

ORIGINAL RESEARCH

TEMPORALIS FASCIA VERSUS PARTIAL-THICKNESS TRAGAL CARTILAGE IN TWO-HANDED ENDOSCOPIC TYMPANOPLASTY FOR CHRONIC OTITIS MEDIA: A PROSPECTIVE MULTICENTRE OBSERVATIONAL STUDYReyazul Janat^{1*}, Ruby Samuel², Meena Maruthi Ohal³¹ Associate Professor, Department of ENT, Madhubani Medical College and Hospital, Madhubani, Bihar, India² Assistant Professor, Department of ENT, KMCT Medical College, Manassery, Kerala, India³ Professor and Head, Department of ENT, Bharat Ratna Atal Bihari Vajpayee Medical College, Pune, Maharashtra, India

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ABSTRACT

Background: Two-handed endoscopic tympanoplasty, performed with the endoscope secured in a mechanical holder, permits bimanual instrumentation while preserving endoscopic visualization. Temporalis fascia is widely used for tympanic membrane reconstruction, whereas cartilage offers greater structural rigidity and resistance to retraction. This study compared anatomical and audiological outcomes of temporalis fascia and partial-thickness tragal cartilage in chronic otitis media. **Methods:** This prospective, comparative, multicentre observational study included a primary graft-comparison cohort of 132 patients aged 10–70 years: 66 underwent endoscopic tympanoplasty with temporalis fascia and 66 with partial-thickness tragal cartilage. A separate descriptive cohort of 42 patients with limited atticointral disease underwent intact canal wall (ICW) inside-out atticoinstomy and was not included in the primary graft comparison. Pure-tone audiometry was performed preoperatively and at the standardized 6-month postoperative assessment and followed up to 16 months. The primary outcome was successful anatomical graft uptake; secondary outcomes included pure-tone average (PTA), air-bone gap (ABG), ABG closure, and exploratory patient-reported benefit. **Results:** Successful graft uptake occurred in 57/66 patients (86.4%) in the fascia group and 60/66 (90.9%) in the cartilage group (absolute difference 4.5 percentage points; Fisher exact $p=0.585$). Mean ABG decreased from 28.6 ± 6.4 to 12.1 ± 4.8 dB with fascia and from 29.4 ± 6.7 to 10.8 ± 4.3 dB with cartilage (within-group $p<0.001$ for both). Mean ABG closure was 16.5 ± 5.6 dB and 18.6 ± 5.8 dB, respectively; the between-group difference was 2.1 dB (95% CI 0.14–4.06; $p=0.036$). Good or excellent subjective improvement was reported by 83.3% and 86.4% of patients in the two graft groups, respectively. **Conclusion:** Temporalis fascia and partial-thickness tragal cartilage were both associated with satisfactory anatomical and functional outcomes. The study did not demonstrate a statistically significant difference in graft uptake. Cartilage was associated with a small statistically significant advantage in mean ABG closure, but the clinical importance of an approximately 2-dB difference is uncertain. Graft selection should therefore be individualised according to perforation characteristics, middle-ear status, and the need for structural stability.

Keywords: chronic otitis media; endoscopic tympanoplasty; temporalis fascia; tragal cartilage; graft uptake; air-bone gap.

INTRODUCTION

Chronic otitis media is a persistent inflammatory disorder of the middle ear that may be associated with tympanic membrane perforation, recurrent or persistent otorrhoea, and conductive hearing loss. It remains an important cause of preventable hearing impairment, particularly in low- and middle-income settings, with consequences for communication, education, employment, and quality of life [1–3].

Management aims to control infection and restore a safe, dry, and functional ear. Topical antimicrobial treatment and aural toilet remain important components of conservative care [4,5], but persistent perforation frequently requires tympanic membrane reconstruction. Surgical success is multidimensional and includes anatomical closure, hearing improvement, and patient-perceived benefit.

Temporalis fascia has traditionally been the most widely used graft material because it is readily available, straightforward to harvest, and provides satisfactory functional outcomes. However, fascia may retract or re-perforate in unfavourable middle-ear conditions. Cartilage is mechanically more stable and resistant to retraction, making it attractive in large or otherwise high-risk perforations [6,7].

Comparative evidence suggests that differences between cartilage and fascia may be more pronounced for anatomical than for functional outcomes. A meta-analysis of 44 studies involving 4,582 patients reported higher morphological success with cartilage, while functional outcomes were broadly comparable [8]. Prospective and comparative studies have similarly reported significant hearing improvement with both graft materials, although results regarding graft uptake and audiological advantage are not uniform [9–11].

The present study was designed as a prospective multicentre observational comparison of temporalis fascia and partial-thickness tragal cartilage in two-handed endoscopic tympanoplasty across a broad age range. The primary objective was to compare anatomical graft uptake between the two materials. Secondary objectives were to compare postoperative hearing outcomes and exploratory patient-reported benefit. Patients undergoing ICW inside-out atticoantrostomy for limited atticoantral disease were analysed separately because their pathology and operation differed from those of the primary graft-comparison cohort.

MATERIALS AND METHODS

Study design and setting

This prospective, comparative, multicentre observational study was conducted in the Departments of Otorhinolaryngology of three tertiary-care centres between 2 April 2022 and 31 January 2026. The study is reported with reference to the STROBE statement for observational studies [12].

Ethical approval was obtained before study commencement from the Institutional Ethics Committee (KMCT/Acad/Ethics/132; 11 February 2021). The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from adult participants; for participants younger than 18 years, consent was obtained from a parent or guardian together with the participant's assent. Data were anonymised for analysis.

Participants and study cohorts

Patients aged 10–70 years with clinically diagnosed chronic otitis media and a tympanic membrane perforation considered suitable for surgery were eligible, provided that adequate preoperative audiological assessment and postoperative follow-up data were available. Exclusion criteria were acute otitis media, previous surgery on the study ear, congenital ear abnormality, significant sensorineural hearing loss, or inadequate preoperative or postoperative documentation.

A total of 197 patients were screened across the three centres, and 174 patients had complete evaluable data and were included in the final analysis. The primary graft-comparison cohort comprised 132 patients: 66 underwent two-handed endoscopic tympanoplasty with temporalis fascia and 66 underwent the same procedure with partial-thickness tragal cartilage. A further 42 patients with limited atticoantral disease underwent ICW inside-out atticoantrostomy and formed a separate descriptive cohort. Because both the underlying pathology and the operative procedure differed, this group was not included in the primary statistical comparison of graft materials.

Sample size and statistical power

The study assumptions anticipated graft uptake rates of approximately 95% with cartilage and 85% with temporalis fascia. A conventional two-sample comparison of proportions under these assumptions, with a two-sided alpha of 0.05 and 80% power, would require approximately 137 patients per group. The actual primary comparison included 66 patients per group and was therefore underpowered to detect a 10-percentage-point difference with 80% power.

Clinical and audiological assessment

All patients underwent otological history taking and examination. Otoscopic and microscopic assessment documented the site and characteristics of the perforation, middle-ear mucosal status, granulation tissue, and ossicular status. Perforations were classified as central or attic.

Pure-tone audiometry was performed preoperatively and at the standardized 6-month postoperative assessment by a qualified audiologist who was blinded to graft material. The total follow up was for a period of 16 months. Air- and bone-conduction thresholds were recorded at 0.5, 1, and 2 kHz. The study-defined pure-tone average (PTA) was the arithmetic mean of air-conduction thresholds at these frequencies. The ABG was calculated as the mean of the corresponding frequency-specific air- minus bone-conduction thresholds. Absolute ABG closure was calculated as preoperative ABG minus postoperative ABG; percentage closure was calculated as absolute closure divided by preoperative ABG and expressed as a percentage.

Surgical technique

All procedures were performed according to a common operative protocol. Endoscopic tympanoplasty used a rigid otoendoscope secured in a mechanical holder, allowing stable visualisation and two-handed instrumentation (Fig 1). The principal steps comprised elevation of the tympanomeatal flap, preparation of the middle ear and graft bed, graft placement, and final inspection of the reconstructed tympanic membrane.

Graft material was selected according to the study protocol and intraoperative assessment. In the fascia group, temporalis fascia was harvested and placed by standard endoscopic underlay technique. In the cartilage group, tragal cartilage was harvested with preservation of auricular contour; perichondrium was removed from one surface, and the cartilage was thinned to partial thickness and fashioned to the perforation while maintaining structural support. In patients undergoing ICW inside-out atticoantrostomy, partial-thickness tragal cartilage was used for scutal reconstruction and retained perichondrium was used for reinforcement where required.



Figure 4. JUSTTACH (ASM-2 PATENT NUMBER: 401115),

The mechanical endoscope holder was a commercially available surgical device. None of the authors reported a financial, proprietary, patent, manufacturing, distribution, or licensing interest in the device or its manufacturer (fig 1).

Outcome measures

The primary outcome was successful anatomical graft uptake, defined as an intact and adequately healed tympanic membrane without a significant residual or recurrent perforation at the final documented postoperative assessment. Graft status was classified as successful uptake, partial uptake/healing, or residual perforation/graft failure.

Secondary outcomes were postoperative PTA, postoperative ABG, absolute and percentage ABG closure, and patient-reported hearing and symptomatic benefit. Outcomes related to perforation type were considered exploratory and were reported descriptively. Formal age-stratified, centre-level, or multivariable analyses were not performed.

Patient-reported outcomes

Patient-reported outcomes were assessed using a structured questionnaire developed for this study rather than a previously validated instrument such as COMOT-15 or the Glasgow Benefit Inventory. The questionnaire covered perceived hearing improvement, reduction in ear-related symptoms, improvement in daily communication, and overall satisfaction. Overall subjective outcome was categorised as excellent, good, fair, or poor according to predefined study criteria.

The questionnaire was administered by a designated clinical assessor who was not involved in the surgical procedure and was blinded to the graft material. Because the questionnaire had not undergone formal psychometric validation, these findings were treated as exploratory and supportive rather than as a primary efficacy endpoint.

Statistical analysis

Continuous variables are presented as mean $\pm$ standard deviation (SD), and categorical variables as frequency and percentage. Within-group preoperative-to-postoperative changes were evaluated using paired-samples t tests. Between-group comparisons of continuous outcomes used independent-samples t tests, and categorical outcomes were compared with the chi-square test or Fisher exact test, as appropriate. All tests were two-sided, with $p < 0.05$ considered statistically significant. Effect estimates are presented with 95% confidence intervals where they can be derived from the reported data. The ICW atticoantrostomy cohort was analysed descriptively and was not included in the primary graft-material comparison.

RESULTS

Participants and baseline characteristics

The final analysed cohort comprised 174 patients: 66 in the temporalis fascia group, 66 in the partial-thickness tragal cartilage group, and 42 in the separate ICW inside-out atticoantrostomy cohort (fig 2). There were 104 men (59.8%) and 70 women (40.2%). The mean age of the overall cohort was 40.0 ± 17.2 years. Central perforations accounted for 113 cases (64.9%) and attic perforations for 61 (35.1%). Baseline characteristics are summarised in Table 1.

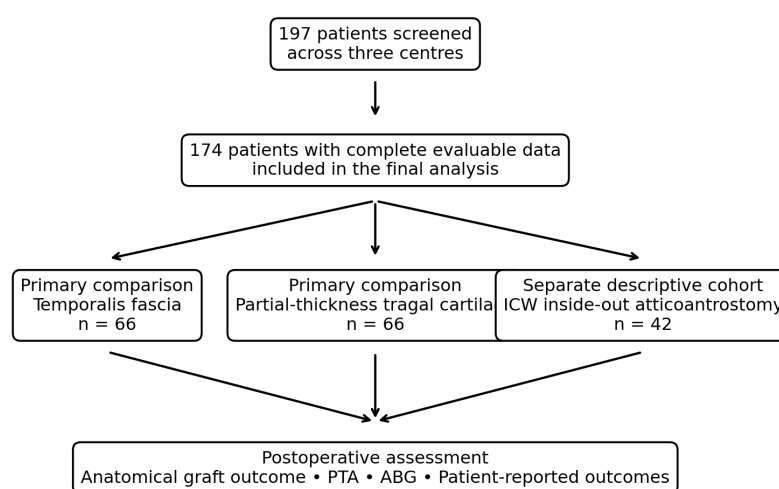


Figure 1. Study population and analytic cohorts.

The primary comparative analysis included 132 patients undergoing two-handed endoscopic tympanoplasty with temporalis fascia or partial-thickness tragal cartilage. The 42-patient ICW inside-out atticoantrostomy cohort was analysed separately (Table 1).

Table 1. Demographic and baseline clinical characteristics.

Variable	Total (n=174)	Fascia (n=66)	Cartilage (n=66)	ICW (n=42)
Age, mean $\pm$ SD (years)	40.0 $\pm$ 17.2	39.5 $\pm$ 17.0	40.2 $\pm$ 17.4	40.5 $\pm$ 17.3
Male, n (%)	104 (59.8)	40 (60.6)	39 (59.1)	25 (59.5)
Female, n (%)	70 (40.2)	26 (39.4)	27 (40.9)	17 (40.5)
Central perforation, n	113	45	46	22
Attic perforation, n	61	21	20	20

ICW, intact canal wall inside-out atticoantrostomy.

Audiological outcomes

Both graft groups showed significant postoperative improvement in PTA and ABG (within-group $p < 0.001$). Mean ABG decreased from 28.6 ± 6.4 to 12.1 ± 4.8 dB in the temporalis fascia group and from 29.4 ± 6.7 to 10.8 ± 4.3 dB in the cartilage group. Mean ABG closure was 16.5 ± 5.6 dB with fascia and 18.6 ± 5.8 dB with cartilage. The between-group mean difference in ABG closure was 2.1 dB (95% CI 0.14–4.06; $p = 0.036$). Although statistically significant, the magnitude of this difference was small and its clinical importance is uncertain (Table 2).

Table 2. Preoperative and postoperative audiological outcomes.

Parameter	Temporalis fascia (n=66)	Cartilage (n=66)	ICW (n=42)
Preoperative PTA (dB)	36.8 $\pm$ 7.1	37.2 $\pm$ 7.4	41.0 $\pm$ 8.2
Postoperative PTA (dB)	22.5 $\pm$ 5.1	21.0 $\pm$ 4.8	25.4 $\pm$ 6.2
Preoperative ABG (dB)	28.6 $\pm$ 6.4	29.4 $\pm$ 6.7	32.1 $\pm$ 7.2
Postoperative ABG (dB)	12.1 $\pm$ 4.8	10.8 $\pm$ 4.3	14.2 $\pm$ 5.7
Mean ABG closure (dB)	16.5 $\pm$ 5.6	18.6 $\pm$ 5.8	17.9 $\pm$ 6.1
Percentage ABG closure (%)	57.7	63.3	55.8
Within-group p value	<0.001	<0.001	<0.001

PTA, pure-tone average; ABG, air-bone gap; ICW, intact canal wall.

Primary anatomical outcome

Successful anatomical graft uptake was achieved in 57/66 patients (86.4%) in the temporalis fascia group and 60/66 (90.9%) in the cartilage group. The absolute difference was 4.5 percentage points (95% CI approximately –6.7 to 15.9 percentage points) and was not statistically significant (Fisher exact $p = 0.585$). The present study therefore does not demonstrate a difference in graft uptake between the two materials; because the study was underpowered for this endpoint, it also does not establish equivalence (Table 3).

Table 3. Anatomical graft uptake and postoperative surgical outcome.

Outcome	Temporalis fascia n (%)	Cartilage n (%)	ICW n (%)
Successful anatomical outcome	57 (86.4)	60 (90.9)	37 (88.1)
Partial uptake or healing	4 (6.1)	3 (4.5)	3 (7.1)
Residual perforation or graft failure	5 (7.6)	3 (4.5)	2 (4.8)
Total	66 (100)	66 (100)	42 (100)

The ICW cohort is shown descriptively and was not included in the primary graft-material comparison.

Exploratory outcomes by perforation type

Among all 174 patients, 113 had central and 61 had attic perforations. Mean preoperative ABG was 26.5 dB in the central-perforation group and 33.0 dB in the attic-perforation group; corresponding postoperative values were 10.8 and 14.5 dB. Successful anatomical outcome was documented in 103/113 patients (91.2%) with central perforations and 51/61 (83.6%) with attic perforations. These comparisons were exploratory and descriptive; no claim of statistical significance is made (Table 4).

Table 4. Exploratory outcomes according to tympanic membrane perforation type.

Parameter	Central perforation	Attic perforation
Proportion of cohort	113/174 (64.9%)	61/174 (35.1%)
Mean preoperative ABG	26.5 dB	33.0 dB
Mean postoperative ABG	10.8 dB	14.5 dB
Mean ABG closure	15.7 dB	18.5 dB
Successful anatomical outcome	103/113 (91.2%)	51/61 (83.6%)
Good/excellent subjective improvement	99/113 (87.6%)	48/61 (78.7%)

Patient-reported outcomes

Good or excellent subjective improvement was reported by 55/66 patients (83.3%) in the fascia group, 57/66 (86.4%) in the cartilage group, and 34/42 (81.0%) in the ICW cohort. The difference between the two primary graft groups was not statistically significant (Fisher exact $p=0.803$). Because the questionnaire was study-specific and nonvalidated, these results should be interpreted as exploratory (Table 5). The comparative hearing outcome is shown in the figure 3.

Table 5. Patient-reported outcomes following surgery.

Patient-reported outcome	Temporalis fascia n (%)	Cartilage n (%)	ICW n (%)
Excellent improvement	25 (37.9)	29 (43.9)	16 (38.1)
Good improvement	30 (45.5)	28 (42.4)	18 (42.9)
Fair improvement	8 (12.1)	6 (9.1)	6 (14.3)
Poor or no meaningful improvement	3 (4.5)	3 (4.5)	2 (4.8)
Good or excellent	55 (83.3)	57 (86.4)	34 (81.0)

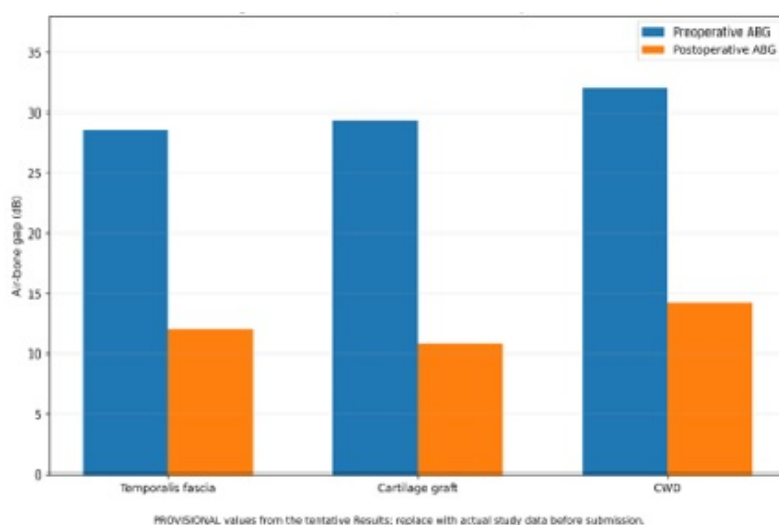


Figure 3. Comparative hearing outcome

DISCUSSION

In this prospective multicentre observational study, temporalis fascia and partial-thickness tragal cartilage were both associated with high graft-uptake rates and substantial postoperative hearing improvement. The primary anatomical comparison showed graft uptake of 86.4% with fascia and 90.9% with cartilage. Although the numerical difference favoured cartilage, it was not statistically significant, and the confidence interval was compatible with both a small disadvantage and a clinically relevant advantage. Because the study included only 66 patients per graft arm, substantially fewer than the number required for 80% power under the prespecified 95% versus 85% assumption, the nonsignificant result should not be interpreted as demonstrating equivalence.

Audiological improvement was substantial in both groups. Mean ABG closure was 2.1 dB greater with cartilage, and this difference reached statistical significance. However, the effect was small, and the clinical importance of an approximately 2-dB between-group difference is uncertain. The result therefore supports comparable functional effectiveness of the two materials more strongly than it supports clinically meaningful superiority of cartilage.

Comparison with published evidence

The direction of the anatomical findings is consistent with the wider literature. Shakya and Nepal reported higher long-term graft uptake with perichondrium-reinforced cartilage palisade than with temporalis fascia for large perforations, while hearing improved in both groups without a significant audiometric difference [13]. Other studies have similarly reported satisfactory hearing outcomes with cartilage despite its greater stiffness [14], and randomised comparisons of cartilage and fascia for large perforations have evaluated both anatomical and functional outcomes [15].

Paediatric studies have also compared temporalis fascia with tragal cartilage and have generally shown that cartilage can provide satisfactory anatomical and hearing results [16,17]. More recently, a prospective randomised endoscopic study reported higher graft uptake and greater structural stability with cartilage, with both materials producing significant hearing improvement [11]. Collectively, these studies suggest that any advantage of cartilage may be more apparent in anatomical stability than in postoperative hearing.

Disease extent and perforation type

Patients with attic perforations had greater preoperative hearing impairment and lower descriptive anatomical success than those with central perforations. Attic disease was also more likely to require atticostomy, making direct graft-material comparisons inappropriate across these different pathological and surgical settings. For this reason, the ICW atticostomy cohort was kept separate from the primary fascia-versus-cartilage analysis.

Limitations

The treatment allocation was observational rather than randomised, creating the possibility of selection and confounding by indication. The exact clinical decision algorithm for choosing fascia versus cartilage was not fully standardised in the available study documentation. Anatomical graft assessment was not documented as blinded, although the audiologist and patient-reported outcome assessor were blinded to graft type. The patient-reported questionnaire was study-specific and had not undergone formal validation. Postoperative complications were not systematically reported in the available dataset and therefore could not be analysed as a comparative endpoint. No multivariable adjustment or formal age- or centre-stratified analysis was performed. Finally, the standardised audiological endpoint was at 6 months; longer-term graft stability requires further study.

CONCLUSION

Temporalis fascia and partial-thickness tragal cartilage were both associated with satisfactory anatomical and functional outcomes after two-handed endoscopic tympanoplasty for chronic otitis media. The study did not demonstrate a statistically significant difference in graft uptake, and its limited power precludes a conclusion of equivalence. Cartilage was associated with a modestly greater mean ABG closure, but the approximately 2-dB difference is of uncertain clinical

importance. Graft selection should therefore be individualised according to perforation characteristics, middle-ear status, surgeon assessment, and the need for structural stability. Adequately powered randomised studies with blinded outcome assessment and longer follow-up are needed to clarify whether cartilage offers a meaningful long-term anatomical advantage without compromising hearing.

Declarations

Ethics approval: Institutional Ethics Committee approval was documented as KMCT/Acad/Ethics/132

Consent: Written informed consent was obtained from adult participants, with parent/guardian consent and participant assent for those younger than 18 years.

Conflicts of interest: None declared.

Funding: None.

Data Availability

The data generated and analysed during the study are not publicly available because they contain potentially identifiable patient information. De-identified data may be made available by the corresponding author on reasonable request, subject to appropriate ethical, institutional, and data-protection requirements.

Authors' Contributions

All authors critically reviewed the manuscript, approved the final version, and accept responsibility for the integrity and accuracy of the work.

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