Volume-12/Issue-II/Dec. 2024/ISSN No.-2321-3450
ORIGINAL RESEARCH ARTICLE
DOI: htttp: /doi.org/10.36611/upjohns/volume12/Issue2/1
Date received: 01.11..2024 / Date Published : 31.12.2024

A COMPARATIVE STUDY OF USING TEMPORALIS FASCIA AND TRAGAL CARTILAGE AS A GRAFT MATERIAL FOR ENDOSCOPIC TYMPANOPLASTY

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ABSTRACT

BACKGROUND

Chronic Suppurative Otitis Media (CSOM) is a significant health issue characterized by persistent infection of the middle ear, leading to tympanic membrane perforation and hearing loss. Tympanoplasty, a surgical procedure aimed at repairing the tympanic membrane, utilizes graft materials like temporalis fascia and tragal cartilage. This study compares the efficacy of these graft materials in endoscopic tympanoplasty, focusing on clinical and audiological outcomes.

INTRODUCTION

CSOM presents a global health challenge, often necessitating surgical intervention for tympanic membrane repair. Temporalis fascia has traditionally been the preferred graft material, but tragal cartilage has gained recognition due to its resilience and stability. This study aims to evaluate and compare the outcomes of temporalis fascia and tragal cartilage grafts in endoscopic tympanoplasty, filling a gap in the existing literature.

METHODOLOGY

This comparative analytical study was conducted at Hind Institute of Medical Sciences (HIMS), Barabanki, over 12 months, enrolling 70 patients aged 18 to 60 years with CSOM requiring type 1 tympanoplasty. Patients were randomly assigned to Group A (temporalis fascia) or Group B (tragal cartilage). Postoperative evaluations included clinical assessments and pure-tone audiometry at 1, 3, and 6 months. Data analysis was performed using SPSS software.

RESULTS

Both temporalis fascia and tragal cartilage grafts demonstrated similar efficacy in improving tympanic membrane integrity and hearing outcomes. Postoperative tympanic membrane integrity was achieved in 85.71% of Group A and 97.14% of Group B, with no statistically significant differences ($p > 0.05$). Audiological improvements were comparable between the groups, with significant intra-group gains in hearing thresholds but no significant inter-group differences. Tragal cartilage offered better structural stability, while temporalis fascia was associated with favorable hearing improvement.

CONCLUSION
The study concludes that both temporalis fascia and tragal cartilage grafts are effective for endoscopic tympanoplasty, with no significant differences in clinical or audiological outcomes. Tragal cartilage provides enhanced graft stability, while temporalis fascia offers effective hearing improvement. The choice of graft material should be tailored to individual patient needs and surgeon expertise, emphasizing a personalized approach in otologic surgery.

KEYWORDS
Chronic Suppurative Otitis Media, Tympanoplasty, Temporalis Fascia, Tragal Cartilage, Endoscopic Ear Surgery, Graft Material.

INTRODUCTION
Chronic Suppurative Otitis Media (CSOM) is a prevalent infectious disease in childhood that poses significant health challenges worldwide[1]. Defined by the World Health Organization and the CIBA Foundation in 1996, CSOM is characterized by a persistent infection of the middle ear cleft, including the Eustachian tube, middle ear, and mastoid, accompanied by a non-intact tympanic membrane and persistent discharge lasting for at least two weeks[2]. This condition is exacerbated by various risk factors such as upper respiratory tract infections, malnutrition, poor hygiene, and familial predispositions. Additionally, specific demographic factors, including low birth weight and craniofacial abnormalities, contribute to its prevalence[3].

The symptoms of CSOM primarily include hearing loss and otorrhea, with the latter defined as the discharge of fluid from the ear canal through a perforated tympanic membrane. Hearing loss in CSOM is usually mild and conductive, ranging from 10 to 20 dB, but can become more pronounced if large perforations or ossicular chain erosion occur. The presence of a cholesteatoma must be carefully evaluated, as it can significantly affect hearing outcomes[4]. Tympanic membrane perforations in CSOM can vary in location and type, being either marginal or central, and moist or dry, depending on the presence of active otorrhea[5].

CSOM is classified into several subtypes based on clinical features and disease progression, including active chronic otitis media with or without cholesteatoma, and inactive forms with various complications such as perforations or ossicular fixation. The condition is a leading cause of tympanoplasty, a surgical procedure aimed at repairing the tympanic membrane and improving hearing. Advances in surgical techniques, particularly the shift towards endoscopic tympanoplasty, have revolutionized the management of CSOM. This approach, which minimizes the need for larger incisions, aligns with contemporary trends in minimally invasive surgery[6,7].

Historically, the choice of graft material for tympanoplasty has predominantly been temporalis fascia due to its ease of access and biocompatibility. However, tragal cartilage, known for its resilience and resistance to retraction, has gained recognition as a valuable alternative[6]. The selection of graft material significantly impacts surgical outcomes and patient satisfaction. Despite the established use of these materials, there is a critical need for comparative studies to determine which grafttemporalis fascia or tragal cartilage

provides superior results in endoscopic tympanoplasty[8].

Several studies have examined the effectiveness of various graft materials and techniques in tympanoplasty, a popular middle ear surgery. Patel J et al. (2015)[9] found endoscopic and microscopic approaches equally effective in achieving favorable outcomes in tympanoplasty, while Akyigit A et al. (2017)[7] emphasized the growing preference for endoscopic methods due to their minimally invasive nature. Kolethekkat AA et al. (2018)[10] and Mohanty S et al. (2018)[11] noted that cartilage rim grafts and composite cartilage perichondrium grafts yielded high success rates, particularly for anterior perforations. Mehta R et al. (2019)[12] observed higher graft uptake with cartilage grafts, although both cartilage and temporalis fascia showed similar long-term hearing outcomes. Özdamar K et al. (2020)[13] and Hasan MI et al. (2021)[14] demonstrated the advantages of tragal cartilage grafts over fascia and perichondrium, with better graft stability and hearing improvement. Varma A et al. (2021) [15] found no significant functional differences between tragal perichondrium and composite cartilage grafts, although structural outcomes favored the latter. Tahir M et al. (2021)[16] and Vadiya SI et al. (2022)[17] also supported the superior hearing outcomes associated with cartilage grafts, particularly conchal cartilage. Finally, Ishfaq U et al. (2023)[18] highlighted the significantly higher success rate of tragal cartilage Type-I underlay tympanoplasty (100%) compared to temporalis fascia (72.5%), regardless of demographic factors or perforation size. These findings collectively underscore the advantages of cartilage-based grafts, particularly in enhancing graft uptake and hearing outcomes.

This research aims to fill the gap in current literature by evaluating the efficacy of these graft materials, thereby informing surgical practices and improving patient outcomes in the management of CSOM.

MATERIAL AND METHODS

The study was conducted at the Hind Institute of Medical Sciences (HIMS), Barabanki, over a period of 12 months, focusing on patients aged 18 to 60 years who presented with Chronic Suppurative Otitis Media (CSOM) at the ENT outpatient department. Employing a comparative analytical study design, a total of 70 patients were recruited and divided equally into two groups. Group A underwent tympanoplasty using temporalis fascia (TF), while Group B received tragal cartilage grafts. The sample size calculation, based on graft healing rates of 94.7% for cartilage and 70% for TF, indicated a minimum of 33 participants per group, resulting in a total sample size of 66, rounded to 70 for robustness.

Sampling was done using consecutive selection of consenting patients meeting the inclusion criteria, which included central perforations requiring type 1 tympanoplasty and exclusion criteria such as age outside 18-60 years and presence of sensorineural hearing loss or unsafe ear conditions. Both graft types were harvested through standard procedures, with temporalis fascia obtained via a hairline incision and tragal cartilage through a permeatal approach. The study involved meticulous surgical steps including freshening of perforation margins, graft placement, and flap repositioning.

Postoperative assessments were conducted at 1, 3, and 6 months, including clinical evaluations and pure-tone audiometry at frequencies of 500Hz, 1000Hz, 2000Hz, and 4000Hz. Success was defined by graft uptake without complications and improved audiological outcomes. Data collection included detailed patient histories and clinical findings, with ethical clearance granted by the Institutional Ethics Committee of HIMS and written informed consent obtained from all participants.

Statistical Analysis:

SPSS software (SPSS Inc., Chicago, IL, USA) was used for statistical analysis with the Windows program (26.0 version).

RESULTS

The comparative analytical study, conducted at the Otorhinolaryngology Department of Hind Institute of Medical Sciences, Barabanki, involved 70 patients aged 18 to 60 years requiring type 1 tympanoplasty for central perforations. Participants were randomly assigned to two groups: Group A, which received temporalis fascia grafts, and Group B, which received tragal cartilage grafts. The demographic analysis revealed no significant differences in mean age (Group A: 36.20 years, SD = 9.24; Group B: 34.63 years, SD = 9.10), gender distribution, or occupational status between the groups(Table 1). Both groups reported identical chief complaints of hearing loss and ear discharge, with no significant differences noted(Figure 1).

DEMOGRAPHICS	GROUP- A (n=35)		GROUP-B (n=35)		P-VALUE
	N/Mean	SD/%	N/Mean	SD/%	
MEANAGE(YEARS)	36.20	9.24	34.63	9.10	t=0.7162 p=0.4763
20-29	10	28.57%	15	42.86%	X=3.779 p=0.2863
30-39	9	25.71%	11	31.43%	
40-49	13	37.14%	6	17.14%	
50-59	3	8.57%	3	8.57%	
GENDER					
Male	7	20.00%	12	34.29%	X=1.086 p=0.1790
Female	28	80.00%	23	65.71%	
OCCUPATION					
Office workers	10	28.57%	12	34.29%	X=0.5398 p=0.9101
Laborers	8	22.86%	9	25.71%	
Students	7	20.00%	6	17.14%	
Others	10	28.57%	8	22.86%	

TABLE1: Demographical characteristics of the patients in both groups

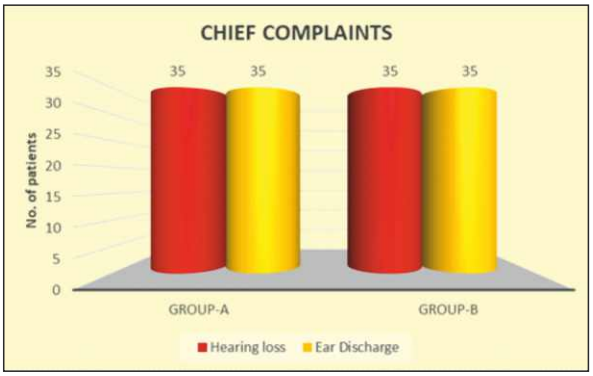

FIGURE 1: Graphical representation of the chief complaints of the patients in both groups

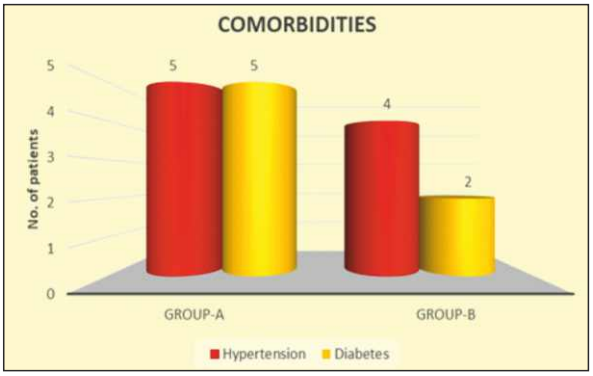

FIGURE 2: Graphical representation of the comorbidities among the patients in both groups.

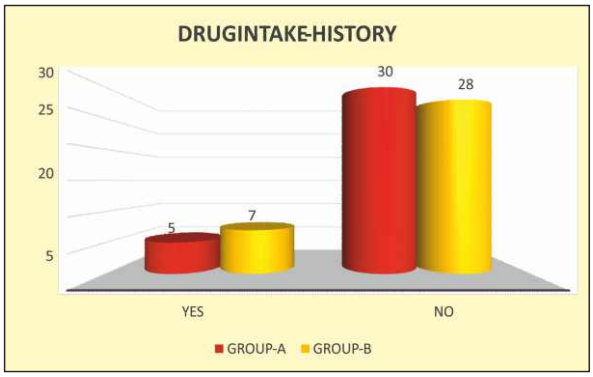

FIGURE 3: Graphical representation of the drug in take history among patients in both groups.

Comorbidity profiles showed similar rates of hypertension and diabetes between groups, and drug intake history was not significantly different(Figure 2,3). Clinical examination revealed no notable disparities in vital signs except for blood pressure, where Group A had slightly lower systolic and diastolic readings compared to Group B, though the clinical relevance of these differences is debatable(Table 2). Abnormal local and radiological findings were also comparable between the groups. Most patients exhibited central perforations of varying sizes, and otoendoscopy showed no significant differences in perforation types between groups(Table 3).

CLINICALEXAMINATIONFINDINGS		GROUP-A (n=35)		GROUP-B (n=35)		P-VALUE
		N/Mean	SD/%	N/Mean	SD/%	
Pallor		2	5.71%	1	2.86%	X=0.3483 p=0.5551
Icterus		0	0.00%	0	0.00%	--
Cyanosis		0	0.00%	0	0.00%	--
Lymphadenopathy		1	2.86%	2	5.71%	X=0.3483p=0.5551
Temperature(°C)		37.1	0.4	37.0	0.3	t=1.183p=0.2408
Pulserate(beats/min)		75.63	5.34	78.42	6.87	t=1.897p=0.0621
Respiratoryrate(breaths/min)		16.63	2.26	17.53	3.86	t=1.190p=0.2380
BLOODPRESSURE(MMHG)	SBP	114.73	4.62	117.92	5.73	t=2.564 p=0.0126*
	DBP	75.72	3.86	77.46	2.97	t=2.114 p=0.0382*
ABNORMALFINDINGS	Cardiovascular system	0	0.00%	0	0.00%	--
	Pulmonarysystem	0	0.00%	0	0.00%	--
	Gastrointestinal system	0	0.00%	0	0.00%	--
	CentralNervous System	0	0.00%	0	0.00%	--

TABLE 2: Clinical examination of the patients in both groups

ABNORMALLOCALEXAMINATIONFINDINGS	GROUP- A(n=35)		GROUP-B(n=35)		P-VALUE
	N	%	N	%	
Pinna	6	17.1%	8	22.9%	X=0.3571p=0.5501
PreandPostauricular region	5	14.3%	7	20%	X=0.4023p=0.5259
Externalauditorymeatus	4	11.4%	6	17.1%	X=0.4667p=0.4945
Tympanic membrane (Centralperforation)	35	100.0%	35	100.0%	X=0.000p>0.9999
Middleearmucosa	7	20%	5	14.3%	X=0.4023p=0.5259

TABLE 3: Abnormal local examination findings of the patients in both groups.

Audiological assessments revealed that pre-operative pure tone audiometry (PTA) scores were slightly higher in Group A, but post-operative scores were similar between groups. Both groups demonstrated significant improvements in PTA scores post-operatively, but no significant inter-group differences were observed(Table 4). The gain in air-bone gap was also comparable, though Group B showed a higher proportion of minimal gains (<5 dB)(Table 5). Post-operative otoendoscopy indicated that Group B had a higher rate of intact tympanic membranes compared to

PTA	GROUP-A[N=35]		GROUP-B[N=35]		P-VALUE
	MEAN	SD	MEAN	SD	
Pre-op	46.26	5.03	42.74	9.45	t=1.945p=0.0559
Post-op	33.37	5.41	32.43	7.24	t=0.6153p=0.5404
p-value	t=10.32 p<0.0001*		t=5.124 p<0.0001*		

Group A, but this difference was not statistically significant(Table 6).

GAININABGAP (db)	GROUP-A[N=35]		GROUP-B[N=35]		P-VALUE
	N	%	N	%	
<5	1	2.86%	8	22.86%	X=7.597 p=0.0551
6-10	9	25.71%	10	28.57%	
11-15	18	51.43%	14	40.00%	
>16	7	20.00%	3	8.57%	

TABLE 4: Puretone audiometry results of the patients in both groups.

OTOENDOSCOPY	GROUP-A [N=35]		GROUP-B [N=35]		P-VALUE
	N	%	N	%	
INTACT	30	85.71%	34	97.14%	X=2.917 p=0.0877
NON-INTACT	5	14.29%	1	2.86%	

TABLE 5: Gainintheair-bone gap among patients in both groups.

TABLE 6: Otoendoscopy findings regarding the tympanic membrane integrity among patients in both groups. (Post-operative)

Overall, the study demonstrated that both graft materials were effective in tympano-plasty, with no significant differences in clinical or audiological outcomes between the two groups.

DISCUSSION

Tympanoplasty, or myringoplasty, involves repairing the tympanic membrane (TM) with a tissue graft to improve hearing, with or without mastoidectomy [2]. According to Wullstein's classification, there are five types of tympanoplasty, ranging from Type I (TM repair alone) to Type V (closed middle ear with round window protection). Autologous grafts, such as temporalis fascia (TF) and tragal cartilage, are commonly used due to their biocompatibility and cost-effectiveness. TF, derived from the temporalis muscle, is versatile and frequently used, with success rates between 93% and 97%[1,8]. Tragal cartilage, known for its stability and minimal donor site morbidity, is preferred in cases requiring enhanced support[8].

In this study, 35 participants were assigned to each Group A and B. The mean age showed no significant difference between Group A (36.20±9.24 years) and Group B (34.63±9.10 years). In Group A, the majority were aged 40-49 years (37.14%), while in Group B, most were aged 20-29 years (42.86%). Female preponderance was noted in Group A (80.00%) and B (65.71%). Office workers were the most common occupation in both Group A (28.57%) and B (34.29%), followed by laborers and students. Overall, there was no significant demographic difference between the groups. In the study by Ishfaq U et al. [18], 80 patients were included, with 40 in the tragal cartilage group and 40 in the temporalis fascia group. The age range was 20–40 years, with a mean age of 29.41 ± 5.75 years. The gender ratio was 1.1:1, comprising 42 men (52.5%) and 38 women (47.5%).JhawarMetal.[19]examined75caseswit hcentral perforation, utilizing temporalis fascia graft in 25 cases, fascia lata graft in 25cases, sliced tragal cartilage graft in 25 cases. The mean ages of the patientswere 34.92±10.29, 36.88±9.23, and 36.68±9.38, respectively. In the study by Mohanty S et al. [11], 187 eardrums

from 168 patients with anterior quadrant perforations were treated. Of these, 87 ears underwent tragal composite cartilage perichondrium island (CCPI) grafting, while 100 ears received temporalis fascia grafting. The mean age was 31.3 ± 4.9 years for the cartilage group and 30.2 ± 4.2 years for the fascia group. Women were the majority in both groups, making up 68.9% and 64%, respectively. The gender distribution was comparable across all groups. Özdamar and Sen [13]analyzed 81 cases (33 women, 48 men, mean age 22.1 ± 10.1 years) who underwent transcanal endoscopic type 1 tympanoplasty. Tahir M et al. [16] included 34 patients, with 17 in the temporalis fascia group and 17 in the tragal perichondrium group. The mean age was 32 ± 10.81 years in the fascia group and 30.82 ± 9.6 years in the cartilage group. Both studies reported male predominance, with no significant differences in age or gender distribution among the groups.
In this study, all participants in both groups reported hearing loss (100%) and ear discharge (100%). Hypertension was present in 14.29% of Group A and 11.43% of Group B, with similar rates of diabetes (14.29% in Group A and 5.71% in Group B). Clinical exams showed no significant differences in pallor, lymphadenopathy, temperature, pulse rate, or respiratory rate. However, significant differences were noted in blood pressure. Central TM perforation was prevalent in both groups (100%). Abnormalities included pinna, pre/post-auricular regions, EAC, and middle ear mucosa, though differences were not statistically significant ($p > 0.05$). These findings align with previous studies emphasizing ear-related symptoms in otologic cases. In conjunction with our own observations, the documented experiences by others underscore the prevalence and clinical relevance of these symptoms such as Ishfaq U et al. [18] reported that every participant presented with dry ear and TM perforations of varying sizes, followed by cases of COM. Jhawar M et al. [19] observed instances of COM, inactive status, mucosal abnormalities, perforations, and conductive hearing loss among their patients. Tahir M et al. [16] illustrated that all individuals included in their study exhibited perforations. Further more, priorresearchhas consistently highlighted ear discharge, perforation, hearing loss as prevalentcomplaintsamongpatients[10].

In this study, tuning fork tests (Rinne's, Weber, and ABC) were uniformly abnormal in both groups (100%), with no significant differences ($p > 0.9999$). Radiological findings showed abnormalities in X-Ray Mastoid Schuller's view for 22.86% in Group A and 31.43% in Group B ($p=0.4201$), while X-ray chest PA view showed no abnormalities in either group. CSOM prevalence in the left ear (LT) was 45.71% in Group A and 42.86% in Group B, with similar rates for the right ear (RT), and the remaining cases were bilateral. Diagnosis distribution showed no significant differences between groups ($p > 0.05$). Our findings align with previous studies. Kolethekkat A et al. [10] reported 54.8% left ear pathology and 45.2% right ear pathology. Özdamar and Sen [13] found similar left ear predominance, with 56.1% in the cartilage group and 55.0% in the fascia group. Tahir M et al. [16] noted equal left and right ear involvement (50% each), though a slight right ear predominance (52.94%) was seen in the fascia group, while the cartilage group had more left ear cases (52.94%).

In the present study, most otoendoscopy findings were medium central perforations,

with 68.57% in Group A and 74.29% in Group B. Large central perforations were seen in 17.14% of Group A and 8.57% of Group B, while small perforations were noted in 5.71% of Group A and 17.14% of Group B. Subtotal perforations were reported only in Group A (8.57%). No significant differences were observed between the groups (p=0.1078). Similar findings were reported by Ishfaq U et al. [18], Mohanty S et al. [11], Özdamar and Sen [13], and Tahir M et al. [16], with most cases involving medium-sized perforations (25-50%) and no significant disparities in perforation rates across groups.

In this study, mean pre-operative PTA scores were 46.26±5.03 dB for Group A and 42.74±9.45 dB for Group B. Post-operatively, scores improved to 33.37±5.41 dB in Group A and 32.43±7.24 dB in Group B. Intra-group analysis showed significant improvements in both groups ($p < 0.0001$), while inter-group comparisons revealed no significant differences in pre-op ($p = 0.0559$) or post-op ($p = 0.5404$) PTA scores. Most participants in both groups achieved AB gap gains within the 11-15 dB range. Group B had a higher proportion of gains <5 dB (22.86%) compared to Group A (2.86%). While Group A showed more gains >16 dB, the difference was not statistically significant ($p = 0.0551$). These findings align with Vamanshankar H et al. [20] and others [13,21], who reported significant post-op improvements in both groups. However, some studies noted slightly better outcomes in the cartilage group, though differences were not statistically significant [22,23]. Overall, hearing outcomes were comparable between cartilage and fascia groups, emphasizing the role of subjective patient experiences in treatment evaluation.

In the present study, most participants in Group A (85.71%) and Group B (97.14%) exhibited an intact tympanic membrane. While Group A had a higher proportion of non-intact grafts (14.29%) compared to Group B (2.86%), the difference was not statistically significant ($p = 0.0877$). Similar findings were reported by Özdamar and Sen [13], with intact grafts in 92.6% of cartilage and 90.0% of fascia cases. Mohanty S et al. [11] noted no graft medialization or lateralization in the cartilage group, unlike the fascia group, where some medialization occurred. Mehta R et al. [12] also found better graft stability in cartilage tympanoplasty, while fascia tympanoplasty presented issues like graft medialization and retraction pockets. However, Ishfaq U et al. [18] and others [24-27] reported significantly better outcomes with cartilage grafts. Although some RCTs found no major differences between techniques in terms of morphology and audiology [28,29], a few studies [30] suggested cartilage tympanoplasty offers better morphological outcomes without significant hearing differences.

Our study, along with existing literature, highlights the varied outcomes in tympanoplasty using different graft materials. Although no significant differences were found between cartilage and fascia grafts regarding clinical parameters like tympanic membrane integrity, symptom prevalence, and hearing tests, some studies suggest trends favoring cartilage for morphological outcomes. However, these differences are not consistently significant across studies. Both graft types effectively improve hearing and repair perforations, with comparable long-term results. The choice of graft material depends on patient-specific factors and

surgeon experience, emphasizing the need for individualized treatment in otologic surgery.

CONCLUSION

The study compared the outcomes of temporalis fascia (TF) and tragal cartilage grafts in endoscopic tympanoplasty, enrolling 70 patients divided equally between the two graft types. No significant differences were found in demographic characteristics, chief complaints, comorbidities, or pre-operative assessments between the groups. Both grafts showed similar efficacy in improving hearing and tympanic membrane integrity post-operatively. However, tragal cartilage was noted to offer better stability and coverage, while temporalis fascia demonstrated effective hearing improvement. Despite these observations, statistical analysis did not reveal significant differences in the overall effectiveness of the two graft materials. Future research could focus on long-term outcomes, graft survival, and patient-reported experiences to further guide surgical choices.

Conflict of Interest: The authors declare that there are no conflicts of interest.

Source of Funding: The study received no external funding.

Consent: Written informed consent has been obtained from all participants in accordance with international or university standards and is maintained by the authors.

Ethical Approval: Ethical approval was granted in compliance with international or university standards, and the written approval is preserved by the authors.

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How to cite this article

Tyagi B, etal; -A Comparative Study of Using Temporalis Fascia and Tragal Cartilage as a Graft Material for Endoscopic Tympanoplasty- UPJOHNS; Dec24; 12(2); page:1-11