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Congenital aural atresia: hearing rehabilitation using active middle-ear implants

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Main Article

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Abstract

Objective. To assess hearing rehabilitation in patients with congenital aural atresia using an active middle-ear implant (Vibrant Soundbridge).

Methods. Of a cohort of 70 microtia and atresia patients, 10 underwent Vibrant Soundbridge implantation between 2008 and 2021. Two of the 10 patients had binaural implantation, resulting in 12 ears for analysis. Pre- and post-operative audiometry data were analysed, and patient satisfaction was evaluated. Surgical issues regarding coupling sites and outcomes were analysed.

Results. Pure tone average (0.5, 1, 2 and 4 kHz) improved from a pre-operative mean (standard deviation) of 65.3 (8.7) dB HL to a post-operative mean of 26.8 (4.9) dB HL. This resulted in a mean pure tone average gain of 38.5 dB HL. The results indicate no obvious difference between stapes ($n = 8$) and incus ($n = 4$) coupling. The mean effective gain for 0.5, 1, 2 and 4 kHz was −17.8 dB HL (standard deviation = 4.3). Concerning effective gain, Vibrant Soundbridge performed best at 2 kHz. Patients reported high overall satisfaction, good sound quality and strongly improved directional hearing.

Conclusion. An active middle-ear implant (Vibrant Soundbridge) allows hearing rehabilitation in selected atretic ears, and provides long-term hearing stability in children and adults.

Introduction

Congenital aural atresia and pinna malformations (microtia types I–III) occur with a prevalence of 0.83–17.4 per 10 000 births depending on the population. Caucasians and Afro-Americans have a lower prevalence compared with people of Hispanic, Asian and Andean (e.g. Ecuador or Chile) ancestry and native Americans. This might be a result of genetic or environmental factors.[1]

Rehabilitation of these patients always involves two segments: cosmetic and functional reconstruction. Therefore, two teams are needed: a plastic reconstructive team and an otological surgery crew. Close collaboration is crucial to achieve the best outcome for these patients.

Patients generally present with a conductive block of 60 dB HL and normal inner-ear function. The ear atresia plate fixes the malformed malleus–incus complex, whereas the stapes is usually intact and mobile. The lenticular incus process can be missing or may remain present as a fibrotic connection towards the stapes head. Displacement of the facial nerve canal can be expected in about 77 per cent of patients with auricular dysplasia, limiting the access towards the oval or round window niche.[2] Conventional hearing aids are not an option because the ear canal is missing, and otological external and middle-ear surgery to correct the sound conduction mechanism is challenging. In the last decade, several hearing implants have been developed. They can be categorised depending on how the acoustic energy is transmitted to the cochlea.

Of the bone-conducting devices available, some are passive (vibrations are generated outside the skull) transcutaneous systems (e.g. Sophono (Medtronic, Minneapolis, USA) or BAHA Attract (Cochlear, Sydney, Australia)). Other bone-conducting devices are passive percutaneous devices (e.g. BAHA Connect (Cochlear) or Ponto Bone Anchored Hearing System (Oticon Medical, Askim, Sweden)). More recent bone-conducting devices can also be active (the vibrating part is implanted) (e.g. Vibrant Bonebridge (Med-El, Innsbruck, Austria) or Osia (Cochlear)).

Other hearing implants used to treat conductive and mixed hearing loss in congenital aural atresia are active middle-ear implants, such as the Vibrant Soundbridge (Med-El).[3,4] This device stimulates mobile structures of the middle ear directly with a floating mass transducer. Different locations within the middle ear can be used to attach the floating mass transducer (e.g. incus, stapes and round window).[5] However, in the case of congenital aural atresia, these ossicles need to be mobilised first by otological middle-ear surgery.

A pre-operative computed tomography (CT) scan of the temporal bone is an absolute necessity for estimating the severity of the temporal bone malformation, in order to assess the dysplasia and fixation of the ossicular chain, and to identify the position of the facial

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nerve. This allows the surgeon to determine the chances of successful surgical reconstruction.

In 2019, the International Microtia and Atresia Workgroup provided recommendations on functional reconstruction in patients with microtia and congenital aural atresia. The Workgroup proposed general consensus recommendations on the options and timing of aesthetic reconstruction and hearing rehabilitation. Obviously, the placement of hearing implants should not interfere with the cosmetic reconstructive process, but implantation may precede, be combined with or follow the aesthetic reconstruction.[6]

In June 2022, a new consensus statement on bone-conduction devices and active middle-ear implants in conductive and mixed hearing loss was released. It provided recommendations for minimal reporting standards.[7] One major key point was to measure hearing improvement not only by calculating functional gain (unaided thresholds *vs* aided post-operative thresholds) but also by computing effective gain. Effective gain is the difference between bone-conduction thresholds and post-operative aided thresholds.[7] Functional gain can sometimes be a misleading value, as it is strongly dependent on the pre-operative air–bone gap. The larger the air–bone gap, the higher the functional gain of any device that bypasses the middle ear.[8] The following example should demonstrate this.

One patient, with a pre-operative air–bone gap of 60 dB HL, receives an imperfect middle-ear implant and reports a functional gain of 40 dB HL with this implant. Another patient, with a pre-operative air–bone gap of 30 dB HL, receives an absolutely perfect middle-ear implant and reports a functional gain of 30 dB HL with this implant.

In this scenario, the imperfect middle-ear implant will report a bigger functional gain, even though it cannot bypass the middle ear as well as the perfect middle-ear implant. In order to better evaluate and compare the capabilities of a middle-ear implant, independently of the pre-existing air–bone gap, effective gain is a more suitable measure. As effective gain is defined as bone-conduction thresholds minus aided post-operative thresholds, a perfect middle-ear implant would have an effective gain of zero. The more negative a reported effective gain, the bigger the remaining post-operative air–bone gap.[8]

The plastic and otological ear atresia team at our institution offers a wide range of cosmetic and functional rehabilitation options, individualised for each patient. This study aimed to present the results in patients with congenital aural atresia who underwent hearing rehabilitation with an active middle-ear implant (Vibrant Soundbridge) at our institution.

Materials and methods

Of our cohort of 70 microtia and atresia (congenital aural atresia) patients, 10 underwent Vibrant Soundbridge implantation between 2008 and 2021. Two of the 10 patients had binaural implantation, resulting in 12 ears for analysis (analysis was performed for each side separately).

In this retrospective study, we examined the patients' characteristics. The CT scans for each ear were used to apply the Jahrsdoerfer grading system.[9] We determined the microtia score, the floating mass transducer coupling site and the type of Vibrant Soundbridge (vibrating ossicular replacement prosthesis) implanted.

Endpoints

The primary endpoints were the functional gain and the effective gain measurements. Secondary endpoints were complications and subjective patient satisfaction, assessed with a questionnaire. The average age at implantation was 15.5 years (standard deviation (SD) = 10.0). Seven patients were male and three patients were female. The most common coupling site was onto the mobile stapes suprastructure using a stapes coupler, in eight ears; incus coupling was performed onto the short process in four ears. Round window coupling was not performed. Patients 8 and 9 had binaural atresia (Table 1).

Pre-operative air-conduction thresholds (unaided, masked) and post-operative soundfield thresholds (aided, masked) were obtained to calculate the mean functional gain for all frequencies. Effective gain was determined by comparing post-operative soundfield thresholds (aided, masked) with bone-conduction thresholds (masked). As secondary endpoints, patient satisfaction and further subjective measures were evaluated with a questionnaire (Appendix 1). Further data to meet the reporting standard of the consensus paper were collected (Appendix 2).

Analysis was performed for all ears and per coupling site. Statistical analysis was performed using Excel® spreadsheet software and the ENTstatistics (Innoforce, Liechtenstein) program.

Results

In the case of microtia repair, functional hearing rehabilitation was performed at the second of three rehabilitation stages, as outlined by Siegert.[10] Microtia repair was carried out using rib cartilage for the framework of the pinna.

Mean air-conduction thresholds improved over all frequencies (0.25–8 kHz), decreasing from a mean of 65.6 dB HL (unaided) before surgery to a mean of 29.7 dB HL (aided) after surgery (Table 2).

Pure tone averages (PTA) (frequencies 0.5, 1, 2 and 4 kHz) improved from a pre-operative mean of 65.3 dB HL (SD = 8.7) to a post-operative mean of 26.8 dB HL (SD = 4.9) (Figure 1). This resulted in a mean PTA gain of 38.5 dB HL.

Effective gain was calculated as bone-conduction thresholds minus post-operative aided soundfield thresholds (0.5, 1, 2 and 4 kHz). The mean effective gain for frequencies 0.5, 1, 2 and 4 kHz was −17.8 dB HL (SD = 4.3) (Figure 2). Optimal gain was reached at 2 kHz; the Vibrant Soundbridge was less efficient at low and high frequencies.

The small number of patients hinders a conclusive analysis between incus and stapes coupling. Both approaches seemed to produce similar results. The average functional gain for incus coupling between 0.5 and 4 kHz was 38.1 dB HL, while the average functional gain for stapes coupling between 0.5 and 4 kHz was 38.8 dB HL (Figure 3).

Secondary endpoints

No revision surgical procedures were required.

All patients wear their speech processors daily. Only 30 per cent of the participants returned the questionnaire. Those who responded reported high satisfaction with the sound quality. The patients reported that they would choose the same treatment option again.

When asked how well they were able to locate the direction of a sound before surgery (1 = never able to locate direction, 10 = perfectly able to locate direction), patients reported an average score of 2.3. The subjective scores on directional hearing after surgery improved to an average of 8.7 (Table 3).

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Table 1. Patients' baseline characteristics

Characteristic	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 7	Patient 8	Patient 8	Patient 9	Patient 10
Ear side affected	Left	Right	Right	Right	Right	Right	Left	Right	Left	Right	Right	Right
Age at surgery (y), sex	23, M	16, F	9, M	6, F	9, M	39, F	4, M	6, M	12, M	16, M	30, M	16, M
Jahrsdoerfer score	8	9	9	9	10	9	9	10	9	9	9	9
Microtia score	3	3	3	3	1	2	1	1	3	1	3	2
FMT fixation location	Stapes	Incus	Incus	Stapes	Incus	Stapes	Stapes	Stapes	Stapes	Stapes	Stapes	Incus
Coupler type*	Clip	SP	SP	Clip	SP	Clip	Clip	Clip	Old clip	Clip	Clip	Clip
VORP model	503	503	503	503	503	503	503	503	502	503	503	503
Year of surgery	2015	2019	2017	2019	2020	2020	2015	2017	2008	2012	2021	2021

*'Clip' refers to a vibroplasty standard clip coupler for the stapes head; 'SP' refers to a short process incus coupler. Y = years; M = male; F = female; FMT = floating mass transducer; VORP = vibrating ossicular prosthesis audio processor (Vibrant Soundbridge)

Discussion

Functional gain and effective gain

Here we discuss the functional gain and effective gain obtained using the Vibrant Soundbridge, and compare the findings with the literature. Overall, only a few studies have analysed hearing rehabilitation in congenital aural atresia patients using a Vibrant Soundbridge device. As congenital aural atresia is a rare condition, many investigations report fewer than 10 participants.[11–14] Furthermore, each study uses a slightly different approach to measure outcomes. Thus, the 2022 published consensus statement on bone-conduction devices and active middle-ear implants should be used to unify different approaches.[7] In order to compare our findings, we focused on recent publications with more than 10 participants (Table 4).[2,15–17]

Our reported mean PTA gain of 38.5 dB HL (0.5, 1, 2 and 4 kHz) compared favourably with the values of 31–38 dB HL reported in the literature. Further tests involved speech recognition and word discrimination scores (Table 4). A larger number of publications with more participant numbers exists for non-congenital aural atresia, including systematic reviews of conductive and mixed hearing loss[18] and of sensorineural hearing loss (SNHL).[19] Ernst *et al.* reported functional gains in conductive and mixed hearing loss patients at three months post operation ranging from 12.5 to 43.4 dB HL, averaging at 29.6 dB HL.[18] In a systematic review of the Vibrant Soundbridge in patients with SNHL, Bruchhage *et al.* reported a functional gain ranging from 12.5 to 33 dB HL, with a higher range of 25–33 dB HL in studies with over 30 cases.[19]

Reporting on the effective gain has only recently been discussed. Therefore, most previous publications did not present these values, and no effective gain values were reported in the congenital aural atresia literature reviewed. In our study, use of the Vibrant Soundbridge in ear atresia patients resulted in a mean effective gain for speech frequencies (0.5, 1, 2 and 4 kHz) of −17.8 dB HL, with the Vibrant Soundbridge performing best at 2 kHz.

Implantation site

There are five possible coupling sites for the floating mass transducer: incus short process, incus long process, stapes, round window and cochleostomy site.

The few existing studies that compare specific coupling sites mainly examine patients with SNHL. Edlinger *et al.* compared short and long incus coupling.[20] Lee *et al.* compared stapes and round window coupling.[21] While all the considered studies stated there was no major difference in hearing rehabilitation depending on the coupling site, none provided large enough numbers of patients to enable a reliable and valid statistical analysis for comparison.

In our study sample, short process incus coupling and stapes coupling were used. Although our patient numbers were too low for statistical analysis, our results indicate no obvious difference between stapes and incus coupling. The average functional gain for incus coupling and stapes coupling differed by less than 3 dB HL.

In congenital aural atresia, the possible coupling site must be evaluated using careful analysis of the pre-operative CT scans. In patients with congenital aural atresia, the incus body is fused to the malformed malleus, and the long process of the incus is usually thin, short and steep towards the stapes

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Table 2. Audiometric data and functional improvement

Parameter	Mean (SD) (dB HL)	Minimum (dB HL)	Maximum (dB HL)
Pre-operative unaided soundfield thresholds, all frequencies	65.6 (7.6)	53.8	77.5
Post-operative aided soundfield thresholds, all frequencies	29.7 (4.3)	24.4	37.5
Functional gain (all frequencies)	35.9 (6.6)	30.0	44.0
Functional gain* (PTA gain)	38.5 (5.4)	27.5	46.3
Effective gain*	−17.8 (4.3)	−23.0	−10.0

*Frequencies 0.5, 1, 2 and 4 kHz. SD = standard deviation; PTA = pure tone average

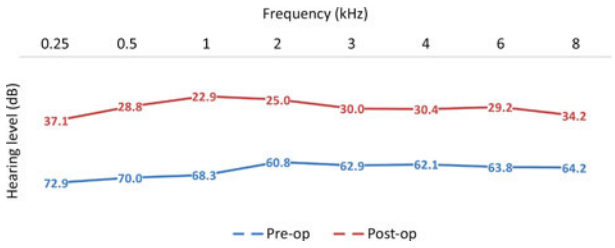


Figure 1. Pre-operative (pre-op) and post-operative (post-op) mean hearing level for all patients, by frequency.

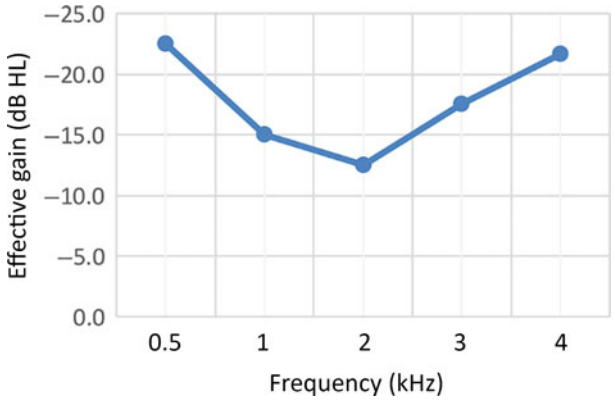


Figure 2. Mean effective gain over frequencies 0.5, 1, 2 and 4 kHz.

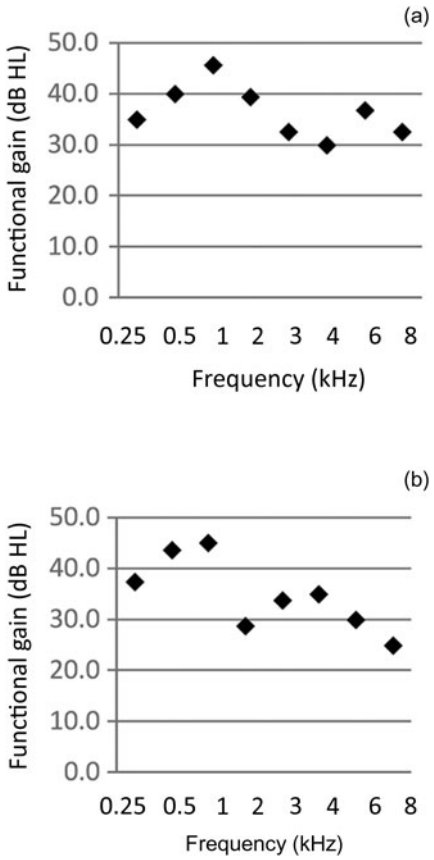


Figure 3. Mean functional gain with (a) stapes coupling and (b) incus coupling.

head, and therefore not accessible for long process coupling. The round window is often hidden by a lateralised facial ridge behind the atresia plate. If short process coupling is anticipated, the floating mass transducer with the appropriate coupler has to fit onto the incus body and malleus complex once they are liberated from the atresia plate, and it also has to fit underneath the tegmen or middle cranial fossa floor. Using this access route, the facial nerve at the outer genu and in the mastoid segment is less of a concern. The proper connection between the malformed incus and the stapes must always be confirmed. In some instances, there is only a fibrous layer with limited sound transmission properties. Even if the CT scan predicts accessible positioning of the short process–floating mass transducer coupling, we suggest having a stapes clip coupler also available in the operating theatre. In cases of limited space between the incus body and the tegmen, a straightforward stapes coupling is considered. In congenital aural atresia patients, the facial nerve within the mastoid must be skeletonised carefully to allow a direct view onto the stapes suprastructure, in order to separate the incus–malleus complex safely from the stapes head, and to clip the stapes clip and floating mass transducer onto the tiny stapes suprastructure. In all our patients, the chorda was either not present or disrupted at surgery while mobilising the malleus complex from the atresia plate. No patient complained of taste disturbance.

In our study population, no patient underwent round window coupling. In our patient cohort, the Jahrsdoerfer score ranged between 8 and 10. Patients with lower scores were not considered as candidates for Vibrant Soundbridge implantation. Patients with a lower score and a distorted anatomy may, however, still benefit from bone-conducting implants. The challenging surgical procedures of canalplasty, meatoplasty and tympanoplasty in these malformations remain an option in highly selected cases. We strongly advise that patients with congenital aural atresia and microtia be sent to a centre with specialised teams working closely together, to provide full rehabilitation regarding form and function.

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Table 3. Subjective questionnaire

Questions	Average score	Scoring range
How severely limited was your hearing ability before treatment?	7.3	1 = not limited at all, 10 = very severely limited
Before treatment, how well were you able to locate the direction from which a sound was coming?	2.3	1 = never able to locate direction, 10 = perfectly able to locate direction
After treatment, how well were you able to locate the direction from which a sound was coming?	8.7	1 = never able to locate direction, 10 = perfectly able to locate direction
After treatment, how satisfied are you with the sound quality on the ear that was affected by congenital aural atresia?	8.3	1 = very bad sound quality, 10 = perfect sound quality
Did the results of the treatment measure up to your expectations?	8.7	1 = treatment did not fulfil expectations, 10 = treatment completely fulfilled expectations
If you could choose again, would you choose the same treatment option?	9.3	1 = definitely not, 10 = definitely yes

Table 4. Vibrant Soundbridge and congenital aural atresia: selected studies with over 10 implanted patients

Study author (year)	Vibrant Soundbridge devices implanted (*n*)	PTA gain* (mean (SD); dB HL)	Effective gain (dB HL)	Speech reception gain
Kiefer *et al.* (2010)[2]	15	31.75[†]	–	–
Roman *et al.* (2012)[16]	12	38.02 (9)	–	WDT50 gain in quiet, in free field = 33.75 dB SPL
Frenzel *et al.* (2015)[15]	19	–	–	Göttinger WRS gain[‡] = 66.6% Freiburger WRS gain** = 70.5% SRT50 (5–9) gain[§] = 13.1 dB HL SRT50 (10–17) gain[#] = 22.7 dB HL
Zhao *et al.* (2020)[17]	16	35.7 (10.3)	–	Mandarin WRS gain (monosyllable), in quiet, 6 months post operation = 36.0%

*For frequencies 0.5, 1, 2 and 4 kHz. [†]A graphic estimate; Kiefer *et al.* reported a functional gain between 20 dB HL and 36 dB HL. [‡]Göttinger word recognition score gain, in children aged five to nine years, comparing after fitting and six months post operation. **Freiburger word recognition score gain, in children aged 10–17 years, comparing after fitting and 6 months post operation. [§]SRT50 (5–9) = sentence recognition thresholds (SRT) (Oldenburg Satztest) in quiet conditions, in children aged five to nine years, at six months post operation. [#]SRT50 (10–17) = Sentence recognition thresholds (Oldenburg Satztest) in quiet conditions, in children aged 10–17 years, at 6 months post operation. PTA = pure tone average; SD = standard deviation; WDT50 = word discrimination thresholds; WRS = word recognition score

Strengths and limitations

All our patients were operated on by one surgeon, which makes the results more comparable. A second strength is the relatively high number of atresia patients for one centre.

- Various implants have recently become available, aimed at overcoming middle-ear hearing difficulties
- These implants provide new options for congenital atresia patients, where malformations prevent seamless acoustic transmission
- Evaluation of different implants has mainly focused on mixed or sensorineural hearing loss patients
- There are few studies on patients with mainly conductive hearing loss as it appears in many congenital middle-ear atresia cases, with none calculating effective gain
- Effective gain is favoured over functional gain in a recent consensus paper on active middle-ear implants, as it can evaluate the implant independently of pre-existing air–bone gap

One major limitation of this study is that we were not able to obtain pre-operative speech audiograms of all, or nearly all, patients. Therefore, gain in speech audiometry could not be calculated. A second limitation of our study is that, even though we provided a relatively large group of atresia patients, the population is still too small to compare subgroups statistically.

Conclusion

The placement of an active middle-ear implant of the Vibrant Soundbridge type allows hearing rehabilitation in selected cases of congenital aural atresia, with a favourable Jahrsdoerfer score, and provides long-term hearing stability in children and adults. A functional gain of approximately 38 dB HL and an effective gain of −17 dB HL can be anticipated. The strength of an implant team lies in the close co-operation between otological and plastic reconstructive surgeons.

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Competing interests. None declared

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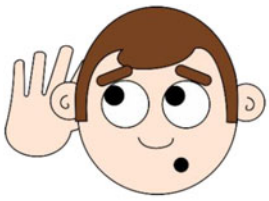
Hearing rehabilitation for Atresia auris congenita with implanted hearing aids

Thank you for supporting us in our research on Atresia auris congenita. Your answers will help to find the best possible therapy for future patients.

Prof. Dr. med. Thomas Linder, Dr. med. Simon Thurnheer, Cand. Med. Tobias Müller

Year of birth:_____

Coding Number: _____



1. Before treatment:

	1 = not restricted at all *10 = very restricted* *1 2 3 4 5 6 7 8 9 10*
How severely impaired were you with hearing in the affected ear before the treatment?	☐☐☐☐☐☐☐☐☐☐

	1 = I always had to guess *10 = was able to locate the direction perfectly* *1 2 3 4 5 6 7 8 9 10*
How well were you able to locate the direction from which a sound is coming before the treatment?	☐☐☐☐☐☐☐☐☐☐

In which situations did you have problems understanding the language before the treatment?	☐ I've never had any problems ☐ A conversation in the quiet living room ☐ A conversation outside in the garden ☐ A conversation in a small group ☐ A conversation in a crowded restaurant



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2. After the treatment:

	1 = not fulfilled at all *10 = totally fulfilled* *1 2 3 4 5 6 7 8 9 10*
Have your expectations regarding the treatment been met?	☐☐☐☐☐☐☐☐☐☐



	1 = poor sound quality 10 = very high sound quality *1 2 3 4 5 6 7 8 9 10*
What is the sound quality in the affected ear after the treatment?	☐☐☐☐☐☐☐☐☐☐

	1 = I always have to guess 10 = I can locate the direction perfectly *1 2 3 4 5 6 7 8 9 10*
After the treatment, how well can you locate the direction from which a sound is coming?	☐☐☐☐☐☐☐☐☐☐



In which situations do you still have problems understanding the language today?	☐ I've never had any problems ☐ A conversation in the quiet living room ☐ A conversation outside in the garden ☐ A conversation in a small group ☐ A conversation in a crowded restaurant

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1 = definitely not 10 = definitely yes

	1	2	3	4	5	6	7	8	9	10
If you could choose again, would you choose the same treatment method again?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

If <5, can you explain why?

_____

_____

_____

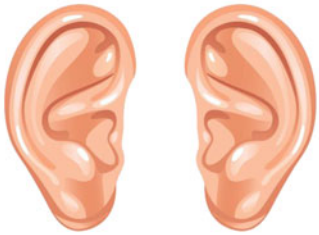
_____

_____

Did you also have a plastic reconstruction of the auricle?

☐ Yes

☐ No



1 = very dissatisfied 10 = very satisfied

	1	2	3	4	5	6	7	8	9	10
If so, how satisfied are you overall with the appearance of the operated auricle today?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Thank you for your cooperation!

Prof. Dr. med. Thomas Linder, Dr. med. Simon Thurnheer, Cand. Med. Tobias Müller

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Appendix 1. Questionnaire assessing hearing rehabilitation for congenital aural atresia with implanted hearing aids

Table 1. Demographics

Case no.	Implanted side	Birth year	Gender	HL type	Aetiology	Malformation type	Malformation severity	VSB Frenzel score	Tegmen–incus distance (mm)	Previous surgical interventions	Revision surgery?	Current otological status after latest ear surgery	AMEI indication criteria fulfilled?	Rational for AMEI therapy
1	Left	1991	Male	CHL	Malformation	Congenital	Jahrsdoerfer score = 8, microtia score = 3	16	6	None	No	Functioning AMEI, no complications	Yes	Hearing rehabilitation
2	Right	2003	Female	CHL	Malformation	Congenital	Jahrsdoerfer score = 9, microtia score = 3	14	4	None	No	Functioning AMEI, no complications	Yes	Hearing rehabilitation
3	Right	2008	Male	CHL	Malformation	Congenital	Jahrsdoerfer score = 9, microtia score = 3	12	4	None	No	Functioning AMEI, no complications	Yes	Hearing rehabilitation
4	Right	2012	Female	MHL	Malformation	Congenital	Jahrsdoerfer score = 9, microtia score = 3	11	3	None	No	Functioning AMEI, no complications	Yes	Hearing rehabilitation
5	Right	2011	Male	CHL	Unknown	Congenital	Jahrsdoerfer score = 10, microtia score = 1	15	5	None	No	Functioning AMEI, no complications	Yes	Hearing rehabilitation
6	Left	1981	Female	CHL	Malformation	Congenital	Jahrsdoerfer score = 9, microtia score = 2	nd	2	None	No	Functioning AMEI, no complications	Yes	Hearing rehabilitation
7a	Left	2010	Male	CHL	Unknown	Congenital	Jahrsdoerfer score = 10, microtia score = 1	12	2	Yes	No	Functioning AMEI, no complications	Yes	Hearing rehabilitation
7b	Right	2010	Male	CHL	Malformation	Congenital	Jahrsdoerfer score = 9, microtia score = 1	11	2	None	No	Functioning AMEI, no complications	Yes	Hearing rehabilitation
8a	Left	1995	Male	CHL	Malformation	Congenital	Jahrsdoerfer score = 9, microtia score = 3	14	5	None	No	Functioning AMEI, no complications	Yes	Hearing rehabilitation
8b	Right	1995	Male	CHL	Malformation	Congenital	Jahrsdoerfer score = 9, microtia score = 1	11	4	None	No	Functioning AMEI, no complications	Yes	Hearing rehabilitation
9	Right	1990	Male	CHL	Malformation	Congenital	Jahrsdoerfer score = 9, microtia score = 2	nd	nd	None	No	Functioning AMEI, no complications	Yes	Hearing rehabilitation
10	Right	2005	Male	CHL	Malformation	Congenital	Jahrsdoerfer score = 9, microtia score = 3	nd	nd	None	No	Functioning AMEI, no complications	Yes	Hearing rehabilitation

HL = hearing loss; VSB = Vibrant Soundbridge; AMEI = active middle-ear implant; CHL = conductive hearing loss; MHL = mixed hearing loss; nd = no data

Table 2. Surgical data

Case no.	Operation date	Age at operation (calculated) (years)	Side implanted	AMEI type implanted	Coupling technique*	Coupling element
1	28/08/2015	24	Left	Soundbridge VORP 503	CliP Coupler	Stapes
2	28/05/2019	16	Right	Soundbridge VORP 503	SP Coupler	Incus short process
3	29/11/2017	9	Right	Soundbridge VORP 503	SP Coupler	Incus short process
4	17/04/2019	7	Right	Soundbridge VORP 503	CliP Coupler	Stapes
5	07/10/2020	9	Right	Soundbridge VORP 503	SP Coupler	Incus short process
6	01/09/2020	39	Left	Soundbridge VORP 503	CliP Coupler	Stapes
7a	22/02/2015	5	Left	Soundbridge VORP 503	CliP Coupler	Stapes
7b	01/05/2017	7	Right	Soundbridge VORP 503	CliP Coupler	Stapes
8a	21/11/2008	13	Left	Soundbridge VORP 502	CliP Coupler	Stapes
8b	18/12/2012	17	Right	Soundbridge VORP 503	CliP Coupler	Stapes
9	14/07/2021	31	Right	Soundbridge VORP 503	CliP Coupler	Stapes
10	23/04/2021	16	Right	Soundbridge VORP 503	CliP Coupler	Stapes

*'CliP' refers to a vibroplasty standard clip coupler for the stapes head; 'SP' refers to a short process incus coupler. Case no. = case number; AMEI = active middle-ear implant; VORP = vibrating ossicular prosthesis

Appendix 2. Further data to meet reporting standard of consensus paper

Table 3. Complications

Case number	Peri-operative complications	Post-operative complications (up to 12 months post operation)	Post-operative complications (12+ months post operation)
1	None	Patient reports that implant reacts with noise to electromagnetic waves (e.g. in shopping precincts)	None
2	None	Patient reports that implant is too loud	Control MRI had to be aborted because patient heard popping noises (like popcorn) in ear at the start of MRI. The subsequent audiometry was unchanged
3	None	None	None
4	None	None	None
5	None	None	None
6	None	None	None
7a	None	None	None
7b	None	None	None
8a	None	None	Sound processor had to be replaced after 7 years because of detrition
8b	None	None	None
9	None	None	None
10	None	Pain at root of musculus temporalis 10 months post-operatively	None

MRI = magnetic resonance imaging

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Table 4. General audiometric data

Parameter 1	Parameter 2	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 7	Pt 8	Pt 8	Pt 9	Pt 10
Pre-operative air conduction thresholds (unaided, masked)	Ear number	Ear 1	Ear 2	Ear 3	Ear 4	Ear 5	Ear 6	Ear 7	Ear 8	Ear 9	Ear 10	Ear 11	Ear 12
	Side	Left	Right	Right	Right	Right	Left	Left	Right	Left	Right	Right	Right
	Coupling	Stapes	Incus	Incus	Stapes	Incus	Stapes	Stapes	Stapes	Stapes	Stapes	Stapes	Incus
	Frequency (kHz)												
	– 0.25	70.0	90.0	60.0	90.0	70.0	95.0	55.0	65.0	75.0	55.0	70.0	80.0
	– 0.5	60.0	80.0	60.0	85.0	75.0	85.0	55.0	60.0	70.0	60.0	75.0	75.0
	– 1	60.0	80.0	55.0	85.0	65.0	70.0	55.0	60.0	80.0	65.0	75.0	70.0
	– 2	50.0	50.0	55.0	70.0	65.0	75.0	60.0	55.0	75.0	60.0	65.0	50.0
	– 3	55.0	60.0	70.0	80.0	65.0	65.0	55.0	55.0	75.0	50.0	70.0	55.0
	– 4	55.0	60.0	70.0	60.0	65.0	70.0	50.0	65.0	65.0	55.0	80.0	50.0
	– 6	65.0	55.0	65.0	65.0	65.0	80.0	50.0	60.0	80.0	70.0	55.0	55.0
	– 8	65.0	50.0	60.0	70.0	65.0	80.0	50.0	70.0	70.0	50.0	65.0	75.0
Mean per ear	All frequencies	60.0	65.6	61.9	75.6	66.9	77.5	53.8	61.3	73.8	58.1	69.4	63.8
Air conduction	0.5, 1 & 2	56.7	70.0	56.7	80.0	68.3	76.7	56.7	58.3	75.0	61.7	71.7	65.0
PTA	0.5, 1, 2 & 4	56.3	67.5	60.0	75.0	67.5	75.0	55.0	60.0	72.5	60.0	73.8	61.3
Post-operative soundfield thresholds (aided, masked)	Ear number	Ear 1	Ear 2	Ear 3	Ear 4	Ear 5	Ear 6	Ear 7	Ear 8	Ear 9	Ear 10	Ear 11	Ear 12
	Side	Left	Right	Right	Right	Right	Left	Left	Right	Left	Right	Right	Right
	Frequency (kHz)												
	– 0.25	25.0	45.0	25.0	60.0	30.0	35.0	25.0	25.0	40.0	35.0	50.0	50.0
	– 0.5	20.0	30.0	20.0	40.0	25.0	35.0	15.0	25.0	30.0	25.0	40.0	40.0
	– 1	25.0	25.0	25.0	35.0	20.0	25.0	15.0	20.0	25.0	20.0	20.0	20.0
	– 2	30.0	30.0	25.0	30.0	25.0	25.0	20.0	25.0	30.0	15.0	20.0	25.0
	– 3	35.0	35.0	25.0	35.0	25.0	30.0	20.0	25.0	35.0	25.0	40.0	30.0
	– 4	40.0	30.0	30.0	40.0	20.0	30.0	35.0	25.0	30.0	30.0	30.0	25.0
	– 6	45.0	40.0	30.0	25.0	25.0	25.0	50.0	25.0	25.0	20.0	15.0	25.0
	– 8	35.0	40.0	30.0	35.0	25.0	35.0	50.0	25.0	30.0	25.0	25.0	55.0
Mean per ear	All frequencies	31.9	34.4	26.3	37.5	24.4	30.0	28.8	24.4	30.6	24.4	30.0	33.8
Air conduction	0.5, 1 & 2	25.0	28.3	23.3	35.0	23.3	28.3	16.7	23.3	28.3	20.0	26.7	28.3
PTA	0.5, 1, 2 & 4	28.8	28.8	25.0	36.3	22.5	28.8	21.3	23.8	28.8	22.5	27.5	27.5

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Functional gain	Ear number	Ear 1	Ear 2	Ear 3	Ear 4	Ear 5	Ear 6	Ear 7	Ear 8	Ear 9	Ear 10	Ear 11	Ear 12
	Side	Left	Right	Right	Right	Right	Left	Left	Right	Left	Right	Right	Right
	Frequency (kHz)												
	– 0.25	45.0	45.0	35.0	30.0	40.0	60.0	30.0	40.0	35.0	20.0	20.0	30.0
	– 0.5	40.0	50.0	40.0	45.0	50.0	50.0	40.0	35.0	40.0	35.0	35.0	35.0
	– 1	35.0	55.0	30.0	50.0	45.0	45.0	40.0	40.0	55.0	45.0	55.0	50.0
	– 2	20.0	20.0	30.0	40.0	40.0	50.0	40.0	30.0	45.0	45.0	45.0	25.0
	– 3	20.0	25.0	45.0	45.0	40.0	35.0	35.0	30.0	40.0	25.0	30.0	25.0
	– 4	15.0	30.0	40.0	20.0	45.0	40.0	15.0	40.0	35.0	25.0	50.0	25.0
	– 6	20.0	15.0	35.0	40.0	40.0	55.0	0.0	35.0	55.0	50.0	40.0	30.0
	– 8	30.0	10.0	30.0	35.0	40.0	45.0	0.0	45.0	40.0	25.0	40.0	20.0
Pre-operative bone conduction thresholds (masked)	Ear number	Ear 1	Ear 2	Ear 3	Ear 4	Ear 5	Ear 6	Ear 7	Ear 8	Ear 9	Ear 10	Ear 11	Ear 12
	Side	Left	Right	Right	Right	Right	Left	Left	Right	Left	Right	Right	Right
	Frequency (kHz)												
	– 0.25	0.0	5.0				0.0			0.0	0.0		
	– 0.5	0.0	5.0	0.0	20.0	10.0	15.0	0.0	0.0	5.0	5.0	5.0	10.0
	– 1	0.0	5.0	0.0	25.0	10.0	10.0	0.0	0.0	20.0	20.0	5.0	0.0
	– 2	15.0	15.0	0.0	35.0	10.0	20.0	5.0	0.0	15.0	15.0	10.0	10.0
	– 3	15.0	15.0	15.0	35.0	10.0	15.0	10.0	0.0	15.0	10.0	10.0	0.0
	– 4	15.0	5.0	15.0	15.0	10.0	5.0	5.0	0.0	10.0	5.0	15.0	5.0
Effective gain	Ear number	Ear 1	Ear 2	Ear 3	Ear 4	Ear 5	Ear 6	Ear 7	Ear 8	Ear 9	Ear 10	Ear 11	Ear 12
	Side	Left	Right	Right	Right	Right	Left	Left	Right	Left	Right	Right	Right
	Frequency (kHz)												
	– 0.5	−20.0	−25.0	−20.0	−20.0	−15.0	−20.0	−15.0	−25.0	−25.0	−20.0	−35.0	−30.0
	– 1	−25.0	−20.0	−25.0	−10.0	−10.0	−15.0	−15.0	−20.0	−5.0	0.0	−15.0	−20.0
	– 2	−15.0	−15.0	−25.0	5.0	−15.0	−5.0	−15.0	−25.0	−15.0	0.0	−10.0	−15.0
	– 3	−20.0	−20.0	−10.0	0.0	−15.0	−15.0	−10.0	−25.0	−20.0	−15.0	−30.0	−30.0
	– 4	−25.0	−25.0	−15.0	−25.0	−10.0	−25.0	−30.0	−25.0	−20.0	−25.0	−15.0	−20.0

Data shown in dB HL. Pt = patient number; PTA = pure tone average

Table 5. Pre-operative air conduction threshold data for stapes

Parameter	Frequency (kHz)	Ear 1 (pt 1, L)	Ear 4 (pt 4, R)	Ear 6 (pt 6, R)	Ear 7 (pt 7, L)	Ear 8 (pt 7, R)	Ear 9 (pt 8, L)	Ear 10 (pt 8, R)	Ear 11 (pt 9, R)
Air conduction thresholds*	0.25	70.0	90.0	95.0	55.0	65.0	75.0	55.0	70.0
	0.5	60.0	85.0	85.0	55.0	60.0	70.0	60.0	75.0
	1	60.0	85.0	70.0	55.0	60.0	80.0	65.0	75.0
	2	50.0	70.0	75.0	60.0	55.0	75.0	60.0	65.0
	3	55.0	80.0	65.0	55.0	55.0	75.0	50.0	70.0
	4	55.0	60.0	70.0	50.0	65.0	65.0	55.0	80.0
	6	65.0	65.0	80.0	50.0	60.0	80.0	70.0	55.0
	8	65.0	70.0	80.0	50.0	70.0	70.0	50.0	65.0
Average	All frequencies	60.0	75.6	77.5	53.8	61.3	73.8	58.1	69.4
Air conduction	0.5, 1 & 2	56.7	80.0	76.7	56.7	58.3	75.0	61.7	71.7
PTA	0.5, 1, 2 & 4	56.3	75.0	75.0	55.0	60.0	72.5	60.0	73.8

Data shown in dB HL. *Unaided, masked thresholds. Pt = patient number; L = left; R = right; PTA = pure tone average

Table 6. Post-operative soundfield threshold data for stapes

Parameter	Frequency (kHz)	Ear 1 (pt 1)	Ear 4 (pt 4)	Ear 6 (pt 6)	Ear 7 (pt 7, L)	Ear 8 (pt 7, R)	Ear 9 (pt 8, L)	Ear 10 (pt 8, R)	Ear 11 (pt 9)
Soundfield thresholds*	0.25	25.0	60.0	35.0	25.0	25.0	40.0	35.0	50.0
	0.5	20.0	40.0	35.0	15.0	25.0	30.0	25.0	40.0
	1	25.0	35.0	25.0	15.0	20.0	25.0	20.0	20.0
	2	30.0	30.0	25.0	20.0	25.0	30.0	15.0	20.0
	3	35.0	35.0	30.0	20.0	25.0	35.0	25.0	40.0
	4	40.0	40.0	30.0	35.0	25.0	30.0	30.0	30.0
	6	45.0	25.0	25.0	50.0	25.0	25.0	20.0	15.0
	8	35.0	35.0	35.0	50.0	25.0	30.0	25.0	25.0
Average	All frequencies	31.9	37.5	30.0	28.8	24.4	30.6	24.4	30.0
Air conduction	0.5, 1 & 2	25.0	35.0	28.3	16.7	23.3	28.3	20.0	26.7
PTA	0.5, 1, 2 & 4	28.8	36.3	28.8	21.3	23.8	28.8	22.5	27.5
Gain (min/max)	0.25	45.0	30.0	60.0	30.0	40.0	35.0	20.0	20.0
	0.5	40.0	45.0	50.0	40.0	35.0	40.0	35.0	35.0
	1	35.0	50.0	45.0	40.0	40.0	55.0	45.0	55.0
	2	20.0	40.0	50.0	40.0	30.0	45.0	45.0	45.0
	3	20.0	45.0	35.0	35.0	30.0	40.0	25.0	30.0
	4	15.0	20.0	40.0	15.0	40.0	35.0	25.0	50.0
	6	20.0	40.0	55.0	0.0	35.0	55.0	50.0	40.0
	8	30.0	35.0	45.0	0.0	45.0	40.0	25.0	40.0

Data shown in dB HL. *Aided, masked thresholds. Pt = patient number; L = left; R = right; PTA = pure tone average; min = minimum; max = maximum

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Table 7. Pre-operative air conduction threshold data for incus

Parameter	Frequency (kHz)	Ear 2 (pt 2)	Ear 3 (pt 3)	Ear 5 (pt 5)	Ear 12 (pt 10)
Air conduction thresholds*	0.25	90.0	60.0	70.0	80.0
	0.5	80.0	60.0	75.0	75.0
	1	80.0	55.0	65.0	70.0
	2	50.0	55.0	65.0	50.0
	3	60.0	70.0	65.0	55.0
	4	60.0	70.0	65.0	50.0
	6	55.0	65.0	65.0	55.0
	8	50.0	60.0	65.0	75.0
Average	All frequencies	65.6	61.9	66.9	63.8
Air conduction	0.5, 1 & 2	70.0	56.7	68.3	65.0
PTA	0.5, 1, 2 & 4	67.5	60.0	67.5	61.3

Data shown in dB HL. *Unaided, masked thresholds. Pt = patient number; PTA = pure tone average

Table 8. Post-operative soundfield threshold data for incus

Parameter	Frequency (kHz)	Ear 2 (pt 2)	Ear 3 (pt 3)	Ear 5 (pt 5)	Ear 12 (pt 10)
Soundfield thresholds*	0.25	45.0	25.0	30.0	50.0
	0.5	30.0	20.0	25.0	40.0
	1	25.0	25.0	20.0	20.0
	2	30.0	25.0	25.0	25.0
	3	35.0	25.0	25.0	30.0
	4	30.0	30.0	20.0	25.0
	6	40.0	30.0	25.0	25.0
	8	40.0	30.0	25.0	55.0
Average	All frequencies	34.4	26.3	24.4	33.8
Air conduction	0.5, 1 & 2	28.3	23.3	23.3	28.3
PTA	0.5, 1, 2 & 4	28.8	25.0	22.5	27.5
Gain (min/max)	0.25	45.0	35.0	40.0	30.0
	0.5	50.0	40.0	50.0	35.0
	1	55.0	30.0	45.0	50.0
	2	20.0	30.0	40.0	25.0
	3	25.0	45.0	40.0	25.0
	4	30.0	40.0	45.0	25.0
	6	15.0	35.0	40.0	30.0
	8	10.0	30.0	40.0	20.0

Data shown in dB HL. *Aided, masked thresholds. Pt = patient number; PTA = pure tone average; min = minimum; max = maximum

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