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OTOLOGY

Vibrant Soundbridge® in preschool children with unilateral aural atresia: acceptance and benefit

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Abstract The aim of this pilot study was to determine the acceptance and benefit from the middle ear implant system Vibrant Soundbridge® (VSB, MED-EL Corporation, Austria) by means of a questionnaire, compared to a previously used conventional bone conducting hearing device, in preschool children with unilateral congenital aural atresia. Prospective cohort study. All nine children with unilateral congenital aural atresia used the VSB and had previous experience with a bone conducting hearing device. The benefit from the VSB was evaluated by questionnaires concerning acceptance of hearing aids, handling, listening effort, behavior, quality of life, and the duration of daily use and compared to the experience with the bone conducting hearing device. In addition, to quantify the benefit from the VSB use, audiological assessment (pure-tone audiometry via free field testing, speech audiometry, and localization test) was performed with and without VSB. The questionnaires and audiological test results were compared pairwise. According to all questionnaire areas, children benefited significantly more from the VSB compared to bone conducting hearing device ($ps < .05$). The most important finding was a significant increase in daily use from 2 h for the bone conducting hearing device to 10 h for the VSB. Children performed significantly better with the VSB than without it in the audiological assessment. Children with unilateral aural atresia benefited significantly more from the VSB compared to a conventional bone conducting hearing device according to the parents' questionnaires and yielded better results in the audiometry and localization test with the VSB than without it.

Keywords Unilateral aural atresia · Middle-ear implant · Vibrant Soundbridge · Bone conducting hearing device

Introduction

The acceptance of conventional bone conducting hearing devices can be very low in children with unilateral aural atresia. The main reasons for this intolerance are the varying and inconsistent adjustment and customization as well as unsatisfactory hearing effects. Moreover, the psychological strain in children and parents is not very high due to normal hearing of the contralateral ear and often unimpaired speech development in these children [1].

Although the majority of affected children seem to cope with language input due to acceptable speech intelligibility in quiet surroundings [2, 3], the effects of a lack of bilateral sound input become evident in more difficult hearing situations, such as listening and intelligibility in noise and auditory spatial perception [4, 5]. The insufficient maturation of the central auditory system based on the lack of auditory input results in reduced cognitive and language

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test scores, as well as in persistent behavioral problems [6] and slower educational progress [7–9]. Numerous studies on children with severe unilateral sensorineural hearing loss demonstrated more academic weaknesses compared to normal-hearing peers in sub-teen age [10, 11]. As children with unilateral aural atresia also present a high level of hearing loss [12, 13], they additionally require an early and consistent intervention.

With the introduction of the middle ear implant, the Vibrant Soundbridge® (VSB, MED-EL Corporation, Innsbruck, Austria), a new perspective for hearing restoration was opened. Originally, the device was designed for and widely employed in patients with sensorineural hearing impairment [14, 15]. However, the indication has been extended to patients with mixed and conductive hearing loss, expanding the application onto various challenging conditions in subjects with malformed external and middle ears [16]. Furthermore, the device indication criterion was expanded from adults to patients under the age of 18 years, with the first implantation of the VSB device in children performed in June 2009.

Although first results in adolescents and children were promising [17–20], there is currently a lack of data on the use of the VSB in toddlers and preschool children with hearing loss caused by malformations of the middle and outer ear. Therefore, the benefit from the VSB use in preschool-aged children is of high interest.

The primary purpose of the study presented here was to determine the parents' subjective judgment on their children's benefit from the VSB use by means of an in-house developed questionnaire compared to the previous use of bone conducting hearing devices. In addition, the benefit from the VSB use was quantified by pure-tone audiometry, speech discrimination in quiet and in noise, and a test on localization abilities with and without VSB.

Materials and methods

Thirteen children were provided with a VSB (VORP 502). Four of these thirteen children did not accept the conventional bone conducting hearing device at all. Therefore, their parents could not fill out the questionnaire on the profit from this hearing device, and these four children had to be excluded from this study. The other nine children did accept it, so that questionnaires could be obtained for both hearing devices: (1) the conventional bone conducting hearing device and (2) VSB. Hence, these nine children—eight boys and one girl, six with unilateral atresia on the right side and three on the left side—could be included in the presented study (Table 1).

All patients were implanted between 2011 and 2013 at the Frankfurt University Hospital. Children included had to have a hearing loss within the device's indication range (as stated on the manufacturer's homepage). Children with implantable bone anchored devices were not included in this study. No further exclusion criteria were applied.

Preoperatively, all nine children received a computed tomography (CT), magnetic resonance imaging (MRI), and a frequency-specific air as well as bone-conducted brainstem evoked response audiometry (BERA) (Table 1). Seven of nine children demonstrated a conductive hearing loss with an air-bone gap of approximately 60-dB normal hearing level (nHL). In two children, no air conduction could be performed due to prolonged duration of anesthesia. The mean implantation age was 31 months. No complications after the implantation of the VSB were identified.

Because no questionnaire was available for the target sample, that is, for preschool children using the VSB, a questionnaire was developed to determine the parents' degree of satisfaction and subjective impression of their children's benefit from the respective hearing aid. The

Table 1 Patient characteristics of the study population

ID	Implantation age in months	Gender	Type of middle ear malformation (Jahrsdoerfer)	AC* (dB nHL)	BC** (dB nHL)	FMT*** localization
1	42	M	8	58	0	Stapes
2	37	M	5	65	5	Round window
3	44	M	3	60	35	Endosteum
4	30	M	8	****	0	Stapes
5	20	M	1	80	10	Round window
6	23	M	5	75	0	Round window
7	50	M	7	65	0	Stapes
8	15	F	9	60	0	Incus
9	22	M	7	****	10	Stapes

* Air conduction, averaged over frequencies .5, 1, 2, 4 kHz; ** bone conduction (click); *** floating mass transducer; **** air conduction could not be carried out due to prolonged duration of anesthesia

questionnaire could not be validated as the target sample size was far too limited (less than 100 children worldwide).

The questionnaire consisted of 20 five-point Likert-scaled questions on five areas: (1) acceptance by the children, (2) handling, (3) listening effort, (4) behavior, and (5) quality of life. Acceptance was examined by questions on readiness, willingness, and resistance of the child to use the hearing aid. Handling was examined by questions on difficulties of putting-on and the fitting/setting of the hearing aid. To determine the listening effort, the parents were asked whether the listening with the hearing aid was easier in quiet and loud surroundings. Parents were also asked about changes in the behavior and activities of the child regarding his or her curiosity, aggressiveness, self-confidence, and joyfulness. The questionnaire section about quality of life comprised questions on benefits or restrictions for the children as well as relief and stress for the parents in daily life caused by the use of the hearing aid. All answers were encoded in a similar way, from "very bad result" (lower values) to "very good result" (higher values).

In addition, the duration of daily use of the hearing devices in hours per day was monitored.

The parents filled out the questionnaires both for the bone conducting hearing device and for the VSB for comparison after an acclimatization period of at least 3 months. To avoid the recall bias, the questionnaires on the satisfaction with the bone conducting hearing device had been filled out before the VSB was implanted. Due to its length (six pages), the questionnaire is not presented here, but it is available on demand and can be obtained from the first authors.

All audiological tests were conducted after the VSB implantation. The examination of quality of care with and without the VSB was carried out by means of the pure-tone audiometry via free field testing (at .5, 1, 2, 4 kHz). Furthermore, speech discrimination in quiet and in noise was tested using AAST (Adaptive Auditory Speech Test [21]) with and without background noise, and localization abilities over six loudspeakers were determined when physically possible. The healthy ear was plugged and covered with a headphone during the examination. The post-VSB bone conduction thresholds were not tested, because most children did not tolerate the testing due to their young age. No audiological testing was feasible with the conventional bone conducting hearing device, because even those nine children, who did accept it, obviously hardly profited from it, which impeded the audiological testing due to minimal compliance.

Informed consent was obtained from all individual participants included in the study.

Statistical analysis

As the data were either ordinal or not normally distributed and the sample size was very limited, non-parametric tests were used.

The pairwise Wilcoxon test was utilized to compare the parents' degree of satisfaction with the bone conducting hearing device and with the VSB according to the Likert-scaled questions (ordinal data). For each question set (e.g., listening effort), medians were calculated based on bone conducting hearing device and VSB questionnaires and compared pairwise. In addition, sums of all ordinally scaled answers—the total scores—in both questionnaires were compared.

For the duration of the daily use, hours per day were compared in a pairwise Wilcoxon test.

An ordinal regression was performed to examine the factors influencing the distribution of ordinal values in the questionnaires, that is, all values except the duration of daily use. The objective of the regression was to determine whether the influence of the dichotomous variable "bone conducting hearing device versus VSB" outweighs the influence of other variables, e.g., gender of the child and atresia location.

Wilcoxon test for two paired groups was utilized to compare the pure-tone audiometry and AAST results with and without the VSB. In the case of the localization tests, the dichotomized results "correct/not correct" of all six loudspeakers were analyzed together by means of a cross table, which resulted in $N = 106$ test values to be compared pairwise.

A probability (p) value of less than .05 was considered significant. Statistical calculations were performed using the statistical software package SPSS 20 (International Business Machines Corporation, Armonk, USA).

Results

According to the Wilcoxon test, the parents' answers in all questionnaire sections demonstrated significant improvements with the VSB compared to the bone conducting hearing device (Ns = 9). Acceptance of hearing aids by the children was significantly higher for the VSB than for the bone conducting hearing device ($Z = -2.68$, $p = .007$). The same was valid for the handling of hearing aids ($Z = -2.54$, $p = .011$). The listening effort decreased significantly for the VSB compared to the bone conducting hearing device ($Z = -2.41$, $p = .016$). The behavior of the test subjects, as defined in the Methods, was estimated to have improved significantly with the use of the VSB ($Z = -2.40$, $p = .017$). The quality of life of both children and their parents received higher values during use of the

VSB ($Z = -2.39$, $p = .017$). Figure 1 shows boxplots with the median values and 95 % confidence intervals of parents' estimations regarding the five questionnaire sections for the children's benefit from the VSB compared with the benefit from the previously used bone conducting hearing device. For summary of outcomes, see Table 2.

The comparison of the total scores of both questionnaires, without the duration of the daily use, revealed that children benefited significantly more from the VSB than from the bone conducting hearing device ($Z = -2.67$, $p = .008$, $N = 9$).

The duration of the daily use of the VSB was significantly higher compared to the bone conducting hearing device with 10 versus 2 h per day ($Z = -2.67$, $p = .008$, $N = 9$).

An ordinal regression was calculated to examine factors influencing the distribution of the questionnaire values. Overall, 40 % of variance were explained according to the Nagelkerke's pseudo R^2, with a goodness of fit of $\chi^2_{(328)} = 519.25$, $p < .001$. Among examined factors—questionnaire section, gender of the child, VSB versus bone conducting hearing device, atresia, and implantation age in months—the influence of the variable "VSB versus bone conducting hearing device" had the highest Wald statistics and the only significant result (Wald $\chi^2_{(1)} = 114.004$, $p < .001$). A positive value of the estimate of 2.572 (95 % CI 2.100–3.044) indicates that the use of the VSB is associated with higher and therewith better values in the questionnaire.

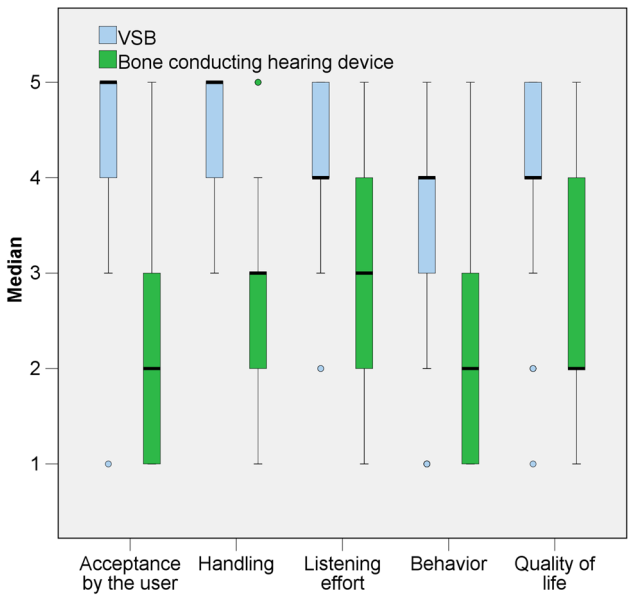

Fig. 1 Subjective judgment on children's benefit from the bone conducting hearing device and the VSB® according to the total scores of subtests in the parents' questionnaires

Table 2 Descriptive statistics on parents' judgment on children's benefit from the VSB: total scores of questionnaire sections

	Bone conducting hearing device Mean/ SD*/median/variance	VSB Mean/ SD*/median/variance
Acceptance by the user	2.21/±1.25/2.00/1.56	4.33/±1.00/5.00/1.00
Handling	2.74/±1.23/3.00/1.51	4.67/±.56/5.00/.31
Listening effort	2.79/±1.06/3.00/1.13	4.22/±.89/4.00/.80
Behavior	2.10/±1.17/2.00/1.37	3.26/±1.26/4.00/1.58
Quality of life	2.63/±1.35/2.00/1.83	4.11/±1.02/4.00/1.03
Daily use in hours	2.43/±2.14/1.50/4.58	9.67/±2.35/10.00/5.50

* *SD* standard deviation

Not all children were able to complete the audiological tests twice, so that the sample sizes decreased to *N*s = 7–8. In the diagnostics by the pure-tone audiometry via free field testing, the paired comparison of all frequencies with and without VSB demonstrated a significant improvement in hearing abilities for each frequency (*N*s = 7; 500 Hz: $Z = -2.21$, $p = .027$; 1000 Hz: $Z = -2.21$, $p = .027$; 2000 Hz: $Z = -2.41$, $p = .016$; 4000 Hz: $Z = -2.39$, $p = .017$), see Table 2. These results are, again, visualized by means of boxplots, see Fig. 2.

In relation to speech understanding that was tested using AAST, the children also performed significantly better with the VSB than without it ($Z = 2.03$, $p = .042$, $N = 8$), see Table 3.

In the localization tests, children were able to identify the correct loudspeaker out of six significantly more often with the VSB than without it ($\chi^2_{(1)} = 21.78$, $p < .001$, $N = 106$). All six speakers and all participants were included in this calculation, which resulted in $N = 106$ test values to be compared pairwise. Without the VSB, correct results were obtained in 61 % of cases (65 out of 106), with the VSB in 79 % of cases (84 out of 106) according to the cross table calculation.

Discussion

In the study presented here, children benefited significantly more from the use of the VSB than from the previously used bone conducting hearing device, as revealed by a comparison of two sets of parents' questionnaires. Despite the small sample size ($N = 9$), the results showed significant improvement in parents' satisfaction regarding VSB use in all questionnaire sections: (1) acceptance by the children, (2) handling, (3) listening effort, (4) behavior, and (5) quality of life. Although the differences were

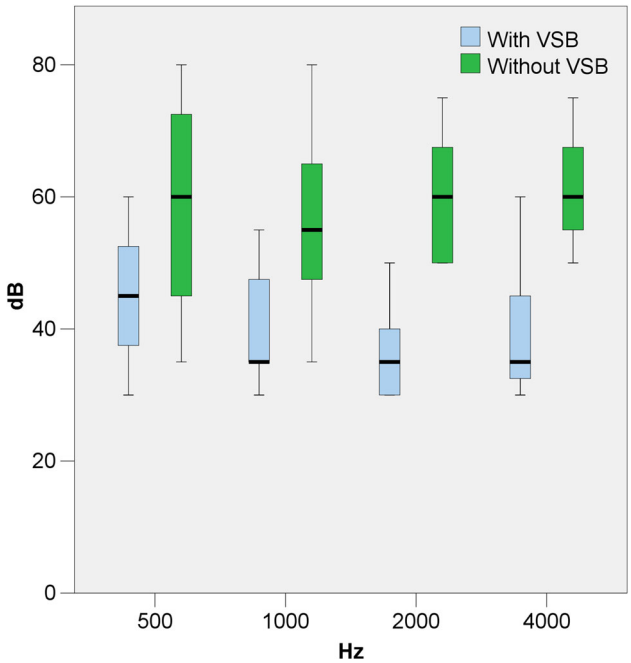

Fig. 2 Results of the pure-tone audiometry via free field testing with and without VSB®

Table 3 Descriptive statistics on objective assessment of hearing abilities: results of pure-tone audiometry via free field testing and Adaptive Auditory Speech Test (AAST)

	Without VSB Mean/ SD/median/variance	With VSB Mean/ SD/median/variance
500 Hz	58.57/±17.96/60.00/ 322.62	44.37/±10.16/42.50/ 103.13
1000 Hz	56.43/±15.20/55.00/ 230.95	38.38/±9.43/35.00/ 88.84
2000 Hz	60.00/±10.41/60.00/ 108.33	36.25/±6.94/35.00/ 48.21
4000 Hz	61.43/±9.00/60.00/ 80.95	39.38/±10.16/35.00/ 103.13
AAST with noise	−9.83/±3.52/–9.50/ 12.33	−9.83/±4.04/–10.50/ 16.33
AAST without noise	45.8/±13.23/40.80/ 175.00	36.40/±15.51/29.20/ 240.52

statistically not highly significant, the small sample size should be taken into account. Hence, in this case, values $p < .05$ provide best possible evidence that the VSB system is an excellent alternative compared to established conventional bone conducting hearing devices for toddlers and preschool children with unilateral aural atresia.

In addition, the examination of quality of care with and without the VSB was analyzed objectively by means of the pure-tone audiometry via free field testing, AAST with and without background noise, and localization tests. Because not all children were able to complete these tests twice, the sample size decreased to $N = 7$–8, seven being the minimal sample size in which statistically significant differences can be identified by means of a Wilcoxon test for two paired groups. However, such differences were indeed found confirming that children did yield better results with the VSB than without it.

Even though the implantation age of the VSB was not limited, its pediatric use was controversially discussed during the 1st International Meeting on VSB in Children and Adolescents in Frankfurt/Main, Germany, on October 3, 2008, first of all due to anatomical reasons [22]. Although the development of the middle ear structure is complete at birth, the tympanon still expands. Thus, some critics argue that early implantation could lead to possible displacement and reduced function of the floating mass transducer in course of growth. However, with a single-point-attachment technique, the stability of the floating mass transducer is not impacted by tympanon expansion [22]. According to the consensus statement, the decision is left to the surgeon's expertise and the implantation of a VSB is possible as long as the anatomy of the tympanon allows the coupling of the floating mass transducer on a vibratory element of the middle ear. Moreover, a displacement of the transducer was not observed in our study population.

Other points of criticism were possible complications (e.g., development of haematomas) related to the invasiveness of the implantation [23], the difficulty of explantation in case of the introduction of more efficient hearing devices/technologies, and the life-long MRI incompatibility of the VSB (VORP 502) [24]. In a recently published review about safety and effectiveness of the VSB, 13 articles with 196 patients were scrutinized with focus on adverse events. First and foremost, FMT extrusion was detected with an occurrence of 6.63 %, followed by wound dehiscence (2.04 %) and dizziness (1.53 %) [25]. In three patients, device failure was observed (1.53 %) and about 10 % of patients needed revision surgery.

In the presented study here, no complications related to the implantation of the VSB were found. However, one of the children developed mastoiditis at the age of 6 years, more than 3 years after VSB implantation. A clear link between implantation and development of mastoiditis can be neither proved nor excluded. Regarding the MRI incompatibility, the introduction of the new VSB model, VORP 503, solved this problem at least for 1.5 T [26]. However, unfortunately, the model VORP 503 is not yet CE-certified for the children below 5 years of age. Therefore, none of the children from our study could be provided with this new model.

Because speech recognition in loud surroundings with low signal-to-noise ratio is often affected, as well as sound

localization abilities, early hearing rehabilitation is essential, especially in young children with regard to maturation processes of the central nervous system. As the conventional conducting hearing devices are often refused by toddlers and younger children, above all by those with unilateral aural atresia, due to discomfort and pressure sores, and are also not accepted by the parents of these children for esthetic reasons [22], alternative hearing devices are required.

Our results underline previously published data and clinical experience on limited acceptance of the conventional conducting hearing device without a real benefit regarding listening effort. Although other systems are available, e.g., bone-anchored hearing aid and Bonebridge®, they are not approved for children under the age of 5 years [27]; the same is valid for the VSB. Yet, in contrast to the latter, both of them do not support the specific stimulation of the impaired ear only, which hinders the selective development of the auditory pathway and the localization skills. Furthermore, even if the bone-anchored hearing aid is considered a good alternative to the conventional bone conducting hearing aids [17], it is often associated with complications, such as recurrent peri-implant skin infections, especially in children younger than 5 years [27], due to inadequate and insufficient hygiene as well as concomitant loosening of the fixture [28].

The study presented here includes a small sample size, which has to be considered a limitation, and larger samples are needed to evaluate the stability of positive effects from the VSB use over time. However, these data reflect one of the first experiences of VSB use in toddlers and preschool-aged children.

The parents who opted for the surgery might have been biased toward success of the therapy, which might have found its reflection in their responses to questionnaire items.

In addition, the questionnaire used in this study could not be validated for the target sample. Yet, no other questionnaire was deemed appropriate to be utilized instead. For instance, the questionnaire IOI-hA [29] consists only of seven items, was developed for self-assessment, has another target group (adults), seems to have some flaws in the statistics related to the validation of its German version, and is thematically dedicated to the satisfaction, but not to other domains covered by our questionnaire (handling, behavior, listening effort, etc.). The Abbreviated Profile of Hearing Aid Benefit (APHAB) [30, 31] was also designed for an adult population. However, the questionnaire developed for this study has to be validated for children implanted with the VSB in the future research.

Nevertheless, the outcomes presented here highlight the middle ear implant VSB as a valid alternative solution compared to the conventional hearing devices, such as bone anchored hearing aids or conservative conducting hearing solutions. This benefit was emphasized by the children themselves in the most important finding of this study, namely, in the increase in daily use from two to ten hours after the transition from the bone conducting hearing device to the VSB.

Conclusion

Although the use of the VSB system in toddlers and younger children with unilateral aural atresia is discussed controversially, its application in this patient group offers the possibility of an effective care for the hearing disorder as an essential precondition of good development of speech and hearing.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study. Earlier results of this study were reported by Barbara Vaerst, Yevgen Zaretsky, Martin Leinung, Timo Stöver, and Christiane Hey at the 85th Annual Meeting of the German Society of Oto-Rhino-Laryngology, Head and Neck Surgery, 28.05-01.06.2014, Dortmund, Germany, in an oral presentation "Versorgung von unilateralen Gehörgangsatresien bei Vorschulkindern mit einer Vibrant Soundbridge®: Erfassung der Versorgungsqualität".

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