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Endoscopic versus microscopic tympanoplasty: A prospective randomized comparison of outcomes

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Ethics Committee Approval
The study was approved by the Manisa Celal Bayar University Faculty of Medicine, Health Sciences Ethics Committee (number 20.478.486) on November 14, 2018.
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

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Abstract

Background/Aim: There is a limited number of systematic comparisons and comprehensive studies on auditory outcomes, graft success, and complication rates between traditional microscopic and newer endoscopic tympanoplasty techniques. Hence, we aim to compare these two techniques, namely endoscopic and microscopic type-1 tympanoplasty, in terms of anatomical and functional outcomes.
Methods: This prospective randomized clinical trial included 40 adult patients, divided equally between those undergoing microscopic and endoscopic tympanoplasty. To eliminate selection bias, the sequence of operations alternated between the two methods based on the patients' arrival order. Each patient's pre-operative conditions and outcomes 6 months post-surgery were evaluated using pure tone audiometry tests and assessments of the tympanic membrane. For both groups, the tragal perichondrial cartilage composite graft served as graft material. Functional assessments evaluated the air conduction threshold and bone conduction threshold averages at frequencies of 500, 1000, 2000, and 4000 Hz, both pre-operatively and 3 months after the operation. Air conduction gain was determined by comparing the air bone gap at application with that 6 months post-surgery. The size of the tympanic membrane perforation was calculated as a percentage of the total area using ImageJ, and the correlation with functional gain was assessed. The condition of the tympanic membrane and graft position were documented 6 months post-surgery using IBM SPSS Statistics Version 26.
Results: We compared mean (standard deviation [SD]) pre-operative air conduction threshold values between the endoscopic group (30.11 [5.19]) and the microscopic group (28.45 [5.19]) and found no significant difference (P=0.404). Similarly, we found no significant difference (P=0.169) in pre-operative air bone gap values between the endoscopic group (24.58 [5.35]) and the microscopic group (27.17 [6.34]). Post-operative air conduction threshold values in the endoscopic group (17.09 [11.28]) and the microscopic group (13.55 [7.99]) also showed no significant difference (P=0.258). The same was true for post-operative air bone gap values in the endoscopic group (13.97 [10.91]) and the microscopic group (9.63 [7.83]) (P=0.156). The average air conduction gain, an indicator we used to evaluate the functional success of the surgery, was similarly non-significant between the endoscopic group (13.08 [7.47]) and the microscopic group (14.90 [5.04]) (P=0.395).
Conclusion: Our study findings suggest that an endoscope is at least as effective as the microscopic method in type-1 tympanoplasty. Moreover, with advantages like reduced surgical time and broad-angle viewing capabilities, the endoscopic method is poised to gain popularity.

Keywords: tympanoplasty, endoscopic, microscopic, functional outcome, type-1

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Introduction

Chronic otitis media (COM) is a persistent inflammation of the middle ear mucosa, typically caused by resistant infections. If COM is untreated or improperly treated, complications like tympanic membrane perforation and hearing loss can occur [1]. In dealing with COM and tympanic membrane perforation, tympanoplasty is a common surgical method. This procedure was first introduced by Wullstein in 1952 [2], followed by Zöllner in 1955 [3]. Wullstein further classified the technique into five subtypes in 1956 [4], with Type-1 tympanoplasty being defined as the repair of only the tympanic membrane without disturbing the ossicular chain. Unlike myringoplasty, it includes creating a tympanomeatal flap [5,6]. Various graft materials and surgical techniques have emerged since the first description of this method. Temporalis fascia (TF) was the usual graft material for a long time until cartilage and perichondrium became popular. These two, having the same origin as TF, offer higher resistance [7] and, hence, result in a higher graft success rate [8].

Tympanoplasty, a common otology procedure, is highly successful in treating tympanic membrane perforations with a success rate of up to 95%, irrespective of chronic inflammation [9,10]. This procedure uses different incision methods, including retroauricular, endaural, and transcanal, for membrane reconstruction. Particularly for anterior quadrant perforations, many otologists prefer the retroauricular approach [11]. However, this method often necessitates a canalplasty [12,13]. The endaural approach is generally effective for posterior perforations, while the less invasive transcanal approach has limited applicability [13,14]. Modern surgery is increasingly utilizing minimally invasive methods. For example, endoscopy in COM surgery is emerging as a less invasive yet effective approach [15,16]. The endoscope not only provides a broader field of view but also eases visibility in areas that are challenging to observe under a microscope. For instance, it simplifies the control of anterior marginal perforations and visualization of hard-to-reach areas such as the attic, hypotympanum, sinus tympani, and facial recess [17].

Endoscopic tympanoplasty is a relatively newer procedure that has been gaining popularity in recent years [17]. Initially, the endoscope was primarily used for preliminary exploration and as an aid in microscopic ear surgeries. The adoption of the endoscope as a primary tool in such surgeries was first documented by Marchioni et al. in 2010 [1]. However, the long-term effectiveness and success rates of endoscopic ear surgeries are not fully established, leading to varying opinions regarding its primary use. Numerous studies have been conducted in recent years to measure the reliability and efficiency of the endoscopic approach in otologic surgery. Unfortunately, comprehensive comparisons and established evidence between traditional microscopic techniques and newer endoscopic tympanoplasty techniques are still lacking, particularly concerning auditory results, graft success, and complication rates [18].

This study directly compares the anatomical and functional outcomes of both microscopic and endoscopic tympanoplasty surgical procedures. The study's primary objective was to compare the functional and anatomical success rates between these groups, while the secondary objective was to examine any possible correlation between the size of a perforation and functional enhancement.

Materials and methods

Design and Study Population

The Institutional Clinical Research Ethics Committee approved this prospective randomized clinical trial (protocol number: 20.478.486). All methods were compliant with the 1964 Helsinki Declaration and its subsequent amendments. The study was initially intended to consist of 78 patients, as determined by a power analysis carried out using G*Power 3.1.9.7 software. This assumed a power of 95% and a significance level of α=0.05 and was based on an effect size for an independent sample t-test. However, time constraints limited the study to 40 patients. Consequently, a revised power analysis was conducted, revealing a power of 70% based on the same effect size and the smaller sample size of 40.

Between December 2018 and January 2020, 40 adult patients who presented to the Otorhinolaryngology Clinic of Manisa Celal Bayar University Hafsa Sultan Hospital had tympanoplasty performed, either endoscopically or microscopically (20 patients each). To avoid selection bias, patients were selected in order of their presentation and alternately assigned to one of the two surgical approaches. Our study, as per the CONSORT guidelines, was therefore characterized as a parallel-design clinical trial with a 1:1 allocation ratio. Patients were simply randomized into groups, again following CONSORT guidance, by a single surgeon.

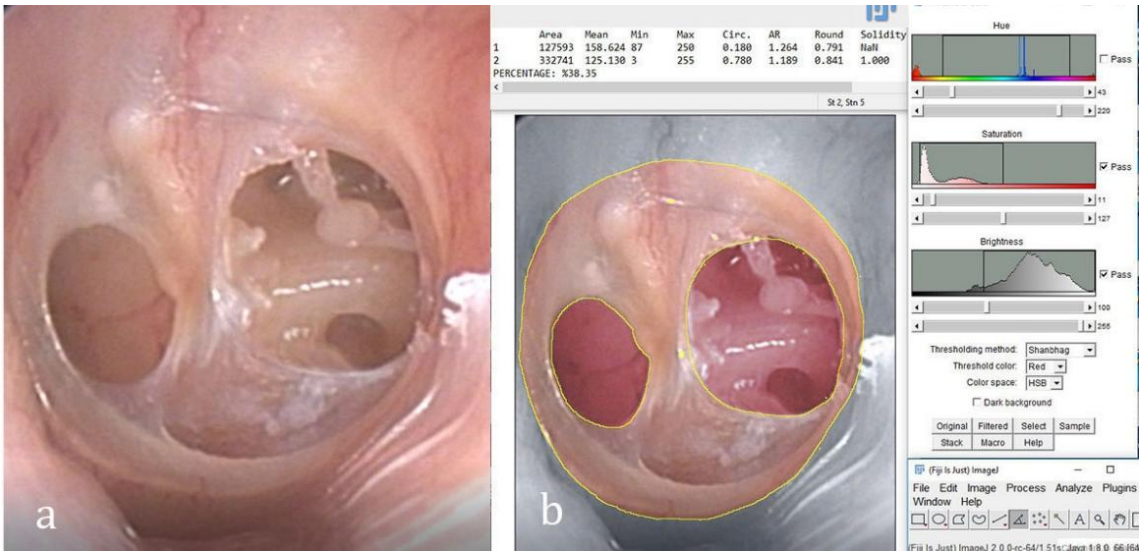
Pre-operative and 6-month post-operative pure tone audiometry examinations were performed on all patients. Exclusion criteria included the presence of a retraction pocket or cholesteatoma, ossicular chain damage, or previous surgery in the same ear. Pre-operative and 6-month post-operative endoscopic tympanic membrane examinations allowed us to record perforation size and location. There were no methodological changes relating to surgical technique or patient selection throughout the study.

Surgical Technique

All patients underwent surgery in the hospital's general operating theater. A postauricular approach was used for microscopic Type-1 tympanoplasty in 20 patients, while transcranial endoscopic Type-1 tympanoplasty was performed on the remaining 20 patients. Both groups received a tragal perichondrial cartilage composite graft (Figure 1). General anesthesia was used in all procedures.

Figure 1: Tragal perichondrial cartilage composite graft, which was used in both groups.

Figure 2: Calculation of perforation size using ImageJ software.



Functional and Anatomical Evaluation

Our study's functional evaluation was carried out at our institution's audio-vestibular unit, and the otoendoscopic recordings were taken from the recording room of the inpatient ward. For functional evaluation, the mean of the air conduction thresholds (ACT) and the bone conduction thresholds (BCT) at frequencies of 250, 500, 1000, 3000, and 4000 Hz were calculated from pre-operative and 3-month post-operative pure tone audiometry. The air bone gap (ABG) was calculated at the time of application and the 6-month post-operative audiometry. We calculated the air conduction gain (ACG) using the formula: $ACG=(ABG^{(pre\text{-}operative)} - ABG^{(post\text{-}operative)}$. The size of the tympanic membrane perforation as a percentage of the total area was measured using ImageJ software (Figure 2). Lastly, the integrity of the tympanic membrane and graft position were examined and recorded 6 months after the operation.

Statistical Analysis

We compared ACG and post-operative ABG values for functional evaluations. Anatomical evaluations involved a comparison of pre- and post-operative otoendoscopic examination records. We used Shapiro-Wilk and Levene tests to analyze variance distribution and equality, respectively. Depending on the results of the Shapiro-Wilk test, we carried out inter-group data comparison using either an independent samples T-test or a one-way analysis of variance (ANOVA) test. Data are presented as mean (standard deviation [SD]), where a 95% confidence interval and $P<0.05$ are considered statistically significant (IBM SPSS Statistics Version 26).

Results

Descriptive Statistics

Our study comprised 40 patients, including 23 females and 17 males, with an average age of 36.20 (13.29), who received Type-1 tympanoplasty. Patients were randomly assigned to either endoscopic or microscopic surgery based on their presentation order, with ten in each group. We found no statistical difference in age between the groups ($P=0.221$), and the Mann-Whitney U test on gender distribution also indicated no significant discrepancy ($P=0.343$).

Functional Results

The ACT, ABG, and ACG values for both groups exhibited a normal distribution ($P>0.05$ for each), suggesting no significant inter-group difference. Specifically, the pre-operative ACT values were 30.11 (5.19) and 28.45 (5.19) for the endoscopic and microscopic groups, respectively ($P=0.404$). The pre-operative ABG values were 24.58 (5.35) and 27.17 (6.34) for the endoscopic and microscopic groups, respectively, and they did not significantly differ ($P=0.169$). Post-operative ACT values were 17.09 (11.28) and 13.55 (7.99) for the endoscopic and microscopic groups, respectively, also revealing no significant difference ($P=0.258$). Similarly, post-operative ABG values, 13.97 (10.91) for the endoscopic group and 9.63 (7.83) for the microscopic group, showed no significant discrepancy ($P=0.156$) (Figure 3). Finally, the mean ACG values used to measure surgery's functional success were 13.08 (7.47) and 14.90 (5.04) for the endoscopic and microscopic groups, respectively, and these did not significantly differ ($P=0.395$) (Figure 4).

Figure 3: Comparative box-plot graph showing post-operative ABG values ($P=0.156$).

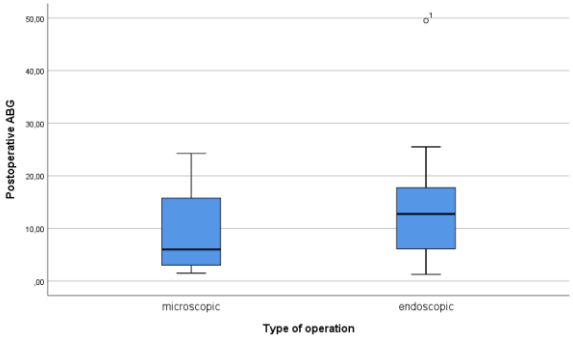
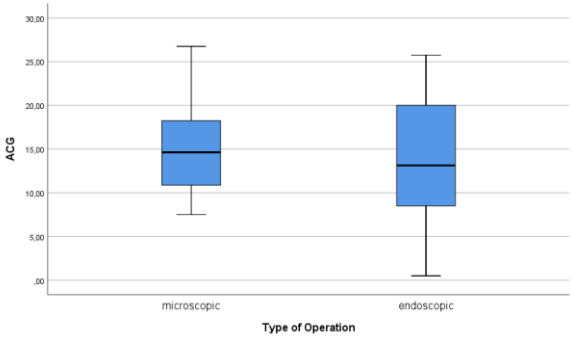


Figure 4: Comparative box-plot graph showing post-operative hearing ACG values by group ($P=0.395$).



Anatomical Results

Anatomical success, defined as the absence of perforation, retraction, and lateralization 6 months post-operation, was achieved in all 20 patients in the microscopic group and 90% of the patients in the endoscopic group. Using the Mann-Whitney U test, which is appropriate for ordinal variables, no significant differences were found in anatomical success between the two groups (P=0.317). The percentage of perforation size, calculated with ImageJ, was 45.05 (26) and 48.65 (25) in the endoscopic and microscopic groups, respectively. Again, no significant differences were noted (P=0.658). Furthermore, the Spearman correlation test revealed no significant association between perforation percentage and ACG (P=0.169, r=-0.222).

Discussion

The current literature contains comparisons of endoscopic and microscopic tympanoplasty techniques regarding functional and anatomical success, but few randomized controlled trials exist [19-21]. Our study, being a prospective randomized controlled trial, should significantly contribute to this comparison. Our patients were alternately randomized to either endoscopic or microscopic surgeries based on their order of presentation. By including only Type-1 tympanoplasty cases, we enhanced the homogeneity of our groups, strengthening our study.

We assessed functional outcomes by calculating the ACG using the difference between post-operative and pre-operative ACT values. With this method, we detected no difference in post-operative functional gains between the two techniques. Pre-operative ABG values, indicating the level of conductive hearing loss, also showed no difference between the groups, further highlighting their homogeneity.

In terms of anatomical success, only two endoscopic group cases had post-operative perforations, a non-statistically significant finding. Furthermore, we innovatively used ImageJ software to calculate the perforation sizes, to our knowledge, the first usage of such methodology. However, we found no significant correlation between calculated perforation size and ACG. We conclude that the perforation size does not impact the final functional success in both groups.

The microscopic approach has traditionally been the norm for tympanic membrane reconstruction and hearing rehabilitation. Despite its widespread use, it presents drawbacks such as restricted visualization of the surgical area, long operation times, and scarring due to incisions [22-24]. Conversely, the endoscopic approach is increasingly preferred as it offers advantages over the microscopic method. Importantly, the transcranial approach prevents visible scar tissue and auricular deformity [25,26]. Research into surgical duration also indicates its superiority in this aspect.

Furthermore, the superior angular view provided by the otoendoscopic method is extremely beneficial for cases involving narrow external auditory canals [27]. A recent meta-analysis has also demonstrated its merits in terms of dysgeusia [18]. However, most studies comparing both techniques are retrospective and exhibit high clinical variability. Our study stands out because it solely focuses on Type-1 tympanoplasty cases. Shakya et al. [30] have also compared these techniques in Type-1 tympanoplasty cases, but their research is retrospective and may be subject to selection bias.

Certainly, the endoscopic method has its drawbacks. For instance, it can be challenging to apply in cases where patients have narrow or difficult-to-navigate external auditory canals. These conditions can impede visibility and the use of tools simultaneously. Likewise, managing bleeding can be problematic due to the difficulty of operating with one hand. Nevertheless, studies are available on methods to counter these challenges [31].

One drawback of our study is not being able to attain the intended number of cases within the project's timeframe. Consequently, the statistical power is slightly compromised. However, the forward-looking approach of our study and balanced randomization of cases between both groups effectively counteract selection bias.

While the microscopic method is traditionally used, it has limitations such as prolonged operation times and scarring. The endoscopic approach is becoming more popular due to its less scarring and suitability for narrow ear canals. This study's findings align with the existing literature, indicating no significant differences in post-operative functional gains between the two techniques. Both methods show similar efficacy in air conduction gains, and the size of tympanic membrane perforations, as measured by ImageJ software, does not seem to have a significant impact. The study implies that the endoscopic technique is functionally on par with the microscopic method, advocating for its wider use in otologic surgeries due to its operational benefits and comparable success rate.

Conclusion

This study indicates that the functional success of endoscopy in Type-1 tympanoplasty is comparable to the microscopic method. Its various advantages suggest an increased future popularity for the endoscopic method.

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