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Original Article

The Baha® Attract System Implantations Significantly Improve the Quality of Life of Hearing-Impaired Patients in Long-Term Observations

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BACKGROUND: The aim of this study was to assess the impact of the Baha® Attract system implantation on the quality of life of hearing-impaired patients, who were qualified for surgery due to various audiological indications.

METHODS: A total of 96 patients implanted with the Baha® Attract system were asked to fill in the set of questionnaires: the Glasgow Benefit Inventory, the Abbreviated Profile of Hearing-Aid Benefit, and the BAHA Aesthetic, Hygiene, and Use. Totally 79 patients responded and were then analyzed. Patients were divided into 4 groups: A: with bilateral mixed or conductive hearing loss, B: with single-sided deafness, C: with unilateral mixed or conductive hearing loss, and D: others.

RESULTS: There was a significant improvement in quality of life measured by the Glasgow Benefit Inventory in all the analyzed groups, with a mean total score of 29.4 points ($P < .001$). Similarly, the evaluation by the Abbreviated Profile of Hearing Aid Benefit questionnaire showed a significant improvement in terms of the global score in all the analyzed groups, with a mean gain of 38.6% ($P < .001$). There were no differences between the groups. More than 90% of patients found the Baha® Attract system easy to place on their heads and maintain good hygiene. Of all the implant users, 81% were satisfied with the final aesthetic effect.

CONCLUSION: The implantation of the Baha® Attract system significantly improves the quality of life of hearing-impaired patients in all subjective scales used. The system is effective for all audiological indications when strictly adhered to. The majority of patients are very satisfied with the aesthetic, hygienic, and utility aspects of the device.

KEYWORDS: Baha® Attract, bone conduction, bone-anchored hearing aid, transcutaneous, APHAB, GBI

INTRODUCTION

Bone-anchored hearing aids (BAHAs) or bone conduction hearing devices are currently well-proven methods of treatment in unilateral or bilateral, conductive or mixed hearing loss, as well as single-sided deafness (SSD). Bone-anchored hearing aids are indicated to patients for whom reconstructive ear surgery or conventional hearing aids are not suitable or not sufficient. The concept of bone conduction hearing has been known for a long time, and nowadays, many different systems are available.[1,2] Since the first implantation reported by Tjellström and Granström in 1977,[3] a variety of bone conduction devices have been introduced to the market.[2] In the more traditional so-called percutaneous BAHA systems, a sound processor is attached to a skin-penetrating abutment, connected with a titanium implant placed in a bone. In turn, in the later introduced so-called transcutaneous BAHAs, the abutment has been replaced by a system of magnets.[1] This solution allows for preserving skin integrity, thus, there are no hygienic problems, and the aesthetic effect is satisfactory.[4-8] However, after the implantation of passive transcutaneous systems (with the transducer positioned outside the body), which are more frequently used, the audiological gain can be limited due to sound attenuation caused by the skin between magnets.[9,10] What is more, the permanent pressure on the skin can cause redness or pain in the area covered by the magnet[7] and sometimes even soft-tissue necrosis.[11] In our previous study concerning the surgery, healing process, and soft tissue condition in a group of 125 cases, we have found mild redness and/or mild pain over the magnet after processor attachment

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in 9.6.% of implanted patients, which fortunately disappeared in all the cases after reducing the strength of the magnet or limiting the daily use of the processor.[7]

The question therefore arises whether this type of treatment actually improves the quality of life (QoL) of hearing-impaired patients in long-term observations and whether the outcomes depend on eligibility criteria.

The aim of the study was to assess the impact of implantation of the Baha® Attract (Cochlear Bone Anchored Solutions AB, Mölnlycke, Sweden), the most popular transcutaneous passive BAHA system, on the QoL of hearing device receivers, qualified for surgery due to various audiological indications.

MATERIALS AND METHODS

Study Design

The study was conducted prospectively in the tertiary referral university ENT Department on consecutive patients implanted with the Baha® Attract between September 2014 and June 2017. In June 2018, 96 hearing-aid receivers were asked to complete a set of 3 questionnaires concerning a change in QoL after implantation. Of those, 79 patients completed at least 1 questionnaire (response rate 82.3%) and were enrolled in the research group. Ethical committee approval was received from the Ethics Committee of Poznan University of Medical Sciences (approval No: 23/16 and 1234/17). Written informed consent was obtained from all participants who participated in this study.

Patients' Characteristics

The analyzed group consisted of 54 females and 25 males, aged 18-77 years, with a mean of 52 years. The most frequent otological indications for the implantation were chronic otitis media usually after an unsuccessful trial of sound transmission system reconstruction (54.4%), and otosclerosis, after an unsuccessful stapedotomy or restapedotomy (21.5%). According to the audiological indications, the patients were divided into 4 groups: A (n = 40; 50.6%): with bilateral mixed or conductive hearing loss, B (n = 28; 35.4%): with single-sided deafness, C (n = 7; 8.9%): with unilateral mixed or conductive hearing loss, and D (n = 4; 5.1%): others including a combination of different types of hearing loss in both ears, for example, conductive in one ear and sensorineural in the contralateral one. The latter was not further analyzed separately because of the small number of samples. The characteristics of the groups are presented in Table 1.

Questionnaires

The following 3 questionnaires (in Polish) were used:

1. The Glasgow Benefit Inventory (GBI, Robinson et al[12]), with 2 additions according to Dutt et al[13] to provide the assessment of the patients' perceived benefits after implantation. The general subscale (GS), social support subscale (SSS), and physical health subscale (PHS) are taken into account. The answers to all the questions give a total score (TS). The response to each question is based on a 5-point Likert scale. Scores range from −100 (the poorest outcome) through 0 (no change) to +100 (the best outcome). Additionally, 4 questions related to the success of BAHA, and a 10-point linear analog scale reflects the health state before and after implantation. Details on the questionnaire can be found in the publication by Dutt et al[13]
2. The Abbreviated Profile of Hearing Aid Benefit (APHAB, Cox and Alexander 1995),[14] the most widely used hearing-specific questionnaire, measures subjective hearing impairment on 4 different subscales pertaining to different listening situations: the ease of communication (EC), background noise (BN), reverberation (RV), and aversiveness to a sound (AV). Thus, lower scores indicate better outcomes in the EC, BN, and RV. On the contrary, the AV subscale, detecting how the noisy situations were misperceived, is characterized by decreasing APHAB values in unaided conditions. Details on the questionnaire can be found in the publication by Cox and Alexander.[14]
3. The BAHA Aesthetic, Hygiene and Use (BAHU) questionnaire (original, Gawęcki et al[4]) is composed of 4 questions concerning aesthetic aspect, hygiene, ease of placing the processor, and stability of the attraction (see Figure 4).

Statistical Analysis

The statistical analysis was performed with Statistica v.13 (TIBCO Software Inc., Palo Alto, CA 94304 USA) and StatXact v. 9.0.0 (Cytel Software Corporation, Waltham, MA 02451 USA). The single-sample *t* test was used to determine the change of the QoL after implantation measured by the GBI scale in the analyzed groups. A paired *t*-test and the Wilcoxon test were used to evaluate the change in health status after implantation (second addition by Dutt et al[13]) and in quality of hearing measured by the APHAB scale in the analyzed groups. The statistical significance of differences between the groups was evaluated by a one-way analysis of variance test (GBI, APHAB), Kruskal–Wallis test (GBI, second addition by Dutt et al[13]), and Fisher–Freeman–Halton test (first addition by Dutt et al[13]) All the statistical analyses were performed by a certified statistician.

Table 1. Patient Characteristics, Categorized into 4 Groups

Group	A (n = 40)	B (n = 28)	C (n = 7)	D (n = 4)
Audiological indications	Bilateral mixed or conductive hearing loss	Single-sided deafness	Unilateral mixed or conductive hearing loss	Others
Otological indications	COM: 30 Otosclerosis: 5 Atresia of the EAC: 5 (congenital: 3, acquired: 2)	Otosclerosis: 12 Unknown: 10 COM: 5 Injury: 1	COM: 4 Atresia of the EAC: 3 (congenital: 1, acquired: 2)	COM: 4
Age	18-72 (41.6)	27-73 (50.9)	22-50 (41.1)	62-77 (69.8)
Sex	Female: 29 Male: 11	Female: 20 Male: 8	Female: 4 Male: 3	Female: 1 Male: 3

COM, chronic otitis media; EAC, the external auditory canal; SSD, single-sided deafness.

RESULTS

Glasgow Benefit Inventory

Altogether, 73 patients responded to the GBI questionnaire (group A: 37, group B: 25, group C: 7, and group D: 4). The results of the study revealed a significant improvement in QoL after the Baha® Attract implantation, with a total score of 29.4 ± 22.6 points ($P < .001$). The improvement in group A was found to be 28.2 ± 23.2 points ($P < .001$), in group B 32.9 ± 24.4 ($P < .001$), and in group C, 20.6 ± 18.6 ($P = .026$). There were no statistically significant differences between the 3 groups ($P = .441$). In all the groups, the highest improvement was observed in the general scale. Altogether, the improvement was 40.3 ± 28.0 points ($P < .001$): in group A: 38.2 ± 28.0 points ($P < .001$), in group B: 43.3 ± 30.3 points ($P < .001$), and in group C: 35.7 ± 28.7 points ($P = .016$). There were no statistically significant differences between the 3 groups ($P = .642$). The worst results were observed in the physical health scale—altogether, 6.8 ± 26.3 points ($P = .029$). There was a mild improvement in group A (9.9 ± 27.6, $P = .036$) and B (8.7 ± 23.1, $P = .073$), but in group C, there was even deterioration (−14.3 ± 31.1, $P = .270$). The differences between the groups were not statistically significant ($P = .119$). The results of the GBI are presented in Figure 1.

The results of the first addition introduced by Dutt et al[13] showed the evident predominance of positive responses ("rather yes" or "definitely yes") to all 4 questions concerning: effectiveness of BAHA: 86.5% (group A: 89.2%, group B: 80.8%, group C: 85.7%, $P = .691$), satisfaction with BAHA: 82.4% (group A: 75.7%, group B: 84.6%, group C: 100%, $P = .318$), effectiveness of BAHA in family's/friends' opinion: 78.4% (group A: 78.4%, group B: 76%, group C: 71.4%, $P = .919$), and recommendation of BAHA to others with similar hearing problems: 70.3% (group A: 67.6, group B: 73.1, group C: 85.7%, $P = .743$). There were no statistically significant differences between the studied groups in any of the evaluated aspects. The detailed answers to the questions are presented in Figure 2.

The second modification, regarding the change in health state, revealed a significant improvement from 47.8% before the Baha® Attract implantation to 78.8% after it (a difference of 31%, $P < .001$). The improvement was observed in all the groups: in group A, from 42% to 77.2% (a difference of 35.2%, $P < .001$); in group B, from 53.8% to 80% (a difference of 26.2%, $P < .001$); and in group C, from 60.8% to 82.5% (a difference of 21.7%, $P = .029$). The differences between the groups were not statistically significant ($P = .264$).

Abbreviated Profile of Hearing-Aid Benefit

The APHAB results were obtained for 67 patients and indicated a significant improvement in the aided conditions compared to the unaided ones in all the groups, in terms of the global score, and in all the subscales, except aversiveness. The mean gain in a global score was 38.6% for all the patients ($P < .001$), 37.4% in group A ($P < .001$), 42.9% in group B ($P < .001$), and 34.0% in group C ($P = .008$). There were no statistically significant differences between the groups ($P = .624$). The APHAB results for all the patients are presented in Figure 3 and for particular groups, in Table 2.

BAHA Aesthetic, Hygiene, and Use

A total of 73 patients completed the questionnaire regarding the aspects of aesthetics, hygiene, and use. The majority of the patients found the Baha® Attract system easy to place on their heads, as well as to maintain good hygiene in the BAHA area. Most of the implant users were satisfied with the aesthetic effect; 11% of the patients had negative feelings about the stability of the attraction; 8 patients, including 6 women, were afraid of losing a processor, mainly because of wearing long hair. Detailed data are presented in Figure 4.

DISCUSSION

This study aimed at a multifaceted QoL assessment of a large series of cases implanted with the most popular transcutaneous passive BAHA system, the Baha® Attract. This system allows the wearer to avoid some previously observed negatives and complications

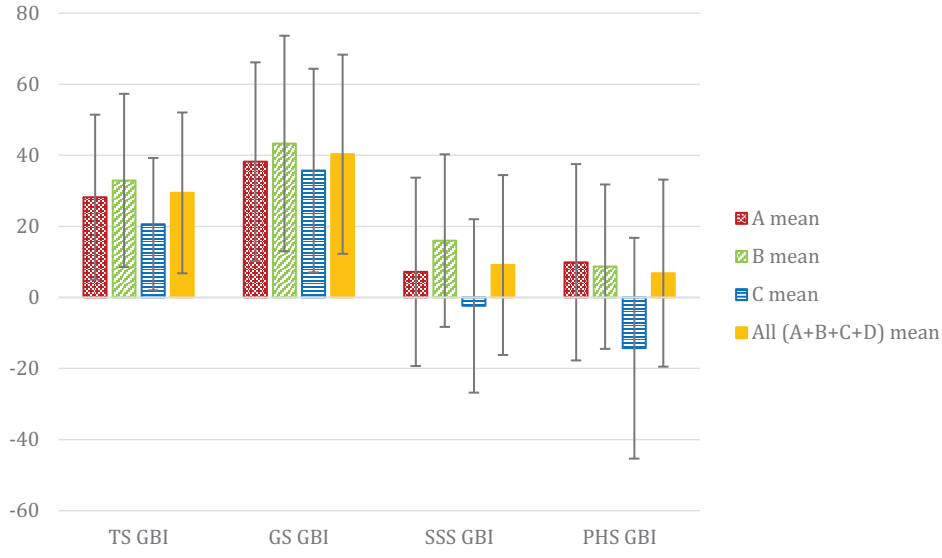

Figure 1. The results of the GBI scale in the analyzed groups. TS, total score; GS, general subscale; SSS, social support subscale; PHS, physical health subscale; GBI, Glasgow Benefit Inventory.

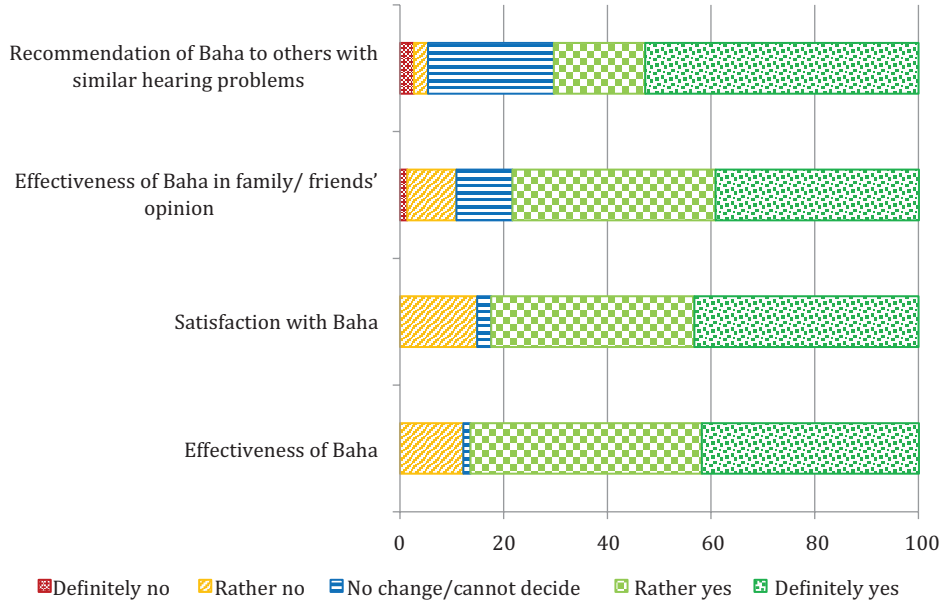

Figure 2. The results of the first addition, introduced by Dutt et al[13], related to the success of the BAHA, according to the patients and their families and friends. BAHA, Bone-anchored hearing aid.

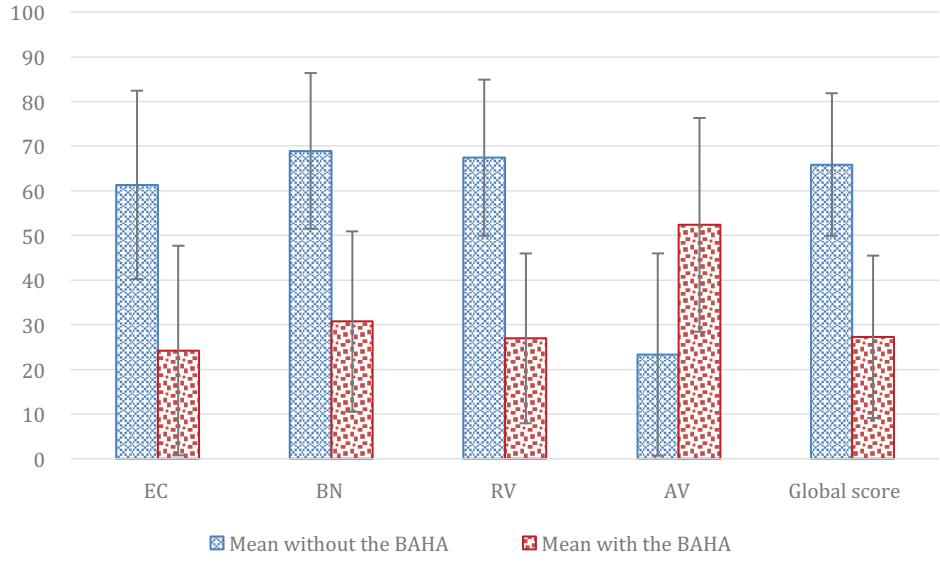

Figure 3. The results of the APHAB for all the patients. EC, ease of communication; BN, background noise; RV, reverberation; AV, aversiveness; Global score, mean of EC, BN, and RV; APHAB, Abbreviated Profile of Hearing-Aid Benefit.

typical of percutaneous devices, and it has been demonstrated to constitute a much better option for aesthetic and hygienic reasons.[4,15,16] What is more, the audiological gain of this device has been proven.[4-6,8,15,16]

The impact of the Baha® Attract implantation on QoL has been demonstrated in many studies and by different questionnaires; however, in most of them, the number of cases was limited or follow-up was short.[4,6,17-22] We have found only 3 studies with more than 30 cases and follow-up for 1 year or longer, 1 single-center[5] and 2 multicenter.[8,16]

In 2017, Dimitriadis et al[5] published the results of 105 cases implanted with the Baha® Attract between 2013 and 2016, among them the results of QoL. In adults, they found after implantation a significant improvement in Client Oriented Scale of Improvement and in GBI scores with a global satisfaction of 84% and 77.4% for those previously aided (measured by Glasgow Hearing-Aid Difference Profile) and unaided (measured by Glasgow Hearing-Aid Benefit Profile), respectively. The evident improvement was observed both in patients with conductive or mixed hearing loss and those with SSD. In the pediatric population, a 22% improvement in Speech, Spatial, and Qualities of Hearing Scale (SSQ-12) mean score was observed.

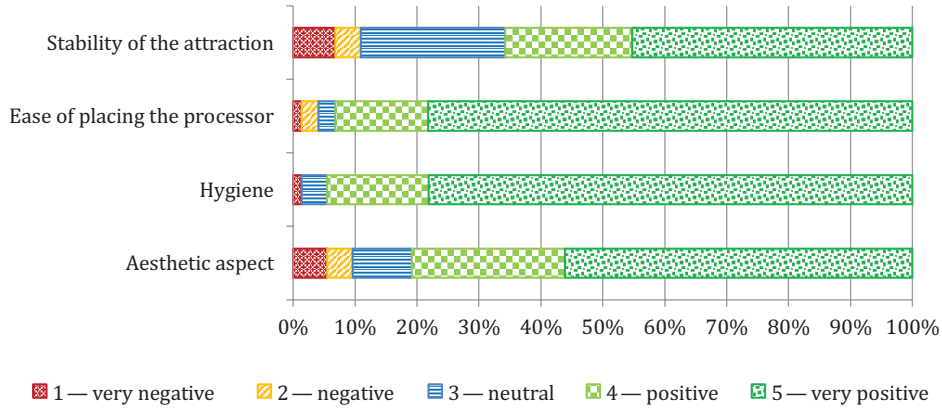

Figure 4. Results regarding the aspects of aesthetics, hygiene, and use, after the implantation of the Baha® Attract—the BAHU questionnaire. BAHU, BAHA Aesthetic, Hygiene, and Use.

In 2018, results of a French multicenter study with 32 patients (25 with conductive and mixed hearing loss and 7 with single-sided deafness), with a 1-year follow-up, were published by Nevoux et al.[16] The authors showed an improvement in all 3 used questionnaires: GBI, Glasgow Health Status Inventory (GHSI), and APHAB. The mean GBI total score was 25.7 and the mean general, social, and physical subscores were 35.6, 10.1, and 1.8, respectively. Unfortunately, the authors did not show the data for both groups separately. The mean global APHAB score was 54.3%. The results for both groups were only presented in a figure (but not given in numbers) and show a more evident gain for the patients with conductive and mixed hearing loss than for those with single-sided deafness. The mean GHSI was 39.1 preoperatively and went up to 51.8 at 12 months after surgery.

In another multicenter study by Kruyt et al,[8] the results of QoL of 54 cases (39 with conductive or mixed hearing loss and 15 with SSD), with follow-up of 2 years, were presented. Three questionnaires were used: Health Utilities Index (HUI3), APHAB, and SSQ. There was a statistically significant improvement in HUI3 attributes of hearing, speech, and pain, the APHAB domains' ease of communication, background noise, reverberation, and global score and on all SSQ scales at the 24-month follow-up compared with the baseline situation. The mean gain in APHAB global score was 21.1 and was much more evident in a group of patients with conductive or mixed hearing loss (24.2) than those with SSD (8.6).

In our study, the information concerning QoL evaluated at least 1 year after implantation was collected from 79 patients. The research design is unique because to gain this knowledge, 3 questionnaires were used, 2 well-established (GBI and APHAB), and the original BAHU questionnaire designed in our department. We have found a significant improvement in QoL in the GBI scale after the Baha® Attract implantation, with a mean total score of 29.4. These results are better than those reported by Neuvox et al[16] (25.7). The improvement in our study was observed in all analyzed groups with no evident differences between them. In our study and in the study by Nevoux et al.[16] the highest improvement was observed in the general scale. On the other hand, the results of both studies did not show an evident effect of implantation on the physical scale. Since the changes in the physical scale are based on 3 questions regarding (1) the frequency of visits to the GP, (2) the frequency of colds or infections, and (3) the frequency of taking medications for any reason before and after surgery, the lack of an impact of the procedure in this part of the scale becomes obvious.

We have also found a significant improvement in the results of the APHAB questionnaire in terms of a global score and in all the subscales, except aversiveness. The mean gain in a global score was 38.6%. This result was in between those previously reported by Neuvox et al[16] (54.3%) and Kruyt et al[8] (21.1%). What is more, a significant improvement was observed in all our analyzed groups with no

Table 2. The Results of the APHAB for the Analyzed Groups.

APHAB/ Group	A					B					C				
	Without the BAHA		With the BAHA			Without the BAHA		With the BAHA			Without the BAHA		With the BAHA		
	Mean	SD	Mean	SD	*P*	Mean	SD	Mean	SD	*P*	Mean	SD	Mean	SD	*P*
EC	64.2	19.3	29.4	26.4	<.001	63.6	19.0	21.8	20.8	<.001	40.7	25.2	9.9	8.0	<.01
BN	70.0	18.1	32.9	20.6	<.001	72.6	16.7	29.9	20.4	<.001	58.4	9.4	21.0	20.2	<.01
RV	68.9	17.9	28.7	20.5	<.001	71.3	13.0	27.3	18.4	<.001	46.8	22.0	12.8	7.6	<.05
AV	22.3	22.8	56.7	23.7	<.001	11.0	23.4	46.1	25.9	<.01	25.5	15.4	46.8	16.6	<.1
Global score	67.7	15.9	30.3	10.7	<.001	69.2	13.0	26.3	7.7	<.001	48.6	17.9	14.6	8.1	<.05

EC, ease of communication; BN, background noise; RV, reverberation; AV, aversiveness; Global score, mean of EC, BN, and RV; SD, standard deviation; APHAB, Abbreviated Profile of Hearing-Aid Benefit.

evident differences between them. This is in contrast to both above-mentioned multicenter studies, which showed much higher benefits in patients with conductive or mixed hearing loss than those with SSD. The especially high score in SSD patients in our study is remarkably interesting (42.9% vs. 8.6% in a study by Kruyt[8]). Our findings in this group are in agreement with the results of a meta-analysis by Kim et al[23], covering 8 studies in patients with SSD that showed a significant improvement in the APHAB questionnaire after implantation with a percutaneous BAHA system.

In our opinion, an especially important finding in our study is the significant improvement of QoL measured by both GBI and APHAB in all the analyzed groups with divergent audiological indications for implantation and lack of differences in QoL improvement between them. Possibly, it might have been caused by an incredibly careful qualification process in our department, especially in the group of patients with SSD. In this group, the decision about implantation is always based on at least 2 outpatient visits, and during each test with a sound processor on softband is performed. What is more, the patient is always informed about alternative options—the contralateral routing of signals (CROS) system and cochlear implantation of the deaf ear, the potential benefits, and risks of all solutions are discussed and the effect of the CROS system is checked. Additionally, the patient has the option to borrow a BAHA processor for several days. Thus, we think that properly qualified patients with all typical indications for the BAHA can remarkably benefit from the magnetic bone conduction hearing implant system.

The additional unique value of this analysis is the use of an original, innovative scale concerning the aesthetic, hygienic, and utility aspects of the implanted site. It shows the added value of being satisfied with the personal appearance and full acceptance of the device by the vast majority of recipients.

The main strengths of the study are the relatively large group of patients, long observation time, and the use of various QoL questionnaires. The study has some limitations, namely, the single-center design and lack of evaluation of audiological gain.

CONCLUSION

The implantation of the Baha® Attract system significantly improves the QoL of hearing-impaired patients in all subjective scales used. The system is effective for all audiological indications when strictly adhered to. The majority of patients are very satisfied with the aesthetic, hygienic, and utility aspects of the device.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of Poznan University of Medical Sciences (approval No: 23/16 and 1234/17).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – W.G.; Design – J.M., W.G.; Supervision – M.W.; Materials – J.M., E.B.; Data Collection and/or Processing – J.M., E.B., I.M.; Analysis and/or Interpretation – J.M., E.B., I.M., W.G.; Literature Review – J.M., W.G.; Writing – J.M., W.G.; Critical Review – M.W.

Declaration of Interests: The authors have no conflict of interest to declare.

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