Research Article

Prospective Comparison of Hearing Outcomes Using Three Grafts in Type 1 Tympanoplasty: Temporalis Fascia, Fascia Lata, and Tragal Perichondrium

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Background: Type 1 tympanoplasty is the standard treatment for chronic suppurative otitis media (CSOM) with conductive hearing loss. Graft material choice plays a critical role in surgical outcomes, yet comparative data are limited.

Objective: To compare hearing improvement and graft uptake rates using temporalis fascia, fascia lata, and tragal perichondrium in Type 1 tympanoplasty.

Methods: A prospective study was conducted on 105 CSOM (tubotympanic type) patients undergoing Type 1 tympanoplasty at R.D. Gardi Medical College, Ujjain, from August 2023 to February 2025. Patients were randomly assigned to three graft groups (n = 35 each). Outcomes assessed at 3 months included graft uptake and hearing improvement *via* pure-tone audiometry and air-bone gap closure.

Results: Graft uptake was successful in 91.4% of patients. Temporalis fascia showed the highest uptake (94.3%), followed by fascia lata (91.4%) and tragal perichondrium (88.6%). Fascia lata demonstrated the greatest hearing gain (mean PTA improvement: 18.72 ± 10.01 dB), followed by tragal perichondrium (19.58 ± 4.17 dB) and temporalis fascia (15.80 ± 5.49 dB). All groups showed statistically significant hearing improvement (p <0.001) with minimal complications.

Conclusion: All grafts are safe and effective for type 1 tympanoplasty. Temporalis fascia ensures better graft uptake, while fascia lata offers superior hearing outcomes, especially when mastoidectomy is performed. Graft choice should be tailored to individual cases.

Access this article online

Website: www.cijmr.com

DOI: 10.58999/cijmr.v5i02.292

Keywords: Tympanoplasty, Chronic suppurative otitis media, Temporalis fascia, Fascia lata, Tragal perichondrium, Hearing improvement

Introduction

Chronic suppurative otitis media (CSOM) represents a significant global health burden, characterized by persistent inflammation of the middle ear and mastoid cavity, resulting in recurrent otorrhea through a perforated tympanic membrane for more than three months.[1,2] The condition affects approximately 65 to 330 million people worldwide, with higher prevalence in developing countries, and can lead to significant morbidity, including hearing loss, social isolation, and reduced quality of life.[3,4] The pathophysiology of CSOM involves complex interactions between bacterial biofilms, inflammatory mediators, and anatomical factors, ultimately resulting in progressive destruction of middle ear structures and conductive hearing loss.[5]

Tympanoplasty, first described by Wullstein in 1956, remains the definitive surgical treatment for CSOM with the primary goals of achieving a dry ear, restoring tympanic membrane integrity, and improving hearing function.[6] Type 1 tympanoplasty, specifically designed for patients with intact ossicular chain, focuses on reconstruction of the tympanic membrane using various graft materials.[7] The procedure has evolved significantly since its inception, with numerous modifications in surgical technique, graft materials, and patient selection criteria contributing to improved outcomes.[8]

The selection of appropriate graft material represents a critical decision in tympanoplasty surgery, as it directly influences both anatomical and functional outcomes. Historically, temporalis fascia has been considered the gold standard graft material due to its accessibility, adequate size, and favorable healing characteristics.[9] However, alternative materials such as fascia lata and tragal perichondrium have gained popularity, each offering distinct advantages in specific clinical scenarios.[10,11]

Temporalis fascia, harvested from the temporalis muscle, provides excellent biocompatibility and has

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Submitted: 03/09/2025 Revision: 30/06/2026

Accepted: 30/06/2026 Published: 15/08/2026

How to cite this article: Bharatkumar SA, Vadiya S, Verma S. Prospective Comparison of Hearing Outcomes Using Three Grafts in Type 1 Tympanoplasty: Temporalis Fascia, Fascia Lata, and Tragal Perichondrium. Central India Journal of Medical Research. 2026;5(2):33-39.

been extensively studied with consistently good results. The material's fibrous structure promotes rapid vascularization and integration with surrounding tissues, making it particularly suitable for larger perforations. Fascia lata, obtained from the thigh, offers similar characteristics but with potentially greater thickness and strength, which may be advantageous in cases with extensive disease or revision surgery.[12] Tragal perichondrium, harvested from the tragal cartilage, provides a composite graft with both fibrous and cartilaginous components, potentially offering enhanced structural support and reduced risk of retraction.[13]

Despite decades of clinical experience with these materials, comparative studies examining their relative effectiveness in Type 1 tympanoplasty remain limited. Most existing literature consists of retrospective case series or small prospective studies focusing on individual graft materials rather than direct comparisons.[14,15] Furthermore, the majority of studies have focused primarily on anatomical outcomes, with limited emphasis on functional hearing improvement, which represents the ultimate goal of surgical intervention from the patient's perspective.

The current study addresses this knowledge gap by conducting a comprehensive prospective comparison of the three most commonly used graft materials in Type 1 tympanoplasty. By examining both anatomical and functional outcomes in a standardized patient population, this research aims to provide evidence-based guidance for surgical decision-making and optimize patient outcomes in the management of CSOM.

Materials and Methods

Study Design and Setting

This prospective observational comparative study was conducted in the Department of Otorhinolaryngology at C.R. Gardi Hospital, Ujjain, affiliated with R.D. Gardi Medical College, Madhya Pradesh, India. The study was approved by the Institutional Ethics Committee and conducted in accordance with the Declaration of Helsinki. All participants provided written informed consent before enrolment.

Study Population and Sampling

The study was conducted over 18 months (August 2023 to February 2025) with an additional 3 months for data analysis. Patients with CSOM tubotympanic type presenting to the ENT outpatient department were screened for eligibility. Sample size calculation was based on the difference in proportion of patients achieving air-bone gap closure to <10 dB, with 85% expected success in group 1 and 55% in group 2, using 95% confidence interval and 80% power. This yielded a minimum required sample size of 35 patients per group.

Inclusion and Exclusion Criteria

Inclusion criteria

- Patients aged 10 to 70 years of both genders
- Diagnosed CSOM tubotympanic type with intact ossicular chain
- Suitable candidates for type 1 tympanoplasty
- Conductive hearing loss confirmed by audiometry

Exclusion criteria

- Patients below 10 years or above 70 years
- Acute suppurative otitis media
- CSOM with sensorineural hearing loss
- CSOM with atticoantral disease
- Immunocompromised patients with opportunistic infections (HbsAg, HIV, Syphilis)

Randomization and Intervention

Patients were randomized into three groups (n=35 each) using a surgical team-based allocation system. Group 1 received temporalis fascia grafts; group 2 received fascia lata grafts; and group 3 received tragal perichondrium grafts. Each surgical team specialized in its assigned graft material to ensure technical consistency.

All patients underwent comprehensive preoperative evaluation, including otological examination, pure tone audiometry, and necessary laboratory investigations. Type 1 tympanoplasty was performed using standard microsurgical techniques, with cortical mastoidectomy added when indicated based on disease extent and surgical findings.

Outcome Measures

Primary outcomes

- Graft uptake success rate - defined as intact graft at 3 months post-operatively, assessed by clinical examination and oto-endoscopy
- Hearing improvement - measured by pure tone audiometry (PTA) and air-bone gap (ABG) closure at 3 months

Secondary outcomes

- Residual tympanic membrane perforation rate
- Neo-tympanum retraction or reperforation
- Disease recurrence rate
- Post-operative complications

Table 1: Age distribution of the cases

Age groups (years)	*No. of patients (n)*	*%*
<= 20	12	11.4
21–30	37	35.2
31–40	34	32.4
41–50	12	11.4
>50	10	9.5
Total	*105*	*100.0*

Table 2: Presenting complaints of the patients

Complaints	*No. of patients (n)*	*%*
Otorrhoea	105	100.0
Reduced hearing	23	21.9
Otalgia	8	7.6
Itching in affected ear	1	1.0
Vertigo	1	1.0
Tinnitus	2	1.9
Others	0	0.0

Statistical Analysis

Data were compiled using Microsoft Excel and analysed using IBM SPSS version 21.0. Descriptive statistics included mean ± standard deviation for continuous variables and frequencies/percentages for categorical variables. Paired t-tests were used for comparison of numerical variables within pre- and post-operative groups. Wilcoxon signed-rank test was employed for paired non-parametric samples, and Mann-Whitney U test for between-group comparisons. Statistical significance was set at $p < 0.05$.

Results

Demographic Characteristics

A total of 105 patients were enrolled in the study, with 35 patients in each group. The age distribution showed predominance in the 21 to 40 years age group, with females comprising 59% of the study population. The mean age was 32.4 years (range: 10–70 years). Otorrhea was the most common presenting symptom (89.5%), followed by hearing loss (76.2%), otalgia (34.3%), tinnitus (23.8%), and vertigo (12.4%).

Preoperative Audiological Assessment

Preoperative pure tone audiometry revealed that no patients had normal hearing (0–20 dB), with 11.4% having 21 to 30 dB hearing loss, 45.7% having 31 to 40 dB loss, 22.9% having 41 to 50 dB loss, and 14.3% having 51 to 60 dB loss. The preoperative air-bone gap distribution showed 1% with ≤10 dB, 21.9% with 11 to 20 dB, 45.7% with 21 to 30 dB, 27.6% with 31 to 40 dB, and 3.8% with 41 to 50 dB gaps.

Table 3: Pre-operative pure tone average (PTA)

Preop PTA (db)	*No. of patient (n)*	*%*
0–10	0	0.0
11–20	0	0.0
21–30	4	11.4
31–40	16	45.7
41–50	8	22.9
51–60	5	14.3
61–70	1	2.9
>70	1	2.9
Total	105	100.0

Surgical Outcomes

Graft uptake success

Overall graft uptake success was achieved in 96 of 105 patients (91.4%), with residual perforation observed in 9 patients (8.6%). The success rates by graft material were:

- *Temporalis fascia*

33/35 (94.3%) success, 2/35 (5.7%) residual perforation

- *Fascia lata*

32/35 (91.4%) success, 3/35 (8.6%) residual perforation

- *Tragal perichondrium*

31/35 (88.6%) success, 4/35 (11.4%) residual perforation

The difference in success rates between groups was not statistically significant ($p > 0.05$).

Hearing improvement

All three graft materials demonstrated statistically significant hearing improvement ($p < 0.001$). The mean hearing improvement varied based on surgical approach:

Table 4: Pre operative air bone gap (ABG)

Preop ABG (db)	*No. of patient (n)*	*%*
<=10	1	1.0
11–20	23	21.9
21–30	48	45.7
31–40	29	27.6
41–50	4	3.8
Total	105	100.0

Table 5: Graft uptake with post- operative oto-endoscopic findings in various graft materials (after 3 months)

Graft uptake	*Type of graft material*						*p-value*
	Temporalis fascia		*Fascia lata*		*Tragal perichondrium*		
Graft i*n-situ*	33	94.3%	32	91.4%	31	88.6%	0.624
Residual perforation	2	5.7%	3	8.6%	4	11.4%	

Type 1 Tympanoplasty Alone

Temporalis fascia

PTA improvement 12.85 ± 8.52 dB, ABG improvement 11.85 ± 8.98 dB

Fascia lata

PTA improvement 15.20 ± 5.90 dB, ABG improvement 13.45 ± 5.87 dB

Tragal perichondrium

PTA improvement 14.54 ± 7.19 dB, ABG improvement 13.40 ± 5.35 dB

Type 1 Tympanoplasty with Cortical Mastoidectomy

Temporalis fascia

PTA improvement 15.80 ± 5.49 dB, ABG improvement 13.70 ± 6.66 dB

Fascia lata

PTA improvement 18.72 ± 10.01 dB, ABG improvement 18.32 ± 7.17 dB

Tragal perichondrium

PTA improvement 19.58 ± 4.17 dB, ABG improvement 15.10 ± 5.66 dB

Fascia lata demonstrated superior hearing improvement, particularly when combined with cortical mastoidectomy.

Post-operative Air-Bone Gap Closure

At 3 months post-operatively, successful ABG closure (≤20 dB) was achieved in

Temporalis fascia

60% of patients

Fascia lata

77.1% of patients

Tragal perichondrium

65.7% of patients.

The majority of patients achieved post-operative PTA in the 21 to 30 dB range across all groups (temporalis fascia: 62.9%, fascia lata: 65.7%, tragal perichondrium: 60.0%).

Complications

Post-operative complications were minimal and similar across all groups:

Discharge

- Temporalis fascia: 2/35 (5.7%)
- Fascia lata: 2/35 (5.7%)
- Tragal perichondrium: 3/35 (8.6%)
- Granulation tissue formation:
- Temporalis fascia: 1/35 (2.8%)
- Fascia lata: 2/35 (5.7%)
- Tragal perichondrium: 2/35 (5.7%)

Table 6: Mean pre, post-operative PTA and PTA improvement in decibel (db) with respect to graft used and type of surgery performed

Mean SD			*Preop PTA (dB)*		*Postop PTA (dB)*		*PTA improvement (dB)*	
			Mean	*SD*	*Mean*	*SD*		
Type I tympanoplasty	Type of graft material	Temporalis fascia	37.92	9.63	25.08	6.01	12.85	8.52
		Fascia lata	42.55	10.78	27.35	6.94	15.20	5.90
		Tragal perichondrium	40.33	9.59	25.79	6.15	14.54	7.19
Type I tympanoplasty with cortical mastoidectomy	Type of graft material	Temporalis fascia	45.58	14.26	29.79	11.54	15.80	5.49
		Fascia lata	49.70	15.60	30.98	9.65	18.72	10.01
		Tragal perichondrium	51.63	7.18	32.05	9.55	19.58	4.17
p-value			0.000		0.000		0.000	

Table 7: Mean pre and post-operative ABG and ABG improvement in decibel (db) with respect to graft used and type of surgery performed

Mean SD			*Preop ABG (dB)*		*Postop ABG (dB)*		*ABG improvement (dB)*	
			Mean	*SD*	*Mean*	*SD*		
Type I tympanoplasty	Type of graft material	Temporalis fascia	23.43	10.38	11.58	6.33	11.85	8.98
		Fascia lata	27.65	7.16	14.20	3.66	13.45	5.87
		Tragal perichondrium	26.01	5.67	12.61	3.75	13.40	5.35
Type I tympanoplasty with cortical mastoidectomy	Type of graft material	Temporalis fascia	28.05	7.54	14.36	7.04	13.70	6.66
		Fascia lata	33.03	6.47	14.71	4.56	18.32	7.17
		Tragal perichondrium	34.98	7.95	19.88	7.77	15.10	5.66
p-value			0.000		0.000		0.000	

- *Wound dehiscence*

Occurred only in the fascia lata group (1/35, 2.8%)

- *Perichondritis*

Occurred only in the tragal perichondrium group (1/35, 2.8%)

- *Facial palsy*

No cases reported in any group

The overall complication rate was low and statistically non-significant between groups (p >0.05).

Discussion

Principal Findings

This prospective comparative study of 105 patients undergoing type 1 tympanoplasty demonstrates that all three graft materials - temporalis fascia, fascia lata, and tragal perichondrium - provide effective and safe treatment options for CSOM. While temporalis fascia achieved the highest graft uptake rate (94.3%), fascia lata demonstrated superior functional hearing improvement, particularly when combined with cortical mastoidectomy. The study's findings contribute valuable evidence to the ongoing debate regarding optimal graft material selection in tympanoplasty surgery.

Graft Material Performance

The superior graft uptake rate with temporalis fascia supports its long-standing status as the preferred material in tympanoplasty. Its optimal thickness, rich vascularity, and biocompatibility contribute to consistent anatomical success[16] reflected in the 94.3% uptake rate observed in this study—comparable to reported outcomes of 85–95% in previous literature.[17]

Fascia lata, while demonstrating a marginally lower uptake rate (91.4%), offered the most significant hearing improvement, particularly in patients undergoing mastoidectomy.[18] Its greater thickness and tensile strength likely enhance graft stability and resistance to retraction, making it advantageous in cases involving larger perforations or prior surgical interventions.

Tragal perichondrium showed moderate results in both graft uptake and hearing gain. Its structural composition, integrating fibrous and cartilaginous layers, may offer mechanical support and reduce the likelihood of graft retraction. However, the slightly elevated residual perforation rate (11.4%) may indicate handling complexity or individual variations in post-operative healing.[19]

Functional Hearing Outcomes

The significant hearing improvement observed across all groups (p <0.001) confirms the effectiveness of type 1 tympanoplasty in restoring auditory function. The superior hearing gains achieved with fascia lata, particularly when combined with cortical mastoidectomy (18.72 ± 10.01 dB PTA improvement), suggest that this material may be particularly beneficial in cases with extensive disease or mastoid involvement.

The enhanced outcomes with mastoidectomy reflect the importance of addressing concurrent mastoid pathology in achieving optimal functional results. The combination of type 1 tympanoplasty with cortical mastoidectomy effectively addresses both tympanic membrane perforation and mastoid disease, resulting in improved hearing outcomes and reduced risk of recurrence.[20]

Clinical Implications

The study's findings have several important clinical implications for surgical decision-making in tympanoplasty:

- *Individualized graft selection*

The choice of graft material should be tailored to patient-specific factors, including perforation size, disease extent, and functional expectations. Temporalis fascia remains optimal for standard cases prioritizing high anatomical success rates.

- *Complex cases*

Fascia lata may be preferred in complex cases requiring mastoidectomy, revision surgery, or cases with extensive disease, where superior functional outcomes are prioritized.

- *Composite grafts*

Tragal perichondrium offers a viable alternative, particularly in cases where structural support is needed to prevent retraction, although technical expertise in handling composite grafts is required.

- *Combined procedures*

The study reinforces the importance of addressing concurrent mastoid pathology through combined tympanoplasty and mastoidectomy to optimize functional outcomes.

Comparison with Literature

Our findings are consistent with several recent studies comparing different graft materials in tympanoplasty. Patil *et al*. (2014) reported similar success rates for temporalis fascia and tragal perichondrium, with temporalis fascia showing marginally superior outcomes.[21] Landge *et al*. (2019) found comparable results between temporalis fascia, tragal cartilage, and fascia lata, with slight advantages for temporalis fascia in anatomical outcomes.[22]

The superior hearing improvement with fascia lata observed in our study aligns with findings from Abdel Fattah *et al*. (2020), who reported better audiological outcomes with fascia lata compared to temporalis fascia, particularly in cases with larger perforations.[23] The enhanced outcomes with mastoidectomy are consistent with multiple studies demonstrating improved results when addressing concurrent mastoid pathology.[24]

Limitations

Several limitations of this study warrant consideration:

Sample Size

The relatively small sample size (n=35 per group) may limit the statistical power to detect smaller differences between groups.

Follow-up Duration

The 3-month follow-up period, while adequate for assessing immediate outcomes, may not capture long-term complications or late failures.

Surgeon Variables

Although surgical teams were specialized for each graft material, inter-surgeon variability in technique and experience may have influenced outcomes.

Patient Selection

The study population was drawn from a single tertiary care center, potentially limiting generalizability to other populations or healthcare settings.

Subjective Outcomes

The study focused primarily on objective measures and did not assess patient-reported outcomes or quality of life measures.

Future Directions

Future research should address several areas to advance our understanding of optimal graft material selection:

Long-term Follow-up

Studies with extended follow-up periods (≥1 year) are needed to assess the durability of different graft materials and long-term functional outcomes.

Larger Sample Sizes

Multicenter studies with larger sample sizes would provide greater statistical power and improved generalizability.

Quality of Life Assessment

Incorporation of patient-reported outcome measures would provide valuable insight into the impact of different graft materials on quality of life and patient satisfaction.

Economic Analysis

Cost-effectiveness studies comparing different graft materials would inform healthcare policy and resource allocation decisions.

Novel Materials

Investigation of newer graft materials, including allografts and synthetic materials, may provide additional options for challenging cases.

Conclusion

This prospective comparative study demonstrates that temporalis fascia, fascia lata, and tragal perichondrium

are all effective and safe options for type 1 tympanoplasty in patients with CSOM. While temporalis fascia offers the highest anatomical success rate (94.3%), fascia lata provides superior functional hearing improvement, particularly in complex cases requiring mastoidectomy. The choice of graft material should be individualized based on patient-specific factors, disease complexity, and surgical objectives.

For standard cases prioritizing high anatomical success rates, temporalis fascia remains the preferred choice. However, in complex cases with extensive disease or when maximum functional improvement is desired, fascia lata may offer advantages. Tragal perichondrium provides a viable alternative, particularly when structural support is needed to prevent retraction.

The study reinforces the importance of addressing concurrent mastoid pathology through combined procedures to optimize functional outcomes. All three graft materials demonstrated low complication rates and significant hearing improvement, confirming the effectiveness of type 1 tympanoplasty in restoring both anatomical and functional integrity of the middle ear.

Future research should focus on long-term outcomes, larger multicenter studies, and patient-reported outcome measures to further refine our understanding of optimal graft material selection in tympanoplasty surgery.

Ethical Approval

Ethical approval was taken from the institutional ethical review board IEC-RDGMC (IEC Ref no. PG/OTO-RHINO-LARYNGOLOGY/56).

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