</td>
<td>125 – 8000 Hz</td>
<td>124 dB (rel 1µN)</td>
</tr>
<tr>
<td>Baha® 5®</td>
<td>Cochlear</td>
<td>250 – 7000 Hz</td>
<td>117 dB (rel 1µN)</td>
</tr>
<tr>
<td>Sophono Alpha 2 MPO®</td>
<td>Medtronic</td>
<td>125 – 8000 Hz</td>
<td>115 dB (rel 1µN)</td>
</tr>
<tr>
<td>Junior BC 811®</td>
<td>Bruckhoff</td>
<td>250 – 6000 Hz</td>
<td>128 dB (rel 1µN)</td>
</tr>
<tr>
<td>contact mini®</td>
<td>BHM-Tech</td>
<td>250 – 6000 Hz</td>
<td>114 dB (rel 1µN)</td>
</tr>
<tr>
<td>ADHEAR®</td>
<td>MED-EL</td>
<td>250 – 8000 Hz</td>
<td>124 dB (rel 1µN)</td>
</tr>
</tbody>
</table>
In preclinical testing the Acousto-Mechanical Sensitivity Level (AMSL), which is the ratio between the force output and the sound pressure input signal, was determined for the ADHEAR audio processor with the skull simulator (Figure 5). By subtracting the input sound pressure level from the corresponding output force level the AMSL was calculated. The AMSL at a 60 dB SPL input at 1600 Hz was 36 dB rel 1 µN/20 µPa.

Evaluation of the ADHEAR System in normal hearing subjects

The ADHEAR System was audiologically evaluated in normal hearing subjects. In particular the study aimed to characterize the audiological performance of the ADHEAR audio processor in combination with the adhesive adapter or the alternative headband and to compare its performance with other bone conduction devices (BCD) on a steel-spring headband or softband.

Eleven normal-hearing, German-speaking subjects, specifically 5 males and 6 females with an average age of 34.5 years (range, 26 to 45 years), were enrolled in the study. Repeated single subject measures were carried out for each subject, with each subject serving as his or her own control for the different devices. Five right sides and six left sides were evaluated. In order to simulate a conductive hearing loss (CHL) the tested ear was occluded with ear plugs during the measurement (Figure 6A). The contralateral untested ear was always occluded and muffled using ear plugs and headphones (Figure 6B). Testing was performed in accordance with the ISO-389 Series; ISO-8253 Series; IEC-60645 Series. For the speech in noise test, speech and noise were presented from the front with a fixed noise level of 45 dB SPL.

An average simulated air-bone gap of 36 dB ± 6 dB (mean ± standard deviation) could be achieved by using the ear plug in the ipsilateral ear. No significant difference in aided sound field thresholds was detected between the tested devices across frequencies (Figure 7).

Speech performance in quiet was evaluated using the Freiburger Monosyllables test (Figure 8A). The speech level was fixed at 65 dB SPL. The word recognition score (WRS) significantly improved with the ADHEAR on the adhesive adapter, the ADHEAR on headband and the BCD compared to the unaided condition. No significant difference was seen between the BCD on softband and the ADHEAR.
Speech understanding in noise was evaluated with the Oldenburger matrix sentence test (OLSA) in sound field by determining the speech reception threshold (SRT) where 50% speech intelligibility is reached at a constant noise level (Figure 8B). The speech level was changed adaptively. The lower the signal to noise ratio (SNR) the better the speech understanding in the respective condition can be interpreted.

SRT was significantly lower with the ADHEAR audio processor being placed on the adhesive adapter, the ADHEAR Audio Processor on a softband and the BCD on a softband, compared to the unaided condition. But again no significant differences between the BCD on headband and the ADHEAR on the adhesive adapter or headband were found.

In conclusion, in normal hearing subjects with simulated conductive hearing loss the ADHEAR System with the ADHEAR Adhesive Adapter performed comparably to another BCD on a softband, in sound field threshold measurements and speech understanding in quiet and in noise.

Clinical Performance of the ADHEAR System

The ADHEAR System is a new treatment option for conductive hearing loss and single-sided deafness. No clinical data has been published in the literature, as it has only recently become available. However, three research institutes already reported on their experience with the ADHEAR System at various conferences. The data that was presented is summarized in the following section (for an overview see Table 2).

Table 2. Overview of clinical studies with the ADHEAR. Number of subjects used for interim analysis (1).

<table>
<thead>
<tr>
<th>STUDY GROUP</th>
<th>OBJECTIVE</th>
<th>NUMBER OF SUBJECTS</th>
<th>OUTCOME MEASURES</th>
</tr>
</thead>
<tbody>
<tr>
<td>McDermott et al. at the Birmingham Children’s Hospital</td>
<td>ADHEAR in children</td>
<td>14</td>
<td>• PTA in sound field • Glasgow children’s benefit inventory (GCBI) • ADHEAR questionnaire</td>
</tr>
<tr>
<td>Skarzynski et al. at the Institute of Physiology and Pathology of Hearing, Warsaw</td>
<td>ADHEAR in BCI users</td>
<td>8</td>
<td>• PTA in sound field • Word recognition score in quiet • Speech reception threshold in quiet • Speech reception threshold in noise</td>
</tr>
<tr>
<td>Mertens et al. at the Antwerp University Hospital</td>
<td>ADHEAR in SSD</td>
<td>17</td>
<td>• Speech perception in noise • Sound localization • Audio Processor Satisfaction Questionnaire (APSQ) • ADHEAR questionnaire</td>
</tr>
</tbody>
</table>

The ADHEAR System in children
McDermott and co-workers from the Birmingham Children's Hospital [McDermott 2017] reported on their experience with the ADHEAR at the Osseo 2017 (Nijmegen, The Netherlands), the ESPCI 2017 (Lisbon, Portugal), the EFAS 2017 (Interlaken, Switzerland) and the CI 2017 (San Francisco, USA). The research group assessed the audiological efficacy of the ADHEAR System in children who had already gained experience with its predecessor, the Adjoin system, for more than one year. This was a prospective study with single subject repeated measures design with each subject serving as their own control. Twenty English speaking children with uni- or bilateral conductive hearing loss who have used the predecessor, Adjoin system, for more than one year, should be included in the study. The audiological testing was planned in three conditions: unaided, with a bone conduction hearing device on a softband, and the ADHEAR System. Subjective outcomes from children and their carers using the manufacturer’s comfort questionnaire as well as the Glasgow Children’s Benefit Inventory was recorded after 4 weeks of use. At the conference the results of 14 subjects were presented. The mean age was 12 years, 10 were male, 4 female. These show comparable audiological outcomes with the
ADHEAR System and the traditional bone conduction solutions on a headband. For both devices a functional gain of approximately 18 dB was achieved in sound field measurements. Early results appeared to demonstrate better high frequency outcomes for the ADHEAR System. The ADHEAR was comfortable and easy to use. The system was very well accepted by children and parents. No skin reactions occurred. Thus the system provides an excellent option for children with conductive hearing loss overcoming the disadvantages of conventional non-surgical bone conduction solutions.

The ADHEAR System in users of bone conduction implants
At the Institute of Physiology and Pathology of Hearing in Warsaw (Poland) Skarzynski and his colleagues assessed the audiological efficacy of this hearing device in experienced users with an existing transcutaneous bone conduction implant and unexperienced users with a bone conduction hearing device on a softband suffering from conductive hearing loss (Skarzynski 2017). Initial data from the study were presented at the Osseo 2017 (Nijmegen, The Netherlands), the EFAS 2017 (Interlaken, Switzerland) and the CI 2017 (San Francisco, USA). The study was designed as a prospective study with single subject repeated measures design with each subject serving as its own control. Native polish adults with uni- or bilateral conductive hearing loss have been included in the study. The comparative device was a transcutaneous BC implant, if the patient had used this device for more than three months. Otherwise a bone conduction device on a softband was used in acute testing. Unaided and two aided conditions with the ADHEAR and the bone conduction device should be compared using the following tests: (1) Sound field audiometry with warble tones. (2) Speech in quiet by determining the word recognition score and speech reception threshold (SRT50) in sound field with Polish monosyllables. (3) Speech in noise by determining the SRT50 in sound field at 65 dB SPL fixed noise level using the Polish Matrix Test with speech and noise coming from the front.

The interim results were presented at the conferences and data collection continues. Data on five subjects with a bone conduction softband (mean age 35.6 ± 10.6 years) and three with a bone conduction implant (mean age 30.5 ± 11.6 years) were presented. The ADHEAR showed good audiological efficacy in this acute clinical study. With the users of the softband a mean functional gain of 19 dB was measured with the ADHEAR System compared to 21 dB with the softband. For users with a bone conduction implant a mean functional gain of 28 dB was reported with the ADHEAR System compared to approximately 25 dB with the implant. In addition, the word recognition score in quiet was comparable within the groups: in the softband group the difference between unaided and aided condition was 54% with the device on a softband and 55% with the ADHEAR System and in the implant group 47% with the implant and 46% with the ADHEAR System. There was no significant difference in the improvement of the speech reception threshold in quiet between the systems: (1) softband group: 21 dB with the ADHEAR and 20 dB with the softband; (2) implant group: 25 dB with the ADHEAR System and 24 dB with the implant. Speech understanding in noise improved significantly by 4.6 dB in the softband group with the ADHEAR System, by 4.8 dB in the softband group with the device on softband, by 3.6 dB in the implant group with the ADHEAR System and by 4.6 dB in the implant group with their own device. In conclusion, the ADHEAR System showed comparable audiological performance to a bone conduction implant and a bone conduction device on a softband. The sound quality was evaluated as natural.

The ADHEAR System in single-sided deafness
Mertens and co-workers at the Antwerp University Hospital investigated the user satisfaction and clinical efficacy of the ADHEAR hearing system in SSD (Mertens 2017). The data was presented at the ESPCI 2017 (Lisbon, Portugal), at the Osseo 2017 (Nijmegen, The Netherlands), the EFAS 2017 (Interlaken, Switzerland) and the CI 2017 (San Francisco, USA). A randomized cross-over study design was conducted using a CROS hearing
The ADHEAR System is safe and effective at any age in patients suffering from conductive hearing loss or single-sided deafness. Considering the treatment options that are currently available on the market for the same intended use, the ADHEAR System represents a state-of-the-art treatment option. In bench tests the audio processor achieved comparable performance data to those of the competitors’ bone conduction devices used on a softband. This further translated in a clinical performance comparable not only to devices on a softband but to passive transcutaneous bone conduction implants based on initial data. In conclusion, the safe and comfortable application of the ADHEAR System did not compromise its functionality providing significant benefit for subjects with conductive hearing loss and single-sided deafness.

Summary of preliminary clinical data with the ADHEAR
Three studies could be identified that reported on performance and safety of the ADHEAR System in prospective clinical trials. In total, data on 39 subjects were reported. Of these, 14 were children with a mean age of 12 years. The ADHEAR System was evaluated in subjects with conductive hearing loss (McDermott 2017, Skarzynski 2017) and subjects suffering from SSD (Mertens 2017). One study (McDermott 2017) assessed the safety of the ADHEAR System in 14 subjects and reported that no soft tissue reactions or other adverse events were observed. Performance of the ADHEAR System was evaluated in all three studies. In subjects with conductive hearing loss (McDermott 2017, Skarzynski 2017) a mean functional gain of 18 to 21 dB could be achieved with the ADHEAR System. This was comparable to bone conduction devices on a softband. An improvement in word recognition score by 46 to 55% was reported (Skarzynski 2017). In addition, speech understanding in quiet improved by 21 to 25 dB and the signal-to-noise ratio decreased by 3.6 to 4.6 dB (Skarzynski 2017). In subjects with SSD sound localization was significantly improved and speech understanding in noise improved if the sound was coming from the deaf side and noise from the better hearing side (Mertens 2017).
References

