DOI: https://doi.org/10.54393/pjhs.v7i9.3673

PAKISTAN JOURNAL OF HEALTH SCIENCES
(LAHORE)
https://thejas.com.pk/index.php/pjhs
ISSN (E): 2790-9352, (P): 2790-9344
Volume 7, Issue 09 (September 2026)



OPEN ACCESS
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Original Article

Postoperative Outcomes of Interlay Versus Underlay Tympanoplasty: A Randomized Controlled Trial

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ARTICLE INFO

Keywords:
Tympanoplasty, Otitis Media, Suppurative, Tympanic Membrane Perforation, Hearing Loss, Conductive, Treatment Outcome

How to Cite:
Israr, M., Aftab, R., Latif, S., Ikram, H. A., Ashraf, M. Z., & Khurshid, M. (2026). Postoperative Outcomes of Interlay Versus Underlay Tympanoplasty: A Randomized Controlled Trial: Postoperative Outcomes of Interlay Versus Underlay Tympanoplasty. Pakistan Journal of Health Sciences, 7(9), 03-08. https://doi.org/10.54393/pjhs.v7i9.3673

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Received Date: 6th December, 2025
1st Revision Received: 13th February, 2026
2nd Revision Received: 31st March, 2026
3rd Revision Received:14th April, 2026
Acceptance Date: 20th April, 2026
Published Date: 30th September, 2026

ABSTRACT

One of the main causes of conductive hearing loss is still chronic otitis media with tympanic membrane perforation. Surgical repair aims to restore hearing and membrane integrity. **Objective:** To compare the postoperative anatomical and functional outcomes of interlay versus underlay tympanoplasty techniques in patients with chronic otitis media. **Methods:** This randomized controlled trial was carried out at the Department of Otorhinolaryngology, Shaikh Zayed Medical Complex, Lahore, from January to June 2025 after approval by the institutional ethical review board. Consecutive Sampling of Patients with Chronic Otitis Media and Large Central Tympanic Membrane Perforations. At the conclusion of the trial period, 78 patients who had both substantial central tympanic membrane perforation and chronic otitis media were included. Post-enrolment, participants were randomly assigned to either underlay or interlay tympanoplasty using simple randomization to minimize allocation bias. Standardized endoscopic procedures using temporalis fascia grafts were performed under general anesthesia. Outcomes were assessed at 12 weeks, and 62 patients completed follow-up and were analyzed. **Results:** Analysis was done on 62 patients in total. The baseline features of the groups were similar ($p>0.05$). The mean air-bone gap was 25.08 ± 4.07 dB before surgery, compared to 26.27 ± 4.03 dB ($p=0.254$). At 12 weeks, postoperative air–bone gap improved to 15.95 ± 4.03 dB versus 11.79 ± 3.70 dB ($p < 0.001$), with greater mean hearing gain in the interlay group (14.48 ± 4.48 dB vs 9.14 ± 3.12 dB; $p<0.001$). **Conclusions:** Interlay tympanoplasty resulted in significantly greater hearing improvement than the underlay technique, with comparable anatomical success.

INTRODUCTION

The symptoms of chronic otitis media (COM), a long-term inflammatory middle ear disease, include tympanic membrane rupture, recurrent ear discharge, and conductive hearing loss [1]. A systematic analysis of community studies conducted in 2025 showed that the prevalence of chronic suppurative COM was 3.8% globally, with poor and middle-income countries(LMICs)accounting for 85% of cases [2]. It is still one of the most common otologic illnesses. Trauma, persistent ear infections, or iatrogenic conditions can all cause tympanic membrane perforation [3]. While some small perforations heal spontaneously, larger or persistent defects require surgery to recover middle ear function and prevent recurrent infections [4]. Tympanoplasty was first described by Berthold in 1879. Wullstein and Zöllner later adapted it, and ear surgeons then considered tympanic membrane reconstruction a routine procedure as well [5]. Type I tympanoplasty without ossicular reconstruction remains

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DOI: https://doi.org/10.54393/pjhs.v7i9.3673

the most commonly performed otologic procedure of any type [6]. Over the years, different graft positioning techniques have been developed (underlay, overlay, and inlay/interlay). Various underlay techniques are based on the insertion between the remnant of the tympanic membrane developed by Shea in 1960 and are employed primarily because they are easy and provide good results. However, some shortcomings of the technique remain, such as graft medialization, anterior blunting, and a decrease in middle ear space, particularly with large or anterior perforations [7]. Although the overlay method for anterior defects is possible, it is associated with a higher incidence of lateralization of the graft, blunt canal wall, epithelial cysts, and delayed epithelialization [8]. To overcome these limitations, the interlay technique was proposed, in which the graft is placed between the fibrous and mucosal layers of the tympanic membrane. This alteration has the advantage of double support and preserving the anatomical contour of the tympanic membrane, which helps to reduce post-operative complications like medialization, lateralization, or entrapment of epithelium [9]. In many studies comparing interlay and underlay tympanoplasties, the interlay technique showed superior results. Albera *et al.* observed a 96% graft success rate and an average post-operative air bone gap ABG of 36.4 dB, which was lowered to 9.7 dB in the interlay technique-repaired group [10]. Sharma *et al.* Alam *et al.* the interlay tympanoplasty was reported to have better hearing gain (12 dB vs. 8.7 dB), graft uptake for interlay tympanoplasty compared with underlay repair (96% vs. 90%) [11, 12]. There is, however, no unequivocally established approach for tympanic membrane reconstruction that is widely agreed upon in the medical community, especially in cases of extensive perforation. The choice of technique is based on the surgeon's preference, characteristics of the perforation, and intraoperative factors [13].

Considering the world of tympanoplasty techniques is advancing, and it necessarily needs to maximize patients' outcomes, there remains a lack of clear consensus regarding the optimal graft placement technique for achieving superior anatomical and functional results. Although both interlay and underlay tympanoplasty are widely practiced, comparative evidence on their effectiveness, particularly in terms of hearing improvement and graft uptake, is still limited and variable. This study was planned because graft placement affects surgical results, patient recovery time, and surgical efficacy in tympanoplasty. The study aimed to compare the anatomical success (graft uptake) and functional hearing outcomes (change in air-bone gap on pure-tone audiometry) of interlay and underlay tympanoplasty by comparing mean hearing gain, graft uptake rate, and complete air-bone gap (ABG) closure in patients with chronic otitis media.

METHODS

With approval from the Institutional Review and Research Advisory Board, this randomized controlled study (NCT07149480) was carried out in the Department of Otorhinolaryngology (ENT) at Shaikh Zayed Medical Complex, Lahore, from January 2025 to June 2025 (TERC/NHRD-SZH/INT-SC/796; dated 9th January 2025). Eligible patients presenting during the study duration were enrolled by non-probability consecutive sampling. After enrollment, patients were allocated to the underlay or interlay group using simple randomization to ensure unbiased assignment. Using an online sample size calculator and assuming a mean postoperative ABG of 17.6 ± 8.7dB in group A and 13.5 ± 5.4dB in group B, a sample size of 78 (39 patients in each group) was determined. 80% power at a 90% confidence level [11]. Every patient got the allotted intervention. Nine patients from group A and seven from group B were lost during the follow-up period. Consequently, 30 underlay and 32 interlay cases were analyzed for outcomes, as shown in the CONSORT flow diagram (Figure 1).

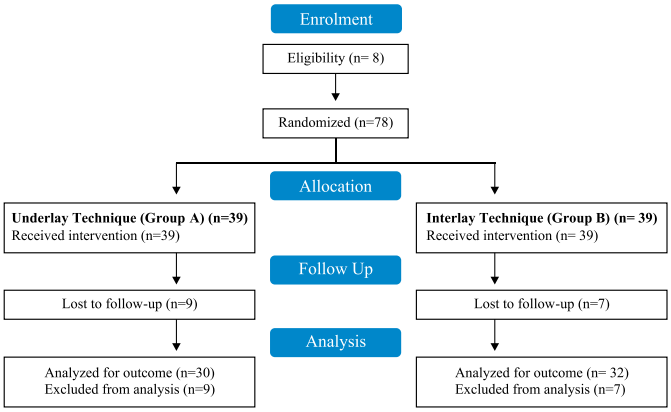


Figure 1: CONSORT-Style Flow Diagram

The study comprised patients between the ages of 16 and 60 who had been diagnosed with chronic otitis media (inactive mucosal illness), had a dry, wide central tympanic membrane perforation that had persisted for at least six weeks, and had pure conductive hearing loss on pure-tone audiometry. Individuals with tympanosclerosis, ossicular necrosis, or active otitis media that affected the mobility of the ossicular chain, as well as those with a history of ear surgery that would have affected the results of tympanoplasty, were not included. Individuals with sensorineural or mixed hearing loss, uncontrolled systemic illnesses such as diabetes mellitus, eustachian tube dysfunction, or concurrent infection of the throat, nose, paranasal sinuses, or oral cavity at the time of surgery were

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also excluded from the study. After the process, any potential risks and advantages of the study were explained to each patient in their native language, and written informed consent was obtained. Following consent, baseline demographic and clinical information was collected, including the patient's age, gender, duration of disease, laterality of the affected ear, and relevant medical history related to chronic otitis media. Every patient underwent a detailed otoscopic examination to check tympanic membrane perforation and to ensure the absence of active infection. Diagnostic pure tone audiometry was executed preoperatively to measure the ABG at standard frequencies (500, 1000, 2000, and 4000 Hz), making a baseline for postoperative comparison. Patients who met the inclusion criteria were divided into two groups, group A and group B, at random using the lottery method for fair distribution. Random allocation was performed using a lottery method; however, formal allocation concealment procedures were not applied. This has been acknowledged as a limitation because it may permit intuition of assignment at enrollment. A single consultant surgeon with endoscopic tympanoplasty experience carried out both surgeries under general anesthesia while using aseptic measures. Using one operator ensured uniform operative technique across both groups; however, this may limit generalizability and introduce potential operator-related bias, which has been acknowledged in the limitations. A tympanomeatal flap was elevated in the underlay group, and a temporalis fascia graft was placed medial to the tympanic membrane remnant after lifting the tympanomeatal flap along the annulus. Before closure, continuity and mobility of the ossicular chain were tested, while reapplying the flap, and gentle packing of the external auditory canal should be done. In the interlay group, a circmferential tympanomeatal flap was raised, leaving the mucosal layer intact. Intraoperatively, the ossicular chain and eustachian tube were inspected for patency. Insertion of the temporalis fascia graft between the fibrous & mucosal layers of the tympanic membrane, resting against the mucosal surface under the malleus handle. The flap was replaced, and the ear canal was packed. Postoperatively, patients were followed up at 1, 4, and 12 weeks after surgery. During each visit, an otoscopic examination was done to check graft integrity, epithelialization, and any signs of infection or graft displacement. The graft uptake was considered successful when the tympanic membrane appeared intact without residual perforation or lateralization at the 12th week follow-up. Pure-tone audiometry (PTA) was used to quantify postoperative hearing improvement; the mean hearing gain was determined by subtracting preoperative from postoperative ABG values. Postoperative complications such as infection or otorrhea, graft lateralization or medialization, residual perforation, and reperforation during follow-up were recorded.

Data were analyzed using SPSS version 26.0. Continuous variables were expressed as mean ± SD, whereas grouped data were shown as frequency and percentage. For continuous data, groups were compared using the Independent Samples t-test, and for categorical data, the Chi-square test was employed. The mean difference and odds ratio with 95% confidence intervals were used to calculate the effect sizes. A p-value of less than 0.05 was considered statistically significant.

RESULTS

The mean age in the underlay group was 33.80 ± 10.92 years and in the interlay group 35.31 ± 12.13 years (p=0.609). Age group distribution did not differ significantly (χ^2=0.644, p=0.725). The males were 33.3% in the underlay and 43.8% in the interlay group (χ^2=0.708, p=0.400). The right ear was operated on in 60.0% versus 62.5% of patients (χ^2=0.041, p=0.840). Mean duration of disease was 15.07 ± 7.69 months in the underlay group and 16.50 ± 7.34 months in the interlay group (p=0.456) (Table 1).

Table 1: Baseline Demographic and Clinical Characteristics of Patients According to Tympanoplasty Technique (n = 62)

Variables	Category	Underlay Technique (Group A)	Interlay Technique (Group B)	Test Statistic (χ^2 / t-value)	Effect Size (OR / MD) [95% CI]	p-value
Age (Years)	Mean ± SD	33.80 ± 10.92	35.31 ± 12.13	t=−0.515	MD = −1.51 [−7.39, 4.36]	0.609
Age Group (Years)	16–30	12 (40.0%)	14 (43.8%)	χ^2=0.644	–	0.725
	31–45	14 (46.7%)	12 (37.5%)			
	46–60	4 (13.3%)	6 (18.8%)			
Gender	Male	10 (33.3%)	14 (43.8%)	χ^2=0.708	OR=0.64 [0.23, 1.80]	0.400
	Female	20 (66.7%)	18 (56.3%)			
Laterality of the Ear	Right	18 (60.0%)	20 (62.5%)	χ^2=0.041	OR=0.90 [0.32, 2.50]	0.840
	Left	12 (40.0%)	12 (37.5%)			
Duration of Disease (Months)	Mean ± SD	15.07 ± 7.69	16.50 ± 7.34	t=−0.751	MD=−1.43 [−5.26, 2.39]	0.456

SD = Standard deviation; MD = Mean difference; OR = Odds ratio; CI = Confidence interval; χ^2 = Chi-square test; Independent t-test used for continuous variables; Pearson's Chi-square test applied for categorical variables

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DOI: https://doi.org/10.54393/pjhs.v7i9.3673

The underlay group's preoperative mean ABG was 25.08 ± 4.07 dB, whereas the interlay group's was 26.27 ± 4.03 dB (p=0.254), indicating no discernible baseline difference. The mean ABG decreased to 15.95 ± 4.03 dB in the underlay group and 11.79 ± 3.70 dB in the interlay group at 12 weeks after surgery; this difference was statistically significant (p<0.001). The interlay group's mean hearing gain was significantly higher than the underlay group's (p<0.001) (Table 2).

Table 2: Comparison of Functional Hearing Outcomes Between Underlay and Interlay Tympanoplasty Techniques (n = 62)

Variables	Underlay Technique (Group A)	Interlay Technique (Group B)	Test Statistic (t-value)	Effect Size (MD) [95% CI]	p-value
Preoperative air–bone gap (ABG, dB)	25.08 ± 4.07	26.27 ± 4.03	−1.152	−1.19 [−3.24, 0.87]	0.254
Postoperative air–bone gap (ABG, dB) at 12 weeks	15.95 ± 4.03	11.79 ± 3.70	4.234	4.16 [2.19, 6.12]	<0.001*
Mean hearing gain (Pre–Post ABG, dB)	9.14 ± 3.12	14.48 ± 4.48	−5.420	−5.34 [−7.32, −3.37]	<0.001*

ABG = air–bone gap (dB); dB=decibel; MD = mean difference; CI=confidence interval. An independent samples t-test was used for between-group comparisons

At 12-week follow-up, successful graft uptake (intact tympanic membrane) was observed in 26 (86.7%) patients of the underlay group and 30 (93.8%) patients of the interlay group (p=0.346) (Figure 2).

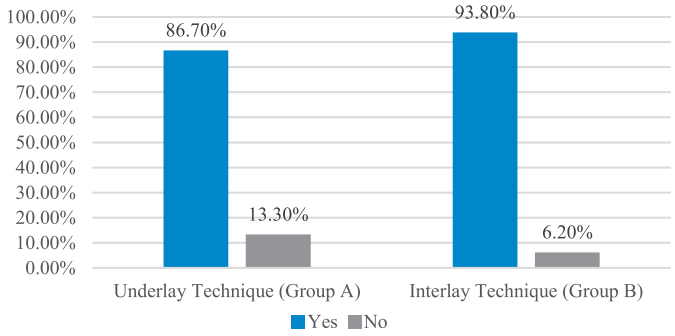


Figure 2: Comparison of Graft Uptake at 12 Weeks Between Underlay and Interlay Tympanoplasty Techniques (p=0.346)

Postoperative infection or otorrhea was observed in 4 (13.3%) patients in the underlay group compared with 2 (6.3%) in the interlay group (p=0.346). Graft lateralization occurred in 2 (6.7%) cases in the underlay group (p=0.138). Similarly, graft medialization was seen in 2 (6.7%) patients in the underlay group (p=0.138). Residual perforation at 12 weeks was detected in 4 (13.3%) of underlay and 2 (6.3%) of interlay cases (p = 0.346) (Table 3).

Table 3: Comparison of Postoperative Anatomical Outcomes and Complications Between Underlay and Interlay Tympanoplasty Techniques (n=62)

Variable	Underlay Technique (Group A)	Interlay Technique (Group B)	p-value
Postoperative infection/otorrhea	4 (13.3%)	2 (6.3%)	0.346
Graft lateralization	2 (6.7%)	0 (0.0%)	0.138
Graft medialization	2 (6.7%)	0 (0.0%)	0.138
Residual perforation at 12 weeks	4 (13.3%)	2 (6.3%)	0.346

Values are presented as n (%). Categorical variables were compared using Pearson's chi-square test

DISCUSSION

This study assessed the results of interlay and underlay tympanoplasty postoperatively in patients with chronic otitis media. Both techniques proved to have positive postoperative results; however, interlay tympanoplasty has shown better functional hearing outcomes with comparable success in anatomical outcomes. Baseline characteristics were statistically similar and confirmed that differences in postoperative course reflected the procedure instead of the patient. The sex ratio was slightly skewed towards females, which was in agreement with Sharma *et al.* and Huq *et al.* which was 48 and 55 percent female, respectively [12, 14]. Ear laterality (right ear 60-62.5%) trends were similar and were also verified by Rajneesh *et al.* and Sharma et al. who demonstrated a slight right ear dominance (55%) [12, 15]. Disease duration was also comparable between the groups (p=0.456), contrasting with earlier literature where average symptom duration before intervention had been documented between 12-18 months [16]. These similar baseline characteristics confirm the demographic similarities between groups and fulfill CONSORT criteria for adequately balanced random allocation. The interlay technique showed a greater improvement in hearing thresholds compared to the underlay method. The mean preoperative ABG values (p=0.254) were statistically similar, certifying a uniform baseline distribution. Postoperatively, interlay tympanoplasty attained a mean ABG decrease of approximately 14.5dB, equated with 9.1dB in the underlay group (p<0.001). Analogous outcomes were found by Sharma *et al.* and Sharif Alam *et al.* where interlay tympanoplasty produced mean hearing gains of 12.0dB versus 8.7 dB and 12.0dB versus 8.7 dB, respectively (p<0.001) [11, 12]. Rajneesh *et al.* noted a 15.05dB mean improvement with interlay compared to 10.84dB with underlay (p< 0.001), mirroring the present study findings [15]. Similarly, Fatouha *et al.* documented postoperative ABG values of 9.2 ± 1.6 dB (interlay) versus 10.5 ± 4.6 dB (underlay) with a significant functional advantage for interlay (p≤0.05) [17]. Takahashi *et al.* noted a postoperative

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DOI: https://doi.org/10.54393/pjhs.v7i9.3673

mean ABG of 6.8 dB for interlay versus 10.1 dB for underlay ($p<0.01$), confirming greater hearing restoration with interlay [18]. In this study, 93.8% of interlay cases achieved ABG closure ≤20dB, a percentage comparable to the 88% closure rate reported by Sajitha & Naveen Kumar and 96% success documented by Sharma *et al.* [12, 16]. The superiority of interlay tympanoplasty in functional outcomes can be attributed to optimal graft positioning between fibrous and mucosal layers, preserving ossicular membrane coupling and avoiding middle ear adhesions that may hinder vibratory transmission. The anatomical success rate in this study was high in both groups, with intact graft uptake noted in 93.8% of interlay and 86.7% of underlay patients, the difference being statistically insignificant. These findings are comparable with those of Sharif *et al.* and Sharma *et al.* who reported graft uptake rates of 96% and 94%, respectively, for interlay and 90% for underlay techniques [11, 12]. Similarly, Rajneesh *et al.* found 94.5% success for interlay versus 89.1% for underlay [15]. The present graft success also aligns with the 92.6% (underlay) and 96.2% (interlay) rates noted by Fatouha *et al.* and 90% overall success documented by El-Feky *et al.* [17, 19]. In contrast, the inlay approach evaluated by Hassan *et al.* confirmed lower success, highlighting that interlay and underlay grafts maintain higher anatomical stability [20]. Complication rates in the current study were low. Postoperative infection or otorrhea happened in 13.3% of underlay versus 6.3% of interlay patients ($p=0.346$). Graft lateralization and medialization were seen only in 6.7% of underlay cases. Residual perforation was noted in 13.3% versus 6.3%, respectively. Analogous patterns were noted by Sajitha and Naveen Kumar, who documented three graft failures because of postoperative upper respiratory infection, and by El-Feky *et al.* where infection accounted for all failures [16, 19].

The randomized controlled trial design, standardized inclusion criteria, and consistent surgical procedure performed by the experienced otologic surgeon are the strengths of the current study. The baseline demographic and clinical characteristics were similar between the interlay and underlay groups, which confirmed validity in this comparison. However, such findings are limited by the small sample size and short follow-up duration, which may not capture long-term hearing stability or late graft failures. External validity to different surgeons and circumstances may therefore be limited, and operator-related bias cannot be excluded, as all procedures were done by a single surgeon. Formal allocation concealment was not implemented, which may introduce selection bias despite random assignment and balanced baseline characteristics. Future research should include larger, multicenter randomized trials with extended follow-up and subgroup analyses.

CONCLUSIONS

The present study concludes that interlay tympanoplasty achieved superior short-term functional outcomes, demonstrated by greater air–bone gap closure and hearing gain at 12 weeks, compared with the underlay technique. Anatomical success remained comparable between techniques, with high graft uptake rates and low complication frequency. A longer follow-up is necessary to verify that these results are durable.

Authors' Contribution

Conceptualization: SL
Methodology: MI, SL
Formal analysis: MI, RA, SL, HAI, MK
Writing and Drafting: MI, RA, SL, HAI, MZA, MK
Review and Editing: MI, RA, SL, HAI, MZA, MK

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflict of Interest

All the authors declare no conflict of interest.

Source of Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

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