

Audiological Outcome in Underlay Versus Interlay Type 1 Tympanoplasty

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ABSTRACT

Background and objective: Type I Chronic Otitis Media (COM) with permanent tympanic membrane perforation is a major cause of conductive hearing loss, particularly in low- and middle-income countries. This prospective comparative study evaluated the anatomical (graft success) and audiological (air-bone gap closure) outcomes of underlay versus interlay techniques using temporalis fascia graft.

Methods: This prospective comparative study was conducted between January 2023 and January 2025 at a tertiary-care hospital in Northern India. Forty-six patients with mucosal COM and large central or subtotal tympanic membrane perforations were randomly allocated to undergo either interlay (n=23) or underlay (n=23) type I tympanoplasty. Preoperative assessment included otoscopic examination and pure-tone audiometry. Patients were followed for three months to evaluate graft integrity and postoperative hearing. The primary outcome was improvement in the air-bone gap (ABG), while graft uptake served as the secondary outcome. Statistical analysis was performed using appropriate parametric and non-parametric tests, with a significance level of $p < 0.05$.

Results: Successful graft uptake was achieved in 91.3% of patients in the interlay

group and 100% in the underlay group, without a statistically significant difference ($p=0.473$). Both techniques resulted in significant postoperative hearing improvement. Mean ABG improvement was significantly greater in the underlay group than in the interlay group (24.7 ± 4.7 dB vs. 11.3 ± 8.7 dB; $p < 0.001$). No postoperative infections or major complications were observed in either group.

Conclusion: Both underlay and interlay type I tympanoplasty are safe and effective techniques for repairing tympanic membrane perforations in chronic otitis media. Although both achieved excellent anatomical outcomes, the underlay technique produced significantly greater audiological improvement. Larger randomized studies with longer follow-up are needed to confirm these findings and evaluate long-term functional outcomes.

Keywords: Tympanoplasty; Underlay; Interlay; Chronic Otitis Media; Air-Bone Gap; Temporalis Fascia; Graft Success

INTRODUCTION

Chronic Otitis Media (COM) is a long-standing inflammatory disorder of the middle ear and mastoid, typically presenting with recurrent ear discharge (otorrhea) and permanent tympanic membrane perforation. Globally, COM affects roughly 297 million people, and 85% of these cases occur in

low- and middle-income nations [1]. In India, the overall prevalence is 5.2%, with community surveys reporting 16 per 1,000 in urban and 46 per 1,000 in rural populations [2]. Such perforations produce conductive hearing loss that can vary from mild to severe and often impact quality of life and employment [1].

The evolution of tympanoplasty techniques has progressed from the early descriptions of reconstructive procedures to modern underlay, overlay, and interlay approaches designed to optimize graft uptake and hearing restoration [3]. The underlay technique, first detailed by Shea in 1957 [6], remains the mainstay in many centres. The graft, usually temporalis fascia, is placed medial to the annulus and beneath the residual tympanic membrane mucosa [7,8]. This position prevents entrapment of squamous epithelium in the middle ear. Failures typically result from poor anchoring, which allows medial graft displacement, or from inadequate anterior support and vascularisation.

The interlay technique was introduced by Komune in Japan in 1992 [10]. The graft is placed between the fibrous and mucosal layers of the residual membrane, creating a “sandwich” construct [10]. This arrangement accelerates epithelialisation and yields higher healing rates with improved auditory outcomes [7]. Because the middle-ear space is preserved, medialisation and lateralisation are virtually absent. Complications are uncommon but can include graft rejection or partial necrosis of the tympanomeatal flap.

The aim of this study was to compare the success rates of underlay and interlay tympanoplasty techniques using the temporalis fascia graft in patients with chronic suppurative otitis media.

MATERIALS AND METHODS

A randomized prospective comparative study was conducted among patients who underwent interlay or underlay tympanoplasty after obtaining written informed consent. The study was performed

between January 2023 and January 2025 in the Department of Otorhinolaryngology at a tertiary-care hospital in Northern India. Ethical approval was done by the committee (No. HIMSR/IEC/00236/2024). 46 Patients aged 18–47 years with mucosal COM and fulfilling the inclusion criteria were enrolled. Eligible patients presented with large central and subtotal perforations, mild-to-moderate conductive hearing loss, a dry ear for at least one month, no active ENT infection, and preserved cochlear function. Patients with cholesteatoma, sensorineural hearing loss, ossicular chain disorders, or previous revision surgery were excluded. Preoperative evaluation included a detailed medical history, clinical examination, pure-tone audiometry at 500, 1000, 2000, and 4000 Hz, otoendoscopy, and X-ray mastoid (Schuller’s view). A total of 46 ears were operated: 23 using the interlay technique and 23 using the underlay technique. Patients were selected regardless of sex, cause of perforation, or side. The tympanic membrane was dry at the time of surgery in all cases.

Surgical Technique

All cases were performed under general anaesthesia via a postaural approach by a team of two surgeons.

In the underlay technique, under strict aseptic conditions, the operative field was prepared and draped. Local infiltration was administered in the postauricular region using Plester’s technique. Wilde’s incision was given and a temporalis fascia graft was harvested. A T-shaped musculoperiosteal incision was made and the flap was elevated. A posterior meatotomy was performed, and the margins of the perforation were freshened. (**Figure 1**) The tympanomeatal flap was elevated 180°, the middle ear was inspected, and the condition of the mucosa and ossicular chain was documented. (**Figure 2**) The temporalis fascia graft was placed lateral to the handle of the malleus. (**Figure 3**) The graft was supported by absorbable material such as gelfoam and carefully tucked on all sides.

The tympanomeatal flap was then repositioned.



Figure 1: Surgical photo of small perforation being operated following posterior meatotomy

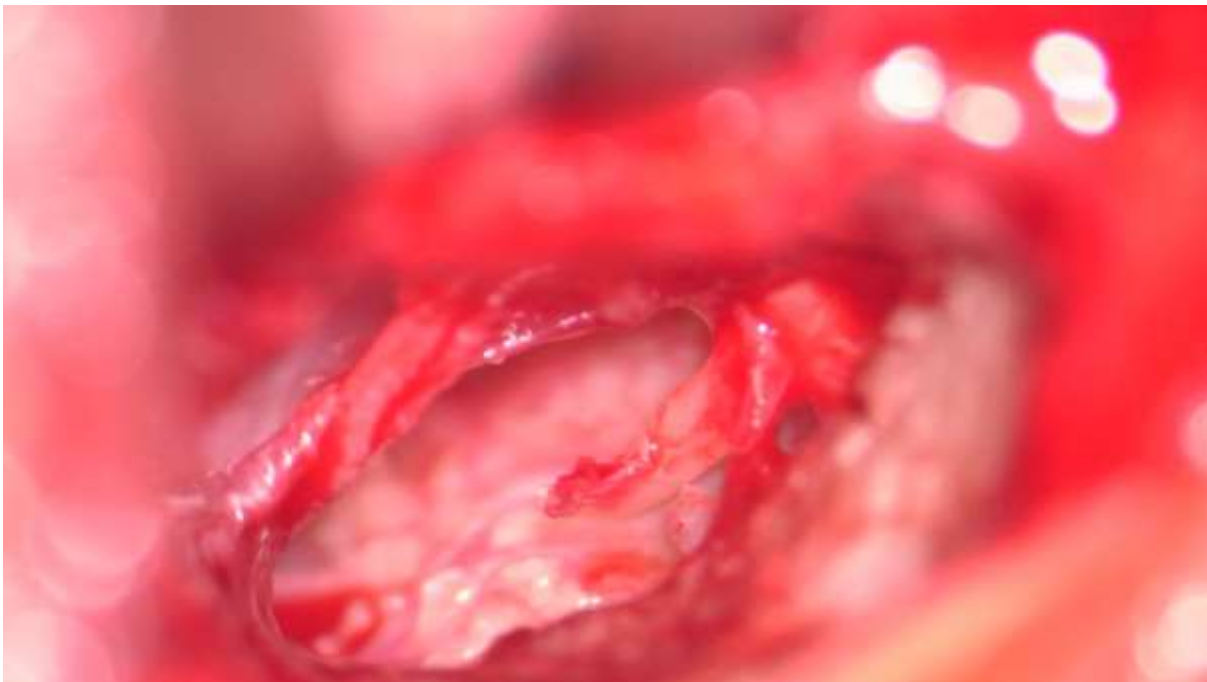


Figure 2: Intraoperative image showing middle ear mucosa and ossicles



Figure 3: Intraoperative picture after underlay graft placement

In the interlay technique, the steps were the same except that the tympanomeatal flap was elevated 360°. The temporalis fascia graft was placed between the fibroepithelial and mucosal layers of the tympanic membrane remnant, carefully tucked on all sides, and the tympanomeatal flap was repositioned.

Both interlay and underlay tympanoplasties were carried out under microscopic visualisation. Immediately following surgery, patients were monitored in the recovery area and received prescribed analgesics and antibiotics. Follow-up visits were scheduled at 1 week, 1 month, 3 months, and 6 months postoperatively. At each visit, otoscopic inspection was performed. A postoperative audiogram was obtained at the third month. The air–bone gap (ABG) was determined by subtracting the bone-conduction pure-tone average from the air-conduction average at 0.5, 1, and 2 kHz. ABG improvement was defined as the difference between the preoperative and postoperative ABG at final follow-up. Complications, including infection, graft lateralisation, and any other adverse events, were systematically documented.

Statistical Analysis

A statistical analysis plan was developed a priori to rigorously evaluate and compare functional hearing outcomes and graft success rates. All analyses were conducted using a two-tailed significance level of $\alpha = 0.05$, with 95% confidence intervals reported where appropriate. An intention-to-treat framework was employed. Statistical assumptions were assessed, and robust non-parametric alternatives were used where necessary. Raw data were entered into a secure database with double data entry and cross-verification. The primary outcome was the change in air–bone gap from preoperative baseline to three months postoperatively, analysed using independent samples t-tests or Mann-Whitney U tests as appropriate, with Cohen's d effect sizes. Analysis of covariance was performed with preoperative ABG as the covariate. Secondary outcomes included graft success at three months (binary), analysed using chi-square or Fisher's exact tests. Normality was assessed with Shapiro-Wilk tests and quantile-quantile plots. All statistical analyses were performed using IBM SPSS Statistics v23.

RESULTS

Study Population and Baseline

Demographics

A prospective comparative analysis was conducted on 46 consecutive patients with chronic suppurative otitis media who underwent tympanoplasty. The cohort was stratified into interlay (n = 23) and underlay (n = 23) groups. Valid ABG measurements were obtained in 21 interlay and 23 underlay patients at three-month follow-up. The interlay group comprised 19 females (82.6%) and 4 males (17.4%) with mean age 30.9 ± 11.1 years (range 18–55). The underlay group comprised 15 females (65.2%) and 8 males (34.8%) with mean age 29.0 ± 9.4 years (range 19–50). There were no statistically significant differences between groups in age ($t = 0.602$, $p = 0.550$) or sex distribution ($\chi^2 = 1.02$, $p = 0.314$). Baseline hearing profiles differed significantly. The interlay group presented with mild-to-moderate conductive hearing loss (preoperative ABG: 21.0 ± 9.6 dB, median 16 dB, IQR 14–30 dB), whereas the underlay group demonstrated moderate-to-severe impairment (preoperative ABG: 39.5 ± 7.0 dB, median 38 dB, IQR 34–47 dB). This 18.3 dB difference was highly significant ($t = -7.30$, $p < 0.001$, Cohen's $d = -2.24$).

Primary Outcome: Air-Bone Gap

Improvement

Interlay Technique

The interlay group demonstrated a mean ABG improvement of 11.3 ± 8.7 dB (median 8 dB, IQR 5–20 dB). Within-group paired t-test confirmed highly significant improvement ($t = 5.79$, $p < 0.001$) with

Cohen's $d = 1.52$ (very large effect). This represented recovery of 53.6% of the preoperative ABG deficit.

Underlay Technique

The underlay group achieved substantially greater hearing improvement with a mean ABG closure of 24.7 ± 4.7 dB (median 26 dB, IQR 23–28 dB). Within-group paired t-test yielded exceptional significance ($t = 24.63$, $p < 0.001$) with Cohen's $d = 3.92$ (very large effect). The underlay group recovered 62.7% of the baseline ABG.

Between-Group Comparison

Direct comparison revealed marked superiority of the underlay technique, with 13.4 dB greater mean improvement ($p < 0.001$). Independent samples t-test yielded $t = -6.26$, $p < 0.001$, with very large effect size (Cohen's $d = -1.91$). Mann-Whitney U test confirmed the finding ($U = 41.5$, $p < 0.001$). The underlay superiority occurred despite the interlay group having 18.3 dB better baseline hearing.

Secondary Outcome: Graft Success and Safety

Graft integration success at three months was 91.3% (21/23) for interlay and 100% (23/23) for underlay. The difference did not reach statistical significance ($\chi^2 = 0.52$, $p = 0.473$; Fisher exact $p = 0.489$). Both groups maintained 100% graft uptake through 10-day and 1-month assessments. Late graft failures were limited to the interlay group at three months. No postoperative infections occurred in either cohort (0/46). Both techniques demonstrated excellent safety profiles.

Table 1. Baseline Characteristics of Patients Undergoing INTERLAY vs UNDERLAY Tympanoplasty

Characteristic	INTERLAY (n = 23)	UNDERLAY (n = 23)	p-value
Age (years), mean $\pm$ SD	30.9 ± 11.1	29.0 ± 9.4	0.550
Sex (Male: Female), n (%)	4 (17%): 19 (83%)	8 (35%): 15 (65%)	0.314
Pre-operative ABG (dB)			
Mean $\pm$ SD	21.0 ± 9.6	39.5 ± 7.0	<0.001*
Median (IQR)	16 (14–30)	38 (34–47)	–
Graft success at 3 months, n (%)	21/23 (91%)	23/23 (100%)	0.473†

*Independent samples t-test. †Fisher's exact test.

Table 2. Hearing Outcomes and Comparative Statistical Analysis Between INTERLAY and UNDERLAY Techniques

Outcome	INTERLAY (n = 21)	UNDERLAY (n = 23)	p-value / Statistic
Post-operative ABG (dB)			
Mean $\pm$ SD	9.8 $\pm$ 4.8	14.7 $\pm$ 5.8	–
Median (IQR)	10 (5–13)	15 (10–20)	–
ABG improvement (dB)			
Mean $\pm$ SD	11.3 $\pm$ 8.7	24.7 $\pm$ 4.7	<0.001*
Median (IQR)	8 (5–20)	26 (23–28)	–
Within-group analysis (Pre- vs Post-op)			
Paired t-test, t (p-value)	5.79 (<0.001)	24.63 (<0.001)	–
Effect size (Cohen's d)	1.52 (large)	3.92 (very large)	–
Between-group comparison (ABG improvement)			
Unpaired t-test (t)	–	–6.26	<0.001
Mann-Whitney U test	–	p = 0.000003	<0.001
Effect size (Cohen's d)	–	–1.91 (very large)	–

DISCUSSION

Chronic otitis media remains a prevalent global health issue, particularly in developing countries, with significant implications for hearing and quality of life [1,2]. The management of tympanic membrane perforations through tympanoplasty has evolved, with underlay, overlay, and interlay techniques developed to optimise anatomical and functional outcomes [6,9,10,16].

The present study demonstrated that both underlay and interlay tympanoplasty are effective techniques with high graft uptake rates (100% and 91.3%, respectively) and comparable postoperative hearing outcomes. These findings are consistent with prior research reporting graft success rates of 85–95% for Type I tympanoplasty [7]. The slightly higher anatomical success in the underlay group aligns with results from Sergi et al. and Gersdorff et al., who found superior graft stability with the underlay approach [6,12,16].

The underlay technique remains the most commonly practised due to its technical simplicity and consistent anatomical results [5,6]. However, limitations include potential for medialisation and restricted visibility of the anterior margin [4,11,16]. The interlay technique offers a “sandwich” placement that promotes epithelial migration and reduces medial displacement [10,15]. Studies by Mandal et al. and Darmawan

have shown excellent healing rates and favourable audiological gains with interlay, particularly in large central perforations [9,10].

These findings are also consistent with studies by Sinha et al., Nemade et al., and Shishegar et al., which reported favourable hearing improvement and high graft uptake following underlay tympanoplasty using different surgical approaches [11,13,16]. In the current study, both groups demonstrated significant postoperative ABG closure, with mean postoperative ABG values of approximately 14.7 dB and 9.8–15.2 dB for underlay and interlay, respectively. This similarity reinforces that successful hearing restoration depends more on appropriate graft placement and ossicular integrity than on the specific grafting plane [6,10,16].

Recent advancements, such as platelet-rich fibrin (PRF) as an adjunct to conventional underlay tympanoplasty, have been associated with enhanced graft uptake and early healing [15]. While not evaluated here, biologically augmented techniques represent promising future directions. From a clinical perspective, surgical technique selection should be individualised according to perforation size, middle-ear status, and intraoperative findings. The underlay technique continues to offer a marginally higher anatomical success rate, whereas the interlay approach provides comparable hearing improvement with the advantage of

maintaining middle-ear space [16]. Larger prospective studies with long-term follow-up are warranted.

CONCLUSION

In this prospective comparative study, both underlay and interlay type I tympanoplasty using temporalis fascia achieved high graft uptake rates and significant postoperative hearing improvement in patients with chronic otitis media with central or subtotal tympanic membrane perforations. Although both techniques were clinically effective and demonstrated favourable anatomical outcomes, the underlay technique was associated with significantly greater improvement in air–bone gap closure, while graft success rates were comparable between the two groups.

These findings suggest that both surgical techniques are reliable options for type I tympanoplasty, with the choice of procedure guided by perforation characteristics, middle-ear status, surgeon expertise, and intraoperative considerations rather than a single universally superior approach. Given the relatively small sample size, short follow-up period, and baseline differences in preoperative hearing between the study groups, the results should be interpreted with appropriate caution. Larger, adequately powered randomized controlled trials with longer follow-up are warranted to validate these findings and to establish the long-term anatomical and audiological outcomes of underlay and interlay tympanoplasty.

Declaration by Authors

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