# Effect of transducer placements on thresholds in ears with an abnormal ear canal and severe conductive hearing loss

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#### Abstract

**Objectives:** Providing hearing compensation to patients with aural atresia is considerably challenging. Hearing aid transducers vibrating the aural cartilage (cartilage conduction; CC) have been devised, and hearing aids utilizing them (CC hearing aids) have quickly become a beneficial option for aural atresia in clinical applications. However, it remains unclear which placement (on the aural cartilage or mastoid) is beneficial to signal transmission.

**Methods:** This study included 35 patients (53 ears with an abnormal ear canal and severe conductive hearing loss) who were using CC hearing aids. Thresholds were compared between the transducers on the aural cartilage and on the mastoid.

**Results:** In ears with bony aural atresia, thresholds were significantly improved when the transducer was placed on the aural cartilage compared to when it was placed on the mastoid for frequencies  $\leq$  500 Hz (*P* < .05). In aural atresia ears with a fibrotic tissue pathway, the aural cartilage stimulation improved the thresholds by approximately 20 dB for frequencies  $\leq$  1000 Hz (*P* < .05). In non-atretic ears, the aural cartilage locations significantly worsened the threshold at 4000 Hz (*P* < .05).

**Conclusion:** Our findings demonstrated that placing the transducer at the aural cartilage improved the mid-to-low frequency thresholds compared to mastoid transduction in aural atretic ears. In contrast, no clear improvement to the signal transmission due to the transducer's placement on the aural cartilage was recognized in non-atretic ears.

Level of Evidence: 2

#### KEYWORDS

bone-anchored hearing aid, bone conduction, cartilage conduction, conductive hearing loss, fibrotic tissue pathway, hearing aid

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# 1 | INTRODUCTION

A loud sound is audible when a transducer is attached to the aural cartilage (particularly, the tragus).<sup>1,2</sup> Three theoretical components, namely cartilage bone conduction (BC), cartilage air conduction (AC), and direct AC, potentially contribute toward signal transmission in cartilage conduction (CC).<sup>3,4</sup> Previous studies have demonstrated the significant contribution of cartilage AC to CC.<sup>3-6</sup> The mechanism underlying the airborne sound generation for cartilage AC resembles that for a vibration speaker.<sup>7</sup> The cartilaginous portion of the ear canal functions as a movable plate, which increases the signal in the ear canal compared to that emitted directly from the transducer.<sup>8,9</sup> This amplified signal drives the eardrum.

Hearing aids (HAs) are clinical applications utilizing CC.<sup>10-13</sup> Neither high contact force nor a headband is required for their attachment. The style and appearance of CC-HAs are similar to those of small behind-the-ear AC-HAs (Figure 1A). Different from AC-HAs, they can deliver a mechanical signal to the aural cartilage and are beneficial even for atretic ears.<sup>13-18</sup> BC-HAs or implantable devices are required for hearing compensation in atretic ears. However, BC-HAs have disadvantages associated with their method of fixing (the transducer is fixed with a contact force using a headband),<sup>19</sup> and implantable devices need surgical procedures. In contrast, CC-HAs have the advantages of comfort, stable fixation, good esthetics, and noninvasiveness.<sup>7</sup> They have been clinically used in Japan since 2017 and have guickly become a beneficial option for patients with aural atresia.<sup>17</sup> The Oto-Rhino-Larvngological Society of Japan presents information related to CC-HAs along with information regarding boneanchored hearing aid (BAHA), Vibrant Soundbridge (VSB), and cochlear implants at their website.<sup>20</sup> The guidelines for implantable devices, such as BAHA, VSB, and Bonebridge, authorized by the Japan Otological Society<sup>21</sup> require CC-HAs to be tested before their indication. Although other devices, such as Osia, Ponto, and Alpha 2MPO,<sup>22</sup> are also effective for patients with aural atresia, they are not currently available in clinical practices in Japan.

Regarding the performance of CC-HAs in bony atretic ears, the signal transmission efficacy is probably inferior to those of BC-HAs or implantable devices because of the lack of their predominant pathway (cartilage AC). The absence of a contact force improves the feeling of wearing but deteriorates the signal transmission via the skull bone. Most patients desire CC-HAs because of their merits: comfort and good esthetics without surgery. Therefore, their fitting should be carefully performed to avoid diminishing their advantages. Signal transmission should be investigated when the transducer is applied without a static force.

CC-HAs provide audiometric outcomes comparable to those of BC-HAs<sup>13,17</sup> and improved sound localization.<sup>23</sup> However, whether there is a difference in signal transmission to the cochlea in atretic ears when the transducer is placed over the bony and cartilaginous tissues without a static force remains unclear. Signals may be attenuated while traveling additionally through the aural cartilage. If the attenuation is significant, the transducer placement may have to be reconsidered. In this study, the thresholds were compared between when the transducer is placed on the aural cartilage and on the mastoid. We also assessed the effect of the external ear condition on the differences in the thresholds. The results would contribute to the determination of optimal hearing devices and transducer placement among patients with severe conductive hearing loss (CHL).

## 2 | MATERIALS AND METHODS

## 2.1 | Patients

Thirty-five patients (13 females and 22 males; average age 29.6  $\pm$  24.5 years) participated in the study. The inclusion criteria were (1) presence of aural atresia or severe CHL and (2) use of CC-HAs in the referred clinical study.<sup>13</sup> Patients without severe CHL were excluded. The experimental procedures were approved by the ethics committee of Nara Medical University (No. 09-KEN011). Participants

## (A) Cartilage conduction hearing aid and apperance of its wearing



#### (B) Transducer



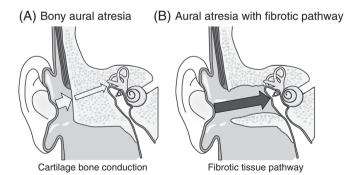
**FIGURE 1** Cartilage conduction hearing aid and its transducer. A. The cartilage conduction hearing aid and its appearance when used by the patient (right). B. A plain transducer that was used for the current measurements. The same model of the transducers is used for cartilage conduction hearing aids

or their parents, if the patient was aged < 20 years, provided written informed consent prior to enrollment.

CC-HAs were used bilaterally and unilaterally by 18 and 17 patients, respectively. Thus, a total of 53 ears were classified into three conditions for further analyses. The ear pathology was diagnosed based on computed tomography findings. The first condition comprised of bony aural atresia, with 35 ears showing congenital bony aural atresia without a history of canaloplasty (Figure 2A). The second condition was aural atresia with a fibrotic tissue pathway (FTP). The obstructing tissue sometimes connects to the ossicles, and the vibrations can travel to the cochlea through this pathway, termed as the FTP (Figure 2B).<sup>24</sup> The FTP often leads to a good hearing performance with CC-HAs. This second condition included eight ears. The third condition included the remaining 10 ears, which were characterized by acquired fibrotic aural atresia without the FTP (n = 5), stenosis of the ear canal with ossicular defects (n = 3), or lateralization of the eardrum (n = 2). There was no normal ear canal case. All 10 ears had ossicular discontinuities or defects. In all included patients, AC-HAs were unavailable or had provided insufficient benefits. Most of them had used BC-HAs prior to CC-HAs.<sup>13</sup>

## 2.2 | Procedures

A transducer, typically employed in CC-HAs, was used for threshold measurements (Figure 1B). The size and mass of the transducer were  $11.9 \times 7.8 \times 4.7$  mm and 1.4 g, respectively. The transducer was attached with double-sided tape for skin (#1522; 3 M Japan Limited, Tokyo, Japan) to the region where the transducer of the CC-HA was usually located. The tape can provide stable adhesion to the transducer. The double-sided tape was quite thin (0.16 mm), and sound absorption was considered negligible. This experimental setting was defined as cartilage stimulation. Additionally, the transducer was



**FIGURE 2** Difference in signal transmission between bony aural atresia and fibrotic aural atresia with a fibrotic tissue pathway (FTP). A. For bony aural atresia, the impedance mismatch between the soft and bony tissues influences the transmission via cartilage bone conduction. This boundary attenuates the signal to the cochlea. B. For fibrotic aural atresia, signal is transmitted to the cochlea via the ossicles when the obstructing fibrotic tissue is connected to the coshlea, bypassing the skull bone

attached to the mastoid, where a conventional BC transducer is placed in conventional audiometry. It was fixed with the double-sided tape in the same manner as in the cartilage stimulation. This experimental setting was defined as the mastoid stimulation. The experiments in the mastoid stimulation were similar to those in BC, except for the transducer and its fixation style (with the double-sided tape or headband). The two measurements (the aural cartilage and mastoid conditions) were performed in a random order.

The transducer was connected to a conventional audiometer (AA-78, Rion, Kokubunji, Japan) that conformed to IEC 60645-1<sup>25</sup>; all threshold measurements were performed with this system. The stimulus frequencies were set at 250, 500, 1000, 2000, and 4000 Hz. The stimulus duration was set at 225 ms. and the stimulus rate was 2.2 Hz. The threshold at which the participant responded to the signal in at least three ascending series using 5-dB steps was determined. The ear that was not tested was masked using a plateau method if it was not an atretic ear. Narrow-band noise was employed as the masker and presented with an earphone. The output level of the transducer was evaluated in force level using an artificial mastoid (Type 4930; Brüel & Kjær, Nærum, Denmark). The transducer was placed on the artificial mastoid with the double-sided tape, without providing additional pressure, to evaluate the output level in the same condition as the threshold measurement. For conventional BC, the reference equivalent threshold force levels were 67, 58, 42.5, 31, and 35.5 dB  $\mu$ N at 250, 500, 1000, 2000, and 4000 Hz, respectively (ISO 389-3).<sup>26</sup> For the transducer, the input levels that provided the same force levels were defined as the reference levels at the respective frequencies. The audiometric tests were performed in a soundproof room.

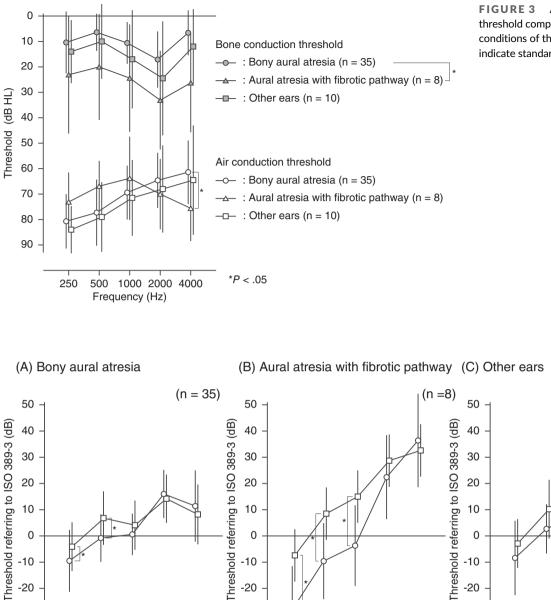
## 2.3 | Statistical analysis

Statistical differences in the AC and BC thresholds in pure-tone audiometry were determined by two-way mixed analysis of variance (ANOVA). The condition of the ear (bony aural atresia, aural atresia with FTP, and other ears) and the frequency were the betweensubject and within-subject factors, respectively. Statistical differences in the thresholds measured with the transducer of CC-HAs were determined in each condition of the ear using two-way ANOVA, with the stimulation method (cartilage and mastoid stimulation) and frequency as the within-subject factors. Bonferroni test was used for post hoc comparisons. The statistical analyses were performed using SPSS version 22 (IBM Corporation, Armonk, New York), and the significance level was set at P < .05.

# 3 | RESULTS

Figure 3 shows the AC and BC thresholds in the three conditions of the ear. For AC, two-way mixed ANOVA revealed significant main effect of frequency (F[4, 200] = 11.764, P < .001); however, no significant differences were found in the condition of the ear (bony aural atresia, aural atresia with FTP, and other ears; F[2, 50] = 0.427, *ns*).





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(n = 10)

Air and bone conductions threshold comparisons among the three conditions of the ear. Vertical bars indicate standard deviations

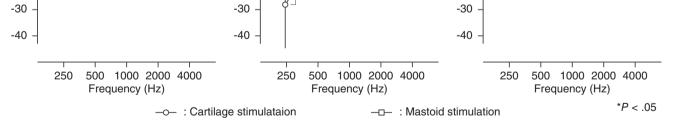


FIGURE 4 Threshold comparisons between the cartilage and mastoid stimulations in each of the three conditions of the ear. For conventional bone conduction, reference equivalent threshold force levels were 67, 58, 42.5, 31, and 35.5 dB µN at 250, 500, 1000, 2000, and 4000 Hz, respectively.<sup>26</sup> The input levels that provided the same force levels were defined as the reference levels at the respective frequencies. Vertical bars indicate standard deviations

Significant interaction was observed between the condition of the ear and frequency (F[8, 200] = 4.703, P < .01). The post hoc test found a significant difference in the AC threshold at 4 kHz between bony aural atresia and aural atresia with FTP, whereas no other significant differences were found at the other frequencies among the three

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conditions of the ear. For BC, two-way mixed ANOVA revealed significant main effects of the condition of the ear and frequency (F[4,200] = 16.609, P < .001 and F[2, 50] = 4.851 P < .05, respectively); however, no significant interactions were observed (F[8, 200] = 0.707, ns). The BC thresholds for the bony aural atresia were

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significantly better than those for aural atresia with FTP, independent of the frequency.

The thresholds for the cartilage and mastoid stimulations in the three conditions of the ear are presented in Figure 4. In the condition of bony aural atresia ears (Figure 4A), two-way ANOVA revealed significant main effects of the frequency (*F*[4, 136] = 57.883, *P* < .001); however, no significant differences were found in the stimulation method (cartilage and mastoid stimulations; *F* [1, 34] = 2.591, *ns*). Significant interactions were recognized between the stimulation method and frequency (*F*[4, 136] = 9.874, *P* < .001). In the post hoc analysis, the thresholds for the cartilage stimulation were significantly lower than those for the mastoid stimulations at 250 and 500 Hz (*P* < .05). The differences in thresholds between cartilage and mastoid stimulations were 5.4 and 7.6 dB at 250 and 500 Hz, respectively. No significant differences were observed above 2000 Hz.

In the condition of aural atresia ears with FTP (Figure 4B), twoway ANOVA revealed significant main effects of the stimulation method and frequency (F[1, 7] = 16.457, P < .01 and F[4, 28] = 51.159, P < .001, respectively). Significant interactions were observed between the stimulation method and frequency (F[4, 28] = 7.373, P < .001). In the post hoc analysis, the thresholds for the cartilage stimulation were significantly better than those for the mastoid stimulation in frequencies  $\leq 1000$  Hz (P < .05), whereas no differences were observed in frequencies  $\geq 2000$  Hz. The differences in thresholds between cartilage and mastoid stimulations were 20.6, 18.1, and 18.8 dB at 250, 500, and 1000 Hz, respectively.

In the condition of other ears (Figure 4C), two-way ANOVA revealed significant main effects of the frequency (F[4, 36] = 13.866, P < .001); however, no significant differences were found in the stimulation method (F[1, 9] = 0.012, *ns*). Significant interactions were recognized between the stimulation method and frequency (F[4, 36] = 6.825, P < .001). In the post hoc analysis, the threshold for the cartilage stimulation was significantly worse than that for the mastoid stimulation at 4000 Hz (P < .05). The difference in threshold between them was 11.0 dB at 4000 Hz. No other significant differences were observed between the two stimulation methods.

## 4 | DISCUSSION

This study investigated the threshold levels for vibration stimulation at the aural cartilage and mastoid in ears with abnormal ear canal and severe CHL. Overall, the differences in thresholds were attributed to transducer placement (ie, at the aural cartilage or mastoid) and the presence of an FTP. Independent of the condition of the ear, the measured threshold was relatively lower for cartilage stimulation than that for the mastoid stimulation at low-to-mid frequencies and worse for cartilage stimulation at 4000 Hz in non-atretic ears.

When the patients with bony aural atresia use CC-HAs, vibration of the skull bone is necessary for signal transmission to the cochlea. For BC, the static force is important for transmission.<sup>27,28</sup> Transmission loss increases when the transducer is placed on soft tissue without a static force.<sup>29</sup> In this study, no difference in the thresholds was observed between the cartilage and mastoid stimulations in ears with bony aural atresia. Furthermore, lower thresholds were obtained for cartilage stimulation in frequencies  $\leq$  500 Hz. In the current setup (the transducer was fixed with the double-sided tape), the transmission loss for the cartilage stimulation might be lower than that for the mastoid stimulation.

In CC, the aural cartilage functions like the movable plate of a vibration speaker in normal ears.<sup>7</sup> A vibration speaker efficiently generates airborne sounds at the resonance frequency of the movable plate.<sup>8,9</sup> Previous studies have suggested that the resonance frequency of the aural cartilage is low. Therefore, low-frequency signals were efficiently transmitted when the transducer was placed on the aural cartilage without a static force. Our findings demonstrated that the attachment of the transducer to the aural cartilage in the atretic ear does not increase the threshold because of the signals traveling additionally through the aural cartilage.

In case of aural atresia with FTP, the threshold decreased for the cartilage stimulation compared to the mastoid stimulation was approximately 20 dB for frequencies  $\leq$  1000 Hz. In these ears, the predominant pathway for CC was considered to be the FTP, that is, the vibrations delivered to the aural cartilage were transmitted to the cochlea via the obstructing fibrotic tissue and the ossicles connected to it.<sup>24,30</sup> The FTP does not involve the skull bone, which contributes to the improvement of the signal transmission. The resonance frequency of the aural cartilage was probably associated with the observed good hearing at low frequency. Furthermore, FTP can attenuate signal during its traveling.<sup>30</sup> Signal attenuation at high frequencies might be responsible for the low boost in hearing.

Severe CHL can result from pathologies distinct from aural atresia. Ossicular discontinuities or defects result in severe CHL,<sup>31</sup> where the predominant signal transmission pathway to the cochlea is considered to involve the skull bone, in a manner similar to the transmission in bony aural atresia. In other ears with an abnormal ear canal and severe CHL, thresholds increased at 4000 Hz for the cartilage stimulation, whereas no threshold differences were observed between the cartilage and mastoid stimulations for frequencies  $\leq$  1000 Hz. The results in other ears with an abnormal ear canal and severe CHL resembled those observed in the bony aural atresia ears, suggesting the identification in the transmission pathway between them.

Most patients with aural atresia usually prefer using CC-HAs, with the transducer attached to the ear without a contact force. The current results demonstrated that the placement of the transducer on the aural cartilage had no disadvantages concerning signal transmission, compared to placement on the mastoid, when the transducer was attached without a contact force. In clinical applications, some patients use CC-HAs with an ear-chip transducer.<sup>17</sup> This transducer is fixed by inserting the ear-chip into a cavity of concha. It can be held with the stiffness of the conchal cartilage, which can restrict the mobility of the transducer instead of the static force provided with a headband.<sup>13</sup> The signal transmission can be improved depending on its coupling condition.

The mastoid stimulation was not equal to conventional BC owing to the difference in their fixation style; there was no restriction due to the static force for the fixation with respect to the mastoid stimulation. Considering the calibration procedures, the similarity in their respective thresholds was not surprising. In the bony aural atresia ears and other ears, the threshold curve for the mastoid stimulation resembled that for BC. The thresholds for the mastoid stimulation increased by approximately 10 dB, which might be attributed to the lack of a contact force. In case of aural atresia with FTP, the threshold at high frequency for the mastoid stimulation also increased compared to that for BC. However, the threshold for the mastoid stimulation decreased as the frequency decreased, and it was lower than the BC threshold at frequencies ≤ 1000 Hz. The threshold curve in the mastoid stimulation resembled those observed in the cartilage stimulation rather than that for the BC threshold. These findings suggested that the vibrations at low-middle frequency traveled to the cochlea via FTP despite the mastoid stimulation. In BC, since the skin is sandwiched between the transducer and skull bone with high contact pressure, the mobility of the tissue is restricted with this contact force. For mastoid stimulation in this study, mobility was not restricted by the static force, which might have enabled the vibration to spread over the surrounding skin. This radiated vibration might have traveled to the cochlea via the fibrotic tissue, contributing to low thresholds at the low-middle frequency in a manner similar to cartilage stimulation. Further studies are required to investigate the impact of the contact pressure for the mastoid stimulation on the thresholds in cases of aural atresia with FTP.

Most patients in this study could not use AC-HAs due to insufficient gain and did not want to use BC-HAs due to fixation-related problems.<sup>13</sup> Compared to BC-HAs, CC-HAs have the advantages of improved comfort, esthetics, stability,<sup>7</sup> and low-frequency hearing<sup>24</sup>; however, the results suggested that they have the disadvantage of decreased sensitivity at high frequencies. To evaluate the efficiency of signal transmission, we measured in this study the thresholds, not speech perception. In the fitting process, insufficient gains at a high frequency reduce speech recognition,<sup>32</sup> and CC-HAs should be finetuned to amplify high frequencies to overcome this disadvantage.33 The applicable range depends on the maximum output levels, which are restricted by the transducer power and feedback problem. Fortunately, the enrolled patients were satisfied with their CC-HAs and continued to use them. When CC-HAs cannot sufficiently compensate for hearing loss because of limitations of the output levels, other options, such as BAHA, Bonebridge, VSB, Osia, Ponto, and Alpha 2MPO,<sup>22,34-37</sup> have to be considered.

# 5 | CONCLUSION

This study investigated the difference in thresholds between the transducer's placement on the aural cartilage and mastoid in ears with an abnormal ear canal and severe CHL. In bony aural atresia, the fixation of the transducer on the aural cartilage improved low-frequency thresholds by 5-10 dB on average. In aural atresia ears with an FTP, the improvement was approximately 20 dB at frequencies < 1000 Hz. In contrast, in patients with other origins of severe CHL, there was no

clear improvement to the sound transmission due to the transducer's placement on the aural cartilage.

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#### CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

#### AUTHOR CONTRIBUTIONS

Tadashi Nishimura: Conceptualization; statistical analysis; investigation; data curation; writing – original draft. Hiroshi Hosoi: Conceptualization; writing – review and editing. Ryota Shimokura: Statistical analysis; investigation. Osamu Saito: Data curation. Tadao Okayasu: Data curation. Chihiro Morimoto: Data curation; funding acquisition. Tadashi Kitahara: Writing – review and editing.

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