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Round Window Application of an Active Middle Ear Implant: A Comparison With Hearing Aid Usage in Japan

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Objective: To report on the safety and efficacy of an investigational active middle ear implant (AMEI) in Japan, and to compare results to preoperative results with a hearing aid.

Design: Prospective study conducted in Japan in which 23 Japanese-speaking adults suffering from conductive or mixed hearing loss received a VIBRANT SOUND BRIDGE with implantation at the round window. Postoperative thresholds, speech perception results (word recognition scores, speech reception thresholds, signal-to-noise ratio [SNR]), and quality of life questionnaires at 20 weeks were compared with preoperative results with all patients receiving the same, best available hearing aid (HA).

Results: Statistically significant improvements in postoperative AMEI-aided thresholds (1, 2, 4, and 8 kHz) and on the speech reception thresholds and word recognition scores tests, compared with preoperative HA-aided results, were

observed. On the SNR, the subjects' mean values showed statistically significant improvement, with -5.7 dB SNR for the AMEI-aided mean and -2.1 dB SNR for the preoperative HA-assisted mean. The APHAB quality of life questionnaire also showed statistically significant improvement with the AMEI.

Conclusion: Results with the AMEI applied to the round window exceeded those of the best available hearing aid in speech perception as well as quality of life questionnaires. There were minimal adverse events or changes to patients' residual hearing. **Key Words:** Active middle ear implant—Conductive or mixed hearing loss—Round window—Vibrant soundbridge.

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Patients with conductive or mixed hearing loss are often unable to use or receive significant benefit from conventional hearing aids, due to medical conditions or insufficient amplification. Middle ear implants can potentially solve these problems, since they do not occlude the ear canal and also bypass the pathologic middle ear (1).

The investigational active middle ear implant (AMEI) in this study was originally developed for use in people with sensorineural hearing loss. It is an implantable device that improves hearing ability by directly vibrating the incus in the middle ear. In the United States, with approval from the FDA, it has been adapted for use by adults with moderate, severe, or profound sensorineural hearing loss. In the European Union and all countries subscribing to the CE mark standards, the AMEI has been adapted for patients with sensorineural, conductive, and mixed conductive-sensorineural hearing loss. In 2005, an application of the AMEI was developed with vibration directly applied to the round window in patients with missing auditory ossicles or a stapes footplate that is fixed due to tympanosclerosis (2). This method allows the device to be adapted to these types of patients, because it provides vibratory stimulus to the cochlea via the round window. The results of trials conducted in Germany and Austria on the AMEI with round window application as a form of treatment for conductive hearing loss and mixed conductive-sensorineural hearing loss

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MED-EL supplied VSB systems including implants and speech processors for this clinical trial as this VSB system had not yet been approved by the Ministry of Health of Japan in 2011.

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indicated a preservation of test subjects' residual hearing ability and an improvement in their hearing ability with regard to everyday conversation levels (3). Publications on numerous studies involving adults as well as children have supported these clinical trial results (4–13).

The present multicenter study from Japan tests the efficacy and safety of the AMEI with round window approach in adult patients with conductive or mixed hearing loss, and compares the subjects' preoperative results using the same type of hearing aid to their postoperative results with the implant.

METHODS

Subjects

A total of 23 patients with conductive or mixed hearing loss (13 males, 10 females) ranging in age from 26 to 75 (mean: 58.6) were included in this study. Twelve of these patients (53%) were implanted with an AMEI in conjunction with the round window coupler, while the other 11 received the AMEI on its own. Preoperatively, these patients used the best available hearing aid in the ear planned for implantation. Patient demographics are presented in Table 1.

Device

The VIBRANT SOUND BRIDGE's (VSB; Med-El, Innsbruck, Austria) audio processor captures sound signals via its microphone, converting these into electromagnetic signals that are then transmitted to the AMEI implanted in the temporal bone of the patient's skull. The AMEI demodulates the received signal and vibrates the transducer (the floating mass transducer [FMT]) positioned at the round window niche via the conducting wire. The vibration is then conveyed to the inner ear and the auditory nerve stimulated.

Inclusion/Exclusion Criteria

All patients were native Japanese speakers aged 18 or older, and fulfilled the following audiological inclusion criteria. The upper indication ranges of bone conduction thresholds were 45 dB (500 Hz), 50 dB (1000 Hz), 65 dB (2000 Hz), and 65 dB (4,000 Hz). Included were patients with middle ear disease (including middle ear malformation) accompanying conductive hearing loss or mixed conductive-sensorineural hearing loss, as well as those whose tympanoplasty or stapedectomy procedures failed to achieve sufficient improvement in hearing ability. Excluded from the study were patients with active inflammation or perforation of the tympanic membrane. Subjects were those who did not obtain adequate benefit from acoustic hearing aids or those who could not tolerate hearing aids due to inflammation of the external auditory canal. All patients were provided with the best available hearing aid of the same type (WIDEX mind330: M3-19).

From the group of patients with external ear malformations (including atresia of the external auditory canal) accompanied by conductive hearing loss or mixed conductive-sensorineural hearing loss, patients in whom the usage of bone conduction hearing aids was impractical were excluded.

Preoperative CT Evaluation

A computed tomography scan was performed preoperatively on both ears of each subject to evaluate the condition of the round window (bony closures, size) and facial nerve pathways

(in patients with anomalies), and to exclude the presence of high jugular bulb disorder.

Surgical Technique

The surgical technique has been published in detail elsewhere (3).

Data Collection and Statistics

Measurements (with hearing aid) were taken for the ear scheduled to undergo surgery at the time of the selection/exclusion evaluation, as well as 20 weeks postimplantation with the AMEI. The ear not being tested was closed by the insertion of an earplug, with a headphone-type soundproofing device (earmuffs) further fitted over the top.

An aided threshold test (warble tones) was conducted in the free field using warble tones from a speaker directly facing the test subject at a distance of 1 m at frequencies of 250, 500, 1000, 2000, 4000, and 8000 Hz. The word recognition score (WRS) in quiet was conducted by presenting a speech signal (50, 60, 70 dB HL) from a speaker directly facing the test subject at a horizontal distance of 1 m. The words were presented from the Japanese monosyllabic 67-S word table. The speech reception threshold (SRT) test in quiet determines the subject's threshold value by examining the level (dB HL) at which 50% intelligibility is achieved, with words also taken from the Japanese monosyllabic 67-S word table. These tests were conducted by presenting a speech signal from a speaker directly facing the test subject at a horizontal distance of 1 m.

The SRT in noise was conducted by presenting a speech signal from a speaker directly facing the test subject at a horizontal distance of 1 m and simultaneously delivering speech noise (at 55 dB HL) at a 90° angle toward the nonimplanted ear.

Quality of Life Questionnaires

APHAB

Subjective efficacy was evaluated using the APHAB (Abbreviated Profile of Hearing Aid Benefit, Cox and Alexander, 1995) questionnaire. The APHAB uses a total of 24 self-assessment items broadly divided into four subscales comprised of six items each. The answers to each item were obtained on a seven-point scale (always: 99%, almost always: 87%, generally: 75%, about half: 50%, sometimes: 25%, rarely: 12%, never: 1%). At the time of the preoperative evaluation, the APHAB survey was conducted with the use of a hearing aid. At the time of the 20-week postimplantation assessment, the APHAB survey was administered to the test subject using the AMEI. The questionnaires were filled in directly by the test subjects themselves.

Statistical Analysis

Data distribution was checked with the Kolmogorov–Smirnov test. Paired sample *t* test was used for approximately normally distributed data. If the normal data distribution was not fulfilled or outliers were present, the nonparametric Wilcoxon-signed rank test was used instead. Statistical significance was set to $p < 0.05$. IBM SPSS Statistics 19 (IBM, Armonk, New York) was used for the analyses. For the questionnaires, the Wilcoxon-signed rank test was performed to see if the difference between the preoperative test condition (with HA) and the 20-week postoperative test condition (with AMEI) was significant.

This study was approved by the Ethics Committee of each institution, and previous written consent was obtained from the patients after a full explanation of the study.

TABLE 1. Demographic information for patients with AMEI

Sex	Age at Surgery	Surgery Ear	Type of HL	Duration of HL (Y)	HA Usage (Y)	Previous Ear Surgeries (Surgery Ear)	Etiology	Use of RW Coupler
Male	50	Right	Mixed	25	17	3	Otosclerosis	Yes
Female	68	Right	Mixed	65	41	5	Chronic otitis media	Yes
Male	70	Left	Mixed	Unknown	30	3	Chronic otitis media	No
Male	58	Right	Mixed	20	Unknown	4	Chronic otitis media	No
Female	64	Left	Mixed	Unknown	Unknown	3	Chronic otitis media	No
Female	64	Right	Mixed	Unknown	0	3	Chronic otitis media	Yes
Male	70	Left	Mixed	58	5	2	Chronic otitis media	No
Male	67	Right	Mixed	47	15	3	Chronic otitis media	No
Male	60	Left	Mixed	33	0	2	Chronic otitis media	No
Male	65	Left	Mixed	58	25	3	Chronic otitis media	Yes
Male	42	Right	Mixed	3	0	3	Chronic otitis media	Yes
Male	70	Right	Mixed	63	3	4	Chronic otitis media	Yes
Male	74	Right	Mixed	68	7	2	Chronic otitis media	Yes
Female	69	Left	Mixed	63	0	2	Chronic otitis media	No
Male	61	Left	Mixed	29	9	4	Chronic otitis media	No
Female	60	Right	Conductive	59	2 mo	5	Chronic otitis media	Yes
Male	34	Right	Conductive	34	22	4	External auditory canal stenosis	Yes
Female	73	Right	Mixed	69	Unknown	5	Chronic otitis media	Yes
Female	75	Left	Mixed	73	0	3	Chronic otitis media	Yes
Female	32	Right	Mixed	32	2	1	Chronic otitis media	No

AMEA indicates active middle ear implant; HA, hearing aid.

RESULTS

Results from the audiometric and speech tests were available for 20 of the 23 patients, and results from the questionnaires for 21 patients. Preoperative HA-assisted audiometric and speech tests in three patients and questionnaires in two patients were missing and these patients were therefore excluded.

Results of the aided threshold tests are shown in Figure 1. The mean values ± standard deviation (median value) for HA-aided thresholds before surgery for each frequency (250, 500, 1000, 2000, 4000, 8000 Hz) were: 48.8 ± 10.5 dBHL (47.5 dBHL), 43.8 ± 10.2 dBHL (42.5 dBHL), 38 ± 9.5 dBHL (40 dBHL), 40.5 ± 10.1 dBHL (40 dBHL), 55.5 ± 18.1 dBHL (55 dBHL), 67.5 ± 20.0 dBHL (72.5 dBHL). The mean ± standard deviation (median value) for the AMEI-aided thresholds at 20 weeks after surgery were: 49.5 ± 10.9 dBHL (50 dBHL), 39.0 ± 12.1 dBHL (35 dBHL), 29.8 ± 7.5 dBHL (30 dBHL), 26.2 ± 7.9 dBHL (27.5 dBHL), 37.0 ± 11.3 dBHL (35 dBHL), 59.8 ± 20.0 dBHL (57.5 dBHL). According to the results of the paired sample *t* test, a significant improvement from preoperative testing (with HA) to 20-weeks postoperative testing (with AMEI) was reached at 1, 2, 4, and 8 kHz.

Results of the word recognition score in quiet are shown in Figure 2. The mean values ± standard deviation (median value) for subjects using hearing aids before surgery were 64 ± 27.7% (75%) at 50 dB HL, 77.3 ± 22.8% (85%) at 60 dB HL, and 85.8 ± 16.4% (90%) at 70 dB HL. The mean values ± standard deviation (median value) for subjects using the AMEI 20 weeks after

surgery were 82.3 ± 16.8% (90%) at 50 dB HL, 88.8 ± 12.6% (92.5%) at 60 dB HL, and 85.8 ± 14.0% (90%) at 70 dB HL. The improvement from preoperative testing (with HA) to 20-weeks postoperative testing (with AMEI) was significant at 50 dB (Wilcoxon-signed rank test: *p* = 0.001) and at 60 dB (*p* = 0.017). No difference was found at 70 dB (*p* = 0.534).

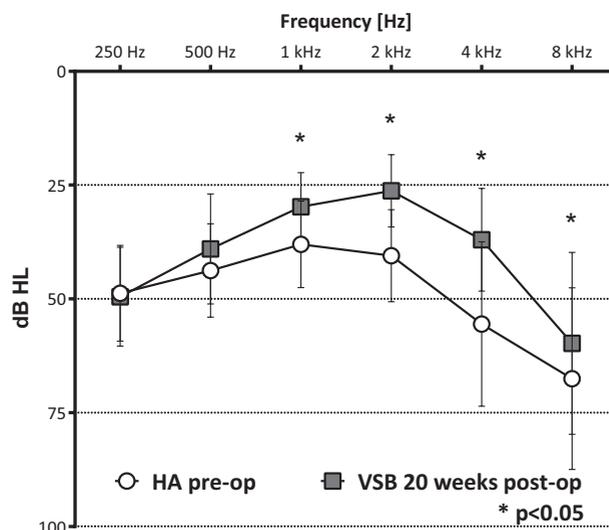


FIG. 1. Aided threshold levels with preoperative HA and postoperative AMEI. Significant improvements in postoperative AMEI were observed at 1, 2, 4, and 8 kHz. Error bars indicate the standard deviation. AMEI indicates active middle ear implant; HA, hearing aid. **p* < 0.05.

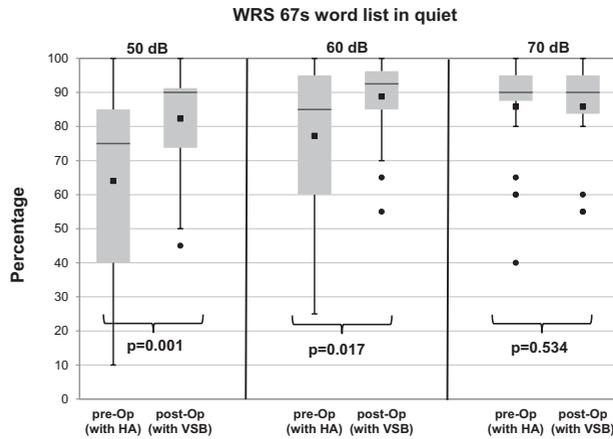


FIG. 2. Word recognition score in quiet with preoperative HA and postoperative AMEI. Significant improvements in postoperative AMEI were observed at 50 and 60 dB. The word recognition score (WRS) was comprised of Japanese 67-S test material. Outliers not included in the whiskers are >2 SD from the mean. AMEI indicates active middle ear implant; HA, hearing aid.

Results of the SRT in quiet test are presented in Figure 3. The mean value \pm standard deviation (median value) of the preoperative reception threshold in quiet with HA was 37.0 ± 11.6 dBHL (35 dBHL), while the value at 20 weeks postoperative with the AMEI was 26.7 ± 9.0 dBHL (25 dBHL). The difference between preoperative testing (with HA) and 20-week postoperative testing (with AMEI) was significant (Wilcoxon signed-rank test: $p = 0.002$).

The results for the SRT in noise (i.e., the signal-to-noise ratio [SNR] that yields 50% speech intelligibility) are shown in Figure 4. The mean preoperative with HA SNR value \pm standard deviation (median value) was

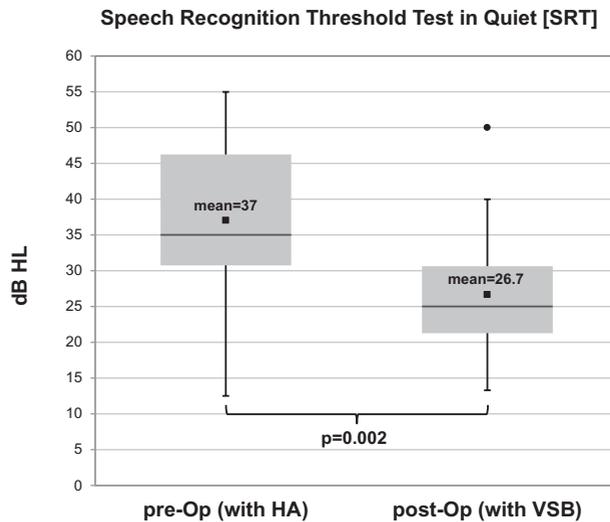


FIG. 3. Speech recognition threshold (SRT) score in quiet with preoperative HA and postoperative AMEI. Outliers not included in the whiskers are >2 SD from the mean. Significant postoperative improvements with the AMEI were observed. AMEI indicates active middle ear implant; HA, hearing aid.

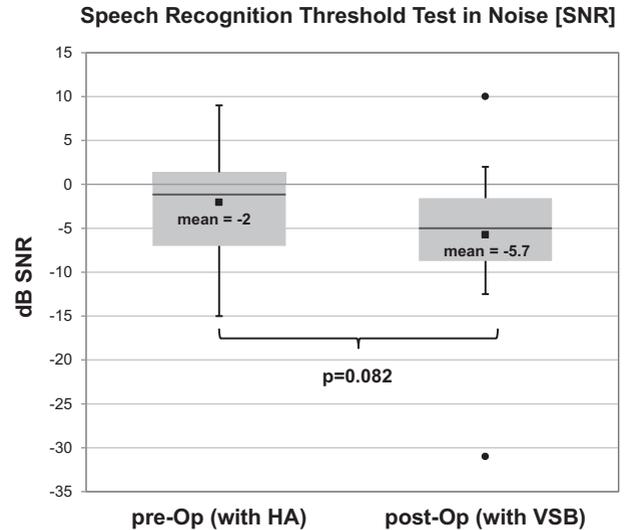


FIG. 4. Speech recognition threshold (SRT) score in noise with preoperative HA and postoperative AMEI. No statistically significant postoperative improvements with the AMEI were observed. AMEI indicates active middle ear implant; HA, hearing aid.

-2.1 ± 6.2 dB (-1.2 dB), while the mean SNR value at 20 weeks postsurgery with the AMEI was -5.7 ± 7.8 dB (-5 dB). While there was no statistically significant difference noted between the hearing aid and AMEI, there may be a trend toward improvement in the AMEI group (Wilcoxon signed-rank test: $p = 0.082$).

APHAB

The results of the APHAB questionnaire are shown in Figure 5. The preoperative HA-assisted mean value \pm standard deviation (median value) for Ease of Communication (EC) was $35.5 \pm 24.9\%$ (29.2%), while the postoperative AMEI-aided mean value was $24.2 \pm 16.1\%$ (24.8%). The preoperative HA-assisted mean value \pm standard deviation (median value) for background noise (BN) was $33.5 \pm 16.5\%$ (33.3%), while the postoperative AMEI-aided mean value was $29.8 \pm 14.5\%$ (31%). The preoperative HA-assisted mean value \pm standard deviation (median value) for reverberation (RV) was $39.3 \pm 20.9\%$ (41.7%), while the postoperative AMEI-aided mean value was $25.7 \pm 12.5\%$ (22.8%). The preoperative HA-assisted mean value \pm standard deviation (median value) for Aversiveness (AV) was $44.9 \pm 29.2\%$ (37.3%), while the postoperative AMEI-aided mean value was $45.5 \pm 24.1\%$ (52%). The preoperative HA-assisted mean value \pm standard deviation (median value) for the Global Scale (sum of EC + BN + RV) was $36.1 \pm 19.3\%$ (35.8%), while the postoperative AMEI-aided mean value was $26.6 \pm 12.8\%$ (26.2%). The postoperative scores on the Global Scale and the subscales EC and RV were significantly better (i.e., lower) than the preoperative scores ($p = 0.020$, $p = 0.028$, and $p = 0.006$). The difference between preoperative and postoperative scoring was not significantly different

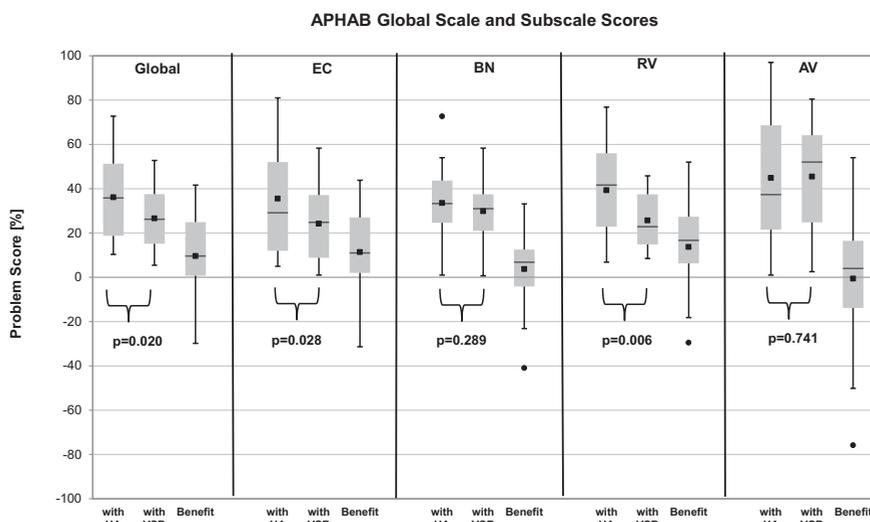


FIG. 5. APHAB global scale and subscale score with preoperative HA and postoperative AMEI. Significant postoperative improvements with the AMEI were observed on the global scale (sum of EC, BN, and RV) and the subscales EC and RV. The “Benefit” column refers to the difference between pre-op and post-op (aided) APHAB scores. Outliers not included in the whiskers are >2 SD from the mean. AMEI indicates active middle ear implant; APHAB, abbreviated profile of hearing aid benefit; AV, aversiveness; BN, background noise; EC, ease of communication; HA, hearing aid; RV, reverberation.

for the BN subscale ($p = 0.289$) or for the AV subscale ($p = 0.741$).

Changes to Residual Hearing

Changes in unaided hearing were evaluated by comparing preoperative unaided air and bone conduction hearing thresholds with postoperative unaided air and bone conduction thresholds at frequencies 500 through 4000 Hz (Fig. 6). There was no significant loss of inner

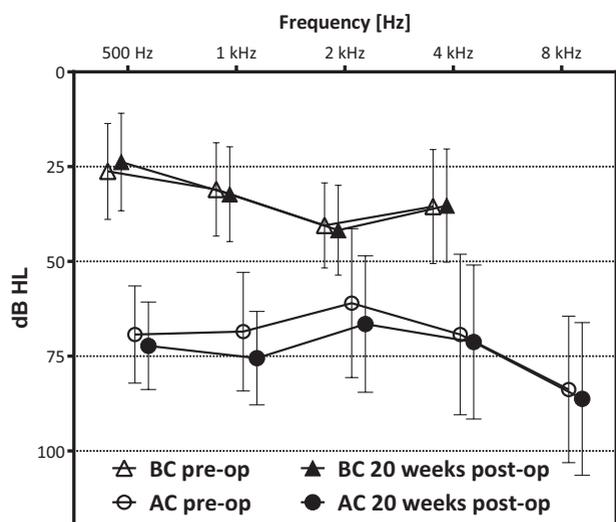


FIG. 6. Pre- and postoperative unaided air and bone conduction hearing thresholds. No significant loss of inner ear function or hearing threshold was observed after VSB implantation. AMEI indicates active middle ear implant; VSB, VIBRANT SOUND-BRIDGE.

ear function in any of the subjects. When required, symmetrical masking was used to detect the real AC and BC thresholds.

We were also interested in examining the patients’ individual postoperative speech perception performance as a function of their air-bone gaps (ABG). Figure 7 presents the pre- (with HA) and postoperative (with AMEI) aided WRS plotted against the pre- and postoperative ABG of individual subjects ($n = 20$). The trend indicates that the higher the ABG, the higher the difference in WRS score between the HA and AMEI. In other words, patients performed better with the AMEI than with the HA.

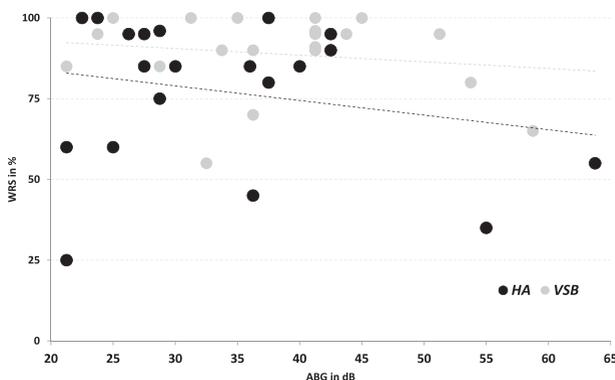


FIG. 7. Relationship between word recognition scores and air-bone gaps with preoperative HA and postoperative AMEI. The trend indicates that the higher the ABG, the higher the WRS score with AMEI than with the HA. ABG indicates air-bone gap; AMEI, active middle ear implant; HA, hearing aid; WRS, word recognition score.

Medical and Surgical Complications

No major medical or surgical complications were reported. Three patients experienced mild dizziness, with all recovered by the end of the study. Other complications reported included swelling of the external auditory canal, external auditory canal haemorrhage, ear drum perforation, postauricular hematoma, tinnitus, dysgeusia, and benign paroxysmal positional vertigo. The majority of complications were completely resolved by the end of the study, with two cases of dysgeusia and one ear drum perforation improved. The only adverse event in which a relation to the investigational device could not be ruled out (paroxysmal positional vertigo) was resolved by the end of the study.

DISCUSSION

The subjects in this study had each undergone an average of 5.1 surgeries (ear surgery accounting for an average of three of these) before the AMEI implantation. Despite the significant mental, physical, and financial costs attributed to these multiple surgeries, the test subjects had been unable to obtain benefit from their hearing aids. In contrast, most of the subjects in this study experienced an improvement in their subjective and objective hearing abilities after implantation with the AMEI, when compared with their preoperative results using the best available hearing aid. An important aspect of our study was that the subjects were preoperatively all fitted with the same type of hearing aid (WIDEX: Mind 330 M3-19), which enabled us to directly compare these results to those with the AMEI. Statistically significant results were obtained on the audiometric and speech tests as well as the quality of life questionnaires. Notably, statistically significant improvements in postoperative AMEI-aided thresholds compared with preoperative HA-aided thresholds at 1, 2, 4, and 8 kHz were observed. On both the speech reception test and word recognition score in quiet, the patients performed better with the AMEI than with the HA. On the most difficult test, the speech reception test in noise, the subjects' mean values showed a tendency toward significant improvement, with the AMEI-aided mean of -5.7 dB SNR and the preoperative HA-assisted mean of -2.1 dB SNR.

The improvements observed from the pre- to postoperative conditions suggest that AMEI usage made it possible for the subjects to better communicate in noisy environments, which represent speech recognition in the real world. A large portion of the information required us to discriminate Japanese speech falls between 1000 and 6000 Hz, and it is generally said that if the amplification above the 1000 Hz frequency range is sufficient, there will be improvement on speech intelligibility tests (14). In this particular frequency range, sound field thresholds of around 35 dB were obtained, which is a value that indicates good speech understanding levels even in a generally noisy environment (15). The high subjective levels of satisfaction with the AMEI recorded on the APHAB questionnaires serve to reinforce the good

audiometric and speech perception test results. There were statistically significant improvements in the global scale as well as the Ease of communication and Reverberation subscales.

Patients with mixed hearing losses often require a large amount of gain to obtain adequate amplification. With the FMT of the AMEI positioned at the round window, less gain is needed, which will resort in less distortion than commonly occurs with conventional hearing aids. This may be a reason for the AMEI's better performance, particularly on the speech understanding in noise tests. We discovered that the patients with higher air-bone gaps experienced more speech discrimination improvement with the AMEI than with the HA. The trend showed improvement in speech performance with AMEI compared with HA from 10% up to 20% with increase in the ABG (range: 20–60 dB). In a study on 16 bilateral mixed hearing loss patients, de Wolf et al. found that patients with an ABG higher than 35 dB performed better with a percutaneous bone conduction implant (poBCI) than with a behind-the-ear HA. Mylanus et al. (16) also compared 34 patients implanted with a poBCI to their preoperative results with a conventional HA, and reported results similar to our study. However, they also found that patients with an ABG of less than about 25 dB experienced better results with the HA than with the poBCI (BAHA), with the patients breaking even at around 25 to 30 dB ABG. All of the subjects in our study, however, performed better with the AMEI than with their HA, with ABG greater than 20 dB. These results show that measuring the size of a patient's ABG could have some bearing on the decision of which type of hearing device to select.

Several studies have appeared in the literature involving the comparison of preoperative hearing aid results in patients with sensorineural hearing loss implanted with the AMEI using the standard incus application (17–23). Todt et al. (17), Uziel et al. (19), Sterkers et al. (20), and Truy et al. (22) all observed the VSB to have superior speech perception results in both quiet and noise when compared with conventional hearing aids. Luetje et al. (18) reported that although their subjects' speech perception results with hearing aids were better in quiet, the AMEI performed better in noise and noted that this was possibly due to ceiling effects. Similarly, Schmuziger et al. (21) observed better results with hearing aids in quiet and more or less equivalent results to the AMEI in noise. Sziklai and Szilvassy (23) observed no difference in their patients with high-frequency sensorineural hearing loss between results with hearing aids and with the AMEI except for a slight trend in favor of the AMEI at 4 to 8 kHz.

Better hearing results with RW application of the AMEI were reported in comparison to ossicular chain reconstruction in patients with chronic otitis media and extensive destruction of the ossicular chain (2,3). In our study, patients with insufficient improvement of hearing loss despite tympanoplasty or stapedectomy procedures underwent AMEI implantation with RW approach, with good functional results obtained compared with HA

usage. In 2013, Marino et al. (8) examined 18 patients' preop hearing aid results to those with the RW application of the AMEI. They found that their patients performed better with the AMEI than with hearing aids on speech perception in noise tests. Gunduz et al. (10) also reported on a group of patients with conductive or mixed hearing loss implanted with the AMEI at the round window and found similar results, with the AMEI showing statistical significance over hearing aid results in the high frequencies. Atas et al. (24) presented quality-of-life questionnaire results on the same group of patients, with the subjects reporting statistically significant satisfaction with their AMEI. Mojallal et al. (25) compared post-operative audiological data of patients with bone conduction devices to those implanted with the AMEI at the RW, and found that the AMEI-RW treatment delivered better results when the preoperative BC thresholds were closer to the range of 35 to 50 dB HL.

The safety of the AMEI was confirmed by the fact that the subjects suffered no major medical or surgical complications. Minor complications were either completely resolved or greatly improved by the end of the study period. In addition, changes to residual hearing were measured by comparing patients' preoperative to post-operative bone conduction thresholds, with minimal and insignificant losses measured.

CONCLUSIONS

- (1) Patients with conductive and mixed hearing loss in this study experienced good hearing ability and a subjective sense of satisfaction in a wide variety of everyday environments, with improvement in their quality of life.
- (2) In the present adaptation, namely for patients of conductive hearing loss and mixed hearing loss who have no other treatment options, results with the AMEI applied to the round window exceeded those of the best available hearing aid on speech perception tests as well as quality of life questionnaires.
- (3) The AMEI was found to be a safe treatment with minimal adverse events and changes to residual hearing experienced by the patients in this study.

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