

Application of Gel to the Transducer of Cartilage Conduction Hearing Aids Improves Their Benefits

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Abstract

Gel is a conduction medium used to improve signal transmission and is applied in ultrasonography to obtain high-quality images; however, it is rarely used in hearing devices. The application of gel to couple the transducer to the ear could potentially improve the benefits of hearing aids, particularly cartilage conduction (CC) hearing aids, which deliver signals by vibration. The aim of this study was to investigate the impact of gel application on the efficacy of CC hearing aids in 23 patients (30 ears). The aided thresholds, maximum speech recognition scores (SRSs), and hearing level at which the maximum SRS was observed were compared before and after the application of gel to the transducer of CC hearing aids. Subjective impressions of hearing improvement, on applying the gel, were also evaluated. The aided thresholds above 1 kHz significantly improved on applying the gel to the transducer. The effectiveness of gel application was better for patients who reported improvement in hearing. The audiometric results were consistent with subjective evaluations. The application of gel has minimal risk, and its benefits can be verified easily with subjective evaluation. Gel application can be considered an effective option for improving the benefits of CC hearing aids.

Introduction

Conventionally, air conduction (AC) and bone conduction (BC) have been considered the two major pathways for sound conduction to the inner ear. However, when a transducer that conveys vibrations is placed on the aural cartilage, particularly on the tragus, a clear, loud sound is audible [1, 2]. This newly suggested form of signal transmission is referred to as cartilage conduction (CC).

There are three candidate signal transmission pathways to the cochlea in CC: direct-AC, cartilage-AC, and cartilage-BC (Fig. 1) [1, 3, 4, 5]. A previous study found that the sound pressure level in the ear canal was amplified by a transducer being attached to the tragus [3]. In other studies, the effects of earplug insertion or water injection in the ear canal on the thresholds and speech perception revealed the peculiar characteristics of CC that were different from AC and BC [4, 5, 6, 7, 8]. Particularly, the thresholds at 0.5 and 1 kHz first increased by the water injection, and then, conversely, decreased when additional injection reached the cartilaginous portion of the ear canal [5, 8]. These findings revealed an important function of cartilage-AC (airborne sound) in individuals with normal hearing. In CC, signals are delivered by vibrating a body part by a process similar to that in BC, but they are transmitted to the cochlea via ossicles by a process similar to that in AC. Airborne sounds also contribute to signal transmission in BC [9, 10, 11] but do not play a predominant role in perception in the same manner as CC. These observations suggest that CC is a unique form of conduction.

Acoustic devices, including smartphones and hearing aids, that utilize CC have been developed [1, 12, 13, 14], and CC hearing aids have been used in clinical practice in Japan since 2017. CC hearing aids are of the behind-the-ear-type and look like receiver-in-the-canal (RIC)-type hearing aids. Unlike RIC-type hearing aids, a small, lightweight transducer is attached to the tip of the electrode instead of the receiver in CC hearing aids. The delivery of signals by vibrations in CC is effective even in the atretic ear, which is

different from that in AC hearing aids [15, 16]. For patients with aural atresia, BC, or implantable, devices are required to achieve sufficient amplification [17, 18, 19, 20]. Unfortunately, BC hearing aids have disadvantages associated with their fixation style; the transducer is fixed with a headband using static force, which induces discomfort, pain, and irritation and has poor aesthetics [18, 21]. Furthermore, implantable devices involve risks related to surgery [18, 22]. To avoid the demerits of BC hearing aids and implantable devices, CC hearing aids are an attractive option for patients with aural atresia. In fact, CC hearing aid has become a popular choice among patients in Japan since its introduction in 2017 [23, 24].

Efficient transmission without signal distortion improves hearing aid performance. For a BC vibrator, the contact force is important for the efficacy of transmission [25, 26, 27], and static contact force is a disadvantage of a BC hearing aid [18]. Given the drawbacks of BC hearing aids, an alternative approach is needed to improve the efficiency of CC hearing aids. Coupling gel is used to improve signal transmission in ultrasonography [28, 29]. An appropriate conduction medium acts as an impedance adaptor and reduces artifacts by preventing the reflection of ultrasound waves between the skin and the probe surface [28, 29]. Thus, the use of coupling gel could potentially improve the efficacy of CC hearing aids.

For audiological transducers, impedance mismatch and the air interface between the transducer and the skin can cause deterioration of signals. To quantify this deterioration, researchers use the threshold of hearing, a measure of the minimal sound level that the human ear can detect. Geal-Dor et al. [27] measured hearing thresholds with indirect contact of the transducer that was achieved by applying ultrasound gel over the mastoid, tragus, and cavum concha. Unfortunately, they measured the thresholds both with and without application of gel just over the mastoid and with the transducer placed approximately 1.5 cm above the skin with the gel applied. When the gel is applied to the transducer, not only signal transmission but also coupling stability and feedback problems are likely to be influenced. The effectiveness of its application may depend on the ear condition and may differ between atretic and normal ears. Thus, the impact of gel application on assisted hearing has not yet been fully elucidated.

In this study, we evaluated the impact of gel application on the efficacy of CC hearing aids in atretic ears, as CC hearing aids are most often required for patients with aural atresia [24]; in these patients, the direct- and cartilage-AC pathways do not exist as the eardrum is lacking. All signals are delivered by vibrating the skin on the aural cartilage [15].

Three types of transducers were prepared for CC hearing aids (Fig. 2). Gel could not be applied to the ear if double-sided tape was used. For simple-type, a double-sided tape was required for its fixation. In contrast, two ear-chip-type transducers were made from acrylic resin, based on the ear impression. These could couple with the ear without double-sided tapes in most of the ears. Atretic ears, in which the ear-chip type was used as the transducer for the CC hearing aid, were employed as subjective ears. The patients who used double-sided tapes for the transducer fixation were excluded. The aided thresholds, maximum speech recognition scores (SRSs), and hearing levels at which these maximum scores were obtained (dBs [Max]) were compared before and after the application of gel (dry and gel conditions,

respectively). Patients' subjective impressions of hearing were also evaluated, and the effectiveness of the application of gel on the audiometric results was compared between the patients who subjectively reported an improvement in hearing and those who reported no change (improved and unchanged patients, respectively.)

Results

Aided thresholds

Figure 3 shows the aided thresholds with and without gel in the improved and unchanged patients. Three-way mixed analysis of variance (ANOVA) revealed a significant main effect for the application of gel and sound frequency ($F[1, 28] = 14.804, p < 0.001$; $F[4, 112] = 45.438, p < 0.001$, respectively); however, no significant main effect was found in the subjective evaluation ($F[1, 28] = 2.088, p = 0.1596$). Overall, the application of the gel and the sound frequency significantly influenced the aided thresholds. Significant interactions were observed between subjective evaluation and application of gel, between subjective evaluation and sound frequency, and between application of gel and sound frequency ($F[1, 28] = 8.434, p < 0.01$; $F[4, 112] = 3.400, p < 0.05$; $F[4, 112] = 7.153, p < 0.001$, respectively); however, no significant main effect was found among these three factors ($F[4, 112] = 1.069, p = 0.375$). Taking these interactions into consideration, post hoc tests were performed.

Regarding the interaction between subjective evaluation and application of the gel, significant simple effects were found in the improved patients and in the gel condition ($p < 0.05$), but not in the unchanged patients and in the dry condition. In other words, aided thresholds were significantly improved with gel in the improved patients. The aided thresholds in the improved patients were significantly better than those in the unchanged patients in the gel condition.

In terms of the interaction between subjective evaluation and sound frequency, significant differences in the aided thresholds were found between the improved and unchanged patients at frequencies of 0.25 and 0.5 kHz ($p < 0.05$), but not at other frequencies. The aided thresholds in the improved subjects were better than those in the unchanged patients at these frequencies.

For the interaction between subjective evaluation and frequency, a significant difference in the aided thresholds was found between the dry and gel conditions at frequencies above 1 kHz ($p < 0.05$), but not at 0.25 and 0.5 kHz. The aided thresholds were significantly improved with the application of gel for frequencies above 1 kHz.

Maximum SRS and dB (Max)

Figure 4 shows the results of speech audiometry. With regard to maximum SRS, a two-way mixed ANOVA did not identify a significant main effect for either subjective evaluation or application of gel ($F[1, 28] = 0.657, p = 0.424$; $F[1, 28] = 0.798, p = 0.379$, respectively), and no significant interaction was found ($F[1, 28] = 0.011, p = 0.918$) (Fig. 4A).

With regard to dB (Max), two-way mixed ANOVA did not identify a significant main effect on both subjective evaluation and application of gel ($F[1, 28] = 3.001, p = 0.094$; $F[1, 28] = 0.90, p = 0.351$, respectively); however, there were significant interactions ($F[1, 28] = 5.852, p < 0.05$). In post hoc tests, a significant difference was observed between the dry and gel conditions in the improved patients ($p < 0.05$). A significant difference was also observed between the improved and unchanged patients in the gel condition but not in the dry condition ($p < 0.05$). Essentially, dB (Max) was decreased by the application of the gel in the improved patients and was better in the improved patients than in the unchanged patients in the gel condition.

Discussion

This study evaluated the aided thresholds and SRSs before and after the application of coupling gel to the transducer of CC hearing aids and is the first to demonstrate the benefits of applying coupling gel for improving hearing devices. Overall, the aided threshold was significantly improved by the application of the gel, and the aided thresholds in the patients with subjective improvement were better than those in patients who subjectively reported no change.

We used a coupling gel in this study, in analogy to the use of gel in ultrasonography. A sufficient amount of gel cannot always be applied in some cases for ultrasonography because of issues with the organ being examined or the skin condition [30, 31, 32, 33], which results in decreased image quality. Therefore, the ultrasonographer may have to apply greater pressure to decrease the air interface with the skin [30, 33]. A similar situation may occur with CC hearing aids. In contrast to BC hearing aids, the transducer of the CC hearing aid couples with the ear without a static force, which can cause an increased air–skin interface. Application of a gel can improve the coupling conditions with the ear. Whereas the effectiveness of ultrasound gel in ultrasonography can be evaluated from image quality [28, 29], the improvement of signal transmission in CC hearing aids cannot be visualized. In this study, we used subjective impressions, hearing thresholds, and SRS for evaluation. The aided thresholds and dB (Max) were improved in patients who experienced subjective improvement.

In terms of the frequency, better-aided thresholds were observed in the improved patients at 0.25 and 0.5 kHz. No differences in the threshold shifts due to gel application were observed between the improved and unchanged patients at these frequencies. The differences in the aided thresholds were considered to be derived from differences in unaided hearing or hearing aid gains. The effectiveness of gel application in improving aided thresholds was observed at frequencies above 1 kHz in the improved patients, although the magnitude of the improvements was not large. However, 11 patients reported subjective improvement in hearing after gel application by a larger magnitude. The audiometric results were consistent with subjective evaluations.

Sensorineural hearing loss causes deterioration in speech recognition [34, 35, 36, 37]. In contrast, SRSs in atretic ears are not very poor if the presentation level is sufficient since the functions of the sensorineural system are maintained. Therefore, the lack of significant differences in maximum SRS in the current

results was considered reasonable. On the other hand, dB (Max) decreased, reflecting an improvement in the aided thresholds. The dB (Max) was significantly lower for the improved patients than for the unchanged patients, although there was no significant difference between these patients in the dry condition. The dB (Max) decreased with the application of the gel in the improved patients. The subjective improvement of the hearing was also reflected in decreased dB (Max). Specifically, there was an improved shift in the speech recognition curve. The quality of the signal might have been improved because the improvement in dB (Max) was larger than that in the aided thresholds. Further objective studies are required using acoustic measurement techniques to clarify the performance in terms of signal quality.

Improvement was achieved by the application of the gel in some patients, but not in others. These variations in the outcome may be due to differences in the coupling conditions among the patients. An ear-chip makes tight contact with the ear because it is shaped according to an impression taken of the ear. However, errors can occur while taking the impression, and while shaping the ear-chip; additionally, ear conditions may change with time. These errors are probably insignificant and are rarely noticed but can induce minor incompatibility between the ear-chip and the ear. Changes in hearing aid effectiveness would not be obtained in cases where ear-chip–ear contact was already appropriate before gel application. In contrast, the application of coupling gel could improve effectiveness when the contact between the ear and the ear-chip was not optimal.

An air interface between the transducer and the skin influences not only sound transmission but also coupling stability. The decrease in the air interface reinforces an attractive force to stabilize the coupling. On the other hand, ear-chip-type transducers are coupled with the ear by the combination of their own weight and the stiffness of the conchal cartilage. Signal transmission with the transducer on the soft tissues deteriorates without a static force [38]. The application of a gel decreases the frictional resistance between the transducer and the skin. The transmission efficacy will deteriorate if the frictional resistance is reduced too much to hold the transducer stably. Various ear conditions caused variations in the effectiveness of the application of the gel. However, the application of gel is considered a minimum risk, and its benefits are easy to verify. The subjective impression agreed with the audiometric results, and the effectiveness of the application of the gel can instantaneously be judged from the subjective impression. The application of gel is considered an effective option to improve the benefits of CC hearing aids.

Various BC hearing devices are used in clinical practice [17, 18, 19, 20]. Most implantable devices are surgically fixed to the bone tissue, and it is difficult to evaluate the effectiveness of the conduction medium applied between the transducer and bone tissue. For non-implantable devices, a conduction medium is not usually applied to improve hearing when the device is used. The air interface between the transducer and skin in BC hearing aids may be less than that in CC hearing aids since the transducer is maintained on the mastoid by a static force. Therefore, the effectiveness of the application of conduction medium for BC hearing aids may be less than that for CC hearing aids. According to Geal-Dor et al. [27], the contribution of the application of the static force to the BC threshold was 10–32 dB larger than that of the application of gel. In contrast, they found that the increase in threshold with the application of 0 N

forces was relatively lower when the transducer was placed on the aural cartilage. They also predicted that the application of a gel might be particularly effective in CC.

The condition of atretic ears may vary. The shape, depth, and width of the cavity, which may influence the benefits, were not evaluated in this study due to the sample size. In addition, subjective impression was evaluated solely with the question whether they felt any improvement in hearing. No detailed evaluation was conducted. These may be considered the limitations of this study, and further research is required for their assessment.

Research on conduction media has typically been carried out in the field of ultrasonography, but rarely in hearing devices. Our results show that the coupling condition between the hearing aid transducer and the ear should be reconsidered, as it can contribute to improving the effectiveness of hearing devices.

Methods

Participants

Participants were recruited from among the patients who visited Nara Medical University Hospital for follow-up CC hearing aid check after a fitting, between October 2019 and December 2020. The inclusion criteria were as follows: age > 6 years; aural atresia or hearing loss caused by severe ear canal stenosis, for which audiometric tests were performed. Hearing loss complicated by any diseases that caused the sensorineural hearing loss was excluded from the study. Furthermore, ears with simple CC hearing aid transducer type, or where the transducer was coupled with the ear using a double-sided tape, were excluded.

This study was performed in accordance with the principles of the Declaration of Helsinki and was approved by the ethics committee of Nara Medical University (No. 2378). Participants provided written informed consent before enrolment in this study. If the patient's age was < 15 years, assent from the patient was obtained instead of informed consent after age-appropriate information was given to the patient. If the patient's age was < 20 years, their parents also provided written informed consent before enrolment.

Finally, 23 patients (7 females and 16 males, age; 20.6 ± 17.3 years, 30 ears) were enrolled. The average AC and BC hearing levels at 0.5, 1, and 2 kHz were 70.6 ± 10.8 dB and 8.3 ± 12.9 , respectively.

Procedures

The aided thresholds at 0.25, 0.5, 1, 2, and 4 kHz and speech recognition tests were established under monaural-aided conditions. Evaluations were performed individually in the left and right ears of binaural CC hearing aid users. If the non-tested ear was normal, it was masked with a narrow band or speech noise. Speech recognition tests were conducted using 20-monosyllable word lists (67-S word lists) according to the standard methods authorized by the Japan Audiological Society [39, 40]. The SRS was

measured in 10-dB steps to describe the speech recognition curve, and the maximum SRS and dB (Max) were obtained.

For the gel condition, a commercial ultrasound gel was used as the coupling gel, and a small amount was thinly applied to cover the surface of the transducer. After the examination, the gel remaining on the transducer and the skin was removed with a paper towel. However, it was difficult to remove it perfectly and restore the ear to a dry condition on the spot. Therefore, audiometric evaluations were first performed in the dry condition and then with the transducer gel. After the measurements in the gel condition, the impression of hearing improvement was subjectively evaluated.

A conventional audiometer (AA-78, Rion Co. Ltd., Kokubunji, Japan) was used in the tests. The stimulus was presented with a loudspeaker (JBL A822, Harman International Industries, Stamford, CT, USA) placed 1 m in front of the patient. Calibration was carried out using a sound-level meter (NA-20; Rion). The tests were performed in a soundproof room.

Statistical analyses

Statistical analyses were performed using SPSS software (IBM Corp., Armonk, NY, USA). Aided thresholds were statistically analyzed using three-way mixed analysis of variance (ANOVA) with subjective evaluation status (improved and unchanged patients) as the between-subject factor and the application of gel and sound frequency as within-subject factors. The maximum SRSs and dB (Max) were statistically analyzed using two-way mixed ANOVA with subjective evaluation as the between-subject factor and the application of gel as the within-subject factor. The Bonferroni method was used for post hoc comparisons. Significance was set at $P < 0.05$.

Declarations

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Author contributions

T.N. planned the study. T.N., H.H., and T.K. managed the study. T.N., and R.S. prepared the measurements. T.N., O.S., C.M., and T.O. performed the measurements. T.N. carried out statistical analysis and wrote the manuscript.

Competing interests

The authors declare no competing interests.

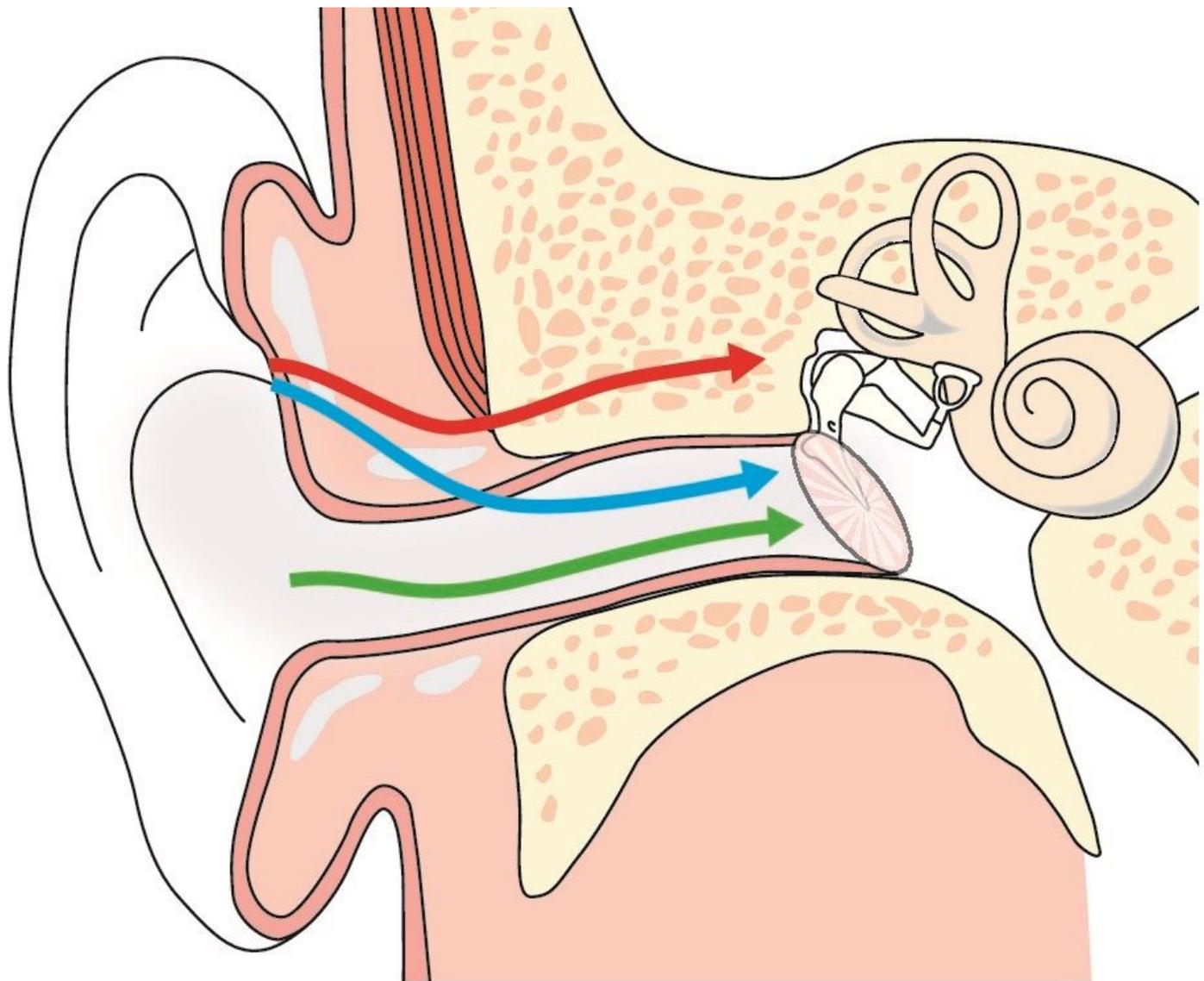
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Figures



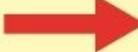
-  Direct-air conduction
-  Cartilage-air conduction
-  Cartilage-bone conduction

Figure 1

Three possible transmission pathways in cartilage conduction (CC) The figure shows three possible transmission pathways when the transducer is placed in the cavity of the concha. In the first pathway, vibrations of the transducer directly produce airborne sound, some of which reach the ear canal and are transmitted to the cochlea via the conventional pathway in air conduction (AC). This pathway is termed “direct-AC.” In the second pathway, vibrations of the aural cartilage and soft tissue are transmitted to the cartilaginous portion. These vibrations induce an acoustic signal in the canal, which is transmitted by the

AC to the eardrum. This pathway is termed “cartilage-AC.” In the third pathway, vibrations of the aural cartilage and soft tissue are transmitted via the skull. This pathway is termed “cartilage-bone conduction.”

Simple type

Ear-chip attachment type

Ear-chip embedded type

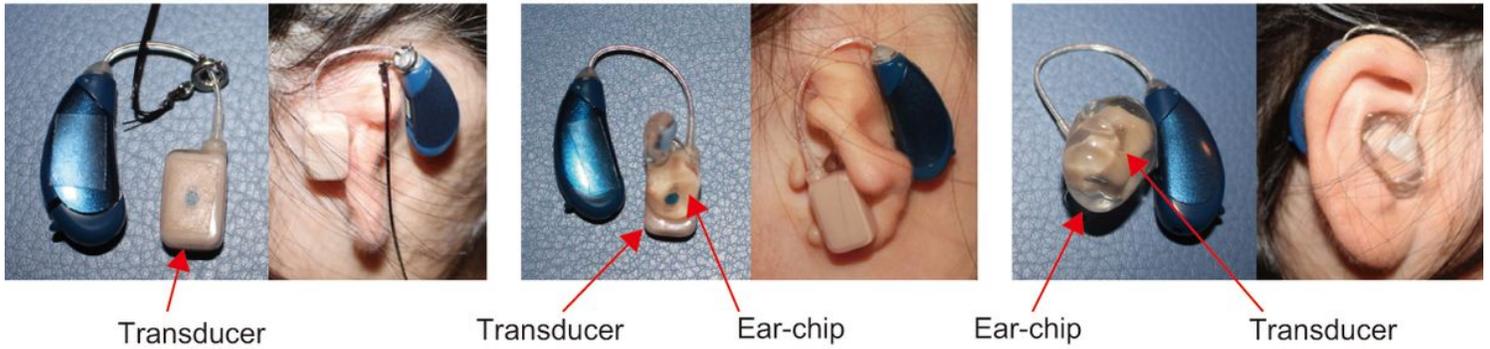


Figure 2

Cartilage conduction (CC) hearing aids. CC hearing aids are a behind-the-ear type hearing aid that consists of a body and a transducer. Three types of transducers are available: simple-, ear-chip attachment-, and ear-chip embedded-types. The figure shows the three types and their wearing forms. The appropriate type is chosen according to the ear condition.

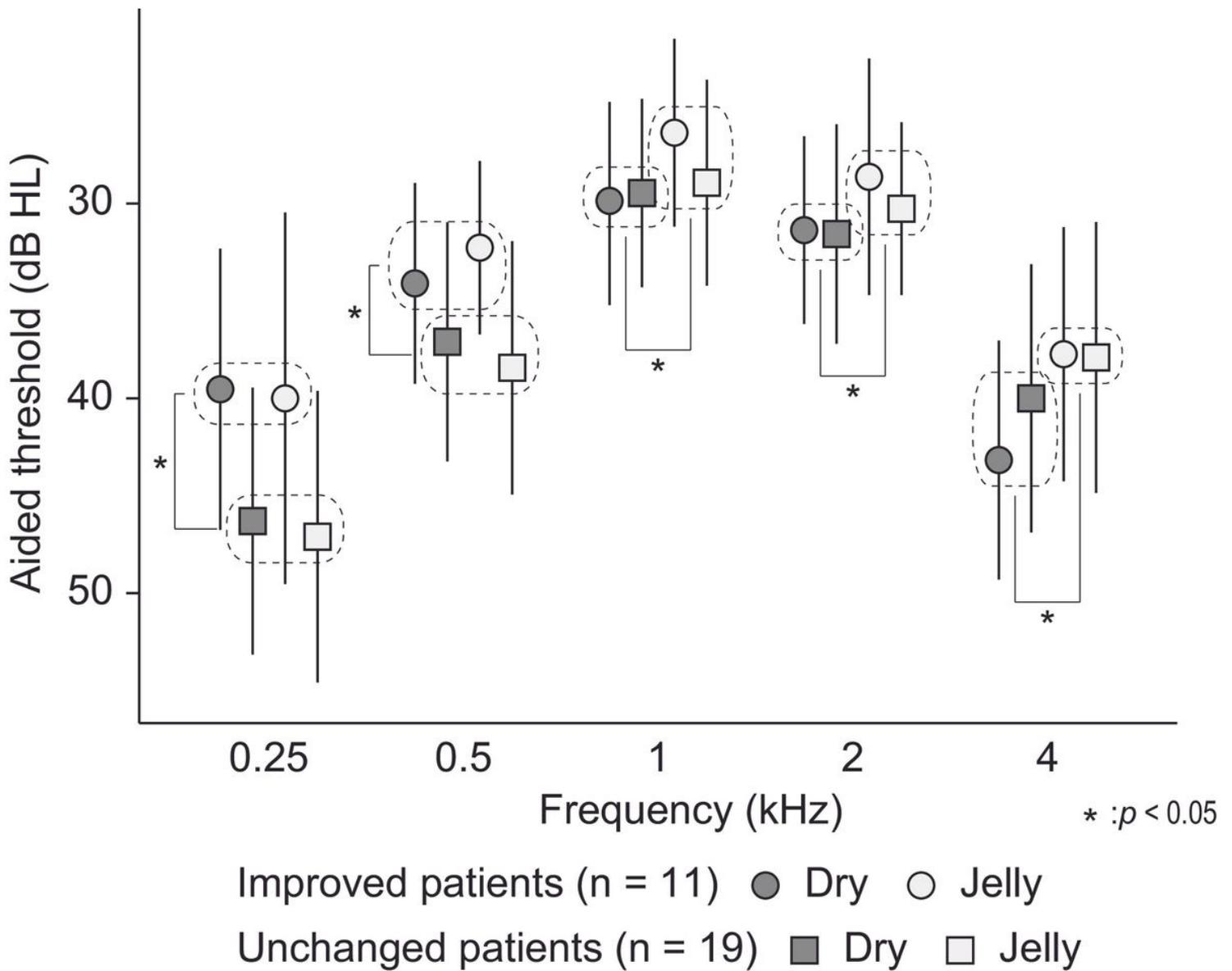


Figure 3

Aided thresholds with and without the gel in improved and in unchanged patients. The circles and squares indicate the results for the improved and the unchanged patients, respectively. The solid and open marks indicate the aided thresholds in the dry and gel conditions, respectively. The vertical bars indicate the standard deviation.

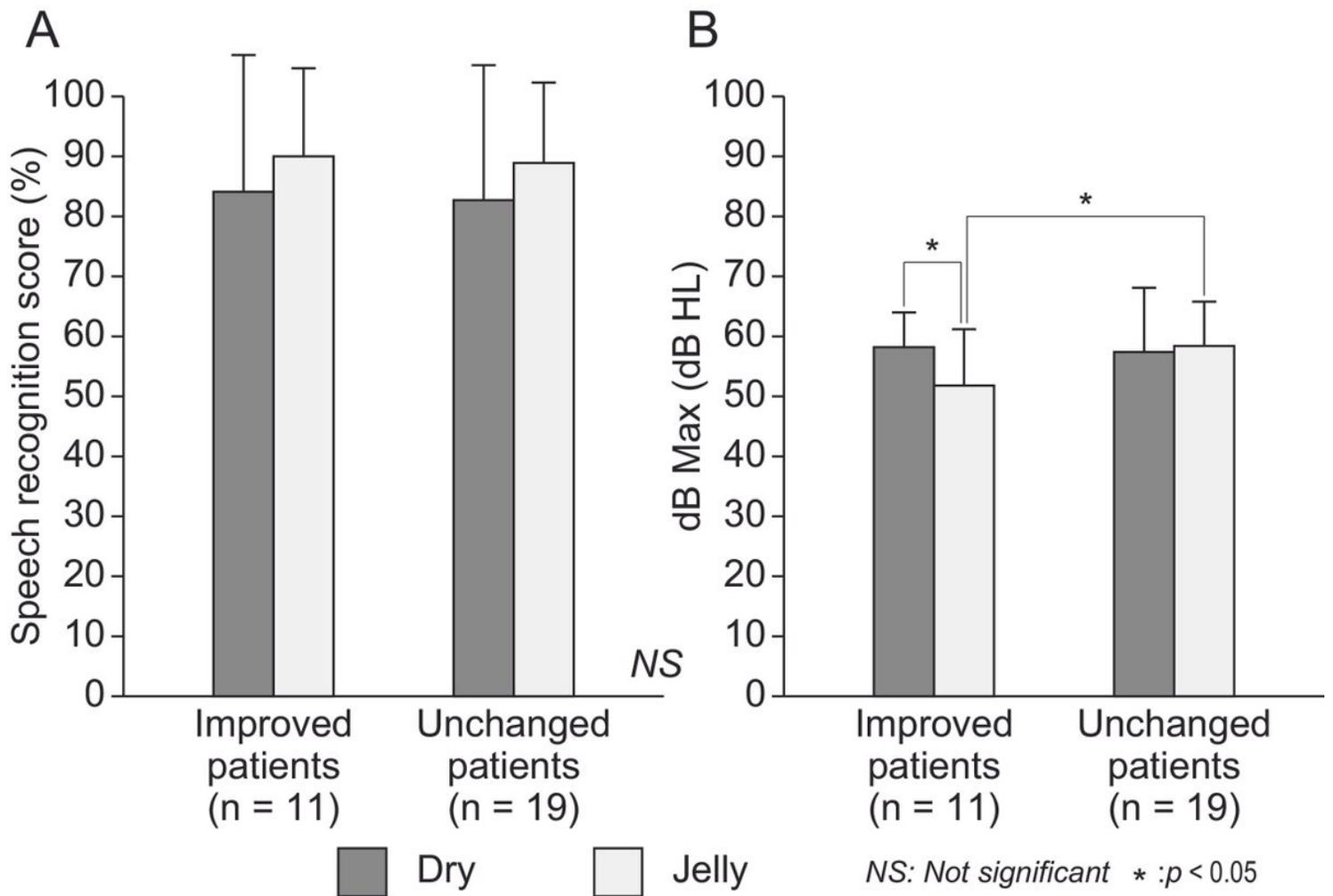


Figure 4

Maximum speech recognition score (SRS) and the presentation level at which the maximum speech recognition scores (dB [Max]) were obtained. The (A) maximum SRSs and (B) dB (Max) are compared between the improved and unchanged patients. The vertical bars indicate the standard deviation.