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A Prospective Randomized Crossover Study in Single Sided Deafness on the New Non-Invasive Adhesive Bone Conduction Hearing System

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Background: Recently, an adhesive bone conduction hearing system has been developed for conductive hearing loss or single-sided deafness (SSD). In SSD cases, this device may be a good solution for patients who are unsuitable for, or who do not wish to undergo, bone conduction implant or cochlear implant surgery. The study aimed to investigate the hearing outcomes with the adhesive hearing system in SSD.
Purpose of the Study: The study aimed to investigate the hearing outcomes with the adhesive hearing system in SSD.
Methods: A randomized crossover study was conducted in 17 SSD participants, using CROS (contralateral routing of signals) hearing aid as a control. Following outcome measurements were administered after a two-week trial: 1) Speech, Spatial and Qualities scale, Audio Processor Satisfaction Questionnaire, and a custom-made questionnaire about the use of the system, 2) sound localization, 3) speech perception in noise.
Results: 70% of the SSD subjects reported that the adhesive hearing system was partially useful or better. Using the APSQ, the adhesive test device was evaluated equally as the control device. Sound localization improved with the adhesive test device and deteriorated with the control device. There was no improvement in speech perception in noise measured with the adhesive test device. Speech perception in noise ($S_{SSD}N_{NH}$) with the control device improved significantly.
Conclusion: To the best of our knowledge, this is the first study to report on the outcomes of the new adhesive system. Users' satisfaction of the adhesive hearing system was found to be comparable to the control device. Since the hearing outcomes vary highly between patients, trials with applicable hearing systems are recommended in SSD patients. **Key Words:** Adhesive bone conduction device—Bone conduction devices—Single-sided deafness.

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Bone conduction implants (BCIs) are known as possible treatment options for patients with conductive or mixed hearing losses as well as for patients with single-sided deafness (SSD). In case of conductive or mixed hearing loss, the BCI bypasses the impaired outer or middle ear by transducing the sound directly to the cochlea via bone conduction. In case of SSD, a BCI implanted on the deaf side, transduces sound via the skull contents (bone, brain and cerebrospinal fluid) to the healthy cochlea contralateral to the deaf ear. Consequently, the BCI does not restore binaural hearing in SSD but it enhances the monaural function of the healthy cochlea by reducing the disadvantages imposed by the head shadow effect.

Previous literature on the application of BCIs in SSD subjects took into account the two major limitations that these subjects have due to the loss of binaural hearing function, i.e., reduced speech discrimination in noise and difficulty with sound localization (1–6). Concerning speech perception in noise, the greatest benefit of BCI for SSD is where the sound is delivered to the BCI side and the noise is delivered to the contralateral healthy cochlea (7). Although speech discrimination in noise has been shown to be greatly improved, no great differences were found in terms of improvement for sound localization (8).

Since objective indicators like speech perception in noise and sound localization do not represents the complete picture of SSD BCI patients' hearing abilities, most studies reviewed subjective questionnaires for satisfactory outcomes and quality of life as well. Both the

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All ADHEAR hearing systems were provided by MED-EL for a 2-week trial.

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Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Glasgow Hearing Aid Benefit Profile (GHABP), commonly used questionnaires, have shown improved hearing capabilities and reduced hearing handicap in SSD BCI users, compared with the unaided condition (1,9–11). Aside from these measures, the Speech Spatial and Qualities of Hearing Scale (SSQ), the Glasgow Benefit Inventory (GBI), and the Bern benefit in SSD questionnaire (BBSS) are commonly used as standards for the measurement of subjective satisfaction and benefit assessment (7).

There are several reasons known why one should prefer a nonsurgical bone conduction device (BCD) over a BCI. 1) Children may be too young to undergo surgery or may have immature anatomy to allow BCI implantation. Therefore, nonsurgical BCD can offer a (temporary) solution in these cases. 2) Also in temporary hearing losses (for example, previous or after middle ear surgeries or arising from middle ear effusion), nonsurgical BCD can be considered. 3) Moreover, a significant number of hearing impaired patients do not wish to undergo surgery and therefore may prefer a nonsurgical BCD. Conventional examples of nonsurgical BCD are bone conduction eyeglasses and bone conduction devices on a softband or on a headband (Oticon Medical, Askim, Sweden and Cochlear Bone Anchored Solutions, Mo?lnlycke, Sweden). However, these skin-drive devices have some drawbacks. 1) Since the vibrations produced by the skin-drive device are transmitted through the soft skin to the bone, the vibrations are attenuated. This mainly affects frequencies above 1 kHz, which are important for speech reception. 2) They apply high static pressure onto the skin, which can result in discomfort and limited use. 3) Moreover, the placement may be unreliable, since the transducer may move out of position. 4) Another reported drawback is the visibility of the devices, which can influence self-consciousness and stigmatization.

In SSD patients, another conventional solution used is a contralateral routing of signals hearing aid (CROS) (12). CROS hearing aids transfer sound from a microphone placed at the level of the deaf ear, to an amplifier and receiver positioned at the level of the normal-hearing ear. Moreover, in addition to CROS and BCD, growing research concluded that cochlear implantation was found to be the best option for the improvement of speech perception and sound localization in SSD (13,14).

Recently, an adhesive hearing system has been developed as a novel non-implantable BCD for conductive hearing loss and SSD. The aim of the study was to investigate the objective and subjective hearing outcomes with this adhesive test device in a SSD population. Since a CROS hearing aid is the comparable non-invasive conventional solution in SSD, a randomized crossover study was conducted, using the CROS hearing aid as a control.

MATERIAL AND METHODS

Study Design

Seventeen SSD participants were included in the randomized crossover study (Fig. 1). Group A started with a trial with the adhesive test device and group B with the control device. After a 2-weeks trial, they were fitted with the other device. The study was conducted in accordance with the recommendations of the ethics committee of the Antwerp University Hospital. The protocol was approved on January 23rd, 2017 (protocol number 16/50/556). Acquisition of consent was the step by which subjects are enrolled into the study. No study enrollment took place unless the information and consent process was conducted and documented by signing and dating the statement of consent.

Adhesive Test Device: ADHEAR

The ADHEAR hearing system (MED-EL, Innsbruck, Austria) received a CE mark since February 17, 2017 according to EC Certificate Full Quality Assurance no. Cl 16 12 17853 118 and is shown in Figure 2. The white paper of Giefing-Kro?ll present the output force level from the ADHEAR hearing system, measured with a skull simulator which simulated the mechanical properties of the skull bone (IEC 60118–9:1985 Hearing aids) (15). 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 vibratory output of the audio processor was measured in force level (dB μN). The gain

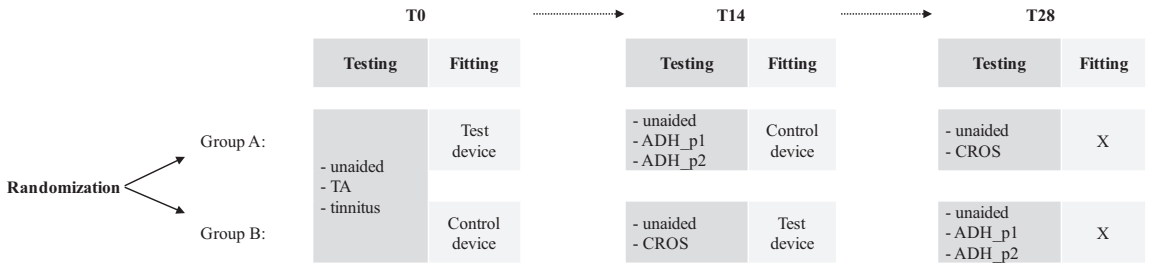

FIG. 1. Crossover design within person comparison. At the first visit (T0), unaided hearing thresholds, transcranial attenuation (TA), and tinnitus loudness were assessed. At T14 (2 weeks after T0), participants of group A were tested in an unaided condition and with the adhesive test device (program 1 and 2) and at T28 (4 weeks after T0) in an unaided condition and with the control device and vice versa for participants of group B.

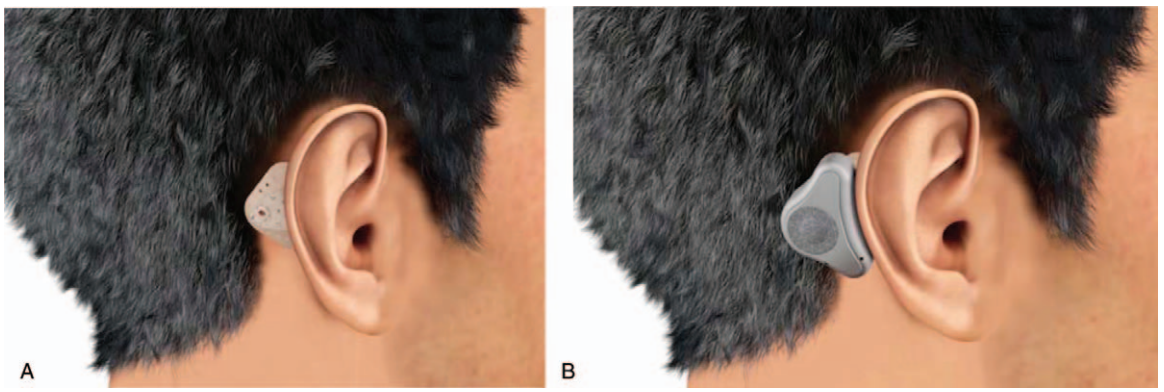

FIG. 2. Test device: adhesive test device. *A*, Adhesive adaptor. *B*, Audio processor (MED-EL, Innsbruck, Austria).

setting during this measurement was full on gain. The Peak OFL at 90 dB SPL was found to be 124 dB rel 1 μN (Fig. 3A) and the peak OFL at 60 dB SPL was 120 dB rel 1 μN (Fig. 3B). The device comprises two parts: an adhesive adapter and an audio processor that are worn behind the ear. The adhesive adapter secures the audio processor and provides a sufficient contact force to provide good physical contact between a vibrating portion of the hearing aid and the user's skull. The adapter is removable, single-use, and has a hypo allergic design. The ADHEAR sound processor contains four pre-configured programs. Two of them were used in the trial: Program 1 was fitted with an automatic adaptive directional microphone, whereas Program 2 was fitted with an omnidirectional fixed microphone. Information regarding the use of the hearing system (positioning of the adhesive adapter, manipulating volume and different programs, battery replacement, etc.) was given by an experienced audiologist. All participants were tested with their normal everyday ADHEAR settings, separately for program1 (ADH_p1) and for program2 (ADH_p2).

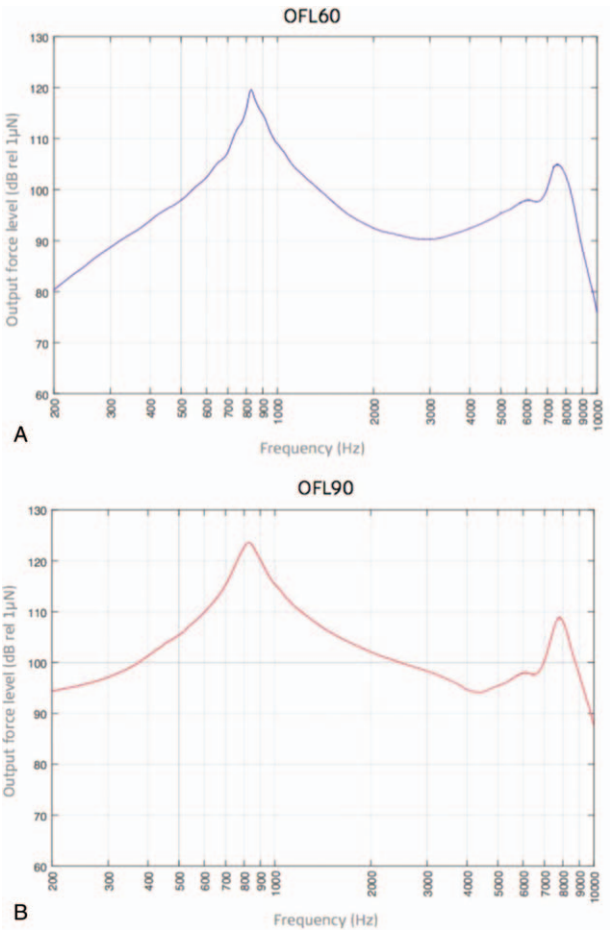

FIG. 3. Output force level (OFL) (in dB rel 1 μN) frequency response (in Hz) for a specific input sound pressure level measured on the skull simulator SKS10 with the adhesive test device. *A*, Represents the OFL at 90 dB SPL and (*B*) the OFL at 60 dB SPL.

Control Device: Contralateral Routing of Signals Hearing Aid

The control device used in the crossover study was a CROS hearing aid (type Phonak Bolero V50M312 in the normal hearing ear and type Phonak CrosII–312 in the single-sided deaf ear, Phonak, Stäfa, Swiss). This system wirelessly transmits the sound from the unaidable ear to a behind-the-ear hearing aid on the normal hearing ear. The hearing aid receives the signal and transmits it into the normal hearing ear.

Participants

Patients consulting the Otorhinolaryngology, Head and Neck Surgery department of the Antwerp University Hospital (UZA), Belgium for their SSD as their primary complaint, were consecutively invited to join the study. A total of 17 SSD patients were recruited from the ENT department. Nine of the 17 participants were women and eight were men. At T0, the median age of the participants was 40;00 (19;00–59;08) years. The median duration of formal education was 3 (0–5) years. Five patients were deaf in the left ear, 12 patients in the right ear. The median duration of deafness was 6 (1–42) years. The

inclusion criteria were as follows: the participant (1) is at least 18 years old at the moment of testing, (2) is suffering from SSD, i.e., contralateral normal hearing ear with pure-tone average ($PTA_{0.5,1,2 \text{ and } 4\,kHz}$) is less than or equal to 20 dBHL, (3) is a native speaker, (4) has a suitable mastoid tip that allows placement of the adhesive system, (5) is willing and able to perform all tests required for the study, and (6) signed, and dated the informed consent before the start of any study specific procedure. A summary of the participants' demographics can be found in Table 1.

Participants' Hearing Profile

Tinnitus Loudness. Using a structured interview, the participants were asked about the presence of permanent tinnitus (''Do you permanently experience tinnitus?''). If applicable, the loudness of tinnitus was evaluated by a numeric rating scale (NRS) going from 0 (no tinnitus) to 10 (extremely loud, cannot get any louder).

Pure Tone Audiometry. At T0, unaided pure tone air-conduction thresholds (0.125–8 kHz) were determined using insert earphones and bone conduction thresholds (0.250–4 kHz) were measured with a B71 transducer. Both ears were open during testing.

Transcranial Attenuation. Transcranial attenuation (TA) was measured in all participants subtracting the unmasked contralateral bone conduction (BC) thresholds (B71 positioned at NH side) from the unmasked ipsilateral bone conduction thresholds (B71 positioned at deaf side).

Outcome Measures

Subjective Reported Benefit

Short Version of the Spatial, Speech, and Qualities Questionnaire (SSQ_{12}). The 12-item version of the SSQ was used to assess participants' self-perceived ''disability'' in daily life activities (16). The scoring scheme is a simple analogue ruler, 10 cm in length, anchored by ''Absolutely not'' and ''Absolutely.'' The left-hand end represents complete disability and the right-hand end complete ability. The higher the SSQ scores, the greater the ability. Participants were evaluated at T0 in their unaided condition and at T14 and at T28 using either the control or the adhesive test device.

Custom-Made Questionnaire. The custom-made questionnaire regarding the use of the adhesive hearing system was used to assess the following specific topics: 1) ''How often did you need to change the adhesive adaptor?,'' 2) ''Did you experience feedback?,'' 3) ''Did the adhesive adaptor fall off during normal use?,'' 4) ''Did you experience skin irritation?,'' 5) ''How do you rate the sound quality?,'' 6) ''How do you rate the appearance of the hearing system?,'' 7) ''During the trial, was the hearing system a useful hearing tool for you?''

TABLE 1. *Participants' demographics, including age at the first test moment (T0); cause, duration (yr), and side of single-sided deafness (SSD; right or left); if applicable tinnitus side and loudness; formal education (yr); and pure-tone average of the unmasked bone conduction (BC) thresholds in the SSD ear ($PTA_{0.5,\ 1,\ 2,\ and\ 4\,kHz}$)*

ID	Age at T0 (yr)	SSD Ear	Cause of SSD	Duration SSD (yr)	Tinnitus Reported	Tinnitus Side	Tinnitus Numerical Rating Scale	Education (yr)	PTA Unmasked BC Thresholds SSD Ear (dB HL)
1	35	Left	Acoustic neuroma	4	Yes	SSD ear	3	3	13
2	19	Right	Labyrinthitis	1	No	x	x	Ongoing	19
3	27	Right	Acoustic neuroma	2	Yes	SSD ear	7	4	9
4	53	Right	Acoustic neuroma	2	Yes	SSD ear	3	4	16
5	41	Right	Acoustic neuroma	9	No	x	x	4	9
6	53	Right	Meningioma	3	No	x	x	3	19
7	40	Right	Meningitis	36	No	x	x	0	19
8	30	Right	Congenital SSD	30	No	x	x	4	14
9	42	Left	Acoustic neuroma	6	Yes	SSD ear	3	4	10
10	30	Right	Acoustic neuroma	1	Yes	SSD ear	4	4	20
11	38	Right	Congenital SSD	38	No	x	x	3	5
12	45	Left	Acoustic neuroma	5	Yes	SSD ear	5	5	15
13	59	Right	Acoustic neuroma	6	Yes	SSD ear	2	0	16
14	55	Right	Sudden deafness	7	Yes	SSD ear	2	3	17
15	45	Left	Acoustic neuroma	11	Yes	SSD ear	8	0	11
16	53	Left	Mastoiditis	42	No	x	x	4	20
17	20	Right	Congenital retrocochlear cholesteatoma	10	No	x	x	3	11

PTA indicates pure-tone average.

Audio Processor Satisfaction Questionnaire (APSQ). The APSQ is a tool to evaluate subjective user satisfaction and focuses on the hardware of hearing systems (MED-EL, Innsbruck, Austria). The APSQ consists of a five-point Likert scale with a range from ''*never*'' to ''*always*'' plus a ''*not applicable*'' field. Participants were asked to evaluate either the control or the adhesive test device at T14 and at T28 using the APSQ.

Sound Localization

In accordance with the study design presented in Figure 1, sound localization skills were investigated in an unaided and an aided condition. Seven broadband Fostex 6301 loudspeakers located in a frontal semicircle in a horizontal plane at subject head level were used. CCITT (Comité Consultatif International Téléphonique et Télégraphique) noise bursts of 1 second duration were presented. The stimuli were roved by ±5 dB (sound levels between 70 and 80 dB SPL). The loudspeakers were positioned in azimuth from −90 degrees to +90 degrees. In each trial six stimuli were offered from each speaker in a random sequence. For each of the 42 stimulus presentations the judged azimuth in response to a loudspeaker k was recorded (ψ_k). Participants' accuracy of sound localization was analyzed via the root mean square localization error (RMSE).

Speech Perception in Noise

In accordance with the study design presented in Figure 1, speech perception in noise was tested in an unaided and an aided condition, using the Leuven Intelligibility Sentences Test (LIST) (17). An adaptive procedure was used to determine the speech reception threshold (SRT in dB SNR). The level of the speech-weighted noise was held constant at 65 dB SPL and the intensity level of the sentences varied in steps of 2 dB adaptively in a one-down, one-up procedure according to the participants' response. The SRT was ascertained based on the level of the last six sentences of one list, including an imaginary 11th sentence. Tests were conducted in free field in an audiometric soundproof booth. Loudspeakers were at ear level at a distance of 1 m from the listener. The following spatial speech-in-noise configurations were used:

1) speech and noise were presented from the front (S_0N_0) to measure the binaural summation effect,
2) speech was presented from the front and noise from the SSD side (S_0N_{SSD}), and
3) speech was presented from the SSD side while noise was presented from the normal hearing side ($S_{SSD}N_{NH}$).

Data Management and Statistical Methods

IBM SPSS Statistics (IMB; Armonk, NY) was used for the statistical analyses. The participants' hearing profiles were summarized using descriptive statistics (median, and range). The primary outcome of the study includes the subjective and objective outcomes with the adhesive test device. In view of the small sample size, non-parametric tests were used. For the same reason, quantitative data are presented as median and range (minimum and maximum). To analyze the subjective outcomes, assessed with the SSQ12 questionnaire, a Wilcoxon signed-rank test was used. The same test was used for the results of the APSQ, with post-hoc correction (Holm's method). Descriptives were used to summarize the outcomes of the custom made questionnaire. For the localization and the speech perception in noise results, a Wilcoxon signed-rank test was used. In addition, to correct for the multiple speech in noise test configurations, a Bonferroni correction was applied. The level of significance was set at $p = 0.01$ and $p = 0.05$, indicated with ** and *.

RESULTS

Participants

Nine out of the 17 participants reported that they suffer from tinnitus. All of these participants who reported permanent tinnitus, indicated that the tinnitus was located in the SSD ear. The median tinnitus loudness, assessed by the tinnitus numerical rating scale, was 4/10 (range, 2/10 –8/10). At T0, the median unaided pure-tone average of the air-conduction thresholds ($PTA_{0.5-4\,kHz}$) in the normal hearing ear was 3 (−2–11) dB HL. As shown in Figure 4, the median transcranial attenuation is 0 (−5–20) dB HL to 15 (−15–−25) dB HL between 0.25 and 4 kHz. The attenuation increased at higher frequencies and became slightly less at 4 kHz. The intersubject variability is large at all frequencies (up to 40 dB HL), as well as the variability within subjects for adjacent frequencies.

Outcomes

Subjective Reported Benefit

SSQ_{12}. SSQ_{12} scores showed no significant differences (Wilcoxon signed-rank test, $p < 0.05$) between the

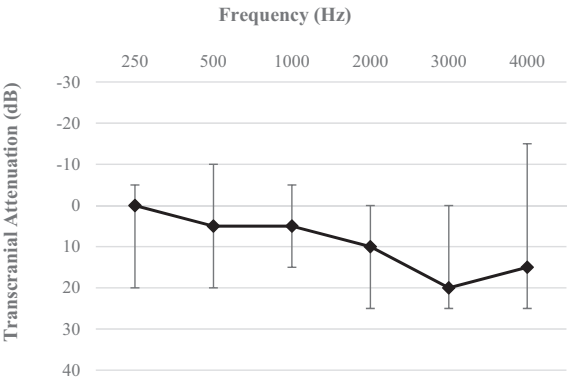

FIG. 4. Median transcranial attenuation (TA) of all participants, measured subtracting the unmasked contralateral bone conduction (BC) thresholds (normal hearing side) from the unmasked ipsilateral bone conduction thresholds (deaf side) in dB. Error bars indicate minimum and maximum values.

unaided condition (median $SSQ_{12\_unaided}$ 4.66 [range, 1.60–7.42]), the condition with the control device (median $SSQ_{12\_control}$ 5.55 [range, 0.67–7.75]), and the condition with the test device (median SSQ_{12_test} 5.67 [range, 2.5–8.17]).

Custom-Made Questionnaire. An overview of the different items of the custom-made questionnaire can be found in Figure 5. The majority (71%) of the SSD population reported that they needed to change the adhesive adapter once, or less than once a week. Only 12% of the participants did not report feedback experiences during the trial with the adhesive test device, while the majority (59%) of the subjects reported that the experienced feedback was (very) burdensome. However, the subjects were able to adjust the gain using the volume button, which resulted in feedback reduction. The majority of the SSD participants reported no skin irritation (76%) and no unexpected cases wherein the adhesive adapter fell off during normal use (88%). For 69% of the subjects, the experienced sound quality was acceptable or better and for 65%, the appearance of the hearing system was acceptable or better. In general, 70% of the SSD subjects reported that the adhesive hearing system was partially useful or better.

Audio Processor Satisfaction Questionnaire (APSQ). Figure 6 shows an overview of the 21 items of the APSQ for the condition with the control device (light boxes) and with the adhesive test device (dark boxes). Positive subjective answers for both the control and the adhesive test device include questions about (1) wearing comfort; (3) putting the processor on its proper place on the head; (4) no skin irritation; (8) no sweating where the processor is located; (9) possibility of heaving a physically active lifestyle with the processor; (11) changing the batteries; (12) no pressure at the place of the processor; (13) combination with wearing glasses; (15) switching the processor on and off; (16) no accidentally falling off of the processor; combination with wearing head-wear; (18) daily maintenance; (19) no suddenly switch off. For the telephone related question, the ''*not applicable*'' option was selected a lot. This corresponds to the expectations, since the SSD study population prefers to call using the contralateral normal hearing ear. Using a Wilcoxon signed-rank test, a significant difference ($p < 0.05$) in favor of the control device was found for the questions about (6) ability to live a more independent life because of the processor; (9) ability to have a physically active lifestyle; (14) ability to enjoy cultural activities; (17) ability to enjoy social activities; (20) the general satisfaction of the processor. However, after post-hoc correction (Holm's method), no significant differences were found between both hearing systems.

Sound Localization

As shown in Figure 7, a Wilcoxon signed-rank test revealed a significant negative influence of the control device on the sound localization abilities compared with the unaided condition ($p < 0.01$). No difference was found in the condition with the adhesive test device in program 1 (directional microphone), while a significant improvement ($p < 0.05$) was found in favor of the adhesive test device in program 2 (omnidirectional microphone). However, since the mean improvement was only 5.1 degrees, there is no conclusive evidence of clinically significant improved sound localization with the test device. Therefore, an absolute statement cannot be made about sound localization with the new adhesive test device.

Speech Perception in Noise (SPIN)

A Wilcoxon signed-rank comparison (with Bonferroni correction) between the unaided condition and the aided

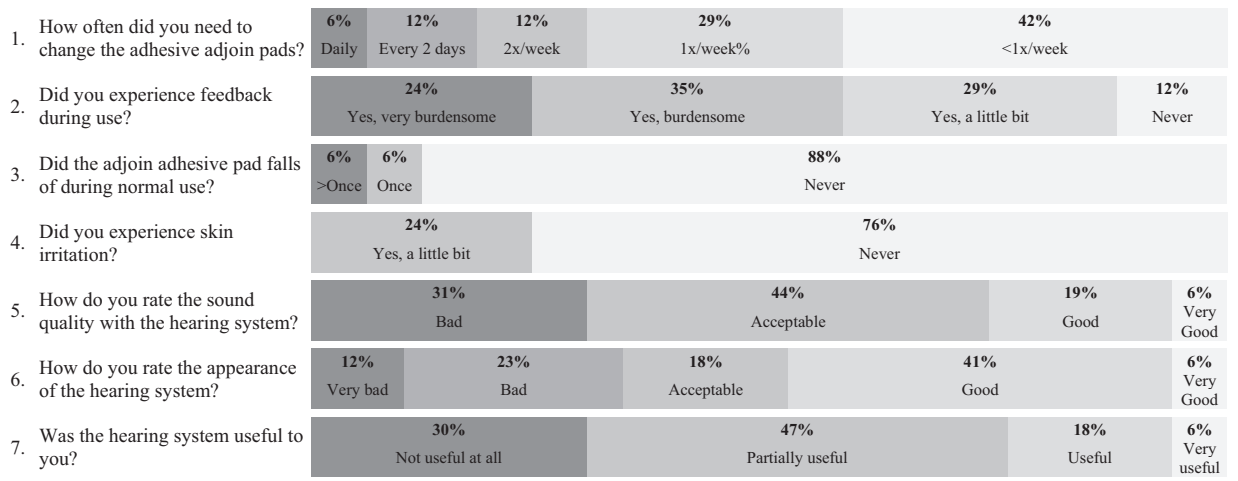

FIG. 5. Overview in percentage (%) of the distribution of the answers on the seven items of the custom-made questionnaire for the condition with the adhesive test device. Dark areas indicate negative responses; light areas indicate positive responses. Six items were filled out by all 17 subjects, item 6 was filled out by 16 subjects.

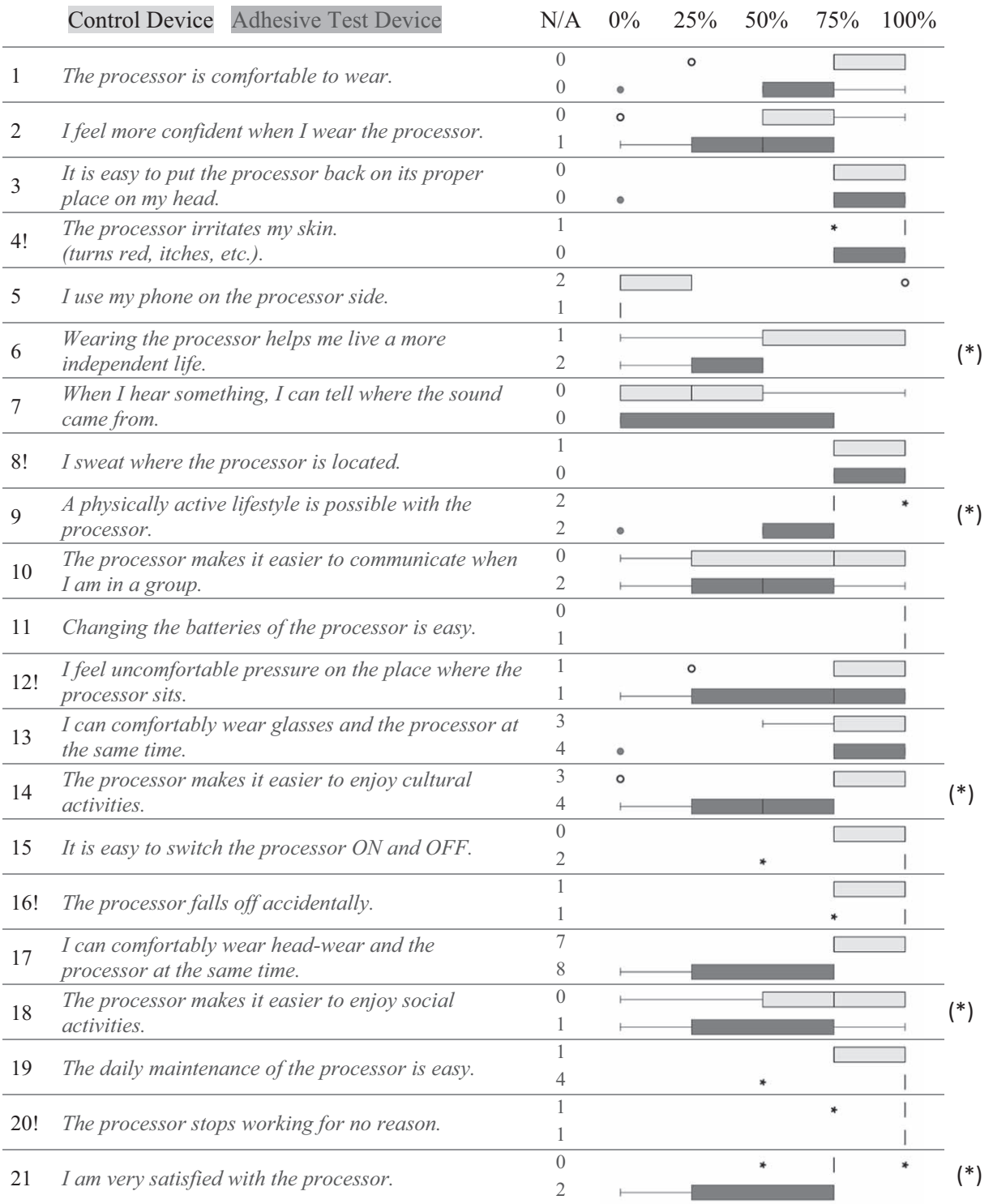

FIG. 6. Overview of the scores on the 21 items of the Audio Processor Satisfaction Questionnaire (APSQ). Light boxplots represent the condition with the control device, dark boxplots represent the condition with the adhesive test device. Boxplots represent minimum, quartile 1, median, quartile 3, and maximum. Scores on the invers questions (indicated with an exclamation point [!]) are transformed. Therefore, the higher the score, the more positive the answer for all items. Significant differences ($p < 0.05$) between the control and the adhesive test device are indicated with an asterisk (*).

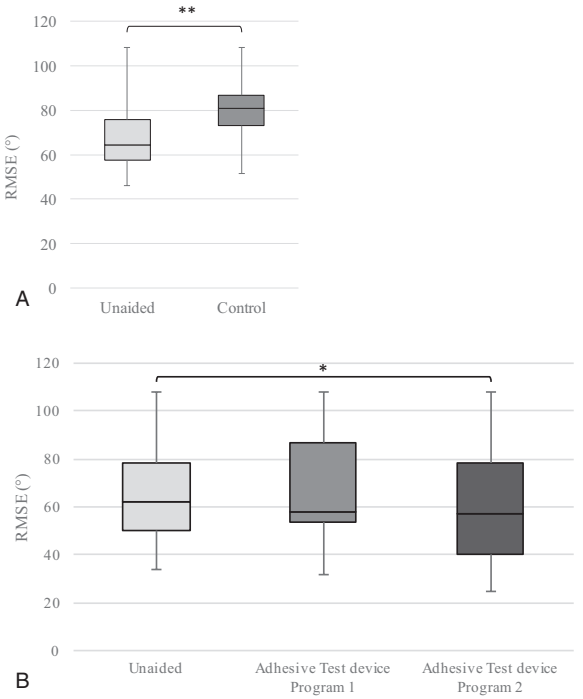

FIG. 7. Boxplots of the sound localization results (root mean square error in degrees) in the different listening conditions. *A*, Presents the difference between the unaided condition and the condition with the control device. *B*, Presents the difference between the unaided condition and the condition with the adhesive test device. Significant differences are indicated with an asterisk (** $p < 0.01$, * $p < 0.05$).

condition with the control device, revealed no statistically significant difference for the S_0N_0 condition. While a significant improvement with the control device over the unaided condition was found in the $S_{SSD}N_{NH}$ condition, a significant deterioration was found for the S_0N_{SSD} condition. No statistically significant differences were found between the unaided condition and the aided condition with the adhesive test device (Wilcoxon signed-rank test with Bonferroni correction). An overview of the SPIN results can be found in Table 2.

DISCUSSION

The present prospective randomized crossover study showed that the new adhesive hearing system can offer a non-invasive hearing solution for patients who are suffering from SSD. In general, 70% of the participants reported after a 2-weeks trial that the adhesive hearing system was partially to very useful to them.

To avoid contribution to the large degree of clinical heterogeneity among studies, the design of the present study was based upon the recently published SSD testing framework (12). Therefore, the study protocol corresponds to the proposed minimal outcomes measures for the assessment of treatment options in SSD patients (i.e., (1) speech perception in noise tests, (2) sound localization tests, (3) quality of life questionnaires, and (4) if applicable, questionnaires to assess tinnitus impact).

No significant improvement was found for speech perception in noise using the adhesive hearing system, while a significant improvement was found for the control device in the $S_{SSD}N_{NH}$ condition. However, a negative influence of the control device was found for the S_0N_{SSD} condition and not for the adhesive hearing system. Previous literature confirms the evidence that CROS hearing aids provide benefit to speech perception in noise when the SNR is more favorable at the SSD side but degrade speech perception when the SNR is less favorable at the SSD side. There is an absence of evidence for any effect of CROS hearing aids on speech perception when the SNR is similar at both ears (18).

In addition to the decreased speech perception in noise in specific listening conditions, sound localization was found to be also degraded when using the control device in SSD patients. Similar to our findings, Lin et al. (19) reported significant deficits to localization performance after use of a CROS hearing aids. For the adhesive hearing system on the other hand, improved localization skills were observed when using the omnidirectional microphone. In the current localization test set-up, the subject was not allowed to move the head during stimulus presentation. Moreover, the level of the localization stimulus was roved (70–80 dB SPL). Therefore, the opportunity to use the head shadow cue was eliminated.

TABLE 2. *Median differences between speech perception in noise in the unaided and the aided condition for three different speech in noise test configurations: S_0N_0 speech and noise from the front; S_0N_{SSD} speech from the front and noise from the deaf side; $S_{SSD}N_{NH}$ speech from the deaf side and noise from the normal hearing side (Control device and Adhesive test device [program 1 and program 2])*

	ΔUnaided versus Control Device	ΔUnaided versus Adhesive Test Device$_1$	ΔUnaided versus Adhesive Test Device$_2$
S_0N_0	−0.67 dB SNR	−1.33 dB SNR	−0.67 dB SNR
	(−2.67–+10.33)	(−5.33–+2.00)	(−4.67–+3.33)
S_0N_{SSD}	−2.33 dB SNR*	0.00 dB SNR	−0.67 dB SNR
	(−6.67–+0.67)	(−4.00–+3.00)	(−4.00–+2.33)
$S_{SSD}N_{NH}$	2.00 dB SNR*	0.67 dB SNR	0.67 dB SNR
	(−2.67–+8.00)	(−1.33–+4.00)	(−3.33–+4.67)

Significant differences ($p < 0.006$; Wilcoxon signed-rank test with post-hoc Bonferroni correction) are indicated with an asterisk. Ranges represent minimum and maximum values.

The head shadow effect in monaural listeners has been reported as the most effective effect for sound localization in SSD subjects (20). Since also the other binaural cues are not available in SSD patients (i.e., interaural time differences and interaural level differences (21)), another hypothesis for the localization improvement in the condition with the adhesive test device (program 2, omnidirectional fixed microphone) is the perception of a different sound quality depending on side of presentation. However, due to the limited significant improvement (5.1 degrees), the small sample size, and the lack of subjective localization improvement, there is no conclusive evidence of clinically significant improved sound localization with the test device. Therefore, an absolute statement cannot be made about sound localization with the new adhesive test device. Further research is stimulated and imperative to further disentangle the clinical relevance of the preliminary improved localization results.

In general, uncertainty remains about the size of the benefit that patients may receive even under listening conditions that favors the use of BCD or CROS hearing aids and whether the magnitude of the benefit would be clinically meaningful. Therefore, counselling of the appropriate expectations about the situations in which benefit may be obtained is very important in SSD candidates. Patients should be given the opportunity to test the device in different listening situations (e.g., at home, at work, in a restaurant, ...) and therefore a trial period should last for at least 2 weeks. However, there are no available guidelines in current scientific literature about the ideal period of a BCD/CROS hearing aid trial.

Using the custom-made questionnaire, 25% of the study population reported an unexpected falling off of the adhesive adapter during the 2-week trial. However, special attention should be paid to the correct placement of the adhesive adapter for optimal sound transmission. Retention of the adhesive adapter onto the skin requires adequate skin preparation. That is, the skin should be clean and dry before application of the adhesive adapter. Correct placement was reported to be very easy by the SSD participants and in no cases did their hair need to be shaved (for optimal sound transmission, no hair is allowed at the site of adhesive adapter placement).

Although contralateral normal hearing is required for fitting of the adhesive device in SSD, it would be desirable to adjust the fitting parameters of the hearing system by the audiologists themselves. Currently, the adhesive hearing system is provided with pre-programmed maps. An optional configuration software, which is currently in development by MED-EL, could provide a further and effective way to reduce feedback by manipulating certain settings of the device relative to the individual user. Tools like an in-situ audiometry could be beneficial to anticipate the inter-subject transcranial attenuation values.

The present study focused on SSD candidates, however, the adhesive hearing system has been developed for conductive hearing losses as well. Also in this conductive hearing loss population, the hearing system can offer a solution for cases wherein BCI implantation is not a suitable hearing solution. Children may be too young to undergo surgery or may show immature anatomy to allow BCI implantation. Also in temporary conductive hearing losses (e.g., previous or after middle ear surgeries, transient middle ear pathologies such as otitis media, ...), the nonsurgical adhesive hearing system can be considered.

Observation in clinical practice shows that, still, the majority of BCD trial experiences in the general SSD population are negative. Main reported reasons for negative BCD trials are perceived limited benefit, cosmetic reasons, no effect on tinnitus, ... However, no clear predictors were found which candidates would benefit most from BCI. Therefore, high level of evidence studies should be conducted to investigate possible prognostic factors that predict the BCD trial outcome (22). Also the present study did not find a significant influence of age, sex, etiology, duration of deafness, hearing loss of the best ear, presence of tinnitus, and the transcranial attenuation on the outcome of the BCD trial. However, more data are needed to investigate the influence of transcranial attenuation on the outcomes with the adhesive hearing system in a SSD population. A regression analysis of Snapp et al. (23) indicated no correlation between TA values and aided speech-in-noise performance for any combined or individual frequencies. Moreover, the lacking influence of tinnitus in the SSD ear on the hearing outcomes is unexpected, since previous research showed a negative influence of the presence of tinnitus on the contralateral speech perception (24). A bigger sample size is needed to retest these conclusions.

In conclusion, since uncertainty remains about the size of the benefit that patients may receive under listening conditions that favors the use of BCD or CROS hearing aids in SSD, all different non-invasive hearing systems should be considered and tested.

Although interesting findings are put forward, the study holds limited statistical power as the study reports on 17 SSD patients. However, to our knowledge, this is the first study on the adhesive hearing system in a SSD population and as such future follow-up research is advised. Future research comparing the results of the adhesive hearing system and results of a soft-band trial, may enable us to further investigate the outcomes of different BC treatment options available for SSD.

Because 70% of our SSD patients found the adhesive hearing system useful and because the use of the hearing system was found to be effortless, it is recommended to try and to watch the possible benefits during the trial in SSD patients.

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