

A Comparative Study of Outcomes Between Temporalis Fascia and Cartilage Graft in Type 1 Tympanoplasty in Mucosal Variety of Chronic Otitis Media in Sub-Himalayan Tertiary Care Hospital

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Abstract

Background: Chronic otitis media (COM) is a prevalent condition, especially in rural India, often necessitating tympanoplasty. This study compares the efficacy of temporalis fascia and cartilage grafts in type 1 tympanoplasty for treating tympanic membrane (TM) perforations due to mucosal COM.

Objective: To evaluate and compare graft uptake and hearing improvement in patients undergoing type 1 tympanoplasty using temporalis fascia versus cartilage grafts.

Methods: A longitudinal, institute-based analytical study was conducted over 18 months at a tertiary care centre in Darjeeling, India. Sixty patients aged 18–50 years with inactive mucosal COM were assigned to receive tympanoplasty with either temporalis fascia (n=30) or cartilage graft (n=30). Audiological assessments and graft uptake evaluations were performed at 8 and 12 weeks postoperatively.

Results: Both groups had comparable demographic profiles. Graft uptake at 12 weeks was higher in the cartilage group (93.3%) compared to the fascia group (86.7%). However, the fascia group exhibited significantly better hearing outcomes, with lower mean air-bone gaps at both 8 weeks (25.3±6.6 dB vs. 29.7±8.4 dB, $p=0.023$) and 12 weeks (23.4±6.8 dB vs. 27.7±8.2 dB, $p=0.031$). No significant differences were observed regarding the presence of perichondrium in the cartilage group.

Conclusion: Temporalis fascia grafts yield superior short-term auditory outcomes, while cartilage grafts offer better graft uptake and long-term stability. Graft selection should be individualized based on patient and disease characteristics.

Keywords: Tympanoplasty, Otitis Media, Suppurative, Tympanic Membrane, Cartilage, Fascia.

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Introduction

Chronic otitis media (COM) is defined as a permanent abnormality of the tympanic membrane (TM), either in the pars tensa or pars flaccida, often resulting from earlier acute otitis media (AOM), negative middle ear pressure, or otitis media with effusion (OME). It can be classified into two types: mucosal and squamous disease. [1] The tympanic membrane, which separates the external ear from the middle ear, consists of three layers and two parts, the pars tensa and pars flaccida. Perforation of the TM, one of the most common clinical presentations in otorhinolaryngology, may be caused by infection, trauma, or rapid environmental pressure changes. Tympanoplasty is a surgical procedure aimed at eradicating middle ear disease

and reconstructing the hearing mechanism with or without TM grafting. Type 1 tympanoplasty specifically focuses on repairing TM perforation while assuming an intact ossicular chain and patent Eustachian tube. [2] The primary goals of this procedure are disease eradication, hearing improvement, and establishing middle ear cleft ventilation. [3] Various graft materials, such as temporalis fascia, tragal cartilage, perichondrium, and adipose tissue have been used over the years for TM repair. Temporalis fascia has been the preferred choice since the 1960s due to its easy accessibility, high survival rate, and minimal complications. [4] However, it is prone to thinning, atrophy, and loss of elasticity. Cartilage grafts, on

the other hand, provide more resistance to pressure changes, but their increased thickness might impact hearing results. [5]

India faces a high burden of ear pathologies, including TM perforations, primarily due to the high prevalence of COM.[6] The rural and poorer communities, especially in sub-Himalayan regions, are more prone to COM due to factors like recurrent exposure to allergens, overcrowding, and poor living conditions.[7] This study was conducted to compare the outcomes of tympanoplasty using either temporalis fascia or cartilage graft in treating TM perforation caused by mucosal variety of COM, with the aim of identifying the most effective and safe surgical procedure for patients in this region.

Materials and Methods

Study Design and Setting: This was an institute-based analytical study with a longitudinal design conducted at the Department of Otorhinolaryngology of the North Bengal Medical College and Hospital, a tertiary care teaching institute located in Darjeeling, India. The study spanned 18 months, from January 2023 to July 2024.

Study Population: The study included patients aged 18 to 50 years diagnosed with inactive mucosal chronic otitis media (COM) who were scheduled to undergo type 1 tympanoplasty using either temporalis fascia or cartilage graft.

Inclusion Criteria

- Patients aged 18-50 years
- Dry ear with central perforation
- Pure conductive hearing loss with an air-bone (AB) gap of more than 25 dB.

Exclusion Criteria

- Patients below 18 or above 50 years of age
- Non-consenters and non-comparative patients
- Pregnant females
- Psychologically unstable or immunocompromised patients
- Patients with uncontrolled type 2 diabetes mellitus, active or inactive squamous disease, ossicular destruction, recurrent revision surgeries, malignancy of the middle ear, or mixed/sensorineural hearing loss
- Patients unable to commit to long-term follow-up.

Sample Size and Sampling Technique: The sample size was calculated using a statistical formula based on the graft uptake rates from a previous study, with an outcome of interest (p1) of 94.8% for cartilage grafts and 93.2% for fascia grafts. With a 10% allowable error and 90% confidence level, the sample size for each group

was 29, rounded off to 30. Non-probability sampling was used to allocate patients to the study groups.

Study Tools: Data was collected using a predesigned questionnaire to gather socio-demographic and illness-related information. Additional tools included:

- Head mirror
- Otoscope
- Aural speculum
- Pure tone audiometer
- Tympanometry machine
- Operating microscope
- Tympanoplasty instruments.

Data Collection Technique: After obtaining informed consent, patients underwent thorough history taking, clinical examination, otoscopic, and microscopic evaluations. Each patient's tympanic membrane (TM) perforation site, size, margin, retraction, middle ear mucosa, and ossicular chain status were assessed. Subsequently, participants underwent type 1 tympanoplasty using either temporalis fascia or cartilage graft.

Patients were recruited into the study groups based on the graft material used in their tympanoplasty, and a non-probability sampling technique was utilized. The procedures were performed using either a transcanal, endaural, or postauricular approach, depending on the patient's individual case.

The postoperative assessment included:

- Weber test
- Examination of mastoid bandage soakage, facial nerve palsy, vertigo, or nystagmus
- Microscopic examination to assess the condition of the gel foam pack and graft uptake (perforation, lateralization, medialization, and gaping) Patients were assessed at subsequent OPD follow-ups after 8 and 12 weeks, using pure tone audiometry and tympanometry findings to evaluate the status of the neo tympanic membrane.

Ethical Considerations: The Institutional Ethics Committee of North Bengal Medical College and Hospital reviewed and approved the project. Informed consent was obtained from all participants, and data was anonymized and stored in a password-protected spreadsheet for analysis.

Data Analysis: Data consistency and completeness were checked and entered into Microsoft Excel, then analyzed using IBM SPSS version 22. Data was categorized and presented using descriptive and inferential statistics.

Continuous data were expressed as mean $\pm$ SD, and a p-value of <0.05 was considered statistically significant.

Results

Thirty patients were assigned to each graft group. The age distribution among the study participants

was not significantly different, with the mean age in the fascia group being 32.3 ± 8.1 years, while the cartilage group averaged 33.4 ± 8.2 years. Both groups had a higher proportion of male participants, with 66.7% in the fascia group and 50% in the cartilage group, but this difference was not statistically significant ($p = 0.190$).

Table 1: Socio demographic and clinical characteristics of the patients (n=60)

Parameters	Fascia group (%)	Cartilage group (%)	p-value
18-24	6(20)	6(20)	0.327
25-29	7(23.3)	4(13.3)	
30-34	3(10)	9(30)	
35-39	7(23.3)	4(13.3)	
≥ 40	7(23.3)	7(23.3)	

Parameters	Fascia group (%)	Cartilage group (%)	p-value
Female	10(33.3)	15(50)	0.19
Male	20(66.7)	15(50)	

Parameters	Fascia group (%)	Cartilage group (%)	p-value
Rural	23(76.7)	20(66.7)	0.390
Urban	7(23.3)	10(33.3)	

Parameters	Fascia group (%)	Cartilage group (%)	p-value
Class II	10(33.3)	7(23.3)	0.718
Class III	9(30)	9(30)	
Class IV	4(13.3)	7(23.3)	
Class V	7(23.3)	7(23.3)	

Parameters	Fascia group (%)	Cartilage group (%)	p-value
Right	18(60)	15(50)	0.436
Left	12(40)	15(50)	

Parameters	Fascia group (%)	Cartilage group (%)	p-value
Small	9(30)	3(10)	0.127
Medium	15(50)	17(56.7)	
Large	6(20)	10(33.3)	

1 a- Age 1 b- Sex 1 c- Residence 1 d- Socioeconomic status (B G Prasad Scale) 1 e- Laterality of Perforation 1 f - Size of Perforation

The majority of participants were from rural households, with 76.7% in the fascia group and 66.7% in the cartilage group. Socioeconomic status was assessed using the modified B.G Prasad scale, and the most common classifications were Class II and III, with no statistically significant difference between the two groups ($p = 0.718$). Regarding the side of ear perforation, 60% of patients in the fascia group and 50% in the cartilage group had right-sided perforations.

In terms of perforation size, medium-sized perforations were predominant in both groups, accounting for 50% in the fascia group and 56.7% in the cartilage group. Small and large perforations were more frequent in the cartilage group, but these

differences were not statistically significant ($p = 0.127$).

Pure tone audiometry findings showed that preoperative air-bone (AB) gaps were similar in both groups (52.4 ± 9.2 dB in the fascia group and 52.7 ± 9.4 dB in the cartilage group, $p = 0.348$). However, at the end of 8 weeks, patients treated with fascia grafts had a significantly lower AB gap (25.3 ± 6.6 dB) compared to the cartilage group (29.7 ± 8.4 dB, $p = 0.023$). This trend continued at the 12-week follow-up, with the fascia group showing an AB gap of 23.4 ± 6.8 dB versus 27.7 ± 8.2 dB in the cartilage group ($p = 0.031$), indicating better auditory outcomes for the fascia grafts.

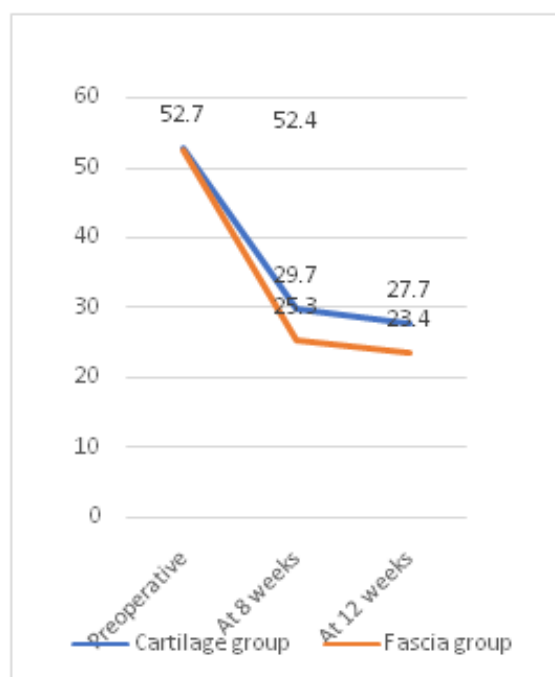


Figure 1: Distribution of study participants according to their pure tone audiometry findings (n=60)

Table 2: Outcome comparison between fascia and graft (n=30)

Parameters	Fascia group (mean $\pm$ SD)	Cartilage group mean $\pm$ SD)	p-value
Pre-operative	52.4 $\pm$ 9.2	52.7 $\pm$ 9.4	0.348
At 8 weeks	25.3 $\pm$ 6.6	29.7 $\pm$ 8.4	0.023*
At 12 weeks	23.4 $\pm$ 6.8	27.7 $\pm$ 8.2	0.031*

Parameters	Fascia group (mean $\pm$ SD)	Cartilage group mean $\pm$ SD)	p-value
At 8 weeks	28(93.3)	30(100)	0.832
At 12 weeks	26(86.7)	28(93.3)	0.771

2 a- Air bone gap (dB) 2 b – Graft uptake

Graft uptake rates were observed at 8 and 12 weeks. At the 8-week mark, the graft uptake rate was 93.3% for the temporalis fascia group and 100% for the cartilage group. By the end of 12 weeks, the uptake rate for the fascia group decreased to 86.7%, while the cartilage group maintained a high rate of 93.3%.

Table 3: Distribution of study participants according to their tympanometry findings at 8 and 12 weeks of observation (n=30)

Tympanometry findings		Fascia group (%)	Cartilage group (%)	p-value
Pre-operative	B Curve	30(100)	30(100)	1.000
At 8 weeks	A Curve	28(93.3)	30(100)	0.832
	B Curve	2(6.7)	0(0)	
At 12 weeks	A Curve	26(86.7)	28(93.3)	0.721
	B Curve	4(13.7)	2(6.7)	

Among the 30 patients in whom cartilage grafts were used, 53.3% had perichondrium, while 46.7% did not. There was no significant impact on hearing outcomes based on whether perichondrium was used or not. Patients without perichondrium had a

mean AB gap of 24.6 ± 2.3 dB at 8 weeks compared to 26.1 ± 9.2 dB in those with perichondrium, and at 12 weeks, it was 22.2 ± 3.1 dB and 24.5 ± 9.3 dB, respectively. These differences were not statistically significant.

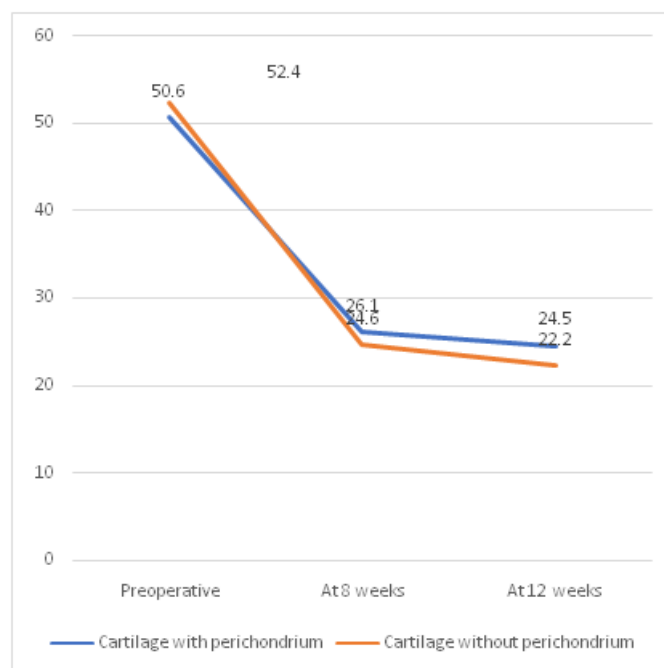


Figure 2: Comparison between cartilage with perichondrium and cartilage without perichondrium with regards to pure tone audiometry findings (n=60)

Discussion

The study found that the graft uptake rate at 8 weeks was 93.3% for the temporalis fascia group and 100% for the cartilage group, with no statistically significant difference between them. By the end of 12 weeks, the uptake rate decreased to 86.7% in the fascia group while it remained high at 93.3% in the cartilage group. These findings align with Sishegar et al., who reported a graft acceptance rate of 100% for the cartilage group and 92.5% for the fascia group, and Vashisth et al., who noted an uptake rate of 83.3% for the fascia group and 90% for the cartilage group.[8,9] Similar results were observed in studies conducted by Khan et al., Yang et al., Jalali et al. and Pradhan et al.[10,11,12,13] In terms of auditory improvement, the pure tone audiometry (PTA) findings revealed that patients treated with fascia grafts had better hearing outcomes than those treated with cartilage grafts. The fascia group showed a mean air-bone (AB) gap of 25.3 ± 6.6 dB at 8 weeks and 23.4 ± 6.8 dB at 12 weeks, compared to 29.7 ± 8.4 dB and 27.7 ± 8.2 dB, respectively, in the cartilage group. The difference was statistically significant, indicating better auditory outcomes with temporalis fascia grafts.

Studies such as Onal et al. and Bozdemir et al. have reported that the mean age of participants was around 30 years, similar to this study, and they found that age might influence the healing process and success rates of tympanoplasty. [14, 15] Younger patients tend to have better regenerative capabilities, contributing to higher success rates in graft uptake and hearing improvement.

Additionally, patients treated with cartilage grafts without perichondrium had a mean AB gap of 24.6 ± 2.3 dB at 8 weeks and 22.2 ± 3.1 dB at 12 weeks, compared to 26.1 ± 9.2 dB and 24.5 ± 9.3 dB, respectively, for those with perichondrium. However, these differences were not statistically significant, indicating that the presence of perichondrium did not substantially impact hearing outcomes. Temporalis fascia has been a preferred graft material due to its ease of harvest, handling, and satisfactory success rates, with reports indicating graft uptake and hearing improvement rates around 85-90%. The fascia's flexibility and resilience allow it to adapt well to the tympanic membrane's dynamic environment, promoting effective healing and integration.

Cartilage grafts, especially tragal cartilage, have gained popularity for their stability and resistance to retraction, making them suitable for cases where a more rigid graft is necessary. The structural integrity of cartilage offers better long-term stability and a lower likelihood of resorption, with success rates ranging from 85-95%. However, the rigidity of cartilage can affect hearing outcomes, as the cartilage graft group in this study exhibited slightly poorer hearing results compared to the fascia group.

While temporalis fascia grafts provided superior short-term auditory outcomes, cartilage grafts offered better graft stability over time. These findings suggest that although fascia grafts may yield better hearing improvements in the early postoperative period, cartilage grafts may be more suitable for maintaining long-term stability,

especially in cases of recurrent infections or significant retraction pockets.

Studies such as Yegin et al. have shown that the long-term outcomes of cartilage grafts tend to be more stable compared to temporalis fascia, supporting the observations of the current study. [16] This reinforces the idea that cartilage grafts can be advantageous for patients who require long-term structural integrity of the tympanic membrane.

Conclusion

The study demonstrates that both temporalis fascia and cartilage grafts are effective in type 1 tympanoplasty, with each having distinct advantages. Temporalis fascia grafts showed superior short-term auditory outcomes, while cartilage grafts demonstrated better long-term stability and graft uptake. The choice of graft material should consider the patient's individual characteristics, the size and site of the perforation, and the potential for future middle ear infections.

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