Objective and subjective results of the Bonebridge transcutaneous active direct-drive bone conduction hearing implant

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ABSTRACT

الأهداف: التحقيق في فعالية نظام زراعة السماعه (تقنية زرع Bonebridge) كعلاج لإعادة التأهيل للأفراد مع فقدان السمع التواصلي أو المختلط.

الطريقة: أجريت دراسة أتراب بأثر رجعي. تم زرع 12 آذانًا مزروعين مع فقدان السمع التواصلي أو المختلط مع هذا الجهاز في مستشفى الجامعي المتخصص خلال الفترة 2012م و2016م. وشملت الاختبارات السمعية التوصيل الهوائي النقي للهواء (AC) وقياسات التوصيل العظمي (BC) وعتبات مجال الصوت بمساعدة وبدون مساعدة. لتقييم مدى وضوح الكلام في بيئة هادئة، تم اختبار درجة التمييز في الكلام (SDS) باستخدام الكلمات أحادية اللغة العربية، وقياس عتبة استقبال الكلام (SRT) باستخدام الكلمات العربية غير المنطوقة التي تحدث أمامها. تم تقييم جودة الصوت الذاتي باستخدام مؤشر جودة صوت السمع (HISQUI).

النتائج: بالمقارنة مع الحالة غير المساعدة، كان هناك تحسن كبير في العتبات المساعدة وSDS، وSRT. مقارنة بين العتبات بمساعدة وبدون مساعدة، تحسن متوسط عتبة AC بمتوسط زيادة وظيفيه قدره40±6.3dB. تم تحسين SRT بدون مساعدة من مستويات السمع 72.5 (HL) (الوسيط) إلى 27.5 HL (الوسيط) عند المساعدة، وأداء المرضى بنسبة 71%، في المتوسط، على أساس SDS بمساعدة الجهاز. كشف استبيان HISQUI عن الرضا العالي لجودة صوت الجهاز.

الخاتمة: يستفيد المرضى الذين يعانون من ضعف التواصلي أو المختلط بشكل كبير من عملية زرع السمع BC النشطة عبر الجلد.

Objectives: To investigate the effectiveness of a bone-anchored hearing implant system (Bonebridge implant technology) as a rehabilitation treatment for individuals with conductive or mixed hearing losses.

Methods: This is a retrospective cohort study. Twelve implanted ears with conductive or mixed hearing losses were implanted with this device at a tertiary university hospital between 2012 and 2016. Audiological tests included pure tone air conduction (AC) and bone conduction (BC) measurements and unaided and aided sound-field thresholds. To evaluate the speech intelligibility in a quiet environment, the speech discrimination score (SDS) was tested using Arabic monosyllabic words, and the speech reception threshold (SRT) was measured using Arabic disyllabic words spoken in front of them. The subjective sound quality was assessed with the Hearing Implant Sound Quality Index (HISQUI).

Results: In comparison with the unaided condition, there was a significant improvement in the aided thresholds, SDS, and SRT. Comparing the aided and unaided thresholds, the average AC threshold improved with an average functional gain of 40±6.3dB. The unaided SRT improved from 72.5 dB hearing levels (HL)(median) to 27.5 dB HL (median) when aided, and patients performed 71% better, on average, based on the SDS with the help of the device. The HISQUI questionnaire revealed high satisfaction with the device sound quality.

Conclusion: Patients with conductive and mixed hearing loss substantially benefit from the Bonebridge active transcutaneous BC hearing implant.

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The air conduction (AC) pathway is modified, restricted, or completely lost in patients with conductive or mixed hearing loss. Although defects of the tympanic membrane and the ossicular chain can be treated to a certain extent by surgery, adequate hearing restoration is not achieved in some cases even with the addition of conventional hearing aids. Active bone conduction (BC) implants can be beneficial to these patients as BC transmission of the acoustic signal bypasses the normal AC pathway.[1] Consequently, BC hearing implants have become a mainstream treatment for conductive, mixed, or single-sided hearing loss that does not benefit from conventional hearing aids.[2] Attempts to effectively restore hearing in these patients have included surgical implantation of percutaneous BC implants. Although effective, safe, and well-established in the market, they were associated with a significant number of post-operative complications leading to revision surgery.[3] In an extensive series of patients (n=602) over a 20-year period, Hobson et al[4] reported a complication rate of 24% and a revision surgery rate of 12%.Therefore, the transcutaneous BC implants were introduced to minimize the complication rate.

The Bonebridge System (BB, Med-El Corporation, Innsbruck, Austria), is one of these transcutaneous bone conduction hearing implants. It is an intact skin semi-implantable hearing system consisting of 2 components: the external audio processor and the internal implantable part known as the BC implant. The transcutaneous BC implants including BB avoids drawbacks associated with percutaneous implants such as skin reactions, the growth of skin over the abutment, implant extrusions, wound infections, and fixture losses. Therefore, it is reported that, the complication rate is higher in percutaneous BC implant in comparison with transcutaneous one.[5] As the BC-implant is secured to bone by screws, the osseointegration process is not required and the device may be activated within 2 or 3 weeks after it is implanted.

It is reported that, the performance of active transcutaneous bone conduction hearing implant is also superior to the passive skin-drive BC devices with implanted magnets that are subjected to atranscutaneous signal attenuation of 10 to 15 dB,[6] because in active transcutaneous BC implant the signal is independent from the thickness of the skin and hair.

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The purpose of the present study was to evaluate the audiological outcome as well as the speech benefit of the BB implanted patients in our center.

Methods. After approval by the Institutional Review Board of King Saud University, College of Medicine, Riyadh, Saudi Arabia data were retrospectively compiled for this study. We reviewed hospital charts of 12 implanted ears that received BB implantations at our university hospital (tertiary referral center) between July 2012 and February 2016. All implanted patients during that period have been included. The incomplete file was our exclusion criteria. Data regarding the general demographics as well as the cause of deafness, onset and duration of deafness, number of patients who had minor or major complications, or those who required revision were collected.

Prior to implantation, pure tone AC and BC thresholds were obtained in both the unaided and aided conditions. When calculating the puretone average (PTA4), the 0.5,1, 2, and 4 kHz thresholds were utilized. The functional gain was calculated as the difference between the mean PTA4AC and aided PTA4.

To evaluate the speech intelligibility, the speech discrimination score (SDS) was tested using Arabic monosyllabic words; speech stimuli were presented at 65 dB hearing level (HL) in a quiet environment. The speech reception threshold (SRT) was measured using Arabic disyllabicwords (50% correct) with speech and the noise signal arriving from the front. All hearing tests were performed monaurally, where the contralateral side plugged and masked while testing the implanted ear.

The Hearing Implant Sound Quality Index (HISQUI) questionnaire was used to evaluate the subjective sound quality of the BB. The questionnaire consists of 29 questions with 7 possible answers each, ranging from "never" to "always". An example question is: "Can you effortlessly distinguish between a male and a female voice?" Each answer has a value between 1 and 7, those values are totaled to obtain the HISQUI score. The HISQUI score corresponds to one of 5 categories between poor and very good sound quality.

Post-operative BB-aided thresholds and audiological data obtained in one-year follow-up visits were compared to the preoperative results. Due to the low number of data points, a normal distribution of the data could not be confirmed. The non-parametric Wilcoxon test was performed to test for significance between groups and the software STATISTICA 12 was used. Graphs were created using GraphPad Prism 7.02.

Results. The individual demographic and clinical data for 12 implanted ears are shown in **Table 1**. In 9 ears, the BC-FMT was placed in the sinodural angle and in 3 ears the BC-FMT had to be placed using a retrosigmoid approach. No intraoperative, minor, or major postoperative complications were observed. There was no incidence of revision surgery in any of the patients.

Pure tone audiometry. We compared the pre- and post-operative BC thresholds (PTA4BC) to assess the safety of the surgical procedure. The difference was not larger than 5 dB for any patient; thus, all were within the accuracy interval of the BC measurement (±5 dB) (**Figure 1**).

Across all frequencies, aided sound field (SF) thresholds were significantly improved by the BB. The mean aided PTA4SF was 29.8dB HL compared with the mean unaided PTA4SF of 74.6 dB HL. The average functional gain was 40±6.3dB HL (**Figure 2**).

Speech audiometry. The hearing ability in a quiet environment also significantly improved. The SRT with BB was lower in all patients compared to the pre-operative SRT. The mean pre-operative SRT decreased from 67.8 dB HL (SD 18.5 dB HL) to 27.9 dB HL (SD 5.6 dB HL) (**Figure 3**).

Table 1 - Demographic and clinical data of 12 implanted ears.

Implanted ear	Side	Air-bone gap	Age at surgery (years)	Surgical indication	Surgical approach
A	Left	29	24	Bilateral CHL	BB left
B	Right	33	24	Bilateral CHL	BB right
C	Left	60	22	Bilateral microtia	BB left, BAHA right
D	Right	54	28	Bilateral microtia	BB right
E	Left	59	28	Bilateral microtia	BB left
F	Right	60	23	Bilateral microtia	BB right, BAHA left
G	Left	54	46	MHL left, Normal hearing right	BB left
H	Left	56	33	Microtia left, Normal hearing right	BB left
I	Left	39	21	Bilateral CHL	BB left
J	Left	48	13	Bilateral CHL	BB left
K	Left	40	57	MHL left, Normal hearing right	BB left
L	Right	60	8	Right Microtia	BB right
Mean		49	27		
SD			9		

BB - Bonebridge, BAHA - bone-anchored hearing aid, CHL - conductive hearing loss, MHL - mixed hearing loss

Before implantation of the BB, the mean SDS was 26.7% (SD 34%) in the unaided condition. One year after implantation, the mean SDS was 90-100% for monosyllables at 65 dB sound pressure level (SPL) (mean: 97.1%, SD 4.8%). The improvement in sound discrimination was statistically significant (p=0.0078) (**Figure 4**).

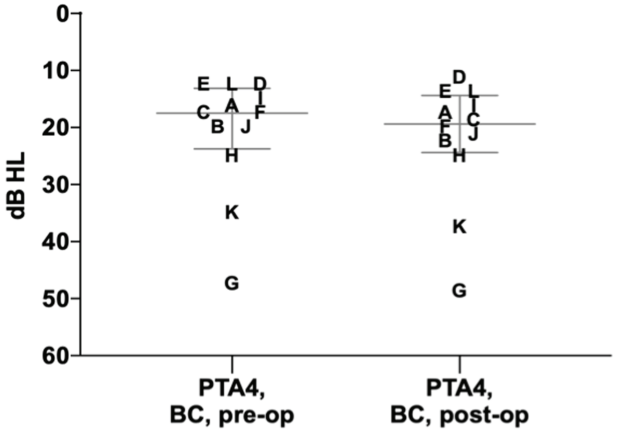


Figure 1 - A comparison of bone conduction (BC) thresholds as pre-operation (pre-op) versus post-operation (post-op) puretone average (PTA4) values. The plot shows the individual data points and each letter represents a tested ear (n=12) and the median (long line) with the interquartile range (25th and 75th percentile, whiskers). The greatest difference between pre- and post-op BC PTA4 values is 2.5 dB hearing levels (HL) (ear B, F and K), which is within the retest variability of 5 dB. Consistent with this trend, all frequency related post-op BC values differ less than 5 dB from the pre-op value.

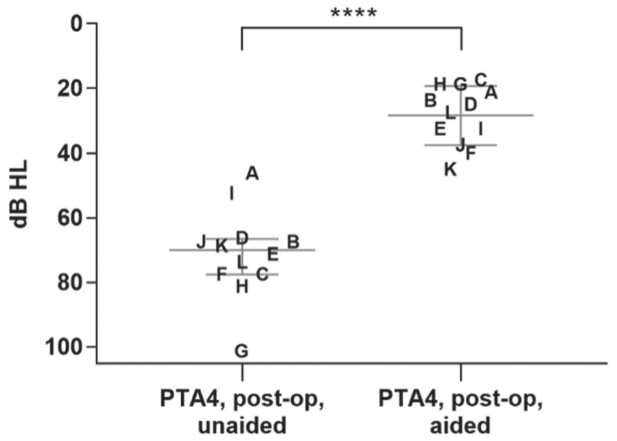


Figure 2 - A comparison of the post-operation (post-op) puretone average (PTA4) (0.5, 1, 2, and 4 kHz) unaided and aided with the Bonebridge implant. The scatter plot shows the individual data points where each letter represents a study participant and the median (long line) with the interquartile range (25th and 75th percentile, whiskers). The non-parametric Wilcoxon test was used to test for statistical significance (p=0.0001, n=12). AC - air conduction, HL - hearing level.

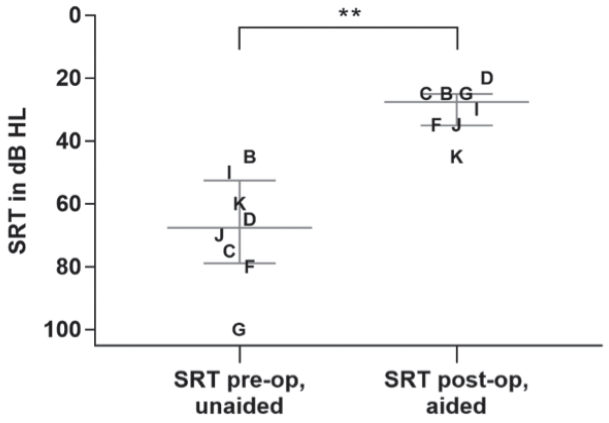


Figure 3 - A comparison of the pre-operation (pre-op) speech recognition threshold (SRT) in a quiet environment, unaided, with the aided values measured post-operatively (post-op). The speech material consisted of Arabic disyllabic words. The plot shows the individual data points where each letter represents a study participant and the median (long line) with the interquartile range (25th and 75th percentile, whiskers). The normal distributed t test was used to test for statistical significance (p=0.001, **p≤0.05, n=8).

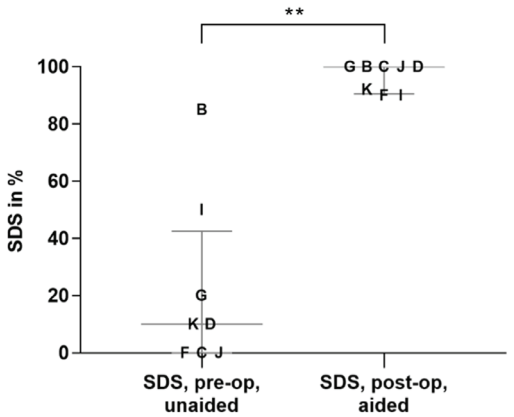
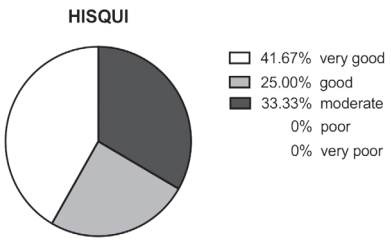


Figure 4 - A comparison of the unaided pre-operation (pre-op) speech discrimination score (SDS) versus the post-operation (post-op) score aided with the Bonebridge. The SDS was measured at 40 dB sensation levels (SL) (65 dB hearing levels (HL), Arabic monosyllabic words).The plot shows the individual data points where each letter represents a study participant and the median (long line) with the interquartile range (25th and 75th percentile, whiskers). The median value of SDS pre-op was 10%, whereas this value was 100% for post-op. The nonparametric Wilcoxon test was used to test for statistical significance (p=0.0078, ** p≤0.05, n=8).

Hearing Implant Sound Quality Index (HISQUI).

The HISQUI questionnaire was used to evaluate the subjective sound quality of the BB. The total satisfaction of the participants regarding sound quality of the BB system was good. (**Figure 5**). Sixty-seven percent of the participants rated the improvement as good to very good.



Participant	Ear	HISQUI
1	A	moderate
2	B	moderate
3	C	very good
4	D	good
5	E	good
6	F	moderate
7	G	good
8	H	very good
9	I	moderate
10	J	very good
11	K	very good
12	L	very good

Figure 5 - The hearing implant sound quality index (HISQUI) questionnaire was used to evaluate the subjective sound quality of the Bonebridge (n=12).

Discussion. This study demonstrates the clinical and subjective benefit of the BB in patients with conductive or mixed hearing losses. In agreement with other recent reports,[7-9] we demonstrated that the BB implant procedure can be considered safe; also, there are clinical and subjective improvements of the hearing threshold in its users. Audiological results showed an improved ABG as well as PTA4, SRT, and SDS values with the BB. Similar to other studies,[7,10] the post-operative BC thresholds remained stable in all the patients implying that their residual hearing was unaffected by the surgical procedure.

The functional gain observed in this analysis (40±6.3dB) was slightly better than those reported by Ihler et al[11] (33.6 ± 7.2 dB), Barbara et al[12] (36.5 dB), Manrique et al,[8] and Hassepass et al.[5] Similarly, another study conducted in 2013[9] reported a mean functional gain of more than 20 dB across all frequencies (0.5, 1, 2, 4 kHz). However, Hougaard et al[17] reported that the functional gain in conductive or mixed hearing loss patients by using BAHA attract was 19.8 dB, which is much lower than the improvement reported by using BB implant. Also, in our study, a significant improvement was observed in speech recognition in a quiet environment; the improvement was on par with those reported by other researchers that used German monosyllabic word lists[11] and by those that used disyllabic word lists in Spanish.[8] In a quiet environment, the efficacy of the BB found in the present study (97.1%, SD 4.8%) was in the same range reported by other studies. Schmerber et al[2] reported a follow-up period of one year, similar to the present study, and their participants achieved a mean speech recognition score of 95% (SD 15%). Meanwhile, Sprinzl et al[9] reported a mean monosyllabic word recognition score of 14.2% in pre-operative investigations that improved to 92.9% post-operatively. A similar improvement,

16.7% pre-operatively versus 80% post-operatively, was observed by Ihler et al.[11] Manrique et al[8] obtained a mean recognition score of 66.2% pre-operatively, improving to 86.2% post-operatively, using a disyllabic word list.

Percutaneous BC implants have been widely used in the treatment of hearing loss for a long time. However, the drawback of percutaneous implants is the risk of infection at the abutment. The intact skin above the BB implant decreases the rate of infection and places the BB in an advantageous position over the well-established percutaneous BC implants. Moreover, it will also help to reduce the stigmatization associated with implantation. Though the BB and the bone anchored hearing aid (BAHA), another hearing implant system,[13] present comparable outcomes, the BB may be more appealing to patients.

Sprinzl et al[9] demonstrated that BB implantation has a very low rate of minor adverse events (5.12%) and revision surgery (0.85%). In our study, after 2 years of BB use, no revision surgery and no skin reactions were reported, similar to short-term follow-up studies.[2,5,8,9,11,14] Moreover, the BB has a much lower complication rate than the BAHA implant (24%) that is associated with a higher rate of revision surgery (12%).[4] In the long-term follow-up (mean: 14 years) of BAHA use, the skin reaction rate (31%), loss of osseointegration (17%), and need for revision surgery (34%) have been reported.[15] The relatively large size of BB implant necessitates a good preoperative radiological evaluation of temporal bone, to examine if the patient has adequate place which could accommodate the implant. Laske et al[16] measured the subjective satisfaction of 9 patients after BB implantation with 2 questionnaires (a modified version of the Speech, Spatial, and Qualities of Hearing questionnaire [SSQ-B] and the Bern Benefit in Single-Sided Deafness Questionnaire [BBS]). Similar to their findings, the majority of our patients reported moderate improvements and 57% rated the improvement as good to very good.

Study limitation. The sample size was a major limitation of the present study.

In conclusions, patients with conductive or mixed hearing losses substantially benefit from the BB active transcutaneous BC hearing implant without minor or major complications.

References

1. Cremers CW, O'Connor AF, Helms J, Roberson J, Clarós P, Frenzel H, et al. International consensus on Vibrant Soundbridge® implantation in children and adolescents. ***Int J Pediatr Otorhinolaryngol*** 2010; 74: 1267-1279.
2. Schmerber S, Deguine O, Marx M, Van de Heyning P, Sterkers O, Mosnier I, et al. Safety and effectiveness of the Bonebridge transcutaneous active direct-drive bone-conduction hearing implant at 1-year device use. ***Eur Arch Otorhinolaryngol*** 2017; 274: 1835-1851.
3. Vyskocil E, Liepins R, Kaider A, Blineder M, Hamzavi S. Sound localization in patients with congenital unilateral conductive hearing loss with a transcutaneous bone conduction implant. ***Otol Neurotol*** 2017; 38: 318-324.
4. Hobson JC, Roper AJ, Andrew R, Rothera MP, Hill P, Green KM. Complications of bone-anchored hearing aid implantation. ***J Laryngol Otol*** 2010; 124: 132-136.
5. Hassepass F, Bulla S, Aschendorff A, Maier W, Traser L, Steinmetz C, et al. TheBonebridgeas a transcutaneous bone conduction hearing system: preliminary surgical and audiological results in children and adolescents. ***Eur Arch Otorhinolaryngol*** 2015; 272: 2235-2241.
6. Mulla O, Agada F, Reilly PG. Introducing the Sophono Alpha 1 abutment free bone conduction hearing system. ***Clin Otolaryngol*** 2012; 37: 168-169.
7. Rahne T, Seiwerth I, Götze G, Heider C, Radetzki F, Herzog M, et al. Functional results after Bonebridge implantation in adults and children with conductive and mixed hearing loss. ***Eur Arch Otorhinolaryngol*** 2015; 272: 3263-3269.
8. Manrique M, Sanhueza I, Manrique R, de Abajo J. A new bone conduction implant: surgical technique and results. ***Otol Neurotol*** 2014; 35: 216-220.
9. Sprinzl G, Lenarz T, Ernst A, Hagen R, Wolf-Magele A, Mojallal H, et al. First European multicenter results with a new transcutaneous bone conduction hearing implant system: shorttermsafety and efficacy. ***Otol Neurotol*** 2013; 34: 1076-1083.
10. Baumgartner WD, Hamzavi JS, Böheim K, Wolf-Magele A, Schlögel M, Riechelmann H, et al. A new transcutaneous bone conduction hearing implant: short-term safety and efficacy in children. ***Otol Neurotol*** 2016; 37: 713-720.
11. Ihler F, Volbers L, Blum J, Matthias C, Canis M. Preliminaryfunctional results and quality of life after implantation of a new bone conduction hearing device in patients with conductive and mixed hearing loss. ***Otol Neurotol*** 2014; 35: 211-215.
12. Barbara M, Perotti M, Gioia B, Volpini L, Monini S. Transcutaneous bone-conduction hearing device: audiological and surgical aspects in a first series of patients with mixed hearing loss. ***Acta Otolaryngol*** 2013; 133: 1058-1064.
13. Pfiffner F, Caversaccio M, Kompis M. Audiological results with Baha in conductive and mixed hearing loss. ***Adv Otorhinolaryngol*** 2011; 71: 73-83.
14. Bianchin G, Bonali M, Russo M, Tribi L. Active bone conduction system: outcomes with the Bonebridge transcutaneous device. ***ORL J Otorhinolaryngol Relat Spec*** 2015; 77: 17-26.
15. Badran K, Bunstone D, Arya AK, Suryanarayanan R, Mackinnon N. Patient satisfaction with the bone-anchored hearing aid: a 14-year experience. ***Otol Neurotol*** 2006; 27: 659-666.
16. Laske RD, Röösli C, Pfiffner F, Veraguth D, Huber AM. Functional results and subjective benefit of a transcutaneous bone conduction device in patients with single-sided deafness. ***Otol Neurotol*** 2015; 36: 1151-1156.
17. Hougaard DD, Boldsen SK, Jensen AM, Hansen S, Thomassen PC. A multicenter study on objective and subjective benefits with a transcutaneous bone-anchored hearing aid device: first Nordic results. ***Eur Arch Otorhinolaryngol*** 2017; 274: 3011-3019.