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Evaluating the effectiveness of bone conduction hearing implants in rehabilitation of hearing loss

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Abstract

Purpose Implantable hearing devices are indicated for candidates who could not benefit from conventional hearing aids. This study aimed at evaluating their effectiveness in rehabilitation of hearing loss.

Methods This study included patients who received bone conduction implants at Tertiary Teaching Hospitals, between December 2018 and November 2020. Data were collected prospectively, and patients were assessed both subjectively using COSI and GHABP questionnaires and objectively using bone conduction and air conduction thresholds, unaided and aided free field speech thresholds. Outcomes of transcutaneous (tBCHD) and percutaneous (pBCHD) bone conduction hearing devices were compared as well as outcomes of unilateral versus bilateral fitting. Postoperative skin complications were recorded and compared.

Results A total of seventy patients were included, thirty-seven of them were implanted with tBCHD and thirty-three with pBCHD. Fifty-five patients were fitted unilaterally compared to 15 bilateral fitting. Preoperative mean of bone conduction (BC) of the overall sample was 23.27 ± 10.91 dB, the Air conduction (AC) mean was 69.27 ± 13.75 dB. There was significant difference between unaided free field speech score ($88.51\% \pm 7.92$) and the aided score (96.79 ± 2.38) with P value $= 0.00001$. The postoperative assessment using GHABP showed a benefit score mean of 70.95 ± 18.79, patient satisfaction score mean of 78.15 ± 18.39. The disability score improved significantly from a mean of 54.08 ± 15.26 to residual score of only 12.50 ± 10.22 with $P < 0.00001$ postoperatively. There was significant improvement in all parameters of COSI questionnaire following fitting. Comparison of pBCHDs vs tBCHDs showed a non-significant difference regarding FF speech as well as GHABP parameters. Comparison of the post-operative skin complications was in favor of tBCHDs as (86.5%) of the patients had normal skin postoperatively, compared to 45.5% of patients with pBCHDs devices. Bilateral implantation showed significant improvement of FF speech scores, GHABP satisfaction score, as well as COSI score results.

Conclusion Bone conduction hearing devices are effective solution for rehabilitation of hearing loss. Bilateral fitting yields satisfactory outcomes in suitable candidates. Transcutaneous devices carry significantly lower skin complication rates compared to percutaneous devices.

Keywords Implantable hearing device · Deafness · BAHA · Osia · Bone conduction

Introduction

Conventional air conduction hearing aids (ACHA) are the standard of care for rehabilitation of moderate-to-severe hearing loss worldwide while cochlear implants are reserved for those with severe to profound hearing deficiencies [1]. Patients with moderate to severe hearing loss who have no benefit from ACHAs or unable to wear them for various reasons needed an innovative option such as implantable hearing devices to fulfill their needs [2].

Implantable hearing devices have been developed to rehabilitate a wider range of hearing loss and overcome many

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of the drawbacks of the ACHAs that includes occlusion effect, inadequate gain and unacceptable look. The available implantable hearing devices nowadays are subdivided into two major categories: active middle ear implants (AMEI) and Bone Conduction Hearing Devices (BCHDs) [3]. They differ in indications, design, technique of implantation, as well as aftercare needed for each device [4, 5].

BCHDs are classified into passive BCHDs (e.g., BAHA—either connect or attract- or the Ponto device by *Oticon*) and active BCHDs (e.g., Med-EL Bonebridge® [6, 7] and the new Osia® system by *Cochlear Ltd*) [8, 9]. These devices are indicated in patients with conductive hearing loss (CHL), mixed hearing loss (MHL) or in single sided deafness (SSD) with stable bone conduction hearing thresholds(BC) within the recommended manufacturer's range [10, 11]. BAHA attract is a passive transcutaneous bone conduction hearing devices (tBCHD) that delivers sound waves to a passive implant magnet across an intact skin barrier whilst Osia® & Bonebridge® are active tBCHDs where the processor transfers acoustic information to the active receiver stimulator package across intact skin which in turn actively recreates the sound signal for transmission by bone conduction [8, 11]. BAHA Connect and the Oticon Ponto are percutaneous devices (pBCHDs) which connect to the processor via a skin-penetrating abutment [8, 10]. Bilateral BCHD fitting has been recently evaluated and shown promising results including increased ability of sound localization, higher audiological gain as well as enhanced hearing ability in presence of noise [12]. The aim of the work was a broader audiological and surgical comparative evaluation of effectiveness of tBCHDs and pBCHDs in rehabilitation of hearing loss and comparison of bilateral vs unilateral fitting outcomes.

Methods

This study was a prospective comparative cohort study conducted in the tertiary Regional Department of Otology and Neurotology spanning the period between 1st December 2018 and 30th November 2020. This study was registered with the Clinical Effectiveness Unit (CEU 9334) who also provided the independent review; hence no separate ethical approval was needed. All patient data were anonymised and protected with compliance to Data Protection Act 2018. To be included in our study, patients had to fulfill the following criteria: patients aged 16 years and over with hearing loss (either conductive or mixed type or single sided deafness with normal or near normal BC thresholds of the other side), BC thresholds within BCHD manufacturer's recommended guidelines, those who have not derived adequate benefit from conventional ACHAs. To be included patients had to have stable bone conduction hearing thresholds (up to 45 dB for Bonebridge® or up to 55 dB for Osia®) within the widely accepted maximal power output of the device. Patients outside the implantation criteria of National Health Services (NHS) Specialised Commissioning Guidelines (2016) were excluded.

Seventy-four patients were recruited into our study; patients were allocated into two groups. Four patients dropped out from the study due to different reasons (three patients were lost follow-up and one patient discontinued using the device). The final number of patients included was 70 patients. Group (A) $n=33$: Included all patients pBCHD (BAHA connect or Oticon Ponto devices) and Group (B) $n=37$: Included all patients with tBCHDs (BAHA attract, Osia®, and Bonebridge® devices). We have also compared the outcome of patients fitted with BCHD bilaterally (15 patients) to patients fitted unilaterally (55 patients).

All patients were reviewed in the BCHD multidisciplinary team clinic employing the pre-operative assessment protocol that included history taking, full examination and audiological evaluation including unaided and aided free field (FF) thresholds and unaided Pure tone average (PTA) mean of 0.5, 1, 2 and 4 kHz as well as adaptive speech recognition in noise and quiet.

Suitable candidates were counselled regarding the different types of BCHDs. Choice of the appropriate device depended on multiple factors including patient's hearing threshold, maximal power output of the devices, indication for implantation, type of hearing loss as well as patient's own preference. As part of their pre-operative assessment, patients were offered a 14-day trial of a BCHD (on loan) using a soft band to mimic post-operative situation and were asked to record a diary of their trial of the device. An informed consent was signed by the patient prior to surgical procedure. For assessment of patient's quality of life and comparing it to pre-implantation situation; we have utilized two of the widely accepted questionnaires; the Glasgow Hearing Aid Benefit Profile (GHABP) and the Client Oriented Scale of Improvement (COSI) questionnaire.

Surgical procedures were carried out as per manufacturer's guidelines for the selected device. For BAHA Connect device; incision was marked to be 2–3 cm long behind the ear and parallel with hair line, with marking the implant site 1 cm posterior to the planned incision line. Drilling is done using a guide drill and a countersink, followed by placement of the implant and the skin-penetrating abutment. For BAHA attract implant, incision is marked to be 2–3 cm long behind the ear and parallel with hair line, with marking the implant site 1 cm posterior to the planned incision line and planned as inferiorly based C-shaped fashion, an internal magnet is secured to the implanted fixture under the skin and incision is closed in layers. In case of Bonebridge implantation, Incision is made further posterior to the implant site with attention to thickness of the overlying skin flap, followed by drilling a bed for floating mass transducer(FMT) and a

periosteal pocket for the attached coil, then the BB is fixed with titanium screws and wound is closed in layers. Patients were reviewed in the outpatient clinic 1 week postoperatively for stitch removal and wound check. Loading, activation, and programming were done during the 4th week of surgery to allow for osseointegration to take place (in case of pBCHDs).

Our primary outcome measures included hearing and quality of life assessment (QOL) in the form of aided audiometry (FF thresholds and PTA [Mean of 0.5, 1, 2 and 4 kHz]), aided assessment using GHABP and COSI questionnaires. The Secondary outcome measures were skin assessment for complications using Holger's classification (for tBCHD), comparison of the outcomes of (tBCHDS) vs (pBCHDs) as well as comparison of the outcomes of unilateral and bilateral implantation with BCHDs.

Statistical analysis

Data analysis was performed using R software version 3.4.4 (R Foundation for statistical computing, Vienna). Our figures were generated using the R package "ggplot2". Categorical outcomes were expressed as counts/frequencies. Meanwhile, the numerical outcomes were presented in the form of mean, standard deviation (SD). Qualitative data were compared via Chi-square (χ^2) test. Pre-operative and postoperative audiometric values were compared using Wilcoxon test. Results with P value less than 0.05 were considered statistically significant.

Results

The mean age of our patients was 53.47 ± 16.59 SD years, and majority of the patients were females (39 cases—45.7%). The commonest hearing loss pattern was mixed hearing loss (MHL) in 58.6% of the overall sample (Fig. 1). Unilateral implantation was done in 55 cases (78.6%), with tBCHDs as the commonest modality implanted in 52.9%. Preoperative audiological assessment showed a mean of Bone conduction (BC) of the overall sample of 23.27 ± 10.91 dB, while the Air conduction (AC) mean was 69.27 ± 13.75 dB. There was significant difference between unaided free field speech score ($88.51\% \pm 7.92$) and the aided score (96.79 ± 2.38) ($P = 0.00001$) (Table 1).

The postoperative GHABP showed a mean benefit score of 70.95 ± 18.79 SD and mean patient satisfaction score of 78.15 ± 18.39 SD. The disability score improved significantly from a mean of 54.08 ± 15.26 SD to residual score of only 12.50 ± 10.22 SD postoperatively ($P < 0.00001$) (Table 2).

There was significant improvement in all parameters of COSI questionnaire following fitting with the BCHDs. Comparison of pBCHDs vs tBCHDs showed a significant difference regarding the preoperative BC and AC levels as patients implanted with pBCHDs had statistically significant lower thresholds ($P = 0.011$, $P = 0.006$ for BC and AC, respectively). There was non-significant difference regarding FF speech either aided or non-aided situations (Table 3). There was non-significant difference regarding GHABP parameters; also, both modalities showed significant improvement of disability scores. There was non-significant difference regarding post-operative COSI scores; except for speaking over the phone which showed a significant difference in favor of transcutaneous devices ($P < 0.001$) and improved feeling

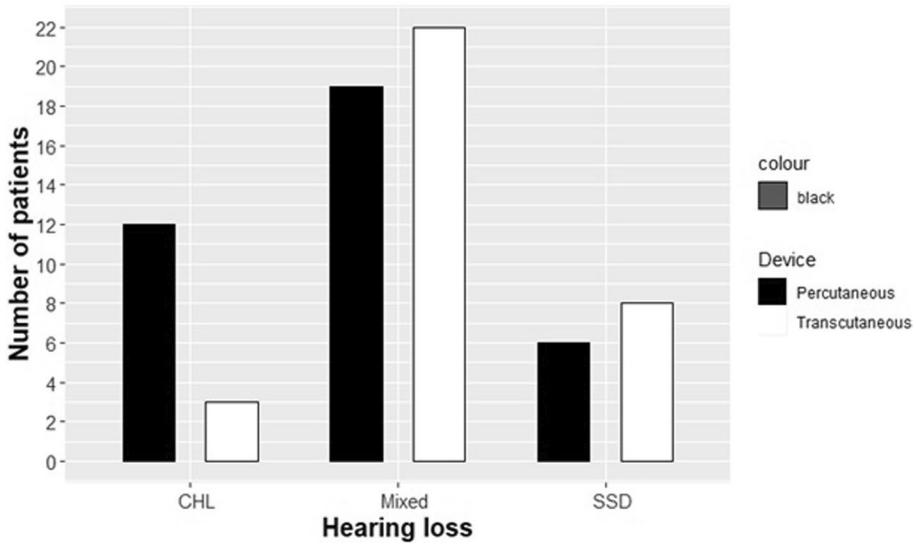

Fig. 1 Types of hearing loss of the patients in relation to device type

Table 1 Overall sociodemographic and clinical data

Parameter			Overall
N			70
Age (mean (SD))			53.47 (16.59)
Gender			
Male			31 (44.3)
Female			39 (45.7)
Hearing loss type (%)			
CHL			15 (21.4)
Mixed			41 (58.6)
SSD			14 (20.0)
Laterality			
Unilateral (%)			55 (78.6)
Bilateral (%)			15(21.4)
Device (%)			
Transcutaneous			37 (52.9)
Percutaneous			33 (47.1)
Device type (%)			
BAHA attract			20 (28.6)
BAHA connect			28 (40.0)
BAHA connect converted to attract			1 (1.4)
Bone bridge			8 (11.4)
OSIA			9 (12.9)
Oticon Ponto			4 (5.7)
Pre-op Audiological data			
BC(dB) (mean ± SD)			23.27 ± 10.91
AC(dB) (mean ± SD)			69.27 ± 13.75
		Wilcoxon Sign Rank Test	*P* value
FF speech unaided (%) (mean ± SD)	88.51 ± 7.92	$z = -6.9588$	< 0.00001
FF speech aided (%) (mean ± SD)	96.79 ± 2.38		

Table 2 Post-operative subjective outcomes of overall sample

GHABP outcome			Overall
Benefit (mean ± SD)			70.95 ± 18.79
Satisfaction (mean ± SD)			78.15 ± 18.39
		Wilcoxon sign rank test	*P* value
Initial/old disability raw score (mean ± SD)	54.08 ± 15.26	$z = -7.2187$. \	< 0.00001
Residual/new disability raw score (mean ± SD)	12.50 ± 10.22		

of embarrassment ($P = 0.043$) (Fig. 2). Comparison of the post-operative soft tissue outcome was in favor of tBCHDs as they had the highest percentage of normal skin following surgery (86.5%), compared to only 45.5% of patients fitted with pBCHDs devices (Fig. 3).

Comparison of bilateral vs unilateral fitting showed that FF speech scores showed significant difference in favor of bilaterally implanted subjects. The patients fitted bilaterally had a more significant initial disability score than the unilaterally fitted patients ($P = 0.001$). The GHABP satisfaction score was significantly higher in bilaterally fitted cases ($P = 0.018$) (Table 4). Both categories showed significant improvement of disability scores postoperatively. For COSI score results, a significant improvement was noted, favoring bilateral fitting,

Table 3 Comparison between different study groups regarding the clinical and demographic data:

Parameter	Device type			Laterality		
	Percutaneous	Transcutaneous	*P*	Unilateral	Bilateral	*P*
N	33	37		15	55	
Age (mean ± SD)	55.88 ± 18.90	51.32 ± 14.14	0.255	61.93 (13.04)	51.16 (16.80)	0.025
Sex = M (%)						
Male	14 (42.4)	17 (45.9)	0.956	6 (40.0)	25 (45.5)	0.933
Female	19 (57.6)	20 (54.1)		9 (60.0)	30 (54.5)	
Hearing loss type (%)						
CHL	3 (9.1)	12 (32.4)	0.058	3 (20.0)	12 (21.8)	0.069
Mixed	22 (66.7)	19 (51.4)		12 (80.0)	29 (52.7)	
SSD	8 (24.2)	6 (16.2)		0 (0.0)	14 (25.5)	
Laterality						
Unilateral (%)	25 (75.8)	30 (81.1)	0.803			
Bilateral (%)	8 (24.2)	7 (18.9)				
Pre op BC (mean ± SD)	26.72 ± 11.58	20.18 ± 9.39	0.011	28.71 ± 7.60	21.78 ± 11.25	0.028
Pre op AC (mean (SD))	74.00 ± 11.49	65.05 ± 14.35	0.006	71.50 ± 6.34	68.66 ± 15.14	0.482
FF speech unaided (mean (SD))	87.06 ± 9.13	89.81 ± 6.52	0.148	83.23 ± 13.48	89.95 ± 4.81	0.003
FF speech aided (mean (SD))	96.21 ± 2.51	97.31 ± 2.16	0.054	94.66 ± 1.93	97.37 ± 2.16	< 0.001

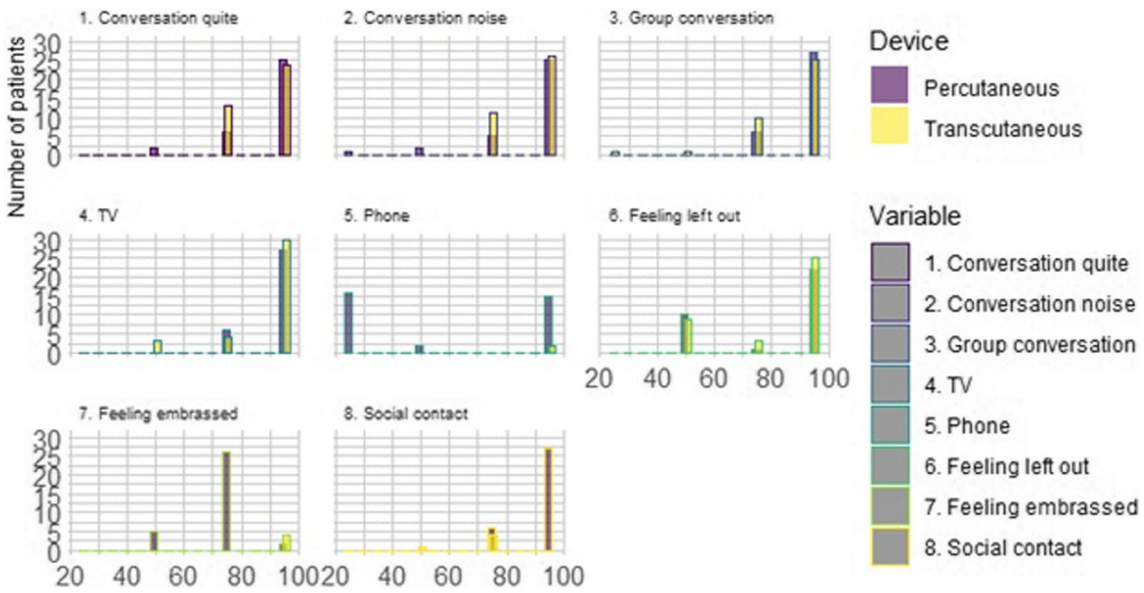

Fig. 2 Comparison of the COSI score of Transcutaneous vs Percutaneous devices

with regard to conversation both in quiet ($P = 0.001$) and with groups ($P = 0.026$) and feeling of embarrassment due to hearing loss ($P = 0.004$) as well as speaking over the phone ($P = 0.023$).

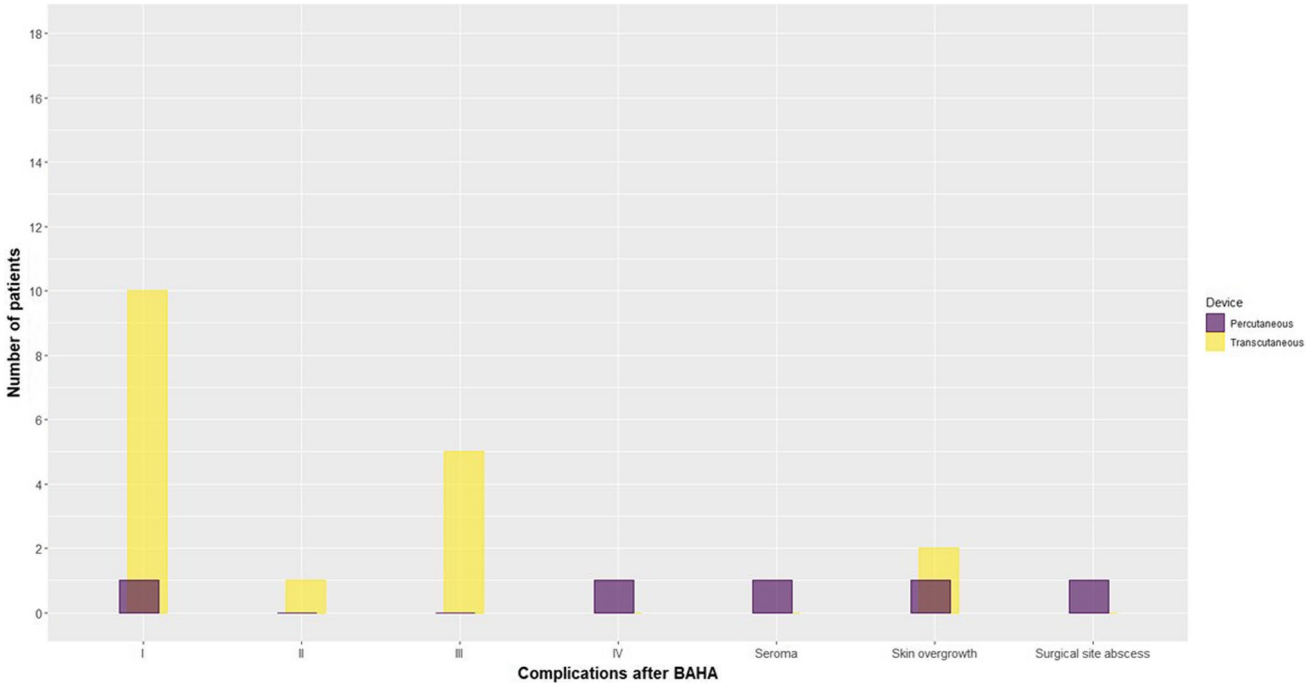

Fig. 3 Comparison of post-operative skin status for both device categories

Table 4 Comparison between different study groups regarding the Post-operative GHABP outcomes

Parameter	Device type			Laterality		
	Percutaneous	Transcutaneous	*p*	Bilateral	Unilateral	*p*
N	33	37		15	55	
GHABP benefit (mean ± SD)	71.37 ± 16.08	70.58 ± 21.12	0.861	77.31 ± 14.40	69.22 ± 19.57	0.14
GHABP satisfaction (mean (SD))	82.01 ± 14.57	74.71 ± 20.82	0.098	88.01 ± 12.76	75.46 ± 18.85	0.018
Initial old disability raw score (mean (SD))	55.49 ± 13.85	52.82 ± 16.51	0.468	65.25 ± 14.64	51.03 ± 14.07	0.001
Residual new disability raw score (mean (SD))	10.52 ± 5.97	14.26 ± 12.73	0.127	12.76 ± 9.36	12.43 ± 10.53	0.914
P value for comparison between initial old and residual new disability raw score	*p* value < 0.00001	*p* value < 0.00001		*p* value = 0.00064	*p* value < 0.00001	

Discussion

Bone conduction hearing devices (BCHDs) are rapidly becoming the standard of care in the rehabilitation of hearing loss where standard air conduction hearing aids (ACHAs) cannot be used or do provide adequate benefit. Such devices improved quality of life (QoL) for a great sector among the hard of hearing community suffering from a wide range of ear conditions causing moderate to severe hearing loss. The pBCHDs were the first to be developed. Despite their drawbacks of skin infection/overgrowth, these devices remain a viable option due to their simplicity and greater audiological gain in comparison to ACHAs and tBCHDs [9].

The tBCHDs were developed to overcome the soft tissue linked drawbacks of percutaneous devices. Such devices are more aesthetically accepted and overcome skin complications occurring due to the skin-penetrating abutment used in pBCHDs. The use of BCHDs is widely approved in health care systems around the developed world. However, they are not widely or uniformly available in developing countries due to its higher cost compared to conventional ACHAs although there is steady growth in availability and uptake [10].

Recently, bilateral fitting was approved in certain countries including the UK, where it was approved in 2016 [11]. Few studies evaluated the effectiveness of such fitting versus unilateral fitting since then. Hence, it is imperative

that their effectiveness is evaluated periodically to ensure they are appropriate for hearing impairment.

The outcomes of patients fitted with unilateral (55 patients) and bilateral (15 patients) BCHDs match the expected outcomes in manufacturer's recommendations as well as the NHS commissioning guidelines in the UK [11, 12].

The patient reported pre- and post-fitting GHABP scores consistent improvement in most domains (a benefit score of 70.95 ± 18.79, a satisfaction score of 78.15 ± 18.39, and reduction in the disability score from 54.08 ± 15.26 down to 12.50 ± 10.22 after fitting). These results are in line with many similar studies. One of the earliest was done by Mcdermott et al. in 2002, who compared the conventional ACHA with the BAHA system utilizing both GHABP and GHADP, with a total of 84 adult patients interviewed. Both benefit and satisfaction of patients were significantly better with the use of BAHA compared to ACHAs [13]. Also, Scotta et al. in 2020 compared the GHABP results of BAHA Attract Vs Bonebridge cases. Both groups attained high results in the form of a mean global score of 83 (standard deviation (SD) ± 23.5) in the Bonebridge group and 84 (SD ± 15.3) in the BAHA Attract group [14]. Wazen et al. (2021) assessed the hearing and quality of life outcomes for SSD patients implanted with BAHA retrospectively and showed significant improvement regarding all measures of the GHABP including disability scores, benefit, and satisfaction of their patients [15].

Although the use of GHABP gives great information aiding to assess the effectiveness of BCHDs, it carries a recall bias as acquiring the information at the follow up stage requires patients to recall the types and degrees of difficulty that they were facing some weeks ago prior to fitting. This carries difficulty, especially for some elderly persons. To overcome this problem, we have asked the patients to fill in the first two columns of the questionnaire prior to surgical interference requesting them to pick their 4 custom situations according to their daily needs, then they were asked to complete the questionnaire one month following fitting.

In the current study, we have also used the Client Oriented Scale of Improvement (COSI) questionnaire as a tool for subjective assessment of hearing. The included patients showed significant improvement for all the subscales of COSI questionnaire following fitting with the BCHD as all parameters have improved in 95% of the time for most of the patients. These results are again in line with Scotta et al. who studied the surgical and audiological outcomes of two transcutaneous devices using different outcome measures including the COSI questionnaire. Patients showed improvement in 5 listening situations, including conversation in noise, conversation in quiet places, listening to music, watching TV, and directionality of sound. This improvement was at scales of 75% and 95% of the time in all cases [14].

The audiological outcome of patients using free field speech scores showed significant improvement ($P < 0.00001$) with an aided score of 96.79 ± 2.38 (mean ± SD) compared to an unaided score of 88.51 ± 7.92 preoperatively. All these results are in favor of using the BCHDs as an effective way in the rehabilitation of hearing loss for suitable candidates. These results are supported by many studies published since the early introduction of BCHDs into the market. Dimitriadis et al. (2017) on a study looking at over a hundred patients implanted with BAHA Attract device showed a significant fall in the disability scores of GHABP from 52.4 to 10.6 ($P < 0.001$). The GHABP benefit score was 88.1% and the satisfaction GHABP score was 77.4% [16]. A multi-center study done by Nevoux et al. in 2018 to evaluate the long-term outcomes of BAHA Attract tBCHD system concluded that BAHA Attract implantation results in a significant hearing gain and improved QOL. They favored using this implant due to its reversibility that allows switching to another system if hearing deteriorates over time [17]. Marszal and colleagues (2022) also studied the long-term impact of BAHA Attract on quality of life for their patients using different parameters. They showed a significant improvement, and most patients were satisfied with the aesthetic and usability aspects of the device [18]. On a wider scale, Magele et al. in 2019 conducted a systematic review and meta-analysis to evaluate the outcomes of active tBCHDs. All outcomes reported confirmed significant audiological gain and high patient satisfaction, as well as low complications rate [19].

In our study, we have compared the outcomes of bilateral implantation of BCHDs vs unilateral implantation. Few published studies have discussed benefits of bilateral implantations till date, and the published data still lack convincing evidence to rely on. Patients are often implanted unilaterally on the side of greater hearing loss, or the patient's preferred ear for those with symmetrical bilateral losses [20]. However, the evidence for the use of bilateral devices is slowly evolving. Initially, they were a controversial issue, as it was felt that one device can stimulate both cochlea and provide an accepted level of amplification to both sides [21, 22]. Despite this, the NHS started commissioning bilateral BCHD implantation in 2016 due to the patient reported benefits. It has been marked however, that the studies on bilateral BCHDs were poor in evidence [23].

In the current study, there was significant difference in favor of bilateral implantation regarding audiological testing including FF speech in both unaided ($P = 0.003$) and aided ($P < 0.001$) conditions, respectively. The GHABP satisfaction score was significantly higher in bilaterally implanted patients 88.01 ± 12.76 compared to 75.46 ± 18.85 ($P = 0.018$). Bilaterally implanted patients had significantly worse Initial disability raw score (mean ± SD) = 65.25 ± 14.64 compared to 51.03 ± 14.07 for unilaterally implanted cohort. Results of COSI outcomes

showed significant improvement, favoring bilaterally fitted patients with regard to conversation both in quiet situations ($P=0.001$) and with groups ($P=0.026$). Both groups were similar in situations such as watching TV, conversation in noise and social contact.

Hilly and colleagues (2020) conducted an interesting study to compare unilateral versus bilateral implantation with regard to hearing in noisy situations. Bilateral amplification was significantly better when signals were presented from the front and noise was presented from both sides. They concluded that bilateral amplification with BCHDs can improve hearing in noise in the binaural implantation [24]. Chin et al. (2021) also demonstrated better hearing threshold, speech reception thresholds in noise and directional hearing with bilateral simultaneous implantation with the tBCHD Bonebridge devices [25]. Similarly, Caspers et al. (2022) studied the efficacy of bilateral implantation with pBCHDs on sound localization [26]. Heath et al. (2021) published a systematic review to assess the outcomes of bilaterally fitted patients. The results of the included studies showed that bilateral BCHDs offer considerable benefit to patients. For the audiological outcomes, improvements were seen in thresholds and understanding speech in quiet and sound localization, as well as restoration of binaural hearing ability. Bilateral BCHDs showed less response in the speech detection in noise. Further advantages of bilateral implantation were found in the QoL results, with all studies reporting overall improvements [11, 21, 27]. Improvements were noted by parents and teachers for those with bilateral losses and bilateral BCHDs compared to unilateral BCHDs [21]. These results might support a second implant for eligible cases, However, an assessment of the potential drawbacks such as additional surgical complications and costs, needs to be conducted to justify the risk of this surgery.

In the current study, we have compared the pBCHDs versus the tBCHDs regarding subjective and objective outcomes and skin complications. There was non-significant difference between both categories regarding FF speech in the unaided and aided conditions. Both tBCHDs and pBCHDs showed significant improvement of GHABP disability scores with $P<0.0001$, with non-significant difference between both categories.

Post-operative skin complications were recorded and compared. There was significant difference in favor of transcutaneous devices ($P=0.002$) (Fig. 3). It is well established that percutaneous devices carry the risk of post-operative skin complications ranging from mild redness and erythema up to skin breakdown and skin overgrowth on top of the abutment requiring daily care to avoid such complications. This is due to the nature of the skin-penetrating abutment. Transcutaneous devices have been developed to overcome such a drawback, but percutaneous devices still have its share of the market and still preferred by many surgeons as well as patients; due to its easier surgical procedure and clear audiological gain. The overall reported skin infection/reaction rate in the literature ranged from 1.2 to 52.4% [28].

Siau et al. (2012) reported very low skin-related complication rates (1.2%) suggesting that soft tissues above the periosteum, including all the hair follicles, could be excised leaving the periosteum itself intact to reduce such complications [29]. Priwin et al. in 2005 suggested that daily cleaning could help avoid skin infections [30]. The study by Chan et al. in 2017 encouraged minimal soft-tissue reduction, as 60% of their cohort that received full-thickness flaps developed major complications compared to 10% for those with no soft-tissue reduction technique [31]. In our series of patients, we did not resort to perform tissue reduction, which may justify the expected skin complication rate. Godbehere et al. (2017) in a comparative study of complications and initial follow-up costs of transcutaneous and percutaneous bone conduction devices showed that percutaneous group had higher rate of skin complications (20%). with three patients (12%) necessitating removal of the abutment despite treatment with antibiotics compared to, only one patient in the transcutaneous device group having minor skin irritation [32]. In 2021, Hernández et al. published a retrospective study evaluating the long-term cutaneous complications related to tBCHDs spanning the period between 2004 and 2018. Out of the total of patients, 49 (55.7%) developed at least one episode of inflammatory/infectious skin reaction. These rates are higher than most of published skin changes related to tBCHDs in literature. This could be explained by the long follow-up period in their study [33].

Whilst still undergoing rapid innovation and refinement, BCHDs are considered a great addition to the audiological armamentarium to improve the quality of life of hard of hearing individuals due to their role in hearing rehabilitation when ACHAs are not effective.

Our study was focused on adult patients and was partly limited by the effect of the COVID-19 pandemic restricting the number of surgical procedures in the latter part of the study period.

In conclusion, BCHDs are effective in rehabilitation of hearing loss whenever indicated. Both transcutaneous and percutaneous devices showed significant reduction of patients' disability scores. Postoperative skin complications remain higher in patients fitted with percutaneous devices. Bilateral fitting is favorable where indicated; due to its significant impact on subjective outcomes and improved binaural hearing, sound localization and patient's self-confidence.

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Availability of data and materials Data are available upon request.

Declarations

Conflict of interest None.

Ethics approval and consent to participate This study was part of quality improvement project registered in Sheffield Teaching Hospitals under Number 9334; no separate ethical approval was needed.

Consent for publication Not applicable.

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