Endoscopic Type 1 Tympanoplasty in Chronic Otitis Media: Comparative Study with a Postauricular Microscopic Approach

Masafumi Ohki, MD¹, Shigeru Kikuchi, MD, PhD¹, and Sunao Tanaka, MD, PhD¹

Abstract

Objective. To compare surgical outcomes after tympanoplasty without ossiculoplasty for chronic otitis media between transcanal endoscopic ear surgery (TEES) and postauricular microscopic ear surgery (PAMES).

Study Design. Case-control study.

Setting. Tertiary care university hospital.

Subjects and Methods. Consecutive patients (N = 122) who had undergone tympanoplasty without ossiculoplasty for chronic otitis media were enrolled in this retrospective study and divided into 2 groups: TEES (n = 47) and PAMES (n = 75). Middle ear condition was graded with the middle ear risk index. Hearing, repair of tympanic membrane perforation, and surgical time were assessed.

Results. The surgical success rate for hearing (air-bone gap <20 dB) was 95.7% in the TEES group and 84.0% in the PAMES group. Lower middle ear risk resulted in similar mean (95% CI) closure of air-bone gaps (TEES: 9.6, 6.5-12.6; PAMES: 8.0, 6.4-9.7; P = .333), whereas higher middle ear risk demonstrated significantly larger closure of air-bone gaps for the TEES group (10.1, 3.3-16.9) than the PAMES group (-0.2, -4.5 to 4.2; P = .009). The surgical success rate for repair of tympanic membrane perforation and surgical time were equivalent between TEES and PAMES.

Conclusion. Under favorable conditions of the middle ear, TEES and PAMES resulted in similar hearing improvement by tympanoplasty without ossiculoplasty. However, under adverse conditions of the middle ear, TEES was a more beneficial approach for hearing improvement than PAMES.

Keywords

endoscopic ear surgery, microscopic surgery, tympanoplasty, transcanal, middle ear risk index

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Patients and Methods

We retrospectively reviewed the medical records of 122 consecutive patients (58 men and 64 women; mean age, 50.4 years; range, 6-81 years) who had undergone tympanoplasty without ossiculoplasty for COM in the Department of Otolaryngology at our institution between January 2011 and August 2016. Patients with cholesteatomas, narrow external ear canal, or active supplicative infections were excluded.

Endoscopic ear surgery was performed with 2 types of endoscopes with visual direction (0° and 30°; view angle, 71° and 68°, respectively). Each endoscope had a diameter of 2.7 mm, an effective length of 158 mm, and a total length of 231 mm. The patients included in this study underwent TEES or PAMES under general anesthesia.

Representative Procedure of TEES

A knife was used to scratch the edges of the perforation circumferentially. The external auditory canal skin was incised with a round knife and dissected with an elevator. The tympanomeatal flap was elevated. The tympanic cavity was visualized, and the condition of the ossicles was surveyed. If pathologic lesions were found (eg, tympanosclerotic lesions, granulation, or fibrosis), they were removed to mobilize the ossicles. The cases with poor ossicle mobility, for which ossiculoplasty was a better indication, were excluded (3 cases each for TEES and PAMES). The TM perforation was closed with a medial-to-malleus underlay technique with the tragal perichondrium or temporalis fascia. The tympanomeatal flap was repositioned over the graft, and the flap and graft were fixed with fibrin glue.

Representative Procedure of PAMES

A postauricular incision was made, and the tympanomeatal flap was elevated. The tympanic cavity was explored, and the condition of the ossicles was surveyed. Mobilization of the ossicles and closure of perforations were performed in the same manner as TEES.

Grading with Middle Ear Risk Index

COM was graded with the middle ear risk (MER) index of Kartush.17 The MER index is composed of risk factors such as otorrhea (Bulluci grade18), perforation, cholesteatoma, ossicular status (Austin/Kartush19), granulation or suffusion in the middle ear, and previous surgery. The MER index is based on the following categories: mild (1-3), moderate (4-6), and severe (7-12). The characteristics of patients are summarized in Table 1. TM perforation was classified according to the number of quadrants involved by the perforation.

Pure tone audiometry was performed prior to and 1 year following ear surgery. Hearing improvement was assessed with the guidelines of American Academy of Otolaryngology—Head and Neck Surgery.20 Hearing levels were the average of dB readings at 500, 1000, 2000, and 3000 Hz. We interpolated a 3000-Hz threshold by averaging the thresholds at 2000 Hz and 4000 Hz when 3000-Hz thresholds were not available, according to the guidelines.21 The word recognition scores (WRSs) and scattergrams21 were also assessed for the 12 patients of the TEES group whose MER index was mild. For the other patients, the WRSs were missing. To assess the inner ear damage, high-tone bone conduction (HT-BC) hearing levels were also calculated (average of thresholds at 1000, 2000, 4000 Hz). Improvement in pure tone averages, air-bone (AB) gaps, closure of AB gaps, and HT-BC hearing levels was compared between the TEES and PAMES groups before and 1 year after ear surgery. A successful hearing result was defined as a postoperative AB gap ≤20 dB 1 year after surgery, as used in many published reports.22,23 A successful TM closure was defined as a dry TM without perforation 1 year after surgery.

All surgeons had extensive experience (>15 years of ear surgery with PAMES and endoscopic sinus surgery) and transitioned from PAMES to TEES at a certain point in their practice. Therefore, we did not make decisions to select endoscope versus microscope. There were no cases that started as TEES and were converted to microscope in this study, and vice versa. The surgeons were all right-handed.

The ethics committee approved the study protocol (Institutional Review Board for Ethics in Clinical Study of Saitama Medical Center, Saitama Medical University), which was performed in accordance with the ethical standards of the Helsinki Declaration. The requirement for informed consent was waived. The results were expressed as means with 95% CIs. Statistical analyses were performed with Ekuseru-Toukei 2012 software (Social Survey Research Information Co Ltd, Tokyo, Japan) and included the t test, paired t test, Fisher’s exact probability test, and Cochran-Armitage test for assessments of differences between groups. All reported P values were 2-tailed.

Results

Patient Characteristics

The characteristics of patients are summarized in Table 1. The proportion of patients with 1, 2, 3, and 4 quadrants involved in the perforation was similar between the TEES and PAMES groups (P = .315). Regarding the perforation location, the anterior perforation seemed to be more in the TEES group than in the PAMES group, but the distributions of the anterior, posterior, and central perforations did not differ significantly (P = .093). With respect to middle ear condition, MER index ratings of mild, moderate, and severe in the TEES group (83.0%, 17.0%, and none, respectively) were similar to the ratings in the PAMES group (89.3%, 10.7%, and none).

Pre- and Postoperative Hearing

The mean (95% CI) preoperative air conductive (AC) thresholds (TEES: 43.4, 37.6-49.2; PAMES: 42.3, 38.6-45.9; P = .728) and AB gaps (TEES: 19.7, 17.4-22.0; PAMES: 20.3, 18.4-22.2; P = .699) were equivalent between the groups (Table 2). After surgery, both groups exhibited significant decreases (P < .001) in AC thresholds (TEES: 32.7,
Acoustic threshold improvement of the TEES and PAMES groups was 10.7 (7.6-13.7) and 8.5 (6.3-10.7), respectively. The postoperative AB gaps of the TEES group were smaller than those of the PAMES group (P = .048), while the closure of AB gaps was not significantly different (P = .092).

The mean (95% CI) preoperative WRS of the TEES group was 95.8% (92.6%-99.1%; Table 1). The mean postoperative WRS of the TEES group was 93.3% (90.5%-96.2%), equivalent to the preoperative one (P = .111). Figure 2 shows the postoperative scattergram of changes in AC threshold and WRS.

With respect to the condition of the middle ear, in the mild category, mean (95% CI) AC threshold improvement was similar (TEES: 10.9, 7.6-14.3; PAMES: 9.9, 7.9-11.8; P = .545); postoperative AB gaps were 9.5 (7.6-11.4) in the TEES group and 11.5 (9.6-13.5) in the PAMES group (P = .081); and closure of AB gaps was 9.6 (6.5-12.6) in the TEES group and 8.0 (6.4-9.7) in the PAMES group (P = .333; Table 3). These factors were all equivalent between groups.
However, in the moderate category, mean (95% CI) post-operative AB gaps (12.9, 7.6-18.2) in the TEES group were significantly smaller than the gaps (26.6, 17.7-35.4) in the PAMES group ($P = .007$), and closure of AB gaps (10.1, 3.3-16.9) in the TEES group was significantly larger than the closure (–0.2, –4.5 to 4.2) in the PAMES group ($P = .009$; Table 4).

### Surgical Results for Hearing

The surgical success rate for hearing (AB gap $\leq$ 20 dB) was 95.7% for the TEES group and 84.0% for the PAMES group ($P = .077$).

With respect to the condition of the middle ear, in the mild category, the success rate for hearing was 97.4% in the TEES group and 88.1% in the PAMES group ($P = .150$). In the moderate category, the hearing success rate was 87.5% in the TEES group and 50.0% in the PAMES group ($P = .282$).

### Inner Ear Damage

The HT-BC hearing levels were assessed (Tables 2-4). The HT-BC thresholds of the TEES and PAMES groups were not significantly changed after the surgery (TEES: $P = .336$, PAMES: $P = .540$). Mean (95% CI) closure of the HT-BC hearing levels in the TEES and PAMES groups were equivalent: 0.6 dB (–0.6 to 1.7) and 0.4 dB (–0.9 to 1.7), respectively ($P = .864$). With respect to the condition of the middle ear, closure of the HT-BC hearing levels of TEES and PAMES groups was not significantly different in the mild ($P = .499$) and moderate ($P = .210$) categories.

### Surgical Results for TM Repair

The surgical success rates for TM closure were 93.6% for the TEES group and 85.3% for the PAMES group, which were not significantly different ($P = .244$; Table 2). The success rates for TM closure of perforation were stratified...
by perforation sizes (1, 2, 3, and 4 quadrants). There was no significant difference in the categories of each perforation size between the TEES and PAMES groups. The success rates for TM closure were also stratified with the MER index (Tables 3 and 4). No significant difference was found in the mild and moderate categories.

**Surgical Time**

The TEES group took a mean (95% CI) 77.2 minutes (69.9-84.5) for surgery, whereas the PAMES group took 86.9 minutes (79.6-94.2, $P = .077$). In the mild category, the surgical times were similar: 78.1 minutes (70.2-86.0) and 84.6 minutes (76.9-92.4), respectively ($P = .270$). However, in the moderate category, the TEES group took a significantly shorter time (72.9 minutes, 49.5-96.3) than the PAMES group (105.9 minutes, 85.8-125.9; $P = .024$).

**Influence of Surgeon Handedness on the TEES Side**

All the surgeons were right-handed. The TEES group showed similar mean (95% CI) postoperative AB gaps of 10.5 (7.8-13.3) on the right-side perforation and 9.7 (7.2-12.1) on the left side ($P = .619$). The surgical time of the TEES group was 71.5 minutes (60.6-82.5) on the right and 82.2 minutes (72.2-92.1) on the left, with no significant difference ($P = .144$).

**Discussion**

The TEES group of our study exhibited the following results: mean postoperative AB gap, 10.1 dB; occurrence rate of a postoperative AB gap $\leq 20$ dB, 95.7%; success rate for TM closure, 93.6% (Table 2). Several authors reported endoscopic myringoplasty$^4,8,12,24-35$ and endoscopic type 1 tympanoplasty.$^a$ The mean postoperative AB gap was 4.0 to 18.1 dB (median, 10.8 dB) in these studies,$^b$ and the occurrence rate of a postoperative AB gap $\leq 20$ dB was 77% to 100% (median, 90.8%).$^c$ Success rates for TM closure were 69% to 100% (median, 88%).$^4,5,7,9-11,13,15,16,24-36,38$ Similar results were obtained from the data of the current study.

The present study demonstrated that the postoperative AB gap was significantly smaller in the TEES group in TP without ossiculoplasty (Table 2). However, it may not be clinically significant and may be due to a few outliers because the closure of AB gaps was not significantly different. Previous comparative studies of TEES and microscopic ear surgery demonstrated equivalent hearing results between groups.$^7-10,12,14,36$ However, in the studies limited to normal mucosae$^9,12$ or normal ossicles,$^7,10,12$ subjects were defined as patients with good conditions of the middle ear, and marginal perforation was excluded.$^7,8$ Therefore, the middle ear condition of patients in these previous comparative studies was good and advantageous (ie, MER 1); treatment around ossicles was not necessary; and closing of the TM perforation was sufficient. However, subjects in the present study were not limited to patients with normal mucosae or normal ossicles. We included patients with pathologic mucosae and ossicles. In a study of pediatric patients, Cohen et al$^{11}$ reported that TEES showed significantly better hearing results in type 1 TP but not in ossiculoplasty. This study was not limited to patients with normal mucosae or normal

$^a$References 5, 7, 9-11, 13, 15, 16, 34, 36-38
$^b$References 7, 9, 10, 12, 13, 16, 24-28, 32-38
$^c$References 8, 12, 24, 29, 30, 33, 34, 36, 38
Table 3. Hearing Results in Middle Ear Risk Index 1-3: Mild Group.

<table>
<thead>
<tr>
<th></th>
<th>Mean (95% CI) or n (%)</th>
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<th>P Value&lt;sup&gt;a&lt;/sup&gt;</th>
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<tr>
<td></td>
<td>TEES</td>
<td>PAMES</td>
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<tr>
<td>AC threshold, dB</td>
<td></td>
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<tr>
<td>Preoperative</td>
<td>41.4 (34.7 to 48.1)</td>
<td>41.2 (37.6 to 44.9)</td>
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<td>.957</td>
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<tr>
<td>Postoperative</td>
<td>30.5 (24.3 to 36.6)</td>
<td>31.4 (27.8 to 34.9)</td>
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<td>.786</td>
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<td>Improvement</td>
<td>10.9 (7.6 to 14.3)</td>
<td>9.9 (7.9 to 11.8)</td>
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<td>.545</td>
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<tr>
<td>BC threshold, dB</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>22.4 (16.8 to 27.9)</td>
<td>21.7 (18.8 to 24.6)</td>
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<tr>
<td>Postoperative</td>
<td>21.0 (15.5 to 26.5)</td>
<td>19.8 (17.0 to 22.6)</td>
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<td>Improvement</td>
<td>1.4 (0.0 to 2.8)</td>
<td>1.8 (0.9 to 2.8)</td>
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<td>.581</td>
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<td>AB gap, dB</td>
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<td></td>
<td></td>
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<tr>
<td>Preoperative</td>
<td>19.0 (16.5 to 21.5)</td>
<td>19.6 (17.7 to 21.4)</td>
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<tr>
<td>Postoperative</td>
<td>9.5 (7.6 to 11.4)</td>
<td>11.5 (9.6 to 13.5)</td>
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<td>.081</td>
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<tr>
<td>Closure</td>
<td>9.6 (6.5 to 12.6)</td>
<td>8.0 (6.4 to 9.7)</td>
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<td>.333</td>
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<tr>
<td>HT-BC threshold, dB</td>
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<tr>
<td>Preoperative</td>
<td>23.2 (17.3 to 29.2)</td>
<td>22.9 (19.5 to 26.2)</td>
<td></td>
<td>.902</td>
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<tr>
<td>Postoperative</td>
<td>22.7 (16.8 to 28.6)</td>
<td>21.8 (18.5 to 25.0)</td>
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<td>.764</td>
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<tr>
<td>Closure</td>
<td>0.6 (–0.7 to 1.9)</td>
<td>1.1 (0.1 to 2.1)</td>
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<td>.499</td>
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<td>Success for hearing</td>
<td>38 of 39 (97.4)</td>
<td>59 of 67 (88.1)</td>
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<td>.150</td>
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<td>Success for TM closure</td>
<td>37 of 39 (94.9)</td>
<td>58 of 67 (86.6)</td>
<td></td>
<td>.322</td>
</tr>
</tbody>
</table>

Abbreviations: AB, air-bone; AC, air conductive; BC, bone conduction; HT-BC, high-tone bone conduction; PAMES, postauricular microscopic ear surgery; TEES, transcanal endoscopic ear surgery; TM, tympanic membrane.

<sup>a</sup>P values: t test for AC threshold, BC threshold, AB gap, and HT-BC threshold; Fisher’s exact test for success for hearing and success for TM closure.

Table 4. Hearing Results in Middle Ear Risk Index 4-6: Moderate Group.

<table>
<thead>
<tr>
<th></th>
<th>Mean (95% CI) or n (%)</th>
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<th>P Value&lt;sup&gt;a&lt;/sup&gt;</th>
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<tr>
<td></td>
<td>TEES</td>
<td>PAMES</td>
<td></td>
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<tr>
<td>AC threshold, dB</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Preoperative</td>
<td>53.1 (44.0 to 62.2)</td>
<td>51.1 (33.9 to 68.3)</td>
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<td>.808</td>
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<tr>
<td>Postoperative</td>
<td>43.8 (33.6 to 53.9)</td>
<td>54.1 (36.2 to 72.1)</td>
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<td>.252</td>
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<tr>
<td>Improvement</td>
<td>9.4 (–0.1 to 18.9)</td>
<td>–3.0 (–14.7 to 8.6)</td>
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<td>.07</td>
</tr>
<tr>
<td>BC threshold, dB</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Preoperative</td>
<td>30.2 (22.6 to 37.8)</td>
<td>24.7 (13.8 to 35.6)</td>
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<td>.347</td>
</tr>
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<td>Postoperative</td>
<td>30.9 (21.8 to 39.9)</td>
<td>27.6 (16.8 to 38.3)</td>
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<td>.590</td>
</tr>
<tr>
<td>Improvement</td>
<td>–0.7 (–4.5 to 3.1)</td>
<td>–2.9 (–11.9 to 6.1)</td>
<td></td>
<td>.606</td>
</tr>
<tr>
<td>AB gap, dB</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>23.0 (16.7 to 29.2)</td>
<td>26.4 (17.3 to 35.5)</td>
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<td>.474</td>
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<tr>
<td>Postoperative</td>
<td>12.9 (7.6 to 18.2)</td>
<td>26.6 (17.7 to 35.4)</td>
<td></td>
<td>.007&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td>Closure</td>
<td>10.1 (3.3 to 16.9)</td>
<td>–0.2 (–4.5 to 4.2)</td>
<td></td>
<td>.009&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td>HT-BC threshold, dB</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>33.5 (26.3 to 40.7)</td>
<td>27.3 (15.3 to 39.3)</td>
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<td>.308</td>
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<tr>
<td>Postoperative</td>
<td>32.9 (23.2 to 42.6)</td>
<td>32.7 (22.3 to 43.1)</td>
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<tr>
<td>Closure</td>
<td>0.6 (–2.9 to 4.1)</td>
<td>–5.4 (–15.7 to 4.9)</td>
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<td>Success for hearing</td>
<td>7 of 8 (87.5)</td>
<td>4 of 8 (50.0)</td>
<td></td>
<td>.282</td>
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<td>Success for TM closure</td>
<td>7 of 8 (87.5)</td>
<td>6 of 8 (75.0)</td>
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<td>.999</td>
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</table>

Abbreviations: AB, air-bone; AC, air conductive; BC, bone conduction; HT-BC, high-tone bone conduction; PAMES, postauricular microscopic ear surgery; TEES, transcanal endoscopic ear surgery; TM, tympanic membrane.

<sup>a</sup>P values: t test for AC threshold, BC threshold, AB gap, and HT-BC threshold; Fisher’s exact test for success for hearing and success for TM closure.

<sup>b</sup>P < .05.
ossicles. We speculated that these differences most likely resulted in differences in hearing outcomes. When we focused on the condition of the middle ear, in case of the better condition (i.e., a MER index of 1-3), the postoperative AB gaps were equivalent between TEES and PAMES, as the previous studies demonstrated. However, in the worse condition (i.e., a MER index of 4-6), the postoperative AB gap in the TEES group was smaller than in the PAMES group. In the worse condition, the TEES group demonstrated the superior result to the PAMES group. We speculate the reason for the difference as follows. When TP without ossiculoplasty in the PAMES group was performed, evaluation of ossicles may have been insufficient. Pathology in ossicles may tend to be underestimated, and removal of the granulation or calcification interrupting ossicle mobility may have been inadequate because of an insufficient field of view. Some cases with poor ossicle mobility, in which ossiculoplasty was a better indication, may have been underestimated as having good mobility, and ossiculoplasty was not performed. These factors may have yielded the differences in the hearing results. We speculate that evaluations of the condition of ossicles, removal of lesions (e.g., calcification, granulation tissue, and fibrous tissue), and a more precise performance of ossiculoplasty may be better in TEES than PAMES because of a better field of view.

Perforation, fixation of ossicles, loss of ossicles, aeration of the middle ear, and condition of the mucosae are influential factors for successful surgery.\textsuperscript{17-19,39} De Vos et al\textsuperscript{40} and Yung and Vowler\textsuperscript{41} statistically demonstrated the importance of the malleus handle, mucosa status, and otorrhea, which is a factor of the MER index. We should evaluate middle ear condition precisely and treat pathologic lesions (e.g., removal of calcification or granulation) around ossicles on demand. Endoscopy is suitable for a precise examination of the middle ear, including the attic, ossicles, and posterior tympanum. Hidden structures, such as the anterior TM perforation, sinus tympani, facial recess, attic, and hypotympanum, may be visualized with an endoscope via a transcanal approach.\textsuperscript{5} An endoscope is advantageous for evaluations of ossicle mobility and condition. Tarabichi\textsuperscript{5} and Kakehata et al\textsuperscript{57} emphasized the good visualization and minimally invasive procedure for ossiculoplasty. A microscope is unsuitable for accessing these areas unless an atticootomy, atticoantrotomy, or mastoideotomy is performed.

The influence to the inner ear function was assessed by the HT-BC hearing levels. The HT-BC thresholds were not significantly changed after the surgery, and closure of the HT-BC hearing levels in TEES and PAMES groups was equivalent. The TEES technique is suggested to be safe for inner ear function.

With respect to TM repair, it is difficult to observe the entire perforation in a single field under microscopic ear surgery. The anterior perforation is frequently in a blind spot from the anterior meatal overhang, and TM repair tends to fail in microscopic myringoplasty.\textsuperscript{42} A postauricular approach or canallplasty is often performed to observe the entire perforation under a microscope. Myringoplasty in TEES may be performed under superior visualization as compared with a microscopic field of view.\textsuperscript{7-9} Eren et al used endoscopic transcanal myringoplasty for anterior perforation and reported its advantages.\textsuperscript{27} Endoscopy enables surgeons to perform myringoplasty and TP in a minimally invasive manner with the transcanal approach without postauricular incision, even in cases with narrow ear canals or anterior meatal overhang.\textsuperscript{4,5} TM repair with TEES is equivalently successful to PAMES.

Surgical times were equivalent between TEES and PAMES under the better middle ear condition. However, under the worse middle ear condition, PAMES had a longer surgical time as compared with TEES. The reason is considered to be that handling a pathologic lesion around ossicles under an insufficient surgical view is laborious and takes time.

**Limitations**

This study had some limitations. First, our study was a retrospective study, although a prospective randomized controlled study would ideally compare TEES and PAMES. Second, the population enrolled in this study was small, especially for patients with moderate/severe ratings on the MER index. Further accumulation of data and reassessment with a larger number of patients are necessary in the future. Third, the surgical learning curve was another possible challenge. All surgeons switched their surgical approach from PAMES to TEES at some date and did not choose whether TEES or PAMES was performed. Surgeons in this study had less experience with TEES than PAMES. Therefore, a learning curve bias is speculated to have adversely affected the results with TEES. All surgeons possessed sufficient skills for endonasal sinus surgery and PAMES, and the use of an endoscope for ear surgery is not difficult. Therefore, any learning curve bias for PAMES is assumed to have been minimal in this study. Last because MER index was not designed with an endoscope, it may miss some important variables. As far as we examined, perforation locations were not biased between the TEES and PAMES groups, and influence of surgeon handedness on TEES was not shown in AB gaps and surgical time.

**Conclusions**

Under the favorable condition, TEES and PAMES produced comparable hearing outcomes. However, in surgery of TP without ossiculoplasty under the adverse condition of the middle ear, TEES was a more beneficial approach for hearing improvement than PAMES. With respect to TM repair, TEES and PAMES were comparably effective.

**Author Contributions**

Masafumi Ohki, conception and study design, conduct, acquisition of data, analysis and interpretation of the data, drafting and revising the article, final approval of the version to be published, and agreement on accountability for the work; Shigeru Kikuchi, study design, acquisition of data, revising the article, final approval of the version to be published, and agreement on accountability for the work; Sunao Tanaka, study design, acquisition of data,
revising the article, final approval of the version to be published, and agreement on accountability for the work.

**Disclosures**

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**References**


