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Bone and Cartilage Conduction

Volume II

Edited by
Tadashi Nishimura and Takanori Nishiyama

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Guest Editors

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Contents

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Editorial

Bone and Cartilage Conduction—Volume II

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Air conduction is the primary pathway for hearing sounds and is widely utilized in various hearing devices. In contrast, other forms of sound conduction—such as bone and cartilage conduction—have not been as commonly applied. However, recent advancements in device development have expanded the applications of these alternative conduction methods across various fields.

In the previous Special Issue on "Bone and Cartilage Conduction", numerous basic and clinical studies on bone and cartilage conduction were published [1,2], reaffirming the growing interest among researchers in this area. To further explore the potential and promote the application of both bone and cartilage conduction, this Special Issue similarly addresses the mechanisms and practical uses of these methods.

Since 2017, a new hearing device utilizing cartilage conduction has been developed and released in Japan. It has gained rapid popularity and is now recognized as a major type of hearing device. Reflecting this trend, most of the contributions in this issue focus on cartilage conduction and hearing aids, with studies reported from various institutions in Japan. We believe that this content will attract considerable interest among researchers—not only in Japan, where such devices are already available, but also in countries where cartilage conduction hearing aids have yet to be introduced. We hope this issue will contribute to a deeper understanding of the field and encourage further international research and development.

This issue includes one review concerning cartilage conduction hearing aids (contribution 1), five research articles (contributions 2–6), one brief report (contribution 7), and one case report (contribution 8). All the research articles focus on cartilage conduction: two of them present basic research, and the other three studies address clinical applications of cartilage conduction hearing aids that are currently in use. The basic research papers report on the (contribution 2), and on studies of sound transmission pathways (contribution 3). The remaining three research articles and the brief report examine cartilage conduction hearing aids, discussing suitable candidates and the effectiveness of the devices (contributions 4–7). The case report explores the effects of using a bone conduction hearing aid as a vibratory stimulus (contribution 8). This study is of particular interest, demonstrating how sensory substitution can deliver sound to patients for whom cochlear implants are not feasible.

This scientific collection is expected to be of interest to a range of professionals, including audiologists, otolaryngologists, physiologists, and acoustic engineers.

Conflicts of Interest: The authors declare no conflicts of interest.

List of Contributions:

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2. Shimokura, R.; Nishimura, T.; Hosoi, H. Cartilage Conduction Sounds in Cases of Wearing Different Transducers on a Head and Torso Simulator with a Manipulated Ear Pinna Simulator. *Audiol. Res.* **2023**, *13*, 898–909. https://doi.org/10.3390/audiolres13060078.
3. Yazama, H.; Arii, S.; Kataoka, H.; Watanabe, T.; Kamitani, R.; Fujiwara, K. In Vivo Measurement of Ear Ossicle and Bony Wall Vibration by Sound Stimulation of Cartilage Conduction. *Audiol. Res.* **2023**, *13*, 495–505. https://doi.org/10.3390/audiolres13040044.
4. Yakawa, S.; Sugiuchi, T.; Myojin, R.; Sato, K.; Murakami, T.; Miyoshi, Y.; Sugio, Y. Management of Cartilage Conduction Hearing Aids in Pediatric Patients. *Audiol. Res.* **2023**, *13*, 871–888. https://doi.org/10.3390/audiolres13060076.
5. Sugimoto, S.; Yoshida, T.; Fukunaga, Y.; Motegi, A.; Saito, K.; Kobayashi, M.; Sone, M. Comparative Analysis of Cartilage Conduction Hearing Aid Users and Non-Users: An Investigative Study. *Audiol. Res.* **2023**, *13*, 563–572. https://doi.org/10.3390/audiolres13040049.
6. Kakuki, T.; Miyata, R.; Yoshida, Y.; Kaizaki, A.; Kimura, A.; Kurashima, K.; Kuwata, R.; Takano, K. The Effects of Utilizing Cartilage Conduction Hearing Aids among Patients with Conductive Hearing Loss. *Audiol. Res.* **2023**, *13*, 408–417. https://doi.org/10.3390/audiolres13030036.
7. Takai, S.; Sato, T.; Miyakura, Y.; Adachi, M.; Honkura, Y.; Yamauchi, D.; Katori, Y. Examination of Factors Affecting the Likelihood of Whether Individuals Would Purchase Cartilage Conduction Hearing Aids. *Audiol. Res.* **2023**, *13*, 347–356. https://doi.org/10.3390/audiolres13030030.
8. Kompis, M.; Langmair, M.; Mantokoudis, G.; Weder, S.; Gawliczek, T.; Caversaccio, M.D. Using a Bone Conduction Hearing Device as a Tactile Aid. *Audiol. Res*. **2023**, *13*, 459–465. https://doi.org/10.3390/audiolres13030040.

References

1. Nishimura, T. Bone and Cartilage Conduction. *Audiol. Res.* **2022**, *12*, 77–78. [CrossRef] [PubMed]
2. Nishimura, T. (Ed.) *Bone and Cartilage Conduction*; MDPI: Basel, Switzerland, 2025; ISBN 978-3-7258-3826-4.

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Review

Cartilage Conduction Hearing Aids in Clinical Practice

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Abstract: A relatively loud sound is audible when a vibrator is attached to the aural cartilage. This form of conduction is referred to as cartilage conduction (CC). In Japan, a new type of hearing aid has been developed using CC and has been available in clinical practice since 2017. A clinical study conducted prior to its launch demonstrated its benefits, particularly in patients with aural atresia who were unable to use air conduction hearing aids. Several studies have been published on the benefits of CC hearing aids since their introduction into clinical practice. Most of the patients included in these studies had canal stenosis or aural atresia, and the purchase rates of CC hearing aids in these patients were relatively high. However, the number of patients with canal-open ears was small, with overall poor results in the trials, with the exception of patients with continuous otorrhea. CC hearing aids are considered a good option for compensating for hearing loss in ears with canal stenosis or atresia in both bilateral and unilateral cases. However, CC hearing aids are not currently considered the first choice for patients with a canal-open ear.

Keywords: bone conduction; cartilage conduction; hearing device; amplification; aural atresia; canal stenosis; conductive hearing loss; chronic otitis media

1. Introduction

Sound is generally delivered to the ear via air conduction (AC) in conventional hearing aids. AC hearing aids amplify signals to help patients with various hearing losses. Unfortunately, some patients are unable to receive adequate benefits from AC hearing aids. For instance, in patients with aural atresia, hearing aids cannot be worn owing to anatomical issues or they receive inadequate benefits even if they can be worn [1]. In addition, continuous otorrhea prevents the use of hearing aids because they can prolong the inflammation, damage hearing aids, and obstruct the bore, thereby deteriorating the signal [2]. Bone conduction (BC) hearing aids have been considered as an alternative. In conventional BC hearing aids, a vibrator with static force is placed on the mastoid using a headband. BC hearing aids are effective in amplifying sound in the above-mentioned cases because sound is transmitted via BC [3–5]. In contrast, the fixed form of BC causes various problems, such as skin induration, long-continued depressions in the skin, and discomfort [3,4]. Furthermore, fixation with a headband is considered an esthetic disadvantage. Therefore, BC hearing aids are not preferred in patients who can use AC hearing aids without serious complications, and are rarely used in patients with unilateral aural atresia.

When a vibrator is attached to the aural cartilage, hearing is significantly improved compared with that in the unattached condition. This phenomenon was confirmed by using a probe microphone [6]. Previous studies have demonstrated this improvement to be significant, particularly at low to middle frequencies [6–9]. This unique form of transmission is called cartilage conduction (CC) [10]. Figure 1A shows the predominant pathways theoretically assumed in CC [11,12]. The first pathway is direct AC. The vibrator radiates sound around it, which cannot be completely eliminated. This airborne sound travels through the ear canal to drive the eardrum and the ossicles. This pathway is considered an AC pathway. The second pathway is the cartilage–BC. Vibrations are delivered to the skull bone via the aural cartilage, and the vibrations of the skull bone are transmitted to the cochlea in the same manner as in BC. Mediation by the aural cartilage could deteriorate these signals. This pathway is considered the BC pathway. The third pathway is the cartilage–AC. The delivered vibrations of the cartilaginous portion of the ear canal generate airborne sounds in the ear canal. The cartilaginous portion of the ear canal functions as a movable plate during this process [13]. This third pathway is not the predominant signaling route in either AC or BC. However, the airborne sound level in the cartilage AC is considered to be larger than that in direct AC in CC. The differences in the elevations of the thresholds with the insertion of an earplug and the injection of water into the ear canal demonstrated a significant cartilage AC function [11,12,14,15]. Previous studies have concluded that CC varies in the transduction method from AC and BC.

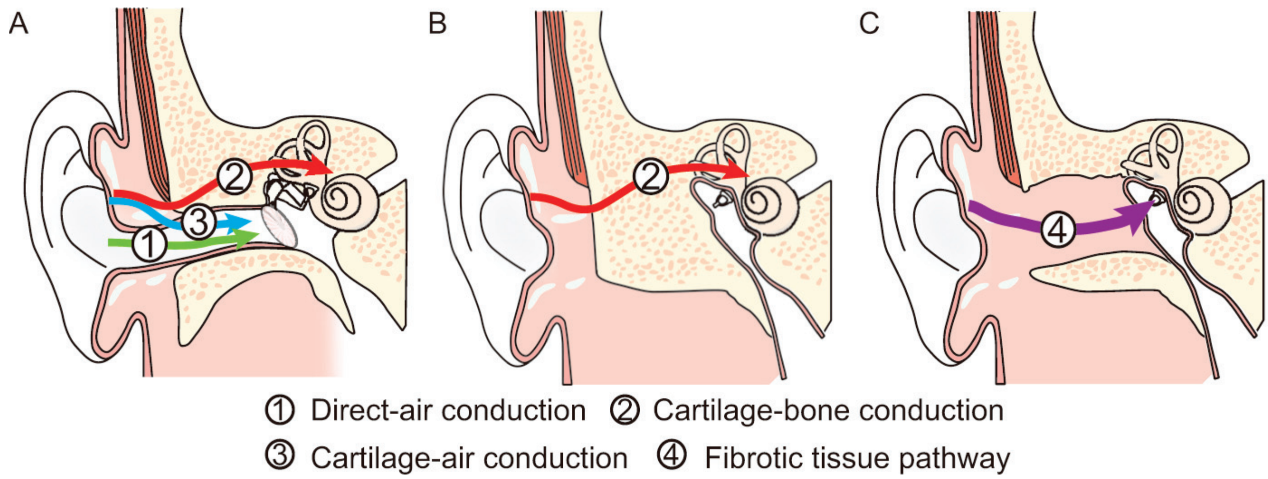

Figure 1. Difference in signal transmission in the normal ear (**A**), a bony atretic ear (**B**), and a fibrotic atretic ear with a fibrotic tissue pathway (FTP) (**C**).

2. Development of CC Hearing Aids

CC hearing aids are new hearing devices utilizing CC [16–18]. CC hearing aids were first developed in 2010 [16]. The characteristics of CC hearing aids are more similar to those of AC hearing aids than BC hearing aids because sound is finally transmitted to the cochlea via the eardrum and ossicles. In contrast to AC hearing aids, CC hearing aids deliver sounds to the aural cartilage as vibrations. In patients with aural atresia, skull vibrations are required to transmit sounds to the cochlea using any hearing device. Sound deterioration in CC is considerably lower than that in AC because it avoids the boundary between the air and the body during sound transmission. The vibrator of a CC hearing aid is placed on the aural cartilage without contact force, which is different from that of BC hearing aids. To fix it, the vibrator is inserted into the cavity or attached with double-sided tape. This fixation style can resolve the problems experienced in BC hearing aid use. In patients with continuous otorrhea, ear canal opening contributes to the continuous use of hearing devices. The vibrator of the CC hearing aid can be placed to keep the ear canal open, thereby contributing to ventilation; moreover, it is completely waterproof, which reduces the risk of damage to the vibrator. The audiological benefits of the prototype CC hearing aids were evaluated in a previous study to demonstrate their benefits, particularly in patients with aural atresia [19].

The initial prototype CC hearing aid was a box type, and the transducer was not compact [16,17]. Furthermore, a piezoelectric transducer was employed, which required a high-voltage battery for proper function. Therefore, using this prototype in clinical practice is challenging. A new electromagnetic transducer was developed as a CC hearing aid for clinical practice. It functions using the same battery used in commercially available AC hearing aids. This new transducer contributed to the miniaturization and production of a behind the ear (BTE)-style hearing aid. A clinical study was performed using the devised BTE CC hearing aids, mainly in patients with aural atresia [19]. Forty-one patients (21, 15, and 5 with bilateral aural atresia, unilateral aural atresia, and other conductive hearing loss, respectively) participated in the study. Most patients with bilateral aural atresia had used BC hearing aids before the trial. No significant differences were observed in the aided thresholds and speech recognition between the CC and BC hearing aids. After the trial, 20 patients with bilateral aural atresia continued to use the CC hearing aids. Nearly none of the patients with unilateral aural atresia used any hearing device. The functional gains obtained using the CC hearing aid were similar to those observed in patients with bilateral aural atresia. After the trial, 14 patients continued to use the CC hearing aids. A clinical study has demonstrated the effectiveness of CC hearing aids [19]; moreover, CC hearing aids were approved as new medical devices by the Ministry of Health, Labor, and Welfare in Japan and have been used in clinical practice in Japan since 2017.

3. Performance of CC Hearing Aids

Commercially available CC hearing aids are small BTE hearing aids, which were developed based on those used in clinical studies. The main body was designed based on that used in commercially available receiver-in-canal (RIC)-style AC hearing aids. The vibrator is connected to the main body with a wire that encapsulates the electrode within. Three types of vibrator units (ear-chip embedded, ear-chip attachment, and simple) are employed (Figure 2). The size and mass of the assembled transducer are $11.9 \times 7.8 \times 4.7$ mm and 1.4 g, respectively. This type was chosen based on the ear condition. The ear chips are custom fitted, made based on ear impressions. Instead of taking an impression of the ear, computed tomography (CT) images can also be utilized for designing the vibrator [20]. Compared to the conventional process, the merits of the design using CT images are as follows: no risks related to taking the ear impression, advantage of understanding the shape of the ear in 3D, no physical transport or shipment of an ear impression, and CT images can be sent instantly via the internet. Therefore, CC hearing aids can be created without visiting the hospital. If a CT scan is performed for diagnosis or other purposes, the images can be used without additional risk. A previous study reported that the performance of a CT-based vibrator is not significantly inferior to that of an impression-based vibrator [20]. In contrast, the simple type is available for all ear conditions and can be prepared in advance; patients can try it quickly and unnecessary ear chip costs are also reduced. However, the simple type requires double-sided tape for fixation. Among the three types, the custom-fitted type is recommended for improved stability when the cavity of the fixation placement is sufficient to hold the transducer. A previous study [21] that investigated the differences in the purchase rates demonstrated a decreased purchase rate particularly in canal-open ears when a simple vibrator was used for the trial of the CC hearing aid.

Two CC hearing aid (HB-J1CC and HB-A2CC; Rion Co Ltd., Kokubunji, Japan) models are commercially available (Figure 2). The transducers used in the vibrator are identical. The functions of the two devices vary slightly. HB-A2CC is a later model that has been modified to reflect the feedback obtained from HB-J1CC users. Both devices were adjusted using fitting software. The gains, compression rates, and maximum output levels can be controlled. Linear amplification is utilized in patients with conduction hearing loss, such as those with aural atresia. The fitting software depicts the frequency responses on the screen; however, these simulated gains are not always equal to the actual values. Therefore, the real gains must be confirmed by measuring the unaided and aided thresholds. Both devices can manage feedback problems and directional modes. While only one program can be memorized for HB-J1CC, three programs can be used to switch memories for HB-A2CC.

Furthermore, HB-A2CC can be connected via Bluetooth with an Android smartphone using an application and equipped with a child safety lock for the battery locker.

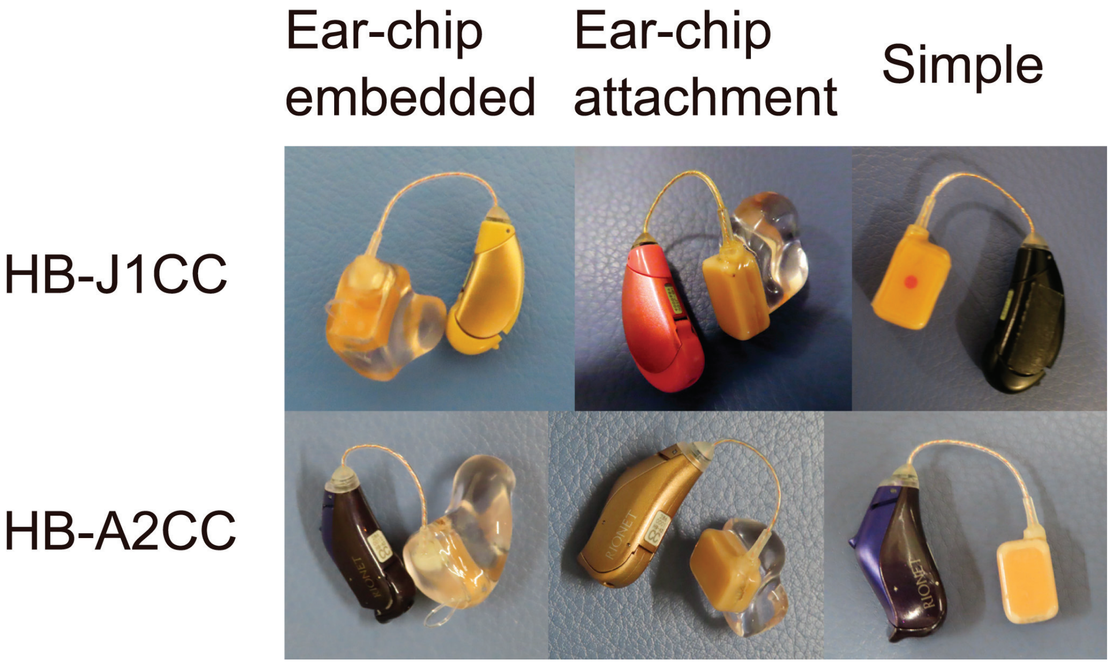

Figure 2. Two models of cartilage conduction hearing aids used in clinical practice: HB-J1CC (**upper**) and HB-A2CC (**lower**). Both models have three transducer types: ear-chip embedded (**left**), ear-chip attachment (**middle**), and simple vibrator (**right**).

4. Benefits of CC Hearing Aids

CC hearing aids were newly devised and first launched in Japan in 2017. To date, no clinical data are available concerning CC. To determine the indications, a clinical survey was conducted in 2019. Nine medical institutions participated in the study, and 256 patients were registered [22]. In total, 113 and 143 patients had bilateral and unilateral hearing loss, respectively. Considering the previous results, CC hearing aids appear promising in patients with aural atresia. A total of 65 patients had bilaterally closed ears (aural atresia or severe stenosis), and 56 (86%) purchased CC hearing aids after fitting. This high purchase rate is consistent with the results of a previous clinical trial [22]. In addition to the atretic ear, it is also difficult to use AC hearing aids in patients with continuous otorrhea. Of nine patients with bilateral chronic continuous otorrhea, seven (78%) purchased CC hearing aids after fitting. The purchase rate was comparable to that of patients with bilaterally closed ears. In contrast, 27 patients with bilateral canal-open ears who could use AC hearing aids without difficulty tried CC hearing aids, and 10 patients (37%) purchased them after fitting. In the unilateral cases, 124 and 13 patients had closed and canal-open ears, respectively. After fitting, 97 patients (78%) with a unilateral closed ear purchased CC hearing aids, while 7 patients (54%) with a unilateral canal-open ear purchased them. The purchase rate for bilateral canal-open ear cases was significantly lower than those for bilateral and unilateral closed ear cases. Furthermore, seven patients with unilateral profound deafness tried CC hearing aids in their dead ear. They anticipated the effectiveness of the transcranial contralateral routing of signal (CROS) hearing aid to be similar to that of the bone anchored hearing aid (BAHA) for single-side deafness [5,23]. After the trial, four patients (57%) purchased hearing aids, indicating a significant benefit of CROS hearing aids in some patients. Thus, the clinical survey suggested that CC hearing aids are a good option not only for patients with closed ears, but also for those who have difficulties with the use of AC hearing aids.

In addition to the abovementioned clinical surveys, several medical institutions have reported the results of CC hearing aid fittings. Sakamoto et al. evaluated the benefits of CC hearing aids in children with unilateral congenital atretic ears and reported that the speech recognition scores improved in noisy environments as well as with the FM system [24]. The authors recommended FM systems and CC hearing aids for audiological management to improve speech recognition in children with unilateral aural atresia in classrooms. Akasaka et al. evaluated the benefits of CC hearing aids for speech perception in patients with unilateral aural atresia [25]. Speech recognition scores at low speech levels significantly improved in the aided atretic ear condition. They demonstrated that CC hearing aids in the unilateral atretic ear provided a diotic summation effect, which is considered a binaural hearing benefit.

Nishiyama et al. assessed the efficacy of CC hearing aids in adult patients with hearing loss and with various anatomical ear canal conditions to identify suitable candidates for CC hearing aids [26]. They categorized patients into three groups based on the anatomy of the ear canal: canal stenosis (or aural atresia), abnormal canal, and normal canal. Over 70% of the participants with canal stenosis purchased CC hearing aids, regardless of their AC hearing thresholds. In contrast, in the abnormal canal group, the purchase rates significantly depended on the AC hearing thresholds. The purchase rate of participants with mild hearing loss was higher than that of participants with severe hearing loss (85.71% vs. 20%). They concluded that patients with ear canal stenosis or atretic ears were the best candidates regardless of their hearing thresholds. Furthermore, they also reported the results of CC hearing aid fitting in children [27]. They fitted CC hearing aids in 48 ears of 42 patients. Forty of them were patients with canal stenosis and atresia. Overall, 72.92% of the participants made purchases after the trial. Additional tape compression was applied over the vibrator and the hearing improvement and adverse effects were assessed. An improvement in gains at low frequencies was observed; moreover, application of the additional compression tape resulted in no side effects. The authors concluded that CC hearing aids are a good option for hearing improvement in children with canal stenosis or aural atresia who cannot use AC hearing aids.

Takai et al. fitted CC hearing aids in 41 patients, 19 (65.9%) of whom purchased them after the trial [28]. They compared the clinical characteristics of the patients who purchased and did not purchase the hearing aids, and found that the rate of congenital canal stenosis or aural atresia was significantly higher in purchased cases than in the non-purchased cases. They also found that those who decided to purchase CC hearing aids showed better hearing thresholds at high frequencies for both AC and BC as well as for aided thresholds when using CC hearing aids.

Several studies have reported the benefits of CC hearing aids in clinical practice in Japan. Most patients who attempted to use CC hearing aids experienced canal stenosis or aural atresia. The audiological benefits in these cases were significant, and the reported purchase rates were good. Patients with unilateral canal stenosis or aural atresia rarely used amplification devices before the CC hearing aid trial. However, the purchase rates of CC hearing aids in these cases were comparable to those in bilateral cases [22]. No significant adverse effects were reported, which probably contributes to the promotion of the use of CC hearing aids in unilateral cases, unlike other hearing devices. Thus, CC hearing aids are considered a good option for compensating for hearing loss in ears with canal stenosis or aural atresia in both bilateral and unilateral cases. However, current CC hearing aids are not considered the first choice for cases with a canal-open ear. Nevertheless, they can provide significant benefits in specific cases such as continuous otorrhea. The indications for the CC hearing aids in these cases are limited. However, the fitting cases in previous studies were not sufficient to draw this conclusion. Further studies are warranted to clarify the indications in canal-open ears.

5. Clinical Studies in Countries Other Than Japan

CC hearing aids are currently used solely in Japan in clinical practice and cannot be purchased in other countries. However, clinical studies have already been conducted in two countries. In Indonesia, Suwento et al. measured the benefits of CC hearing aids in ten patients (aged <20 years) with microtia and aural atresia whose hearing dysfunction did not improve after ear reconstruction surgery [29]. They found a significant difference between unaided and aided thresholds. Speech recognition thresholds and speech discrimination levels were also significantly improved with the use of CC hearing device. Almost all the parents reported satisfaction with the performance of the CC hearing aids upon daily communication with their children.

Considering the effectiveness of CC hearing aids in the atretic ear, the difference between the benefits of BC devices and CC hearing aids is an interesting subject. In the United States, Nairn et al. compared the benefits of BC devices (BAHA 5, BAHA 5 power (Cochlear Limited, Sydney, Australia) and Ponto 4 (Oticon Medical, Smørum, Denmark)) and CC hearing aids (HB-A2CC) using a crossover study design [30]. Sixteen adults (19 ears) with congenital aural atresia or overclosed ear canals who previously underwent BC device implantation participated in the study. The mean aided pure tone averages with the BC device and CC hearing aids were 27 and 32 dB, respectively, and the mean functional gains were 54 and 49 dB, respectively. Significant differences were observed between them. Regarding speech perception, the mean consonant-nucleus-consonant scores with the BC device were 90% (best aided) and 80% (aided ear isolated), and those with the CC hearing aid were 86% and 76%, respectively. The mean AzBio scores were 90% (quiet), 77% (+10 dB signal to noise ratio (SNR)), and 52% (+5 dB SNR) when isolating the BC device ear, and 90%, 73%, and 41% when isolating the CC hearing aid ear. No difference in speech scores achieved statistical significance, except for AzBio isolated from the aided ear in the 15 dB SNR condition, which favored the BC device. They concluded that pure-tone audiometric outcomes with the BC device demonstrated a small advantage over the CC hearing aid, with the difference being driven mainly by high-frequency responses. Speech outcomes were equivalent, except for the 15dB SNR condition. Regarding the differences between BC devices and CC hearing aids, Nishiyama et al. compared the benefits of the BAHA, CC hearing aids, and ADHEAR (MED-EL, Innsbruck, Austria) [31]. They reported data from six patients who underwent comparative trials. The functional gains for the BAHA and CC hearing aids improved compared with those of the ADHEAR in Japan. In contrast, no clear tendency was observed among the three devices in a quality of life evaluation. They indicated the need for comparative trials and consultations when selecting a device.

6. Signal Transmission Pathway to the Cochlea in Atretic Ears

CC hearing aids are effective in the atretic ear, and most patients purchased them after the trial. From the viewpoint of signal transmission, the pathway to the cochlea in the atretic ear is quite different from that in the normal ear. The cartilage–AC predominantly contributes to hearing in normal ears. However, both direct and cartilage–AC pathways are absent in the atretic ear. Theoretically, the signal transmission pathway should include the skull bone in the atretic ear for conduction. Thus, the predominant pathway to the cochlea switches from cartilage–AC to cartilage–BC in the atretic ear (Figure 1B). The transmission efficacy may decrease in the atretic ear based on the difference in contribution to the threshold between cartilage–AC and BC in the normal ear. Compared with the vibrator placed on the mastoid, the delivered vibrations could deteriorate because they are delivered to the skull bone via the cartilaginous tissues. A previous study compared the thresholds of a vibrator on the aural cartilage and those on the mastoid (cartilage and mastoid stimulation conditions) [32]. A previous study demonstrated the thresholds at low frequencies to be significantly better in the cartilage stimulation condition, and that no difference was present in the thresholds at high frequencies, implying that the fixation placement had no negative effect. Furthermore, the static force is important for signal transmission in BC [33,34]. In a normal ear, the sound pressure level in the ear canal produced by CC is also influenced by static forces [6]. It increases as a function of the static force. One of the greatest benefits of CC hearing aids is their comfort while wearing them, which is attributed to their fixation style. CC hearing aids are typically used without static force; this fixation style could negatively affect signal transmission.

7. Benefits of CC in Atretic Ears with Fibrotic Pathways

An absent ear canal can occur due to congenital anomalies, as well as acquired factors such as inflammation, injury, and surgical treatment. In the latter case, the ear canal is usually closed with no bony tissue, and signals delivered to the cartilaginous tissue travel via the fibrotic tissues to drive the remaining ossicles when fibrotic tissues are connected to the remaining ossicles (fibrotic tissue pathway) (Figure 1C). Signals are effectively transmitted in cases involving the fibrotic tissue pathway because vibrations of the large-mass skull bone are not mandatory in this transmission. A previous study compared the CC and BC thresholds in patients with and without fibrotic tissue pathways [35]. The findings demonstrated an improvement in the thresholds of the fibrotic pathway, and the benefits became more significant as the frequency decreased. In another study, the thresholds in atretic ears with a fibrotic pathway significantly improved by approximately 20 dB at frequencies below 1000 Hz when the transducer was placed on the aural cartilage [32]. No differences were observed in the thresholds at frequencies above 2000 Hz. The threshold difference between cartilage and mastoid stimulations increases in the atretic ear via a fibrotic pathway. These findings imply that the audiological benefits of CC hearing aids are greater in the atretic ear via the fibrotic pathway. Komune et al. used CC hearing aids to manage residual hearing following lateral temporal bone resection in patients with temporal bone malignancies [36]. The hearing outcomes of patients who have undergone external auditory meatus reconstruction vary widely. They used CC hearing aids instead of ear canal reconstruction to compensate for the hearing loss. The performance of CC hearing aids revealed individual variations. They found that the difference between the aided and BC thresholds increased as the distance between the bone and cartilage increased. Although there is still room for improvement in the surgical techniques, they concluded that CC hearing aids provide noninvasive postoperative hearing compensation following lateral bone resection.

8. Sound Localization in Bilateral Atretic Ears

One benefit of binaural hearing is sound localization. Patients with bilateral aural atresia often exhibit poor sound localization due to BC features (low intracranial attenuation). However, most patients using CC hearing aids have reported improvements. Nishimura et al. evaluated sound localization by using eight loudspeakers positioned in a full-circle at 45 degree intervals in patients with bilateral aural atresia [37]. They compared the results of hearing unaided, aided by previously used hearing aids (AC or BC hearing aids), and aided by CC hearing aids. The ability to distinguish sounds originating from the left or right side for participants aided by CC hearing aids was significantly better than that for the other conditions. The transmission pathway to the cochlea involves the skull in all cases. Therefore, another cue that distinguishes between the left and right may function in the CC. They hypothesized the involvement of another mechanism, such as the contribution of the vibration sensation. The vibrator on the aural cartilage vibrates for sound transmission, and this vibration may induce both the auditory and somatic sense [37]. This somatic sense could provide a cue for differentiating between the left and right sides. BC hearing aids transmit sounds transcutaneously. However, the vibrator is tightly attached to the bone in the BC hearing aid; thus, the somatic sense may become damaged and dull. Conversely, the vibrators of the CC hearing aids were attached without high contact pressure, and the somatic sensation was maintained. However, the contribution of the somatic sense to sound localization remains to be clarified, and further studies are warranted.

Kitama et al. measured the sound localization in patients with unilateral atretic ears using a CC hearing aid, BAHA, and ADHEAR on the atretic ear. Compared with the un-aided condition, no significant improvement was observed in any of the three aided conditions [31]. However, the comparison was provided for only one patient. Thus, a firm conclusion could not be drawn regarding the effect of CC hearing aids on sound localization in patients with unilateral atretic ears.

9. Auricular Prosthesis

Esthetic problems are considered a disadvantage of hearing devices. Compared to BC hearing aids, CC devices are smaller and a headband is not required for fixation. Unfortunately, CC hearing aids are not devoid of esthetic problems, despite the esthetic advantages in comparison with BC hearing aids. Congenital aural atresia is often accompanied by microtia, which also causes esthetic problems. Nishiyama et al. developed an auricular prosthesis incorporating a cartilage conduction hearing aid (APiCHA) to achieve the challenging goal of simultaneously improving both esthetic problems [38]. Compared with the CC hearing aid alone, the functional gain was approximately 2 dB lower at high frequencies from 1 kHz and above, and approximately 2 dB higher at high frequencies from 900 Hz when the CC hearing aid was used with the APiCHA. They reported that the combined use of the APiCHA and CC hearing aids can be considered a noninvasive and clinically applicable treatment option to achieve both esthetic and auditory improvements for microtia.

10. Conclusions

CC hearing aids were launched in Japan in 2017. The number of clinical cases in which this new device has been used has increased greatly, with several studies reporting its benefits. According to the results, CC hearing aids are considered a good option for compensating for hearing loss in ears with canal stenosis or aural atresia in both bilateral and unilateral cases. However, CC hearing aids are not currently considered the first choice in patients with a canal-open ear. Nevertheless, they can provide significant benefits in specific cases, such as continuous otorrhea. Further studies are warranted to clarify the indications for use in canal-open ears.

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References

1. Mylanus, E.A.; van der Pouw, K.C.; Snik, A.F.; Cremers, C.W. Intraindividual comparison of the bone-anchored hearing aid and air-conduction hearing aids. *Arch. Otolaryngol. Head Neck Surg.* **1998**, *124*, 271–276. [CrossRef]
2. Snik, A.F.; Mylanus, E.A.; Cremers, C.W. The bone-anchored hearing aid: A solution for previously unresolved otologic problems. *Otolaryngol. Clin. N. Am.* **2001**, *34*, 365–372. [CrossRef]
3. Dillon, H. CROS, bone-conduction, and implanted hearing aids. In *Hearing Aids*; Dillon, H., Ed.; Thieme: Stuttgart, Germany, 2001; pp. 434–450.
4. Lo, J.F.W.; Tsang, W.S.S.; Yu, J.Y.K.; Ho, O.Y.M.; Ku, P.K.M.; Tong, M.C.F. Contemporary hearing rehabilitation options in patients with aural atresia. *Biomed. Res. Int.* **2014**, *2014*, 761579. [CrossRef] [PubMed]
5. Ellsperman, S.E.; Nairn, E.M.; Stucken, E.Z. Review of bone conduction hearing devices. *Audiol. Res.* **2021**, *11*, 207–219. [CrossRef] [PubMed]
6. Shimokura, R.; Hosoi, H.; Nishimura, T.; Yamanaka, T.; Levitt, H. Cartilage conduction hearing. *J. Acoust. Soc. Am.* **2014**, *135*, 1959–1966. [CrossRef]
7. Miyamae, R.; Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Yamanaka, T.; Kitahara, T. Perception of speech in cartilage conduction. *Auris Nasus Larynx* **2017**, *44*, 26–32. [CrossRef] [PubMed]
8. Nishimura, T.; Miyamae, R.; Hosoi, H.; Saito, O.; Shimokura, R.; Yamanaka, T.; Kitahara, T. Frequency characteristics and speech recognition in cartilage conduction. *Auris Nasus Larynx* **2019**, *46*, 709–715. [CrossRef]
9. Blondé-Weinmann, C.; Joubaud, T.; Zimpfer, V.; Hamery, P.; Roth, S. Characterization of cartilage implication in protected hearing perception during direct vibro-acoustic stimulation at various locations. *Appl. Acoust.* **2021**, *179*, 108074. [CrossRef]

10. Hosoi, H.; Nishimura, T.; Shimokura, R.; Kitahara, T. Cartilage conduction as the third pathway for sound transmission. *Auris Nasus Larynx* **2019**, *46*, 151–159. [CrossRef]
11. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Yamanaka, T.; Levitt, H. Is cartilage conduction classified into air or bone conduction? *Laryngoscope* **2014**, *124*, 1214–1219. [CrossRef]
12. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Yamanaka, T.; Kitahara, T.; Levitt, H. Cartilage conduction is characterized by vibrations of the cartilaginous portion of the ear canal. *PLoS ONE* **2015**, *10*, e0120135. [CrossRef]
13. Nishimura, T.; Hosoi, H.; Shimokura, R.; Morimoto, C.; Kitahara, T. Cartilage Conduction Hearing and Its Clinical Application. *Audiol. Res.* **2021**, *11*, 254–262. [CrossRef] [PubMed]
14. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Yamanaka, T.; Kitahara, T.; Levitt, H. Cartilage conduction efficiently generates airborne sound in the ear canal. *Auris Nasus Larynx* **2015**, *42*, 15–19. [CrossRef]
15. Nishimura, T.; Hosoi, H.; Saito, O.; Akasaka, S.; Shimokura, R.; Yamanaka, T.; Kitahara, T. Effect of fixation place on airborne sound in cartilage conduction. *J. Acoust. Soc. Am.* **2020**, *148*, 469. [CrossRef]
16. Hosoi, H.; Yanai, S.; Nishimura, T.; Sakaguchi, T.; Iwakura, T.; Yoshino, K. Development of cartilage conduction hearing aid. *Arch. Mater. Sci. Eng.* **2010**, *42*, 104–110.
17. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Iwakura, T. Benefit of a new hearing device utilizing cartilage conduction. *Auris Nasus Larynx* **2013**, *40*, 440–446. [CrossRef] [PubMed]
18. Shimokura, R.; Hosoi, H.; Iwakura, T.; Nishimura, T.; Matsui, T. Development of monaural and binaural behind-the-ear cartilage conduction hearing aids. *Appl. Acoust.* **2013**, *74*, 1234–1240. [CrossRef]
19. Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Yamanaka, T.; Kitahara, T. Cartilage Conduction Hearing Aids for Severe Conduction Hearing Loss. *Otol. Neurotol.* **2018**, *39*, 65–72. [CrossRef]
20. Nishimura, T.; Hosoi, H.; Morimoto, C.; Okayasu, T.; Shimokura, R.; Kitahara, T. Comparison of Cartilage Conduction Hearing Devices Designed by Ear Impression and Computed Tomography. *Appl. Sci.* **2023**, *13*, 6152. [CrossRef]
21. Nishimura, T.; Hosoi, H.; Sugiuchi, T.; Matsumoto, N.; Nishiyama, T.; Kenichi, T.; Sugimoto, S.; Yazama, H.; Sato, T.; Komori, M. Factors Influencing the Purchase Rate of Cartilage Conduction Hearing Aids. *J. Am. Acad. Audiol.* **2022**, *33*, 14–22. [CrossRef]
22. Nishimura, T.; Hosoi, H.; Sugiuchi, T.; Matsumoto, N.; Nishiyama, T.; Kenichi, T.; Sugimoto, S.; Yazama, H.; Sato, T.; Komori, M. Cartilage conduction hearing aid fitting in clinical practice. *J. Am. Acad. Audiol.* **2021**, *32*, 386–392. [CrossRef]
23. House, J.W.; Kutz, J.W., Jr.; Chung, J.; Fisher, L.M. Bone-anchored hearing aid subjective benefit for unilateral deafness. *Laryngoscope* **2010**, *120*, 601–607. [CrossRef] [PubMed]
24. Sakamoto, Y.; Shimada, A.; Nakano, S.; Kondo, E.; Takeyama, T.; Fukuda, J.; Udaka, J.; Okamoto, H.; Takeda, N. Effects of FM system fitted into the normal hearing ear or cartilage conduction hearing aid fitted into the affected ear on speech-in-noise recognition in Japanese children with unilateral congenital aural atresia. *J. Med. Investig.* **2020**, *67*, 131–138. [CrossRef] [PubMed]
25. Akasaka, S.; Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Morimoto, C.; Kitahara, T. Benefits of Cartilage Conduction Hearing Aids for Speech Perception in Unilateral Aural Atresia. *Audiol. Res.* **2021**, *11*, 284–290. [CrossRef] [PubMed]
26. Nishiyama, T.; Oishi, N.; Ogawa, K. Who are good adult candidates for cartilage conduction hearing aids? *Eur. Arch. Otorhinolaryngol.* **2021**, *278*, 1789–1798. [CrossRef]
27. Nishiyama, T.; Oishi, N.; Ogawa, K. Efficacy of cartilage conduction hearing aids in children. *Int. J. Pediatr. Otorhinolaryngol.* **2021**, *142*, 110628. [CrossRef]
28. Takai, S.; Sato, T.; Miyakura, Y.; Adachi, M.; Honkura, Y.; Yamauchi, D.; Katori, Y. Examination of Factors Affecting the Likelihood of Whether Individuals Would Purchase Cartilage Conduction Hearing Aids. *Audiol. Res.* **2023**, *13*, 347–356. [CrossRef]
29. Suwento, R.; Widodo, D.W.; Airlangga, T.J.; Alviandi, W.; Watanuki, K.; Nakanowatari, N.; Hosoi, H.; Nishimura, T. Clinical Trial for Cartilage Conduction Hearing Aid in Indonesia. *Audiol. Res.* **2021**, *11*, 410–417. [CrossRef]
30. Nairn, E.M.; Chen, A.S.; Nishimura, T.; Berezovsky, A.; Stucken, E.Z. Hearing outcomes of a new cartilage conduction device vs bone conduction devices. *Otolaryngol. Head Neck Surg.* **2023**, *168*, 821–828. [CrossRef]
31. Kitama, T.; Nishiyama, T.; Iwabu, K.; Wakabayashi, T.; Shimanuki, M.N.; Hosoya, M.; Oishi, N.; Ozawa, H. Comparison of cartilage conduction hearing aid, bone anchored hearing aid, and ADHEAR: Case series of 6 patients with conductive and mixed hearing loss. *Appl. Sci.* **2022**, *12*, 12099. [CrossRef]
32. Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Morimoto, C.; Okayasu, T.; Kitahara, T. Effect of transducer placements on thresholds in ears with an abnormal ear canal and severe conductive hearing loss. *Laryngoscope Investig. Otolaryngol.* **2021**, *6*, 1429–1435. [CrossRef] [PubMed]
33. Nilo, E.R. The relation of vibrator surface area and static application force to the vibrator-to-head coupling. *J. Speech Hear. Res.* **1968**, *11*, 805–810. [CrossRef] [PubMed]
34. Lau, C.C. The effect of coupling force on bone conduction audiometry. *Br. J. Audiol.* **1986**, *20*, 261–268. [CrossRef] [PubMed]
35. Morimoto, C.; Nishimura, T.; Hosoi, H.; Saito, O.; Fukuda, F.; Shimokura, R.; Yamanaka, T. Sound transmission by cartilage conduction in ear with fibrotic aural atresia. *J. Rehabil. Res. Dev.* **2014**, *51*, 325–332. [CrossRef]
36. Komune, N.; Higashino, Y.; Ishikawa, K.; Tabuki, T.; Masuda, S.; Koike, K.; Hongo, T.; Sato, K.; Uchi, R.; Miyazaki, M.; et al. Management of Residual Hearing with Cartilage Conduction Hearing Aid after Lateral Temporal Bone Resection: Our Institutional Experience. *Audiol. Res.* **2021**, *11*, 263–274. [CrossRef]

37. Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Yamanaka, T.; Kitahara, T. Sound localisation ability using cartilage conduction hearing aids in bilateral aural atresia. *Int. J. Audiol.* **2020**, *59*, 891–896. [CrossRef]
38. Nishiyama, T.; Hayashi, S.; Oishi, N. A novel auricular prosthesis which incorporates a cartilage conduction hearing aid based on 3D data processing technique: A preclinical evaluation. *Eur. Arch. Otorhinolaryngol.* **2022**, *279*, 3741–3744. [CrossRef]

audiology research

MDPI

Article

In Vivo Measurement of Ear Ossicle and Bony Wall Vibration by Sound Stimulation of Cartilage Conduction

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Abstract: The cartilage-conduction pathway was recently proposed as a third auditory pathway; however, middle-ear vibrations have not yet been investigated in vivo. We aimed to measure the ossicles and bone vibration upon cartilage-conduction stimulation with a non-contact laser Doppler vibrometer. We recruited adult patients with normal ear structures who underwent cochlear implant surgery at our hospital between April 2020 and December 2022. For sound input, a cartilage-conduction transducer, custom-made by RION Corporation (Tokyo, Japan), was fixed to the surface of the tragus and connected to an audiometer to regulate the output. A posterior tympanotomy was performed and a laser beam was directed through the cavity to measure the vibration of the ossicles, cochlear promontory, and posterior wall of the external auditory canal. Five participants (three men, mean age: 56.4 years) were included. The mean hearing loss on the operative side was 96.3 dB HL in one patient, and that of the other patients was off-scale. The vibrations were measured at a sound input of 1 kHz and 60 dB. We observed vibrations of all three structures, demonstrating the existence of cartilage-conduction pathways in vivo. These results may help uncover the mechanisms of the cartilage-conduction pathway in the future.

Keywords: cartilage conduction; ossicular vibration; bone vibration

1. Introduction

Sound has conventionally been thought to be transmitted through two pathways: air conduction and bone conduction. In air conduction, vibrations in the air are transmitted to the tympanic membrane, where they are converted into mechanical vibrations that amplify the sound pressure as they travel through the ossicles to the cochlea. Bone conduction mainly induces mechanical vibrations in the temporal bone and skull, which are subsequently transmitted to the cochlea. However, bone conduction may occur through multiple pathways, including through the cerebrospinal fluid and ossicles. The sound transmission mechanisms for these pathways have been extensively investigated and are clearly explained by Stenfelt et al. [1]. Recently, Hosoi et al. [2] proposed cartilage conduction as a third auditory pathway. They showed that sound generated by a cartilage-conduction transducer usually reaches the inner ear via three different pathways in humans with normal anatomical structures: the direct air-conduction, cartilage–air-conduction, and cartilage–bone-conduction pathways (Figure 1). In direct air-conduction, sound is transmitted to the cochlea via conventional air conduction. In cartilage–air-conduction, vibrations of the auricular cartilage induce acoustic signals in the ear canal, which are transmitted to the cochlea via conventional air conduction. In cartilage–bone-conduction, vibrations from the auricular cartilage are transmitted to the cochlea via the temporal bone. The acoustic estimation of these conduction pathways has been reported by Nishimura et al. [3] and Shimokura et al. [4]. Nishimura et al. [5] investigated which pathway is dominant for cartilage conduction, concluding that it is the cartilage–air-conduction pathway. However, evidence for the existence of the two cartilage-conduction pathways, cartilage–air-conduction and cartilage–bone-conduction, is currently insufficient in terms of whether the vibrations are actually being transmitted along them. Although such evidence has been produced in a model of the external auditory canal [6], in vivo validation in humans is lacking. Therefore, measurement of the vibration of the ossicles during cartilage conduction in vivo may provide useful information.

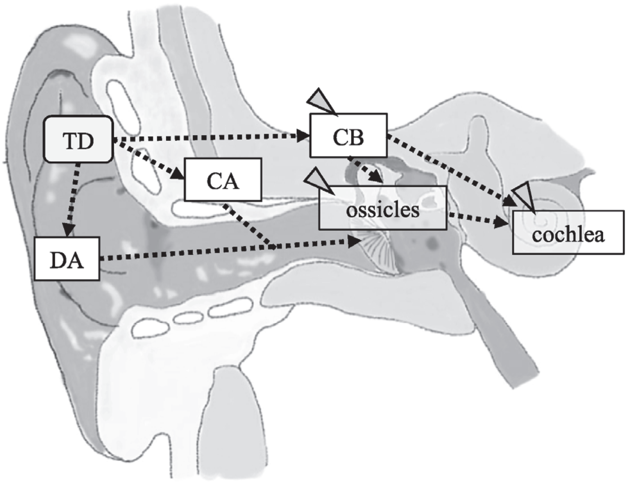

Figure 1. A schema of the structures contributing to cartilage conduction (CC) pathways. CC is achieved via a direct air-conducted pathway (DA), cartilage–bone-conducted pathway (CB), and cartilage–air-conducted pathway (CA). Dashed lines indicate predicted pathways. The gray arrowheads indicate the pathway and structures to be analyzed in this study. TD, cartilage-conducting transducer.

We previously analyzed vibrations in the human tympanic membrane and ear ossicles induced by acoustic excitation using a non-contact laser Doppler vibrometer (LDV) and examined how sound pressure acting on the tympanic membrane is transmitted to the cochlea through the middle-ear sound-transduction system [7,8]. In particular, we focused on the phase difference and amplitude of the measured signal relative to the excitation signal to evaluate the state of ossicular vibration. In this study, we attempted to demonstrate the existence of all three pathways of cartilage conduction using the same method as previously reported to measure the vibrations of the ossicles, cochlear promontory, and bones of the external auditory canal by using a cartilage-conduction transducer. Such measurements have not been performed in humans with an almost physiologically intact middle-ear conduction system, as in the present study. In this study, we aimed to confirm the presence of the cartilage-conduction pathway in vivo and to evaluate how much of the transmitting force is transmitted to the ossicles and bones. Moreover, the dominant pathway is the cartilage–air-conduction pathway, and measurements of ossicular vibration transmitted via cartilage conduction should yield results similar to those transmitted via tympanic membrane vibration. Therefore, we also compared these measurements with our previously reported measurements of ossicular vibration via the air-conduction pathway.

2. Materials and Methods

2.1. Participants

In this study, participants were recruited from patients who underwent cochlear implant surgery at our hospital between April 2020 and December 2022. We selected participants with normal structures of the external, middle, and inner ear to minimize errors in measuring the vibration of the ossicles, cochlear promontory, and external auditory canal wall. In addition, we selected patients in whom the middle ear was fully developed. Therefore, the selection criteria were as follows: at least 20 years of age at the time consent was obtained; no external or middle ear disease; no malformation of the ossicles or inner ear; surgery to open the middle ear cavity was planned; and consent was obtained from the patients. As the only patients who met these criteria were patients with cochlear implants, we included adult patients undergoing cochlear implant surgery. The exclusion criteria were a lack of consent or withdrawal of consent for participation in the study.

This study was approved by the Tottori University Ethics Review Committee (approval number: 2100). All the participants were informed of the research aims, and their written consent was obtained before their inclusion in the study.

2.2. Output Characteristics of the Cartilage-Conduction Transducer

The output characteristics of the cartilage-conduction transducer were measured to determine how much vibration was induced by the force generated. These measurements were performed by RION Corporation (Tokyo, Japan), the developer of the transducer. They used an artificial mastoid (Artificial Mastoid, B&K 4930; Brüel & Kjær, Nærum, Denmark) for the measurements. A cartilage-conduction transducer was connected to an audiometer (RION AA-73A; RION Corporation, Kokubunji, Japan), and the excitation and output characteristics were measured, the results of which were provided to us.

2.3. Vibration Generation and Vibration Measurement Equipment

The cartilage-conduction transducer, the source of the vibrations used in this study, was custom-made by RION Corporation (model number: F0198L1). It was connected to an audiometer (RION AA-73A) for the ability to adjust the sound output. Figure 2 is a schema of the experimental system for vibration measurement. In the system, a surgical microscope (OPMI; Zeiss, Oberkochen, Germany) is usually equipped with an eyepiece and a CCD camera located between the objective and the eyepiece. Instead of an eyepiece, an LDV (VH300; Ometron, Hertfordshire, UK) was mounted, using a goniometer to adjust the laser beam and the visual axis. The laser beam and microscope focus were adjusted before the measurements were taken. As a result, the laser beam was bent by the prism of the eyepiece along the visual axis of the microscope and delivered through the objective lens to the measurement site. The laser beam was reflected from the measurement site back to the LDV.

The LDV operates by comparing the frequency of an emitted beam with that of the beam reflected from a moving surface. The accuracy of the comparison between the emitted and reflected beams depends on the amplitude of the reflected beam that returns to the velocity decoder. Clearly delineated amplitudes were extracted because too small an amplitude would result in noisy velocity estimates. The laser output power was adjusted to less than 1 mW in accordance with the safety standards of the U.S. Food and Drug Administration. The measured data were recorded and digitized using an analog-to-digital converter (PULSE356-B-130; Brüel & Kjær) with a sampling frequency of 131,072 (=2^{17}) Hz. The vibration frequency component of the cartilage-conduction transducer was extracted from the measured velocity signal by using a lock-in amplifier algorithm, and the vibration amplitude was obtained by integrating the velocity at the frequency of the excitation signal. The phase difference of the excitation signal was also obtained.

2.4. Vibration Measurement

For the sound pressure input, a transducer was fixed to the skin surface of the tragus with double-sided tape, covered with waterproof tape, and disinfected (Figure 3). After a mastoidectomy under general anesthesia without muscle relaxants, a posterior tympanotomy was performed, and the round window niche and superstructure of the stapes were identified. The operating and measuring microscopes were exchanged while maintaining a clean field. A laser beam was produced by the LDV and directed through the cavity. The focus of the laser beam was adjusted according to the monitor. The measurement sites were the malleus head, incus body, incudostapedial (I-S) joint, cochlear promontory, and posterior wall of the external auditory canal (Figure 4). The audiometer was set to an output of 1 kHz at 60 dB, and the velocity and phase were measured at each measurement site. The measurements were started at the same time as the tonal stimulus. The measurements at each point took about 5 s. Following the measurements, the microscopes were promptly switched for completion of the operation. We anticipated approximately 30 min of extended anesthesia time for a series of measurement procedures, and none of the participants greatly exceeded the anticipated time.

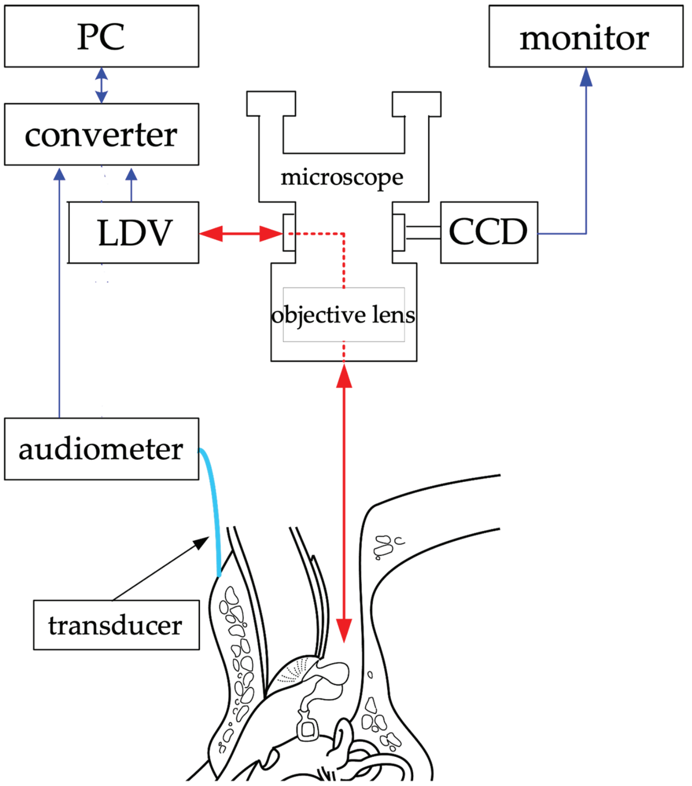

Figure 2. Experimental system for measurement of vibration. The red arrows represent the incoming and outgoing laser beams, and the blue arrows represent the transmission and reception of data. The arrowheads indicate the direction of data and laser exchange. Laser beams are emitted through a microscope to measure vibrations at various points. PC: personal computer, LDV: laser Doppler vibrometer, CCD: charge-coupled device camera. (Reproduced from Kunimoto et al. [8], with permission.)

Figure 3. Fixed transducer. The transducer is attached to the surface of the tragus by using double-sided tape and covered with waterproof tape to secure it in place.

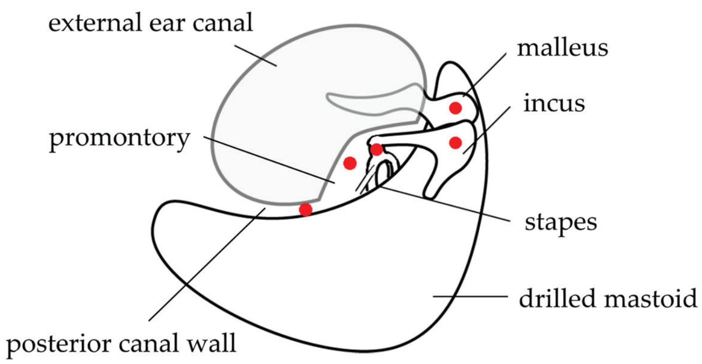

Figure 4. Measurement points. Mastoidectomy and posterior tympanotomy are performed, and the measurement sites (the malleus head, body of the incus, incudostapedial joint, cochlear promontory, and the mastoid side of the posterior wall of the external auditory canal after mastoidectomy) are placed under clear view. This figure was modified from Kunimoto et al. [8], with permission.

2.5. Vibration Analysis

The relative motion of each ear ossicle was calculated from the measurements in Section 2.4. Continuous amplitude changes at each measurement site were calculated using phase shifts from the sinusoidal excitation. The amplitudes of each measured section were averaged across the measurements and visualized. The accuracy was verified using the same protocol as in a previous report [7].

3. Results

3.1. Participant Characteristics

Nineteen patients underwent cochlear implant surgery at our institution between April 2020 and December 2022. Among these, 10 patients were excluded because they were under 20 years of age, and one adult patient was excluded because of an inner-ear malformation (please see the inclusion and exclusion criteria described in the Section 2). Consent for participation was obtained from six of the eight remaining patients. One of these participants was excluded from the analysis because of poorly recorded data. Finally, five participants were included. Their mean age was 56.4 years (range: 42–69), and three were men. The mean hearing loss on the operative side was 96.3 dB HL in one patient, whereas that of the other patients was >100 dB HL.

3.2. Output Characteristics of the Cartilage-Conduction Transducer

The measurement results are displayed in Figure 5. The output of the cartilage-conducting transducer was very strong: the transmission force used in the experiment was 446,684 μN, at a frequency of 1 kHz and audiometer output of 60 dB. Assuming a tympanic membrane diameter of 1 cm and sound pressure of 100 dB SPL (2×10^6 μPa), the input from the tympanic membrane to the ossicles was 157 μN, which is approximately 2800 times greater than that with acoustic excitation at 100 dB SPL [7].

3.3. Vibration Measurement

The measured vibration responses are listed in Table 1 and illustrated in Figures 6 and 7. At a vibration frequency of 1 kHz and an audiometer output of 60 dB, we were able to measure the vibrations of the I-S joint, malleus head, and body of the incus for all the participants. The smallest vibration amplitude was 0.04 μm and the largest was 0.9 μm. The phase difference in the response to the excitation force indicates that the malleus head and body of the incus vibrate in almost the same phase. The I-S joint and malleus head vibrate in nearly opposite phases, with the exception of those in participant 4. Vibrations of the cochlear promontory could only be measured in participants 1 and 2. These amplitudes were very small compared to those of the ossicles (on the order of 1/100). The vibrations of the posterior wall of the external auditory canal could be measured in participants 2 and 5.

Again, these amplitudes were very small compared to those of the ossicles, on the order of 1/100 for participant 1 and 1/10 for participant 2.

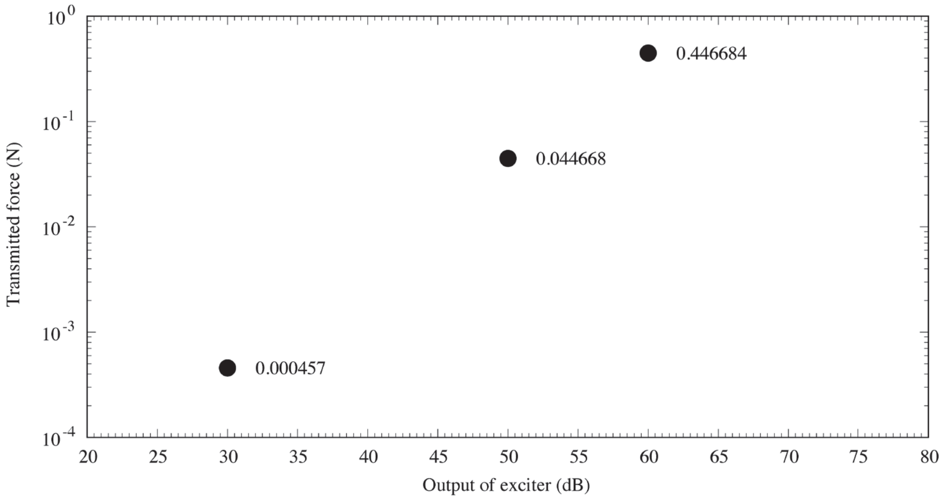

Figure 5. Output characteristics of the cartilage-conduction transducer. The three points represent the transmitted force from the cartilage–conduction transducer corresponding to a certain audiometer dial setting, and the value next to each point is the measured value (N). The output results demonstrate linearity with the transmitted force, indicating that the transducer performed very well.

Table 1. Vibratory measurements during cartilage-conducted stimulation.

Participant	Measurement Point	Amplitude (μm)	Phase (Degrees)
Volunteer 1 69 y.o. man	Stapes	0.0806	96.36
	Malleus head	0.0794	249.24
	Incus body	0.0414	236.78
	Promontory	0.0008	135.94
	Canal wall	-	-
Volunteer 2 54 y.o. woman	Stapes	0.0874	149.77
	Malleus head	0.1012	6.10
	Incus body	0.0944	−0.06
	Promontory	0.0040	149.99
	Canal wall	0.0041	153.42
Volunteer 3 42 y.o. woman	Stapes	0.3999	174.64
	Malleus head	0.5338	−41.60
	Incus body	0.1670	−80.34
	Promontory	-	-
	Canal wall	-	-
Volunteer 4 68 y.o. man	Stapes	0.4785	−57.38
	Malleus head	0.3159	−22.72
	Incus body	0.4062	−32.96
	Promontory	-	-
	Canal wall	-	-
Volunteer 5 49 y.o. man	Stapes	0.1833	−67.81
	Malleus head	0.5938	139.81
	Incus body	0.9187	139.11
	Promontory	-	-
	Canal wall	0.0566	−26.25

y.o., years old.

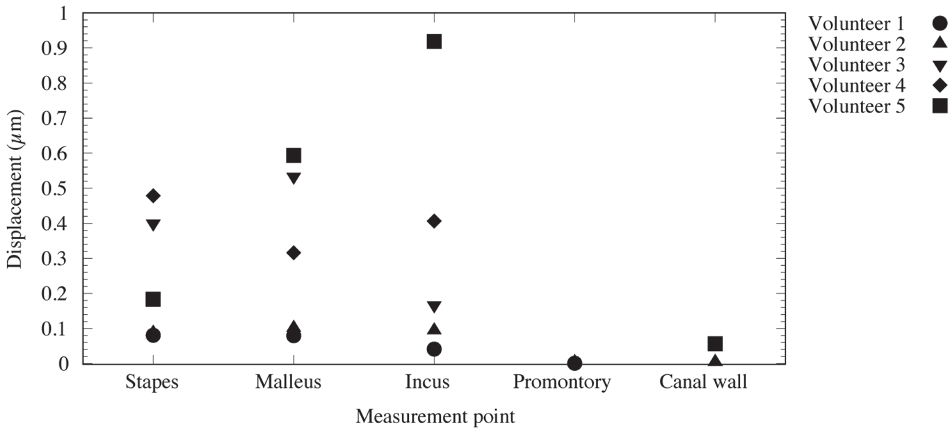

Figure 6. State of ossicle vibration during cartilage-conducted stimulation.

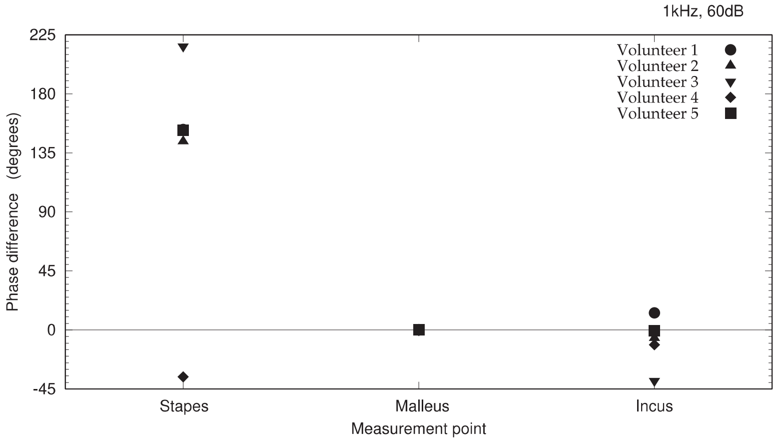

Figure 7. Phase differences of ossicle vibration relative to excitation signal during cartilage–conducted stimulation. The phase of the incus and the stapes with respect to the malleus is indicated. The phase at each measurement point is expressed as the phase difference compared to the reference phase.

4. Discussion

Vibrations generated in the ear ossicles or bones indicate the transmission of a force, such as sound pressure. An evaluation criterion is needed to compare the state of transmission among different pathways. In air-conducted vibration, the excitation force transmitted to the ossicles can be estimated from the sound pressure input from the tympanic membrane [7]. On the other hand, we measured the force produced by the cartilage-conduction transducer as the force transmitted to the site where the transducer was attached; the actual force acting on the ossicles cannot be estimated. We believed that the magnitude of the vibration of the ossicles during air-conducted vibration could be used as a crude criterion for the transmitted force, indicating a large or small force. Therefore, we focused on the vibration state, especially the vibration amplitude, in this study.

LDV is a noncontact optical technique used for basic research on the dynamics of hearing [9–11]. Such studies have been conducted on the temporal bones of live humans and those of cadavers [9,10,12–15]. We previously reported measuring the vibrations of the ossicles and tympanic membrane in response to acoustic stimulation via the air-conducted pathway [7,8]. In the present study, we applied the same method to measure the vibration of the ossicles, external auditory canal bone, and cochlear promontory in response to excitation from a cartilage-conduction transducer and attempted to verify the cartilage-conducted pathway. We believe that LDV is the most appropriate measurement method for two reasons. First, contact-type vibration measuring devices may be affected by the dead weight of the transducer itself, which may suppress fine vibrations. Second, as the measurements were to be made within the surgical field, sterility was crucial.

The measurement results (Table 1) appear to reveal interindividual differences in amplitude. Two explanations for these differences may be provided. First, the difference in size and shape of the auricular cartilage between the individuals might have resulted in differences in the degree of adhesion of the transducer. In fact, the conduction efficiency changes just by shifting the location of the transducer [2]. Second, differences in the angle of incidence of the laser light and the direction of vibration may be considered. The velocity was measured on the axis of the laser beam excitation. Therefore, if the directions of the target vibration and laser excitation do not coincide, only the vibration component of the target in the direction of the laser excitation is measured. In such cases, the value is smaller than the actual vibration component (cosine component). The roughness of and liquid buildup on the surface of the target cause diffusion of the laser-beam reflection, reducing the accuracy of the measurement. As demonstrated in Table 1 and Figures 6 and 7, results that could not be accurately measured were excluded from this study.

In this study, the vibrations could be measured in the stapes, malleus head, and body of the incus in all the subjects. Thus, we have provided evidence that the excitation force from the cartilage-conduction transducer was transmitted to the ossicles via the temporal bone. The maximum amplitude of air-conducted vibration in a previous study was 0.03 μm at 1 kHz and 100 dB output [7], whereas the smallest amplitude was 0.08 μm with cartilage-conducted vibration in this study, and the largest amplitude exceeded 0.5 μm, 17 times larger than that obtained with air-conduction excitation. However, considering that the excitation force of the cartilage-conduction transducer is approximately 2800 times that of the air-conduction excitation, the amplitude produced by cartilage-conduction does not appear to be very large. Although cartilage conduction resulted in greater vibration of the ossicles than air conduction, this pathway has proven to be greatly attenuated during transmission through the temporal bone. The phase difference detected in response to the excitation force (Figure 7) indicates that the vibration state of the ossicles is similar to that of air-conduction transmission [8]. From the vibration pattern, the cartilage-conduction pathway seems to have a similar mechanism of vibration transmission to air conduction. However, given the amplitude, other pathways, such as movement of the ear ossicles, may have an effect. Specifically, the malleus head and the incus body are connected and should have the same phase of vibration. The difference in the phases of the malleus head and incus body in this study (Figure 7) might have been due to changes in the vibrational state during sequential measurements. A linear system would result in the same phase throughout; as this is not the case, the system must contain non-linear elements in various places.

Minute vibrations of the cochlear promontory and posterior wall of the external auditory canal were measured, demonstrating that the excitation force from the cartilage-conduction transducer propagates directly to the bone. However, such vibrations were detected in only two of the five participants. This may be owing to the fact that the vibrations were very weak and therefore susceptible to noise, resulting in poor measurements. Other possibilities are that the cochlear promontory is located in the deepest part of the middle-ear cavity, which is difficult for the laser to reach, and that laser excitation of the posterior wall of the external auditory canal was affected by the technique, such as the difficulty of hitting the wall perpendicularly. On the other hand, in terms of the phase, synchronous vibrations were observed in the stapes, cochlear promontory, and posterior wall of the external auditory canal, respectively, all of which was considered to be almost synchronous with the acoustic vibration. Although bone vibrations were confirmed, several questions remain, such as whether vibrations propagated in the cochlea can be perceived as hearing, and if so, to what extent compared to hearing propagated in the cochlea from otoacoustic vibrations.

Based on the abovementioned questions that remain regarding ossicles and bony vibrations, we discuss the pathways through which vibrations are transmitted to the cochlea via cartilage conduction again.

First, we consider the cartilage–air-conduction pathway, in which the vibrations of the temporal bone are transmitted through the canal wall to the air in the auditory canal, which vibrates the tympanic membrane, similar to the air-conduction pathway. In this study, we demonstrated that the ossicles also vibrated substantially, suggesting that it can also be considered a major transmission pathway.

Second, a possible pathway is the transmission of vibrations from the temporal bone via the surrounding ligaments and tympanic membrane to the ossicles, which transmit to the vibrations to the cochlea. In a broad sense, this pathway is consistent with the cartilage–air-conduction pathway, although the ossicles are unlikely to vibrate and transmit vibrations as efficiently. Further studies are needed to examine the differences between these two cartilage–air-conduction pathways and should include a measurement of the sound pressure in the external auditory canal.

Third is the cartilage–bone-conduction pathway, in which vibrations from the temporal bone are transmitted directly to the cochlea. Although this pathway was investigated by Shimokura et al. [4], they were not able to measure sound pressure in their experiments, possibly because the excitation was measured in the contralateral ear, which might have caused substantial attenuation via a shielding effect. As bone can be considered a viscoelastic material, differences in density, Young's modulus, and internal damping of various parts of the skull may affect the propagation path of vibrations from the transducer. In this study, the velocity changes in the direction of the laser excitation were below a measurable level in several cases; however, that does not mean that the vibration was not transmitted. The excitation force likely still propagated through the elastic body and could be perceived as hearing. Rather, the fact that the velocity could be measured indicates that the input was reliably propagated. In other words, the fact that bone vibration could be measured is evidence of the cartilage–bone-conduction pathway. In cartilage conduction, the transducer is similar to the voice coil in a speaker and the cartilage itself is thought to have a mechanism similar to that of a speaker diaphragm [2]. As demonstrated in this study, vibration may attenuate as it is transmitted to the bone; thus, transmission may be sufficient to the ipsilateral ear and insufficient to the contralateral ear. If this hypothesis is correct, cartilage-conduction hearing aids may be more effective at localizing sound sources. Further studies on bone conduction in the normal ear are required to determine the mechanism by which vibrations are transmitted, as well as the mechanism by which sound is perceived.

On the other hand, bone microvibrations and excitation forces propagating within the elastic body may have an important role. Stenfelt et al. [16] reported that fluid inertia caused by cochlear vibration had the greatest effect on basal membrane vibration in the normal ear when listening to bone-conducted sound of 0.1–10 kHz. Once that relationship is clarified, the benefits of direct vibration of the cochlear promontory should become apparent. We speculate that if the cochlea itself vibrates, it directly vibrates the organ of Corti without the transmission of vibration from the oval window and directly induces vibrations of the hair cells. This makes sense, as the degree of vibration directly affects the perception of sound loudness. However, the amplitude required to vibrate the organ of Corti is unknown and difficult to determine with fixed specimens or cadavers, because protein denaturation may affect vibration transmission. The amplitude will need to be determined in physiologically intact living organisms.

In the present study, we included only five participants; hence, the results were not averaged and may not be applicable to all adults. Limitations also exist in the interpretation of the data owing to the effects of anatomical differences in the participants, differences in the settings of the measurement equipment, and increased noise due to measurement surface roughness and fluid buildup. In addition, as the participants were different ages, the stiffness of the cartilage and bone was likely not be uniform, which could have caused a sampling bias.

Despite these limitations, the results of this study provide evidence for the mechanism of the cartilage-conduction pathways in vivo. The results of the present study should be explored in more detail in future studies for a better understanding of the vibration-based conduction pathway. For example, research on patients with external auditory canal atresia who undergo middle-ear implant surgery would allow study of the cartilage–soft tissue pathway, which would lead to a more detailed elucidation of the mechanism of cartilage conduction.

5. Conclusions

In the present study, we observed vibrations in the ossicles and bones, which provides in vivo evidence for the cartilage–air- and cartilage–bone-conduction pathways. The pattern of ear ossicle vibration induced by cartilage conduction was similar to but much larger than that induced by air conduction. This suggests that the cartilage–air-conduction pathway is not the only significant pathway by which vibrations are transmitted during cartilage conduction. Furthermore, our methodology may be useful for future clarification of the details of vibration transmission patterns.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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References

1. Stenfelt, S.; Goode, R.L. Bone-conducted sound: Physiological and clinical aspects. *Otol. Neurotol.* **2005**, *26*, 1245–1261. [CrossRef] [PubMed]
2. Hosoi, H.; Nishimura, T.; Shimokura, R.; Kitahara, T. Cartilage conduction as the third pathway for sound transmission. *Auris Nasus Larynx* **2019**, *46*, 151–159. [CrossRef] [PubMed]
3. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Yamanaka, T.; Kitahara, T.; Levitt, H. Cartilage conduction efficiently generates airborne sound in the ear canal. *Auris Nasus Larynx* **2015**, *42*, 15–19. [CrossRef] [PubMed]
4. Shimokura, R.; Hosoi, H.; Nishimura, T.; Yamanaka, T.; Levitt, H. Cartilage conduction hearing. *J. Acoust. Soc. Am.* **2014**, *135*, 1959–1966. [CrossRef] [PubMed]
5. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Yamanaka, T.; Levitt, H. Is cartilage conduction classified into air or bone conduction? *Laryngoscope* **2014**, *124*, 1214–1219. [CrossRef] [PubMed]
6. Shimokura, R.; Nishimura, T.; Hosoi, H. Vibrational and acoustical characteristics of ear pinna simulators that differ in hardness. *Audiol. Res.* **2021**, *11*, 327–334. [CrossRef] [PubMed]
7. Kunimoto, Y.; Hasegawa, K.; Arii, S.; Kataoka, H.; Yazama, H.; Kuya, J.; Kitano, H. Sequential multipoint motion of the tympanic membrane measured by laser Doppler vibrometry: Preliminary results for normal tympanic membrane. *Otol. Neurotol.* **2014**, *35*, 719–724. [CrossRef] [PubMed]
8. Kunimoto, Y.; Hasegawa, K.; Arii, S.; Kataoka, H.; Yazama, H.; Kuya, J.; Fujiwara, K.; Takeuchi, H. Sequential motion of the ossicular chain measured by laser Doppler vibrometry. *Acta Otolaryngol.* **2017**, *137*, 1233–1237. [CrossRef] [PubMed]
9. Peacock, J.; von Unge, M.; Dirckx, J. Measurement of the vibration of the middle ear ossicles with removed eardrum: A method for quantification of ossicular fixation. *Med. Eng. Phys.* **2013**, *35*, 1786–1792. [CrossRef] [PubMed]
10. Rosowski, J.J.; Nakajima, H.H.; Merchant, S.N. Clinical utility of laser-Doppler vibrometer measurements in live normal and pathologic human ears. *Ear Hear.* **2008**, *29*, 3–19. [CrossRef]
11. Huber, A.; Linder, T.; Ferrazzini, M.; Schmid, S.; Dillier, N.; Stoeckli, S.; Fisch, U. Intraoperative assessment of stapes movement. *Ann. Otol. Rhinol. Laryngol.* **2001**, *110*, 31–35. [CrossRef]

12. Morris, D.P.; Bance, M.; Van Wijhe, R.G. Vibration characteristics and function of atelectatic segments in the tympanic membrane in fresh human cadaveric temporal bones. *Clin. Otolaryngol. Allied Sci.* **2004**, *29*, 133–137. [CrossRef]
13. Rosowski, J.J.; Mehta, R.P.; Merchant, S.N. Diagnostic utility of laser-Doppler vibrometry in conductive hearing loss with normal tympanic membrane. *Otol. Neurotol.* **2003**, *24*, 165–175. [CrossRef] [PubMed]
14. Jakob, A.; Bornitz, M.; Kuhlisch, E.; Zahnert, T. New aspects in the clinical diagnosis of otosclerosis using laser Doppler vibrometry. *Otol. Neurotol.* **2009**, *30*, 1049–1057. [CrossRef] [PubMed]
15. Peacock, J.; Dirckx, J.; von Unge, M. Intraoperative assessment of ossicular fixation. *Hear. Res.* **2016**, *340*, 99–106. [CrossRef] [PubMed]
16. Stenfelt, S. Inner ear contribution to bone conduction hearing in the human. *Hear. Res.* **2015**, *329*, 41–51. [CrossRef] [PubMed]

audiology research

Article

Cartilage Conduction Sounds in Cases of Wearing Different Transducers on a Head and Torso Simulator with a Manipulated Ear Pinna Simulator

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Abstract: Cartilage conduction is known widely as a third hearing transmission mechanism after the air and bone conduction methods, and transducers dedicated to the production of cartilage conduction sounds have been developed by several Japanese companies. To estimate the acoustic performance of the five cartilage conduction transducers selected for this study, both airborne sounds and cartilage conduction sounds were measured. Airborne sounds can be measured using a commercial condenser microphone; however, cartilage conduction sounds are impossible to measure using a conventional head and torso simulator (HATS), because the standard-issue ear pinna simulator cannot reproduce cartilage conduction sounds with the same spectral characteristics as the corresponding sounds measured in humans. Therefore, this study replaced the standard-issue simulator with a developed pinna simulator that can produce similar spectral characteristics to those of humans. The HATS manipulated in this manner realized results demonstrating that transducers that fitted the entrance to the external auditory canal more densely could produce greater cartilage conduction sounds. Among the five transducers under test, the ring-shaped device, which was not much larger than the entrance to the canal, satisfied the spectral requirements.

Keywords: cartilage conduction; pinna simulator; head and torso simulator; sound pressure level

1. Introduction

Cartilage conduction offers a sound transmission pathway into the cochlea, in addition to the air and bone conduction routes [1–3]. The human aural pinna and the exterior half of the external auditory canal are composed of aural cartilage, in which amplified sound propagates when a transducer touches the aural cartilage. The transmission pathways by which the sound reaches the cochlea can be assumed in the following three cases to be as shown in Figure 1 [4,5]. The first pathway is that where the airborne sound from the transducer arrives at the ear drum directly through the external auditory canal (air pathway). In this case, the aural cartilage does not intervene in the hearing process. The second pathway is that where the oscillated cartilage generates the sound in the canal, and this sound then propagates through the eardrum and the middle ear (cartilage–air pathway). The third pathway is the case where the vibration of the cartilage is transmitted into the skull bone (cartilage–bone pathway). Our acoustic measurements and psycho-acoustic experiments have proved previously that the cartilage–air pathway contributes in a dominant manner to the hearing of users without any disorder of the outer ear [4–6]. Yazama et al. (2023) confirmed transmitted vibrations at ear ossicles (i.e., middle ear) by using a non-contact laser Doppler vibrometer when a transducer was stimulated at the ear tragus of participants under cochlea implant surgery [7]. Because sounds in the air and cartilage–bone pathways are classified as only airborne and bone-borne sounds, respectively, the unclassified sound transmitted through the cartilage–air pathway is referred to as the third pathway [3]. Besides cartilage conduction, the third form of hearing has been introduced in various research (e.g., non-osseous bone conduction [8], body conduction [9], ankle audiometry [10,11], or distantly presented bone conduction perception [12]). However, in this study, the used transducers actively stimulated the aural cartilage, so it is reasonable to define it as cartilage conduction.

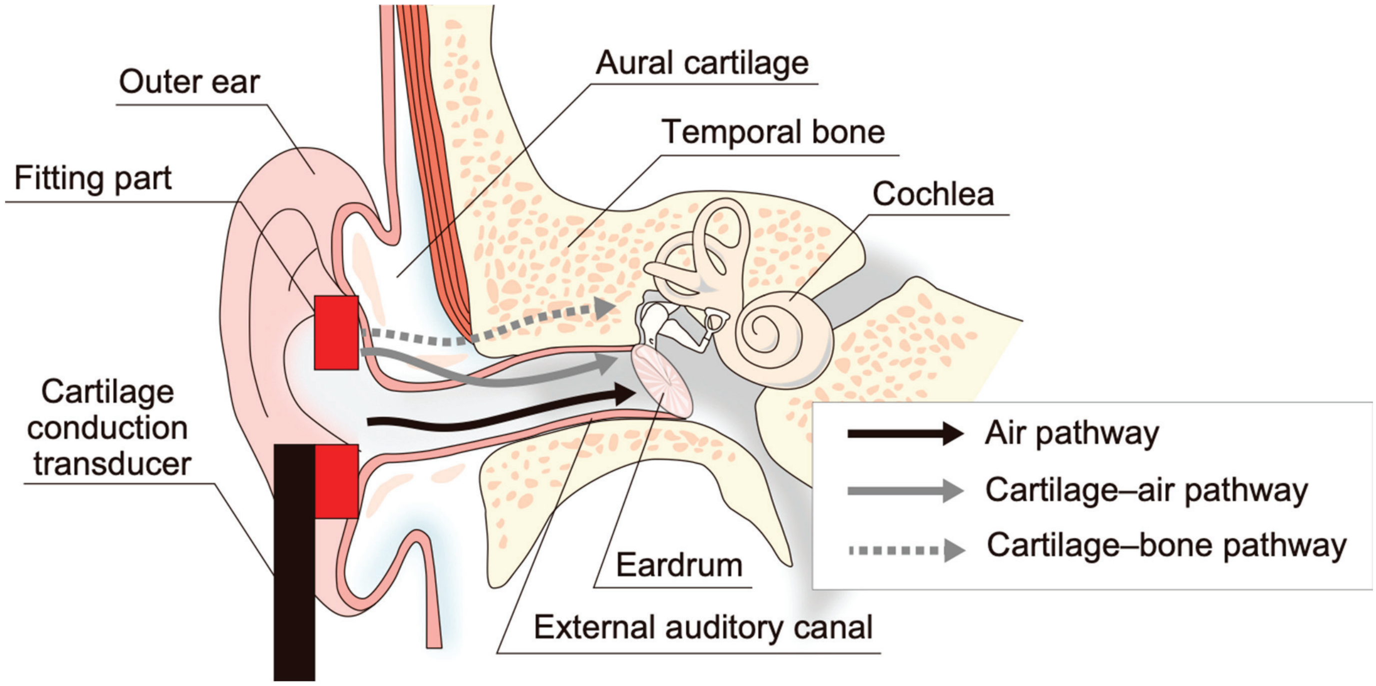

Figure 1. Possible transmission pathways when a transducer is placed on the aural cartilage.

The main performance requirement for a cartilage conduction transducer is to transmit vibrations to the aural cartilage effectively. As shown in Figure 2, the first transducer was designed in a ring shape to gain a contact surface with the entrance to the auditory canal [13]. The ring shape shown can produce sound without occluding the external auditory canal; however, the standing wave formed in the canal ensures that the sound leakage is minimized [14]. A piezoelectric bimorph covered in elastic material is built in the shaft part and an acrylic ring (fitting part) is connected to the bimorph. In most papers at the beginning of our cartilage conduction research, the first transducer type was used (e.g., [4–6,13,14]). In this study, we compared the output performances of successive cartilage conduction transducers when cartilage conduction was induced. The piezoelectric transducer is one of the target transducers assessed in this study (Figure 3a).

To minimize the transducer size, we developed electromagnetic transducers in anticipation of their use in commercial release hearing aids (Figure 2). Finally, the Japanese hearing aid manufacturer RION Co., Ltd. (Kokubunji, Japan) developed their first electromagnetic transducer embedded in a cartilage conduction hearing aid, as shown in Figure 3b [15]. The cartilage conduction hearing aid was developed to support conductive hearing losses (e.g., atresia of the external auditory canal and the otorrhea). Therefore, the transducers that are available in the market are covered with custom-made acrylic ear plugs, because they do not need to maintain ventilation with respect to the external auditory canal. Although patients with the conductive hearing loss are generally counseled to use bone conduction hearing aids, cartilage conduction hearing aids realize similar hearing thresholds after fitting the bone conduction and bone-anchored hearing aids [16,17]. In this study, the electromagnetic transducer was used without a cover to retain the gap with respect to the entrance to the auditory canal (Figure 3b).

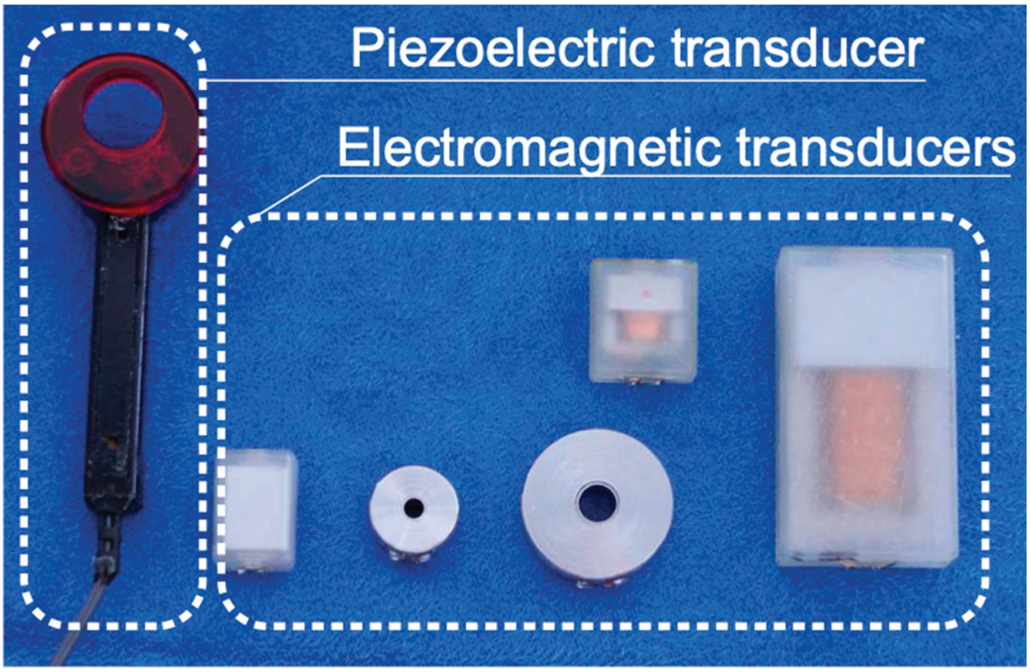

Figure 2. Piezoelectric transducer and electromagnetic transducers developed in our group.

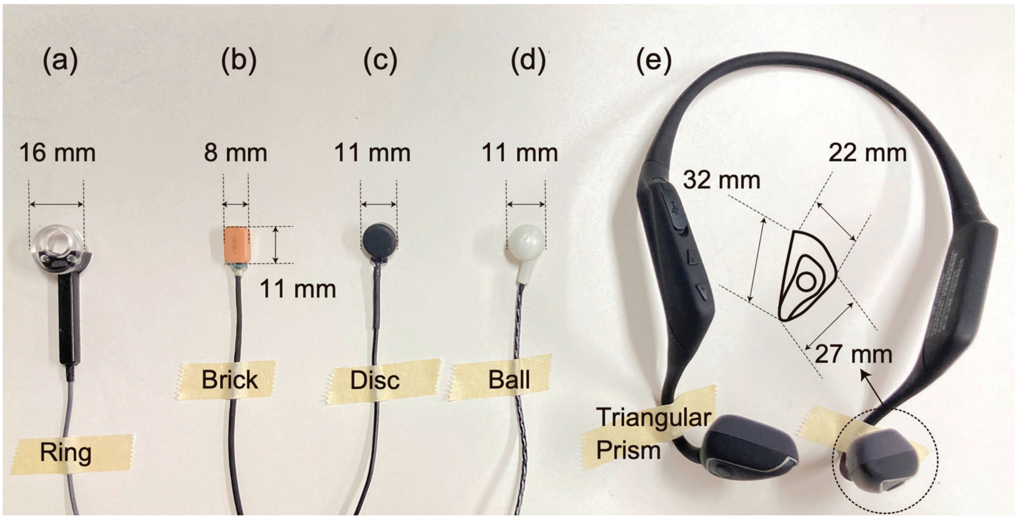

Figure 3. Five cartilage conduction transducers used in this study. (**a**–**e**) Photos and dimensions for transducers A to E, respectively.

After the release of the cartilage conduction hearing aid above, a company specializing in the manufacture of cartilage conduction transducers, CCH Sound Co., Ltd. (Kyoto, Japan), was established [18]. This company has developed two types of mass-produced transducer (the CCH sound disk and the CCH sound ball), which were optimized to induce cartilage conduction while also maintaining the existing market prices. Electromagnetic drivers were applied in these transducers. The CCH sound disk was not designed to fit on the canal entrance because it is a mounted component, while the CCT sound ball is designed to be fixed on the canal entrance, as shown in Figures 3c and 3d, respectively. The CCH sound disk and the CCH sound ball were used in their factory shipped states in this study.

Based on the existing patents and through consultation with CCH Sound, the audio equipment maker Audio Technica Co., Ltd. (Machida, Japan) developed the world's first earphone specifically for cartilage conduction hearing [19]. The two transducers are connected via a flexible wire arm and placed on the ear tragi to hold the head (Figure 3e). As a result, these transducers do not occlude the external auditory canals and it is recommended that the user does something such as listen to music in the background. The transducer can be connected to a player through Bluetooth. Because the stimulation at the temple is unsuitable for transmitting sound via bone conduction [20], the cartilage conduction sound may support the primary contribution of hearing by this device.

The purpose of this study was to compare the cartilage conduction sounds produced by the five transducers (Figure 3) that were specifically developed to generate them. Before the measurement of the cartilage conduction sounds, the outputs for airborne sounds were measured using a 1/2-in condenser microphone. The cartilage conduction sounds were simulated using a head and torso simulator (HATS), in which the ear pinna simulator had been replaced with the specially designed simulator to realize the cartilage conduction sounds [21]. The new simulator was used because the default pinna simulator used in the HATS is made from silicone rubber and is too soft to reproduce a spectral shape that is the same as that of the measured cartilage conduction sounds in humans [22]. The limitation of such an artificial head has also been reported in research on hearing protection [23,24]. As described above, cartilage conduction is not classified as airborne sound because the sound source is simply part of the body (i.e., the aural cartilage). Therefore, the HATS that is commonly used for the calibration of air conduction hearing aids [25] is useless for the evaluation of cartilage conduction sounds. In our previous study, we found that the hardness of the pinna simulator should match that of the actual aural cartilage and skin (durometer hardness: A10 to A20) to simulate cartilage conduction sounds [26], although the hardness of the pinna shows a large deviation according to the measurement equipment and individuals [27–29]. Because the pinna simulator of the HATS is removable from the body, we fabricated a mold that enabled us to form new pinna simulators with three different hardnesses (A10) [21]. Although the modified HATS was specifically constructed for cartilage transducers, there remain some errors in terms of the spectral representation, which are referred to in the discussion section. This study concentrates solely on comparing the different performances among cartilage conduction transducers. In previous studies related to cartilage conduction, a few types of transducers were used [4–7,14]. The main novelty of this study is to clarify the optimal shape and configuration for stimulating the aural cartilage.

2. Method

2.1. General Methods

The input signal to the transducer was a pure-tone train with frequencies ranging from 125 Hz to 16 kHz in 1/12 octave steps. The tones were 1 s in duration and each tone was followed by a 0.5 s long silent interval. The input levels were varied according to the transducer type. For the piezoelectric transducer (termed Transducer A in Figure 3a), the input levels were 2, 1, and 0.5 V; however, for the electromagnetic transducers (Transducers B, C, D, and E in Figure 3b, Figure 3c, Figure 3d, and Figure 3e, respectively), the input levels were 0.2, 0.1, and 0.05 V to adjust the differences for efficient amplification. The sound pressure levels (SPLs) were determined based on the spectral peaks at the corresponding pure-tone frequencies. In this study, the differences in the input levels were conveniently termed the high, middle, and low inputs in descending order.

The pure tones, which were recorded using a condenser microphone and the HATS (see Sections 2.3 and 2.4 for further details), were adjusted using a conditional amplifier (NEXUS; Brüel & Kjær, Naerum, Denmark). Both the output and input data were digitized at a sampling rate of 44.1 kHz and with 16-bit resolution via an analog-to-digital/digital-to-analog (AD-DA) converter (Fireface UCX, RME, Haimhausen, Germany); the resulting data were then controlled using a PC (MacBookPro; Apple, Cupertino, CA, USA). The sound recordings were made in a soundproof chamber with background noise of less than 30 dB.

2.2. Cartilage Conduction Transducers

The five specialized transducers for cartilage conduction (Transducers A to E) are shown in Figure 3. Transducers A to D have line connections and transducer E is available via a Bluetooth connection. Although transducer E has two drivers for the left and right sides, only the right side was used during the measurements. Although transducer E has several digital signal processing (DSP) options, it was reset to its factory settings. Since all the transducers maintain the ventilation of the external auditory canal, the occlusion effect, which is known for increasing sound pressure below 1.2 kHz, could be minimized [30–33].

2.3. Measurement of Airborne Sound

To evaluate the simple acoustic output, the signals were measured using a 1/2-in condenser microphone (4191, Brüel & Kjær, Naerum, Denmark), which was separated from the transducers by a distance of 7 to 10 mm (Figure 4a). The transducers were hung in order to face the vibrating surfaces toward the diaphragm of the microphone.

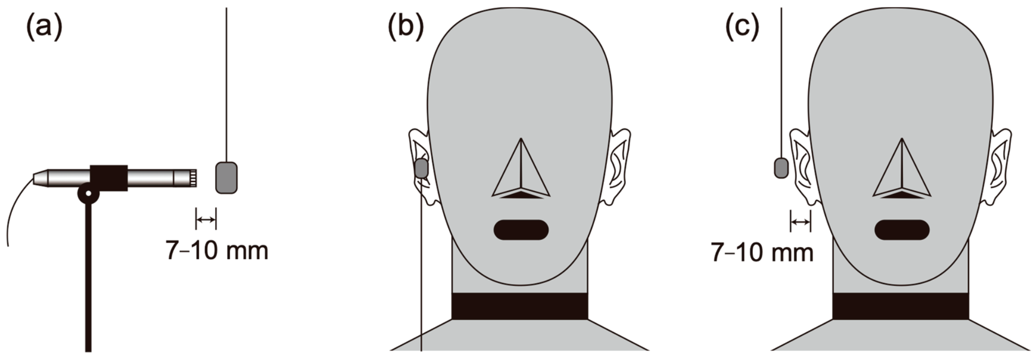

Figure 4. Measurement conditions for (**a**) airborne sound and cartilage conduction sound under (**b**) the touching condition and (**c**) the non-touching condition.

2.4. Measurement of Cartilage Conduction Sound

To evaluate the cartilage conduction sounds, the signals were measured using the right ear of a HATS (4128, Brüel & Kjær, Naerum, Denmark). As shown in Figure 5, the existing pinna simulator of the right ear was replaced with our pinna simulator, the hardness of which was adjusted to reproduce the cartilage conduction sound more correctly [21]. The spatial gap between the pinna simulator and the HATS body was filled using rubber cement (Blu Tack, Bostik Australia Pty. Ltd., Thomastown, Australia) to prevent sound leakage.

To estimate the cartilage conduction gains, we performed the measurements under two conditions. The first condition involved placing the transducer in contact with the pinna simulator (the touching condition shown in Figure 4b); in the second condition, the transducer was placed in essentially the same position, but without touching the aural cartilage (the non-touching condition shown in Figure 4c). Because the transducer generated a collateral airborne signal (the air pathway shown in Figure 1), the difference between the SPLs achieved under these two conditions allowed us to specify the amount of the signal to be transmitted through the cartilage–air pathway alone (cartilage–air pathway shown in Figure 1) [4]. Transducers A to D were placed on the entrance to the canal, and transducer E was placed on the ear tragus (Figure 5b) in the touching condition. In the non-touching condition, transducers A to D were hung and transducer E was disconnected from the ear tragus by inserting a small piece of rubber cement between the flexible wire arm and the HATS body.

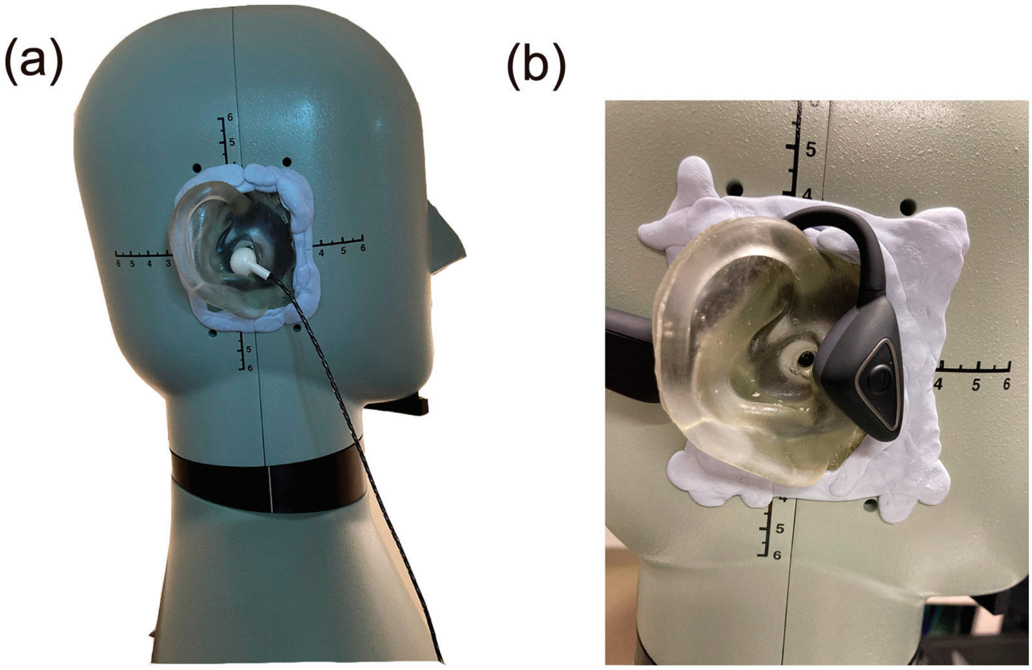

Figure 5. Head and torso simulator (HATS) with the hardness-adjusted pinna simulator with (**a**) transducer D and (**b**) transducer E.

3. Results

Figure 6 shows the SPLs for the airborne sounds radiated from the five transducers. Because the input levels of the piezoelectric and electromagnetic transducers differed and transducer E received unknown amplification from the DSP, the values for the five transducers were not comparable. However, their specific spectral gains could be found. The SPL of transducer A showed a low-pass-like filter characteristic that decayed below approximately 2.5 kHz, but remained relatively flat above that frequency (Figure 6a). The spectral shapes of transducers D and E were the flattest among the five transducers and they showed one resonance peak each in the low- (420 Hz) and high (14 kHz)-frequency ranges, respectively (Figure 6d,e). Transducers B and C both had two resonance peaks that made their spectral shapes look like bandpass filter characteristics (Figure 6b,c).

Figure 7 shows the SPLs obtained when using the manipulated HATS under the touching (solid lines) and non-touching conditions (dash lines). The cartilage conduction signals and airborne signals were measured under the touching and non-touching conditions, respectively. The spectral shapes recorded under the non-touching condition were close to the SPLs of the airborne sounds (Figure 6). Although the SPL of transducer A decayed considerably in the low-frequency range when it was not touching the pinna simulator, this reduction was avoided by making contact with the pinna simulator (Figure 7a). The SPL difference (i.e., the SPL under the touching condition minus the SPL under the non-touching condition) was a large positive value in the frequency range below 1.5 kHz, as shown in Figure 8a. Additionally, in transducers B to E, gain in the low-frequency range could be observed; however, the amplification was not as high and it was only induced in the lower-frequency range (below 500 Hz). The amplification produced by the cartilage–air pathway could be observed in the SPL difference, as illustrated in Figure 8b–e. Among the observed results, the amplifications recorded around 250 Hz were relatively high for transducers B and D.

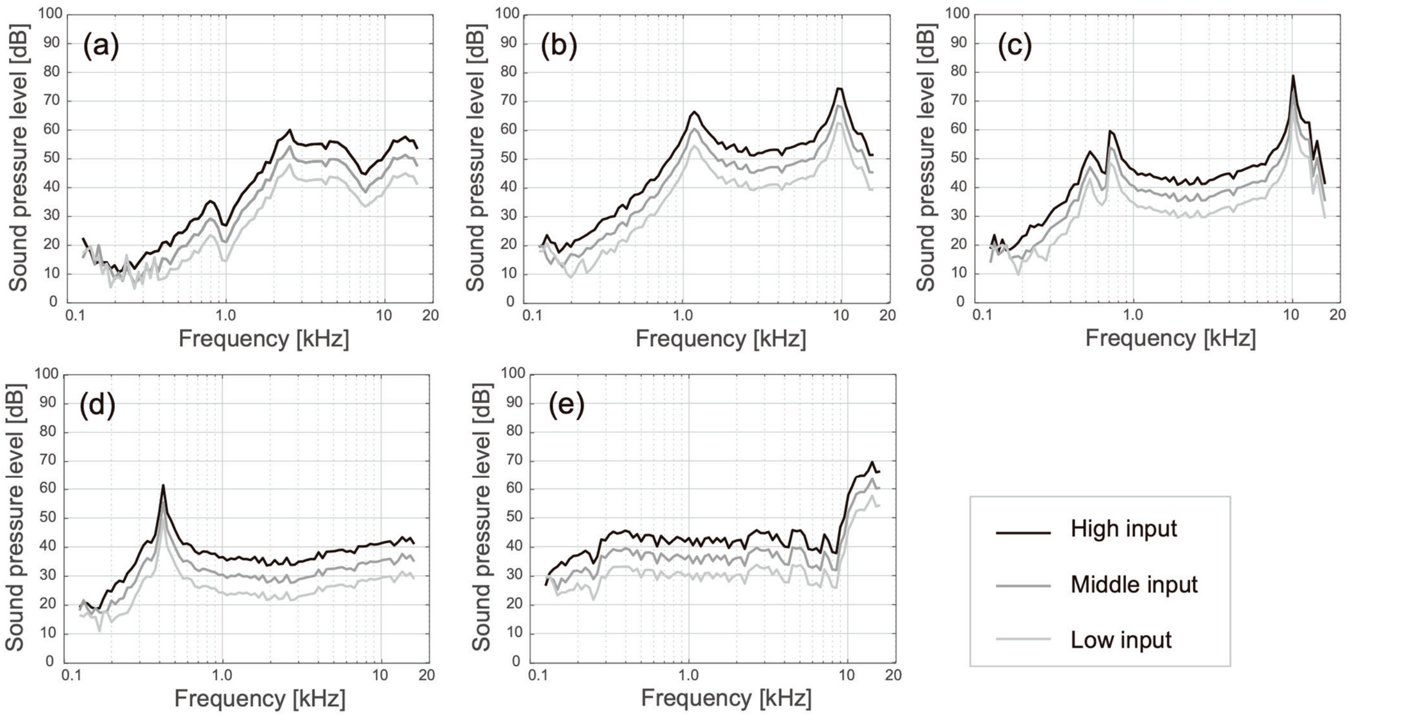

Figure 6. Sound pressure level (SPL) of airborne sound as a function of frequency. (**a**–**e**) Represent the results for transducers A to E, respectively.

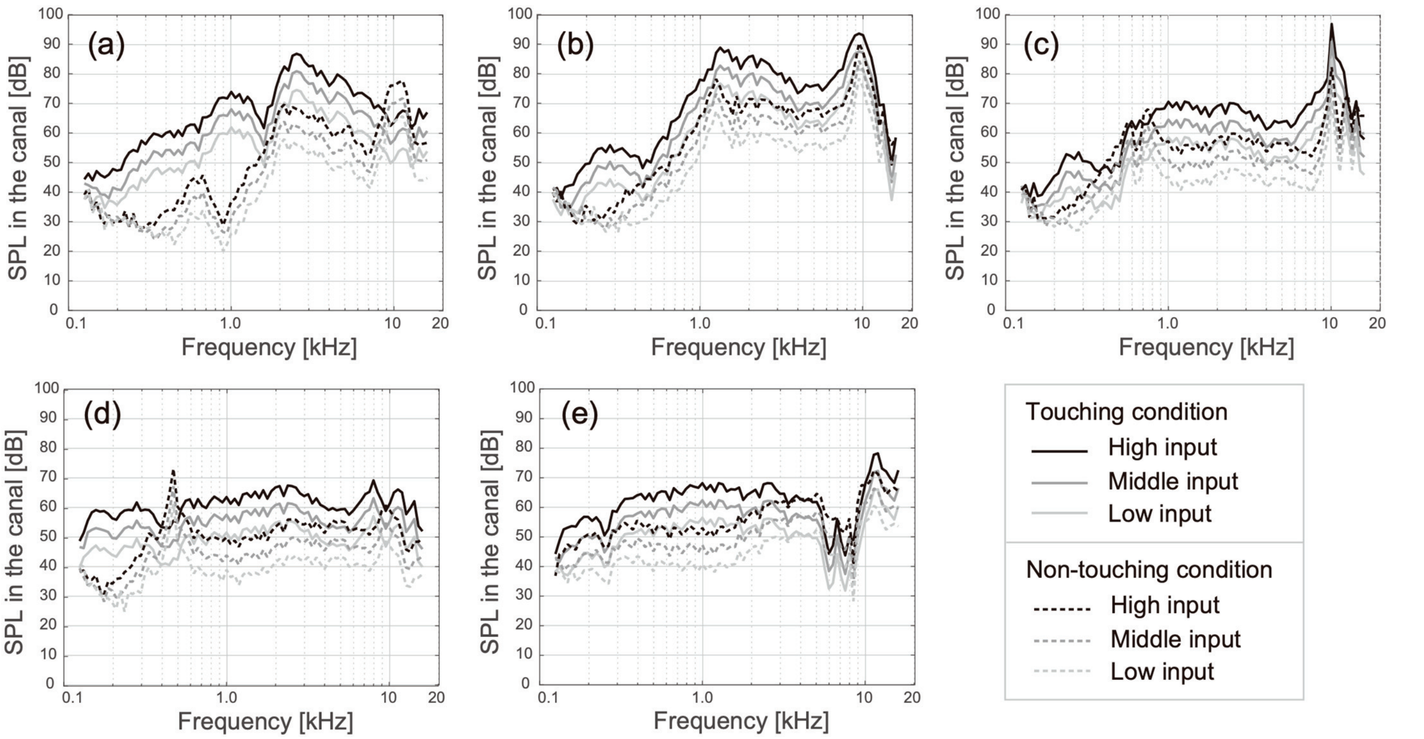

Figure 7. SPLs of cartilage conduction signal under the touching condition (solid lines) and airborne signal under the non-touching (dashed lines) condition. Differences in the gray scale indicate the input levels. (**a**–**e**) Represent the results for transducers A to E, respectively.

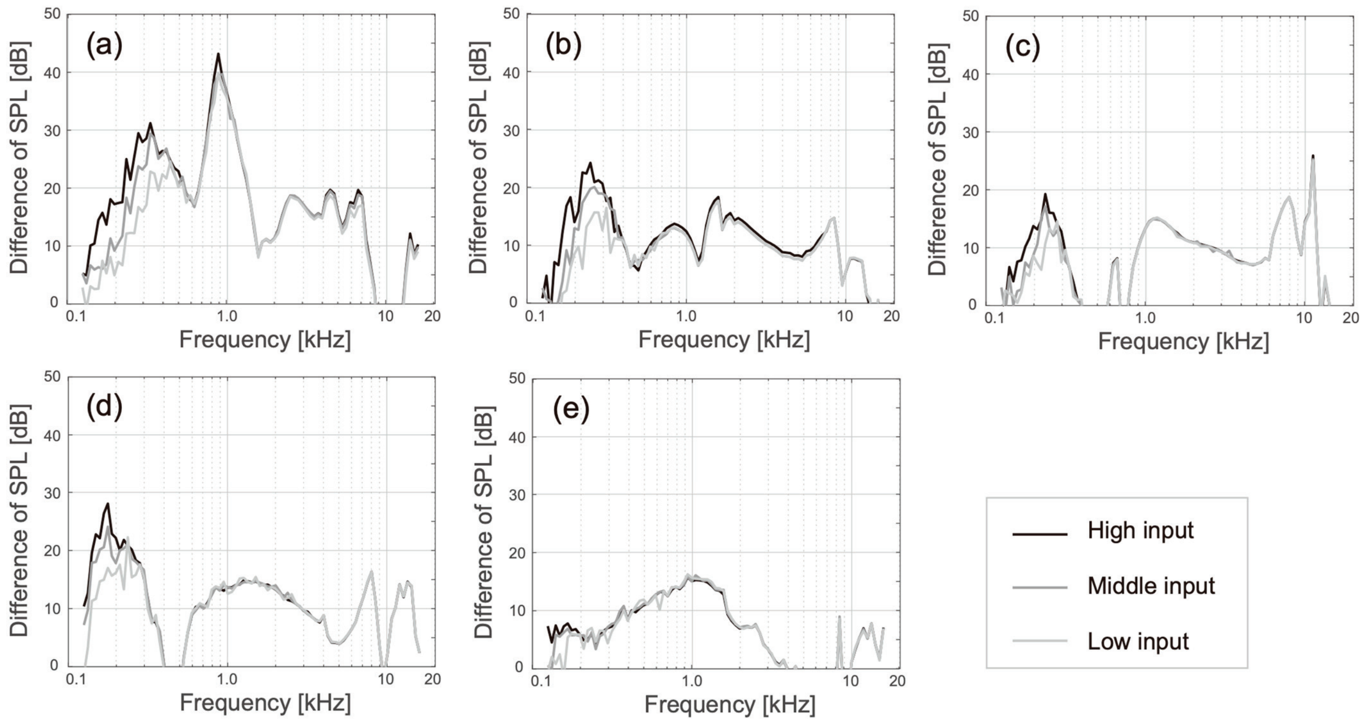

Figure 8. Differences between the SPLs under the touching and non-touching conditions. (**a**–**e**) Represent the results for transducers A to E, respectively.

4. Discussion

Before discussing these results, we confirmed the ability of the current pinna simulator to reproduce the measured cartilage conduction sound in humans. In the previous study, the cartilage conduction sounds produced using the same hardness-adjusted HATS were compared with those produced by humans when transducer A oscillated at the canal entrance [21]. Although the corresponding values and spectral shapes were entirely similar to each other, the measured cartilage conduction sound was approximately 5 dB higher than the simulated cartilage conduction sound in the frequency range below 800 Hz. Additionally, in the frequency range higher than 5 kHz, the simulated cartilage sound was greater than the measured sound, which means that the simulated sound in this range had a lower reliability.

As shown in Figure 1, the sound transmissions during the usage of the transducers were separated into the air, cartilage–air, and cartilage–bone pathways. When a listener has normal outer ears which do not suffer from atresia of the external auditory canal, the hearing contribution via the cartilage–bone pathway is to a small extent due to the mismatch of the mechanical impedance between the aural cartilage and skull bone, and the proportion of the air and cartilage–air efforts can be quantified comparing the two cases where the transducer contacts (touching condition) or does not contact (non-touching condition) the aural cartilage [4]. In the touching condition, both the air and cartilage–air pathways work, while, in the non-touching condition, only the air pathway is functional. So, the difference between the two cases in dB indicates added sound coming through the cartilage–air pathway. For normal listeners, the transmission via this pathway is essential cartilage conduction sound.

Among the five transducers, only transducer A applied a piezoelectric driver, which was distinguished from the fitting part (the acrylic ring). Transducer A was developed for laboratory use and fitted on the averaged size of the canal opening. Transducer A could not produce airborne sound in the frequency range below 2.5 kHz (Figure 6a and dashed lines in Figure 7a); however, the cartilage conduction sound could fill this gap by contacting the pinna simulator (solid lines in Figure 7a), and the amplification by touching to the cartilage was the highest among the five transducers (Figure 8a). In the touching condition, sound arrived to the ear drum via the air and cartilage–air pathways, while, in the non-touching condition, it arrived only via the air pathway (Figure 1). Therefore, the difference between the two conditions theoretically indicates the amount of cartilage conduction sound via the cartilage–air pathway. Because the drive part of transducer A is long, thin, and located away from the entrance to the canal, the transducer can minimize the airborne sound and maximize the cartilage conduction sound. Furthermore, a larger ring-shaped fitting part extended the boundary of the canal's entrance, which means that increased contact pressure and a larger contact surface may maximize the cartilage conduction sound. In fact, the amplitude of the sound produced by the cartilage conduction transducer increased with an increasing application force at the contact surface [4] and the aural cartilage was vibrated satisfactorily in the low-frequency range [34]. A consideration of the simulation gap described at the beginning of this section indicates that the solid lines shown in Figure 7a may shift upward in parallel by an additional 5 dB.

Generally, a versatile transducer should produce equivalent outputs in accordance with the frequency. In that sense, transducers D and E are ideal because of their flat spectral shapes for the airborne sound (Figure 6d and 6e, respectively). Transducers D and E were developed for directly fitting on the canal opening and tragus without any supporting accessories, respectively. Transducers D and E are currently applied to sound collectors for conversation over a window counter and earphones for listening to music, respectively. The cartilage conduction sound amplitude was greater for transducer D than for transducer E, as shown in Figure 8d and 8e, respectively. The shape of transducer D is designed to fit the canal entrance, and thus, its contact surface may be larger than that of transducer E. In contrast, transducer E was placed on the ear tragus, which was located 1 cm away from the entrance to the canal, because the tragus is one of the best positions to maximize the transducer–cartilage coupling [34,35]. The flexible wire arm was designed to hold the head softly enough to enable the use of the device over long periods (Figure 5b). Therefore, transducer E could not realize sufficient amplification via the cartilage–air pathway.

Although transducers B and C had two resonance peaks in their airborne sound characteristics (Figure 6b and 6c, respectively), the lower peak around 1 kHz faded into the cartilage conduction sounds (solid lines in Figure 7b and 7c, respectively). The higher peak around 10 kHz remained visible against the cartilage conduction sounds; however, our developed pinna simulator overaccentuated the simulated SPL in the frequency range above 5 kHz [21], and the resulting simulation errors may have emphasized the higher peaks. The cartilage conduction sounds were comparable with those of transducers B and C. Transducers B and C were both smaller in size than the canal entrance (Figure 3b and 3c, respectively); therefore, they were simply placed on the entrance without any contact pressure. These transducers are embedded within ear plugs during actual use. Transducer B has not been installed in any product yet, while transducer C with the ear plugs is used for commercially available hearing aids. When the fitting parts are designed to maximize the contact pressure and the contact surface in a painless manner, the cartilage conduction sounds may then be greatly improved.

Which factor in the transducers influenced the different gains in cartilage conduction sound? To discuss the question, we calculate the averaged SPL of cartilage conduction sound, as shown in Figure 8. In this calculation, the negative values (e.g., around 10 kHz in Figure 8a) were excluded, and the used data were only the SPLs in response to the high input (black lines in Figure 8). The averaged SPLs of the cartilage conduction sound were 19.26 dB for transducer A, 11.61 dB for transducer B, 10.41 dB for transducer C, 12.03 dB for transducer D, and 8.35 dB for transducer E. To compare these values, we estimate the rough value of the contact surface to the entrance of the canal or ear tragus. Transducer A has a ring shape, so it can be assumed that the lower half part of the rim (exterior edge of the ring) touches the entrance of the canal. Because the thickness of the ring is 5 mm, the contact surface area can be estimated as 126 mm^2. Transducer B may contact at the larger face of the cube shape, so the contact surface is 88 mm^2. Similarly, transducer C contacts at the circle face of the disk, so the contact surface area is 95.03 mm^2. Transducer D has a ball shape, so the contact surface is likely to be a lower half part of the inner hemisphere, as shown in Figure 5a. This prediction derives that the contact surface should be 95.03 mm^2. Transducer E has a triangular-prism shape, and it contacts the ear tragus at the triangle face. When the longest side is assumed roughly as the hypothenuse of a right triangle, the contact surface area becomes 297 mm^2.

When the generation efficiency of the cartilage conduction sound is expressed by the averaged SPL per the contact surface area, they were 0.15 dB/mm^2 for transducer A, 0.13 dB/mm^2 for transducer B, 0.11 dB/mm^2 for transducer C, 0.13 dB/mm^2 for transducer D, and 0.03 dB/mm^2 for transducer E. The generation efficiency of transducer E was much lower than those of the other transducers. One of the reasons for this is the overrated contact surface area. The bumpy surface around the tragus may reduce the contact area in the triangle face. Although the tragus is estimated to be an appropriate position to fit the cartilage conduction transducer [34,35], the area of tragus is too small and bumpy, so the pinpoint stimulation on it is so hard. Wearing and fixing a transducer on the entrance of the canal seems to be the most reasonable way of oscillating the aural cartilage effectively.

In transducers A to D, the maximum generation efficiency was presented by transducer A. It seems that the SPL of the cartilage conduction sound may be determined not only by the contact surface area, but also the contact pressure (application force). Transducers B to D were put on the entrance of the canal without any application force; however, transducer A pushed the boundary of the canal's entrance softly. According to the previous study, the relationship between the SPL of the cartilage conduction sound and application force is 34 dB/N below 1 N of force [4]. If the application forces on putting transducers B and D can be assumed to be 0 N, the application force for transducer A becomes 0.08 N ($(19.26 - 0.13 \times 126)/34$). Compared with the required application force of a bone conduction transducer (1 N), we can understand that the required force for oscillating the aural cartilage is much lower.

5. Conclusions

To evaluate the performances of five transducers that were developed specifically to produce cartilage conduction sounds, airborne sounds and cartilage conduction sounds were measured using a condenser microphone and a custom HATS with a manipulated ear pinna simulator, respectively. The ring-shaped transducer (transducer A) was able to minimize the airborne sound and maximize the cartilage conduction sound because the contact pressure and contact surface with the canal entrance appeared to be the largest among the five transducers. To maximize the cartilage conduction sound, it is important to design the fitting part to maximize both the contact pressure and the contact surface within the range in which the user does not feel pain. In cases where it is necessary to maintain the ventilation with respect to the external auditory canal, the ring-shaped fitting part may be the optimal choice.

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References

1. Hosoi, H. Receiver. Japanese Patent Application Number 166644, 4 June 2004.
2. Hosoi, H. Approach in the Use of Cartilage Conduction Speaker. Japanese Patent Number 4541111, 17 November 2004.
3. Hosoi, H.; Nishimura, T.; Shimokura, R.; Kitahara, T. Cartilage conduction as the third pathway for sound transmission. *Auris Nasus Larynx* **2019**, *46*, 151–159. [CrossRef]
4. Shimokura, R.; Hosoi, H.; Nishimura, T.; Yamanaka, T.; Levitt, H. Cartilage conduction hearing. *J. Acoust. Soc. Am.* **2014**, *135*, 1959–1966. [CrossRef] [PubMed]
5. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Yamanaka, T.; Levitt, H. Is cartilage conduction classified into air or bone conduction? *Laryngoscope* **2014**, *124*, 1214–1219. [CrossRef] [PubMed]
6. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Yamanaka, T.; Kitahara, T.; Levitt, H. Cartilage conduction is characterized by vibrations of the cartilaginous portion of the ear canal. *PLoS ONE* **2015**, *10*, e0120135. [CrossRef] [PubMed]
7. Yazama, H.; Arii, S.; Kataoka, H.; Watanabe, T.; Kamitani, R.; Fujiwara, K. In vivo measurement of ear ossicle and bony wall vibration by sound stimulation of cartilage conduction. *Audiol. Res.* **2023**, *13*, 495–505. [CrossRef]
8. Vento, B.A.; Durrant, J.D. Assessing bone conduction thresholds in clinical practice. In *Handbook of Clinical Audiology*; Katz, J., Burkard, R., Hood, L., Medwetsky, L., Eds.; Lippincott, Williams & Wilkins: Baltimore, MD, USA, 2009.
9. Ravicz, M.E.; Melcher, J.R. Isolating the auditory system from acoustic noise during functional magnetic resonance imaging: Examination of noise conduction through the ear canal, head, and body. *J. Acoust. Soc. Am.* **2001**, *109*, 216–231. [CrossRef]
10. Verrecchia, L.; Fredén Jansson, K.J.; Westin, M.; Velikoselskii, A.; Reinfeldt, S.; Håkansson, B. Ankle Audiometry: A Clinical Test for the Enhanced Hearing Sensitivity for Body Sounds in Superior Canal Dehiscence Syndrome. *Audiol. Neurootol.* **2023**, *28*, 219–229. [CrossRef]
11. Brantberg, K.; Verrecchia, L.; Westin, M. Enhanced Auditory Sensitivity to Body Vibrations in Superior Canal Dehiscence Syndrome. *Audiol. Neurootol.* **2016**, *21*, 365–371. [CrossRef]
12. Ishikawa, H.; Otsuka, S.; Nakagawa, S. Basic properties of distantly-presented bone-conduction perception. In Proceedings of the 2021 43rd Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC), Mexico, 1–5 November 2021; pp. 6376–6379.
13. Hosoi, H.; Yanai, S.; Nishimura, T.; Sakaguchi, T.; Iwakura, T.; Yoshino, K. Development of cartilage conduction hearing aid. *Arch. Mater. Sci. Eng.* **2010**, *42*, 104–110.
14. Shimokura, R.; Hosoi, H.; Iwakura, T.; Nishimura, T.; Matsui, T. Development of monaural and binaural behind-the-ear cartilage conduction hearing aids. *Appl. Acoust.* **2013**, *74*, 1234–1240. [CrossRef]
15. Available online: https://www.rionet.jp/product/series/ccha/ (accessed on 1 August 2023).
16. Nairn, E.M.; Chen, A.S.; Nishimura, T.; Berezovsly, A.; Stucken, E.Z. Hearing outcomes of new cartilage conduction device vs bone conduction devices. *Otol. Neurotol.* **2022**, *168*, 821–828. [CrossRef]
17. Kitama, T.; Nishiyama, T.; Iwabu, K.; Wakabayashi, T.; Shimanuki, M.N.; Hosoya, M.; Oishi, N.; Ozawa, H. Comparison of cartilage conduction hearing aid, bone anchored hearing aid, and ADHEAR: Case series of 6 patients with conductive and mixed hearing loss. *Appl. Sci.* **2022**, *12*, 12099. [CrossRef]
18. Available online: https://cch-sound.co.jp/ (accessed on 1 August 2023).
19. Available online: https://www.audio-technica.co.jp/product/ATH-CC500BT (accessed on 1 August 2023).
20. Wang, J.; Stenfelt, S.; Wu, S.; Yan, Z.; Sang, J.; Zheng, C.; Li, X. The effect stimulation position and ear canal occlusion on perception of bone conducted sound. *Trends Hear.* **2022**, *26*, 23312165221130185. [CrossRef]
21. Shimokura, R.; Nishimura, T.; Hosoi, H. Manipulating the hardness of HATS mounted ear pinna simulators to reproduce cartilage sound. *Appl. Sci.* **2022**, *12*, 12532. [CrossRef]
22. Shimokura, R.; Hosoi, H.; Nishimura, T.; Iwakura, T.; Yamanaka, T. Simulating cartilage conduction sound to estimate the sound pressure level in the external auditory canal. *J. Sound Vib.* **2015**, *335*, 261–268. [CrossRef]
23. Berger, E.H. Hearing Protector Performance: How They Work-and-What Goes Wrong in the Real World. 1980. Available online: https://multimedia.3m.com/mws/media/893183O/earlog-5.pdf (accessed on 6 November 2023).
24. Berger, E.H. Preferred methods for measuring hearing protector attenuation. In *INTER-NOISE and NOISE-CON Congress and Conference Proceedings*; Institute of Noise Control Engineering: Reston, VA, USA, 2005; Volume 2005, pp. 4432–4441.
25. *IEC 60318-7*; Electroacoustics—Simulations of Human Head and Ear—Part 7: Head and Torso Simulator for the Measurement of Hearing Aids. International Electrotechnical Commission: Geneva, Switzerland, 2011.
26. Shimokura, R.; Nishimura, T.; Hosoi, H. Vibrational and acoustical characteristics of ear pinna simulators that differ in hardness. *Audiol. Res.* **2021**, *11*, 30. [CrossRef]
27. Griffin, M.F.; Premakumar, Y.; Seifalian, A.M.; Szarko, M.; Butler, P.E.M. Biomechanical characterization of human auricular cartilages; Implications for tissue engineering. *Ann. Biomed. Eng.* **2016**, *44*, 3460–3467. [CrossRef] [PubMed]

28. Nayyer, L.; Birchall, M.; Seifalian, A.M.; Jell, G. Design and development of nanocomposite scaffolds for auricular reconstruction. *Nanomedicine* **2014**, *10*, 235–246. [CrossRef]
29. Tamura, A.; Irwansyah; Otsuka, S.; Nakagawa, S. Effects of morphology and hardness of the pinna and gender on detection threshold of cartilage conduction. *Proc. Autumn Meet. Acoust. Soc. Jpn.* **2022**, *11*, 943–944. (In Japanese)
30. Wheatstone, C. Experiments on audition. *Q. J. Sci. Lit. Art* **1827**, *24*, 67–72.
31. Zwislocki, J. Acoustic attenuation between the ears. *J. Acoust. Soc. Am.* **1953**, *25*, 752–759. [CrossRef]
32. Elpern, B.S.; Naunton, R.F. The stability of the occlusion effect. *Arch. Otolaryngol.* **1963**, *77*, 44–52. [CrossRef]
33. Stenfelt, S.; Wild, T.; Hato, N.; Goode, R.L. Factors contributing to bone conduction: The outer ear. *J. Acoust. Soc. Am.* **2003**, *113*, 902–913. [CrossRef] [PubMed]
34. Shimokura, R.; Hosoi, H.; Nishimura, T.; Yamanaka, T. Aural cartilage vibration and sound measured in the external auditory canal for several transducer positions. *J. Temp. Des. Arc. Env.* **2014**, *12*, 137–143.
35. Blondé-Weinmann, C.; Joubaud, T.; Zimpfer, V.; Hamery, P.; Roth, R. Characterization of cartilage implication in protected hearing perception during direct vibro-acoustic stimulation at various locations. *Appl. Acoust.* **2021**, *179*, 108074. [CrossRef]

audiology research

Article

Management of Cartilage Conduction Hearing Aids in Pediatric Patients

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Abstract: Forty-nine children who started wearing cartilage conduction hearing aids (CC-HAs) before completing elementary school (17 with bilateral hearing loss and 32 with unilateral hearing loss) were followed-up and examined. The wearing and utilization status of the CC-HA and its progress to date were evaluated. In addition, 33 participants who purchased the CC-HAs were interviewed to assess the wearing effect. Eleven of seventeen children with bilateral hearing loss and 25 of 32 children with unilateral hearing loss continued to use the CC-HAs. In terms of wearing effect, a good wearing effect was reported, even by those with unilateral hearing loss. In cases where it was difficult to wear CC-HAs stably with pasting or ear tips, it was possible to fix them stably using commercially available hair bands and eyeglass vines. In two cases, the CC-HAs were worn from infancy. With ingenuity and appropriate educational and medical support, it is possible to wear CC-HAs from infancy.

Keywords: atresia; cartilage conduction hearing aids; conductive hearing loss; infant

1. Introduction

Acoustic energy traveling from a cartilage conduction transducer to the cochlea reportedly occurs via three different pathways [1]. The first is the air conduction (AC) pathway from the transducer to the eardrum, which includes the resonance effect in the canal (air pathway) because the transducer also generates a low-level air-borne signal. Vibrations of the aural cartilage and tissue surrounding the external auditory canal generate sound in the ear canal that reaches the eardrum via the AC. The second pathway, the bone conduction (BC) pathway, involves the transmission of skull bone vibrations induced by a transducer to the cochlea [2].

The third pathway, first reported in 2004, involves bone and cartilage conduction via the skull from the transducer to the cochlea (cartilage–bone pathway) [3]. Unlike AC, mechanical signals can be transmitted directly to the tissues during cartilage conduction (CC). The CC also avoids the impedance mismatch between air and skin, gaining transmission advantages in the atretic ear over the AC.

Air and cartilage–bone pathways are common routes that operate based on the same principles that pertain to regular air and bone conduction hearings, respectively. AC and BC hearing aids (HAs) use the first two types of sound transmission pathways. In contrast, the cartilage–air pathway is not a common sound conduction route. Applying vibrations generated by gently placing a transducer on the auricular cartilage can transmit audible sounds with clarity similar to that of AC or BC, leading to the development of a new type of hearing aid called a cartilage conduction hearing aid (CC-HA) [1,4]. However, the exact acoustic details of CC-HAs remain unclear.

CC-HAs can amplify and transmit sound signals to the inner ear by simply attaching a vibration generator to the skin of the auricular cartilage [5,6]. In contrast, bone conduction hearing aids (BC-HAs) also use a vibration generator placed on the body but require strong pressure and fixation on the temporal bone [7–11]. Both types of HAs are suitable for individuals with conductive or mixed hearing loss who cannot wear AC-HAs and for those with good bone conduction thresholds, such as individuals with microtia or external auditory canal atresia. The greatest advantage of using CC-HAs in clinical settings is that the transducer is significantly smaller and lighter than the conventional BC-HA. Moreover, it does not require compression fixation, which enables the CC-HAs to be attached to the skin to deliver sound vibrations to the ear. Furthermore, using CC-HAs eliminates the necessity of surgery and provides users with cosmetic advantages [12].

Since the release of CC-HAs, the attachment-only method has become the preferred option and has gained popularity as an alternative to BC-HAs [1,5,6,8,13–17]. Nishiyama et al. [17] investigated adult candidates eligible for using CC-HAs and concluded that patients with external auditory canal stenosis or anotia are the most suitable candidates. They also reported positive results in children with similar ear conditions [18]. A recent clinical trial involving CC-HA use among children has revealed that almost all parents of the patients reported satisfaction with the performance of the device and an improved daily communication in children with hearing loss [19].

Since 2020, safety measures such as battery boxes have been fully integrated, allowing the use of the device even for children under three age of 3 years [18]. In the case of infants, there are many opportunities to re-examine the possibility of using CC-HAs after starting BC-HAs; however, there have been no reports of initiating the use in infancy. Therefore, in this study, we investigated the usage and wearing progress of CC-HAs in infants and toddlers, presented cases of their application from infancy, and discussed case-specific suitability of various CC-HAs based on the unique requirements of each child.

2. Materials and Methods

2.1. Participants

This study enrolled 49 children (17 with bilateral hearing loss and 32 with unilateral hearing loss), including 28 boys and 21 girls, in whom trial hearing was initiated using the CC-HA before primary school age at our hospital. The guardians/parents of these children requested the use of CC-HAs. Trial hearing was initiated between the ages of 0 (3 months) and 11 years in children with bilateral hearing loss and between 0 (6 months) and 10 years in those with unilateral hearing loss. The mean age of the participants was 5.02 $\pm$ 2.71 (SD) years.

Figure 1 shows the age distribution of the participants at the time of trial initiation. Figure 2 presents the ratios of diagnoses of ears fitted with CC-HAs (HB-J1CC, HB-A2CC, RION Co., LTD., Tokyo, Japan).

Among the participants with bilateral hearing loss, eight had conductive hearing loss, eight had mixed hearing loss, and one participant could not undergo bone conductometry. Among the participants with unilateral hearing loss, 29 had conductive hearing loss, one had mixed hearing loss, and two could not undergo bone conductometry. Among the participants with bilateral hearing loss, two had chromosome 21 trisomy, and the remaining participants each had Treacher Collins syndrome, chromosome 18 trisomy, FOXP1 syndrome, and Primrose syndrome.

The presence of a history of HA use was not observed in cases of unilateral hearing loss, and it was only observed in five of the 17 cases of bilateral hearing loss (BC-HA: two cases at the ages of 6 and 7 years, unilateral-AC-HA: one case at the age of 5 years).

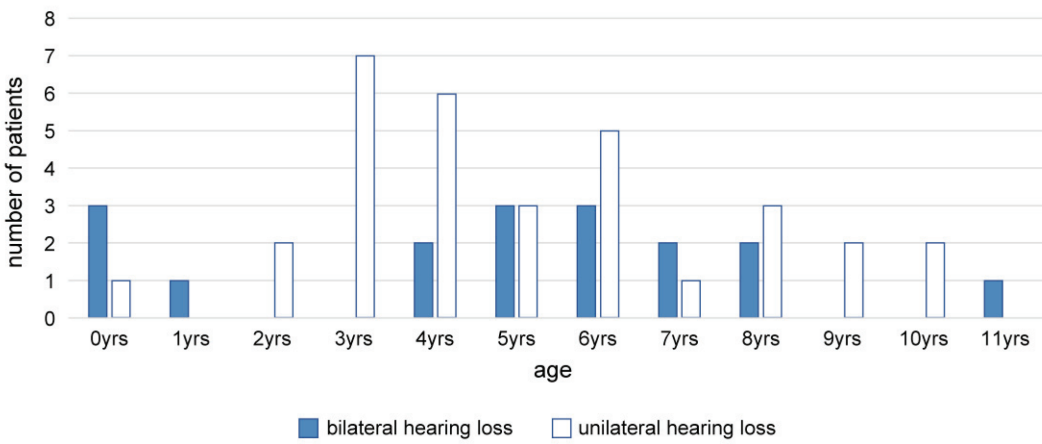

Figure 1. Age distribution of the participants at the time of the initiation of trial hearing (n = 49).

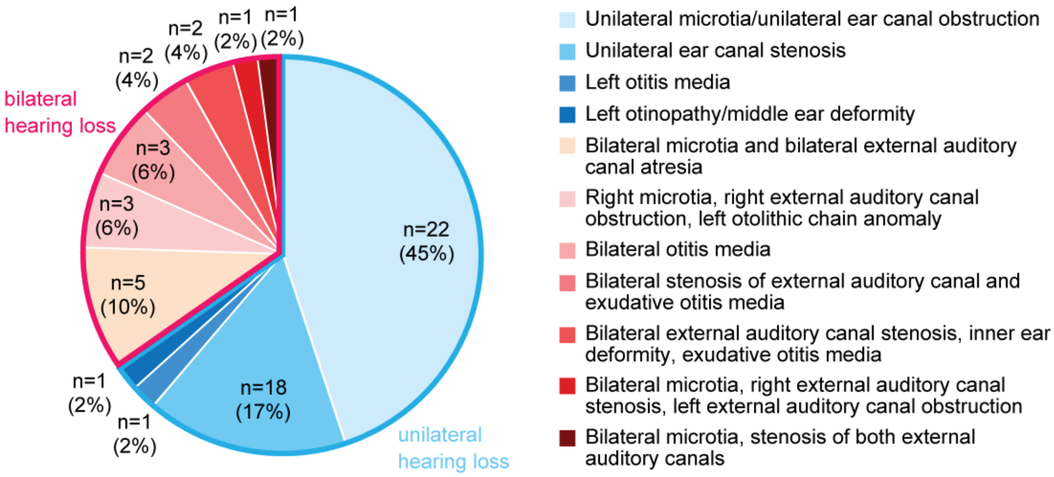

Figure 2. Diagnoses of the fitted ears.

2.2. Hearing Assessment

Auditory thresholds were assessed by an experienced audiologist in a standard soundproof room using a commercially available audiometer (Model AA-HI, RION Co., LTD., Tokyo, Japan). Pure-tone thresholds were determined using over-ear headphones (125 Hz to 8 kHz) to assess the air conductance thresholds and a calibrated bone-conducting transducer (500 Hz to 4 kHz) to assess the bone conductance thresholds. The sound field (SF) thresholds were evaluated to assess the effects of the CC-HAs. Complementary and non-complementary hearing thresholds were assessed by introducing an azimuthal angle of 0° and transmitting warble tones from a loudspeaker positioned 1 m away from the participant. As the CC-HAs were fitted on only one side in participants with unilateral hearing loss, noise masking was provided to the other ear through headphones such that the test tone could not be heard. The complementary hearing threshold for CC-HAs could not be accurately assessed in participants with unilateral hearing loss; therefore, the hearing threshold was used as the reference value. Behavioral hearing tests, such as behavioral observation audiometry (BOA) and visual reinforcement audiometry (VRA) were used to assess the hearing ability if the participant was too young to undergo the hearing tests described above. Behavioral hearing tests were performed in a manner similar to those used in previous reports from Japan [20].

2.3. Adjustment and Fitting of the Devices and Ethical Standards

The devices were fitted at the Sugiuchi Clinic. Participants or guardians were provided explanations regarding the CC-HAs. Concurrently, ENT examinations, hearing tests, and imaging were conducted to confirm HA history and indications prior to initiating the trial hearing. Trial hearing with the fitted CC-HAs was continued for 1–3 months free of charge, and the participants were instructed to assess the usefulness and comfort of using the CC-HA in their daily lives during the trial hearing period. We provided the participants with the option to extend their trial period until a satisfactory agreement was reached, which could be approximately 6 months.

The initial adjustment of the HAs was performed using the sedation level version 5 (DSL v5) procedure [21]. This procedure and the determination of the hearing threshold for the CC-HAs were similar to those for the AC-HAs. After the hearing aid was tested in an outpatient setting, the hearing threshold was assessed, and the gain and output of the HAs were predicted; fine adjustments were made if necessary. Subsequently, the trial hearing was continued for 1–2 weeks in a real-life setting. The fitting conditions and effectiveness of the HAs were evaluated during this period, and the HA was readjusted based on the user's wishes. The listening tests and adjustments were repeated until the participant or guardian decided whether to purchase the HAs without any psychological burden on the participant.

The vibration terminal (transducer) of the CC-HA was attached to the skin overlying the tragus cartilage and fixed with a double-sided adhesive tape. As the morphology and location of the tragus and auricular cartilage were not well mapped in patients with microtia or congenital aural atresia, the transducer was carefully applied to the skin overlying the cartilage near the assumed location of the tragus, with a subtle concavity (Figure 3). The sound processor of the CC-HA was affixed to the skin overlying the posterior auricle using double-sided adhesive tape. An earmold (referred to as an ear tip) was fabricated if the attachment with the adhesive tape was difficult or if the attachment was unstable, and the transducer was attached to a depressed area such as the cavity of the concha (Figure 4).

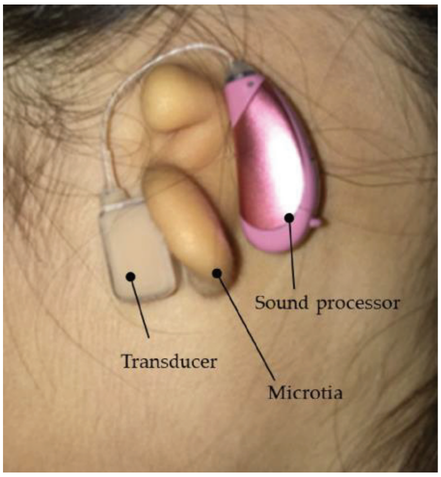

Figure 3. Profile view (left side) of a patient with congenital external ear canal atresia fitted with a cartilage conduction hearing aid (CC-HA). The transducer and sound processor components of the CC-HA (HB-J1CC, RION Co., LTD.; Tokyo, Japan) are attached to the skin using a double-sided adhesive tape.

In principle, the hearing test was initiated as described above. CC-HAs were attached to the posterior parts of both the auricles in participants with bilateral hearing loss. The CC-HAs were fitted to the affected ear in participants with unilateral hearing loss, similar to those with unilateral congenital auricular atresia. The two CC-HAs were fitted for participants with bilateral hearing loss, similar to those with bilateral congenital auricular atresia. The hearing test conditions were the same for participants with one and two CC-HAs.

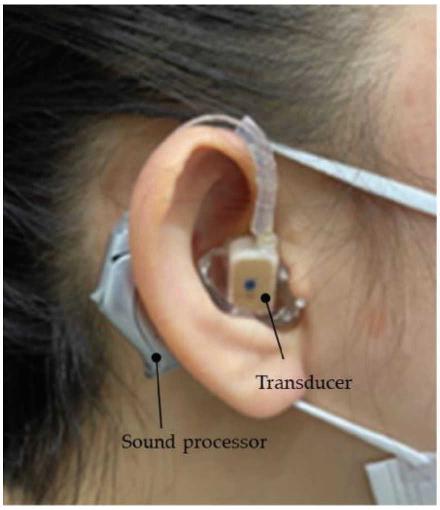

Figure 4. Profile view (right side) of a patient with congenital external ear canal atresia fitted with a cartilage conduction hearing aid (CC-HA). The transducer (with ear tips) is attached to the skin using a double-sided adhesive tape (sound processor components of the CC-HA: HB-J1CC, RION Co., LTD.; Tokyo, Japan).

Explanations regarding the indicated HAs, such as bone-conduction HAs, BAHAs (Cochlear Limited, Sydney, Australia), and the ADHEAR system (MED-EL, Innsbruck, Austria), were provided, and demonstrations via test hearing were also provided, if possible, upon request. Furthermore, the staff at the rehabilitation institution provided information regarding the need for HAs, and the model and adjustment of HAs. The final decision regarding the purchase of HAs was made by the parents based on the HA use thresholds and the combined observations and evaluations of the parents and caregivers.

This study was conducted in accordance with the "Ethical Principles for Medical Research Involving Human Subjects" [22] as stated in the Declaration of Helsinki and approved by the Ethics Committee of Kanto Rosai Hospital (Approval No.: 2023-1). The details of the study were posted in the clinic examination room. Verbal informed consent was obtained from all the participants and their guardians. The requirement for written consent was waived in accordance with the ethical guidelines for medical and health science research involving human participants [23]. Information regarding the study, including its purpose and use, was made publicly available or notified to the research participants. Participants and their guardians were informed that they could refuse to participate at any time and requested that their data be deleted after the start of the study. This information was included in the medical records of each participant.

2.4. Purchase Rate and the Evaluation of Cases That Did and Did Not Purchase CC-HA(s)

The overall purchase rate was evaluated and the participants were divided into two groups based on whether the CC-HA was purchased: purchase and non-purchase groups. Information regarding age, sex, condition of the ear fitted with the HA (affected or good ear), and mean hearing thresholds (500, 1000, and 2000 Hz) of the participants were collected and used for comparison. Participants who were too young to undergo hearing assessments such as sound field thresholds were excluded from the study.

2.5. A Simple Way to Improve Hearing Aid Fixation

The following methods were used when the HAs could not be stabilized by attaching CC-HA transducers and sound processors.

Use of hairband: In this method, a silicone rubber was sewn onto a commercially available flat rubber-like hairband to which the hearing aid body was fixed. The transducer was subsequently attached to double-sided adhesive tape (Figures 5 and 6).

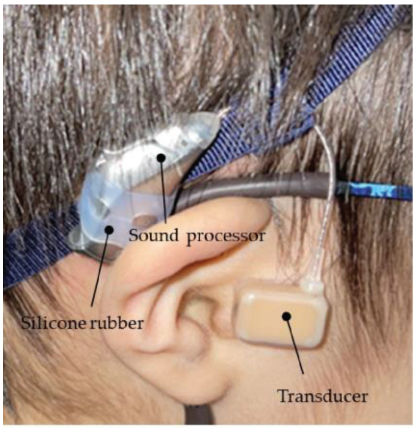

Figure 5. Profile view (right side) of a patient with Downs syndrome who has bilateral external ear canal stenosis with exudative otitis media and congenital external ear canal atresia fitted with a cartilage conduction hearing aid (fixed onto the headband with silicone rubber). The transducer is attached to the skin using a double-sided adhesive tape.

Figure 6. Silicone rubber, which is sold as a stationery item, can be used for attaching the main body of the hearing aid to the temple of the glasses or headbands.

Use of eyeglasses: In this method, the sound processor of the CC-HA was fixed to the temple of the glass using rubber or silicone rubber, and the transducer was subsequently attached (Figure 7).

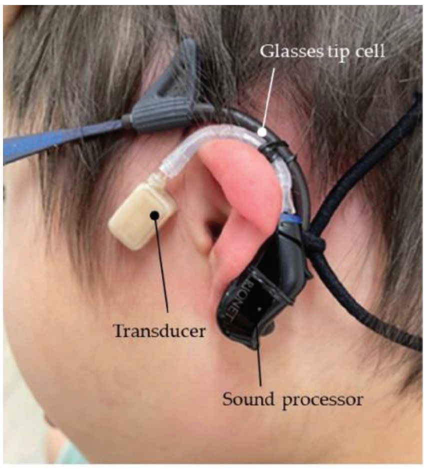

Figure 7. Profile view (left side) of a patient with bilateral external auditory canal stenosis with exudative otitis media wearing a cartilage conduction hearing aid fixed to the temples of glasses. The transducer is attached to the skin using a double-sided adhesive tape.

2.6. Evaluation after Purchase

The participants or their guardians who purchased the CC-HAs were interviewed during the consultation to understand their post-purchase status, and the participants were evaluated. The questions included the duration and effectiveness of HA use and requests for HA use. Questions and options regarding the duration and effectiveness of HA use were determined in advance.

3. Results

3.1. Purchase Rates and Differences between the Participants Who Did and Did Not Purchase CC-HAs

Among the 17 participants with bilateral hearing loss, 11 (64.7%) had purchased a CC-HA. Among the 32 patients with unilateral hearing loss, 25 (78.1%) had purchased CC-HAs. We examined the average hearing thresholds according to age, bilateral hearing loss, and unilateral hearing loss and divided the participants into purchase and non-purchase groups; however, no significant difference was observed between the purchasing and non-purchasing groups in terms of any of the measured characteristics (Table 1). Among the participants with bilateral hearing loss who purchased CC-HAs, three (17.6%) used the CC-HA only on one side, whereas AC-HAs were used on the opposite side with external auditory canal stenosis or inner ear/middle ear anomalies. None of the participants reported experiencing any complications with the use of CC-HAs, such as skin irritation. Representative cases of varying hearing conditions and fitting requirements are presented as case reports.

Table 1. Characteristics of the purchasing and non-purchasing groups.

Characteristics	Purchase Group	Non-Purchase Group	*p* Value
Age at fitting (year, Mean ± SD)	5.3 ± 2.6 (n = 36)	4.4 ± 3.0 (n = 13)	0.376 [b]
Bilateral hearing loss, Average hearing threshold [a] of the better ear (dB HL, Mean ± SD)	46.5 ± 17.3 (n = 8)	56.7 ± 16.7 (n = 3)	0.427 [b]
Threshold [a] of the worse ear (dB HL, Mean ± SD)	65.8 ± 20.3 (n = 8)	61.7 ± 22.5 (n = 3)	0.796 [b]
Unilateral hearing loss, Average hearing threshold [a] of the better ear (dB HL, Mean ± SD)	9.7 ± 5.2 (n = 24)	9.6 ± 3.4 (n = 4)	0.948 [b]
Threshold [a] of the worse ear (dB HL, Mean ± SD)	70.4 ± 12.2 (n = 24)	59.6 ± 16.3 (n = 4)	0.281 [b]

[a] Average of AC hearing thresholds at 500, 1000, and 2000 Hz. [b] Independent *t*-test.

3.2. Participants Who Did Not Purchase CC-HAs

There were various reasons for not purchasing the CC-HAs. Among the five participants with bilateral hearing loss in the non-purchase group, the parents of a 3-month-old infant selected the BC-HA because of its ease of attachment and detachment. The parents of the 6-month-old infant started using the BC-HA at a different hospital. The parents of a 7-year-old patient with bilateral microtia who was currently using a BC-HA (with a fabric headband) wished to continue using the BC-HA until ear reconstruction surgery. A child with right external auditory canal stenosis and a left middle ear anomaly was found to have an enlarged right external auditory canal during the process of making an ear impression for CC-HA ear tip fabrication; thus, AC-HA was selected.

Furthermore, a 4-year-old child with chronic otitis media and immunodeficiency with selective IgG2 deficiency (Primrose syndrome [24]) had the intention to avoid middle ear infections through HA use. However, surgical therapy was successful in achieving a stable usage.

Seven participants with unilateral hearing loss in the non-user group refrained from purchasing HAs because of their personal reluctance to use it.

3.3. Aided and Unaided Hearing Thresholds of the Purchase and Non-Purchase Groups

Some participants were too young and it was very difficult to measure the hearing thresholds, even at the sound field threshold, and a few participants, especially in the non-purchase group, chose not to wear the HAs early and did not undergo measurement. Figure 8 shows the SF thresholds (mean values) without HAs and with CC-HAs at each frequency for the purchase and non-purchase groups, separately for bilateral and unilateral hearing loss. Considering these averages, it can be seen that the SF hearing thresholds were improved by the CC-HAs at all frequencies within each group, indicating auditory effectiveness. There was no significant difference in the SF hearing thresholds between the two groups, except for the unaided thresholds of 2 KHz and 4 KHz in unilateral hearing loss.

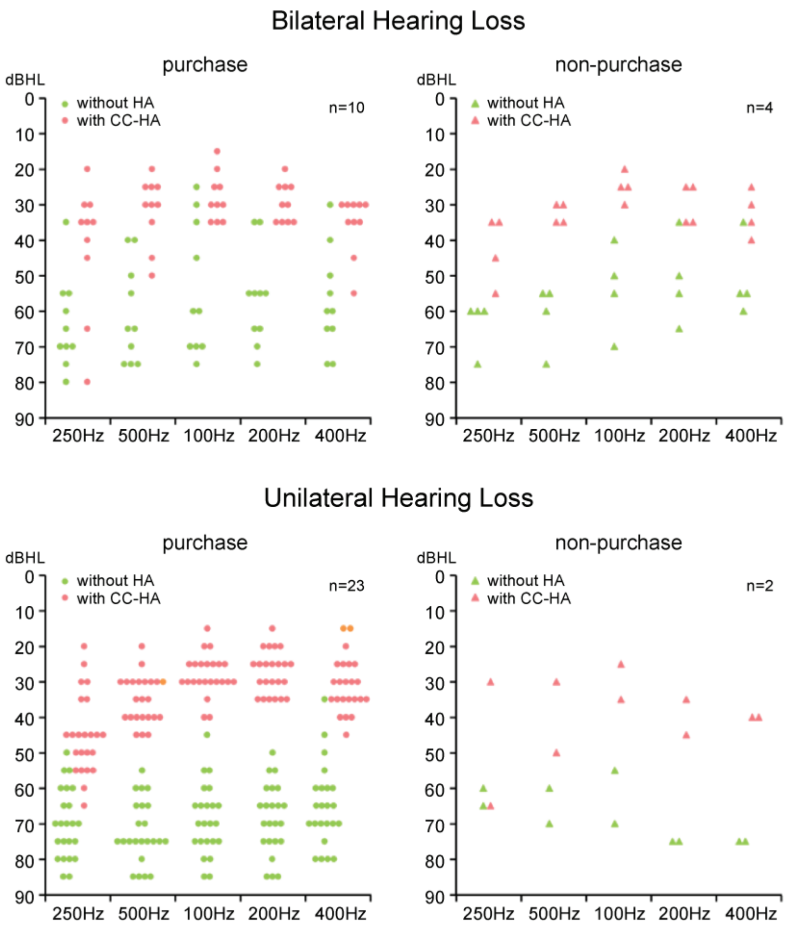

Figure 8. Average unaided and aided sound field hearing thresholds in bilateral and unilateral hearing loss of participants in purchase and non-purchase groups. The dots on this graph represent the raw data for each frequency for each case.

Hearing aids other than the CC-HA, that is, the BC-HA or AC-HA, could only be auditioned in the binaural hearing loss group. Of the cases with this comparative hearing loss, the SF thresholds for each HA were measured in eight cases (five with the CC-HAs and three without it). All these patients had better thresholds with the CC-HA than without HAs, with the CC-HA being better than or equal to other HAs in all cases except for one in the non-purchased group (Figure 9). The AC-HA was not available in all cases in the unilateral hearing loss group, and only BC-HA was indicated; however, none of the cases were auditioned due to reluctance to use a catheter-type headset or crimp the bone-conducting terminal.

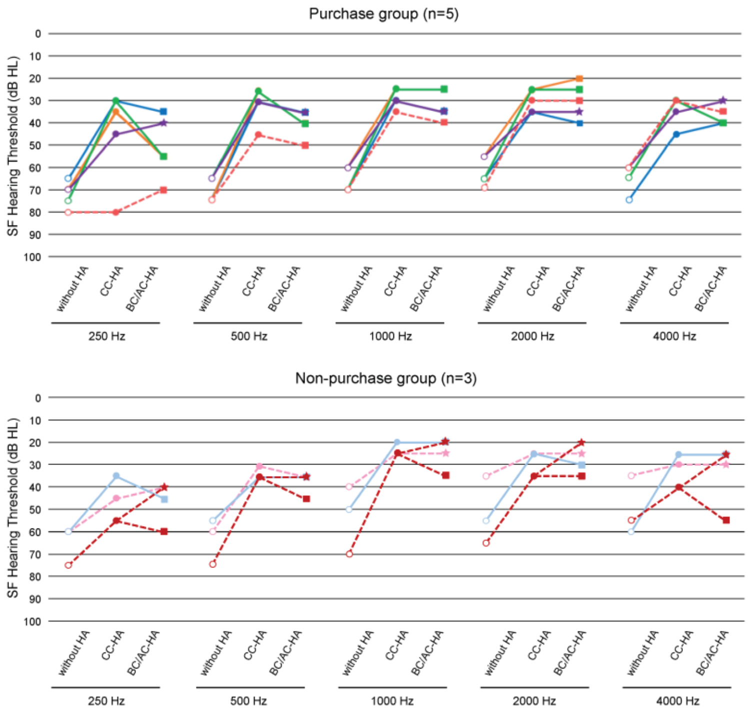

Figure 9. Comparison of SF hearing thresholds in three conditions: without HA, with CC-HA, and with BC-HA/AC-HA. Three-pairs of dots at a given test frequency are data from one participant in the binaural hearing loss group. In both graphs, the hearing thresholds for two or three types of hearing aids are represented by dots of different colors for each case. The differences are shown by connecting the dots with lines of the same color. Open circles indicate thresholds without HA, filled circles indicate thresholds with CC-HA, filled squares indicate thresholds with BC-HA, and filled stars indicate thresholds with AC-HA. The solid line connecting the dots also indicates that the patient was binaural and the dashed line indicates that the patient was uninaural.

3.4. Post-Purchase Evaluation-Wearing Status According to the Questionnaire Survey

A questionnaire survey was conducted during the post-purchase evaluation of 36 cases, and responses were obtained from 33 participants. All participants with bilateral hearing loss (100%) and 22 of 25 participants with unilateral hearing loss (88.0%) responded to the survey (Figure 10). Three participants could not be interviewed due to discontinuation of follow-up. All participants had unilateral microtia and external auditory canal atresia.

Regarding the effectiveness of wearing, among the statements “noticed voices from behind more easily”, “easier understanding of conversations in noisy places, such as parks or restaurants”, “better understanding of the direction of sounds and voices”, and “easier understanding of conversations with multiple people”, participants with bilateral hearing loss and unilateral hearing loss responded with “strongly agree” or “agree” in over 50% of the cases (Figure 10). However, for “conversations with multiple people”, the agreement rate was low. This tendency was particularly pronounced in patients with unilateral hearing loss.

The wearing behaviors of the participants are shown in Figure 11. Among the eleven participants with bilateral hearing loss, three participants reported wearing CC-HAs daily from “morning, upon waking up” to “night, before going to bed”, two participants reported wearing the aid in the weekdays “morning, upon waking” to “night, before bedtime”, and three participants reported wearing CC-HAs until “returning home”, and the remaining two participants reported wearing CC-HAs “only at nursery school/school”.

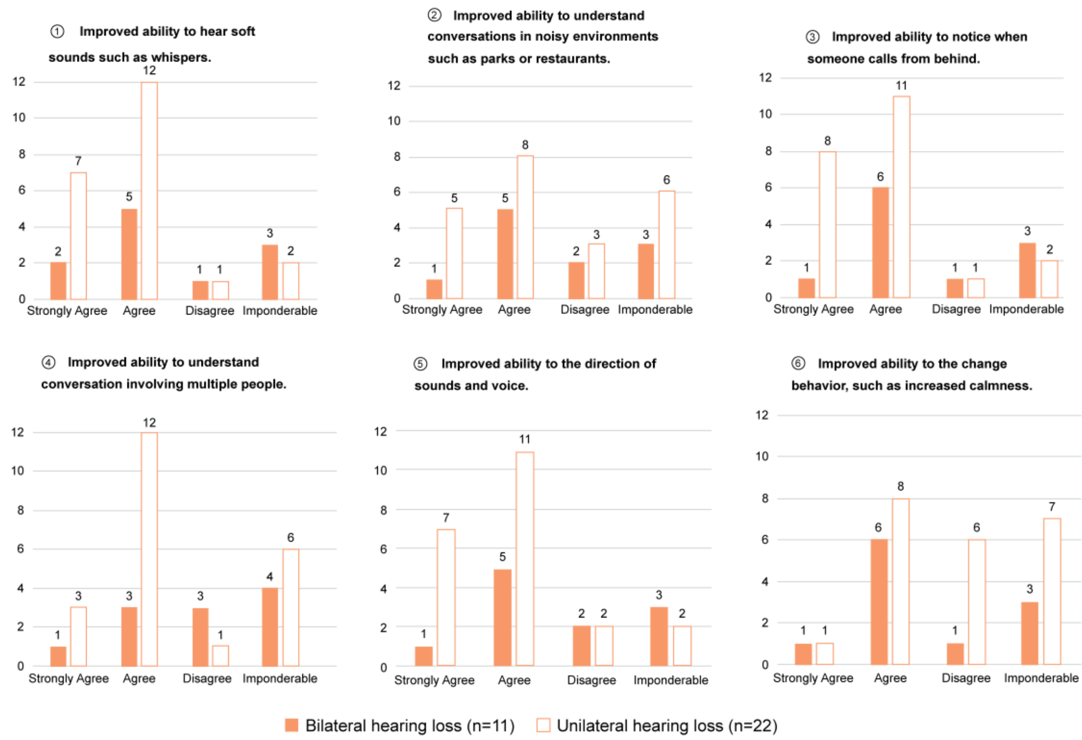

Figure 10. Response to a questionnaire survey to assess the post-purchase evaluation of effectiveness of wearing the hearing aid.

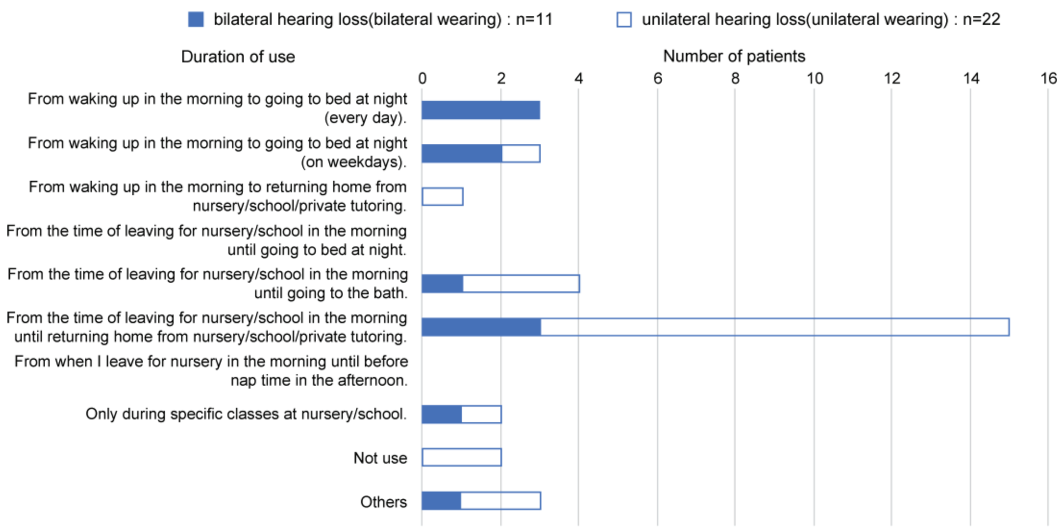

Figure 11. Duration of use of cartilage conduction hearing aids.

Among the 22 participants with unilateral hearing loss, one participant reported wearing CC-HA from "morning, upon waking up" to "night, before going to bed", one participant reported wearing CC-HA until "returning home", and the majority of 15 participants (68.2%) reported wearing CC-HAs from "when going to nursery school/school" to "returning home". One participant reported wearing CC-HA "only at nursery school/school" and the remaining four participants reported wearing CC-HAs only when spoken to (Figure 11).

The requests for HA usage were classified into six categories (n = 46): "concerns regarding adhesives (tape)", "issues with wearing and handling", "concerns regarding shape and structure", "waterproofing concerns", "concerns regarding background noise", and "concerns regarding social acceptance". Among these categories, "concerns regarding adhesives (tape)" were the most common (34.8%), with noticeable responses indicating that the tape tended to become less adhesive over time, owing to sweat. The second most common category was "issues with wearing and handling", accounting for 23.9% of the responses, with difficulties mentioned in children independently using and putting on the device (Figure 12).

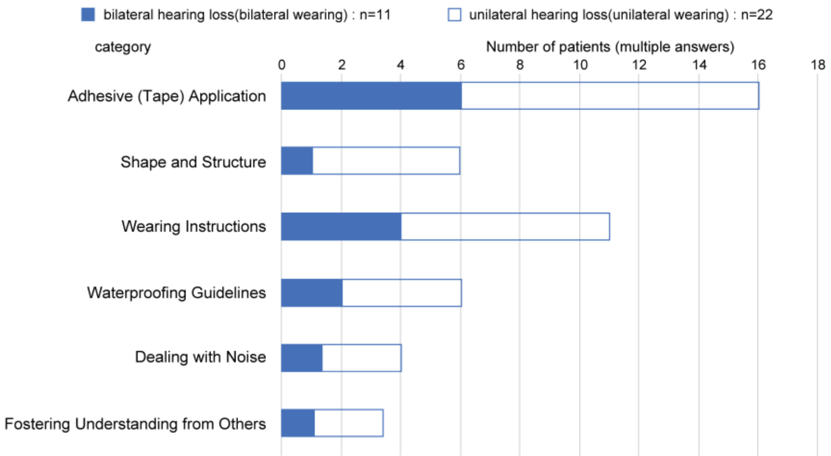

Figure 12. Cartilage conduction hearing aid use (categorized into 6 items).

3.5. Case Reports

Case 1 was a 3-year-2-month-old girl born at 37 weeks and 1 d of gestation, weighing 2690 g. The patient had multiple malformations (Treacher Collins syndrome), including micrognathia, ptosis, down slanted palpebral fissures, and cleft palate. Tracheotomy was performed after 9 days. The patient required medical care and attended school for the deaf and Kotoba-no-mori.

The first visit was at the age of 6 months. Trial hearing with the CC-HA with both the transducer and attached body was initiated, and the clinical course was mostly favorable. Trial hearing with the BC-HA (with a fabric headband) was initiated for comparative listening purposes. Both HAs had similar wearing efficacies (Figure 13). However, the parents of the participant purchased the CC-HA because the participant was able to remove the BC-HA, which could not be stabilized. Additionally, the participants' mother believed that the CC-HA was easier to work with. Around the age of 9 months, it became somewhat noticeable that the participant could remove the HA immediately after fitting. Therefore, the HA, including the transducer, was sewn into a ready-made hairband (Figure 14) at the age of 14 months. The HA was worn for a longer duration without changes to the threshold and with favorable wearing efficacy. The participant's mother modified the hairband when the participant was 23 months old. Silicon rubber was sewn to the outer side of the hairband such that the microphone on the CC-HA body was placed outside the hairband. The best wearing efficacy was obtained when a hole was created in the hairband such that the transducer was directly in front of the upper part of the ear, and the hairband was used to cover the transducer (Figure 15). At the age of 26 months, the patient attempted to wear the CC-HA body and transducer via affixation. Initially, the duration of use of the unit was limited. However, the duration increased gradually, and the participant used the device throughout the day (Figure 16).

Case 2 was of a child aged 1 year and 11 months who was born at 38 weeks of gestation and weighed 2398 g. Chromosomal abnormalities (chromosomes 18 and 3) and FOX P1 syndrome were identified. The patient is currently receiving education at a municipal development facility. Significant stenosis was observed in both the external auditory canals during the initial visits at the age of 1 year and 1 month. The possibility of conductive hearing loss was indicated by the auditory steady-state response (ASSR). Following the experience in Case 1, the HA was attached to a commercially available cloth headband, with the transducer placed outside the band for testing purposes (Figure 17). By the age of 1 year and 2 months, the child could wear the HA for approximately 6 h a day, and the mother reported improved sound responsiveness with fewer instances of howling. As the child could remove the headband from the age of approximately 1 year and 5 months, the mother started attaching the main body and transducer directly to the skin for wearing. Currently, for safety reasons, the shoulder area is secured with a short strap, and an HA is used without a headband for a few hours daily (Figure 18). The parents are considering using ear tips in the future.

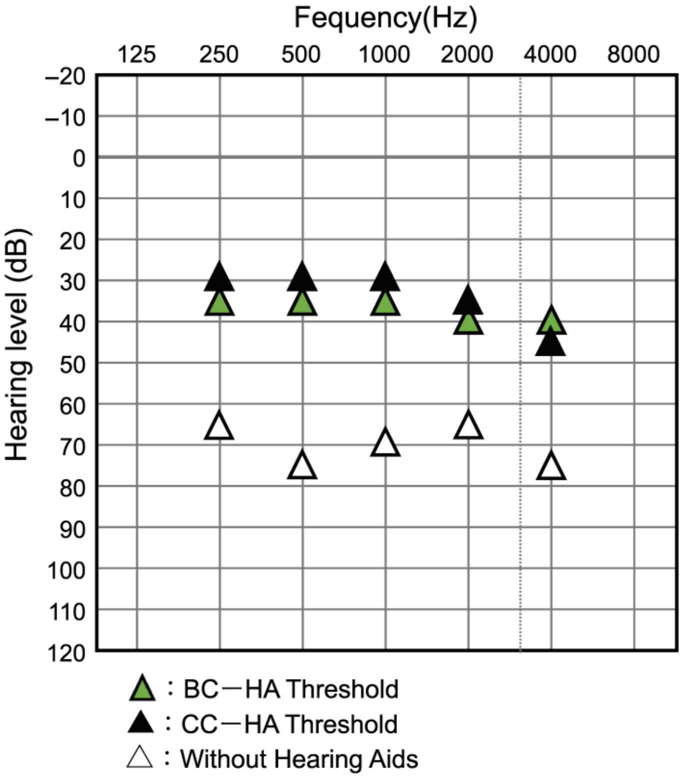

Figure 13. Case 1: Comparison of bone conduction hearing aids' threshold and cartilage conduction hearing aids' threshold.

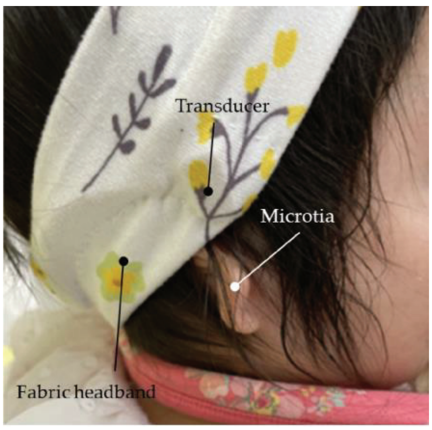

Figure 14. Profile view (right side) of a 6-month-old patient with Treacher Collins syndrome who has bilateral external auditory canal stenosis with exudative otitis media, wearing CC-HA. The main body of the hearing aid and the terminals are sewn into the inside of the headband.

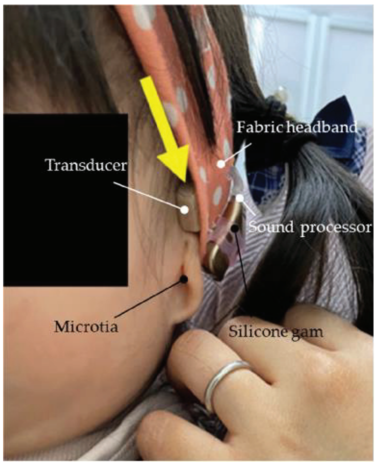

Figure 15. Profile view (left side) of Case 1 (a patient who is over 1 year old with Treacher Collins syndrome with bilateral external auditory canal stenosis and exudative otitis media) using cartilage-conducting hearing aid. The hearing aid is sewn to the headband, the transducer is placed outside the headband, and the transducer is attached with double-sided tape near the ear-pearl cartilage (Yellow arrow indicate the transducer peeking through the headband).

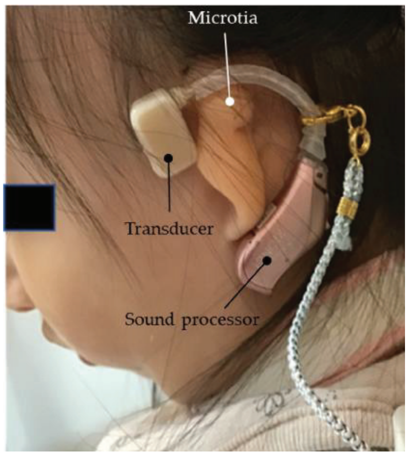

Figure 16. Profile view (left side) of Case 1 (2 years old) with bilateral external auditory canal closure. The terminals and hearing aid body are attached using double-sided tape.

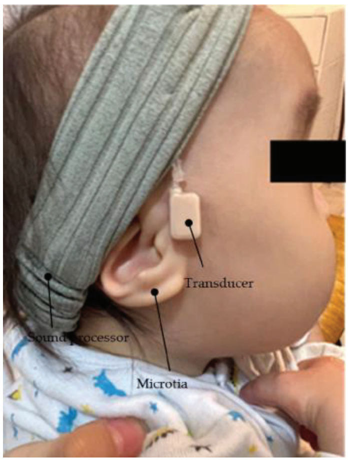

Figure 17. Profile view (right side) of Case 2 (severe bilateral external auditory canal stenosis). The terminals are attached using double-sided tape, and the body of the hearing aid is secured to a fabric headband for wearing.

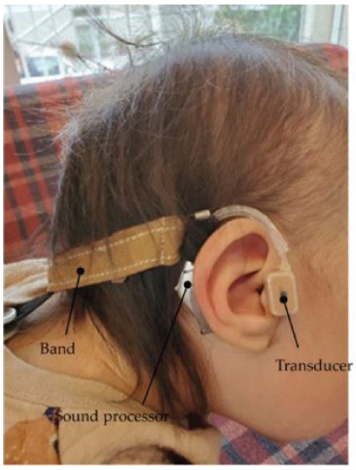

Figure 18. Profile view (right side) of Case 2. The terminals and the hearing aid body are attached using double-sided tape and secured to the back with a mischief-prevention belt.

4. Discussion

This study aimed to evaluate the effectiveness and fitting/wearing status of the CC-HA in children with hearing loss, and to examine the indications for HAs in children as they grow older. The primary finding of this study was that it is possible to continuously and stably wear HAs from infancy by devising a fitting method while monitoring developmental status and wearing conditions. The discovery of cartilage conduction pathways has uncovered new possibilities for auditory function.

Continuous monitoring should be accompanied with specific strategies for children with unilateral hearing loss and latent disabilities [25]. Hearing aids are highly effective for treating late-onset conductive hearing loss. Conventional AC-HAs and BC-HAs are effective strategies; however, the former device is not suitable for patients with aural atresia and chronic otitis media, and the latter has esthetic disadvantages because of the requirement of headbands or headsets, causing hesitation in individuals and parents. The small and lightweight CC-HA has minimal resistance and excellent effectiveness, thereby reducing psychological resistance [26]. As a result, CC-HAs are being considered as an alternative to conventional bone-anchored HAs, vibrant sound bridges (VSBs), and cochlear implants, and are frequently used during the pre-surgery stage [12].

We initiated a trial hearing of the CC-HA in 49 cases, ranging from infants to elementary school students, and 36 patients proceeded to decide on and utilize the device. While promoting the suitability of CC-HAs for infants and young children, particularly those with developmental disorders, we encountered difficulties in achieving stable attachment using the recommended methods of adhesion or ear tips alone. Initially, we proposed attaching the transducer using a double-sided tape and securing it further with tape [18]; however, this did not result in a stable attachment. Therefore, taking inspiration from the headbands used for the BC-HA, we collaborated with the participants' mothers and created prototypes of the CC-HA headbands that quickly made it possible to wear the device. Based on this experience, we found that attaching a hearing aid to the temples of the glasses or using a favorite headband proved to be successful in other cases.

Treacher Collins syndrome (as seen in Case 1), also known as mandibulofacial dysostosis, is an autosomal dominant inherited genetic disorder with an incidence of 1 in 50,000 [27,28]. Common symptoms of this syndrome include hypoplasia of the facial bones, especially the mandible and zygoma, drooping of the cleft palate, lid coloboma, and cleft palate [29]. Conductive hearing loss is observed in 50% of patients and is attributed to malformations of the outer and middle ear [30,31]. Previous studies have reported on auditory rehabilitation in patients using the BC-HAs or BAHAs. The importance of early auditory rehabilitation to ensure the appropriate development of language and learning is well-known [32–35]; however, the use of BC-HAs is associated with local pain, discomfort, and concerns related to appearance [8,10]. BAHAs require surgery [36,37] and implant protrusion is disadvantageous in terms of appearance [8]. In contrast, the use of CC-HAs is not associated with these problems and is considered an effective alternative to AC-HAs. In this study, a headband was used as an adaptation to the device. Initially, concerns were raised regarding headband shifting; however, no issues were encountered during the study period. Factors such as the child being calm, having minimal body movements during infancy or other life stages, or being at a stage of greater understanding may also have influenced the results.

FOXP1 syndrome (Case 2) is associated with intellectual disability, language impairment, autism spectrum disorder, myotonia, mild dysplasia, and congenital abnormalities of the brain, heart, and urinary system. Hearing loss has also been reported in patients with this syndrome. Lozano et al. [38] reported that all individuals with FOXP1 syndrome must be evaluated for hearing loss and should promptly undergo hearing replacement. CC-HA was effective in the treatment of hearing loss in a patient with trisomy 18. Trisomy of chromosome 18 is the second most frequent autosomal disorder after Down syndrome and 22q11.2 deletion syndrome, with a reported frequency of 1 in 3500–8500 live births. The prognosis is often poor [39,40]; however, marked improvements in vital prognosis have been reported. With the advances in newborn hearing screening tests and early detection of hearing loss, it is desirable for HAs to be worn safely, without burden, and consistently from 0 years of age, even in cases where AC-HAs are difficult to apply, such as in patients with atresia of the external auditory canal.

In this study, five participants with bilateral hearing loss had a history of HA use prior to the CC-HA trial. Four participants used bilateral BC-HAs, and one participant used AC-HA on the side without external auditory canal stenosis. The preference for switching to the CC-HA primarily came from caregivers because of limited wearing time, concerns regarding esthetic aspects, and discomfort caused by the pressure of the BC transducer in the BC-HA. Among the three participants with bilateral microtia and external auditory canal atresia, all participants except one, who was awaiting transition to CC-HA after auricular reconstruction surgery, immediately transitioned to CC-HA. In one participant with unilateral microtia, external auditory canal stenosis, and contralateral ear ossicular malformation, external auditory canal enlargement was observed while making a near impression of the CC-HA, resulting in the selection of the AC-HA. In cases of bilateral hearing loss with microtia, external auditory canal closure, or stenosis since birth, conventional BC-HAs (with cloth headbands) are commonly used by both medical professionals and caregivers because they are easy to wear and readily available. However, CC-HAs offer the potential for stable use from infancy by adapting the wearing method as the child grows and are expected to have wider applications. This adaptation requires repeated prototyping. Moreover, collaboration with parents, especially the mother, is essential, as the mother observes the child's behavior and experiences the benefits of wearing a HA. The support and involvement of healthcare professionals and caregivers are crucial in increasing the motivation for wearing HAs and encouraging their active utilization.

An evaluation of the post-purchase experience revealed that HAs were used almost throughout the day by participants with bilateral hearing loss. Moreover, both individuals and their surroundings experience the positive effects of their usage. Similar results were observed in the participants with unilateral hearing loss; however, there were some instances of shorter wearing times. Educational and medical support are crucial for the effective use of HAs, particularly in cases of unilateral hearing loss. Additionally, a higher proportion of individuals with unilateral hearing loss reported perceiving the benefits of wearing a HA compared to those with bilateral hearing loss, which may be attributed to the presence of non-usage periods, making the effects of the HA more noticeable. This is believed to reflect the binaural hearing effects reported by Kagaet al. [41]. Regarding the challenges related to HAs, participants with bilateral and unilateral hearing loss identified improvements in the adhesive-wearing method, particularly addressing issues with sweat and difficulties in re-application, as future tasks.

It is assumed that, in the case of bilateral hearing loss, patients are more open to wearing HAs, irrespective of the type, to improve their quality of life and learning abilities. On the other hand, if the child has hearing loss on only one side from birth, caregivers are not keen on providing HAs. In this context, the high rate of device purchase by children with unilateral hearing impairment demonstrated the perceived utility of binaural hearing. The findings also suggested that CC-HAs are one of the most comfortable HAs to wear, and provide reliable and adequately amplified speech.

Participants with unilateral hearing loss had no history of using HAs, and the CC-HA was the first HA selected for these participants because there were limited options available in terms of other models, as they required surgical intervention. In recent years, implants such as the BAHA Attract System (Cochlear Limited), Bonebridge (MED-EL, Innsbruck, Austria), and Sophono (Medtronic, Dublin, Ireland) have been developed. In the case of children, the decision to undergo surgery is primarily made by caregivers (parents). Considering the currently available evidence, identifying one type of HA (AC-HA, BC-HA, or CC-HA) over others is not justified. When deciding on a particular HA, the cases that are more adaptable should be defined. Furthermore, patients' perceived functional gains, specific hearing status, extent of hearing loss in individual patients, and the cost of HAs should be considered. In pediatric cases, it is also important to consider the developmental status. However, the use of CC-HAs as a policy until the age when the child's own will can be taken into consideration is also an important option.

5. Conclusions

Even in cases where it is challenging to use AC-HAs, such as in patients with external auditory canal closure, the ability to consistently use HAs from infancy is crucial for the development of language and communication skills in children with hearing loss. The CC-HA allows for continuous and stable usage from infancy to early childhood by adjusting the fitting method according to a child's growth. The use of CC-HAs involves utilizing options such as headbands or attaching the HAs to glass frames. The device is likely to reduce the physical and psychological burden on the infant, as well as on parents or caregivers. Parents of a high percentage of children with unilateral hearing loss in this study purchased and used HAs, indicating positive sentiments toward the device. Collaboration with caregivers is necessary for implementing these adaptations, and an effective use of HAs requires educational and medical support.

Author Contributions: Conceptualization, S.Y. and T.S.; methodology, T.M.; validation, S.Y., T.S. and Y.M.; formal analysis, K.S.; investigation, K.S. and R.M.; resources, T.S.; writing—original draft preparation, T.S.; writing—review and editing, T.M.; supervision, Y.S.; project administration, S.Y.; funding acquisition, T.S. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board (or Ethics Committee) of KANTO ROSAI HOSPITAL (approval no.: 2023-1;2023.4.4).

Informed Consent Statement: Verbal informed consent was obtained from all participants and their guardians. Written consent was not required according to the ethical guidelines for medical and health science research involving human subjects.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. Shimokura, R.; Hosoi, H.; Nishimura, T.; Yamanaka, T.; Levitt, H. Cartilage conduction hearing. *J. Acoust. Soc. Am.* **2014**, *135*, 1959–1966. [CrossRef] [PubMed]

2. Stenfelt, S. Model predictions for bone conduction perception in the human. *Hear. Res.* **2016**, *340*, 135–143. [CrossRef] [PubMed]
3. Hosoi, H. Approach in the Use of Cartilage Conduction Speaker. Japanese patent number 4541111, 2004.
4. Hosoi, H.; Nishimura, T.; Shimokura, R.; Kitahara, T. Cartilage conduction as the third pathway for sound transmission. *Auris Nasus Larynx* **2019**, *46*, 151–159. [CrossRef]
5. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Yamanaka, T.; Levitt, H. Is cartilage conduction classified into air or bone conduction? *Laryngoscope* **2014**, *124*, 1214–1219. [CrossRef] [PubMed]
6. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Yamanaka, T.; Kitahara, T.; Levitt, H. Cartilage conduction is characterized by vibrations of the cartilaginous portion of the ear canal. *PLoS ONE* **2015**, *10*, e0120135. [CrossRef] [PubMed]
7. Akasaka, S.; Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Morimoto, C.; Kitahara, T. Benefits of cartilage conduction hearing aids for speech perception in unilateral aural atresia. *Audiol. Res.* **2021**, *11*, 284–290. [CrossRef] [PubMed]
8. Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Yamanaka, T.; Kitahara, T. Cartilage conduction hearing aids for severe conduction hearing loss. *Otol. Neurotol.* **2018**, *39*, 65–72. [CrossRef]
9. Stenfelt, S.; Goode, R.L. Bone-conducted sound: Physiological and clinical aspects. *Otol. Neurotol.* **2005**, *26*, 1245–1261. [CrossRef]
10. Dillon, H. CROS, bone-conduction, and implanted hearing aids. In *Hearing Aids*; Dillon, H., Ed.; Thieme: Stuttgart, Germany, 2001; pp. 434–450.
11. Lo, J.F.; Tsang, W.S.; Yu, J.Y.; Ho, O.Y.; Ku, P.K.; Tong, M.C. Contemporary hearing rehabilitation options with aural atresia. *Biomed Res. Int.* **2014**, *2014*, 761579. [CrossRef]
12. Nishimura, T.; Hosoi, H.; Shimokura, R.; Kitahara, T. Cartilage conduction hearing aids in clinical practice. *Audiol. Res.* **2023**, *13*, 506–515. [CrossRef]
13. Hosoi, H. Cartilage Conduction Hearing Aids: The Third Pathway for Sound Transmission and Its Application, ENT & Audiology News. 2020. Available online: https://www.entandaudiologynews.com/features/audiology-features/post/cartilage-conduction-hearing-aids-the-third-pathway-for-sound-transmission-and-itsapplication (accessed on 22 September 2020).
14. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Iwakura, T. Benefit of a new hearing device utilizing cartilage conduction. *Auris Nasus Larynx* **2013**, *40*, 440–446. [CrossRef] [PubMed]
15. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Yamanaka, T.; Kitahara, T.; Levitt, H. Cartilage conduction efficiently generates airborne sound in the ear canal. *Auris Nasus Larynx* **2015**, *42*, 15–19. [CrossRef] [PubMed]
16. Morimoto, C.; Nishimura, T.; Hosoi, H.; Saito, O.; Fukuda, F.; Shimokura, R.; Yamanaka, T. Sound transmission by cartilage conduction in ear with fibrotic aural atresia. *J. Rehabil. Res. Dev.* **2014**, *51*, 325–332. [CrossRef] [PubMed]
17. Nishiyama, T.; Oishi, N.; Ogawa, K. Who are good adult candidates for cartilage conduction hearing aids? *Eur. Arch. Otorhinolaryngol.* **2020**, *278*, 1789–1798. [CrossRef]
18. Nishiyama, T.; Oishi, N.; Ogawa, K. Efficacy of cartilage conduction hearing aids in children. *Int. J. Pediatr. Otorhinolaryngol.* **2021**, *142*, 110628. [CrossRef] [PubMed]
19. Suwento, R.; Widodo, D.W.; Airlangga, T.J.; Alviandi, W.; Watanuki, K.; Nakanowatari, N.; Hosoi, H.; Nishimura, T. Clinical trial for cartilage conduction hearing aid in Indonesia. *Audiol. Res.* **2021**, *11*, 410–417. [CrossRef] [PubMed]
20. Kitagawa, K.; Mitsuzawa, H.; Shintani, T.; Go, M.; Himi, T. Audiological chronological findings in children with congenital anomalies of the central nervous system. *Int. J. Pediatr. Otorhinolaryngol.* **2009**, *73*, 1105–1110. [CrossRef]
21. Scollie, S.; Seewald, R.; Cornelisse, L.; Moodie, S.; Bagatto, M.; Laurnagaray, D.; Beaulac, S.; Pumford, J. The desired sensation level multistage input/output algorithm. *Trends Amplif.* **2005**, *9*, 159–197. [CrossRef]
22. World Medical Association Declaration of Helsinki. Recommendations guiding physicians in biomedical research involving human subjects. *JAMA* **1997**, *277*, 925–926. [CrossRef]
23. Ministry of Health, Labour and Welfare, Ethical Guidelines for Medical and Health Research Involving Human Subjects Provisional Translation. Available online: https://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/0000080278.pdf. (accessed on 20 September 2020).
24. Yamamoto-Shimojima, K.; Imaizumi, T.; Akagawa, H.; Kanno, H.; Yamamoto, T. Primrose syndrome associated with unclassified immunodeficiency and a novel ZBZB20 mutation. *Am. J. Med. Genet. A* **2020**, *182*, 521–526. [CrossRef]
25. Lieu, J.E.C.; Kenna, M.; Anne, S.; Davidson, L. Hearing loss in children: A review. *JAMA* **2020**, *324*, 2195–2205. [CrossRef] [PubMed]
26. Sugimoto, S.; Yoshida, T.; Fukunaga, Y.; Motegi, A.; Saito, K.; Kobayashi, M.; Sone, M. Comparative analysis of cartilage conduction hearing aid users and non-users: An investigative study. *Audiol. Res.* **2023**, *13*, 563–572. [CrossRef] [PubMed]
27. Martini, A.; Calzolari, F.; Sensi, A. Genetic syndromes involving hearing. *Int. J. Pediatr. Otorhinolaryngol.* **2009**, *73*, S2–S12. [CrossRef] [PubMed]
28. Plomp, R.G.; Bredero-Boelhouwer, H.H.; Joosten, K.F.; Wolvius, E.B.; Hoeve, H.L.; Poublon, R.M.; Mathiijssen, I.M. Obstructive sleep apnoea in Treacher Collins syndrome: Prevalence, severity and cause. *Int. J. Oral. Maxillofac. Surg.* **2012**, *41*, 696–701. [CrossRef] [PubMed]
29. Katsanis, S.H.; Jabs, E.W. Treacher Collins syndrome. In *Gene Reviews*; Adam, M.P., Feldman, J., Mirzaa, G.M., Pagon, R.A., Wallace, S.E., Bean, L.J.H., Gripp, K.W., Amemiya, A., Eds.; Thieme Medical: Seattle, WA, USA, 1993.
30. Hylton, J.B.; Leon-Salazar, V.; Anderson, G.C.; De Felippe, N.L. Multidisciplinary treatment approach in Treacher Collins syndrome. *J. Dent. Child.* **2012**, *79*, 15–21.

31. Lesinskas, E.; Stankeviciute, V.; Petrulionis, M. Application of the Vibrant Sound bridge middle-ear implant for aural atresia in patients with Treacher Collins syndrome. *J. Laryngol. Otol.* **2012**, *126*, 1216–1223. [CrossRef]
32. Marsella, P.; Scorpecci, A.; Pacifico, C.; Tieri, L. Bone-anchored hearing aid (Baha) in patients with Treacher Collins syndrome: Tips and pitfalls. *Int. J. Pediatr. Otorhinolaryngol.* **2011**, *75*, 1308–1312. [CrossRef]
33. Marres, H.A. Hearing loss in the Treacher-Collins syndrome. *Adv. Otorhinolaryngol.* **2002**, *61*, 209–215.
34. Thompson, J.T.; Anderson, P.J.; David, D.J. Treacher Collins syndrome: Protocol management from birth to maturity. *J. Cranofac. Surg.* **2009**, *20*, 2028–2035. [CrossRef]
35. Verhagen, C.V.; Hol, M.K.; Coppens-Schellekens, W.; Snik, A.F.; Cremers, C.W. The Baha Softband. A new treatment for young children with bilateral congenital aural atresia. *Int. J. Pediatr. Otorhinolaryngol.* **2008**, *72*, 1455–1459. [CrossRef]
36. House, J.W.; Kutz, J.W., Jr. Bone-anchored hearing aids: Incidence and management of postoperative complications. *Otol. Neurotol.* **2007**, *28*, 213–217. [CrossRef] [PubMed]
37. Hobson, J.C.; Roper, A.J.; Andrew, R.; Rothera, M.P.; Hill, P.; Green, K.M. Complications of bone-anchored hearing aid implantation. *J. Laryngol. Otol.* **2010**, *124*, 132–136. [CrossRef] [PubMed]
38. Lozano, R.; Gbekie, C.; Siper, P.M.; Srivastava, S.; Saland, J.M.; Sethuram, S.; Tang, L.; Drapeau, E.; Frank, Y.; Buxbaum, J.D.; et al. FOXP1 syndrome: A review of the literature and practice parameters for medical assessment and monitoring. *J. Neurodev. Disord.* **2021**, *13*, 18. [CrossRef] [PubMed]
39. Jones, K.L. *Trisomy 18 Syndrome. Smith's Recognizable Patterns of Human Malformation*, 8th ed.; Elsevier: Amsterdam, The Netherlands, 2006; pp. 13–17.
40. Carey, J.C. Trisomy 18 and Trisomy 13 Syndromes. In *Management of Genetic Syndromes*, 2nd ed.; Cassidy, S.B., Allanson, J.E., Eds.; Wiley-Liss: Hoboken, NY, USA, 2005; pp. 555–568.
41. Kaga, K.; Setou, M.; Nakamura, M. Bone-conducted sound lateralization of inte-raural time difference and interaural intensity difference in children and a young adult with bilateral microtia and atresia of the ears. *Acta. Otolaryngol.* **2001**, *121*, 274–277. [CrossRef]

audiology research

Article

Comparative Analysis of Cartilage Conduction Hearing Aid Users and Non-Users: An Investigative Study

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Abstract: Clinical findings on cartilage conduction hearing aids (CCHAs) have gradually become clear; however, few reports include a large number of cases. This study included 91 ears from 69 patients who underwent CCHA fitting in our hospital. Their ears were divided into six groups (i.e., bilateral aural atresia or severe canal stenosis, unilateral aural atresia or severe canal stenosis, chronic otitis media or chronic otitis externa with otorrhea, sensorineural hearing loss, mixed hearing loss, and conductive hearing loss) according to their clinical diagnosis and type of hearing loss. Most clinical diagnoses were aural atresia or meatal stenosis (bilateral, 21.8%; unilateral, 39.6%). The purchase rate of CCHAs was higher in the closed-ear group (bilateral, 77.3%; unilateral, 62.5%). In the bilateral closed-ear group, air conduction thresholds at 1000, 2000, and 4000 Hz and aided thresholds with CCHAs at 4000 Hz were significantly lower in the purchase group than the non-purchase group. No significant difference was observed between the purchase and non-purchase groups in the unilateral closed-ear group. In the bilateral closed-ear group, air conduction thresholds and aided thresholds were associated with the purchase rate of CCHAs. In the unilateral closed-ear group, factors other than hearing might have affected the purchase rate of CCHAs.

Keywords: cartilage conduction hearing aid; aural atresia; meatal stenosis; bone conduction hearing aids; conductive hearing loss

1. Introduction

Cartilage conduction hearing aids (CCHAs) are a new type of hearing aid. Hosoi found that an unmistakable sound can be heard when a vibration signal is delivered to the auricular cartilage using a transducer, a process which was termed “cartilage conduction” [1]. Hosoi and Nishimura’s group continued their cartilage conduction research [2–5] and developed a CCHA [6–8]. The prototype CCHA was first reported in 2010 [6]. Body-aid [7] and behind-the-ear [8] types were developed shortly afterwards. To fix the transducers of the CCHAs, a double-sided skin tape and ear chip were used. A double-sided skin fixation is available for all ear conditions. On the one hand, ear chip fixation is only employed in select cases, but is useful for improving comfort. Acoustic devices that utilize cartilage conduction, including earphones and smartphones, have also been developed [4]. CCHAs that can adjust their volume depending on the frequency are most desirable for patients with hearing loss. CCHAs have the advantages of comfort, stable fixation, aesthetics, and non-invasiveness [9,10]. Based on the characteristic mechanism of cartilage conduction, CCHAs provide benefits for patients with aural atresia and chronic otitis media, with which it is difficult to use air conduction hearing aids (ACHAs), and these patients require bone conduction hearing aids (BCHAs) [6,7,10,11]. CCHAs have been used clinically in Japan since November 2017, and the clinical characteristics of CCHAs have been reported [12–20]. Nishiyama et al. investigated child and adult candidates for CCHA treatment separately and reported that patients with ear canal stenosis or aural atresia were the most suitable candidates [12,13]. Sakamoto et al. evaluated the benefits of CCHA in patients with unilateral congenital aural atresia and reported that their speech recognition scores improved in noisy environments [14]. Komune et al. investigated patients after lateral temporal bone resection and reported upon the availability of CCHAs for postoperative hearing compensation [15]. To investigate the clinical use of CCHAs in Japan, we conducted a survey of nine medical institutions with 256 patients who had tried CCHAs [16]. The survey reported a high purchase rate in ears with aural atresia or severe canal stenosis. In addition, a high purchase rate was also reported among patients with refractory continuous otorrhea who experienced difficulties with ACHAs. In this way, clinical findings on CCHAs have gradually become clear; however, there are few reports with a large number of cases. In this study, we investigated cases with CCHAs in our hospital and identified some ways to improve CCHA fitting.

2. Materials and Methods

2.1. Participants

The study included 91 ears from 69 patients (35 men and 34 women; age range, 2–83 years) who underwent CCHA fitting in our university hospital between December 2017 and December 2022. To examine the effect of CCHAs on closed ears clearly in this study, we excluded ears on which meatoplasty had been performed. Cases with aural atresia or severe canal stenosis were recruited into bilateral or unilateral closed-ear groups. Cases with chronic otitis media or chronic otitis externa with otorrhea who experienced difficulties with ACHAs were recruited into the continuous otorrhea group. Other diseases were divided into three groups (i.e., sensorineural hearing loss, mixed hearing loss, and conductive hearing loss) according to the type of hearing loss.

2.2. Audiometry

Pure-tone audiometry was performed on patients aged 6 and older using an AA-78 diagnostic audiometer (Rion Co. Ltd., Tokyo, Japan). Behavioral audiometry was performed on patients aged 2 to 5 using an AA-73 diagnostic audiometer (Rion). These tests were performed in a soundproof compartment, primarily on the patient's first visit to our hospital. Air and bone conduction audiometric measurement thresholds were calculated for each ear at 250, 500, 1000, 2000, and 4000 Hz. The air and bone conduction threshold averages were calculated using five averages (250, 500, 1000, 2000, and 4000 Hz thresholds).

2.3. CCHA Fitting and Evaluations

HB-J1CC and HB-A2CC CCHAs (Rion) were used for CCHA fitting. When patients tested the CCHAs, a double-sided skin tape (#1522; 3M Japan Limited, Tokyo, Japan) was used to fix the transducers to the tragal area, which consists mostly of cartilage. The position of the transducers was similar to that of previous reports [10,16,17]. Aided thresholds at 250, 500, 1000, 2000, and 4000 Hz were measured via sound field tests using an AA-76 diagnostic audiometer (Rion) in a soundproof compartment in all patients, primarily at the time of first fitting. The aided threshold average was calculated using five averages (250, 500, 1000, 2000, and 4000 Hz thresholds). The patients brought CCHAs home and tested them for at least two weeks. The patients then decided whether to purchase CCHAs. They were asked why they purchased or did not purchase CCHAs. Ear impressions were taken during the purchase stage if ear-chip-type transducers were available.

2.4. Ethics Review

This study was approved by the Ethics Review Committee of the Nagoya University School of Medicine, Nagoya, Japan (No. 2022-0492).

2.5. Statistical Analyses

The IBM SPSS Statistics software (version 28, IBM Corp., Armonk, NY, USA) was used for statistical analyses. The significance level was set to 5%. The sex distribution and presence of previous hearing aids were compared between the two groups using the X^2 test. Air and bone conduction thresholds, aided thresholds with CCHAs, and mean ages were compared between CCHA purchase and non-purchase cases using the Mann–Whitney U test. Comparisons between aided thresholds with previous hearing aids and those with CCHAs were also assessed using the Mann–Whitney U test.

3. Results

Table 1 shows the demographic and clinical data for ears fitted with CCHAs. Most clinical diagnoses were aural atresia or meatal stenosis (62 ears, 61.4%), and there were more unilateral cases (40 ears, 39.6%) than bilateral cases (22 ears, 21.8%). The bilateral closed-ear group included 18 cases with congenital aural atresia or meatal stenosis, 2 cases with acquired fibrotic aural atresia caused by chronic irritation and inflammation, and 2 cases with congenital meatal stenosis with chronic inflammation. The average air conduction threshold in all ears was 63.1 dB. All cases had bilateral hearing loss. The unilateral closed-ear group included 36 cases with congenital aural atresia or meatal stenosis and 4 cases with acquired fibrotic aural atresia caused by carcinoma operations in the ear canal or chronic irritation and inflammation. The average air conduction threshold in all opposite ears was 17.3 dB. There were four opposite ears with average air conduction thresholds of more than 30 dB. The continuous otorrhea group included five cases. Most cases were affected bilaterally. All cases had bilateral hearing loss. The variation in bone conduction hearing was small, including in the ipsilateral and contralateral ears. The sensorineural hearing loss group included three cases. The average air conduction threshold in all opposite ears was 46.3 dB. There was an opposite ear with normal hearing and another two ears with average air conduction thresholds of more than 50 dB. The mixed hearing loss group included 16 cases. The average air conduction threshold in all opposite ears was 61.4 dB. There were two opposite ears with normal hearing and another fourteen ears with average air conduction thresholds of more than 30 dB. The conductive hearing loss group included five cases. Most cases were affected bilaterally. All cases had bilateral hearing loss.

Table 1. Demographic and clinical data for ears fitted with CCHAs.

Group	n	Age (Year)	Sex	Previous Hearing Aids	Air Conduction Thresholds (dB HL)	Bone Conduction Thresholds (dB HL)	Aided Thresholds CCHA (dB HL)	Purchase Rate CCHA
		Average (SD)	(Female /Male)	(No/ACHA /BCHA)	Average (SD)	Average (SD)	Average (SD)	
Bilateral aural atresia or severe canal stenosis	22	21.1 (12.2)	12/10	6/0/16	63.1 (12.2)	9.9 (6.5)	33.0 (3.2)	77.3%
Unilateral aural atresia or severe canal stenosis	40	13.7 (13.9)	20/20	39/0/1	70.6 (9.5)	9.0 (7.7)	38.6 (6.5)	62.5%
Chronic otitis media or chronic otitis externa with otorrhea	5	74.2 (4.5)	5/0	0/5/0	65.2 (14.0)	43.6 (3.4)	44.3 (7.5)	20.0%
Sensorineural hearing loss	3	64.7 (20.3)	0/3	1/2/0	58.3 (8.4)	53.3 (9.5)	45.0 (4.2)	0.0%
Mixed hearing loss	16	38.3 (30.4)	7/9	8/6/2	73.8 (12.9)	27.6 (14.4)	42.6 (6.8)	6.3%
Conductive hearing loss	5	9.8 (3.4)	2/3	2/1/2	48.8 (13.4)	1.4 (2.2)	32.0 (2.9)	60.0%
Total	91	24.6 (25.3)	46/45	56/14/21	67.5 (12.9)	15.6 (15.3)	37.9 (6.9)	51.6%

ACHA, air conduction hearing aid; BCHA, bone conduction hearing aid; CCHA, cartilage conduction hearing aid; SD, standard deviation.

Patients bought CCHAs for a total of 47 ears. Forty-two of these ears suffered from aural atresia or severe canal stenosis (purchase rate in bilateral cases, 77.3%; purchase rate in unilateral cases, 62.5%). The remainder included an ear with chronic otitis externa with otorrhea (purchase rate, 20.0%), an ear with mixed hearing loss (purchase rate, 6.3%), and three ears with conductive hearing loss (purchase rate, 60.0%). The purchase rate for sensorineural hearing loss was 0%. In the unilateral closed-ear group, patients whose opposite ear's hearing level was more than 30 dB had a higher purchase rate than those whose opposite ear's hearing level was less than 30 dB. (100% vs. 58.3%). In the four purchase cases with mixed or conductive hearing loss, all four opposite ears suffered from conductive hearing loss. Three patients chose CCHAs for cosmetic reasons and refused to try the ordinary behind-the-ear type of ACHA. Another patient, whose opposite ear had severe canal stenosis, chose CCHAs because he wanted to use the same hearing aids bilaterally. We focused on the closed-ear group because both the number of ears and the purchase rate were high.

Table 2 shows comparisons between the CCHA purchase and non-purchase cases in bilateral aural atresia or severe canal stenosis. The mean age was younger in the purchase group; however, no significant difference was observed. The age distribution is shown in Figure 1. For all cases aged 6 years and younger, CCHAs were purchased. Many ears had been fitted with hearing aids, all of which were BCHAs. The number of patients with a history hearing aids and the sex distribution between the two groups did not differ significantly. Air conduction thresholds were lower at all frequencies in the purchase group, for which there was a significant difference at 1000, 2000, and 4000 Hz, but there was no significant difference in the bone conduction thresholds. Aided thresholds with CCHAs were lower in the purchase group, except at 250 Hz, and a significant difference was found at 4000 Hz. When comparing aided thresholds with previous hearing aids and those with CCHAs in each group, the aided thresholds with CCHAs were slightly higher in both groups at many frequencies. There was a significant difference in the non-purchase group at 1000 Hz.

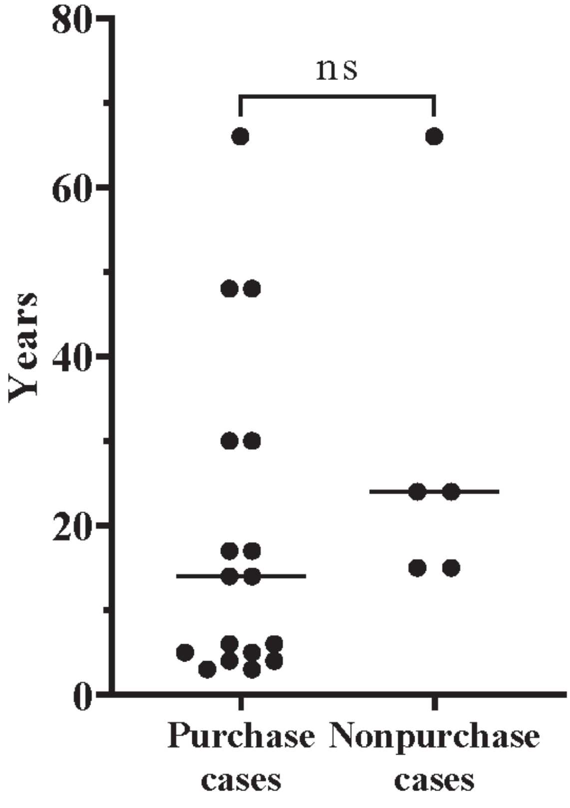

Figure 1. The age distribution between CCHA purchase and non-purchase cases in bilateral aural atresia or severe canal stenosis.

To observe the effect of CCHAs on unilateral aural atresia or severe canal stenosis clearly, we performed a comparison between CCHA purchase and non-purchase cases in unilateral closed ears whose opposite ear's hearing level was less than 30 dB (Table 3). The mean age was younger in the purchase group; however, no significant difference was observed. The age distribution is shown in Figure 2. No patients over 47 years old purchased CCHAs. Since the opposite ear's hearing level was less than 30 dB in all cases, no patients were fitted with hearing aids before their first visit to our hospital. The number of patients with a history of hearing aids and the sex distribution between the two groups did not differ significantly. Although affected ears, as well as the contralateral ears, were examined, no significant difference was observed between the two groups when their hearing was compared. There was no significant difference in the aided thresholds for CCHAs.

Table 2. Comparison between CCHA purchase cases and non-purchase cases in bilateral aural atresia or severe canal stenosis.

	Purchase (*n* = 17)	**Non-Purchase (*n* = 5)**
	Average (SD)	Average (SD)
Age (Year)	18.8 (18.6)	28.8 (19.0)
Sex (Female/Male)	9/8	3/2
Previous hearing aids (No/BCHA)	5/12	1/4
Air conduction thresholds (dB HL)		
250 Hz	67.9 (20.1)	81.0 (5.8)
500 Hz	65.9 (19.3)	83.0 (8.7)
1000 Hz *	60.0 (13.9)	71.0 (5.8)
2000 Hz *	54.1 (7.7)	64.0 (5.8)
4000 Hz *	52.6 (13.0)	68.0 (8.7)
Bone conduction thresholds (dB HL)		
250 Hz	5.0 (8.6)	3.0 (6.8)
500 Hz	5.0 (8.9)	1.0 (4.9)
1000 Hz	13.2 (12.0)	6.0 (8.6)
2000 Hz	20.3 (11.0)	26.0 (7.3)
4000 Hz	7.1 (7.1)	9.0 (12.4)
Aided thresholds with CCHA (dB HL)		
250 Hz	37.9 (5.2)	33.0 (2.4)
500 Hz	33.5 (5.1)	34.0 (2.0)
1000 Hz	27.6 (4.6)	30.0 (0.0) *
2000 Hz	31.2 (5.3)	33.0 (2.4)
4000 Hz *	32.1 (9.4)	45.0 (11.0)
Aided thresholds with previous hearing aids (dB HL)		
250 Hz	37.8 (16.3)	47.5 (17.5)
500 Hz	33.3 (15.6)	30.0 (5.0)
1000 Hz	28.3 (7.8)	22.5 (2.5) *
2000 Hz	27.2 (7.9)	30.0 (10.0)
4000 Hz	33.2 (8.9)	37.5 (7.5)

BCHA, bone conduction hearing aid; CCHA, cartilage conduction hearing aid; SD, standard deviation; * $p < 0.05$.

Table 3. Comparison between CCHA purchase cases and non-purchase cases in unilateral aural atresia or severe canal stenosis in which the opposite ear's hearing level was less than 30 dB.

	Purchase (*n* = 21)	**Non-Purchase (*n* = 15)**
	Average (SD)	Average (SD)
Age (Year)	10.3 (7.0)	19.6 (19.6)
Sex (Female/Male)	11/10	8/7
Previous hearing aids (No/Yes)	21/0	15/0
Ears with atresia auris or meatal stenosis		

Table 3. *Cont.*

	Purchase (*n* = 21)	Non-Purchase (*n* = 15)
Air conduction thresholds (dB HL)		
250 Hz	85.7 (11.5)	81.0 (10.7)
500 Hz	78.3 (12.6)	78.7 (11.9)
1000 Hz	67.1 (13.1)	70.7 (10.9)
2000 Hz	61.0 (11.5)	67.0 (14.2)
4000 Hz	61.2 (14.1)	64.3 (14.9)
Bone conduction thresholds (dB HL)		
250 Hz	5.6 (11.0)	5.0 (8.0)
500 Hz	7.1 (15.5)	6.4 (7.2)
1000 Hz	7.9 (10.8)	10.7 (4.9)
2000 Hz	16.3 (10.2)	16.1 (8.7)
4000 Hz	5.3 (10.1)	9.6 (12.0)
Aided thresholds with CCHAs (dB HL)		
250 Hz	51.8 (14.6)	42.1 (12.3)
500 Hz	39.3 (7.6)	41.1 (8.7)
1000 Hz	31.9 (5.5)	34.6 (4.0)
2000 Hz	33.8 (6.5)	35.7 (5.9)
4000 Hz	36.2 (8.7)	42.9 (11.3)
Unaffected ears		
Air conduction thresholds (dB HL)		
250 Hz	18.8 (8.2)	17.7 (6.5)
500 Hz	15.7 (8.6)	13.0 (7.7)
1000 Hz	11.7 (6.8)	11.0 (8.2)
2000 Hz	10.2 (7.0)	9.7 (9.4)
4000 Hz	8.8 (7.9)	12.0 (8.1)
Bone conduction thresholds (dB HL)		
250 Hz	12.3 (6.4)	13.9 (5.7)
500 Hz	9.6 (8.9)	10.0 (5.3)
1000 Hz	8.1 (5.7)	12.8 (5.3)
2000 Hz	13.5 (7.4)	10.6 (5.0)
4000 Hz	5.0 (10.4)	6.7 (10.5)

CCHA, cartilage conduction hearing aid; SD, standard deviation.

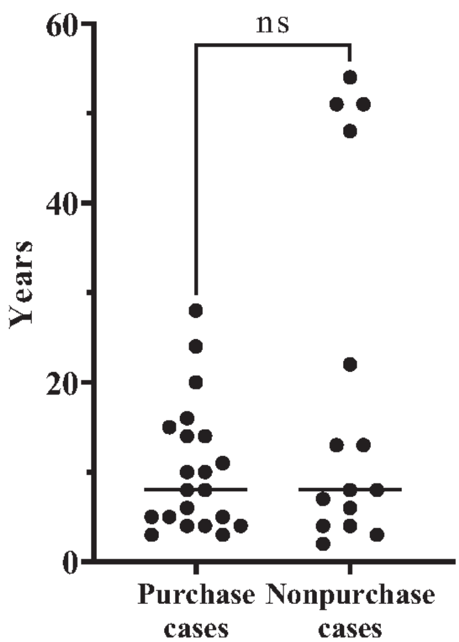

Figure 2. The age distribution between CCHA purchase and non-purchase cases in unilateral aural atresia or severe canal stenosis in which the opposite ear's hearing level was less than 30 dB.

4. Discussion

In this study, we investigated 91 ears that underwent CCHA fitting in our hospital. The number of ears and the purchase rate were high in the closed-ear group, as reported previously [16,17].

Patients with bilateral closed ears usually require hearing aids [21–23]. The percentage of previous hearing aid users in the bilateral closed-ear group was highest in the six groups. Regarding the bilateral closed-ear group, purchase cases showed significantly lower aided thresholds with CCHAs at 250 and 500 kHz than the non-purchase cases [17]. Our study found that aided thresholds at 4000 Hz were significantly lower in the purchase group. Overall, better aided thresholds with CCHAs contribute to CCHA purchases. Many cases with bilateral closed ears had been fitted with BCHAs. The patients compared the new CCHAs with their current BCHAs and decided whether to purchase the CCHAs. The aided thresholds with CCHAs in the bilateral closed-ear group were relatively good; therefore, most patients bought CCHAs. The BCHA transducer is relatively big and fixed with a headband or a similar device; therefore, BCHAs are more visible than CCHAs and ACHAs. If BCHCs are to function well, the transducer must be pushed tightly against the head. However, continued use can cause pain, irritation, and discomfort [24,25]. Meanwhile, BCHAs have the advantage of being easy to put on and take off. Most closed-ear cases cannot use ear chips and must use a double-sided skin tape to fix CCHA transducers, which makes it difficult to attach or remove CCHAs. Even after purchasing CCHAs with appropriate aided thresholds, some patients with bilateral closed ears continued to use BCHAs in combination with them, mainly in situations where it was necessary to put the hearing aid on and take it off easily. Parents in the bilateral closed-ear group often had a strong desire to improve the appearance of their children, as well as their hearing. Many of them decided in advance to purchase CCHAs for their children before visiting a doctor. If a patient's aided threshold with CCHAs is poor compared to with BCHAs, we must propose that parents make their purchasing decisions carefully, especially for young children who cannot express their own opinion about which aid is better.

Patients with unilateral closed ears often have another ear with normal hearing and do not consider hearing aids to be essential. On the other hand, the negative effect of unilateral severe hearing loss on communication, development, and education has been reported [26,27], and hearing aids for the affected ear are desirable. In the unilateral closed-ear group, in which the opposite ear's hearing level was normal, it was reported that purchase cases were significantly younger than non-purchase cases and no obvious differences were observed in both aided and unaided thresholds [17]. The mean age was also younger in the purchase group in our study; however, no significant difference was observed. Most patients with unilateral closed ears were under 30 years old. Meanwhile, the other four middle-aged patients did not purchase CCHAs. These four cases appeared to raise the mean age of the non-purchasing group. We compared these four middle-aged cases with the other young candidates. However, no difference was observed in air and bone conduction thresholds, aided thresholds with CCHA, or reasons for not purchasing CCHAs (itchiness, noise, and annoyances associated with using CCHA). For middle-aged candidates in the unilateral closed-ear group, the discomfort of wearing CCHAs might have outweighed the benefits of reducing the left–right difference in hearing. On the other hand, in the unilateral closed-ear group, in which the opposite ear's hearing level was more than 30 dB, the need for hearing aids was considered higher than in the group with unilateral hearing loss.

The purchase rate in the continuous-otorrhea group was lower than that reported previously [16,17]. All our cases with continuous otorrhea were over 70 years old. Due to age-related hearing loss, it is plausible that a decrease in the purchase rate occurred because the adequate aided thresholds were not reached. The conductive hearing loss group showed a high purchase rate similar to the closed-ear group; however, there were only five ears in the conductive hearing loss group, and CCHAs were mainly purchased for them because the patients considered CCHAs to look better than the ordinary behind-the-ear type of ACHAs. This purchase rate may be overestimated, and further investigations are required. In this study, few patients with sensorineural or mixed hearing loss chose to purchase CCHAs. Meanwhile, more than 36% of patients purchased CCHAs in relatively similar groups in previous studies [12,16,17]. The purchase rate might have deteriorated because we provided an opportunity to compare CCHAs with ACHAs, which are often less expensive and usually have higher acoustic gain than CCHAs. ACHAs appear to be suitable for patients with sensorineural or mixed hearing loss. In the study, when patients tested the CCHAs, a double-sided skin tape was used to fix the transducers. If ear impressions had been taken in advance and ear-chip-type transducers were available at the time of CCHA fitting, the purchase rate might have been higher. Using the ear chip increases the transducer stability of CCHAs and allows patients to put CCHAs on and take them off easily. Ear-chip-type fixation is recommended when its insertion is enabled by the placement of the fixation [17]. However, a double-sided skin tape fixation for CCHA fitting has advantages. This fixation method is available for all ear conditions and reduces the time required for fitting and unnecessary ear chip costs [17].

It is necessary to consider the possibility that hearing aid prices influence hearing aid purchases. One HB-J1CC CCHA costs JPY 300,000, and two HB-J1CC CCHAs cost JPY 510,000. One HB-A2CC CCHA costs JPY 350,000, and two HB-A2CCs cost JPY 600,000. In this study, most previously used BCHAs were Mini Digital BCHAs (Starkey Hearing Technologies, Minnesota, MN, USA) fixed with hard headbands. One Mini Digital BCHA costs JPY 189,000, and two Mini Digital BCHAs cost JPY 346,000. ACHAs range from cheap to expensive, but some behind-the-ear types of ACHAs can be purchased for JPY 100,000 to JPY 200,000 per unit. CCHAs and some behind-the-ear types of ACHAs are sold at special prices for those under 20 years of age. In Japan, one HB-J1CC CCHA costs JPY 150,000, and two HB-J1CC CCHAs cost JPY 300,000. One HB-A2CC CCHA costs JPY 175,000, and two HB-A2CCs cost JPY 350,000. Some behind-the-ear types of ACHAs cost approximately JPY 43,900 in special cases. Meanwhile, Mini Digital BCHAs are sold at the same price regardless of age. These prices can be summarized as follows: for those over 20, ACHAs and BCHAs are cheaper than CCHAs. For those under 20, ACHAs are also cheaper than CCHAs. However, the price of BCHAs is not much different from that of CCHAs. In this study, two-thirds of patients who tested CCHAs were under 20, and those who used BCHAs might have been more likely to choose CCHAs from an economic point of view.

There are some limitations to the present study. The purchase rate could be influenced not only by the attainment of suitable aided thresholds, but also by considerations of aesthetics, comfort, and the economic dimension. The purchase rate is not a pure measure of CCHA effectiveness. Meanwhile, when considering which patients should be recommended for CCHAs, it is good to focus on the purchase rate, as their appearance, comfort and economic advantages are also considered when they are compared with BCHAs, which are often competitive. Due to the examination taking place in only one facility, regional factors, such as subsidies by local governments, might have affected our results. We used data from a relatively early sales stage; therefore, purchase trends may change in the future. Further investigations are required.

5. Conclusions

The purchase rate of CCHAs was particularly high in ears with aural atresia or severe canal stenosis. In the bilateral closed-ear group, air conduction thresholds and aided thresholds were associated with the purchase of CCHAs. In the unilateral closed-ear group, factors other than hearing might affect the purchase of CCHAs.

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References

1. Hosoi, H. Approach in the Use of Cartilage Conduction Speaker. Japanese Patent 4541111, 17 November 2004.
2. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Yamanaka, T.; Levitt, H. Is cartilage conduction classified into air or bone conduction? *Laryngoscope* **2014**, *124*, 1214–1219. [CrossRef] [PubMed]
3. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Yamanaka, T.; Kitahara, T.; Levitt, H. Cartilage conduction is characterized by vibrations of the cartilaginous portion of the ear canal. *PLoS ONE* **2015**, *10*, e0120135.
4. Shimokura, R.; Hosoi, H.; Nishimura, T.; Iwakura, T.; Yamanaka, T. Simulating cartilage conduction sound to estimate the sound pressure level in the external auditory canal. *J. Sound Vib.* **2015**, *20*, 261–268. [CrossRef]
5. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Yamanaka, T.; Kitahara, T.; Levitt, H. Cartilage conduction efficiently generates airborne sound in the ear canal. *Auris Nasus Larynx* **2015**, *42*, 15–19.
6. Hosoi, H.; Yanai, S.; Nishimura, T.; Sakaguchi, T.; Iwakura, T.; Yoshino, K. Development of cartilage conduction hearing aid. *Arch. Mat. Sci. Eng.* **2010**, *42*, 104–110.
7. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Iwakura, T. Benefit of a new hearing device utilizing cartilage conduction. *Auris Nasus Larynx* **2013**, *40*, 440–446. [CrossRef]
8. Shimokura, R.; Hosoi, H.; Iwakura, T.; Nishimura, T.; Matsui, T. Development of monaural and binaural behind-the-ear cartilage conduction hearing aids. *Appl. Acoust.* **2013**, *74*, 1234–1240.
9. Hosoi, H.; Nishimura, T.; Shimokura, R.; Kitahara, T. Cartilage conduction as the third pathway for sound transmission. *Auris Nasus Larynx* **2019**, *46*, 151–159.
10. Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Morimoto, C.; Kitahara, T. Cartilage conduction hearing and its clinical application. *Audiol. Res.* **2021**, *11*, 254–262. [CrossRef]
11. Morimoto, C.; Nishimura, T.; Hosoi, H.; Saito, O.; Fukuda, F.; Shimokura, R.; Yamanaka, T. Sound transmission by cartilage conduction in ear with fibrotic aural atresia. *J. Rehabil. Res. Dev.* **2014**, *51*, 325–332. [CrossRef]
12. Nishiyama, T.; Oishi, N.; Ogawa, K. Who are good adult candidates for cartilage conduction hearing aids? Eur. *Arch. Otorhinolaryngol.* **2020**, *59*, 891–896.
13. Nishiyama, T.; Oishi, N.; Ogawa, K. Efficacy of cartilage conduction hearing aids in children. *Int. J. Pediatr. Otorhinolaryngol.* **2021**, *142*, 110628. [CrossRef] [PubMed]
14. Sakamoto, Y.; Shimada, A.; Nakano, S.; Kondo, E.; Takeyama, T.; Fukuda, J.; Udaka, J.; Okamoto, H.; Takeda, N. Effects of FM system fitted into the normal hearing ear or cartilage conduction hearing aid fitted into the affected ear on speech-in-noise recognition in Japanese children with unilateral congenital aural atresia. *J. Med. Investig.* **2020**, *67*, 131–138. [CrossRef] [PubMed]
15. Komune, N.; Higashino, Y.; Ishikawa, K.; Tabuki, T.; Masuda, S.; Koike, K.; Hongo, T.; Sato, K.; Uchi, R.; Miyazaki, M.; et al. Management of residual hearing with cartilage conduction hearing aid after lateral temporal bone resection: Our institutional experience. *Audiol. Res.* **2021**, *11*, 263–274.
16. Nishimura, T.; Hosoi, H.; Sugiuchi, T.; Matsumoto, N.; Nishiyama, T.; Takano, K.; Sugimoto, S.; Yazama, H.; Sato, T.; Komori, M. Cartilage conduction hearing aid fitting in clinical practice. *J. Am. Acad. Audiol.* **2021**, *32*, 386–392. [CrossRef]
17. Nishimura, T.; Hosoi, H.; Sugiuchi, T.; Matsumoto, N.; Nishiyama, T.; Takano, K.; Sugimoto, S.; Yazama, H.; Sato, T.; Komori, M. Factors influencing the purchase rate of cartilage conduction hearing aids. *J. Am. Acad. Audiol.* **2022**, *33*, 14–22. [CrossRef]
18. Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Yamanaka, T.; Kitahara, T. Cartilage conduction hearing aids for severe conduction hearing loss. *Otol. Neurotol.* **2018**, *39*, 65–72. [CrossRef]
19. Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Yamanaka, T.; Kitahara, T. Sound localization ability using cartilage conduction hearing aids in bilateral aural atresia. *Int. J. Audiol.* **2020**, *59*, 891–896. [CrossRef]
20. Suwento, R.; Widodo, D.W.; Airlangga, T.J.; Alviandi, W.; Watanuki, K.; Nakanowatari, N.; Hosoi, H.; Nishimura, T. Clinical trial for cartilage conduction hearing aid in Indonesia. *Audiol. Res.* **2021**, *11*, 410–417. [CrossRef] [PubMed]
21. Aziz, M.A. Congenital aural atresia. *J. Craniofac. Surg.* **2013**, *24*, 418–422. [CrossRef]
22. Spring, P.M.; Gianoli, G.J. Congenital aural atresia. *J. LA. State Med. Soc.* **1997**, *149*, 6–9. [PubMed]
23. Truong, M.T.; Liu, Y.C.C.; Kohn, J.; Chinnadurai, S.; Zopf, D.A.; Tribble, M.; Tanner, P.B.; Sie, K.; Chang, K.W. Integrated microtia and aural atresia management. *Front. Surg.* **2022**, *10*, 3389. [CrossRef] [PubMed]

24. Dillon, H. CROS Bone Conduction and Implanted Hearing Aids. In *Hearing Aids*, 1st ed.; Thieme Medical Publishers: New York, NY, USA, 2001; pp. 435–450.
25. Lo, J.F.W.; Tsang, W.S.S.; Yu, J.Y.K.; Ho, O.Y.M.; Ku, P.K.M.; Tong, M.C.F. Contemporary hearing rehabilitation options in patients with aural atresia. *BioMed Res. Int.* **2014**, *2014*, 761579. [CrossRef] [PubMed]
26. Cañete, O.M.; Purdy, S.C.; Brown, C.R.S.; Neeff, M.; Thorne, P.R. Behavioural performance and self-report measures in children with unilateral hearing loss due to congenital aural atresia. *Auris Nasus Larynx* **2021**, *48*, 65–74. [CrossRef]
27. Jensen, D.R.; Grames, L.M.; Lieu, J.E. Effects of aural atresia on speech development and learning: Retrospective analysis from a multidisciplinary craniofacial clinic. *JAMA Otolaryngol. Head. Neck Surg.* **2013**, *139*, 797–802. [PubMed]

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The Effects of Utilizing Cartilage Conduction Hearing Aids among Patients with Conductive Hearing Loss

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Abstract: The cartilage-conduction hearing aid (CC-HA) is a new hearing device that is suitable for use in patients with conductive hearing loss. It has been 5 years since the introduction of the CC-HA. Although the number of users has increased, the CC-HA is not yet widely known. This study examines the effects of CC-HA on patients with conductive hearing loss and investigates factors that affect the willingness to use the device by comparing purchasers and non-purchasers of CC-HA in patients with unilateral conductive hearing loss. Eight patients had bilateral conductive hearing loss, and 35 had unilateral conductive hearing loss. Each patient underwent sound field tests and speech audiometry, and the effects of the CC-HA were compared with those of conventional bone conduction hearing aids (BC-HA). In patients with bilateral conductive hearing loss, the CC-HA was non-inferior to BC-HA. The CC-HA improved the hearing thresholds and speech recognition in patients with unilateral conductive hearing loss. Moreover, in patients with unilateral conductive hearing loss, experiencing the effect of wearing the CC-HA under conditions such as putting noise in the better ear could affect patients' willingness to use the CC-HA.

Keywords: cartilage conduction; hearing aid; conductive hearing loss; speech recognition

1. Introduction

It has long been postulated that auditory sound conduction is facilitated solely through two pathways: air conduction (AC) via the ear canal and bone conduction (BC) through the skull. However, in 2004, Hosoi [1] discovered that the application of vibrations containing sound information to the cartilage produces a sound that is as clear as air or bone conduction. This phenomenon was termed "cartilage conduction" (CC). CC was subsequently established as the third auditory pathway following air and bone conduction.

Three sound conduction pathways are now believed to exist from the CC transducer to the inner ear: the vibration of the ear cartilage produces air-conducted sound in the external auditory canal, which reaches the tympanic membrane; it is referred to as "cartilage AC". Vibrations of the otocardium generate vibrations in the temporal bone, which are transmitted to the inner ear, which is known as "cartilage BC". The CC transducer vibrates the air surrounding it, and the resulting air-conducted sound enters the external auditory canal through its entrance and reaches the tympanic membrane. This is called "direct AC". These three pathways have been previously described [2,3].

The concept of CC has been utilized in the development of products such as hearing aids, smartphones, and earphones [4]. Specifically, the development of cartilage-conduction hearing aids (CC-HA) [5–7] that were introduced in 2017 has progressed rapidly.

Conventional sound conduction methods for hearing aids typically rely on air conduction. A condition that is difficult to manage with an air-conduction hearing aid (AC-HA) is aural atresia (e.g., microtia). In such cases, the use of AC-HA can be difficult or ineffective due to the closed outer ear. In these patients, bone-conduction hearing aids (BC-HA), implantable bone-conduction hearing aids (BAHA, BONEBRIDGE), and middle ear implants (VSB) have been employed. BC-HA is bone conductive; therefore, sound conduction is not significantly affected even if the ear canal is closed. However, a headband must be used to attach the transducer to the bone to achieve optimal hearing. However, prolonged use is challenging because of local pain, indentation, redness, and erosion caused by headband fixation, which is also aesthetically unappealing. BAHA, BONEBRIDGE, and VSB can address the limitations of bone-anchored hearing aids because they are surgically implanted. However, the requirement for surgery is a significant drawback [8–10]. The CC-HA is suitable for use even with microtia, as conduction occurs through vibrations in the ear cartilage, and it is painless because the transducer does not need to be firmly clamped to the body, as in the case of BC-HA. The CC-HA does not require a headband for fixation, and the transducer can be easily secured. Additionally, the CC-HA does not require surgery. In summary, the lightweight and compact CC-HA transducer is more comfortable and aesthetically pleasing than the BC-HA [11–15]. In CC-HAs, the degree of contribution to the above three conduction pathways changes according to the frequency of sound and the condition of the outer and middle ears, meaning it is difficult to simplify their effects. For example, the cartilage-AC route is the main route in an ear with a normal ear canal, whereas the cartilage-BC route is the main route in an ear with aural atresia. CC-HAs are, therefore, different from conventional AC and BC-HAs, and there are cases where they have merit over conventional hearing aids if these characteristics can be utilized.

Nishimura et al. [12] reported the benefits of CC-HAs in patients with severe conductive hearing loss and concluded that the functional gains for CC-HAs were nearly equivalent to that for previously used hearing aids, with 39 out of 41 patients continuing to use CC-HAs instead of their original hearing aids. Nishiyama et al. [13] assessed the efficacy of CC-HAs in 37 adult patients with hearing loss who had various anatomical conditions in their ear canal, and they concluded that adult patients with ear canal stenosis or closure were the best candidates for CC-HAs, regardless of their hearing thresholds. Nishiyama et al. [14] also reported the efficacy of CC-HAs in 42 pediatric patients with hearing loss, and they concluded that CC-HAs were efficacious in producing hearing improvements in children, especially in patients with atresia or canal stenosis who could not use AC-HAs.

It has been 5 years since the introduction of the CC-HA, and although the efficacy of the CC-HA, such as those mentioned above, has been reported, it is not yet widely used worldwide. In this study, we examined the effect of wearing the CC-HA on patients with conductive hearing loss at our hospital who had a hearing aid trial with the CC-HA.

2. Materials and Methods

Participants included eight patients with bilateral conductive hearing loss and 35 patients with unilateral conductive hearing loss who underwent a hearing aid trial with the CC-HA at our hospital (Sapporo Medical University) over a period of 5 years from December 2017 to December 2022. Among patients with bilateral conductive hearing loss, we included patients who were using BC-HAs as their conventional hearing aid and excluded patients who were not using BC-HAs. Patients with bilateral conductive hearing loss were 6–27 years of age (median 13 years) and consisted of two males and six females, whereas those with unilateral conductive hearing loss were 4–64 years old (median 15 years), consisting of 20 males and 15 females. Among the patients with bilateral conductive hearing loss, six had microtia, and two had external auditory canal stenosis or atresia with a normal concha. Of the patients with unilateral conductive hearing loss, 30 had microtia, three had external auditory canal stenosis or atresia with a normal concha, one had a middle ear malformation, and one had undergone surgery for external auditory canal cancer.

For the hearing aid trial, from December 2017 to October 2020, HB-J1CC (Rion Co., Ltd., Kokubunji, Japan) was used, and from October 2020, HB-A2CC, a new model of the same device, was used. The transducers selected were ear-chip-embedded or simple types according to the ear condition. Since HB-J1CC does not have a child lock function, it was said to be suitable for ages 3 and up. However, the HB-A2CC was equipped with a child lock function to prevent the accidental swallowing of the battery, allowing for its use from a younger age.

Simple pure-tone audiometry, sound field tests, and speech audiometry were performed in patients with bilateral conductive hearing loss. Regarding speech audiometry, two patients did not consent to participate, and speech audiometry was not performed. For the sound field test and speech audiometry, the test results obtained when using conventional BC-HA were compared with those obtained using the CC-HA. For patients with unilateral conductive hearing loss, we performed simple pure-tone audiometry, sound field tests, and speech audiometry. Similar to the method described by Akasaka et al. [16] to examine the effect of binaural hearing with the CC-HA in unilateral aural atresia, from December 2017 to September 2019, we compared speech recognition scores (SRS) with and without the CC-HA at sound pressure 10 dB lower than the sound pressure at which the highest SRSs were obtained without a hearing aid. After October 2019, we conducted a sound field test with 70 dB noise (narrow band noise) from headphones worn on the better ear with and without the CC-HA and compared the results to further clarify the effect of wearing the CC-HA. The noise was set at 70 dB to avoid excessive discomfort to the better ear, but in some patients with a high threshold on the affected ear, sound field hearing without the CC-HA may have been incorrect. Similarly, we compared the SRSs conducted at a presentation sound pressure of 60 dB with 70 dB noise (speech noise) in the better ear with and without the CC-HA. One patient did not cooperate with the sound field test, and four patients did not cooperate with the speech audiometry. The results of the pure-tone audiometry and sound field tests were averaged at thresholds of 500, 1000, and 2000 Hz. Speech audiometry was performed using the 57-S list and 67-S list authorized by the Japan Audiological Society. The 57-S or 67-S word lists included 50- or 20-monosyllable words, respectively. For a detailed evaluation, it was better to use the 57-S list, which had a large number of monosyllables but took a long time to examine. Therefore, the 67-S list was used when conducting speech audiometry to obtain the highest standard SRS without hearing aids. On the other hand, the 57-S list was used in the speech audiometry to compare the difference with and without the CC-HA. Pure tone audiometry, sound field testing, and speech audiometry were all performed in a soundproof room. In the sound field test and speech intelligibility test, speakers were located at a distance of 1 m from the patient and at an angle of 45 degrees to the left and right.

Welch's *t*-test and a chi-squared test were used for statistical analyses. Analyses were performed using Microsoft 365 Excel (Microsoft Co., Redmond, WA, USA), and statistical significance was set at $p < 0.05$.

We revealed the purpose and content of the survey to the participants and ensured the protection of privacy. This study was approved by the Ethics Committee of Sapporo Medical University in an official letter on 27 February 2023 (Protocol number: 342-232).

3. Results

The clinical characteristics of the study participants are summarized in Table 1. Patients with bi- and unilateral conductive hearing loss were divided into a group that purchased CC-HA and a group that did not, alongside their age, sex, and pure-tone audiometry results, which were compared. There was only one patient with bilateral conductive hearing loss in the non-purchase group, and the values for each of the cases are shown. There was no significant difference between the purchase and non-purchase groups in terms of age, sex, or pure-tone audiometry results for unilateral conductive hearing loss. Statistical analysis could not be performed for bilateral conductive hearing loss because there was only one patient in the non-purchase group.

Table 1. Characteristics of patients.

Bilateral Conductive Hearing Loss					
	N	**Age (Year, Mean ± SD)**	**Female/Male**	**PTA in Poorer Hearing Ear (dB HL, Mean ± SD)**	**PTA in Better Hearing Ear (dB HL, Mean ± SD)**
Purchase	7	15.5 ± 2.0	5/2	72.7 ± 8.0	66.4 ± 16.1
Non-purchase	1	6	1/0	78.8	76.3
Unilateral Conductive Hearing Loss					
	N	**Age (Year, Mean ± SD)**	**Female/Male**	**PTA in Poorer Hearing Ear (dB HL, Mean ± SD)**	**PTA in Better Hearing Ear (dB HL, Mean ± SD)**
Purchase	24	16.3 ± 13.2	9/15	78.9 ± 10.4	10.2 ± 6.0
Non-purchase	11	13.3 ± 6.6	6/5	72.7 ± 12.7	11.6 ± 3.6

PTA: pure-tone average of thresholds at 500, 1000, and 2000 Hz. Purchase: a group that purchased CC-HA. Non-purchase: a group that did not purchased CC-HA.

Figures 1 and 2 show the results of the sound field test and speech audiometry for bilateral conductive hearing loss using conventional BC-HA and CC-HA. Those with circles at both ends and a solid line show the results for the purchase group, and those with squares at both ends and a dotted line show the results for the non-purchase group. In the sound field test in eight patients with bilateral conductive hearing loss (Figure 1), the results were 30.1 ± 1.7 dB for the BC-HA and 28.4 ± 1.6 dB for the CC-HA with no significant difference, indicating the non-inferiority using CC-HA. On the other hand, a comparison of the purchase and non-purchase groups using CC-HA could not be statistically analyzed because there was only one patient in the non-purchase group. In the speech audiometry in six patients with bilateral conductive hearing loss (Figure 2), the results were 88.1 ± 3.3% for the BC-HA and 91.8 ± 2.5% for the CC-HA, with no significant difference, indicating the non-inferiority of CC-HA in the speech audiometry as well as the sound field test.

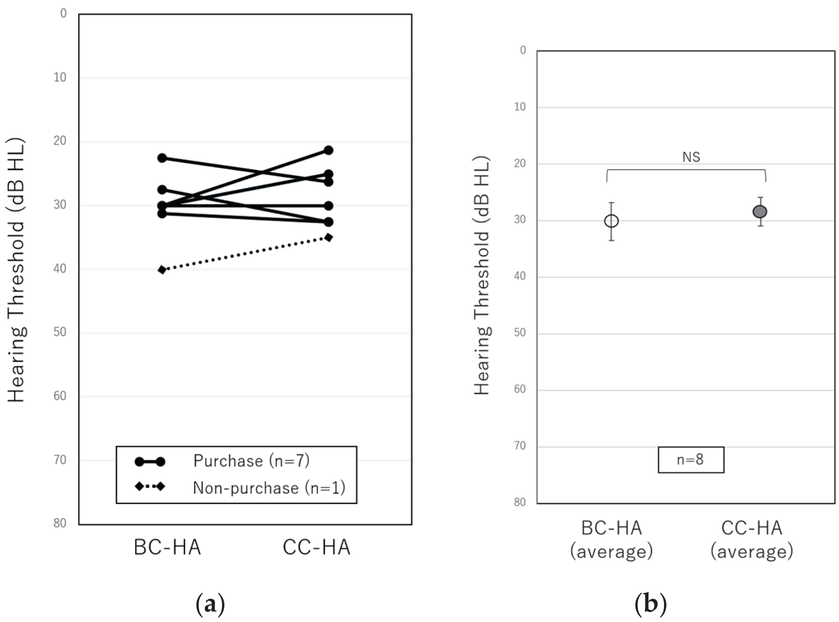
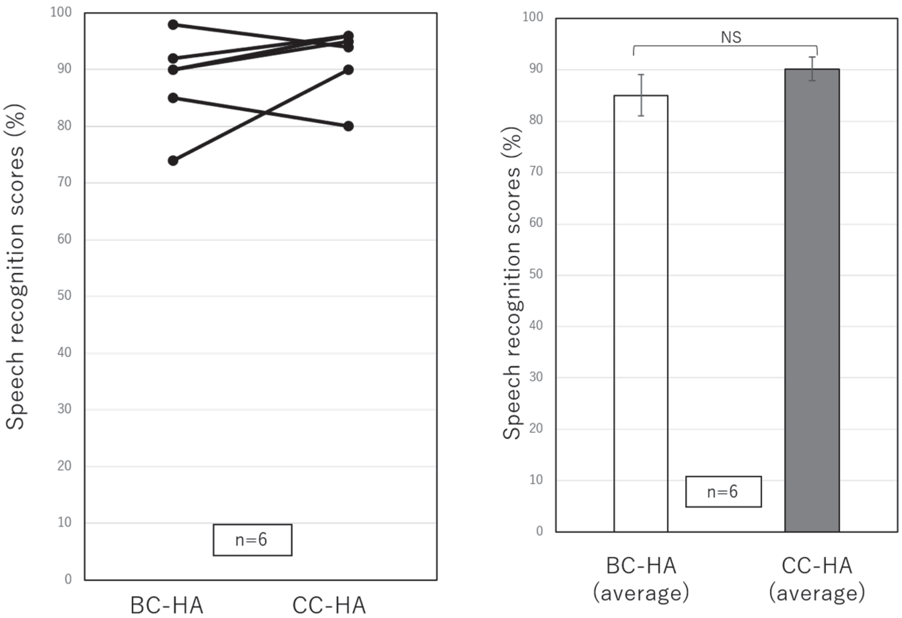


Figure 1. (**a**) Comparisons of individual hearing thresholds in sound field tests using the conventional BC-HA and the CC-HA. The solid line represents purchasers, and the dotted line represents non-purchasers. (**b**) Comparisons of the average hearing thresholds of eight patients using the BC-HA and the CC-HA. The error bars indicate standard errors. BC-HA: bone conduction hearing aid, CC-HA: cartilage conduction hearing aid, NS: not significant.



(**a**) (**b**)

Figure 2. (**a**) Comparisons of individual speech recognition scores obtained from speech audiometry using the conventional BC-HA and the CC-HA. (**b**) Comparisons of the average SRSs of six patients using the BC-HA and the CC-HA. The error bars indicate standard errors. BC-HA: bone conduction hearing aid, CC-HA: cartilage conduction hearing aid, NS: not significant.

Figure 3 shows the speech audiometry results for 15 patients with unilateral conductive hearing loss who underwent the CC-HA hearing aid trial between January 2018 and October 2019. The average SRS in 15 patients with unilateral conductive hearing loss was 74.9 $\pm$ 3.0% without CC-HA, whereas it was 80.3 $\pm$ 3.1% while wearing CC-HA, showing a significant difference in speech clarity when using CC-HA (Figure 3b). However, the 15 patients were divided into the purchase and non-purchase groups, and the difference in the SRS with and without the CC-HA was compared between the two groups, but no significant difference was observed (Figure 3c).

Figures 4 and 5 show the results of the sound field test and speech audiometry with and without CC-HA in 20 patients with unilateral conductive hearing loss who underwent the CC-HA hearing aid trial between October 2019 and December 2022. These tests were performed with 70 dB of noise in the good ear, as described above. The average of the sound field test in 19 patients with unilateral conductive hearing loss was 54.3 $\pm$ 2.5 dB without CC-HA and 36.8 $\pm$ 1.9 dB while wearing the CC-HA, showing a significant improvement while wearing CC-HA (Figure 4b). However, when the 19 patients were divided into the purchase and non-purchase groups, the difference in the sound field test results with and without CC-HA was compared between the two groups, and no significant difference was observed (Figure 4c). The average SRS in 16 patients with unilateral conductive hearing loss was 30.7 $\pm$ 4.4% without CC-HA and 58.9 $\pm$ 3.9% while wearing it, showing a significant improvement while using CC-HA (Figure 5b). When comparing the difference in SRS with and without CC-HA between the purchase and non-purchase groups, no significant difference was observed (p = 0.054); however, SRS tended to be better in the purchase group than in the non-purchase group when noise was produced in the good ear (Figure 5c).

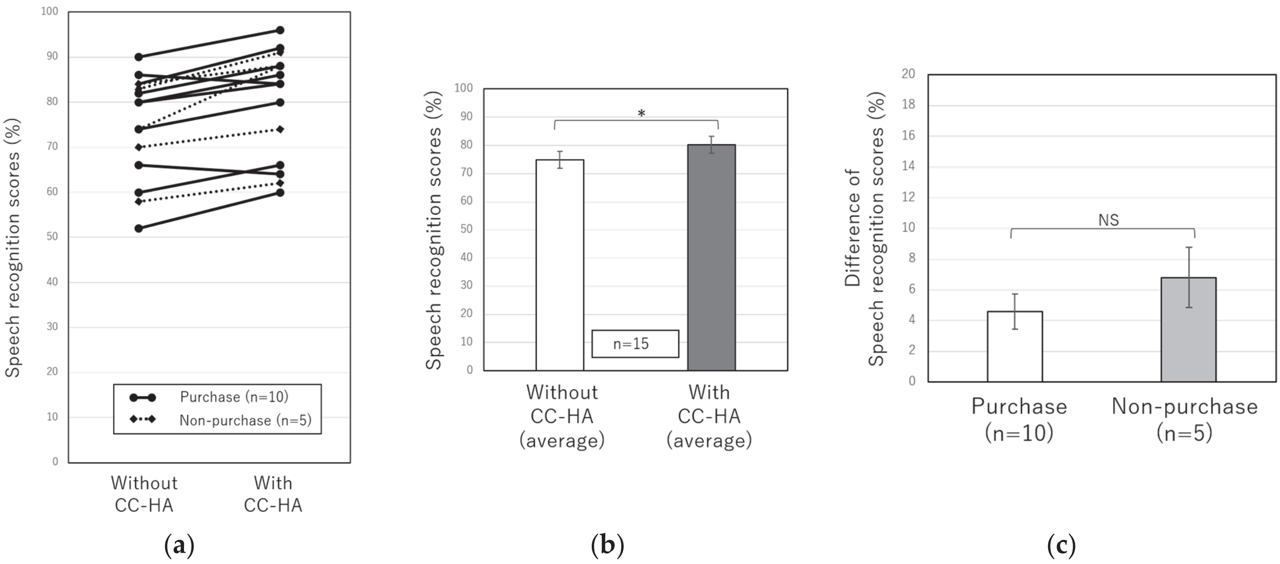


Figure 3. (**a**) Comparisons of individual speech recognition scores with and without the CC-HA at a sound pressure 10 dB lower than the sound pressure at which the highest SRSs were obtained without a hearing aid. The solid line represents purchasers, and the dotted line represents non-purchasers. (**b**) Comparisons of the average SRSs of 15 patients with and without the CC-HA. (**c**) Comparisons of SRSs between the purchasers and non-purchasers. The error bars indicate standard errors. NS: not significant, *: $p < 0.05$.

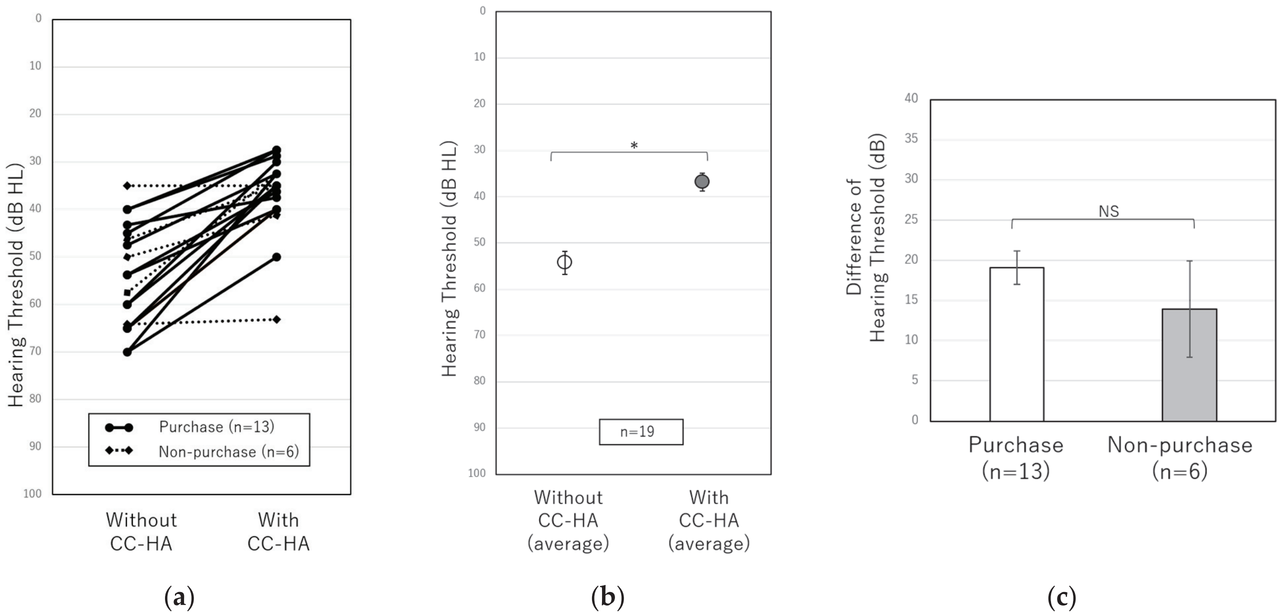


Figure 4. (**a**) Comparisons of individual hearing thresholds in sound field tests with and without CC-HA with 70 dB noise in the good ear. The solid line represents purchasers, and the dotted line represents non-purchasers. (**b**) Comparisons between the average hearing thresholds of 19 patients with and without the CC-HA. (**c**) Comparisons of hearing thresholds between the purchasers and non-purchasers. The error bars indicate standard errors. NS: not significant, *: $p < 0.05$.

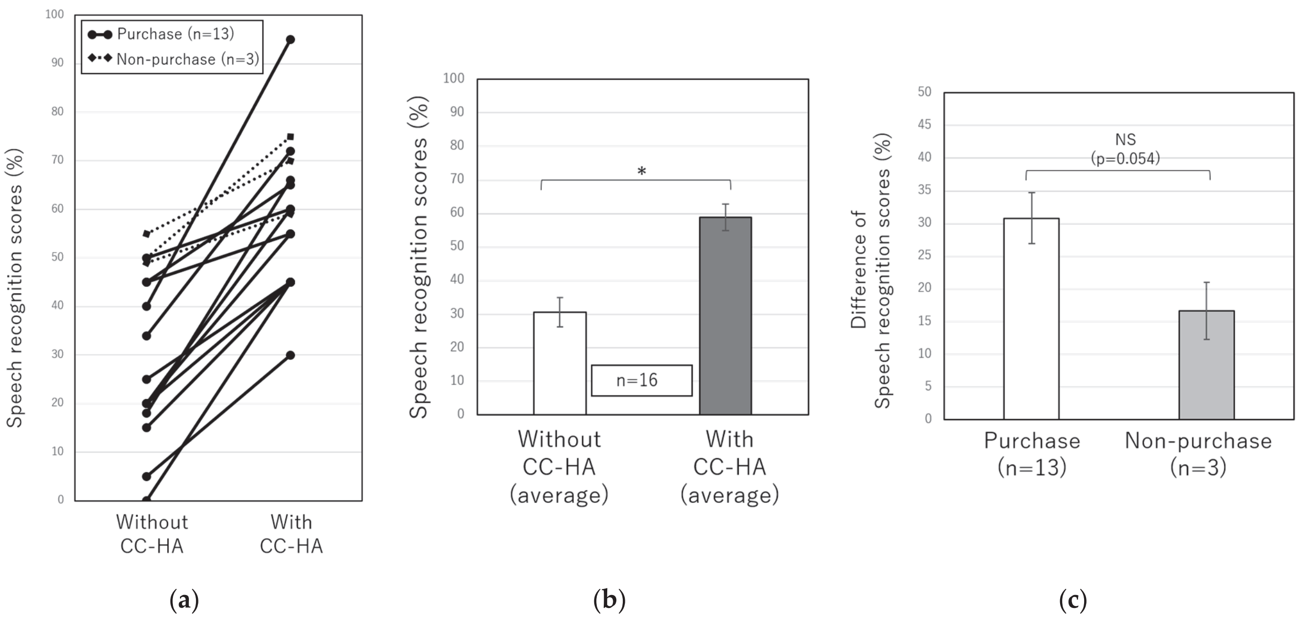


Figure 5. (**a**) Comparisons of individual speech recognition scores with and without the CC-HA with 70 dB noise in the good ear. The solid line represents purchasers, and the dotted line represents non-purchasers. (**b**) Comparisons of the average SRSs of 16 patients with and without CC-HA. (**c**) Comparisons of SRSs between the purchasers and non-purchasers. The error bars indicate standard errors. NS: not significant, *: $p < 0.05$.

4. Discussion

In this study, we first examined whether the test results differed between BC-HAs and CC-HAs in patients with bilateral conductive hearing loss. We did not observe a significant difference, and the average results of the sound field test and speech audiometry both improved slightly; therefore, CC-HA was shown to be non-inferior to BC-HA. Although not included in this study, there was one patient with bilateral conductive hearing loss who used an AC-HA as a conventional hearing aid, and CC-HA was as effective as the AC-HA in both sound field testing and speech audiometry. Although patients with bilateral conductive hearing loss were classified into purchase and non-purchase groups to compare the test results, there was only one non-purchaser; therefore, statistical analysis could not be performed. Further studies with more participants are needed to examine whether differences between CC-Has and BC-Has affect their willingness to use CC-HAs. Other differences between the BC-HA and the CC-HA may be perceived as comfort when wearing hearing aids. In fact, some patients who experienced wearing the BC-HA commented that after wearing the CC-HA for a while, skin pain and feelings of pressure were improved. Alternatively, some patients chose to wear the CC-HA with a simple transducer rather than the ear-chip-embedded transducer and felt that it was troublesome to stick them on. Furthermore, BC-HAs were often only worn in one ear for aesthetic reasons because if they were worn in both ears, the crimping feeling became stronger. In contrast, CC-HAs are often worn on both ears for comfort. Reeder et al. [17] reported that there was little difference in the hearing performance in silence when comparing unilateral hearing loss patients and those with normal hearing; however, in noisy conditions, it was significantly reduced in patients with unilateral hearing loss. Bagatto et al. [18] reported the benefits of binaural hearing. In fact, among the participants of this study, six out of seven patients with bilateral conductive hearing loss who purchased CC-HAs wore them in both ears. Based on this, those who choose CC-HAs tended to choose to wear them in both ears, and the fact that they could be worn in both ears may also lead to a willingness to wear CC-HAs.

Next, we investigated whether the binaural hearing effect of wearing CC-HA improved speech recognition in patients with unilateral conductive hearing loss. First, we compared SRS with and without CC-HA at a sound pressure 10 dB lower than the sound pressure at which the highest SRSs were obtained without a hearing aid. As a result, an improvement in the SRS was observed when wearing CC-HA. This result was similar to the result of the study reported by Akasaka et al. [16], who examined the binaural hearing effect of CC-HA in patients with unilateral aural atresia. However, in our study, the average difference with and without the CC-HA was small (approximately 5%), and when the patients with unilateral conductive hearing loss were divided into the purchase and non-purchase groups, there was no significant difference in the improvement of SRS between the two groups. Therefore, we modified the testing method and performed a sound field test and speech audiometry with 70 dB of noise in the good ear. In this method, the noise masked the good ear, thus confirming the effectiveness of wearing CC-HA on the affected side. The results of the sound field test and speech audiometry significantly improved with the use of CC-HA, and some patients commented on the effect of wearing CC-HA. On the other hand, when we compared the patients in the purchase and non-purchase groups, no significant differences were found in the results of sound field and speech audiometry under noise. However, there was a tendency for the purchase group to perform better than the non-purchase group on speech audiometry with noise in the good ear. Since the number of cases was small, further investigation is necessary, but it is possible that feeling the effect of wearing the CC-HA on speech recognition may affect patients' willingness to wear it. In addition, regarding the sound field test under noise, the noise was set at 70 dB to avoid excessive discomfort to the good-hearing ear. Therefore, it was possible that some patients with a higher threshold on the affected side did not correctly obtain the sound field hearing on the affected side before wearing CC-HA, resulting in no difference between the purchase and non-purchase groups, and further study design was considered necessary.

In addition, the economic situation may also influence the willingness to wear CC-HAs because of their high cost. When introducing CC-HAs to patients, it is important to provide appropriate information not only about their effect on hearing but also about the comfort and aesthetics of CC-HAs, as well as the cost of purchasing CC-HAs and the available subsidies.

The limitations of this study included the low number of non-purchasers, which resulted in an imbalance between purchasers and non-purchasers. In particular, there was only one non-purchaser among the patients with bilateral conductive hearing loss, which was considerably low. It is not possible to perform a statistical analysis separating the CC-HA purchasers and non-purchasers. The acquisition of additional participants was, therefore, necessary. Additionally, because of the low number of non-purchasers, it was thought that patients who were not proactive in purchasing were not very cooperative in examinations, and there were cases where data could not be obtained, suggesting the presence of selection bias. Furthermore, there were many young patients with microtia at our hospital. As a result, confounding factors such as the presence or absence of subsidies for purchases may have been at play.

5. Conclusions

This study examined the effectiveness of CC-HA in patients with bi- and unilateral conductive hearing loss and investigated the predictive factors that lead to their willingness to wear CC-HA. The results indicate that CC-HA was non-inferior to BC-HA in patients with bilateral conductive hearing loss, and its usefulness was demonstrated in patients with unilateral conductive hearing loss. In patients with unilateral conductive hearing loss, good results on speech audiometry while wearing CC-HA with noise in the good ear may influence their willingness to wear CC-HA.

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Institutional Review Board Statement: This study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Sapporo Medical University in an official letter on 27 February 2023 (Protocol number: 342-232).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. Hosoi, H. Approach in the Use of Cartilage Conduction Speaker. Japanese Patent 4541111, 17 November 2004.
2. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Yamanaka, T.; Levitt, H. Is cartilage conduction classified into air or bone conduction? *Laryngoscope* **2014**, *124*, 1214–1219. [CrossRef] [PubMed]
3. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Yamanaka, T.; Kitahara, T.; Levitt, H. Cartilage conduction is characterized by vibrations of the cartilaginous portion of the ear canal. *PLoS ONE* **2015**, *10*, e0120135. [CrossRef] [PubMed]
4. Hosoi, H.; Nishimura, T.; Shimokura, R.; Kitahara, T. Cartilage conduction as the third pathway for sound transmission. *Auris Nasus Larynx* **2019**, *46*, 151–159. [CrossRef] [PubMed]
5. Hosoi, H.; Yanai, S.; Nishimura, T.; Sakaguchi, T.; Iwakura, T.; Yoshino, K. Development of cartilage conduction hearing aid. *Arch. Mater. Sci. Eng.* **2010**, *42*, 104–110.
6. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Iwakura, T. Benefit of a new hearing device utilizing cartilage conduction. *Auris Nasus Larynx* **2013**, *40*, 440–446. [CrossRef] [PubMed]
7. Shimokura, R.; Hosoi, H.; Iwakura, T.; Nishimura, T.; Matsui, T. Development of monaural and binaural behind-the-ear cartilage conduction hearing aids. *Appl. Acoust.* **2013**, *74*, 1234–1240. [CrossRef]
8. Thomas, J.P.; Voelter, C.; Neumann, K.; Dazert, S. Vibroplasty in severe congenital or acquired meatal stenosis by coupling an active middle ear implant to the short process of the incus. *Otol. Neurotol.* **2017**, *38*, 996–1004. [CrossRef]
9. Lin, J.; Chen, S.; Zhang, H.; Xiong, H.; Zhang, Z.; Liang, M.; Zhang, X.; Ye, H.; Zheng, Y. Application of implantable hearing aids and bone conduction implant system in patients with bilateral congenital deformation of the external and middle ear. *Int. J. Pediatr. Otorhinolaryngol.* **2019**, *119*, 89–95. [CrossRef]
10. Weiss, R.; Loth, A.; Leinung, M.; Balster, S.; Hirth, D.; Stöver, T.; Helbig, S.; Kramer, S. A new adhesive bone conduction hearing system as a treatment option for transient hearing loss after middle ear surgery. *Eur. Arch. Oto-Rhino-Laryngol.* **2020**, *277*, 751–759. [CrossRef] [PubMed]
11. Lo, J.F.W.; Tsang, W.S.S.; Yu, J.Y.K.; Ho, O.Y.M.; Ku, P.K.M.; Tong, M.C.F. Contemporary hearing rehabilitation options in patients with aural atresia. *BioMed Res. Int.* **2014**, *2014*, 761579. [CrossRef] [PubMed]
12. Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Yamanaka, T.; Kitahara, T. Cartilage Conduction Hearing Aids for Severe Conduction Hearing Loss. *Otol. Neurotol.* **2018**, *39*, 65–72. [CrossRef] [PubMed]
13. Nishiyama, T.; Oishi, N.; Ogawa, K. Who are good adult candidates for cartilage conduction hearing aids? *Eur. Arch. Oto-Rhino-Laryngol.* **2021**, *278*, 1789–1798. [CrossRef] [PubMed]
14. Nishiyama, T.; Oishi, N.; Ogawa, K. Efficacy of cartilage conduction hearing aids in children. *Int. J. Pediatr. Otorhinolaryngol.* **2021**, *142*, 110628. [CrossRef] [PubMed]
15. Sakamoto, Y.; Shimada, A.; Nakano, S.; Kondo, E.; Takeyama, T.; Fukuda, J.; Udaka, J.; Okamoto, H.; Takeda, N. Effects of FM system fitted into the normal hearing ear orcartilage conduction hearing aid fitted into the affected ear on speech-in-noise recognition in Japanese children with unilateral congenital aural atresia. *J. Med. Investig.* **2020**, *67*, 131–138. [CrossRef]
16. Akasaka, S.; Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Morimoto, C.; Kitahara, T. Benefits of Cartilage Conduction Hearing Aids for Speech Perception in Unilateral Aural Atresia. *Audiol. Res.* **2021**, *11*, 284–290. [CrossRef]

17. Reeder, R.M.; Cadieux, J.; Firszt, J.B. Quantification of speech-in-noise and sound localisation abilities in children with unilateral hearing loss and comparison to normal hearing peers. *Audiol. Neurotol.* **2015**, *20*, 31–37. [CrossRef] [PubMed]
18. Bagatto, M.; Moodie, S.; Brown, C.; Malandrino, A.; Richert, F.; Clench, D.; Scollie, S. Prescribing and verifying hearing aids applying the American academy of audiology pediatric amplification guideline: Protocols and outcomes from the ontario infant hearing program. *J. Am. Acad. Audiol.* **2016**, *27*, 188–203. [CrossRef] [PubMed]

audiology research

Brief Report

Examination of Factors Affecting the Likelihood of Whether Individuals Would Purchase Cartilage Conduction Hearing Aids

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Abstract: Cartilage conduction hearing aids (CC-HAs) are a novel type of hearing aid relying on cartilage conduction, the so-called third auditory conduction pathway. However, CC-HAs have only recently entered routine clinical use, and therefore data on their usefulness are lacking. The purpose of this study was to examine the possibility of assessing whether individual patients would show good adaptation to CC-HAs. Thirty-three subjects (41 ears in total) underwent a free trial of CC-HAs. Age, disease category, and the pure-tone threshold of air and bone conduction, unaided field sound threshold, aided field sound threshold, and functional gain (FG) at 0.25, 0.5, 1, 2, and 4 kHz were compared between patients who subsequently purchased and did not purchase the CC-HAs. Overall, 65.9% of the subjects purchased CC-HAs after the trial. In comparison to non-purchasers, those who decided to purchase CC-HAs showed better pure tone hearing thresholds at high frequencies for both air conduction (2 and 4 kHz) and bone conduction (1, 2, and 4 kHz), as well as for aided thresholds in the sound field (1, 2, and 4 kHz) when using CC-HAs. Therefore, the high-frequency hearing thresholds of subjects trialing CC-HAs might be helpful for identifying those who are likely to benefit from them.

Keywords: cartilage conduction hearing aids; air conduction; bone conduction; aided threshold; atresia

1. Introduction

The cartilage conduction pathway was first advocated as a third auditory conduction pathway by Hosoi in 2004 [1]. The cartilage conduction hearing aid (CC-HA) relies on hearing characteristics different from those of conventional air conduction hearing aids, a transducer being placed on the cartilage of the ear to generate sound from the cartilage in the external auditory canal [2–4].

In Japan, CC-HAs have been in daily clinical use since November 2017, ahead of any other country in the world [5]. CC-HAs provide adequate hearing amplification without the need for surgery in patients with fibrotic and bony aural atresia, who are unable to wear conventional air conduction hearing aids (AC-HAs). Additionally, CC-HAs avoid local pain and skin irritation caused by high contact pressure because the transducer does not need to be fixed to the patient using a headband, as with conventional bone-conducting hearing aids (BC-HAs) [4]. Therefore, they have been drawing increasing attention as a good alternative for such patients [6–8]. However, data about which patients would be most suited for CC-HAs, what the range of hearing that can be sufficiently effective is, and the factors that might influence whether patients would purchase them, are still insufficient [9,10].

At our institution, CC-HAs trials and fittings have been available since November 2017. In this study, we evaluated the factors that influenced the decision to purchase CC-HAs, including age, the pure-tone threshold of air and bone conduction before the CC-HA trial, and functional gain. In particular, the effect of bone-conduction hearing threshold on the likelihood of CC-HA purchase has not been assessed previously. The purpose of this study was to investigate the possibility of assessing patient adaptation to CC-HAs based on their demographic characteristics and hearing test results, etc.

2. Materials and Methods

This study was approved by the Ethics Committee of Tohoku University Graduate School of Medicine (2022-1-1165), and informed consent was obtained in the form of opt-out on the website. All studies were conducted in accordance with the guidelines of the Declaration of Helsinki (1991).

Thirty-three patients who requested trials of CC-HAs at our institution between November 2017 and July 2022, whose pure tone hearing thresholds with air and bone conduction were testable prior to the CC-HA trial, were included in this study. Of these patients, 20 were male, and 13 were female, with a mean age ± standard deviation (SD) of 33.12 ± 25.55 years (range 4–83 years). Figure 1 shows the distribution of the participants according to age decade.

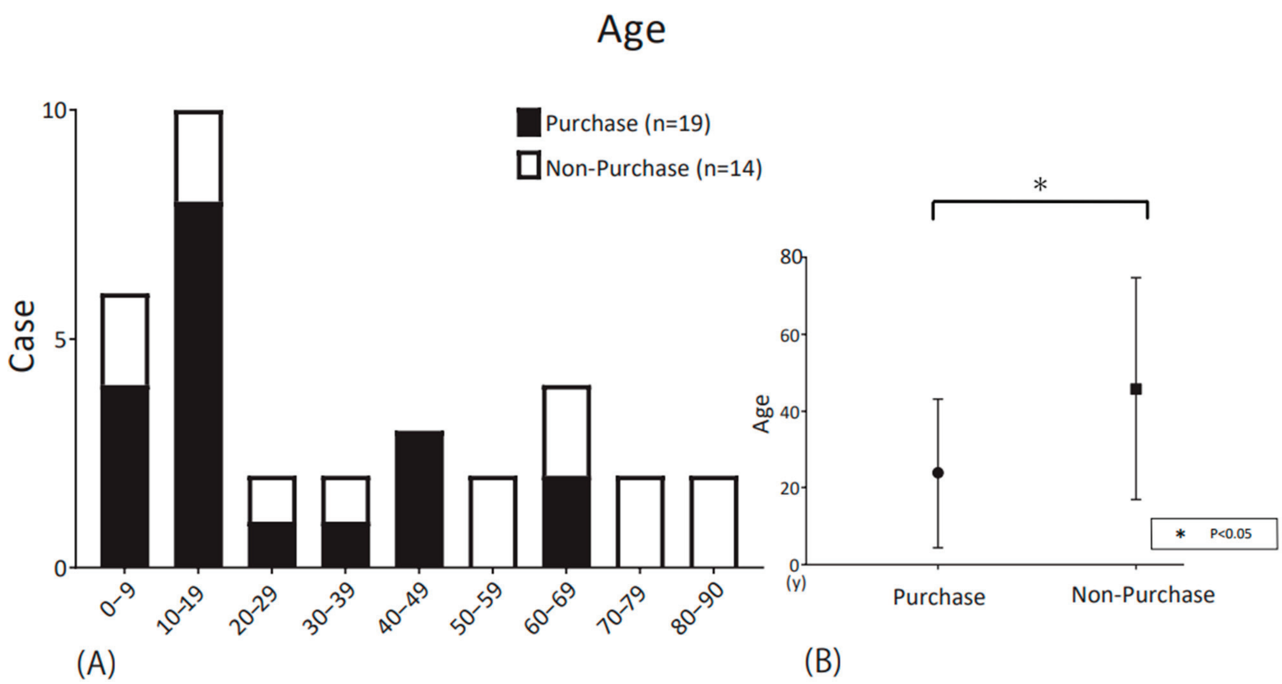

Figure 1. (**A**) Age distribution of the participants according to decade. The number of patients in each decade is shown. The portion of the bar (black) outlined by dashes indicates participants who decided to purchase CC-HAs after the trial period; white indicates non-purchasers. (**B**) Comparison of the ages of CC-HA purchasers and non-purchasers after the trial, represented by the mean and SD.

Audiological thresholds were measured by expert audiometric technicians in a standard sound-attenuated room using a commercially available audiometer (Model AA-H1, RION Co., Ltd., Tokyo, Japan). Pure-tone thresholds were obtained with over-ear headphones to assess AC (125 Hz to 8 kHz) and with a calibrated BC vibrator to assess BC (500 Hz to 4 kHz). Sound-field thresholds (SF) were measured to assess CC-HA-aided and unaided thresholds using warble tones delivered from a loudspeaker located 1 m from the subject at 0° azimuth. For patients with unilateral hearing loss fitted with a CC-HA in only the affected ear, we delivered 70 dB masking noise to the other ear through the headphones to prevent that ear from hearing the test sounds.

An HB-J1CC (Rion Corporation, Kokubunji, Japan) was used for all fittings. Transducers were chosen among ear-chip-embedded, ear-chip-attached, and simple types based on ear condition. The ear tip was made based on an ear mold, allowing for tight attachment to the ear and optimal stability of the transducer. On the other hand, the simple type used double-sided tape for fixation and thus could be applied for any ear condition, regardless of any ear abnormality.

Subjects were allowed to try their fitted CC-HAs without charge at a follow-up visit two weeks to one month later. At the follow-up visit, they were asked to assess the utility and comfort of the CC-HAs in their daily activities using the speech, spatial, and qualities of hearing scale (SSQ) questionnaires [11] and to undergo measurement of their unaided and aided sound-field thresholds, respectively. Finally, participants were free to choose whether or not to purchase the CC-HA without pressure from the investigator or staff.

The results obtained were compared between purchasers and non-purchasers in terms of age, disease category, SSQ score, the pure-tone threshold of air and bone conduction, the unaided and aided sound field threshold, and functional gain (FG) at 0.25, 0.5, 1, 2, and 4 kHz.

Mann–Whitney U test, chi-square test, and analysis of variance (ANOVA) were employed for statistical analyses using GraphPad Prism 7.0 (GraphPad Prism Software Inc., San Diego, CA, USA). Bonferroni tests were used for post hoc comparisons in ANOVA. The statistical significance level was set at $p < 0.05$.

3. Results

This study evaluated the results of the CC-HA trial in 41 ears (33 patients). CC-HAs were purchased for 27 ears (19 patients) and not purchased for 14 ears (14 patients), giving an overall purchase rate of 65.8% for ears that trialed the CC-HAs. Table 1 summarizes the demographic characteristics of the study participants and their hearing assessments before and after listening to the CC-HAs. There were no significant differences between groups with regard to sex and functional gains. Significant differences were found for age, clinical characteristics, and unaided and aided sound field thresholds.

Table 1. Demographic characteristics of participants according to group: purchase or non-purchase.

Characteristics	**Purchase Case (n = 19)**	**Non Purchase Case (n = 14)**	***p* Value**
Sex, male; female	11; 8	9; 5	0.710 †
Age at fitting (yr, Mean ± SD)	23.8 ± 18.9	45.8 ± 27.9	0.037 ‡
Clinical characteristics Congenital canal atresia/stenosis; others	17; 2	9; 5	0.004 †
Average unaided sound field thresholds * (dB HL, Mean ± SD)	65.9 ± 11.2	76.2 ± 14.8	0.036 ‡
Average Aided sound field thresholds * (dB HL, Mean ± SD)	38.2 ± 9.2	55.3 ± 16.3	<0.001 ‡
Average Functional Gain * (dB HL, Mean ± SD)	27.6 ± 9.2	20.9 ± 11.6	0.063 ‡

* Average of hearing thresholds at 500, 1000, 2000, and 4000 Hz; † Chi-square test; and ‡ Mann–Whitney U test.

Figure 1 shows the age distribution of purchasers and non-purchasers by ten-year age group. Among the subjects, 19 were purchasers, and 14 were non-purchasers. The mean age ± standard deviation (SD) of the purchasers was 23.8 ± 18.9 years (range 4–67 years), whereas that of the non-purchasers was 45.8 ± 27.9 years (range 4–83 years) (Table 1). The purchasers were significantly younger than the non-purchasers ($p < 0.05$; Mann–Whitney U-test).

Figure 2 compares the clinical characteristics of purchasers and non-purchasers in the form of a histogram. Congenital aural atresia/ear canal stenosis was present in 28 ears (28/41, 68.3%). The next most frequent conditions were atresia auris after ear canal cancer surgery (6/41, 14.6%), otosclerosis (5/41, 12.2%), and postoperative otitis media (2/41, 4.9%). The purchase rate was 79% (22/28 ears) in the congenital aural atresia/ear canal stenosis group and 17% (1/6 ears) in the acquired atresia auris group. In the otosclerosis group and postoperative otitis media group, the purchase rate was 80% (4/5) and 0%

(0/2 ears), respectively. Congenital atresia/ear canal stenosis had a significantly higher purchase rate among study participants compared to the other conditions (Table 1).

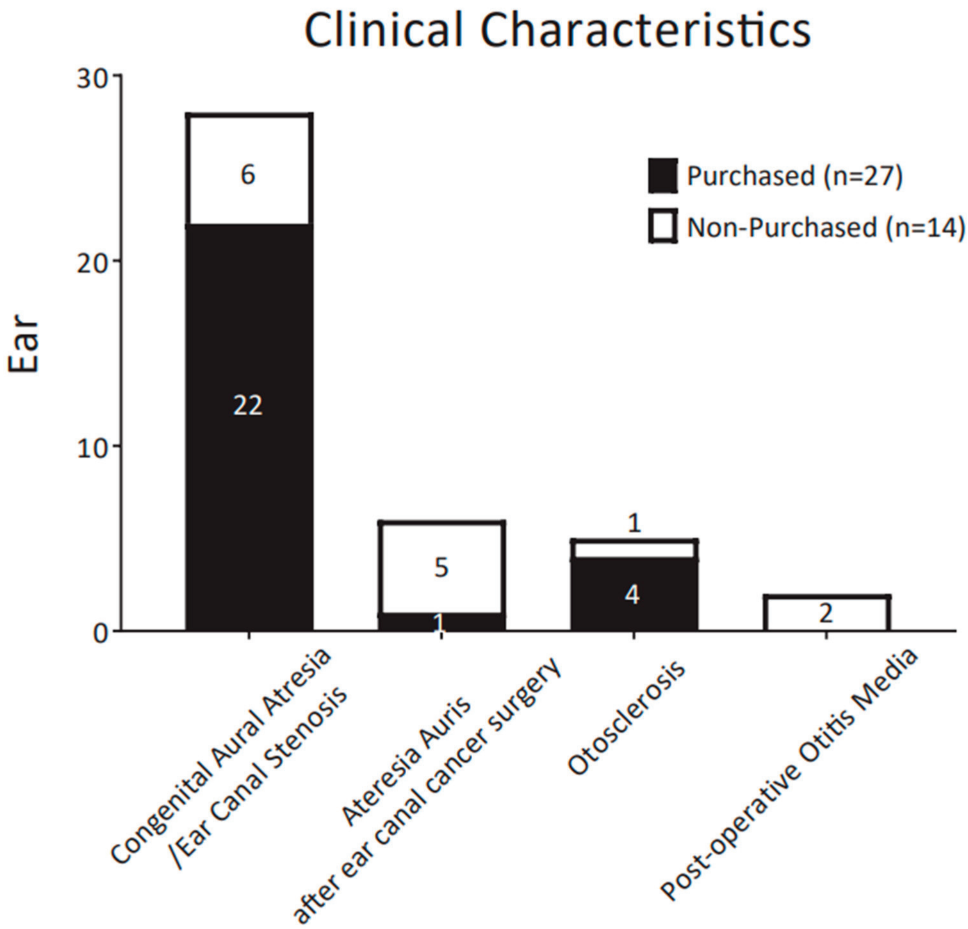

Figure 2. Distribution of the participants' clinical characteristics. The number of patients in each decade is shown. The portion of the bar (black) outlined by dashes indicates participants who decided to purchase CC-HAs after the trial period; white indicates non-purchasers.

Figures 3 and 4 show the mean pure tone audiometry values for air and bone conduction prior to the CC-HAs trial, respectively, at 0.25, 0.5, 1, 2, and 4 kHz in the purchasers and non-purchasers. Two preschool children (4 ears) could not be tested. Therefore, 31 patients (37 ears) were evaluated.

For the air conduction thresholds in Figure 3, two-way ANOVA demonstrated significant main effects for frequency (F (4,175) = 2.687, $p = 0.033$) and purchase rate (F (1,175) = 14.66, $p < 0.001$). The interaction between frequency and purchase rate was significant (F (4,175) = 3.366, $p < 0.05$). Post hoc comparisons showed that purchasers had significantly better air conduction thresholds than non-purchasers at 2 kHz and 4 kHz ($p < 0.05$ post hoc Bonferroni test). For the bone conduction thresholds in Figure 4, two-way ANOVA demonstrated significant main effects for frequency (F (4,175) = 7.823, $p < 0.001$) and purchase rate (F (1,175) = 52.24, $p < 0.001$). The interaction between frequency and purchase rate was not significant (F (4,175) = 1.651, $p = 0.164$). Post hoc comparisons showed that purchasers had significantly better bone conduction thresholds than non-purchasers at 1 kHz, 2 kHz, and 4 kHz ($p < 0.01$ post hoc Bonferroni test).

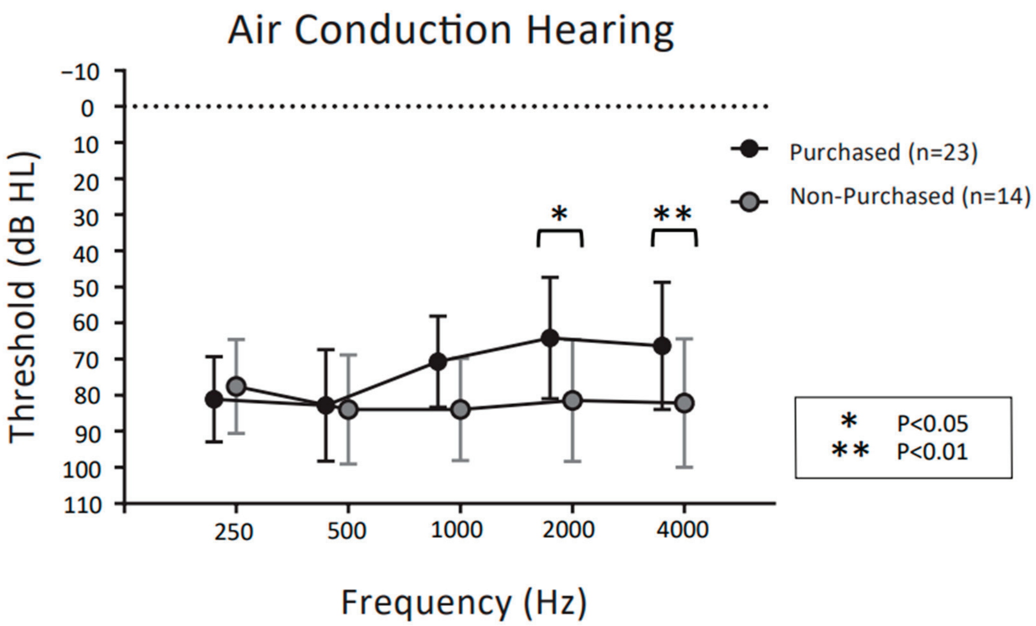

Figure 3. Comparison of air conduction hearing in pure tone auditory between CC-HA purchasers and non-purchasers, represented by the mean and SD. The dotted polygonal line (black) indicates participants who decided to purchase CC-HAs after the trial period; grey indicates non-purchasers.

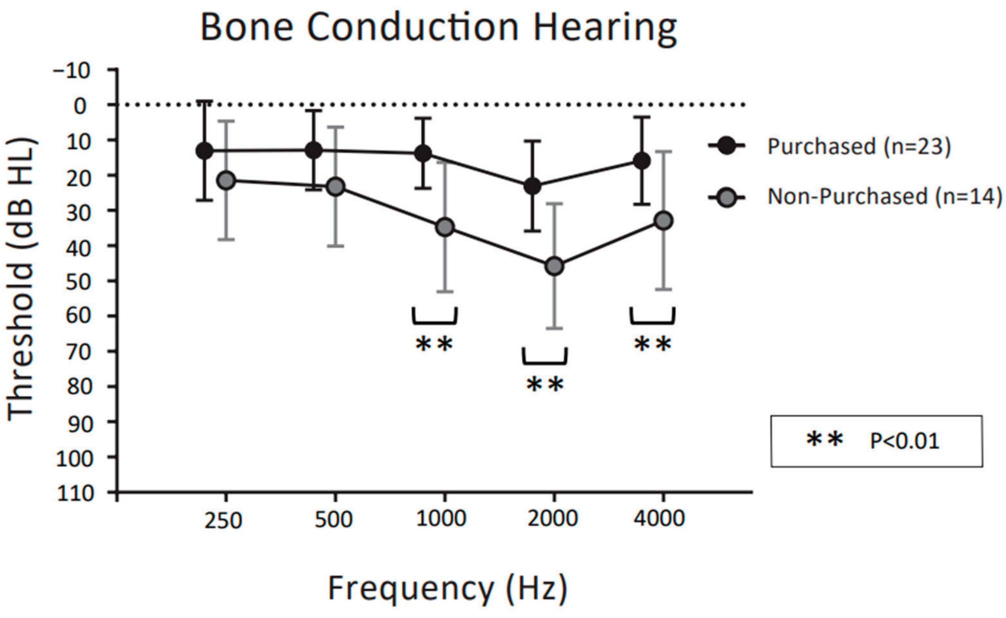

Figure 4. Comparison of bone conduction hearing in pure tone auditory between CC-HA purchasers and non-purchasers, represented by the mean and SD. The dotted polygonal line (black) indicates participants who decided to purchase CC-HAs after the trial period; grey indicates non-purchasers.

Figures 5 and 6 show unaided and aided thresholds in the sound field at the follow-up visit for purchasers and non-purchasers of CC-HAs, respectively. For the unaided thresholds in the sound field in Figure 5, two-way ANOVA demonstrated significant main effects for frequency ($F(4,155) = 2.612$, $p = 0.038$) and purchase rate ($F(1,155) = 15.15$, $p < 0.001$). There was no significant interaction between frequency and purchase rate ($F(4,155) = 0.574$, $p = 0.68$).

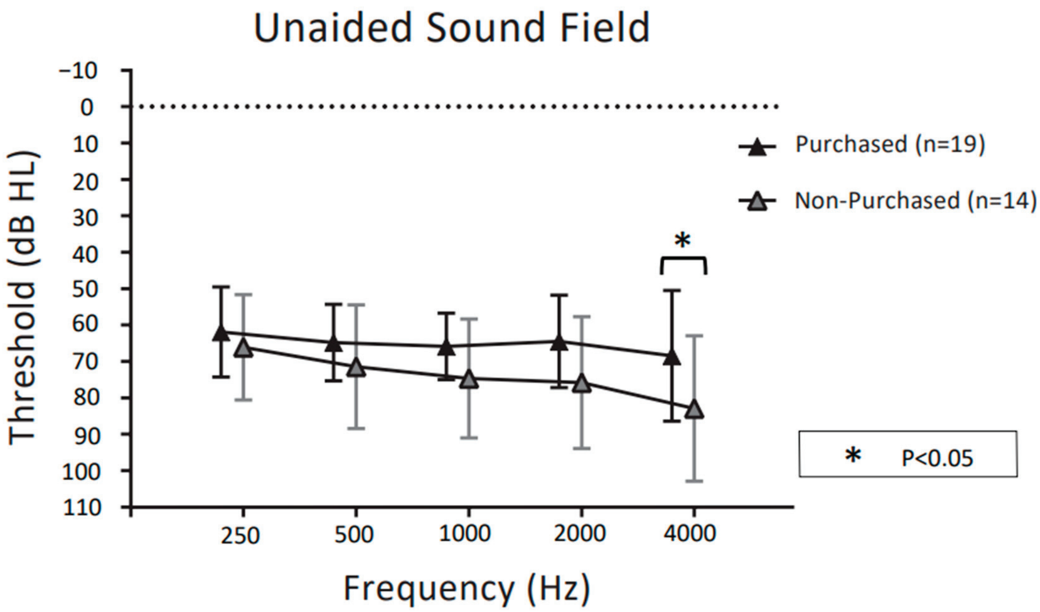

Figure 5. Comparison of unaided sound field thresholds between CC-HA purchasers and non-purchasers, represented by the mean and SD. The dotted polygonal line (black) indicates participants who decided to purchase CC-HAs after the trial period; grey indicates non-purchasers.

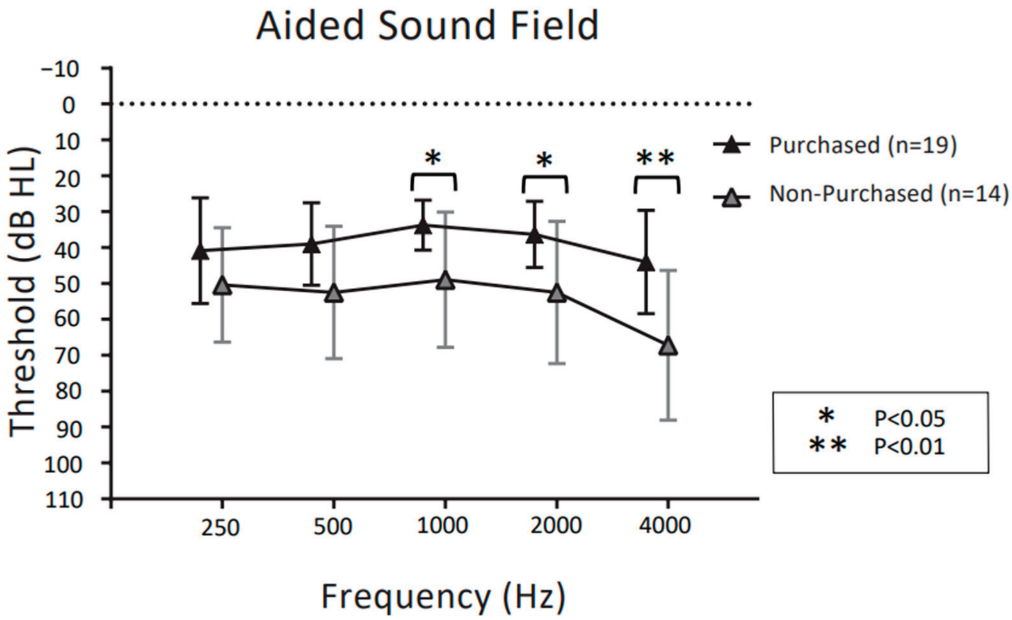

Figure 6. Comparison of aided sound field thresholds between CC-HA purchasers and non-purchasers, represented by the mean and SD. The dotted polygonal line (black) indicates participants who decided to purchase CC-HAs after the trial period; grey indicates non-purchasers.

Post hoc comparisons showed that purchasers had significantly better unaided thresholds in the sound fields than non-purchasers only at 4 kHz ($p < 0.05$ post hoc Bonferroni test). For the aided thresholds in the sound field in Figure 6, two-way ANOVA demonstrated significant main effects for frequency (F (4,155) = 4.068, $p = 0.0036$) and purchase rate (F (1,155) = 42.90, $p < 0.001$). The interaction between frequency and purchase rate was not significant (F (4,155) = 0.876, $p = 0.480$). Post hoc comparisons showed that purchasers had significantly better bone conduction thresholds than non-purchasers at 1 kHz, 2 kHz, and 4 kHz ($p < 0.05$ post hoc Bonferroni test).

Figure 7 shows the functional gain (FG) for purchasers and non-purchasers of CC-HAs, respectively. Two-way ANOVA revealed significant main effects for frequency

(F (4,155) = 4.068, $p = 0.036$) and purchase rate (F (1,155) = 42.90, $p < 0.001$), but no significant interaction between frequency and purchase rate (F (4,155) = 0.876, $p = 0.48$). Further post hoc comparisons showed that purchasers did not have significantly higher FG than non-purchasers at any frequency ($p < 0.05$ post hoc Bonferroni test).

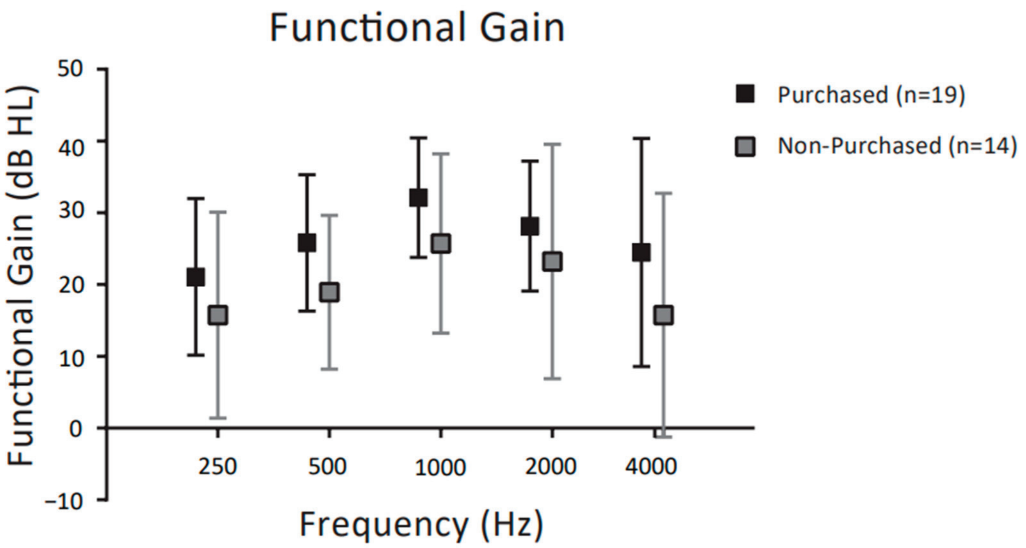

Figure 7. Comparisons of the functional gain achieved using CC-HAs between purchasers and non-purchasers, represented by the mean and SD. The dotted (black) outline indicates participants who purchased CC-HAs after the trial period; grey indicates non-purchasers.

Figure 8 shows the mean scores of each SSQ questionnaire for CC-HA purchasers and non-purchasers. Purchasers had significantly higher mean scores for SSQ speech and SSQ quality than non-purchasers ($p < 0.05$; Mann–Whitney U-test). On the other hand, SSQ spatial did not differ significantly between purchasers and non-purchasers.

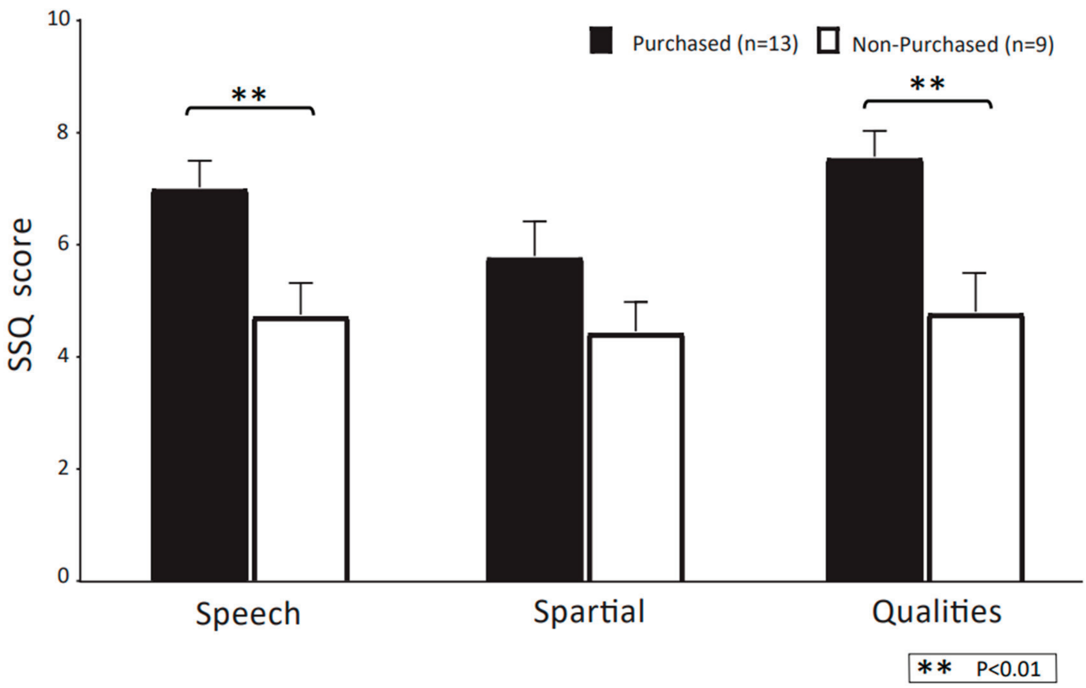

Figure 8. Comparisons of the speech, spatial, and qualities of hearing scale (SSQ) using CC-HAs between purchasers and non-purchasers, represented by the mean and SEM. The dotted (black) outline indicates participants who purchased CC-HAs after the trial period; white indicates non-purchasers.

4. Discussion

This study aimed to evaluate the efficacy of CC-HAs for hearing-impaired patients who were unable to use conventional air- or bone-conduction hearing aids, and the factors that contribute to the decision to purchase them. In particular, we were interested in whether test results obtained prior to the start of CC-HA use, such as those of pre-trial pure tone audiometry, could be used to assess whether patients would adapt well to CC-HAs.

The overall rate of CC-HA purchase in this study was 65.9% (27/41 ears), which is within the ranges reported previously [6,7,9,10]. In the congenital aural atresia/ear canal stenosis group, the purchase rate was 79% (22/28 ears), a significantly higher purchase rate than for other conditions (Table 1). Nishimura reported high CC-HA purchase rates of 86% and 78% in the Bi-Closed and Uni-Closed groups, respectively [9]. This was similar to the rate in our congenital aural atresia/ear canal stenosis group. On the other hand, in the group with acquired atresia auris after ear canal cancer surgery, the purchase rate was lower at 17% (1/6 ears). In that group, the average air conduction threshold was poor, with a hearing loss of more than 70 dB in almost all cases. Nishiyama et al. also reported that the rate of CC-HA purchase in patients with canal stenosis, including both congenital and acquired atresia, was lower in individuals with severe hearing loss exceeding 70 dB [6]. In summary, it is suggested that CC-HAs may not be sufficiently effective for the improvement of hearing in individuals with severe hearing loss of 70 dB or more.

In the present study, CC-HA purchasers were significantly younger than non-purchasers. Regarding the relationship between purchase rate and age, it has been reported that purchasers are significantly younger than non-purchasers among patients with hearing loss due to unilateral atresia auris [9,10]. This result might be due to the more perceived benefits of binaural hearing for communication and education in younger than in older individuals [12,13]. Furthermore, in Japan, social support for children with mild/moderate hearing loss is often provided for the purchase of hearing aids. This may account for the difference in purchase rates between younger and older children.

In this study, more than 80% of the subjects trialing CC-HAs had aural atresia/ear canal stenosis. In previous studies, CC-HAs have been used most frequently in patients with congenital atresia or acquired atresia due to surgical treatment, such as ear canal cancer, and have been reported to improve hearing [3,4,14–16]. In addition, CC-HAs were trialed in five ears with otosclerosis, and the subsequent purchase rate was 80% (4/5 ears). Although CC-HAs may be a good option for otosclerosis patients, there have been few reports of trials for such patients [6], and further investigations are required.

With regard to pure tone hearing thresholds, these were significantly better in purchasers than in non-purchasers at frequencies of 2 kHz and 4 kHz for air conduction and at 1 kHz, 2 kHz, and 4 kHz for bone conduction. This means that for both air conduction and bone conduction, the pure tone hearing thresholds at higher frequencies were significantly better in the individuals who purchased CC-HAs than in those who did not. Previous reports have often compared CC-HAs unaided and aided with sound field thresholds [4,6,7,9,10], and thus the results suggest that residual thresholds for high tone frequencies may be an important and novel factor affecting the likelihood of CC-HA purchase.

For aided thresholds in the sound field, these were significantly better among CC-HA purchasers than among non-purchasers at 1 kHz, 2 kHz, and 4 kHz. Previous reports suggested that purchasers had significantly better sound field assistance thresholds than non-purchasers at lower frequencies of 0.25 kHz and 0.5 kHz, in contrast to the present results. However, one study comparing the transmission efficiency of cartilage conduction (CC), air conduction (AC), and bone conduction (BC) revealed that the threshold increases were significantly better for BC than for CC at frequencies of 1 kHz and 2 kHz [14]. Therefore, CC has a lower transmission efficiency than BC at higher frequencies, which may support our present results. Certainly, CC-HAs may provide less effective hearing compensation than BC-HAs. However, CC-HAs are small and lightweight, and there is no pain or occurrence of skin laceration due to transducer pressure with a fixation headband, which is common with BC-HAs [3,4,17,18]. This feature is considered one of the advantages of CC-HAs.

No significant difference in FG was found between purchasers and non-purchasers at any frequency, suggesting that threshold increases in the two groups were similar. Previous reports have also indicated that CC-HAs improved hearing thresholds at all frequencies, regardless of the purchase outcome of CC-HA trials [6,7,17]. In summary, this trial of CC-HAs for patients with hearing loss demonstrated a similar functional gain in both non-purchasers and purchasers. However, the functional gain may have been insufficient for hearing impairment at higher frequencies because of the lower transmission efficiency attributable to the transmission features of the CC. In the previous study [19] comparing hearing test results between CC-HAs and BC-HAs, BC-HAs had significantly better functional gains at high-frequency $\geq$ 1 KHz. The results of this previous study supported our findings. Therefore, the high-frequency hearing thresholds of subjects undergoing CC-HA trials might be a helpful criterion for identifying individuals for whom CC-HAs would be effective.

In the present study, we evaluated hearing aid use using the SSQ questionnaire to assess the usefulness and comfort of the CC-HAs. Purchasers had significantly higher SSQ speech and SSQ quality than non-purchasers. On the other hand, SSQ spatial was not significantly different between purchasers and non-purchasers, but there was a tendency for advantages among purchasers. Although the evaluation of CC-HAs using questionnaires has been studied in the past using "Evaluation of hearing before and after wearing a hearing aid, [4]" there are still few reports on this topic, and further studies are needed.

The limitations of this study included its small sample size, lack of speech audiometry assessment, and absence of any comparison between CC-HAs and other hearing aids (e.g., AC-HAs and BC-HAs). It has already been reported that speech audiometry assessments are improved, as well as the hearing threshold [4,17]. The economic background of patients, which may also influence whether they purchase CC-HAs, was also not examined. We suggest that residual hearing in the high-frequency range is a potentially useful criterion for indicating individuals who would benefit from CC-HAs. However, for further confirmation, future studies with a larger number of cases are needed.

5. Conclusions

This study investigated the factors influencing the decision of patients to purchase CC-HAs on the basis of trials performed in our department. Overall, 62.2% of the subjects purchased CC-HAs after the trials. Purchasers had better air-conduction and bone-conduction thresholds for pure tone hearing thresholds than non-purchasers at high frequencies, as well as for aided thresholds in the sound field when fitted with CC-HAs. Hearing-impaired patients with better pure tone hearing thresholds at relatively high frequencies may be better candidates for CC-HAs. However, there are still few reports investigating the clinical adaptation of CC-HAs. Further comparisons with other types of hearing aids, such as AC-HAs and BC-HAs, are needed.

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Conflicts of Interest: The authors declare no conflict of interest.

References

1. Hosoi, H. Approach in the Use of Cartilage Conduction Speaker. Japanese Patent 4541111, 17 November 2004.
2. Hosoi, H.; Yanai, S.; Nishimura, T.; Sakaguchi, T.; Iwakura, T.; Yoshino, K. Development of cartilage conduction hearing aid. *Arch. Mat. Sci. Eng.* **2010**, *42*, 104–110.
3. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Iwakura, T. Benefit of a new hearing device utilizing cartilage conduction. *Auris Nasus Larynx* **2013**, *40*, 440–446. [CrossRef] [PubMed]
4. Nishimura, T.; Hosoi, H.; Saito, O.; Shimokura, R.; Yamanaka, T.; Kitahara, T. Cartilage Conduction Hearing Aids for Severe Conduction Hearing Loss. *Otol. Neurotol.* **2018**, *39*, 65–72. [CrossRef] [PubMed]
5. Hosoi, H.; Nishimura, T.; Shimokura, R.; Kitahara, T. Cartilage conduction as the third pathway for sound transmission. *Auris Nasus Larynx* **2019**, *46*, 151–159. [CrossRef] [PubMed]
6. Nishiyama, T.; Oishi, N.; Ogawa, K. Who are good adult candidates for cartilage conduction hearing aids? *Eur. Arch. Oto-Rhino-Laryngol.* **2021**, *278*, 1789–1798. [CrossRef] [PubMed]
7. Nishiyama, T.; Oishi, N.; Ogawa, K. Efficacy of cartilage conduction hearing aids in children. *Int. J. Pediatr. Otorhinolaryngol.* **2021**, *142*, 110628. [CrossRef] [PubMed]
8. Sakamoto, Y.; Shimada, A.; Nakano, S.; Kondo, E.; Takeyama, T.; Fukuda, J.; Takeda, N. Effects of FM system fitted into the normal hearing ear or cartilage conduction hearing aid fitted into the affected ear on speech-in-noise recognition in Japanese children with unilateral congenital aural atresia. *J. Med. Investig.* **2020**, *67*, 131–138. [CrossRef] [PubMed]
9. Nishimura, T.; Hosoi, H.; Sugiuchi, T.; Matsumoto, N.; Nishiyama, T.; Kenichi, T.; Sugimoto, S.; Yazama, H.; Sato, T.; Komori, M. Factors Influencing the Purchase Rate of Cartilage Conduction Hearing Aids. *J. Am. Acad. Audiol.* **2022**, *33*, 14–22. [CrossRef] [PubMed]
10. Nishimura, T.; Hosoi, H.; Sugiuchi, T.; Matsumoto, N.; Nishiyama, T.; Kenichi, T.; Sugimoto, S.; Yazama, H.; Sato, T.; Komori, M. Cartilage Conduction Hearing Aid Fitting in Clinical Practice. *J. Am. Acad. Audiol.* **2021**, *32*, 386–392. [CrossRef] [PubMed]
11. Gatehouse, S.; Noble, W. The Speech, Spatial and Qualities of Hearing Scale (SSQ). *Int. J. Audiol.* **2004**, *43*, 85–99. [CrossRef] [PubMed]
12. Jensen, D.R.; Grames, L.M.; Lieu, J.E. Effects of aural atresia on speech development and learning: Retrospective analysis from a multidisciplinary craniofacial clinic. *JAMA Otolaryngol.–Head Neck Surg.* **2013**, *139*, 797–802. [CrossRef] [PubMed]
13. Cañete, O.M.; Purdy, S.; Brown, C.R.; Neeff, M.; Thorne, P.R. Behavioural performance and self-report measures in children with unilateral hearing loss due to congenital aural atresia. *Auris Nasus Larynx* **2021**, *48*, 65–74. [CrossRef] [PubMed]
14. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Matsui, T.; Levitt, H. Is cartilage conduction classified into air or bone conduction? *Laryngoscope* **2014**, *124*, 1214–1219. [CrossRef] [PubMed]
15. Nishimura, T.; Hosoi, H.; Saito, O.; Miyamae, R.; Shimokura, R.; Yamanaka, T.; Kitahara, T.; Levitt, H. Cartilage Conduction Is Characterized by Vibrations of the Cartilaginous Portion of the Ear Canal. *PLoS ONE* **2015**, *10*, e0120135. [CrossRef] [PubMed]
16. Morimoto, C.; Nishimura, T.; Hosoi, H.; Saito, O.; Fukuda, F.; Shimokura, R.; Yamanaka, T. Sound Transmission by Cartilage Conduction in Ear with Fibrotic Aural Atresia. Doctoral Dissertation, US Department of Veterans Affairs, Washington, DC, USA, 2014.
17. Suwento, R.; Widodo, D.W.; Airlangga, T.J.; Alviandi, W.; Watanuki, K.; Nakanowatari, N.; Hosoi, H.; Nishimura, T. Clinical Trial for Cartilage Conduction Hearing Aid in Indonesia. *Audiol. Res.* **2021**, *11*, 410–417. [CrossRef] [PubMed]
18. Dillon, H. *Hearing Aids*; Hodder Arnold: London, UK, 2008.
19. Nairn, E.M.; Chen, A.S.; Nishimura, T.; Berezovsky, A.; Stucken, E.Z. Hearing Outcomes of a New Cartilage Conduction Device vs Bone Conduction Devices. *Otolaryngol. Neck Surg.* **2023**, *168*, 821–828. [CrossRef] [PubMed]

audiology research

Case Report

Using a Bone Conduction Hearing Device as a Tactile Aid

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Abstract: Background: With the advent of cochlear implants, tactile aids for the profoundly deaf became obsolete decades ago. Nevertheless, they might still be useful in rare cases. We report the case of a 25-year-old woman with Bosley–Salih–Alorainy Syndrome and bilateral cochlear aplasia. Methods: After it was determined that cochlear or brainstem implants were not an option and tactile aids were not available anymore, a bone conduction device (BCD) on a softband was tried as a tactile aid. The usual retroauricular position and a second position close to the wrist, preferred by the patient, were compared. Sound detection thresholds were measured with and without the aid. Additionally, three bilaterally deaf adult cochlear implant users were tested under the same conditions. Results: At 250–1000 Hz, sounds were perceived as vibrations above approximately 45–60 dB with the device at the wrist. Thresholds were approximately 10 dB poorer when placed retroauricularly. Differentiation between different sounds seemed difficult. Nevertheless, the patient uses the device and can perceive loud sounds. Conclusions: Cases where the use of tactile aids may make sense are probably very rare. The use of BCD, placed, e.g., at the wrist, may be useful, but sound perception is limited to low frequencies and relatively loud levels.

Keywords: tactile aids; vibratory sensation; cochlear aplasia; sound field; bone conduction; sound processor

1. Introduction

Cochlear implants have been the standard method of treatment of profound or even severe hearing loss [1,2] for several decades, now. Their efficiency can at times be nothing less than amazing, and cochlear implants have been called “arguably, the most successful device at the machine-brain interface” [3].

In the light of this undeniable success, older methods and former ideas, such as tactile aids [4–6], have become all but forgotten. However, tactile aids seem to still have been in use as late as the beginning of this century [7]. With these devices, profoundly deaf persons were able to perceive sounds as vibrations despite their hearing loss. Sophisticated devices with one to seven channels or frequency bands were available [6,7]. They allowed the vibrotactile perception of sounds, in some cases sound recognition or improved lip-reading [6], and sometimes reportedly even limited word recognition [7]. Today, cochlear implants are considered superior.

As the largest centre for cochlear implantation at this time in our country, we have never used or prescribed tactile aids until, amazingly, this very year, when we learned that they may still be of some limited value in some very rare cases.

2. Case Presentation

The parents of a 25-year-old woman diagnosed with Bosley–Salih–Alorainy syndrome [8–11] contacted us. Their daughter was completely deaf in both ears and she, as well as her parents, wanted her to be able to perceive at least some loud sounds. Their hope and motivation was that she might be able to react to loud warning sounds and possibly notice when somebody called out to her.

The patient had bilateral cochlear aplasia, which is known to occur in some, but not in all, patients with Bosley–Salih–Alorainy syndrome [8,11]. Figure 1 shows an MRI of the temporal bone with a bilateral cochlear aplasia, an aplasia of the labyrinth on the right and a dysplastic vestibule on the left.

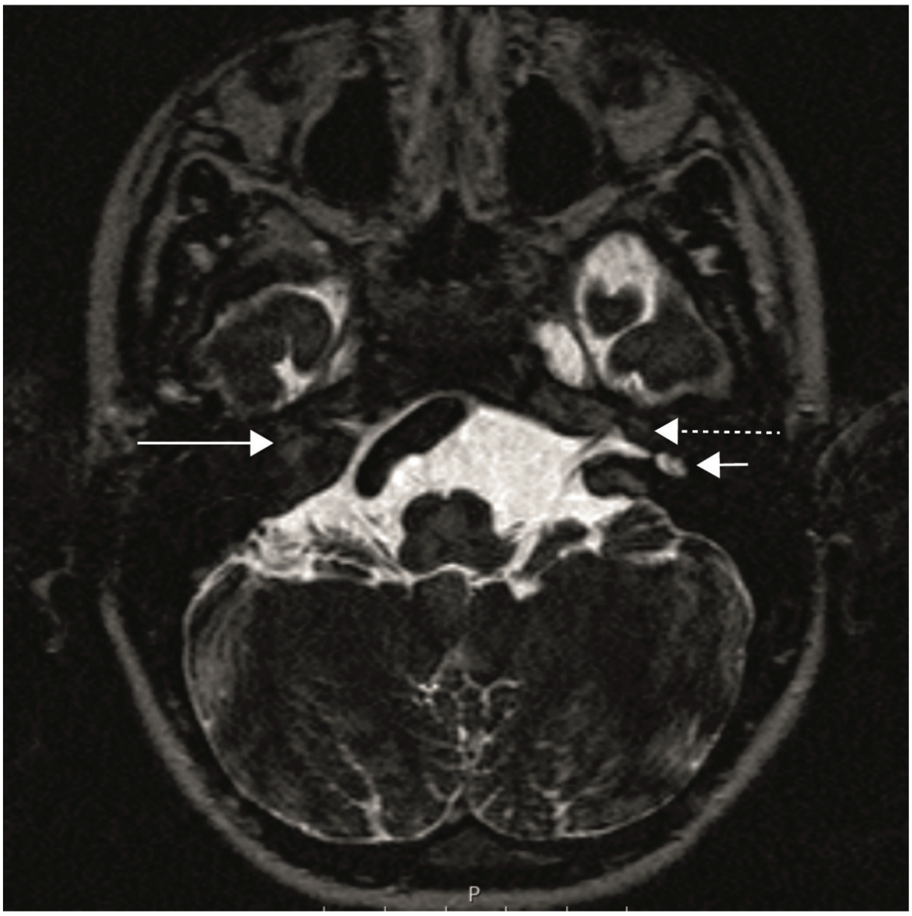

Figure 1. MRI of the temporal bone (axial plane), CISS sequences (constructive interference in steady state) with a right cochlear aplasia (long solid arrow), aplasia of the right inner ear canal, left cochlear aplasia (long dashed arrow) and dysplastic left vestibule (short arrow).

In the audiometric assessment, we found a bilaterally normal impedance audiometry and observed normal otoscopic findings, but no otoacoustic emissions could be evoked in either ear. In pure tone audiometry, no hearing was found in either ear, at any of the audiometric frequencies, and neither in the air conduction (AC) measurements (125–8000 Hz) nor in the bone conduction (BC) measurements (250–800 Hz) up to the audiometer limits, i.e., up to 120 dB HL for the AC measurements and up to 80 dB HL for BC measurements.

Cognitive and behavioural abnormalities have also been described in Bosley–Salih–Alorainy syndrome [9,11], and the patient showed developmental challenges and an additional steady decline of her cognitive abilities which had started approximately in her late teens. At the time of the consultations, she was able to read and to write in a limited manner. Furthermore, she exhibited a significant decrease in vertical ocular movement. Abnormalities in ocular motility are common in Bosley–Salih–Alorainy syndrome [9,10].

In the absence of both cochleae, cochlear implantation was not an option. Anatomically, a brain stem hearing implant [12,13] was conceivable, but the age of the patient, the lack of any prior hearing experience, and her continuing cognitive decline led to the decision against this route. In this decision-making process, our prior experiences with auditory brainstem implants and with poor results after late cochlear implantations in congenitally deaf adults and the cognitive decline played an important role.

With the options thus severely limited, we searched for tactile aids but did not find any that were commercially available anymore. In this situation, we performed a trial with a Cochlear Baha 6 max (Cochlear Inc., Mölnlycke, Sweden) [14] bone conduction (BC) sound processor fixed on a softband [15]. At higher sound levels and at low frequencies, its vibrations can be easily felt with the fingertips. Nevertheless, we had never previously tried to use it in other positions than that mounted on the head, and we had never seriously considered these vibrations to be a possibly useful output signal for a user. Before the actual trial, we evaluated other possible bone conduction devices, namely the ADHEAR (Medel Inc., Innsbruck, Austria) and the Ponto 5 SuperPower Device (Oticon Medical, Askim, Sweden). With the Baha 6 max, we believed we had found a reasonable compromise between size, weight and attainable output force levels in the low frequency range, which is important for this application. Nevertheless, we believe that it is very much possible that these other devices are similarly well suited.

We tried the sound processor on a softband in the usual position behind the ear, and indeed the patient could perceive loud sounds in the order of magnitude of 70 dB to 90 dB HL in the frequency range of 250 to 1000 Hz as vibrations. In contrast, no sound detection was found without the device, at least not up to the maximum levels available with our sound field audiometer. The audiometer was an Equinox 2.0 (Interacoustics A/S, Middelfart, Denmark) and it was connected to a Genelec type 8030C loudspeaker (Iisalmi, Finland). The frequency-dependent maximum sound field levels of the system are shown in Figure 2. The device was fitted using the Cochlear Fitting Suite 1.10.22628.0 (Cochlear Inc., Mölnlycke, Sweden) in such a way as to have a high gain at the lower frequencies below 2 kHz. The gain was limited above 2 kHz, as no vibratory sensation was found at these higher frequencies and acoustical feedback could thus be limited.

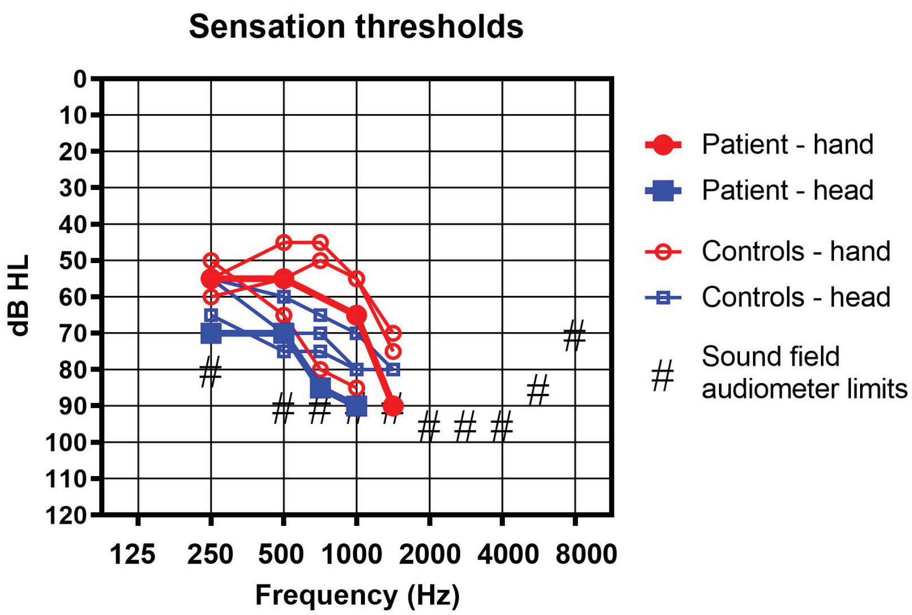

Figure 2. Sound field measurement with the bone conduction aid used as a tactile aid in the classic retro auricular position (blue squares) and on the hand (red circles) in the reported patient (thick lines and filled symbols) and 3 profoundly deaf controls (thin lines and empty symbols).

We felt that perception thresholds as high as 70 to 90 dB HL were not satisfactory. In order to improve the range, we tried another position: above the wrist of the subject (Figure 3). Indeed, perception thresholds improved by 15 to 25 dB, as shown in Figure 2.

Figure 3. A bone conduction device (Cochlear Baha 6 max) used as a tactile aid just behind the wrist on a shortened softband.

The patient took the device home for a trial and now uses it on an irregular, almost but not quite daily basis, for up to several hours a day. She clearly prefers the position close to the wrist over any placement on the head. For practical reasons (limitation of the movement of her hand), she prefers a position behind the wrist, as shown in Figure 3.

3. Comparative Measurements

As we had no prior experience of our own, it was unclear to us whether the absolute perception thresholds found were typical and, specifically, if the difference between the head and the hand positions was real and could also be found in other subjects. A literature search was rather unfruitful, as research on vibratory sensations seems to be mostly concentrated on low to very low frequencies of often 300 Hz or even lower, and to sensations at the hands, e.g., [16].

In order to learn more about these vibratory thresholds, we asked three cochlear implant users to help us with a limited additional evaluation. Two of the subjects were male, one was female. The age range was 23–85 years. All three had bilateral profound deafness and air conduction hearing thresholds well above the maximum sound field levels our audiometer could emit at any frequency. All of their bone-conduction hearing thresholds were above the maximum output limits of our audiometer, but one control subject was able to perceive the vibration of the bone vibrator at 250 Hz and 500 Hz, as shown in Figure 4. The sensation he described was clearly tactile and not hearing.

Their perception thresholds were measured under sound-field conditions using narrow-band noise signals, with their cochlear implant sound processors taken off. Measurements were performed with the BC sound processor mounted on a softband and placed either in the usual position behind the ear on their non-implanted side, or the wrist, in a position as similar as possible to the one preferred by the patient. Vibratory sensation rather than auditory perceptions were expected and also reported by all three subjects. For all subjects, a third measurement was performed without any sound processor.

Figure 2 shows the results. None of the subjects could perceive any of the sounds presented without their cochlear implant processor and without the BC sound processor. With the BC device in place, thresholds were lowest (best) in the frequency range 250 to 750 Hz and the average difference between the head and the hand positions was found to be exactly 10 dB in our small sample. However, in one subject, thresholds were slightly better behind the ear above 750 Hz.

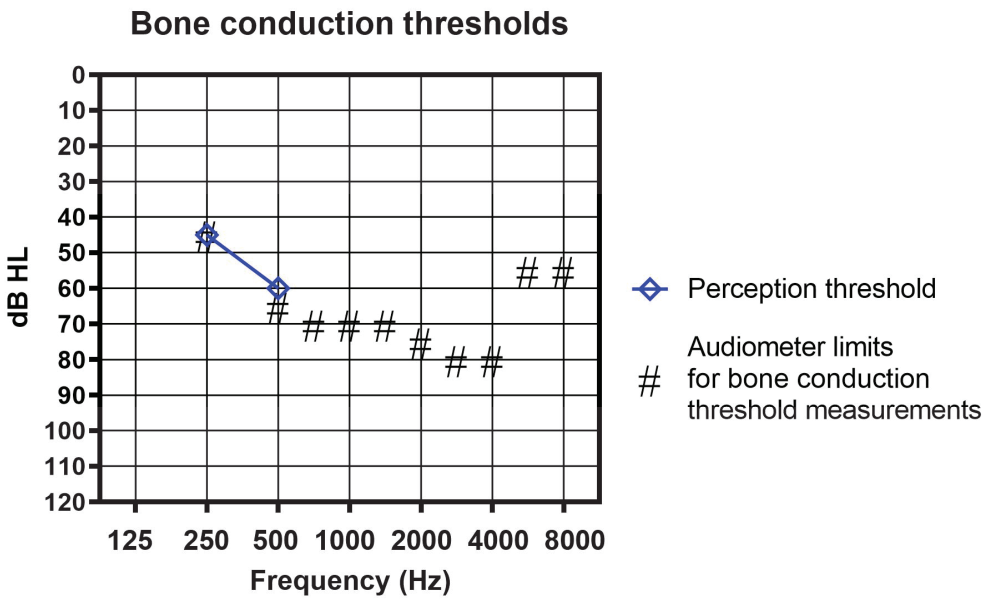

Figure 4. Bone conduction (BC) threshold measurements. Neither the patient nor any of the controls reported any hearing sensation in the conventional BC thresholds measurement up to the frequency-dependent maximum levels (#) available with our audiometers. One control subject reliably detected the vibration at 250 and at 500 Hz (shown here as blue diamonds) and described the sensation clearly as tactile and not as hearing.

Above the individual thresholds, sounds could be reliably detected and very rough temporal patterns (basically switching the acoustic signal on and off again) were reliably perceived. Any further discrimination seemed to be next to impossible, at least without training.

4. Discussion

Cochlear implants have been used since 1990 at our department and, until recently, the use of tactile aids was not even seriously considered. Somewhat to our surprise, we found that there may still be justifiable applications, although they are probably very rare. It is interesting to note that a very different application of tactile aids than the one reported here may also be useful. Specifically, it has been found that a multisensory approach, i.e., combined auditory and tactile stimulation, can improve speech understanding in noise [17].

The bone conduction sound processor used as a tactile aid does indeed allow the perception of acoustical signals. However, it is limited to relatively loud sounds and to low frequencies, and the sensation is vibrotactile. By itself, it is certainly unsuitable for any but possibly the simplest forms of oral communication. It is unclear how much it can help, e.g., by supporting lip reading, as the limited cognitive capabilities of our patient did not allow a closer examination. We would expect at most a limited help. Nevertheless, the patient does use the device and it seems to be helpful to detect some of the louder acoustical signals in her surroundings.

Bone conduction devices such as the one used here were developed to elicit auditory sensations via the BC pathway, the cochlea and, ultimately, the auditory nerve. We have no indication that this is happening here. All subjects reported clearly tactile sensations and no hearing sensations through the BC device. This holds true for the position at the head as well as at the wrist. Consequently, we believe that we have measured purely tactile sensations.

The placement of the BC processor does affect perception thresholds. The placement behind the wrist seems, in this respect, to be better than the normal placement of BC hearing aids behind the ear, not only in our patient, but mostly also in the small sample tested. Certainly, each placement has also its own practical challenges, such as, e.g., limitations of own movements, visibility, or risk of contact to clothing. It is conceivable that other placements than the two reported here may be better.

Although BC devices can be used as tactile aids to perceive acoustic signals, it is important to stress that in most cases this is one of the last resorts. If at least one cochlea with an intact auditory nerve is present, cochlear implantation should clearly be considered first and will probably lead to much better results in most cases. Even in patients with bilateral cochlear aplasia and bilateral auditory nerve aplasia, the use of tactile aids is one of the last solutions to be evaluated. Auditory brainstem implants should be considered first, even though results are generally poorer than with cochlear implants [12]. As with all auditory implants in congenitally and bilaterally deaf patients, early implantation is a key factor for its success.

5. Conclusions

Cases where the use of tactile aids may make sense are probably very rare. The use of bone conduction devices, placed preferably close to the wrist, may be useful, although the perception of sound signals is limited to low frequencies and relatively loud levels, and sound discrimination must be expected to be very poor.

Author Contributions: Conceptualization, M.K., G.M. and S.W.; Methodology, M.K.; Validation, M.K., M.L. and T.G.; Formal Analysis, M.K. and G.M.; Investigation, M.K. and M.L.; Resources, M.D.C. and M.K.; Writing—Original Draft Preparation, M.K.; Writing—Review and Editing, M.K., G.M., S.W., M.D.C. and T.G.; Visualization, M.K. and G.M.; Supervision, M.K. and M.D.C.; Project Administration, M.K. All authors have read and agreed to the published version of the manuscript.

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Informed Consent Statement: Informed consent was obtained in writing from all subjects involved in this report, including the patient, her parents and the cochlear implant users.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. Carlson, M.L. Cochlear Implantation in Adults. *N. Engl. J. Med.* **2020**, *382*, 1531–1542. [CrossRef] [PubMed]
2. Lenarz, T. Cochlear implant—State of the art. *GMS Curr. Top. Otorhinolaryngol. Head Neck Surg.* **2018**, *16*, 1–29. [CrossRef] [PubMed]
3. Géléoc, G.S.G.; Holt, J.R. Sound Strategies for Hearing Restoration. *Science* **2014**, *344*, 1241062. [CrossRef] [PubMed]
4. Working Group on Communication Aids for the Hearing-Impaired. Speech-perception aids for hearing-impaired people: Current status and needed research. *J. Acoust. Soc. Am.* **1991**, *90*, 637–683. [CrossRef]
5. Weisenberger, J.M.; Kozma-Spytek, L. Evaluating tactile aids for speech perception and production by hearing-impaired adults and children. *Am. J. Otol.* **1991**, *12*, 188–200. [PubMed]
6. Plant, G.; Gnosspelius, J.; Levitt, H. The use of tactile supplements in lipreading Swedish and English: A single-subject study. *J. Speech Lang. Hear. Res.* **2000**, *43*, 172–183. [CrossRef] [PubMed]
7. Karimi-Yazdi, A.; Sazgar, A.A.; Nadimi-Tehran, A.; Faramarzi, A.; Nassaj, F.E.; Yahyavi, S. Application and usage of tactile aid in Iran. *Arch. Iran. Med.* **2006**, *9*, 344–347. [PubMed]
8. Patil, S.J.; Karthik, G.A.; Bhavani, G.S.; Bhat, V.; Matalia, J.; Shah, J.; Shukla, A.; Girisha, K.M. Bosley-Salih-Alorainy syndrome in patients from India. *Am. J. Med. Genet. A* **2020**, *182*, 2699–2703. [CrossRef] [PubMed]
9. Bosley, T.M.; Salih, M.A.; Alorainy, I.A.; Oystreck, D.T.; Nester, M.; Abu-Amero, K.K.; Tischfield, M.A.; Engle, E.C. Clinical characterization of the HOXA1 syndrome BSAS variant. *Neurology* **2007**, *69*, 1245–1253. [CrossRef] [PubMed]
10. Oystreck, D.T.; Salih, M.A.; Bosley, T.M. When straight eyes won't move: Phenotypic overlap of genetically distinct ocular motility disturbances. *Can. J. Ophthalmol.* **2011**, *46*, 477–480. [CrossRef] [PubMed]
11. Bosley, T.M.; Alorainy, I.A.; Salih, M.A.; Aldhalaan, H.M.; Abu-Amero, K.K.; Oystreck, D.T.; Tischfield, M.A.; Engle, E.C.; Erickson, R.P. The clinical spectrum of homozygous HOXA1 mutations. *Am. J. Med. Genet. A* **2008**, *146A*, 1235–1240. [CrossRef] [PubMed]
12. Veronese, S.; Cambiaghi, M.; Tommasi, N.; Sbarbati, A.; Galvin, J.J., 3rd. Ten-year follow-up of auditory brainstem implants: From intra-operative electrical auditory brainstem responses to perceptual results. *PLoS ONE* **2023**, *18*, e0282261. [CrossRef] [PubMed]

13. Martins, Q.P.; de Franceschi Schirmer Gindri, B.; Dellinghausen Valim, C.; Ferreira, L.; Soares Aurélio Patatt, F. Hearing and language development in children with brainstem implants: A systematic review. *Braz. J. Otorhinolaryngol.* **2022**, *88* (Suppl. 3), S225–S234. [CrossRef] [PubMed]
14. Kara, A.; Kalcioglu, M.T.; Adigul, Ç.; Topcu, M.T.; Koçoğlu, M.; Celik, B.; Yilmaz, M.S. Comparison of two different bone anchored hearing instruments. *Eur. Arch. Otorhinolaryngol.* **2022**, *online ahead of print*. [CrossRef] [PubMed]
15. Gawliczek, T.; Wimmer, W.; Munzinger, F.; Caversaccio, M.; Kompis, M. Speech Understanding and Sound Localization with a New Non-implantable Wearing Option for Baha. *BioMed Res. Int.* **2018**, *2018*, 5264124. [CrossRef] [PubMed]
16. Gandhi, M.S.; Sesek, R.; Tuckett, R.; Bamberg, S.J. Progress in vibrotactile threshold evaluation techniques: A review. *J. Hand Ther.* **2011**, *24*, 240–255. [CrossRef] [PubMed]
17. Cieśla, K.; Wolak, T.; Lorens, A.; Heimler, B.; Skarżyński, H.; Amedi, A. Immediate improvement of speech-in-noise perception through multisensory stimulation via an auditory to tactile sensory substitution. *Restor. Neurol. Neurosci.* **2019**, *37*, 155–166. [CrossRef] [PubMed]

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