A new bone conduction hearing aid to predict hearing outcome with an active implanted device

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ABSTRACT

Purpose: We compared our historical medium-term data obtained with an active semi-implanted bone conduction device and the hearing results of a new passive bone conduction hearing device to determine its predictive value for the hearing results with the semi-implanted device.

Methods: The study sample was 15 patients with an active bone conduction implant (mean follow-up 26 months). Pure tone audiometry was performed with headphones, sound field speech audiometry was conducted unaided, and free-field speech audiometry was carried out with both the active bone conduction system and the passive device switched off.

Results: As compared with the unaided condition, speech reception was significantly improved with both devices. Comparison of speech reception threshold at 100% of word recognition showed no difference between the active and the passive device. At lower intensity the difference in speech perception was significant in the patients with monaural fitting (group A) and was non-statistically significant in those with binaural fitting (group B); the speech reception threshold at 50% of word recognition was 26.00 dB (±10.22) with the active implant and 30.50 dB (±7.98) with the passive device in group A (p=0.047) and 24.00 dB (± 5.48) and 29.00 dB (±2.24) in group B (p=0.052), respectively.

Conclusions: The hearing outcome after active bone conduction implant was comparable to published data. Compared with the unaided condition, speech recognition was significantly improved with the passive device. The device may also provide value to predict the hearing outcome with the implanted device, especially at higher intensities.

The Authors declare that they have no conflict of interest

Key words: bone conduction implant, hearing rehabilitation, predictor of hearing outcome, speech reception

Level of evidence: 4

INTRODUCTION

Treatment options for hearing rehabilitation of mixed and conductive hearing loss have widened with the introduction of an active semi-implantable bone conduction auditory prosthesis [1]. The only currently available active implant is the Bonebridge™ (MED-EL, Innsbruck, Austria). The Bonebridge™ produces direct stimulation of the bone through an electromagnetic transducer fixed to the skull. The fixing screw transmits the sound vibrations to the bone and the receiver implanted under the skin is driven by an external processor. The surgical procedure for positioning the implant is safe and associated with a low complications rate [2,3]. The Bonebridge™ system has been shown effective in improving audiometric threshold and speech discrimination in quiet and in noise, as well as attaining patient satisfaction [1,4].

As implantation of the device requires surgery, patients need to be informed about what they can realistically expect. An important aspect in patient counselling is the prediction of hearing outcome. A trial with external stimulation by a bone conduction device for simulation of the functional result after implantation is generally recommended before implant

surgery [5]. Ilher et al. [6] reported that the application of a bone conduction hearing device (Cochlear ™ Baha ® 3 Power, BP110 Power sound processor) through a dedicated headband could be a valuable tool for the realistic prediction of speech recognition with a semi-implantable bone conduction hearing system.

The ADHEAR™ is a recently developed bone conduction concept based on adhesive bone conduction. The system works with an adapter that has, on one side, an adhesive surface to attach it to the hairless skin behind the pinna and, on the other side, a connection to which the audio processor can be easily connected and disconnected. The adhesive adapter delivers the vibratory energy to the skull. The system has been developed to limit power dispersion and to be as efficient as possible, while reducing the weight of the adhesive, the materials, and the dimension of the area in contact with the skin. The materials in contact with the skin are biocompatible. Clinical data for this pressure-free adhesive bone conduction device are still limited but have indicated that the audiological outcomes are good even at higher frequencies and that the subjective benefits are excellent with no skin irritation or pain [7, 8].

The Bonebridge™ device is indicated in conductive and mixed hearing loss with a bone conduction threshold within 45 dB, while the ADHEAR™ should be used with a bone conduction threshold within 25 dB. This difference is due to a limit in the sound transmission capacity of an adhesive bone conduction system, which is a passive system with the transducer attached to the skin. The expected hearing gain is lower, especially at higher frequencies [8]. While indications for the one device or the other differ, both can find use in some cases. This is why direct comparison of the two devices may be useful when discussing with patients the expected results of implantation with and the active device.

To date no studies have compared the intraindividual results of speech recognition in noise with external stimulation by a pressure-free, adhesive bone conduction device and the results obtained with an active semi-implantable transcutaneous bone conduction device. The aim of the present study was two-fold: to collect data about the gain of fitting ADHEAR™ in patients with conductive and mixed hearing loss and to evaluate the predictive value of hearing data acquired with a passive, pressure-free bone conduction hearing device by comparing these data against our historical, medium-term data obtained with an active semi-implanted bone conduction device.

MATERIALS AND METHODS

Compliance with Ethical Standards: The study was approved by the Ethics Committee of our institution (protocol n. 0026286; CS2/622 on March 13, 2018).

Patients

Since 2014, 18 patients have received the Bonebridge™ device (MED-EL, Innsbruck, Austria) at the ENT Division of Città della Salute e della Scienza (Turin, Italy). Indications for implantation included failure with acoustic hearing aids after middle ear surgery for chronic otitis media, isolated or syndromic aural atresia. Three patients continued to use the device but were eventually excluded from the study because they changed residence and received follow-up at another ENT division. The final analysis included the data from 15 patients: female-to-male ratio 12:3; mean age 40 ±20 years. Ear malformations were present in 7 patients; the cause of hearing loss in 8 patients was chronic otitis media. Two patients had unilateral hearing loss with contralateral normal hearing: the one was a 24-year-old man who requested bilateral hearing rehabilitation because the monaural deficit limited his social and work activities during meetings, while the other was a woman who was uncomfortable with monaural hearing loss and had received a middle ear implant

(Vibrant Soundbridge™) in which displacement of the floating mass transducer occurred. The mean duration of follow-up was 26 ±18 months (range 5 – 62). Table 1 presents the demographic and clinical characteristics of the 15 patients.

Surgical procedure: Surgery was performed via retrosigmoidal approach in 13 of 15 patients; the implant was positioned in the mastoid in 2 patients because space was needed to fit the floating mass transducer of the Bonebridge™.

A monaural bone conduction device had been implanted in the worse ear in the patients with bilateral mixed hearing loss; those with bilateral symmetric hearing loss due to bilateral atresia had received a binaural implant.

Devices: All patients were implanted with a semi-implantable bone conduction device (Bonebridge™ MED-EL). The device is CE certified since April 4, 2012 (No. I7120351383010). For non-invasive bone conduction hearing, ADHEAR™, a new device distributed by MED-EL was used (ADHEAR™ is CE certified since 2017, No. G1161217853118).

Study protocol: Patients underwent clinical examination and pure tone audiometry (PTA) in an anechoic chamber (thresholds were measured at 0.5, 1.0, 2.0, and 4.0 kHz in dB HL) without any device. To evaluate the hearing results, speech audiometry in unaided conditions in free field, with a signal-to-noise ratio of +10, was performed in unaided condition, in aided condition with the Bonebridge™ device on and with the ADHEAR™ device on and the Bonebridge™ device off. Testing was conducted on two days so that patients could familiarize themselves with the adhesive device and so that we could perform the calibrations for optimization of subjective auditory benefit. PTA was performed on day 1 with headphones and free-field speech audiometry in unaided condition and with the Bonebridge™ device on. Speech audiometry with ADHEAR™ on was performed on day 2 after of fitting. Tests were conducted with speech coming from the loudspeaker in front of the patient and noise from the loudspeaker behind the patient. In free-field audiometry testing, the intensity level in dB at which 50% of the words are recognized (speech reception threshold [SRT50]) and SRT100, the level in dB at which 100% of the words are recognized, were measured. In the 10 patients with a monaural implant, and in the patients with bilateral mixed hearing loss, speech audiometry in aided and unaided conditions was conducted with the contralateral ear plugged with a customized insert and muffled. During measurements the external device was positioned on the side of the Bonebridge™ implant in the patients with a monaural implant; ADHEAR™ was positioned bilaterally in the patients with a bilateral implant and the Bonebridge™ (mono or bilateral) was temporary inactivated. All audiological measurements were performed by professional staff using a clinical audiometer (Inventis, Padua, Italia).

Outcome Measures

Statistical Analyses: Wilcoxon matched-pairs signed-rank test was used in STATA version 13.1 (Stata Corp., College Station, TX, USA).

RESULTS

At clinical examination no patients reported implant migration or skin irritation. The mean SRT100 at baseline without amplification was 62.27 dB ± 11.91 in 11 out of 15 patients (73%); the mean SRT50 was 47.50 dB ± 14.11 in 14 patients (93%). In patients with a Bonebridge™ implant, the mean SRT100 was 48.67 dB ± 12.88 and the mean SRT50 was 25.33 dB ± 8.76. The mean SRT100 was 50.00 dB ± 8.32 in the 14 out of 15 (93%) patients with an ADHEAR™ device and the mean SRT50 was 30.00 dB ± 6.55 in all 15 patients (Table 2). The improvement in SRTs was statistically significant.

The patients were then divided into two subgroups: 10 with asymmetric hearing loss implanted monaurally (group A) and 5 with bilateral middle ear malformation implanted binaurally (group B). Audiometric assessment results are presented in Tables 3 and 4. The bone conduction data are the same for both ears (Table 4). The patients with ear malformation were young (mean age 21.8 years) and presented no cochlear damage due to age or noise exposure that would have altered bone threshold. Table 5 compares the thresholds (SRT100 and SRT50) obtained with the Bonebridge™ and the ADHEAR™ devices. A positive correlation was found between bone conduction and hearing gain with both devices for all 15 patients. The SRT50% with the active bone conduction implant had a positive correlation of 0.55 (p=0.031); the correlation was 0.68 (p=0.005) with the bone conduction hearing aid (Figure 1 and Figure 2).

DISCUSSION

The Bonebridge™ active bone conduction implant has been shown to be a safe device with very good cutaneous tolerance [4]. In our patient series, no cases of infection, loss of stability or revision surgery were recorded at a follow-up of 5 to 62 months. Considering hearing outcomes in terms of speech recognition, there was a significant reduction in the signal intensity level to recognize 100% and 50% of the words in noise: a reduction of 13.6 dB for SRT100 and of 22.17 dB for SRT50. Schmerber et al. [4] reported similar results in quiet: the mean intensity level needed to reach the maximum speech recognition score in quiet was 66 dB in the unaided condition vs. 47 dB with the Bonebridge™ device, with a difference of 19 dB.

All of the 15 patients in the present series, including the 2 with monaural implant and contralateral normal hearing, continued to use their device. Indeed, our longer follow-up data corroborate the safety of the Bonebridge™ [2,3]. A further aim of the present study was to compare our historical medium-term Bonebridge™ results with the new ADHEAR™ system. The two devices differ in the mechanism of bone stimulation. The Bonebridge™ is a bone conduction system with the transducer implanted in the bone, whereas the ADHEAR™ is a passive, pressure-free, adhesive bone conduction hearing aid. Importantly, the purpose of the comparison was not to evaluate which device works better; the Bonebridge™ is an active system that provides pure tone gain comparable with a more powerful transcutaneous system when the bone conduction threshold is better than 45 dB [9]. The functional gain of the ADHEAR™ implant is lower, especially at higher frequencies: the mean functional gain at 4 kHz is 11.2 dB with the ADHEAR™ [8] versus 12.0 dB with bone conduction stimulation with a headband and 25.6 dB with the Bonebridge™ [6].

The rationale for the comparison was to determine whether the ADHEAR™ can simulate the Bonebridge™ outcome in terms of speech perception in certain conditions and, if not, to determine how much of a difference is there between the two devices. This is important to know when considering treatment options with patients and discussing how much improvement might be expected after fitting the active bone conduction implant. The audiological gain with the ADHEAR™ for the whole group, i.e., the mean reduction in SRT, was 17.5 dB for SRT50 and 12.27 dB for SRT100. These differences were statistically significant compared with baseline values. As expected, the mean reduction was slightly lower with the passive device; the active device is more powerful and, as shown in the correlation study, it is less influenced by the bone conduction threshold than the passive device (correlation of 0.55 vs. 0.68; both statistically significant). In order to compare the two devices and reduce sample dishomogeneity, we pooled the data of the monaurally fitted (group A) and the bilaterally fitted (group B) to analyse the intragroup results.

The difference in SRT between the devices was higher at lower intensity in the patients with monaural fitting and it was statistically significant: the SRT50 was 26 dB with the Bonebridge™ and 30.50 dB with the ADHEAR™. The SRT50

was not statistically different for group B. This difference in SRT100 was considerably smaller for both groups and it was not statistically significant. There are many possible explanation for these findings; the absence of recruitment, because of conductive and mixed hearing loss, allows for improvement in speech perception with increasing intensity and a ceiling effect for SRT100. In contrast, to reach SRT50 at lower intensity, the ADHEAR™ is more affected by the bone conduction threshold than the Bonebridge™ (Figure 1 and Figure 2). This difference was greater in group A for two likely reasons: because bone conduction was worse in this group (22.90 – 22.17 versus 16.4 in group B) and because bilateral amplification increased the gain due to the summation effect [10].

One limitation of the present study is the short period between adhesive bone conduction hearing aid fitting and speech testing. Nonetheless, since all patients were bone conduction implant users, it was relatively easy to fit them with the new device according to their suggestions for attaining the best conditions.

In conclusion, our study provides longer follow-up data as further evidence for the safety of the Bonebridge™ implant. The non-invasive ADHEAR™ device showed very good results with a significant improvement in SRT as compared with the unaided condition and so it can be considered a valuable option for patients who require a bone conduction hearing aid for only a short period of time, for children who do not have sufficient skull thickness for receiving an active or a percutaneous implant device, and as an alternative for adults in whom surgery is contraindicated. Clearly, we will not stop implanting the active device, especially because of the difference at low intensity in mixed hearing loss after middle ear surgery. In the patients with conductive hearing loss and ear malformation there was a difference of 5 dB for SRT 50. The Bonebridge™ is recommended in patients with bone conduction threshold better than 25 dB.

The ADHEAR™ device can be considered a valid tool to predict hearing results with an active bone conduction implant, especially at higher levels of stimulation. The ADHEAR™ is currently used off label in hearing rehabilitation for mixed hearing loss;. As expected, the active device has an SRT50 4 dB lower than the passive system in mixed hearing loss, but the difference is only 1.44 dB for SRT100. It is at the high intensities of speech audiometry, near 50 dB that the ADHEAR™ may be used for predicting hearing outcome with the Bonebridge™ system. These details are important for better counselling of the patients requiring hearing rehabilitation for conductive or mixed hearing loss.

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