

A Prospective Comparative Observational Study of Clinical and Audiological Outcomes of Temporalis Fascia Graft versus Tragal Cartilage Graft in the Repair of Tympanic Membrane Perforations

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How to citation this article: Dr Vitthal D. Kale, Dr Preksha Pandey, Dr Shrinivas S. Chavan, Dr Pravina Gavit, “A Prospective Comparative Observational Study of Clinical and Audiological Outcomes of Temporalis Fascia Graft versus Tragal Cartilage Graft in the Repair of Tympanic Membrane Perforations”, IJMACR– October– 2026, Volume – 9, Issue – 5, P. No. 168 – 176.

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Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: The choice of graft material in Type 1 tympanoplasty remains clinically relevant because temporalis fascia and tragal cartilage may differ in anatomical stability, hearing outcomes and operative characteristics. This study compared clinical, audiological and intraoperative outcomes of temporalis fascia and full-thickness tragal cartilage island grafts.

Objectives: To compare anatomical graft uptake and audiological outcomes between temporalis fascia and tragal cartilage grafts in Type 1 tympanoplasty, and to

evaluate operative duration and intraoperative blood loss during graft harvest.

Methods: This prospective, comparative, observational study included adults aged 18–60 years with central pars tensa perforations secondary to tubotympanic chronic suppurative otitis media. Twenty-nine patients underwent Type 1 tympanoplasty using autologous temporalis fascia and 29 using a full-thickness tragal cartilage island graft with attached lateral perichondrium. Surgery was performed under general anaesthesia using a postauricular microscopic approach

and standardized underlay technique. Primary outcomes were graft uptake and audiological outcome at 2 months. Secondary outcomes were operative duration and graft-harvest blood loss. Statistical analysis was performed using IBM SPSS Statistics version 26.

Results: At 2 months, graft uptake was 79.3% (23/29) with fascia and 93.1% (27/29) with cartilage, an absolute difference of 13.8 percentage points (95% CI -3.6 to +31.2; Fisher exact $p=0.253$). Mean ABG closure was 13.6 ± 6.9 dB with fascia and 16.0 ± 6.7 dB with cartilage ($p=0.182$). Both groups showed significant within-group ABG improvement ($p<0.001$). Cartilage required longer surgery (91.8 ± 12.6 vs 84.0 ± 14.2 min; $p=0.031$) but had lower graft-harvest blood loss (7.8 ± 3.9 vs 13.1 ± 3.3 mL; $p<0.001$). No major complications occurred.

Conclusions: Both graft materials provided satisfactory anatomical and audiological outcomes. Cartilage showed a numerically higher graft uptake rate, although the difference was not statistically significant, and produced comparable hearing improvement. Cartilage required modestly longer operative time but significantly less harvest blood loss. The findings support selective and broader use of cartilage, particularly in higher-risk perforations, while temporalis fascia remains a valid option for primary tympanoplasty.

Keywords: Tympanoplasty; Temporalis Fascia, Tragal Cartilage, Graft Uptake, Air-Bone Gap, Chronic Suppurative Otitis Media, Hearing Outcome.

Introduction

Type 1 tympanoplasty is a standard reconstructive procedure for chronic central tympanic membrane perforations associated with conductive hearing loss. Autologous temporalis fascia has long been widely used because of its availability, pliability and favourable handling characteristics. Cartilage grafts provide greater

structural rigidity and resistance to deformation and have therefore been increasingly used, particularly when anatomical conditions are considered less favourable for fascia.¹⁻⁷

Comparative studies and systematic reviews have generally suggested an anatomical advantage for cartilage, whereas audiological outcomes have been more variable and often broadly comparable between materials. Differences in perforation size, middle-ear status, Eustachian tube function, cartilage technique and follow-up duration may account for the heterogeneity of published findings.⁸⁻¹²

In the Indian setting, long-standing disease and larger perforations are commonly encountered, making locally derived comparative evidence relevant to surgical decision-making. The present study therefore compared autologous temporalis fascia with a full-thickness tragal cartilage island graft in adults undergoing Type 1 tympanoplasty, assessing anatomical graft uptake, hearing outcomes, operative duration and graft-harvest blood loss.

Materials and Methods

Study Design and Setting

This was a prospective, comparative, observational study conducted over 12 months in the Department of Otorhinolaryngology and Head and Neck Surgery at a tertiary care teaching hospital in Mumbai. The study was undertaken after Institutional Ethics Committee approval and in accordance with the Declaration of Helsinki, Indian Council of Medical Research ethical guidance and Good Clinical Practice principles.

Participants

Adults aged 18–60 years with tubotympanic (mucosal) chronic suppurative otitis media, a central pars tensa tympanic membrane perforation documented on

otoscopic/otoendoscopic examination, and conductive hearing loss documented by pure-tone audiometry were eligible. Patients with atticofurcal disease, significant sensorineural hearing loss, medical comorbidities precluding general anaesthesia, or those declining participation were excluded.

Sample Size and Allocation

A sample size of 29 patients per group was calculated a priori using expected graft uptake rates of 68% for fascia and 95% for cartilage from a comparable 2023 Indian study, with 80% power and a two-sided α of 0.05. Allocation was determined by the operating surgeon as part of routine clinical decision-making; the study was therefore observational rather than randomized.

Surgical Technique

All procedures were performed under general anaesthesia through a postauricular microscopic approach using a standardized underlay technique. Group A received an autologous temporalis fascia graft. Group B received a full-thickness tragal cartilage island graft with attached lateral perichondrium. The tragal incision preserved a peripheral cartilage rim to maintain tragal contour. The graft was fashioned appropriately and placed medially with Gelfoam support.

Outcome Measures

The primary anatomical outcome was successful graft uptake at the 2-month visit, assessed by otomicroscopy and otoendoscopy. Audiological outcomes were assessed by pure-tone audiometry, with the air–bone gap calculated as the mean of thresholds at 500, 1000, 2000 and 3000 Hz. Secondary outcomes were total operative duration and intraoperative blood loss during graft harvest. Bone-conduction thresholds were monitored for evidence of sensorineural deterioration.

Statistical Analysis

Analysis was performed using IBM SPSS Statistics version 26. Continuous variables were compared using the unpaired Student t-test or Mann–Whitney U test as appropriate. Categorical variables were compared using Pearson chi-square or Fisher exact testing. Preoperative and postoperative ABG within each group were compared using the paired Student t-test. Statistical significance was set at $\alpha=0.05$. A pre-specified descriptive subgroup analysis stratified perforations into small/medium (<50% of pars tensa) and large/subtotal ($\geq 50\%$).

Results

Patient Flow and Baseline Characteristics

Seventy-six patients were screened. Twelve were excluded (3 atticofurcal disease, 4 significant sensorineural hearing loss, 3 medical comorbidity precluding anaesthesia and 2 declined participation). Sixty-four underwent surgery, with 32 allocated to each graft group. Six patients (3 per group) were lost to follow-up before the 2-month assessment. Fifty-eight patients therefore comprised the final analysis, 29 in each group.

Characteristic	Fascia (n=29)	Cartilage (n=29)	p-value
Age, years, mean $\pm$ SD	31.3 $\pm$ 9.4	30.5 $\pm$ 8.6	0.750
Sex, M:F	17:12	16:13	1.000
Ear, R:L	17:12	16:13	1.000
Duration of CSOM, years, mean $\pm$ SD	4.9 $\pm$ 2.2	4.9 $\pm$ 2.8	0.996
Perforation size, S/M/L/Subtotal	9/16/3/1	8/6/9/6	0.011

Perforation site, A/P/I/Central	4/8/2/15	8/4/7/10	0.092
Contralateral ear, Normal: Diseased	18:11	14:15	0.428

Table 1: Demographic and baseline clinical characteristics

The groups were broadly comparable for age, sex, side operated, duration of disease, perforation site and contralateral ear status. Perforation size was significantly imbalanced, with larger perforations preferentially allocated to the cartilage group, reflecting the observational clinical selection process.

Anatomical Outcome

Successful graft uptake at 2 months occurred in 23/29 (79.3%) patients in the fascia group and 27/29 (93.1%) in the cartilage group. The absolute difference was 13.8 percentage points (95% CI -3.6 to $+31.2$), and the difference was not statistically significant (Fisher exact $p=0.253$).

Outcome	Fascia	Cartilage	p-value
Successful graft uptake	23 (79.3%)	27 (93.1%)	0.253
Graft failure/residual perforation	6 (20.7%)	2 (6.9%)	—
Absolute difference (cartilage–fascia)	+13.8%	+13.8%	95% CI -3.6 to $+31.2$

Table 2: Primary anatomical outcome at 2 months.

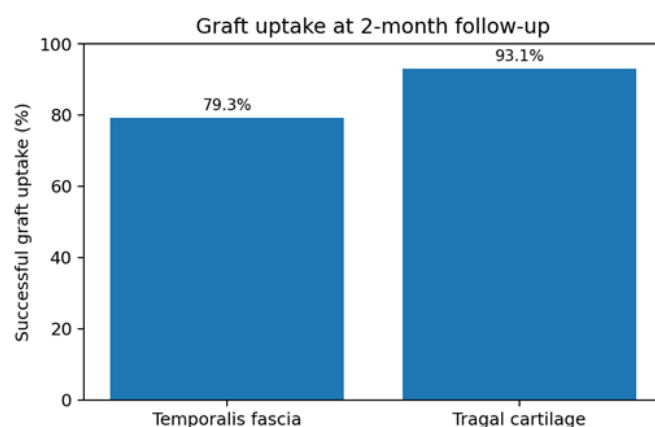


Figure 1: Graft uptake at 2-month follow-up.

Audiological Outcomes

The mean preoperative ABG was 26.8 ± 5.5 dB in the fascia group and 31.3 ± 7.9 dB in the cartilage group ($p=0.014$). At 2 months, postoperative ABG was 13.2 ± 7.1 dB and 15.3 ± 11.5 dB, respectively ($p=0.402$). Mean ABG closure was 13.6 ± 6.9 dB with fascia and 16.0 ± 6.7 dB with cartilage ($p=0.182$). Both groups demonstrated significant within-group improvement ($p<0.001$).

Audiological variable	Fascia (n=29)	Cartilage (n=29)	p-value
Preoperative ABG, dB	26.8 ± 5.5	31.3 ± 7.9	0.014
Postoperative ABG, dB	13.2 ± 7.1	15.3 ± 11.5	0.402
ABG closure, dB	13.6 ± 6.9	16.0 ± 6.7	0.182
Within-group pre/post ABG	$p<0.001$	$p<0.001$	—
ABG closure ≤ 20 dB	25 (86.2%)	19 (65.5%)	0.125
ABG closure ≤ 10 dB	11 (37.9%)	11 (37.9%)	1.000
BC change, dB	0.5 ± 1.4	0.8 ± 1.3	0.347

Table 3: Audiological outcomes at 2 months.

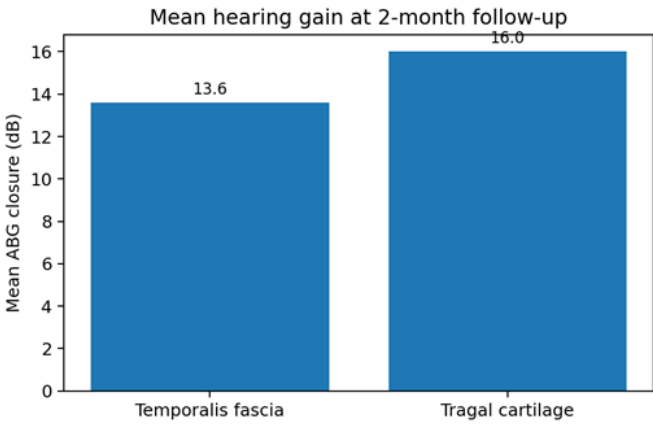


Figure 2. Mean hearing gain (ABG closure) at 2 months.

Bone-conduction thresholds changed by less than 1 dB on average in both groups, with no significant between-group difference, indicating no clinically significant sensorineural deterioration.

Secondary Outcomes

Mean operative duration was 84.0±14.2 minutes for fascia and 91.8±12.6 minutes for cartilage, a statistically significant difference of 7.8 minutes (p=0.031). Graft-harvest blood loss was significantly lower with cartilage (7.8±3.9 mL) than with fascia (13.1±3.3 mL; p<0.001).

Variable	Fascia (n=29)	Cartilage (n=29)	p-value
Duration of surgery, min	84.0±14.2	91.8±12.6	0.031
Harvest blood loss, mL	13.1±3.3	7.8±3.9	<0.001

Table 4: Secondary intraoperative outcomes.

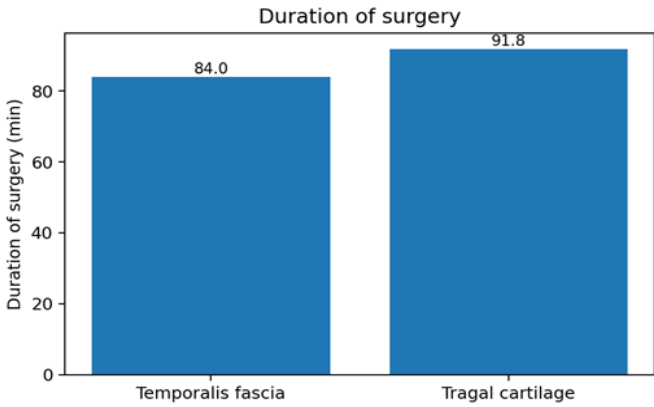


Figure 3: Duration of surgery.

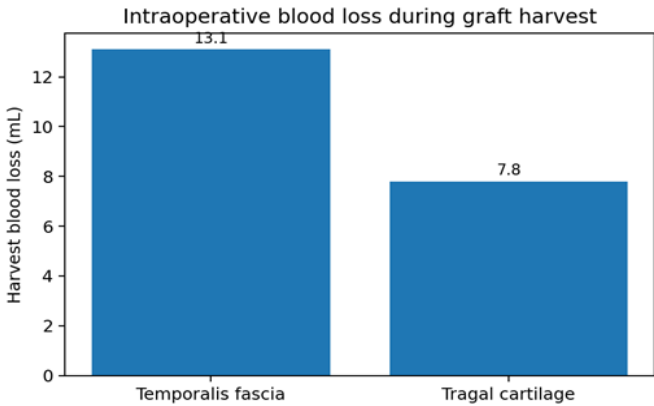


Figure 4: Intraoperative blood loss during graft harvest.

Subgroup Analysis by Perforation Size

In the small/medium stratum, uptake was 20/25 (80.0%) with fascia and 14/14 (100.0%) with cartilage. In the large/subtotal stratum, uptake was 3/4 (75.0%) and 13/15 (86.7%), respectively. Formal statistical testing was not undertaken because of small cell sizes. These descriptive findings should be interpreted cautiously because perforation size was imbalanced between groups.

Perforation size	Fascia	Cartilage	Absolute difference
Small/Medium	20/25 (80.0%)	14/14 (100.0%)	+20.0%
Large/Subtotal	3/4 (75.0%)	13/15 (86.7%)	+11.7%
Overall	23/29 (79.3%)	27/29 (93.1%)	+13.8%

Table 5: Graft uptake stratified by perforation size.

Complications

No major intraoperative or postoperative complications were observed. In the fascia group, residual/recurrent perforation occurred in 6 patients (20.7%) and mild postoperative otitis externa in 2 (6.9%). In the cartilage group, residual perforation occurred in 2 patients (6.9%), anterior tympanomeatal angle blunting in 3 (10.3%), and transient mild tragal donor-site tenderness in 3 (10.3%); the tenderness resolved spontaneously and no cosmetic tragal deformity was reported.

Complication	Fascia n (%)	Cartilage n (%)
Residual/recurrent perforation	6 (20.7%)	2 (6.9%)
Postoperative otitis externa	2 (6.9%)	1 (3.4%)
Anterior tympanomeatal angle blunting	0	3 (10.3%)
Transient tragal tenderness	0	3 (10.3%)
Major complications	0	0

Table 6: Complications observed at 2-month follow-up.

Discussion

The principal finding of this prospective comparative observational study was a numerically higher anatomical graft uptake with full-thickness tragal cartilage island grafts than with temporalis fascia (93.1% versus 79.3%). Although the absolute difference of 13.8 percentage points favoured cartilage, it did not reach statistical significance. The confidence interval was wide and included both no difference and clinically meaningful benefit, reflecting the modest sample size. This direction of effect is consistent with systematic reviews and randomized-trial meta-analysis reporting higher graft success with cartilage⁹⁻¹¹.

The direction of the anatomical effect is consistent with the comparative literature summarized in the thesis, in

which cartilage has generally demonstrated greater structural stability and favourable graft-take rates. The present findings are also within the range reported by Indian comparative series. However, because the current study was observational, the groups were not exchangeable: larger perforations were preferentially treated with cartilage. This baseline imbalance is particularly important because larger perforations may carry a different risk of graft failure and greater preoperative conductive hearing loss. Indian randomized evidence has also reported higher short-term graft uptake with cartilage, although other randomized studies of large perforations have found no significant difference¹³⁻¹⁴.

Both groups achieved substantial hearing improvement. Mean ABG closure was 13.6 dB with fascia and 16.0 dB with cartilage, but the between-group difference was not statistically significant. The higher preoperative ABG in the cartilage group is relevant to interpretation of threshold-based outcomes. Despite a numerically greater continuous hearing gain with cartilage, fewer cartilage patients reached an ABG of ≤ 20 dB; this likely reflects, at least in part, the greater baseline conductive deficit in the cartilage group. Continuous measures of ABG and hearing gain are therefore more informative than a single dichotomous threshold when baseline severity differs. This is consistent with systematic reviews showing broadly comparable postoperative hearing despite differences in graft integration.^{8-11,15}

Operative duration was approximately eight minutes longer with cartilage, consistent with the additional harvest and shaping required for a rigid island graft. Conversely, blood loss during the harvest step was approximately 5 mL lower with cartilage. Although these absolute differences are unlikely to be clinically

important for most healthy adults, they are relevant to operative workflow and may have greater practical importance in selected patients. Additional cartilage preparation and shaping have been described in comparative techniques^{16,17}.

The complication profile was favourable in both groups. Residual perforation was more frequent in the fascia group, corresponding to the lower graft uptake rate. The cartilage group had some anterior tympanomeatal angle blunting and transient donor-site tenderness, recognised trade-offs of cartilage harvest and thickness. No major complications or clinically significant sensorineural deterioration were observed.

The study has several strengths, including its prospective design, structured data collection, standardized surgical and postoperative protocols, a priori sample-size calculation, systematic audiological assessment and a pre-specified perforation-size subgroup analysis. Important limitations include the non-randomized design and associated selection bias, the baseline imbalance in perforation size, small subgroup numbers, single-centre setting, restriction to adults with tubotympanic CSOM and central perforations, and the relatively short 2-month follow-up. Late graft failures and longer-term stabilization of hearing outcomes may therefore not be captured. Longer comparative studies have used follow-up periods up to 24 months, so the present 2-month endpoint may not capture late reperforation or graft morphological changes^{10,14}.

Conclusion

Autologous temporalis fascia and full-thickness tragal cartilage island grafts both provided satisfactory anatomical and audiological outcomes in Type 1 tympanoplasty for central perforations associated with tubotympanic chronic suppurative otitis media. Cartilage

achieved a higher numerical graft uptake rate (93.1% vs 79.3%), but the difference was not statistically significant. Audiological improvement was substantial and comparable between groups. Cartilage required modestly longer operative time but significantly less blood loss during graft harvest. These findings support the use of cartilage as an important graft option, particularly when anatomical risk factors favour greater structural stability, while temporalis fascia remains an effective and practical material for primary tympanoplasty. Larger randomized studies with longer follow-up and stratification by perforation size are warranted.

Ethics Approval and Consent to Participate

The study was approved by the Institutional Ethics Committee of the participating tertiary care teaching hospital in Mumbai before commencement. Written informed consent was obtained from all participants. The study was conducted in accordance with the Declaration of Helsinki, relevant Indian ethical guidance and Good Clinical Practice principles. The specific ethics approval number/date was not available in the extracted thesis material and should be inserted from the final ethics certificate before submission.

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