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Changes in Tinnitus After Middle Ear Implant Surgery: Comparisons With the Cochlear Implant

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Objectives: Tinnitus is a very common symptom in patients with hearing loss. Several studies have confirmed that hearing restoration using hearing aids or cochlear implants (CIs) has a suppressive effect on tinnitus in users. The aim of this study was to analyze the effect of other hearing restoration devices, specifically the middle ear implant (MEI), on changes in tinnitus severity.

Design: From 2012 to October 2014, 11 adults with tinnitus and hearing loss underwent MEI surgery. Pure-tone audiometry, tinnitus handicap inventory (THI), and visual analog scale scores for loudness, awareness, and annoyance and psychosocial instruments were measured before, immediately after, and 6 months after surgery. Changes in hearing thresholds and THI scores were analyzed and compared with those of 16 CI recipients.

Results: In both MEI and CI groups, significant improvements in tinnitus were found after the surgery. The THI scores improved in 91% of patients in the MEI group and in 56% of those in the CI group. Visual analog scale scores and psychosocial scale scores also decreased after surgery, but there were no statistical differences between the groups.

Conclusions: The results indicate that the MEI may be as beneficial as the CI in relieving tinnitus in subjects with unilateral tinnitus accompanying hearing loss. Furthermore, this improvement may manifest as hearing restoration or habituation rather than a direct electrical nerve stimulation, which was previously considered as the main mechanism underlying tinnitus suppression by auditory implants.

Key words: Cochlear implant, Middle ear implant, Tinnitus, Tinnitus handicap inventory.

(Ear & Hearing 2015;36;705–709)

INTRODUCTION

Tinnitus is a disturbing sensation that affects between 10% and 15% of the population; of those affected, 20% experience a significant decrease in quality of life as a result of tinnitus (Axelsson & Ringdahl 1989). Previous studies have revealed no compelling evidence suggesting the efficacy of any pharmacologic agent in the treatment of tinnitus (Patterson & Balough 2006). The inadvertent therapeutic effects of cochlear implantation on previously existing tinnitus had been noted in initial studies on cochlear implants (CIs; Vallés-Varela et al. 2013). Many authors have reported that existing tinnitus improved by up to 93% in patients after cochlear implantation (Ito 1997; Tyler 1995). The postulated effect of the CI on tinnitus was that by restoring the auditory input, the patient could recover the tonotopic reorganization of the auditory pathway after implant programming (Vermeire et al. 2008), and a masking effect could be produced (Culling et al. 2012). Recently, the middle ear implant (MEI) has become an alternative to conventional hearing devices for patients with moderate to severe sensorineural hearing loss. MEIs can also restore auditory input, and we hypothesized that MEIs show a therapeutic effect on existing tinnitus in patients with moderate to severe hearing loss.

We investigated the effect of MEIs in patients who experienced tinnitus with moderate to severe hearing losses compared with treatment with a CI.

MATERIALS AND METHODS

The assessment was carried out on patients with ipsilateral tinnitus who received unilateral MEIs from 2012 to 2014. These patients were then compared with patients who had tinnitus and received CIs. Patients in both groups experienced sensorineural hearing loss and asymmetrical hearing loss, and they also had unilateral tinnitus. Although they were primarily annoyed with the hearing loss, they were also aware of the tinnitus and wanted to get rid of the discomfort caused by it.

We used the following inclusion criteria: age greater than 15 years; a history of stable unilateral tinnitus for over 2 years; and the absence of a response to any previous treatment. The following conditions were considered as exclusion criteria: the existence of possible organic causes for tinnitus, presence of cochlear nerve aplasia or dysplasia, retrocochlear regrowth at any stage of evolution, and a history of implantations with problematic results.

Every patient of the MEI group (MEI group, n = 11) received the Vibrant Soundbridge (MED-EL, Innsbruck, Austria), while the implants used in the CI group (CI group, n = 16) varied among the CI 24RE, CI422, and Medel-Sonata models according to the patient's cochlear status.

To assess pre- and postoperative tinnitus severity, we performed several interviews in addition to obtaining the initial medical history. The first interview was carried out preoperatively with a tinnitus handicap inventory (THI proposed by McCombe et al.), visual analogue scale (VAS for loudness, awareness, and annoyance, with ratings from 0 to 10), Beck depression inventory (BDI), and Brief Encounter Psychosocial Instrument (BEPSI). The subsequent interviews were conducted immediately after and 6 months after implantation and involved the same tests and full compliance. Without any tinnitus retraining therapy and any further treatments for tinnitus during the periods, all patients were followed up. We supposed that the tinnitus reduction effect occurred as a masker. We characterized an "improvement" as a decrease of over 20% in postoperative THI scores compared with the preoperative THI scores (Khedr et al. 2008) or a decrease of more than 2 THI score grades according to McCombe's (McCombe et al. 2001) classification (Table 1). We also defined an improvement in VAS, BDI, and BEPSI as a decrease of more than 20% in postoperative scores compared with the preoperative scores.

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TABLE 1. Classification of the tinnitus handicap inventory (THI) scores according to McCombe et al. (2001)

Total Score	Indication	Grade
0–16	Slight (only heard in quiet environments)	Grade 1
18–36	Mild (easily masked by environmental sounds and easily forgotten with activities)	Grade 2
38–56	Moderate (noticed in the presence of ackground noise, although daily activities can still be performed)	Grade 3
58–76	Severe (almost always heard, leads to disturbed sleep patterns and can interfere with daily activities)	Grade 4
78–100	Catastrophic (always heard, disturbed sleep patterns, difficulty with any activities)	Grade 5

Power analysis was based on the differences in tinnitus improvement between patients with CI activated or deactivated, as described by Van de Heyning et al. (2008). We hypothesized that if the mean THI in the MEI group was not 25% higher than that in the CI group with a power of 0.80 and a two-sided value of $p < 0.05$, 12 individuals would have to be included for both groups. Results were analyzed using the Fisher exact test and the Mann-Whitney-Wilcoxon test. The level of significance was set at $p < 0.05$. A bivariate correlation analysis was used to analyze the correlation between the THI and the pure-tone audiometry (PTA) results. Statistical analyses were performed using SPSS v21.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

In patients with an MEI, the therapeutic effects on tinnitus were encouraging. The initial mean THI score was 43.82±31.51, and 6 months after surgery, the mean THI score was 24±19.09 ($p = 0.001$). Of the 11 patients, 10 (91%) showed more than 20% improvement in the THI score and 6 (54%) showed more than two grades of improvement in the THI score according to McCombe's classification.

We compared the therapeutic effects of MEIs on tinnitus with those of CIs. In both MEI and CI groups, there were no significant differences in the preoperative clinical characteristics surveyed except for hearing thresholds (Table 2). The initial mean THI scores for the MEI and CI groups were 43.82±31.51 and 46.46±32.96, respectively ($p = 0.097$). The THI scores markedly improved 6 months after surgery in both groups (Fig. 1).

TABLE 2. The demographic and clinical characteristics of the study populations

Variables	MEI Group (n = 11)	CI Group (n = 16)	*p* Value
Age (yr)	58.45±6.44	51.94±13.73	0.112
Sex (male:female)	6:5	10:6	0.302
Implant site (right: left)	5:6	8:8	0.791
Pre-PTA	57.0±15.64	94.63±23.24	**<0.001**
Post-PTA	38.55±8.86	39.77±10.54	0.747
Time of tinnitus	6.73±7.77	8.43±7.64	0.549
Pre-THI scores	43.82±31.51	46.46±32.96	0.097

A p value < 0.05 value was set as the significance level, and significant differences between groups are shown in bold.
ME, Middle ear implant; PTA, pure-tone audiometry; THI, tinnitus handicap inventory.

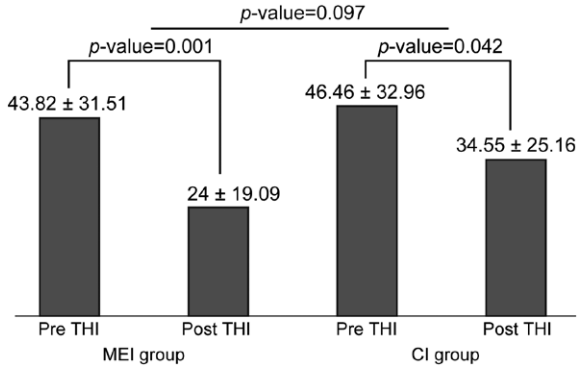

Fig. 1. The improvements in tinnitus handicap inventory (THI) scores at 6 months after the surgery in both middle ear implant (MEI) and cochlear implant (CI) groups ($p = 0.001$, $p = 0.042$, respectively). There is no significant difference between the MEI and the CI groups ($p = 0.097$).

The characteristics of tinnitus between both groups were similar (Table 3), but the maskability for tinnitus, which was evaluated after using hearing aids over 3 months, was better in the MEI group than that in the CI group ($p = 0.02$). Comparing the differences between the pre- and the postoperative THI scores in the MEI and CI groups, the improvement in the MEI group was bigger than that in the CI group but not significantly different ($p = 0.097$). Considering the 20% decrease in score criteria, the MEI group showed a higher improvement rate (91%) than the CI group (56%), but no significant difference was observed (Table 3; $p = 0.284$). According to McCombe's classification, the MEI group (54%) and the CI group (56%) both showed similar improvement rates in THI grades (Table 4). However, there was no significant difference in the grade change distributions between the groups ($p = 0.118$).

The patients in each group were also questioned on how the tinnitus affected their lifestyle and emotions in terms of loudness, awareness, and annoyance using a symptom rating scale based on a VAS self-reported questionnaire (Fig. 2A), as well as BDI and BEPSI (Fig. 2B). In the MEI group, the improvement in loudness, annoyance, and awareness on the VAS assessments was 55%, 55%, and 45%, respectively (Table 5). Similarly, in the CI group, the improvements were

TABLE 3. Characteristics of tinnitus of the study populations

Character	MEI Group (n = 11)	CI Group (n = 16)	*p* Value
Character			0.41
Buzz/murmur	6 (55%)	7 (43%)	
Pure tone	2 (18%)	3 (19%)	
Other	1 (9%)	2 (13%)	
Missing	2 (18%)	4 (25%)	
Type of tinnitus			0.66
Continuous	4 (36%)	6 (37%)	
Variable	4 (36%)	4 (25%)	
Missing	3 (27%)	6 (37%)	
Maskability*			**0.02**
Yes	4 (36%)	1 (7%)	
No	1 (9%)	12 (74%)	
Missing	6 (55%)	3 (19%)	

**Maskability for tinnitus evaluated after using hearing aid over 3 months before the surgery.*
A p value <0.05 value was set as the significance level, and significant differences between groups are shown in bold.
MEI, Middle ear implant.

TABLE 4. The THI score and grade changes (final THI–start THI) for patients in the MEI and the CI groups

	Variables	MEI Group	CI Group	*p* Value
THI score changes	Improved	10 (91%)	9 (56%)	0.284*
	Unchanged	0 (0%)	4 (25%)	
	Worsened	1 (9%)	3 (19%)	
THI grade changes	Improved	6 (55%)	9 (56%)	0.118*
	Unchanged	4 (36%)	4 (25%)	
	Worsened	1 (9%)	3 (19%)	

**Fisher exact test.*
MEI, Middle ear implant; THI, tinnitus handicap inventory.

63% in loudness, 69% in annoyance, and 44% in awareness. There was also no statistically significant difference between the MEI and the CI groups in terms of improvement and no changes or worsening in the symptoms assessed in the VAS self-reported questionnaire. The BDI and BEPSI were used to assess the relationship between the type of implant and the psychological disorders, such as stress, anxiety, and depression. In the MEI group, the improvements were 73% on the BDI and 55% on the BEPSI. In the CI group, the improvements were 88% on the BDI and 62% on the BEPSI. As expected, the differences between the MEI and the CI groups in both BDI and BEPSI were not statistically significant.

The correlation between the variability in THI scores and the variability in PTA was not significant (Fig. 3); the correlation coefficient was 0.133 ($p = 0.696$) in the MEI group and 0.246 ($p = 0.359$) in the CI group.

DISCUSSION

We compared the effects of an MEI on tinnitus with those of a CI. The MEI decreased the severity of tinnitus in many patients, and there was no significant difference in THI score variability between patients in the MEI and CI groups. We suggest that the degree of recovery in terms of hearing threshold is not correlated with tinnitus improvement and that slight amplifications of sound can improve tinnitus. The recovered hearing threshold after the surgery does affect the severity of tinnitus, regardless of the difference between the pre- and postoperative hearing threshold. The results indicate that MEIs may be as beneficial as CIs in subjects with unilateral tinnitus accompanying moderate to severe hearing loss.

In our study, preoperative thresholds of PTA were significantly different (57.0 ± 15.64 in the MEI group versus 94.63 ± 23.24 in the CI group). Because the indications for the operation were different, we performed the MEI surgery on patients with moderate to severe sensorineural hearing loss (SNHL) and CI surgery on patients with severe to profound SNHL. However, despite the differences in hearing thresholds, both severity and duration of tinnitus before the surgery were not significantly different between the groups ($p > 0.05$).

Hearing aid technology has improved markedly over the past 3 decades, offering ever-evolving device options for patients seeking to overcome their hearing deficits. MEIs provide an alternative to conventional hearing aids for patients who experience untoward feedback, the occlusion effect, or difficult fitting. Furthermore, as MEIs offer an effective method of rehabilitating moderate to severe SNHL, the use of MEIs may become an important treatment for patients with hearing loss (Colletti et al. 2006; Baumgartner et al. 2010). As hearing loss is related to tinnitus occurrence, we suggest that MEIs could be effective in patients who have moderate to severe hearing loss accompanied by tinnitus. To our knowledge, there has been no evidence of the effect of MEI on tinnitus before our study.

Many authors have pointed out improvements in tinnitus after cochlear implantation, with improvements reported in 40% to 93% of implanted patients (Tyler 1995; Ito 1997). Perhaps the most notable aspect of the influence of the CIs on tinnitus is the discussion about the physiopathology of tinnitus itself. Vermeire et al. suggested that tonotopic reorganization of the cochlea, auditory pathway, and the cortex itself occurs after implant programming and that the auditory infrastructure consequently adapts to the new situation of frequencies (Vermeire et al. 2008). Thus, cochlear implantation may produce a masking effect on the existing tinnitus. In contrast, there are no known pathophysiologic accounts pertaining to the effects of MEIs for tinnitus. However, considering the principles underlying MEIs and hearing aids, the positive effect of MEIs on tinnitus could have occurred like in the case of hearing aids by: (1) reducing the attention toward

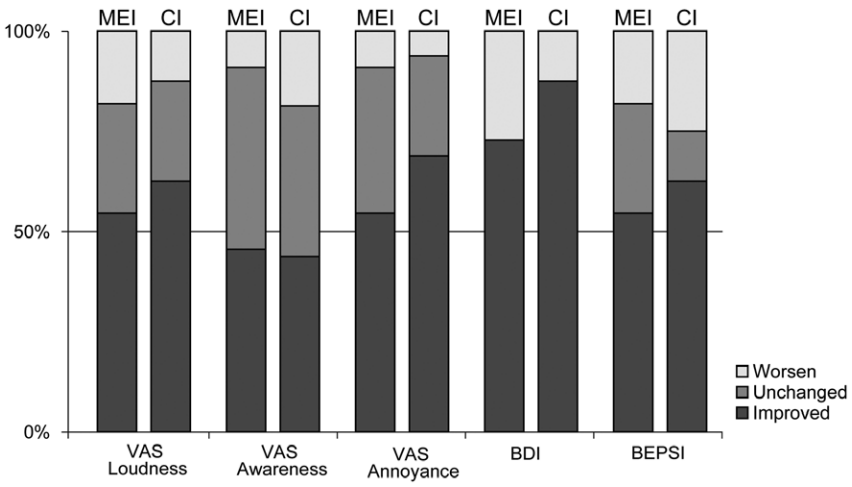

Fig. 2. The changes on symptom rating scales based on a visual analog scale (VAS) self-reported style questionnaire (A), as well as Beck depression inventory (BDI) and Brief Encounter Psychosocial Instrument (BEPSI) (B) at 6 months after the surgery in the middle ear implant (MEI) and cochlear implant (CI) groups.

TABLE 5. A comparison between MEI and CI groups in assessing annoyance, sleep disruption, depression, concentration, and tinnitus loudness and pitch

	MEI Group		CI Group	
VAS Status	No.	%	No.	%
Loudness*				
Improved	6	55	10	63
Unchanged	3	27	4	25
Worsened	2	18	2	12
Awareness†				
Improved	5	45	7	44
Unchanged	5	45	6	38
Worsened	1	10	3	18
Annoyance‡				
Improved	6	55	11	69
Unchanged	4	36	4	25
Worsened	1	9	1	6
BDI§				
Improved	8	73	14	88
Unchanged	0	0	0	0
Worsened	3	27	2	12
BEPSI¶				
Improved	6	55	10	62
Unchanged	3	27	2	13
Worsened	2	18	4	25

*Fisher exact test results: *p value = 0.894, †p value = 0.773, ‡p value = 0.754, §p value = 0.332, ¶p value = 0.614.*
BDI, Beck depression inventory; BEPSI, Brief Encounter Psychosocial Instrument; MEI, middle ear implant; VAS, visual analog scale.

hearing loss (Newman 1999); (2) complete or partial masking of tinnitus by amplified noise/instrumental noise (Del Bo & Ambrosetti 2007); (3) counseling associated with the material (Searchfield 2006); and (4) reduction of central gain by increasing auditory nerve activity (Moffat et al. 2009). These are consistent with a basic understanding of the Jastreboff model (Sheldrake & Jastreboff 2004). The maskability of hearing aids before the MEI surgery showed a greater percentage of improvement than that in CI (36% versus 7%). The results from the present study suggest that restoring the normal sensory input could be a more fundamental and physiological solution for the treatment of tinnitus after middle ear implantation. Without stimulating the nerve directly, only the amplification of sound and the restoration of serviceable hearing may decrease the severity of tinnitus and the reactions resulting from the limbic and autonomic nervous system (Hazell & Jastreboff 1990).

To treat tinnitus, objective measurement of the severity of tinnitus is important (Henry et al. 2014). However, a lack of objective measurement methods for tinnitus can complicate studies on the condition. Therefore, we compared several proven tests for tinnitus such as the VAS system for subjective symptoms, BDI and BEPSI, as well as THI. The VAS improvements in loudness, awareness, and annoyance of tinnitus showed similar rates of occurrence in both groups. The results of this study concur with those of a study supported by the Tinnitus Research Initiative (TRI) and Med-El that investigated the effects of an MEI and showed that five patients with severe tinnitus and high-frequency hearing loss achieved relief of their tinnitus after implantation (Biesinger & Mazzoli 1988). Considering our results, the use of MEIs could be an optional treatment for patients experiencing tinnitus with moderate to severe hearing loss.

Because tinnitus is related deeply to mood disorders, evaluations of the psychological problems associated with tinnitus are important. The severity of tinnitus is associated with psychiatric distress such as anxiety and depression in tinnitus patients (Crocetti et al. 2009). Cho et al. recommended psychological counseling for tinnitus patients, particularly if the patient receives a THI score in excess of 38 (classified as moderate or more severe suffering as a result of tinnitus) (Cho et al. 2013). Using the BDI and BEPSI tools, we showed that both MEI and CI groups showed effective postimplantation improvements in the stress, anxiety, and depression associated with tinnitus.

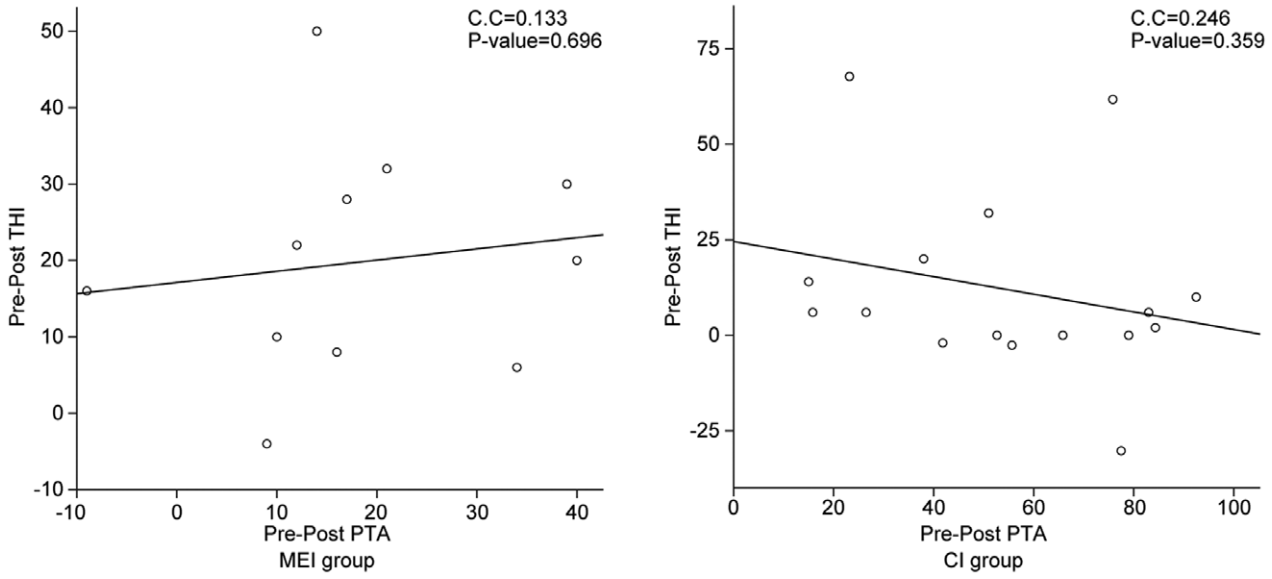

Fig. 3. The correlation between the variability in tinnitus handicap inventory (THI) scores and the variability in pure-tone audiometry (PTA) scores was not significant. The correlation coefficient (C.C) is 0.133 ($p = 0.696$) in the middle ear implant (MEI) group and 0.246 ($p = 0.359$) in the cochlear implant (CI) group.

CONCLUSIONS

After implantation of MEIs and CIs, improvements in tinnitus were observed in both groups. The results indicate that middle ear implantation in subjects with unilateral tinnitus accompanying moderate to severe hearing loss may be as beneficial as cochlear implantation.

ACKNOWLEDGMENTS

This work was supported by the National Research Foundation of Korea (NRF) grant funded by the Korea government (MSIP) (2014R1A2A1A11049478).

The authors declare no conflict of interest.

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Received September 12, 2014; accepted May 6, 2015.

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