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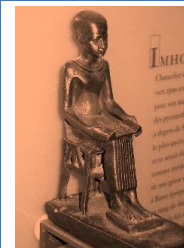
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## Original Article

# Double Door Tympanoplasty for Management of Subtotal and Total Perforation

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## ABSTRACT

### Article information

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**Background:** Chronic otitis media leads to tympanic membrane [TM] perforation which impairs hearing and predisposes to recurrent infections. Large subtotal and total perforations are challenging to repair.

**Aim of the study:** The aim of this work is to assess the efficacy of endoscopic double door tympanoplasty for Subtotal and Total TM Perforations as regard to graft uptake and hearing results.

**Materials and Methods:** This prospective study was conducted on 40 ears with subtotal and total TM perforation that underwent double door tympanoplasty. Graft uptake, postoperative air-bone gap and postoperative complications were assessed.

**Results:** A total of 36 patients [90%] achieved successful graft uptake, while 4 patients [10%] experienced failed graft uptake, indicating a successful outcome. Post-operative audiogram air-bone gap mean is  $12.25 \pm 1.43$  dB. The mean change from pre-operative audiogram readings is  $20.58 \pm 1.69$  dB. Compared to pre-operative. The post-operation compliance mean is  $11.85 \pm 2.77$  mL. The mean difference from pre-operative compliance is  $8.68 \pm 3.04$  mL. External ear infection rates drop from 15% after one week to 5% at three months. At three months, 7.5% of respondent's report discomfort, down from 30% at one week [p= 0.0095].

**Conclusion:** Double door tympanoplasty is an effective technique for repairing large subtotal and total perforations with high graft success rates and significant air conduction improvement. It provides excellent structural and vascularized support combined with a double-layer water tight seal.

**Keywords:** Otologic Surgical Procedures; Tympanic Membrane Perforation; Suppurative Otitis Media.



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## INTRODUCTION

The tympanic membrane [TM] is a thin partition that separates the outer ear canal from the middle ear cavity. It measures approximately 9–10 mm in vertical length and 8–9 mm in horizontal width [1]. It's a fibrous connective tissue layer, with skin on the outside and mucosa on the inside [2]. The TM, working together with the ossicular chain, plays a crucial part in transmitting sound from the environment to the oval window [3].

Tympanic membrane perforation occurs when the eardrum ruptures, causing a breach between the external and middle ear [2]. Complete perforations are characterized by the presence of only a small rim of membrane around the annulus and along the malleus handle, whereas subtotal perforations are larger than 50% but smaller than complete perforations [4].

Tympanoplasty is surgery to eliminate of disease in the ME and restore of function [5]. The underlay technique [medial] and overlay technique [lateral] are two conventional approaches to repairing eardrum perforations. These methods have been utilized for a considerable period of time, each having its own pros and cons [6]. To address these issues, surgeons have employed various surgical methods including utilizing the William's microclip, performing sandwich graft tympanoplasty, loop overlay tympanoplasty, and over-underlay tympanoplasty [4].

The double door tympanoplasty technique involves using a temporalis fascia graft is being harvested, and the posterior tympanomeatal flap is being elevated to access the middle ear. Following this, the anterior tympanomeatal flap is being created. The fascia is being trimmed to fit the eardrum perforation, allowing its anterior tip to be accessible through the anterior flap. The posterior flap is then being advanced, and the graft is being inserted into the middle ear through this flap. Finally, the posterior flap is being repositioned, ensuring the graft is covering the perforation, with its front end aligned with the skin tunnel at the front of the ear canal [7,8].

This surgical procedure holds potential for effectively correcting large tympanic membrane perforations; however, it is considered a specialized and advanced surgical technique and is typically performed by experienced otolaryngologists or ENT surgeons. The aim of this work is to assess the efficacy of endoscopic double door tympanoplasty for subtotal and total TM perforations as regard to successful of graft taking and improved hearing results.

## PATIENTS AND METHODS

This prospective study was conducted on 40 patients with subtotal and total tympanic membrane perforation attending Otorhinolaryngology Department, Al-Azhar

University Hospital [Damietta] between February 2022 and December 2023.

The inclusion criteria for the procedure encompass individuals within the age group of 15 to 60 who are affected by chronic otitis media and present with subtotal or total tympanic membrane perforation.

Patients meeting any of the following criteria were excluded from the study: recurrent perforation following prior myringoplasty, ongoing inflammation of the middle ear, a narrow external auditory canal, ossicular disruption or fixation, immunocompromised states such as uncontrolled diabetes, chronic liver or kidney diseases, and the presence of a cholesteatoma mass.

**Data collection:** All patients underwent a comprehensive preoperative assessment, including a detailed medical history and physical examination. Ear examination searching for check if there are any active infection or other abnormality like tympanosclerosis. Pure tone audiometry was done for all patients before and after surgery to assess the level of hearing.

## Surgical technique

Surgery was applied under general anesthesia. The process starts with a trans-canal endoscopic examination of the tympanic membrane. A temporalis fascia graft was collected using standard methods, compressed, and then dried. A portion of tissue surrounding the perforation was removed to ensure complete removal of epithelial tissue from the inner surface of the remaining tympanic membrane. Local anesthesia was injected into the canal skin. An incision was made in the posterior canal wall 6-8 mm from the annulus, from 1 to 5 o'clock, and then the posterior tympanomeatal flap was raised, connecting to the posterior tympanic annulus to access the middle ear space. Subsequently, a circumferential anterior tympanomeatal flap was initiated [figure 1]. A horizontal incision was made just beside the anterior part of the annulus. The canal skin and anterior annular ring were cautiously lifted inward with a Rosen Needle [figure 2].

The 1 mm right-angle hook was used to enter the middle ear through the medial side of the annulus. It pierced the middle ear mucosa until reaching the tip of the instrument, which went through the TM perforation. Special care was taken to protect the integrity of the annular ring while creating the anterior canal skin tunnel. The fascia graft, which had been harvested earlier, was cut to fit the perforation and adjusted to have an anterior tip that could be later pulled from the middle ear through the anterior tympanomeatal flap.

The flap located at the back of the ear canal and eardrum was moved forward. Then, a piece of fascia graft

that had been trimmed was inserted into the middle ear by going through the flap at the back [figure 3]. The flap at the back was then positioned back to its original place, and the fascia graft was properly placed to cover the perforation in the eardrum. The front end of the graft was aligned directly with the skin tunnel in the front of the ear canal

Next, the front end of the graft was grasped with a right-angle hook and pulled through the tunnel beneath the edge of the eardrum. It was then pulled out through an incision in the skin of the ear canal and left as a tag, which was placed against the normal skin in the front of the ear canal. The middle ear was subsequently filled with dry gel foam, followed by gel foam soaked in an antibiotic solution. Antibiotic-soaked ribbon gauze was placed in the ear canal.

**Post-operative follow-up:** A typical ear pressure dressing was put on for the initial 24 hours and then taken off. The outer canal packing [ribbon gauze] was removed during the first post-operative visit, one week later. Antibiotic drops were started and used twice daily for a week until the second post-operative visit. An endoscopic follow-up assessment was conducted after three weeks, and the follow-up pure tone audiometry [PTA] and tympanogram were performed after three months.

**Outcomes:** Outcomes were evaluated at 1 month and 3 months using otoscopic endoscopic examination. The primary outcome was successful graft uptake. Success was defined as closure of  $\geq 90\%$  of perforation. PTA was done 1 month and 3 months after surgery. Post-operative complications were evaluated.

**Administrative and Ethical Design:** Approval was obtained from the ethical committee in the faculty of medicine [Institutional Research Board IRB], and written consent was obtained from each patient enrolled in the study.

**Data management and Statistical Analysis:** The information was gathered, organized, and analyzed using the SPSS software version 22. This included tasks like editing, coding, and entering the data into a computer. Statistical methods were employed to process the quantitative and qualitative data, and appropriate tests were used to assess significance. Quantitative data were presented as mean  $\pm$  SD for parametric data and median with range for non-parametric data, while qualitative data were expressed in terms of frequencies and relative percentages. For comparisons between two dependent groups of normally distributed variables, statistical tests like the paired t-test were used, with all comparisons being two-tailed and a significance level set at  $p$ -value  $< 0.05$ .

## RESULTS

**Demographic data:** The mean age was  $34.15 \pm 13.66$  years, in terms of sex distribution, 45% of the patients were male, while 55% were female. The patients were categorized based on their residence, with 40% living in urban areas and 60% in rural areas. The mean BMI was  $26.88 \pm 3.27$  kg/m<sup>2</sup>, and 20% of patients were smokers [Table 1].

**Perforation data:** Types of perforation were categorized as subtotal and total, with 35% of patients having subtotal perforation and 65% having total perforation. In terms of the side of perforation, 65% of the patients had right-sided perforation, while 35% had left-sided perforation [Table 2].

**Primary outcome:** Clinical outcome of included patients, 36 patients [90%] achieved successful graft uptake, while a total of 4 patients [10%] experienced failed graft uptake [Table 3].

**Pre-operative audiological evaluations:** The audiogram air-bone gap had a mean of  $32.83 \pm 2.02$  dB, and tympanometry results indicated that all patients [100%] had a flat tympanogram and reduced compliance. The compliance value had a mean of  $3.18 \pm 0.98$  mL [Table 4].

**Post-operative audiological evaluations:** Post-operative audiological evaluations among included patients showed air-bone gap post-operation is reported with a mean of  $12.25 \pm 1.43$  dB. Additionally, the difference with pre-operative audiogram values is provided with a mean difference of  $20.58 \pm 1.69$  dB. Furthermore, compliance values post-operation is shown with a mean of  $11.85 \pm 2.77$  mL. The difference with pre-operative compliance values is given with a mean difference of  $8.68 \pm 3.04$  mL [Table 5].

**Pre and post-operative audiological evaluations:** Pre and post-operative audiological evaluations, regarding to reduced compliance, there was a highly significant difference between pre-operative & 3 months post-operative regarding reduced compliance [ $p = < 0.001$ ]. The compliance value in pre-operative had mean  $3.18 \pm 0.98$  while at 3 months had mean  $11.85 \pm 2.77$  mL with highly statistically significant difference [ $p = < 0.001$ ] between the two groups. Audiogram air bone gap in pre-operative had mean  $32.83 \pm 2.02$  dB, while at 3 months had  $12.25 \pm 1.43$  dB. There was highly significantly different between pre and post-operative regarding audiogram air bone gap [ $p = < 0.001$ ].

**Post-operative complications:** Complications occurrence among included patients, regarding to infection, there was non-statistically significant different among included

patients either in 1 week or 3 months post-operative [p=0.1395]. Regarding pain, there was statistically significant different among included patients between 1 week & 3 months post-operative [p=0.0095]. Regarding swelling

there was non-statistically significant different among included patients between 1 week & 3 months post-operative [p=0.0793] [Table 7].

**Table [1]:** Demographic data and basal characteristics among included patients

		Value [N = 40]
Age [years]		34.15 ± 13.66
Sex	Male	18 [45%]
	Female	22 [55%]
Residence	Urban	16 [40%]
	Rural	24 [60%]
BMI [Kg/m <sup>2</sup> ]		26.88 ± 3.27
Smoking		8 [20%]

**Table [2]:** Perforation data among included patients

		Value [N = 40]
Type of perforation		
	Subtotal	14 [35%]
	Total	26 [65%]
Side of perforation		
	Right	26 [65%]
	Left	14 [35%]

**Table [3]:** Primary outcome of included patients

	Value [N = 40]
Successful graft uptake	36 [90%]
Failed graft uptake	4 [10%]

**Table [4]:** Pre-operative audiological evaluations among included patients

	Value [N = 40]
Tympanometry	
Flat Tympanogram	40 [100%]
Reduced Compliance	40 [100%]
Compliance Value [mL]	3.18 ± 0.98
Pre-operative air bone gap [dB]	32.83 ± 2.02

**Table [5]:** Post-operative audiological evaluations among included patient

	Value [N = 40]
Pre-operative air bone gap [dB]	32.83 ± 2.02 dB
Post-operative air bone gap [dB]	12.25 ± 1.43 dB
Difference with pre-op [dB]	20.58 ± 1.69 dB
Compliance Value [mL]	11.85 ± 2.77 mL
Difference with pre-operative [mL]	8.68 ± 3.04 mL

**Table [6]:** Comparison between pre- and post-operative audiological evaluations among included patients

	Pre-operative [N = 40]	3 Months Post-operative [N = 40]	P. Value
Reduced Compliance	40 [100%]	4 [10%]	<0.001**
Compliance Value [mL]	3.18 ± 0.98	11.85 ± 2.77	<0.001**
Pre-operative air bone gap [dB]	32.83 ± 2.02	12.25 ± 1.43	<0.001**

**Table [7]:** Post-operative complications occurrence among included patients

	1 Week [N = 40]	3 Months [N = 40]	P. value
Infection	6 [15%]	2 [5%]	0.1395*
Pain	12 [30%]	3 [7.5%]	0.0095*
Swelling	10 [25%]	4 [10%]	0.0793*

## DISCUSSION

Tympanoplasty, a widely performed procedure on the ear, seeks to eliminate the underlying issues and regain normal functioning of the middle ear in cases of chronic otitis media. Having an intact tympanic membrane [TM] is crucial for proper impedance matching in the middle ear and protecting the round window, thereby enabling effective sound transmission to the inner ear [9].

In tympanoplasty, it's crucial to decide how to attach the graft to the malleus handle. Several techniques, including medial attachment, lateral attachment, and the sandwich method, have been described [10]. While the graft is usually positioned under the malleus to prevent displacement, it can also be placed alongside the malleus to provide additional support at the center of the graft [11]. Placing the fascia on the malleus is beneficial for cases with a retracted handle or exposed tissue at the promontory. The sandwich technique involves using two fascia grafts, one placed medially and the other laterally to the malleus, creating an enclosure around it to help secure its position [12].

In our study, we observed that 90% of patients had successful graft uptake, while 10% experienced failed uptake, indicating a positive overall outcome. Following the procedure, the average improvement in audiogram air-bone gap was  $20.58 \pm 1.69$  dB, reducing from  $32.83 \pm 2.02$  dB to  $12.25 \pm 1.43$  dB at three months. Compliance values also showed a significant increase from  $3.18 \pm 0.98$  mL to  $11.85 \pm 2.77$  mL, reflecting substantial improvement. Particularly noteworthy was the decrease in compliance from 100% preoperatively to 10% at three months, demonstrating the procedure's effectiveness in enhancing graft uptake, reducing air-bone gap, and improving compliance.

A study by **Park et al.** [10] on swing-door overlay tympanoplasty in 306 patients reported an overall graft success rate of 98.4%. Although five graft failures occurred, the air-bone gap closure improved significantly, with postoperative closure to  $\leq 20$  dB in 86.9%.

Similarly, **Bedri et al.** [13] compared single-layer and double-layer tympanic membrane grafting techniques and found that the double-layer technique improved tympanic membrane healing to 90.3%, significantly higher than the single-layer closure rate of 76%. They also observed an average improvement in extended pure tone average [EPTA] for conductive hearing loss of 20.14 dB with no significant difference compared to the single-layer group.

In a recent case-control study, **Elsheikh et al.** [14] evaluated the efficacy of double-layer temporalis fascia grafting for myringoplasty in subtotal tympanic membrane [TM] perforations. The double-layer technique demonstrated

a higher success rate of TM healing at 100% compared to 87.7% in the control group, with significant differences in hearing gains [ $>10$  dB].

Conversely, **Choi et al.** [15] assessed the clinical benefits of Endoscopic Tympanoplasty [ET] for large TM perforations in 239 patients, reporting a graft success rate of 86.2% and a graft failure rate of 13.8%.

The surgical management of large tympanic membrane perforations has sparked debate in the field of otolaryngology, particularly regarding the optimal technique for successful closure in challenging cases [16]. The debate often revolves around the benefits and drawbacks of using fascia and cartilage grafts. While fascia grafts are known for their pliability, they are associated with potential long-term hearing deficits, whereas cartilage grafts offer structural support and stability but raise concerns about rigidity and extrusion [17]. Amidst this debate, the potential role of double door tympanoplasty has emerged as an intriguing alternative, offering added structural support and potentially addressing limitations associated with single-layer closures. Proponents argue that double door tympanoplasty offers advantages in achieving closure for large perforations, especially in terms of stability and long-term outcomes.

The double-layered repair creates a waterproof seal while still allowing for mobility of the reconstructed eardrum. It reinforces the eardrum remnant and prevents further collapse, providing long-lasting closure of even the largest perforations. The cartilage prevents recurrent perforation and the fascia layer protects the underlying medial granulation tissue and thin eardrum remnant, enhancing the likelihood of successful hearing restoration [7,8].

Our study demonstrated a notable decrease in postoperative infection, from 15% at one week to 5% at three months, although the reduction lacked statistical significance [ $p=0.1395$ ]. We also observed a significant reduction in postoperative pain, with 30% reporting it at one week decreasing to 7.5% at three months [ $p=0.0095$ ]. The decrease in swelling from 25% at one week to 10% at three months was notable but not statistically significant [ $p=0.0793$ ].

Additionally, **El-Kholy et al.** [18] demonstrated minimal complications in both endoscopic single and double flap tympanoplasty groups, with no cases of anterior blunting, tympanic membrane lateralization, or sensorineural hearing loss in either group. The occurrence of fungal infection was the only reported complication, with insignificant differences between the single and double flap groups.

Furthermore, in a study by **Choi et al.** [15] on endoscopic tympanoplasty for large TM perforations, it

was noted that no patient developed graft lateralization or blunting, and there were no instances of major or minor intraoperative complications.

The current study was limited by small sample size, being a single center study the lack for control group and relatively short follow up period.

In conclusion, double door tympanoplasty technique is a safe and effective procedure for repairing total and subtotal TM perforation, with excellent graft success rate reaching as high as 90%, with satisfying hearing results. Additional research comparing larger groups of people over an extended period is necessary to validate our findings and to determine the factors that might contribute to unsuccessful outcomes.

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