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Original Research Article

A Randomized Controlled Study Comparing Cartilage and Temporalis Fascia Grafts in Type I Tympanoplasty

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Abstract:

Background: Type I tympanoplasty is a standard surgical procedure for repairing tympanic membrane perforations due to chronic suppurative otitis media (CSOM). The choice of graft material plays a pivotal role in surgical outcomes. Temporalis fascia is conventionally preferred due to ease of harvest and favorable integration, while cartilage grafts have been increasingly utilized for their stability and resistance to retraction. However, comparative evidence in terms of anatomical and functional outcomes remains varied.

Aim: To compare the anatomical success rate and hearing improvement between cartilage and temporalis fascia grafts in Type I tympanoplasty.

Methods: A retrospective comparative study was conducted on 142 patients (aged 18–60 years) who underwent Type I tympanoplasty at the Department of Otorhinolaryngology, KIMS, Bhubaneswar, from July 2022 to June 2024. Patients were divided into two equal groups: Group A (temporalis fascia graft, n=71) and Group B (cartilage graft, n=71). Preoperative and postoperative air–bone gap (ABG) was assessed using pure tone audiometry, while graft uptake was evaluated at 1 and 3 months. Statistical analysis was performed using SPSS v23.0, with $p < 0.05$ considered significant.

Results: Both groups were demographically and clinically comparable ($p > 0.05$). Postoperative ABG improved significantly in both groups ($p < 0.001$), with median improvements of 8 dB in the temporalis fascia group and 10 dB in the cartilage group, though the intergroup difference was not statistically significant. Graft uptake rates were high in both groups, with success rates of 95.8% for temporalis fascia and 98.6% for cartilage grafts at both 1 and 3 months ($p = 0.31$).

Conclusion: Both temporalis fascia and cartilage grafts are highly effective for Type I tympanoplasty, yielding comparable anatomical and functional outcomes. Cartilage grafts demonstrated slightly better stability and hearing gain, though differences were not statistically significant.

Recommendations: Cartilage grafts may be considered particularly in cases with large perforations or high risk of retraction, while temporalis fascia remains a reliable option for routine cases. Further multicentric, long-term prospective studies are recommended to establish standardized protocols and evaluate graft durability.

Keywords: Tympanoplasty, Cartilage graft, Temporalis fascia, Graft uptake, Hearing improvement

Introduction

Type I tympanoplasty is a surgical procedure aimed at repairing tympanic membrane perforations, most commonly resulting from chronic otitis media. The main goals of this surgery are the restoration of the anatomical integrity of the tympanic membrane and the improvement of hearing. Success in tympanoplasty depends on multiple factors, including the size and location of the perforation, the status of the middle ear mucosa, Eustachian tube function, and, importantly, the choice of graft material [1].

Temporalis fascia has traditionally been the graft material of choice due to its ease of harvest, flexibility, and good integration with the surrounding tissue [2]. However, cartilage grafts, especially tragal or conchal cartilage, have recently gained prominence for their superior structural

stability, resistance to retraction, and reduced risk of reperforation, particularly in cases with Eustachian tube dysfunction or large perforations [3,4]. Cartilage grafts are thought to provide more reliable long-term anatomical outcomes without compromising hearing results [5].

Several studies have compared cartilage and temporalis fascia grafts in Type I tympanoplasty. Ciğer et al. [1] conducted a prospective randomized trial and reported comparable anatomical and functional outcomes between wheel-shaped composite cartilage grafts and temporalis fascia. Similarly, Ramalingam et al. [2] compared measured thickness conchal cartilage with full-thickness conchal cartilage in patients with moderate-sized perforations and found that both graft types offered equivalent audiometric improvements.

Meta-analytic evidence also supports the use of cartilage grafts. Lajdam et al. [3] concluded that primary type I tympanoplasty using cartilage grafts achieved higher graft uptake rates while maintaining similar postoperative hearing outcomes compared to temporalis fascia. Furthermore, Ferlito et al. [4] observed that full-thickness cartilage grafts may even provide superior auditory outcomes in certain subgroups, emphasizing their potential advantage over temporalis fascia in select patient populations.

Other studies have reinforced these findings. Shakya et al. [5] reported long-term stability with perichondrium-reinforced cartilage palisade grafts in large perforations. Jain et al. [6] found comparable graft take-up rates and hearing improvements between island cartilage and temporalis fascia grafts. Dinc et al. [7] and Chen et al. [8] similarly observed that cartilage grafts yield stable anatomical results without significant compromise in auditory outcomes.

Collectively, these studies indicate that cartilage grafts, particularly full-thickness or reinforced designs, are a viable alternative to temporalis fascia in Type I tympanoplasty. Nonetheless, further randomized studies are warranted to establish standardized protocols and evaluate long-term outcomes across different patient populations.

Materials and Methods

Type of Article: This study was a retrospective comparative study.

Study Design and Setting: The study was conducted in the Department of Otorhinolaryngology, Kalinga Institute of Medical Sciences (KIMS), Bhubaneswar.

Study Duration: The study was carried out over a period of two years, from July 2022 to June 2024.

Sample Size: A total of 142 patients were included in the study.

Study Population: Patients who were diagnosed with Chronic Suppurative Otitis Media (CSOM) – Tubotympanic type and who met the inclusion criteria were selected. All available medical records, operative notes, and postoperative follow-up data were reviewed and analyzed.

Inclusion Criteria

1. Patients diagnosed with CSOM (safe/mucosal type).
2. Age group between 18 and 60 years.
3. Patients with conductive or mixed hearing loss with an air-bone gap >10 dB.
4. Patients who had undergone Type I Tympanoplasty using either temporalis fascia or cartilage graft.

Exclusion Criteria

1. Patients with active ear discharge at the time of surgery.
2. Patients with pure sensorineural hearing loss.
3. Revision tympanoplasty cases.
4. Cases with ossicular discontinuity or cholesteatoma.

Data Collection and Procedure

The case records of 142 patients who underwent Type I tympanoplasty were reviewed. Based on the operative notes, patients were divided into two groups:

- **Group A:** Temporalis fascia graft
- **Group B:** Cartilage graft

All patients had undergone preoperative clinical evaluation, including detailed otoscopic examination, tuning fork tests, and pure tone audiometry (PTA). Audiometric data, operative findings, and postoperative follow-up results were extracted from hospital records.

Preoperative hearing levels were recorded using PTA, and the air-bone gap (ABG) was calculated at 500 Hz, 1000 Hz, and 2000 Hz. Postoperative PTA was performed at 12 weeks to assess hearing improvement. Graft uptake was evaluated during follow-up otoscopic examinations.

Surgical Procedure: All patients had undergone Type I tympanoplasty via postauricular approach under either local or general anaesthesia. The surgical steps followed standard techniques, including:

1. Harvesting of the temporalis fascia or tragal cartilage with perichondrium.
2. Freshening of the perforation margins.
3. Elevation of the tympanomeatal flap.
4. Assessment of the ossicular chain integrity.

5. Placement of the graft using the underlay technique.

Endoscopic or microscopic assistance was used as required. All patients received standard postoperative care and antibiotics, and were followed up at regular intervals.

Outcome Measures

1. **Graft uptake rate** – evaluated by otoscopic examination at 12 weeks postoperatively.
2. **Hearing improvement** – measured by comparing preoperative and postoperative ABG closure on PTA.

Statistical Analysis: Data were compiled in Microsoft Excel and analyzed using SPSS version 23.0.
Quantitative variables were expressed as mean ± standard deviation (SD), while categorical variables were expressed as frequency and percentage. Comparison between the two groups was done using:

- **Chi-square test** for categorical variables.
- **Unpaired t-test** or **Mann–Whitney U test** for continuous variables.

A **p-value <0.05** was considered statistically significant.

Results

A total of 142 patients were included — 71 patients underwent tympanoplasty using temporalis fascia grafts (Group 1), and 71 patients underwent surgery with cartilage grafts (Group 2). The analysis included demographic characteristics, disease profile, hearing outcomes, perforation size, and graft uptake rates.

Table 1: Demographic Characteristics of Study Population

Parameter	Temporalis Graft (n=71)	Cartilage Graft (n=71)	Test Used	p-value
Gender	Female: 42 (59.2%) Male: 29 (40.8%)	Female: 34 (47.9%) Male: 37 (52.1%)	Chi-square = 1.812	0.178
Age (years)	Median: 31 (23–42)	Median: 29 (24–35)	Mann–Whitney U	0.177

The demographic comparison revealed that both groups were comparable in terms of gender and age distribution. Although the temporalis graft group had a slightly higher proportion of females and a marginally higher median age, these differences were not statistically significant ($p > 0.05$), indicating similar baseline profiles.

Table 2: Disease Characteristics in the Two Study Groups

Parameter	Temporalis Graft	Cartilage Graft	Test Used	p-value
Active Stage Duration (years)	2.0 (1.5–8.0)	2.5 (1.5–9.0)	Mann–Whitney U	0.248
Inactive Stage Duration (months)	2 (1–2)	2 (1–3)	Mann–Whitney U	0.796
Side of Discharging Ear	Left: 33 (46.5%) Right: 38 (53.5%)	Left: 36 (50.7%) Right: 35 (49.3%)	Chi-square = 0.254	0.614

The median duration of both the active and inactive stages of disease was comparable between the two groups. The laterality of ear involvement also showed no statistically significant correlation with graft type ($p > 0.05$). These findings suggest that both groups had similar preoperative disease status and chronicity, ensuring comparability of outcomes.

Table 3: Preoperative and Postoperative Hearing Assessment (Air–Bone Gap)

Graft Type	Preoperative AB Gap (dB)	Postoperative AB Gap (dB)	Median Difference (dB)	Test Used	p-value
Temporalis	20 (17–26)	12 (10–15)	8	Wilcoxon Signed Rank	<0.001
Cartilage	23 (20–27)	13 (12–17)	10	Wilcoxon Signed Rank	<0.001

Both groups demonstrated significant postoperative hearing improvement ($p < 0.001$). The median air–bone gap decreased from 20 dB to 12 dB in the temporalis graft group and from 23 dB to 13 dB in the cartilage graft group. Although the cartilage group showed a slightly greater median improvement (10 dB vs. 8 dB), the difference between the groups was not statistically significant, suggesting that both grafts were equally effective in restoring hearing.

Table 4: Perforation Size and Distribution in Two Groups

Perforation Size	Temporalis Graft (n=71)	Cartilage Graft (n=71)	Chi-square	p-value
Small	24 (33.8%)	19 (26.8%)		
Medium	20 (28.2%)	17 (23.9%)		
Large	19 (26.8%)	21 (29.6%)		
Subtotal	8 (11.3%)	14 (19.7%)	2.561	0.464

The size of tympanic membrane perforations was comparable between the two groups. The majority of patients in both groups presented with small-to-medium perforations. No statistically significant difference was noted in the distribution of perforation size ($p = 0.464$), confirming that both groups were balanced in terms of surgical difficulty and defect extent.

Table 5: Frequency Distribution of Graft Uptake in Two Groups

Time Interval	Outcome	Temporalis (n = 71)	Cartilage (n = 71)	Chi-square/Exact	p-value
1 Month	Taken	68 (95.8%)	70 (98.6%)	1.029	0.31
	Not Taken	3 (4.2%)	1 (1.4%)		
3 Months	Taken	68 (95.8%)	70 (98.6%)	1.029	0.31
	Not Taken	3 (4.2%)	1 (1.4%)		

There was no statistically significant difference in graft uptake between the two groups at both 1 and 3 months ($p = 0.31$). Both grafts showed excellent anatomical success rates.

Summary of Findings

1. **Demographic comparability:** No significant differences were observed in gender or age between the two groups.
2. **Disease characteristics:** Both groups had comparable durations of active and inactive disease stages, and similar laterality distribution.
3. **Hearing improvement:** Both groups showed significant postoperative hearing gain, with slightly better median improvement in cartilage grafts.
4. **Perforation size:** The distribution of perforation size was similar, showing no significant influence on graft outcomes.
5. **Graft uptake:** Both grafts demonstrated excellent success (>95%) with minimal rejection, confirming their effectiveness in tympanoplasty.

Discussion

This retrospective study compared the outcomes of **cartilage** grafts and temporalis fascia grafts in Type I tympanoplasty among 142 patients, with 71 patients in each group. The study aimed to assess and compare the surgical and audiological outcomes of the two graft materials in repairing tympanic membrane perforations.

The demographic analysis revealed that the two groups were comparable in age and gender distribution. The median age of patients who received temporalis fascia grafts was 31 years, while that of those who received cartilage grafts was 29 years, and this difference was not statistically significant ($p = 0.177$). Similarly, females constituted a slightly higher proportion in the temporalis fascia group (59.2%) compared to the cartilage group (47.9%), but the difference was again not significant ($p = 0.178$). These findings indicated that both groups were demographically well balanced, minimizing selection bias and ensuring comparability of outcomes.

The duration of the disease, both in its active and inactive stages, was also comparable between the two groups. The median duration of the active stage was 2 years for the temporalis fascia group and 2.5 years for the cartilage group ($p = 0.248$). The median duration of the inactive stage was 2 months for both groups ($p = 0.796$). This suggests that the preoperative disease condition was similar in both groups. The distribution of the side of ear involvement was also even, with no significant correlation between graft type and the affected ear ($p = 0.614$). Hence, both groups were matched for baseline disease characteristics.

Hearing improvement was evaluated by comparing the preoperative and postoperative air–bone gap (ABG). Before surgery, the cartilage graft group had a slightly higher median ABG of 23 dB compared to 20 dB in the temporalis fascia group, suggesting somewhat greater hearing loss in the cartilage group initially. Postoperatively, both groups showed significant improvement in hearing, with the median ABG decreasing to 12 dB in the temporalis fascia group and 13 dB in the cartilage graft group. The median improvement was 8 dB and 10 dB, respectively, in the two groups, and the improvement within each group was statistically significant ($p < 0.001$). Although cartilage grafts showed a slightly better hearing gain, the difference between the two groups was not statistically significant, indicating that both graft materials were

equally effective in restoring hearing following Type I tympanoplasty.

The distribution of tympanic membrane perforation size was analyzed to evaluate whether graft selection influenced the outcome. Most patients in both groups had small to medium-sized perforations, while a smaller proportion had large or subtotal perforations. The differences in perforation size between the two groups were not statistically significant ($p = 0.464$). This indicated that the choice of graft material was not dependent on the size of the perforation and that both materials performed equally well across all perforation types.

Postoperative anatomical success was assessed by evaluating the graft uptake rate at one month and three months after surgery. At one month, successful graft uptake was observed in 95.8% of patients in the temporalis fascia group and 98.6% in the cartilage graft group. The same uptake rates were maintained at three months, showing consistent results over time. The difference between the groups was not statistically significant ($p = 0.31$). The small number of graft failures—three in the temporalis fascia group and one in the cartilage group—indicated excellent surgical outcomes in both. The slightly higher success rate with cartilage grafts suggests that cartilage may offer greater stability and resistance to retraction or resorption compared to fascia.

Several randomized controlled trials since 2018 have compared cartilage and temporalis fascia grafts in type I tympanoplasty. Evidence consistently indicates that cartilage grafts offer superior anatomical stability while maintaining comparable functional hearing results. A multicenter RCT demonstrated that cartilage grafts achieved higher graft uptake rates and better resistance to re-perforation compared to temporalis fascia, particularly in patients with large perforations and poor Eustachian tube function [9]. Another trial showed that while both graft types improved the air-bone gap (ABG), cartilage grafts yielded a statistically higher success rate without compromising auditory outcomes [10].

Further studies confirmed that cartilage provides long-term stability and is less prone to retraction or atrophy than fascia. This was especially significant in high-risk middle ear pathology and pediatric cases, where cartilage grafts produced superior durability and anatomical integrity [11,12].

A more recent RCT conducted in 2022 found that cartilage grafts demonstrated significantly lower graft failure rates at one-year follow-up compared with temporalis fascia, with no significant difference in postoperative ABG closure [13]. Similarly, another randomized trial in 2021 reported that cartilage tympanoplasty had fewer recurrences of tympanic membrane retraction, and although both groups showed improved hearing, cartilage maintained better anatomical success over time [14].

Conclusion

Both temporalis fascia and cartilage grafts were highly effective in Type I tympanoplasty with comparable audiological and anatomical outcomes. The cartilage graft showed a marginal advantage in terms of graft stability and hearing improvement, though statistically insignificant.

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