Title: Sound transmission by cartilage conduction in the ear with fibrotic aural atresia

Short Title: Cartilage conduction in fibrotic atresia

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Abstract

A hearing aid using cartilage conduction (CC) has been proposed by Hosoi (2004) as an alternative to bone conduction (BC) hearing aids. The transducer developed for this application is lightweight, requires a much smaller fixation force than a bone conductor, and is more convenient to use. CC can be of great benefit to patients with fibrotic aural atresia. Fibrotic tissue connected to the ossicles provides an additional pathway, (termed fibrotic tissue pathway) for sound to reach the cochlea by means of CC. To address the function of fibrotic tissue pathway, BC and CC thresholds were measured in six ears with fibrotic aural atresia. The relationship between the CC thresholds and the results of computed tomography was investigated. In the ears with the presence of a fibrotic tissue pathway, the CC thresholds were lower than the BC thresholds at 0.5 and 1 kHz. At 2 kHz, no significant difference was observed between the BC and CC thresholds. The current findings suggest that sound in the low to middle frequency range is transmitted more efficiently by CC via a fibrotic tissue pathway than BC. The development of hearing devices using CC can contribute to rehabilitation, particularly in patients with fibrotic aural atresia.

Key words: Acquired aural atresia, Air-borne sound, Binaural hearing, Bone anchored hearing aid, Bone conduction, External auditory canal, Hearing aid, Occlusion effect, Fibrotic tissue pathway, Soft tissue pathway

Abbreviations

AC=air conduction, BC=bone conduction, CC=cartilage conduction, CT=computed tomography

Introduction

Hearing loss results in reduced communication in daily life and is a major factor contributing to reduced quality of life. Aural atresia is a hearing disorder that is difficult to treat. Conventional hearing aids using air conduction (AC) provide little benefit owing to the fixation problem, feedback oscillation, and insufficient gain [1]. Methods of intervention include surgical treatment, or fitting of bone conduction (BC) hearing aids [2]. However, the surgical treatment involves the risk associated with the operation [3,4], and sometimes results in the stenosis and lateralization of the repaired ear canal, and the hearing improvement is worsened after long term observation [5,6]. For BC hearing aids, the transducer has to be tightly pressed against the mastoid [2] or directly fixed with an attachment screw embedded in the bone, referred to as a bone anchored hearing aid [7,8]. Unfortunately, both methods involve respective disadvantages. For conventional BC hearing aids, the transducer has a relatively large mass and a large fixation force is needed for the device to function properly. Long term use can also cause skin irritation, long-continued depressions in the skin, and discomfort [2]. For bone anchored hearing aids, surgery is required, the portion of the implant exposed to open air can induce infection, and some cases are required for revision surgery owing to skin overgrowing the abutment [9,10].

Hosoi found that a clear sound can be heard when a vibration signal is delivered to the aural cartilage from a transducer [11]. This form of signal transmission is referred to as "cartilage conduction (CC)". Utilizing CC, a novel hearing device was developed for patients with conductive hearing loss and for whom a conventional AC hearing aid was not effective [12, 13]. A later study demonstrated superior benefit of a CC hearing device especially in patients with postoperative aural atresia [14]. These results suggest that novel hearing devices can be developed using CC as an alternative to BC in hearing aids and other audiological instruments.

When the CC transducer is placed on the aural cartilage, sound is transmitted to the cochlea via three possible routes in an anatomically normal ear, as shown in Figure 1(a). In the first pathway, vibrations of the transducer produce air-borne sounds, some of which reach the ear canal and are transmitted to the cochlea via the conventional pathway for AC. Such stray sound is also radiated by BC transducers [15, 16]. This pathway is termed “Direct AC”. In the second pathway, vibrations of the aural cartilage are transmitted to the cartilaginous portion of the ear canal. These vibrations induce an acoustic signal in the canal which is transmitted by AC to the eardrum. This pathway is termed “Cartilage AC” which is a different pathway that is not part of either the AC or BC pathways. In the third pathway, vibrations of the aural cartilage are transmitted to the cochlea via the skull bone. This pathway is termed “Cartilage BC”.

There are important differences between the proposed method of delivering sound by means of CC and the conventional method of delivering sound by means of BC. A major difference between CC and BC is

the fixation position of the transducer. CC allows for a small lightweight transducer to be placed conveniently on the aural cartilage for sound transmission. In BC, the fixation position is either the mastoid or forehead bone which is some distance from the ear. There is also the problem of transcranial transmission with BC. The precision of transducer placement is also not well controlled for mastoid placement leading to relatively large test-retest variability in BC measurements. A second, more important difference is the fixation force. A small fixation force of 0.06 N is sufficient for sound transmission with a CC transducer. In contrast, a BC transducer requires a fixation force of 5.4 N which is almost a hundred times larger and is a source of discomfort in BC hearing aids.

In an ear with aural atresia, most of the air-borne sound in the ear canal cannot reach the cochlea as with direct AC. There is, however, an additional pathway for CC in an ear with fibrotic aural atresia. In a previous study by Nishimura et al. [14], the ear canal was occluded with fibrotic tissue not bony tissue. In addition, the fibrotic tissue was connected to the stapes, thereby providing a fourth pathway for CC sound to reach the cochlea. This fourth pathway in fibrotic aural atresia is termed the "fibrotic tissue pathway" of CC (Figure 1(b). Nishimura et al. [14] obtained a large gain below 2 kHz in patients with a fibrotic tissue pathway using the prototype CC hearing aid.

The above observation leads to the underlying rationale for the current study. It was hypothesized that for those ears showing a fibrotic tissue link to the ossicles, the CC threshold will be lower than that for BC at frequencies below 2 kHz. In order to test this hypothesis, BC and CC thresholds were measured for outpatients in our hospital with fibrotic aural atresia which had already been diagnosed with computed tomography (CT scans)

Methods

Six patients with acquired aural atresia participated in the study. The characteristics of the subjects are shown in Table 1.Their ear canals were occluded with fibrotic tissue, which was induced after surgical operation in five subjects. The laterality of the aural atresia was right in all the subjects by chance. The experimental procedure was approved by the ethics committee of Nara Medical University. Participants provided written informed consent.

The thresholds of AC and BC were measured by a conventional pure tone audiometer (AA-78, Rion, Tokyo, Japan). The AC and BC stimuli were presented to the ear and mastoid using earphones (AT-02, Rion, Tokyo, Japan) and a bone vibrator (BR-41, Rion), respectively. The earphones and bone vibrator were calibrated with a sound pressure meter (AG-64; Rion) and artificial mastoid (Type 4930; Brüel & Kjær, Nærum, Denmark) according to ISO 389-1 and 389-3, respectively [17, 18]. For CC, the transducer was placed on the cavity of the concha except for subject 3. In subject 3, it was fixed on the tragus with a commercial tape because it could not be hung on the cavity of the concha due to the postoperative deformation. The property of the transducer is described later.

Thresholds were obtained at frequencies of 0.5, 1, 2, and 4 kHz, respectively. Tone bursts of 300 ms

including rise/fall ramps of 50 ms were employed for the stimulus. The signals were generated by a function generator (WF1946, NF Electronic Instruments, Yokohama, Japan) and the intensity was controlled by a programmable attenuator (PA5.0, Tucker-Davis Technologies, Gainesville, FL). The threshold was determined by the same ascending method as in conventional audiometry. The opposite ear was masked by a narrow band noise using a plateau method. The experiment was performed in a sound proof room.

Figure 2 shows the CC transducer. The output level of the CC transducer was calibrated with the artificial mastoid (Type 4930) in the same manner as BC. In the calibration of the BC transducer, it is fixed to the artificial mastoid with the fixation force of 5.4 N, which is the same as the fixation to the mastoid for the threshold measurement. In contrast, the CC transducer was held in place by a combination of its own weight and the stiffness of the conchal cartilage. The CC transducer weighs 6 g and the fixation force excluding the stiffness of the conchal cartilage was estimated to be approximately 0.06 N. The force exerted by the stiffness of the conchal cartilage is similarly relative low. However, the transducer has to be tightly fixed to the artificial mastoid in order to measure the force level. Thus, the CC transducer was also fixed to the artificial mastoid with the fixation force of 5.4 N in the same manner as the BC transducer. The output level of CC was represented in hearing level based on ISO 389-3 [18]. The fixation force is important factor for the sound transmission via BC [19, 20]. Because the CC transducer was placed on the cavity of the concha with a force much less than 5.4 N, the efficiency of sound conduction from CC transducer to cartilage is expected to be less than that for BC transducer to bone.

Results

Figure 3 shows the audiograms for the ears with fibrotic aural atresia. All the audiograms show a large air-bone gap due to the aural atresia. Figure 4 shows the results of CT. Soft tissue density was observed in the ear canals implying fibrotic aural atresia. For subject 1, the bony portion was maintained, and fibrotic tissue did not exist in the bony portion. In contrast, for subject 2, the bony portion was filled with fibrotic tissue induced by irritation and inflammation. For subjects 3, 4, 5, and 6, the bony portion of the ear canal was resected in the operation of carcinoma of the ear canal. With regard to the connection between occluding fibrotic tissue and ossicles, the CT scans for subjects 2, 4, 5, and 6 show a substantial connection of occluding fibrotic tissue with the ossicles, implying the presence of a fibrotic tissue pathway. There is no such connection evident in the CT scans for subjects 1 and 3.

Figure 5 shows the comparison of BC and CC thresholds. In the ears with a fibrotic tissue pathway (subjects 2, 4. 5, and 6), the CC thresholds were lower than the BC thresholds at frequencies of 0.5 and 1 kHz. At 2 kHz, no significant difference was observed between the BC and CC thresholds. At 4 kHz, the BC threshold was lower in subjects 2, 4, and 5. In the ears without a fibrotic tissue pathway (subjects 1 and 3), the CC thresholds were lower than the BC thresholds at 0.5 kHz, but not at higher frequencies.

Discussion

The main hypothesis is supported in that ears with a fibrotic tissue pathway, as determined by the CT scans, showed lower CC thresholds than BC thresholds at frequencies below 2 KHz. It is argued that the connection of the fibrotic tissue to the ossicles created a fourth pathway for CC sound to reach the cochlea (the fibrotic tissue pathway) thereby lowering the CC thresholds. It should also be noted that the CC thresholds at 4 kHz were substantially poorer than those for BC. Our previous study showed low gain at 4 kHz for the prototype CC hearing aid [14]. The current results are consistent with the gain of the prototype CC hearing aid as a function of frequency.

When the fibrotic tissue is not connected to the ossicles, the transmission pathway to the cochlea has to involve the skull bone or the air cavity between the fibrotic tissue and ossicles. In the case of the cartilage BC pathway, the fixation force is an important factor for efficient sound transmission particularly at high frequencies [19, 20]. The low fixation force of the CC transducer may account for the poor CC thresholds at high frequencies. In the case of the cartilage AC pathway, air-borne sounds from the fibrotic tissue have to vibrate the ossicles without the tympanic membrane. Considering the elevation in thresholds for the ear with the lateralized tympanic membrane [21], sound transmission without a fibrotic tissue pathway is not efficient.

Despite the inefficient transmission without a fibrotic tissue pathway, the CC threshold at 0.5 kHz was lower than that of BC. A possible explanation for the low CC threshold at 0.5 kHz is the occlusion effect. When the ear canal is occluded, a low frequency resonance is introduced such that the threshold for air-borne sounds in the canal is lowered in the region 0.4-1.3 kHz [22]. There are several factors that contribute to the measured CC threshold and it is not clear which is the dominant factor as a function of frequency. The findings of this study identify a factor that has not been considered in previous investigations, that of a fibrotic tissue pathway in ears with fibrotic aural atresia.

The current findings demonstrated the function of a fibrotic tissue pathway. An ear in which a fibrotic tissue pathway is present has characteristics that are advantageous with respect to the development of an improved CC hearing aid. Compared to AC, sound is delivered by vibrating the aural cartilage, which is not mediated by the air. The acoustic feedback resulting from the impedance mismatch between the air and fibrotic tissue is substantially less than that for an anatomically normal ear. As a consequence, the gain of the hearing aid can be greater for CC than for conventional air conduction before the onset of uncontrolled acoustic feedback (whistling). Compared to BC, the lower CC thresholds indicate more efficient sound transmission at low to middle frequencies. Vibration of the skull bone is not needed for sound transmission in CC. The output level from the CC transducer is sufficient if it can vibrate the aural cartilage and fibrotic tissue. For this application, the smaller size and lower weight of the CC transducer relative to a BC transducer are significant advantages. A more substantial advantage is that the fixation force for the CC transducer is about one thousandth of that required for a BC transducer (0.06 N vs 5.4 N). The large fixation force required for BC transducers is a major source of discomfort with

bone-conduction hearing aids. Sound transmission in bone is more efficient than in cartilage which has both advantages and disadvantages. For example, attenuation of sound across the skull is small resulting in significant transcranial stimulation in a BC hearing aid [23, 24]. Cross-over stimulation results in additional stimulation of the cochlea contralateral to the ear with the BC transducer, thereby reducing the efficacy of binaural hearing [25]. In contrast, with the fibrotic tissue pathway, because the force levels at the thresholds for CC were lower than those for BC, the transmission of CC sound is dominantly mediated by not the skull bone but the fibrotic tissue which connects to the ipsilateral cochlea. Consequently, CC sound is perceived by the ipsilateral ear with negligible crossover to the contralateral ear. A binaural CC hearing aid can thus maintain the benefits of binaural hearing, unlike the loss of these benefits with a binaural BC hearing aid [13].

Conclusions

In the ear with fibrotic aural atresia, the connection of the fibrotic tissue to the ossicles contributes to more efficient sound transmission by means of CC. In the presence of this fibrotic tissue pathway, CC is more efficient than BC, while also providing advantages over BC in terms of transducer weight, substantially smaller fixation force and greater convenience and comfort. The development of hearing devices using CC can contribute to rehabilitation, particularly in patients with fibrotic aural atresia.

Whereas it is recognized that the incidence of aural atresia is relatively low with an estimated annual incidence of "0.6 cases per 100,000 inhabitants" [26], the estimated number of new cases per year in the USA is 2,000 which is not an insignificant number. It is also likely that veterans with hearing damage resulting from blast injuries will have a significantly higher incidence of acquired aural atresia as a result of damage to the ear and related surgical intervention.

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Author Contributions:

Study concept and design: T. Nishimura, H. Hosoi

Acquisition of data: C. Morimoto, O. Saito, F. Fukuda

Analysis and interpretation of data: R. Shimokura, T. Yamanaka

Drafting of manuscript: C. Morimoto, T, Nishimura

Study supervision: H. Hosoi

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Participant Follow-Up: The authors do not plan to inform the participants of the publication of this study due to a lack of contact information.

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Table 1. Characteristics of patients

Subject	Age	Sex	Laterality	Cause of fibrotic aural atresia	Condition of the opposite ear
1	10	Female	Right	Re-atresia after the operation of congenital fibrotic aural atresia and cholesteatoma in the occluded ear canal	Normal
2	70	Female	Right	Chronic irritation and inflammation	Chronic otitis media
3	47	Male	Right	Operation of the carcinoma of the ear canal	Normal
4	76	Female	Right	Operation of the carcinoma of the ear canal	Profoundly deaf
5	45	Female	Right	Operation of the carcinoma of the ear canal	Normal
6	74	Male	Right	Operation of the carcinoma of the ear canal	Sensorineural hearing loss

Figure legends

Figure 1. Sound transmission pathway of cartilage conduction

In a normal anatomical ear, sound is transmitted to the cochlea via three possible routes (a). In the ear with fibrotic aural atresia, fibrotic tissue in the ear canal blocks air conduction. However, if the fibrotic tissue is connected to the ossicles, sound is transmitted via the connection to the cochlea (b). This fourth pathway is termed fibrotic tissue pathway.

Figure 2. Cartilage transducer

The transducer comprises a piezoelectric bimorph and covering material. A ring made of acrylic acid resin is glued to the transducer tip. The outer and inner diameters of the ring are 16 and 8 mm, respectively. Its thickness is 5 mm. The total weight of the transducer is 6 g.

Figure 3. Audiograms in six subjects

Arrows means that the threshold was higher than the masked level. It was not determined within the current maximum output level.

Figure 4. Results of computed tomography

The triangles indicate the connection of the fibrotic tissue to the ossicles.

Figure 5. Comparison of threshold in force level between cartilage and bone conduction

Arrows means that the threshold was higher than the masked level. It was not determined within the current maximum output level.

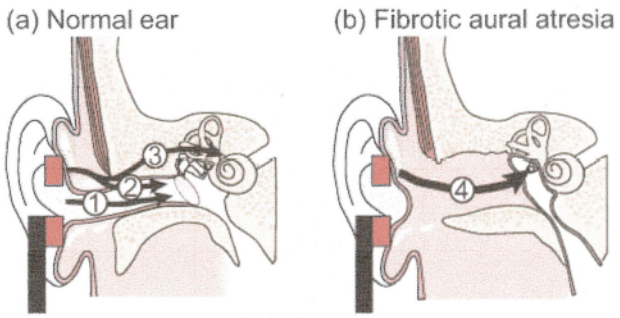


Figure1

Figure2

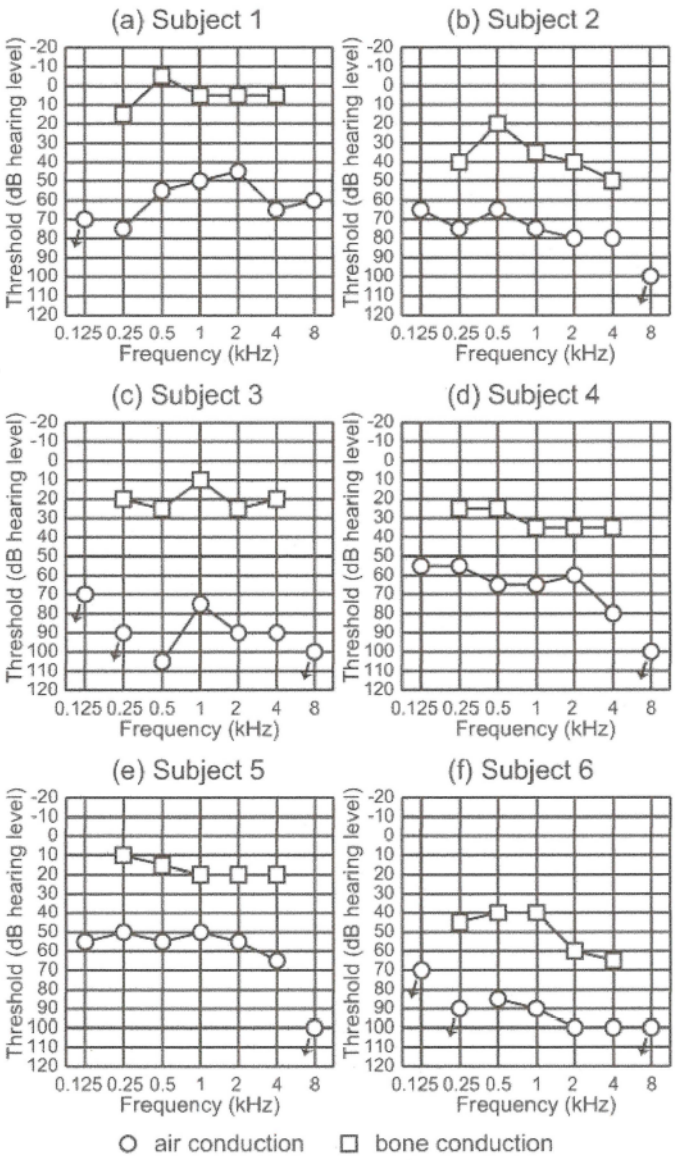


Figure3

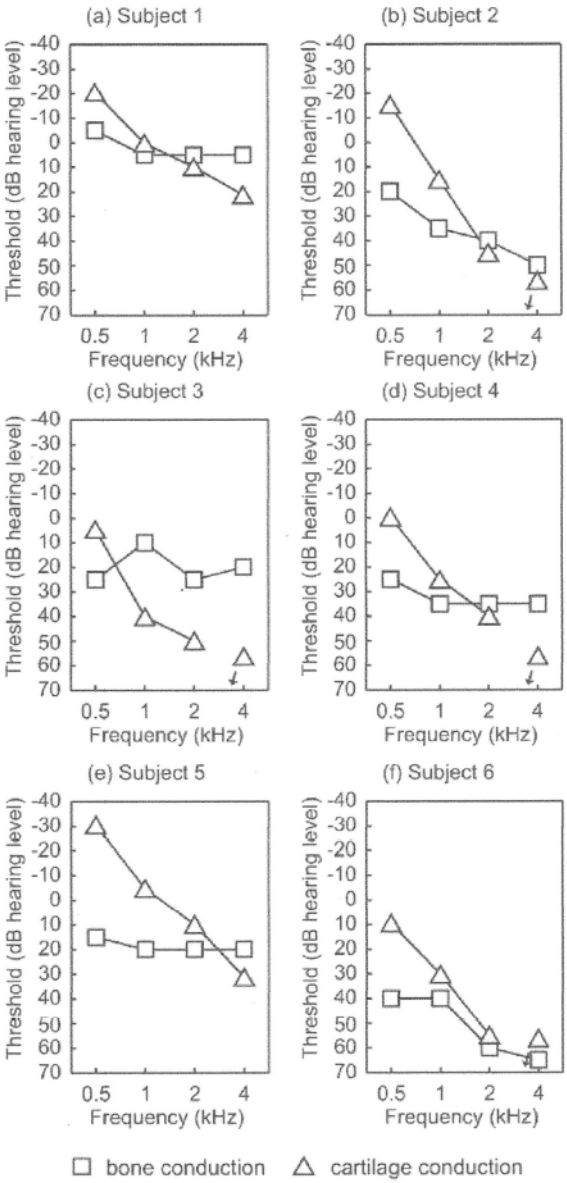
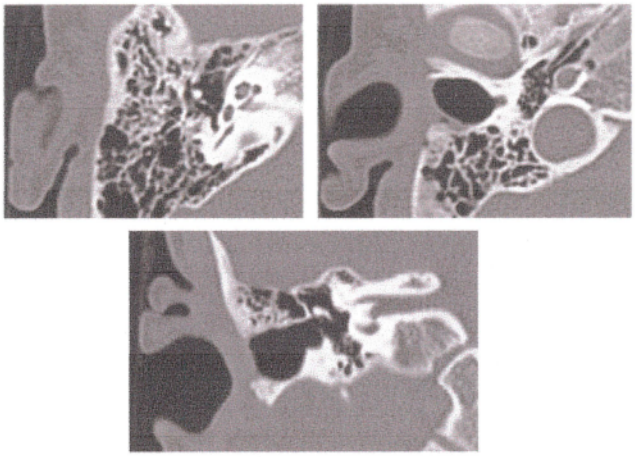


Figure5

(a) Subject 1



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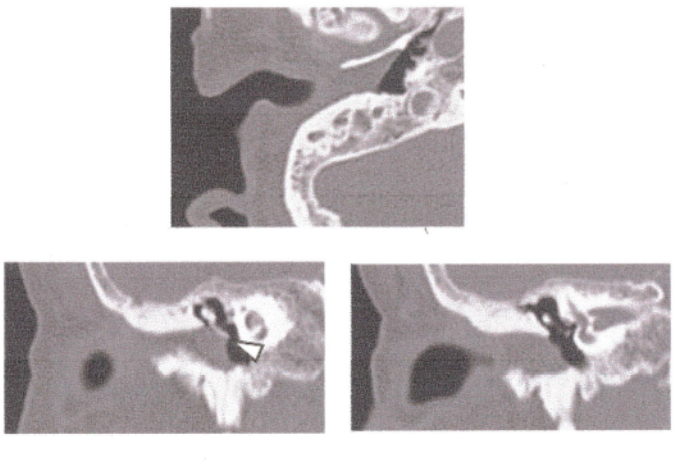

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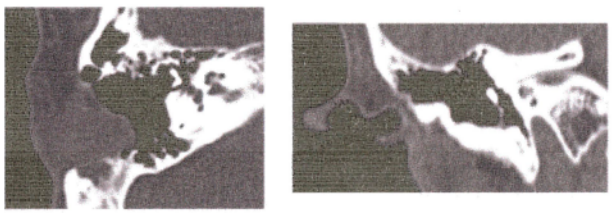

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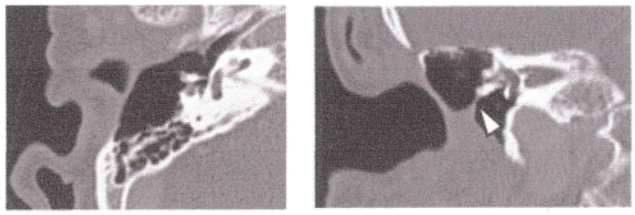

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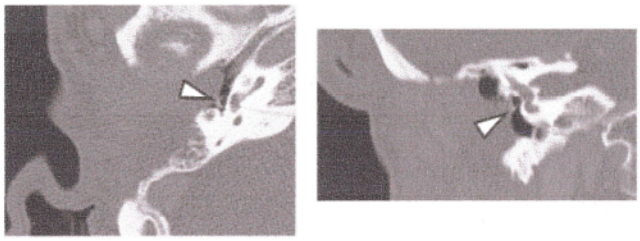

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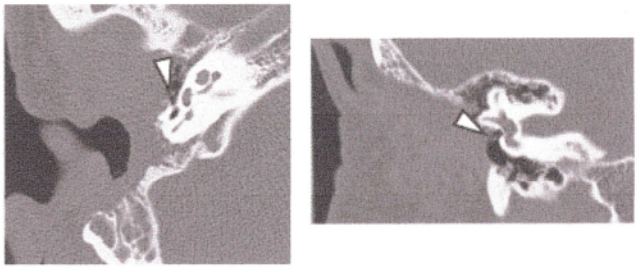

Figure4