

OTOLOGY

Speech performance and subjective satisfaction of middle ear implant in congenital aural atresia

Performance del parlato e grado di soddisfazione soggettiva del paziente affetto da atresia auricolare congenita e sottoposto a impianto dell'orecchio medio

Farid Alzhrani^{1*}, Salman F. Alhabib^{1*}, Medhat Yousef^{1,2}

¹ King Abdullah Ear Specialist Center (KAESC), College of Medicine, King Saud University, Riyadh, Saudi Arabia;

² Audiology Unit, ENT Department, Menoufia University, Menoufia, Egypt

*F. Alzhrani and S.F. Alhabib contributed equally to this work.

SUMMARY

Objectives. To evaluate the safety, speech performance in noise and subjective satisfaction of patients with congenital aural atresia (CAA) implanted with the active middle ear implant.

Methods. This retrospective study included 13 patients (15 ears) implanted with middle ear implants with different methods of floating mass transducer attachment. In 6 ears, the floating mass transducer (FMT) was coupled with the short process of incus; in 8 ears, a clip coupler was used; and in one ear, a round window coupler was used. Patients were assessed preoperatively, and at one, three, and six months postoperatively. The assessment included Pure Tone Average (PTA4), Speech Reception Threshold (SRT) and Speech Discrimination Score (SDS). The Speech Spatial and Qualities of Hearing scale (SSQ12) was also used to evaluate levels of satisfaction.

Results. The mean aided PTA4 using Vibrant Sound Bridge (VSB) was 26.44 ± 4.03 dB HL compared to 61.88 ± 1.53 dB HL unaided. The SDS improved significantly ($p = 0.002$) from 51% ($\pm 9.17\%$) to 94.60% ($\pm 4.43\%$). Furthermore, there was a significant improvement in SDS in noise ($p = 0.008$) and SSQ12 responses ($p < 0.0001$).

Conclusions. Patients with hearing loss due to CAA can substantially benefit from VSB, with highly satisfactory subjective results and a negligible rate of complications.

KEY WORDS: middle ear implant, congenital aural atresia, vibrant soundbridge, hearing loss

RIASSUNTO

Obiettivi. Valutare la sicurezza, la performance del parlato in ambiente rumoroso ed il grado di soddisfazione soggettiva dei pazienti affetti da atresia auricolare congenita (CAA) e sottoposti ad impianto dell'orecchio medio.

Metodi. È stato condotto uno studio retrospettivo su 13 pazienti (15 orecchie) a cui sono stati posizionati degli impianti a livello dell'orecchio medio con diversi metodi di fissaggio del trasduttore di massa flottante. In 6 orecchie, l'FMT è stato abbinato al processo dell'incudine; in 8 orecchie è stato utilizzato l'accoppiatore di clip; e in un orecchio è stato utilizzato l'accoppiatore alla finestra rotonda. I pazienti sono stati valutati prima dell'intervento e a uno, tre e sei mesi dopo l'intervento. La valutazione ha compreso il Pure Tone Average (PTA4), la soglia di percezione del parlato (SRT) e il punteggio di discriminazione vocale (SDS). Per valutare i livelli di soddisfazione è stata utilizzata anche la scala Speech Spatial and Quality of Hearing (SSQ12).

Risultati. Il PTA4 medio utilizzando Vibrant Sound Bridge (VSB) era di 26,44 ± 4,03 dB HL rispetto a 61,88 ± 1,53 dB HL senza aiuto. L'SDS è migliorato significativamente ($p = 0,002$) dal 51% ($\pm 19,17\%$) al 94,60% ($\pm 4,43\%$). Inoltre, c'è stato un miglioramento significativo dell'SDS nel rumore ($p = 0,008$) e delle risposte SSQ12 ($p < 0,0001$).

Conclusioni. I pazienti con ipoacusia dovuta a CAA possono beneficiare sostanzialmente di VSB, con risultati soggettivi altamente soddisfacenti e un tasso trascurabile di complicanze.

PAROLE CHIAVE: impianto dell'orecchio medio, atresia auricolare congenita, ponte sonoro vibrante, perdita dell'udito

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Correspondence

Farid Alzhrani

King Abdullah Ear Specialist Center (KAESC),
College of Medicine, King Saud University, PO
Box 245 Riyadh 11411, Saudi Arabia
Tel. 00966 11 4773101. Fax 00966 11 4775524
E-mail: Faz1420@hotmail.com

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Introduction

Congenital aural atresia (CAA) causes moderate to severe hearing loss, usually conductive or mixed type¹. The degree of external auditory canal (EAC) deformity varies from complete absence to mild stenosis, with a small tympanic membrane. These deformities are often associated with ossicular chain malformations².

The surgical techniques for reconstructing the EAC and ossicular chain are sometimes difficult to perform, and the results may be unsatisfactory. EAC re-stenosis failed middle ear prostheses, and synechiae formation are the main reasons for poor hearing outcomes after surgery^{3,4}. Moreover, most of these patients require hearing aids to obtain optimal benefits. Unfortunately, earmolds are often not well-tolerated and cause recurring infections in the reconstructed ear canals².

Atresioplasty is not recommended for children younger than 6 years⁵. Therefore, for very young children, bone conduction hearing aids (BCHAs) are a viable option⁶. BCHAs improve hearing; however, aided hearing thresholds are not often optimal. Other disadvantages of these devices include discomfort due to pressure applied to the skull by the transducer, inconsistent sound quality and poor cosmetics⁶.

Percutaneous bone-anchored hearing implants (BAHIs) have been approved for children aged 5 years and older. Gain control and wearing comfort were found to be improved using BAHIs compared to BCHAs. The major benefits of the BAHI include steady hearing results, acceptable aided hearing thresholds and a simple surgical process⁷⁻⁹. However, BAHIs may be associated with local inflammation, extrusion, or poor osseointegration and require constant hygiene control to avoid infections¹⁰. The aesthetic aspect and psychological apprehension caused by a transcutaneous implant are other reasons that make some parents reluctant to choose this option^{2,6,10}.

The Vibrant Soundbridge (VSB; MED-EL, Innsbruck, Austria) is an active middle ear implant. In 2006, VSB extended its indications to include mixed or conductive deafness^{6,11} in adults and, then, to children⁶. The use of VSB for hearing rehabilitation in patients with CAA was first described in 2009¹². The use of VSB in CAA has been reported using different sites of crimping for the floating mass transducer (FMT), which allows the rehabilitation of more complex ossicular malformations^{1,2,6,10,12}. Both BAHIs and VSB have been considered as alternatives or adjuncts to conventional atresioplasty^{6,9}.

Although some articles have been published on the application of VSB in atretic ears, most are case reports or case series. The highest number of cases in one study was 28 patients in a multicentric (4 centres) study¹³. The reasons behind the limited number of publications on this topic are the rarity of

the pathology, availability of other treatment modalities, VSB being a newly introduced option for such patients, and a limited number of expert surgeons who conduct this procedure.

Moreover, the literature is lacking publications on patient performance, which is considered as a goal for the different treatment modalities. There is a limited number of studies that reported on speech in noise outcomes and satisfaction levels on quality of sound with VSB in CAA patients.

Therefore, there is a need for additional studies to confirm the safety and efficacy of VSB in congenital aural atresia. This study aimed to evaluate the safety, speech performance, and satisfaction levels of VSB in children and adults with hearing loss due to CAA.

Materials and methods

Subjects

After the ethical approval of the Institutional Review Board, data were retrospectively compiled for this study. All aural atresia patients who underwent VSB implantation at our university hospital (tertiary referral centre) between August 2017 and February 2020 were included.

Data regarding the demographic characteristics, including patient age, sex, laterality of the aural atresia, duration of follow-up, and previously reported otologic surgeries, were collected. Moreover, patients who presented minor or major postoperative complications or those who required surgical revision were reported.

Surgical procedure

Surgery was performed under general anaesthesia and with intraoperative facial nerve monitoring. A post-auricular incision or posterior atresia incision was made according to the degree of microtia and depending on the need for subsequent auricular reconstruction.

SHORT PROCESS COUPLING

Mastoidectomy and superior tympanotomy were performed to expose the whole attic region. After visualising the malformed malleus-incus complex, the middle ear was opened to assess the ossicle integrity and mobility via posterior tympanotomy, after identifying the facial and chorda tympani nerves. After confirming the ossicle integrity and mobility, the FMT was coupled to the short process of incus¹⁴.

OTHER TYPES OF COUPLING

Mastoidectomy and access to the middle ear were performed by removing the bony atresia plate as well as the lateral chain of the malformed ossicles. Next, FMT placement was decided based on the middle ear anatomy determined from individual intraoperative findings.

Audiological assessment

Audiological evaluations were conducted for all subjects preoperatively, and at one, three, and every six months postoperatively. The audiological results of the last postoperative follow-up visit were used for analysis. The mean follow-up period was 15 ± 8 months (range, 6-36 months). Pure tone average (PTA4) for air conduction (AC) and bone conduction (BC) thresholds were obtained. The thresholds of 0.5, 1, 2, and 4 kHz were utilised to calculate PTA4. Clinical masking was applied when required. Unaided thresholds were additionally measured in the sound-field.

The speech reception threshold (SRT) was measured using spondee words. The speech discrimination score (SDS) was tested using phonetically balanced monosyllabic words and all speech stimuli were presented at 65 dB HL in a quiet environment and in the presence of speech noise (+5 dB SNR) positioned from the front (90° azimuth). Postoperatively, all measurements were reconducted in the aided conditions using the SAMBA audio-processor. The mean functional gain (for each frequency and the PTA4) was calculated as the difference between the unaided preoperative and aided postoperative sound field thresholds.

Subjective evaluation

The short version of the Speech, Spatial and Qualities of Hearing Scale (SSQ12) was used to evaluate the participants' satisfaction with VSB. The SSQ12 questionnaire¹⁵ was administered at the preoperative assessment for all

subjects and then re-administered every three months after receiving the implant to assess performance. This questionnaire consists of 12 items; each item evaluates the patient's satisfaction and difficulties in different realistic communication scenarios of daily life. The subjects/caregivers rate their communication performance using a score of 0 to 10, where 10 indicates that the patient was able to perform perfectly in that situation and 0 indicates extreme difficulty in that situation.

Statistical analysis

The following steps were performed to analyse the differences between the patient outcomes pre- and postoperatively, in other words, in the unaided and aided situations. First, we computed the descriptive values, including the mean, standard deviation, and ranges (i.e., minimum, and maximum values). Second, the normality of data in both situations was tested. Therefore, the appropriate t-test was selected to check for differences. Statistical significance was set at $p < 0.05$. Statistical analyses were performed using GraphPad Prism™ version 8.4.0 (GraphPad Software, La Jolla, CA, USA).

Results

Demographic

The individual demographic and clinical data for the 15 implanted ears are shown in Table I. The study population

Table I. Demographic and clinical data for the implanted ears.

Subjects	Implanted ear	Age at implantation (years)	Follow-up duration (months)	Jahrsdoerfer grading scale	Complications	Type of the coupler
Subj#1L	Left	18	36	9	None	SP
Subj#1R	Right	19	24	9	None	SP
Subj#2L	Left	24	26	8	None	SP
Subj#2R	Right	25	12	6	Haematoma	Clip
Subj#3	Left	23	18	8	Secondary facial palsy	SP
Subj#4	Right	6	17	8	None	SP
Subj#5	Right	6	15	8	None	SP
Subj#6	Right	16	13	5	None	RWS
Subj#7	Left	11	12	7	None	Clip
Subj#8	left	35	10	5	None	Clip
Subj#9	Right	6	9	7	None	Clip
Subj#10	Right	36	9	8	None	Clip
Subj#11	Left	9	6	7	None	Clip
Subj#12	Right	5	6	8	None	Clip
Subj#13	Right	58	6	6	None	Clip
Average		18 ± 14	15 ± 8			

L: Left; R: Right; SP: short process; RWS: round window soft.

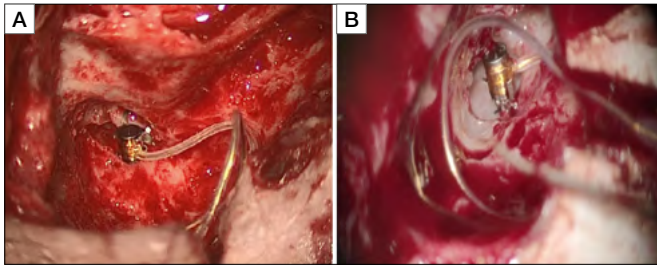


Figure 1. Intraoperative illustration showing the placement of (A) short process coupler, and (B) clip coupler.

was comprised of 13 patients: 6 adults (30 ± 13 years), and 7 children (7.2 ± 2.3 years). Eight patients (61.5%) were unilateral atretic, and 5 (38.5%) were bilaterally atretic. Two patients underwent bilateral implantation. The Jahrsdoerfer classification was used to categorise congenital aural atresia¹⁶. All operated ears had a grading score between 5 and 9 (Tab. I).

In 6 ears, the FMT was coupled to the short process of incus (Fig. 1A), in 8 ears the Clip coupler was used (Fig. 1B), and in one ear the round window coupler was used. No intraoperative, minor, or major complications were observed. One patient developed secondary facial palsy 3 days postoperatively, which completely resolved with oral steroids. Another patient had a postoperative haematoma that resolved spontaneously within 2 days. No revision surgery was reported in any of the patients.

Audiological outcomes

To assess the safety of the surgical procedure, the pre- and postoperative BC thresholds were compared. The mean difference was 2 dB, which was not greater than the safe level of 5 dB for any patient at all frequencies (Fig. 2A). Across all frequencies, the aided sound field (SF) thresholds were significantly improved by using the VSB. The mean aided PTA4SF was (26.44 ± 4.03 dB HL) compared with the mean unaided PTA4SF of (61.88 ± 1.53 dB HL). The average functional gain was 35.44 dB, as shown in Figure 2B. The analysis of this improvement revealed a significant difference ($p < 0.0001$).

Speech understanding in a quiet environment also showed significant improvement. The SRT measurements with VSB were significantly better in all patients compared to preoperative measurements ($p < 0.0001$). The mean preoperative SRT (Fig. 3) decreased from 63.33 ± 10.63 dB HL to 24.67 ± 8.95 . Before implantation of the VSB, the mean SDS in quiet conditions was 51% (SD 19.17%) in the unaided condition. The post-implantation mean aided SDS was 94.60% (SD 4.43%) for monosyllables at 65 dB HL. The improvement in speech discrimination was statistically significant ($p = 0.002$), as shown in Figure 4A. Moreover, speech discrimination in noise was significantly improved ($p = 0.008$) from ($27.75\% \pm 12.49$) preoperatively to ($78.50\% \pm 11.75$) postoperatively (Fig. 4B).

Subjective evaluation

The SSQ12 questionnaire was used to evaluate the subjective

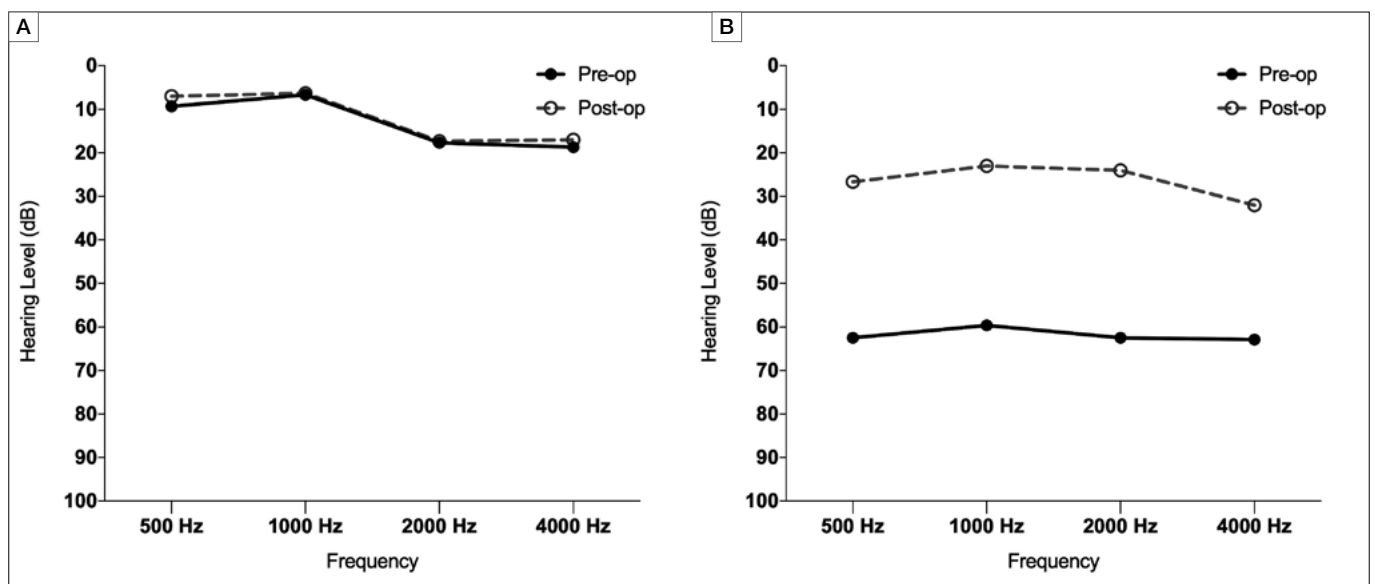


Figure 2. (A) Pre- and postoperative bone conduction threshold showed stable results. (B) The post-operative sound field using VSB was significantly better than the preoperative unaided one.

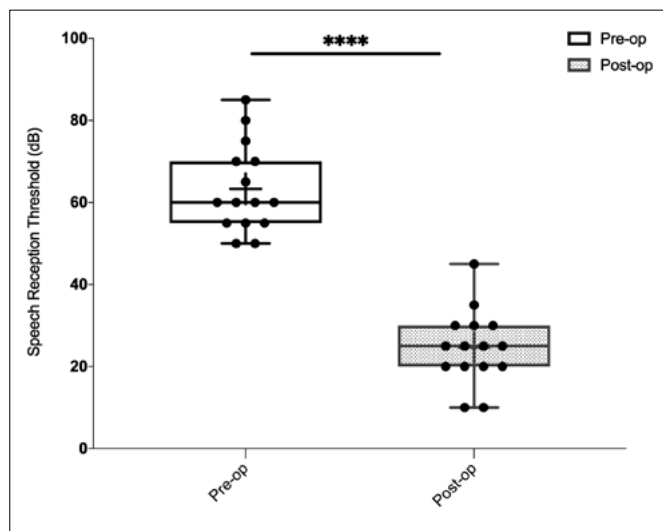


Figure 3. The postoperative speech reception threshold using VSB was significantly lower than the preoperative unaided one.

tive sound quality using the VSB. The overall satisfaction of participants regarding sound quality after using the VSB system was better than that of the preoperative one (Fig. 5). All participants had a clear improvement in the SSQ12 score postoperatively compared to the preoperative score ($p < 0.0001$).

Discussion

This study demonstrates the clinical, subjective and ob-

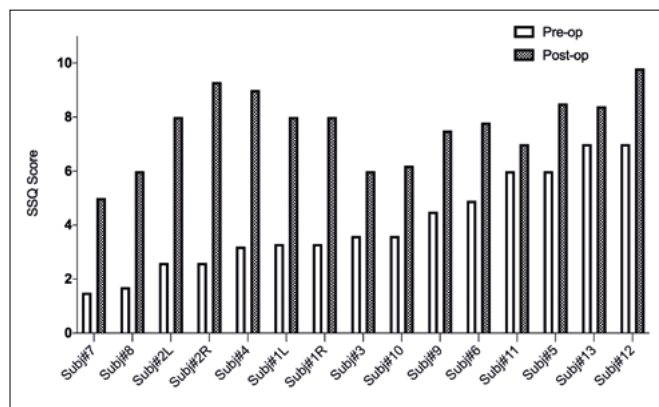


Figure 5. Comparison of SSQ12 score preoperatively unaided with postoperative aided one using VSB.

jective benefits of VSB in patients with hearing loss due to congenital aural atresia. The audiological and speech evaluations showed improved PTA4, SRT, and SDS values with the VSB. Significant audiological improvement using VSB in aural atresia cases has been reported in the literature^{1,2,10,12,14}. In addition to the improvement in the audiological outcome of VSB in atretic ears, the patient satisfaction scores with the SSQ12 questionnaire were also high. Leinung et al.¹⁷ studied the acceptance and benefit of the VSB by means of a questionnaire and compared the results with questionnaires filled for conventional BCHA used previously in preschool children with unilateral congenital aural atresia. They found significant improvements in all

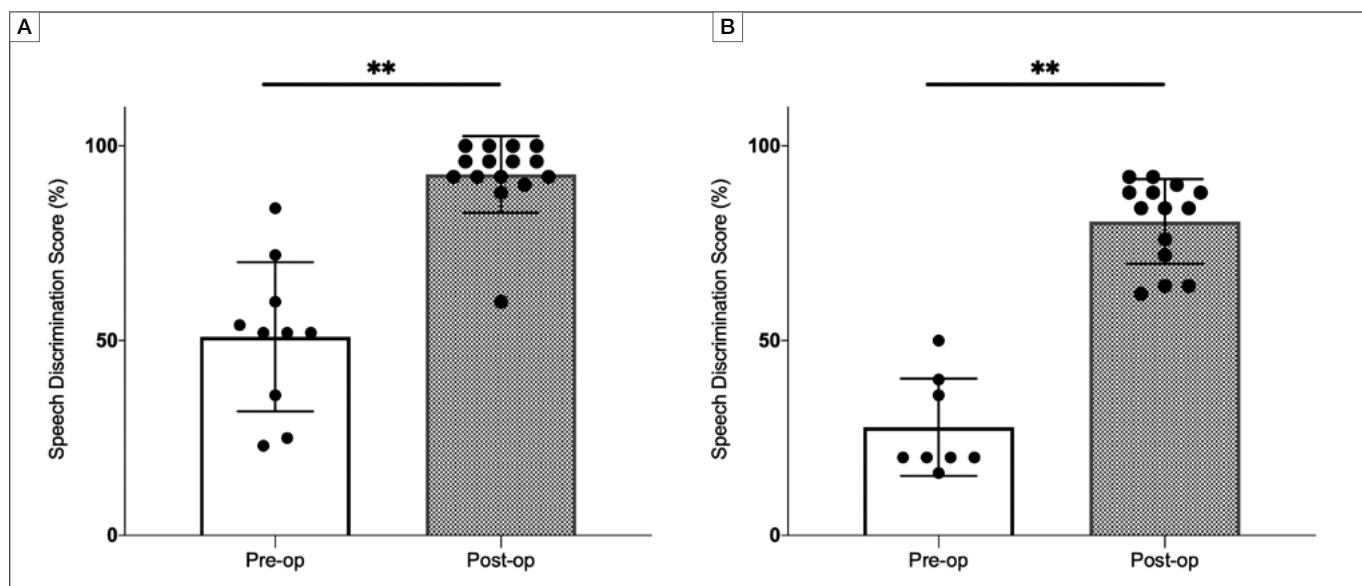


Figure 4. The postoperative speech discrimination score using VSB in a quiet situation (A) and in noise (B) was significantly better than the preoperative unaided one.

questionnaire sections, with higher acceptance in favour of VSB than for BCHAs.

The post-operative functional gain in our present study was 35.44 dB. This outcome was comparable to prior studies on individuals with congenital aural atresia who used other BAHI devices. The functional gain of bone anchored hearing aids and bone bridge devices was 33.1 and 47.2 dB, respectively^{18,19}. They also reported improved word recognition and quality of life following implantations. In terms of directional hearing, it was observed that localisation abilities were increased when either active middle ear implants or BAHI devices were used, with no statistically significant differences between the two systems^{20,21}.

In agreement with other recent reports^{1,2,10-12,14}, we demonstrated that the VSB implant procedure can be considered safe, as the postoperative BC thresholds remained stable in all the patients, implying that their residual hearing was unaffected by the surgical procedure. Moreover, only two minor postoperative complications were documented in the present study, which completely resolved.

The youngest patient in the current series was 5 years old at the time of implantation. An international consensus on VSB in children published in 2010 stated that the committee decided not to limit the age at implantation; rather, it mentioned that the decision for implantation should be based on the surgeon's judgement and expertise⁶. The lowest Jahrsdoerfer score in the present study was five. McKinnon et al.¹³ reported a successful VSB implantation with a Jahrsdoerfer score of four. Moreover, they found that the scores did not correlate to or predict postoperative audiological outcomes¹³.

Coupling FMT to stapes superstructure is the most commonly used technique in aural atresia cases^{1,10,12,13,22}. However, FMT placement to multiple middle ear structures has been described previously, such as footplate, round window, long process of the malformed malleus-incus complex, and promontory fenestration^{1,2,6,10,12,13,22}. Recently, coupling the FMT to the short process of incus proved its efficiency in aural atresia cases^{15,23,24}. Furthermore, the VSB was implanted successfully in external and middle ear malformations for different reasons, such as Fanconi anaemia and fibrous dysplasia of the temporal bone^{25,26}. Reconstructive surgery for conductive hearing loss in patients with fibrous dysplasia of the temporal bone (FDTB) carries a high risk of poor hearing rehabilitation due to the chance of restenosis of the EAC, graft failure and EAC cholesteatoma. Therefore, VSB can be an alternative choice for hearing rehabilitation in patients with FDTB²⁵. The limitations of the present study are the limited number of participants, retrospective study design and short duration of follow-up. Therefore, we recommend further

studies with a larger number of participants and a longer follow-up period.

Conclusions

In conclusion, patients with hearing loss due to CAA benefit substantially from VSB with highly satisfactory subjective results and negligible rate of complications. In addition, the presence of different couplers allows the surgeon to attach the FMT to different anatomic sites, suitable for ears with malformations.

Conflict of interest statement

The authors declare no conflict of interest.

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Authors' contributions

FA and SFA contributed with idea generation, methodological development, data analysis, and writing the manuscript. MY was in charge of data collecting and analysis. Moreover, assessing and approving the final manuscript version.

Ethical consideration

This study was approved by the Institutional Ethics Committee (King Saud University) (approval No. E-19-4224). The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki.

Written informed consent was obtained from each participant/patient for study participation and data publication.

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