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ORIGINAL RESEARCH

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Outcomes and learning curve of endoscopic tympanoplasty: A retrospective analysis of 376 patients

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Abstract

Objective: This study aimed to evaluate the procedural outcomes and learning curve of type I endoscopic tympanoplasty (ET) performed by a single surgeon.

Methods: This was a retrospective study of 376 patients who underwent type I ET performed by a single surgeon over 7 years. We evaluated the pre/post air-bone gap (ABG), time required for surgery, changes in pain after surgery, success, and failure rate of type I ET.

Results: Hearing results indicated an ABG of approximately 17.8 dB before surgery but decreased significantly to 9.8 dB at 6 months after surgery. The time required for the operation gradually decreased. In particular, the time required for the procedure was 67.6 min in the first year and decreased to 31.5 minutes in the fifth year, a drastic reduction. The graft failure rate up to 6 months after surgery was 13.0% and was the same for both primary and revision surgeries. Graft failure was significantly greater with increasing size of the preoperative tympanic perforation. The success rate varied depending on graft material, and the group with only acellular allogenic dermal matrix showed the lowest success rate. Postoperative pain significantly decreased from 2.01 immediately after surgery to 0.78 points the next day, and there were no severe complications during surgery.

Conclusions: ET produces superior cosmetic results with minimal pain and is associated with stable hearing improvement and high success rate. The operation time decreased with surgeon experience and continued to decrease until the fifth and final year of this analysis.

Level of Evidence: 4

KEYWORDS

chronic otitis media, endoscopic ear surgery, hearing loss, operation, tympanoplasty

1 | INTRODUCTION

There have been substantial changes and developments in surgery in recent decades. Among them, the processes and procedures for ear surgery have advanced through technological innovations. In particular, development of optical technology for microsurgery has improved the process and allowed the surgeon to operate with a much better field of view. Since the early 1950s, the surgical microscope has been

TABLE 1 Patient demographics

Variable	Overall ($n = 376$)
Age (years)	47.4 ± 16.9
Sex (male:female)	144:232
OP side (right:left)	172:204
TM perforation (*n*)	
< 25%	176
25%–50%	122
51%–75%	73
76%–100%	5
Flap reconstruction (*n*)	
Tragal perichondrium	302
Tragal perichondrium + megaderm	23
Temporalis fascia	31
Megaderm	14
Tragal cartilage	6
Anesthesia (general:local)	370:6

a useful tool for middle ear surgery.[1,2] However, the transcanal approach does not provide an outstanding field of view even with use of a surgical microscope.[3]

The use of endoscopes in ear surgery began in the 1990s.[4] The important benefits of transcanal endoscopic ear surgery (TEES) include good visualization and minimal invasiveness. The endoscope has higher magnification than the microscope, and it is possible to visualize a complex part of the anatomy with a very high resolution.[5] In addition, structures that are difficult to see with a conventional microscope can be better visualized at various angles using an endoscope.

Although many studies on TEES have been published since the mid-2000s, most studies have simply compared the results of conventional microsurgery and TEES. Moreover, it is rare for a single study to report more than 100 TEES results. We also reported the results of endoscopic tympanoplasty (ET) in 25 patients in 2017.[6] This time, we report the experience and results of surgeries for 376 patients, all conducted by a single surgeon.

2 | MATERIALS AND METHODS

2.1 | Subjects

A total of 376 patients (144 males and 232 females) who underwent type I ET from April 2014 to February 2021 were enrolled through a retrospective electronic medical record review. Of these, 372 patients had perforation of the tympanic membrane due to chronic suppurative otitis media, and four patients underwent surgery for traumatic perforation. All patients were operated on by a single surgeon at Samsung Medical Center. The average age of subjects was 47.4 years (SD: 16.9 years, range: 10–79 years). The perforation size was classified as small (perforation <25% of the total area of the tympanic membrane), medium (perforation size ≥25% to <50%), large (perforation size 50% to <75%), or near total (perforation size ≥75%). Small perforations were the most common and were reported in 184 cases (48.9%); only five patients (1.3%) had a large perforation. The graft material for tympanic membrane reconstruction, tragal perichondrium, was used alone in most patients (302 cases, 80.3%), whereas perichondrium and acellular allogenic dermal matrix (Megaderm, L&C BIO Inc.) were used together in 23 patients (6.1%) with a large/near total perforation. Temporalis muscle fascia (31 cases, 8.2%) or acellular allogenic dermal matrix (14 cases, 3.7%) was used alone when extra graft material was required due to the large size of the perforation or when it was not possible to use the tragal perichondrium because of a previous surgery. Butterfly cartilage tympanoplasty was performed using tragal cartilage without elevation of the tympanomeatal flap for a small perforation located in the anterior (6 cases, 1.6%) (Table 1).

Written informed consent was obtained from all participants. This study was approved by the Institutional Review Board at Samsung Medical Center and followed the tenants of the Declaration of Helsinki (IRB no. 2021-10-119).

2.2 | Surgical techniques

Transcanal type I ET was performed in all patients. A total of 371 patients underwent surgery under general anesthesia, and five patients underwent local anesthesia either because of their wishes or due to general health conditions. During the course of surgery, only harvesting of graft material (e.g., tragal perichondrium) was performed under a microscope or naked eye, and all other procedures were performed using a 0° or 30° 3-mm ear endoscope system (Karl Storz). For surgery, a local anesthetic (2% lidocaine with 1:100,000 epinephrine) was injected into the external auditory canal to reduce bleeding. The periphery of the perforated site was trimmed using a sharp pick, and a transverse incision was made 5-6-mm lateral to the tympanic annulus. A tympanomeatal flap was elevated for middle ear cavity visualization, the chorda tympani nerve was conserved as much as possible, and the flap was expanded to ensure sufficient space to insert the graft material.

2.3 | Outcome assessment

Prior to surgery, pure-tone audiometry (PTA) and speech audiometry (SA) tests were conducted in a double-walled, soundproof booth to determine the patient's degree of hearing loss (Orbiter 922, Madsen and GSI-61, Grason-Stadler). To analyze the surgical outcomes, PTA was performed at 3 months, 6 months, or 1 year after surgery, and the pain was evaluated immediately after surgery, 3–6 h postoperatively, and the next day. The pain scale was scored using an 11-item, patient-reported numeric rating scale of intensity (NRS-11, range 0–10). The graft success rate was evaluated 3 months after surgery using endoscopic examination of the tympanic membrane. A dry,

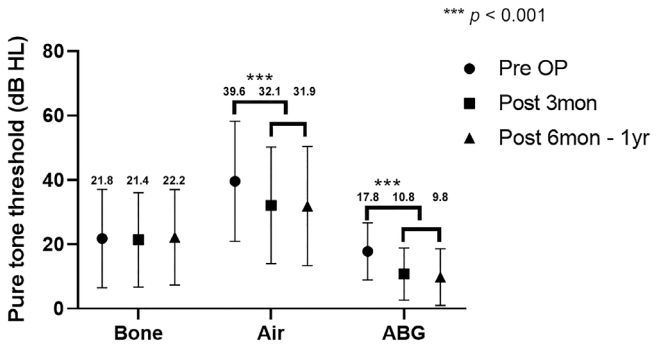

FIGURE 1 Hearing outcomes of type I endoscopic tympanoplasty (ET). The air conduction threshold and air-bone gap (ABG) significantly decreased at 3 months after surgery and at subsequent follow-up visits compared with before surgery.

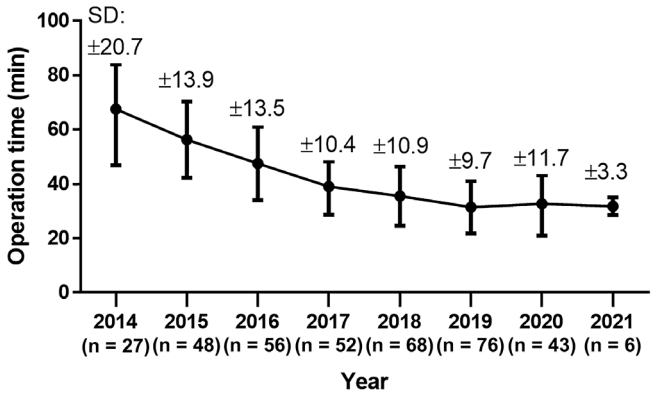

FIGURE 2 Changes in surgical duration over time. Due to surgeon's increased familiarity and expertise, the operating time significantly decreased over time.

clean ear canal without tympanic membrane perforation was considered graft success. In addition, the time required for the operation was measured by evaluating the start and end times for all surgeries.

2.4 | Statistical analysis

The surgical success rate based on perforation size and graft material was analyzed using linear-by-linear association. Repeated-measures ANOVA was used for changes in audiometric parameters and pain over time after surgery. Bonferroni's correction was performed for repeated measurements. All statistical analyses were performed using SPSS version 26.0 (IBM Co.).

3 | RESULTS

Among the 376 patients, 329 underwent type I ET as a primary surgery and 47 underwent revision surgery. Before surgery, the bone conduction threshold was 21.8 dB HL (±15.3 dB HL), and it does not

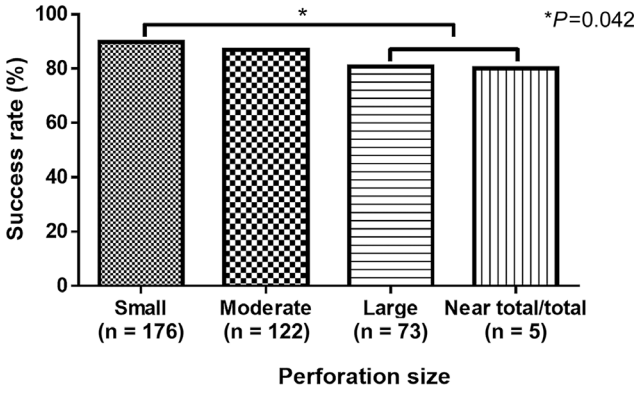

FIGURE 3 Surgical success rate based on size of the tympanic perforation. The success rate decreased with increased size of the perforation. Specifically, the success rate for cases with a large perforation (>50%) was significantly lower than in cases with a small perforation (<25%).

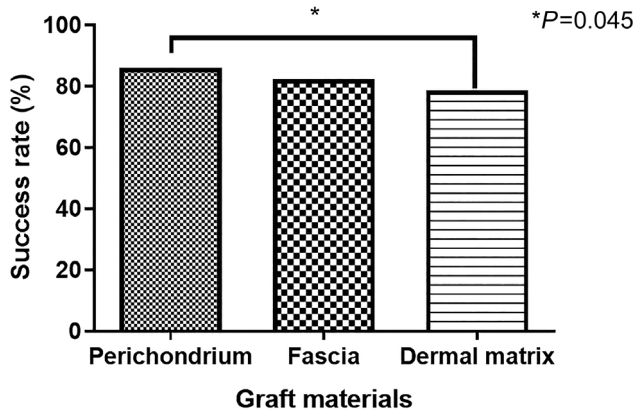

FIGURE 4 Surgical success rate in small to moderate-size perforations based on graft materials. The surgical success rate was lowest when only acellular allogenic dermal matrix was used.

change at 6 months or 1 year postoperatively, as a 22.2 dB HL (±14.8 dB HL) in the surgical side. After surgery, the air conduction threshold significantly improved, and the air-bone gap (ABG) before surgery significantly decreased ($p < .001$) from 17.8 to 10.8 dB HL at 3 months after surgery and to 9.8 dB HL at 6 months or 1 year after surgery (Figure 1).

The average time required for surgery was 44.7 ± 19.75 min. Considering the surgeon's learning curve, the time required for surgery was analyzed based on time period. The operation, which took approximately 67 min at the beginning of ET, dramatically decreased to approximately 31 minutes after 5 years of experience (Figure 2).

In the endoscopic examinations performed at 3 months after surgery, 49 patients had re-perforation of the tympanic membrane, and the success rate was 87.0%. Among the 49 patients, primary operation was performed in 41 cases and revision in eight cases. When the success rate of surgery was analyzed by group based on primary and revision surgeries, the same rate was observed for the two groups (87.2%; 287/329 vs. 41/47). Among the 49 patients who experienced

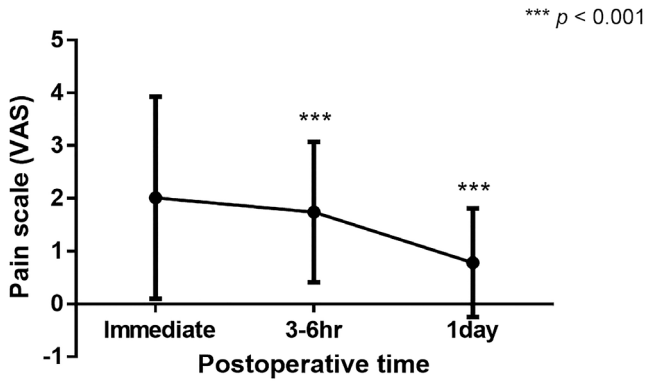

FIGURE 5 Postsurgical changes in pain score over time. The reported visual analog scale (VAS) score, which was 2.01 immediately after surgery, significantly decreased to 1.74 points 3–6 h after surgery and to 0.78 points the next day.

re-perforation, 13 underwent another revision type I ET, of whom two experienced re-perforation.

When the graft failure rate was analyzed, the results indicated a significantly higher probability of failure with larger perforation size. In particular, the success rate of large (80.8%) and near total (80.0%) perforations was significantly ($p < .05$) lower than that of small (89.8%) perforations (Figure 3). The success rate was affected by the graft material used in small to moderate perforations (Figure 4); the success rate of acellular allogenic dermal matrix alone showed a rate of 80.0%, lower than that of perichondrium (87.9%) and temporalis fascia (82.4%) alone. Statistical significance was found only with the dermal matrix and perichondrium graft materials ($p < .05$).

Postoperative pain was analyzed using the visual analog scale (VAS). The VAS score was 2.01 (±1.93) immediately after the operation and decreased to 1.74 (±1.33) after 3–6 h and to 0.78 (±1.03) the next day ($p < .001$, Figure 5). Among all patients, only 14 patients complained of pain with a VAS score of 7 or higher within 6 h after surgery, and only two of them complained of a pain with a VAS score of 5 or higher until the next day after surgery. Immediate postoperative complications, including changes in taste, were not reported.

4 | DISCUSSION

Over the last 20 years, TEES has received significant attention in the field of otology, and many developments have been made to improve the outcomes associated with this procedure.[7] As the indications for TEES have expanded, various surgical cases and results have been reported, and many comparative studies have been conducted to assess the surgery when using a conventional microscope. In several studies, a learning curve for new surgical methods was reported[8–10]; however, the studies included less than 300 cases and were not conducted over an extended period of time. This study analyzed the results of type I ET performed by one surgeon at a single institution over a 7-year period.

The main goal of tympanoplasty is to improve hearing. When comparing the difference in ABG before and after surgery using an endoscope, most studies showed an improvement of approximately 10 dB HL, similar to that of microscopic tympanoplasty (MT).[11] In another systematic review, improvement in ABG was 2.02 dB less with ET compared with MT.[12] Another study mentioned that the reason why ET is inferior to MT in hearing improvement is that the use of the one-handed TEES method has a problem with bleeding control and heating damage caused by the endoscope.[13] It is more difficult to control bleeding during TEES than when using a microscope; however, type I ET is less likely to cause severe bleeding. Therefore, it is difficult for the authors to agree that the bleeding that occurred during ET may have affected hearing. In addition, thermal damage has been shown to have no effect on the middle ear if a 3-mm endoscope is used without xenon as a light source.[14,15] In the present study, ABG was approximately 17.8 dB HL before surgery and significantly decreased to 9.8 dB HL at 6 months after surgery. The slight decrease in ABG compared with the results of other studies is likely due to better hearing before surgery.

The graft failure rate of type I ET is approximately 10%–15%.[9–11] Most study results have shown similar success rates for conventional microsurgery and endoscopic surgery.[12] In the present study, graft failure rate was 13.0%, similar to other reports. When the effect on success rate was analyzed, the results indicated that perforation size of the tympanic membrane before surgery had a significant effect. In addition, when the perforation size was small to moderate, a significant difference in surgical success rate was observed depending on type of graft. In particular, the success rate of dermal matrix is significantly lower than that of perichondrium, so it is recommended to use tragal perichondrium as a graft material. Not all perforation sizes were analyzed because graft materials are generally selected based on the size of the perforation at the time of surgery.

The time required for the operation decreased dramatically over the study period. Initially, the surgeon required more than 67.6 min to perform the procedure in the first year, which was reduced to 31.5 min in the fifth year. After the fifth year, the operation time did not decrease significantly, and the learning curve was determined to be complete. In numerous studies, reduction in surgery time was observed with increasing skill of the surgeon. In type I tympanoplasty, the procedure is relatively simple but requires more time because a microscope is used in the surgery. Reportedly, during the first 30 surgeries, the operating time rapidly decreased and continued to gradually decrease as the number of cases increased.[10] If the surgeon was accustomed to performing tympanoplasty using a microscope, the operation time was shorter if an endoscope was used compared with a surgeon not familiar with this approach, and the result improved with surgeon's familiarity.[9] Based on other reports, ossiculoplasty and stapes surgery, which are more complicated surgical procedures, showed no significant difference in operating time when using a microscope or an endoscope.[7,16] This result indicates that, although

there are some initial challenges with a one-hand surgical approach, the adaptation time is relatively short and the difficulty is not significantly different from that of microscopic surgery.

The most significant advantage of TEES from the patient's perspective is that the procedure is less invasive and results in less pain after surgery. Specifically, a less invasive approach was associated with less pain and greater cosmetic benefits. In terms of cosmetics, ET was significantly superior to MT in a systematic review.[12] In previous studies, patients reported similar pain levels immediately after ET or MT; however, ET showed much faster pain reduction with time.[6] In the present study, the pain score of approximately 2.01 points based on the VAS recorded right after surgery was significantly reduced to 0.78 points the next day. In a limited number of patients ($n = 14$), the VAS score increased to 7 points immediately after surgery; however, most values decreased to 0–2 points after 1 day. After surgery, patients took acetaminophen (650 mg bid) as standard; if pain could not be controlled, pethidine HCL inj 250 mg was administered. However, among 376 patients, only eight received additional pethidine. Among the 376 surgeries, serious complications, such as severe damage to the inner ear or facial paralysis, were not reported.

A significant strength of this study is that it traced the results of a relatively large number of cases over 7 years, although results cannot be generalized because all surgeries were performed by a single surgeon. Second, only patients with chronic otitis media were analyzed, and other medical conditions that can affect operation success were not considered. In particular, evaluation of eustachian tube function was insufficient, diabetes, and autoimmune diseases were not considered. However, the results of this study will be helpful for predicting the prognosis of type I ET and to predict an approximate learning curve for beginner surgeons who are adapting to or starting to perform TEES.

5 | CONCLUSIONS

Here we show that a tympanoplasty type I approach using an endoscope can have comparable surgical success rate to surgery using a conventional microscope for both large and small perforations. Surgical experience over 5 years can result in shorter operation time regardless of perforation size or complexity of case. In addition, TEES can be considered as a good alternative to conventional microsurgery due to its low postoperative pain.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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