# **Original Research Article**

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# A comparative study of temporalis fascia and fascia lata graft in type-1 tympanoplast

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#### **ABSTRACT**

**Background:** Chronic Suppurative Otitis Media (CSOM) is most commonly faced otological condition by ENT surgeons. Tympanoplasty is the established surgical management for tympanic membrane perforation. In this study we are comparing temporalis fascia and fascia lata as graft material in type-1 tympanoplasty to compare the graft taken up and post-op hearing improvement.

**Methods:** A retrospective study over 80 patients with CSOM of mucosal type, dry ear for more than 6-8 weeks and the age of 15-60 years enrolled in the study. The patients who underwent the surgery for randomly assigned into 2 groups: group-1: tympanoplasty operated with temporalis fascia graft, group-2: tympanoplasty operated with fascia lata graft. All surgeries done under general anesthesia. The patients were evaluated post operatively in terms of graft taken up and hearing status.

**Results:** In our study post op tympanoplasty graft taken up with temporalis fascia was 86.36% whereas fascia lata graft contributed 88.88%. Hearing gain on an average with temporalis fascia graft was 11.46 dB while with fascia lata graft was 10.09 dB. Statistical data proved that there was no significant difference between two groups. So both groups had their own merits and demerits.

**Conclusions:** Overall graft uptake rate and hearing gain with temporalis fascia and fascia lata in type 1 tympanoplasty are almost equal. There was no significant difference in both groups so ultimately it is surgeon choice and level of expertise that decides use of graft material in tympanoplasty.

Keywords: Chronic suppurative otitis media, Tympanoplasty, Temporalis fascia, fascia lata

#### **INTRODUCTION**

The restoration of hearing as a aim of surgery was introduced in 1952-1953 only; though history of surgery of deafness goes back to almost 700 years. Chronic otitis media is the most common problem faced by ENT surgeons in society, characterized by ear discharge and permanent perforation in the tympanic membrane. It affects both sexes and all age groups. In India prevalence rate is higher in rural area 46/1000 persons and lesser in urban area 16/1000 persons 1. Myringoplasty is an

operation in which the reconstructive procedure is limited to repair of tympanic membrane perforation assuming that the middle ear ossicles are functioning normally, where as tympanoplasty is an operation in which inspection and repair of middle ear sound conductive apparatus with reconstruction of tympanic membrane.<sup>2</sup> The graft tissue selection factors include biological properties, probability of survival and size and ease of procurement.<sup>3</sup> However due to its anatomic proximity, translucency, high basal metabolic rate temporalis fascia is the most preferred grafting material among the

otologist; success rate is 90% in primary tympanoplasty.<sup>4,5</sup> Failure rates are higher in larger perforation with this material whereas fascia lata graft has better dimensional stability and is more preferred for large perforation as it is more resistant to negative middle ear pressure.<sup>4,5</sup> The objective of this study is to compare the graft uptake rate and to assess hearing gain by comparing preoperative and postoperative Air-bone gap (ABG) in pure tone audiogram using different grafting materials. Multiple studies have been done for quantitative assessment regarding postoperative hearing gain. But postoperative anatomical graft assessment is always subjective and there is always a chance of bias regarding oto-microscopic picture of graft uptake. This is lacuna regarding this study.

#### **METHODS**

#### Study design

The present retrospective, observational, and interventional study was carried out after approval of ethical committee at Department of ENT, GMERS Medical College and General Hospital, Himmatnagar, from August 2020 to October 2021.

### Study population

The study population i.e. sample size was decided according to patients consulting to ENT department with CSOM within the time duration of study period, who fulfil standard criteria for tympanoplasty entered in software OpenEpi, Version 3, open source calculator –SS Propor

Sample sie 
$$n = DEFF \times Np(1-p) \div d^2 \div Z21 - \alpha$$
  
  $\div 2 \times (N-1) + p \times (1-p)$ 

Population size (for finite population correction factor or fpc) (N):120

Hypothesized % frequency of outcome factor in the population (p):  $7.8\%\pm6$ 

Confidence limits as % of 100 (absolute±%)(d):6%

Design effect (for cluster surveys-DEFF):1

Here at 95% confidence interval sample size =83

We have taken 80 cases

#### Study methods

All the patients of the age of 15-60 years having CSOM of mucosal type, having dry ear for at least 6-8 weeks were included in this study. Patients having squamous type of chronic otitis media, with active mucosal suppurative otitis media, with sensorineural hearing loss

were excluded from study. 80 patients were randomly selected fulfilling the above criteria and randomly assigned into 2 groups: group 1-tympanoplasty operated with temporalis fascia graft, group-2: tympanoplasty operated with fascia lata graft. After the clinical examination was over, all patients underwent pure tone audiometry (PTA) and X-ray mastoids. All the surgeries were carried out under General anesthesia by experienced surgeons. The standard post aural approach for surgical procedure was adopted. a) in cases where temporalis fascia graft was used dissection was done until the temporalis fascia reached which was identified by its white glistening colour. b) In cases where fascia lata were used. Local infiltrated in to the lateral aspect of the thigh. the center of which lies over the junction of the upper two-third and lower one-third. A longitudinal incision, approximately 2-3 cm long, is made along the lateral thigh, approximately 8 cm above the lateral condyle. Dissection carried out until fascia lata identified. Fascia of adequate size was harvested and then the fascia was pressed, spread out and dried.

Table 1: Confidence level with respective to sample size.

Confidence level (%)	Sample size
95	83
80	59
90	74
97	88
99	96
99.9	104
99.99	108

Wound was closed in layers in fascia lata cases. Under microscopic view freshening of the margins of perforation. Posterior tympanomeatal flap raised anteriorly from 12'o clock position to 6'o clock position to expose the middle ear. Mobility of the ossicular chain is checked. The harvested graft was placed by inlay method. The tympanomeatal flap was reposited back carefully and antibiotic and steroid soaked gel foam was kept in the canal and wick soaked in Neosporin ointment was kept. Postaural incision was closed in layers and mastoid bandage was applied.

Post-operatively all the patients were given a course of antibiotics, antihistamines, analgesic and antacids. Patients are called for regular follow ups and advised regarding care of ear. Patients were observed at their follow up visits on 1 week, 2 weeks, 6 weeks and 3 months from post-operative day. Pure tone audiogram was done at the end of 3 months.

#### Statistical method

In this study the qualitative data like status of graft uptake (anatomical outcome) was studied by Chi square test by quantpsy.org online calculator.



Figure 1: Post auricular incision.



Figure 2: Temporalis fascia graft.



Figure 3: Fascia lata incision.

Here p>0.05 so there was no statistical significance and the quantitative data like hearing gain was measured with t-est was used comparing pre-op and post-op hearing level by Microsoft excel, version 2016. In this study, p<0.05. So, the data is highly significant.

## **RESULTS**

In our study, main stream of patients within the age group of 15-30 years (n=48), the youngest patient was 16 years of age, and oldest was 56 years. The average age is 30.19 years. Patients were selected randomly in the study irrespective of their sex. In our study Male: Female ratio is 1.5:1. All our patients had complained of ear discharge either in present or in past. All patients were taken for

surgery in dry state. Majority of the patients complained of some degree of hearing loss, remaining may not complained of decreased hearing due to unilateral mild deafness though it is evident on audiometry. More than half of the patients agreed for surgery after having ear discharge intermittently for more than 5 years. The reason for this may be ignorance, patient want to go for conservative treatment in initial stages, lack of education regarding need of treatment and difficulty in access for health care.



Figure 4: Fascia lata graft.

Table 2: Mean hearing loss in relation to size of perforation.

	Present study		
Size of perforation	No. of patients	Case in %	Mean hearing loss
Small	16	20	20 dB
Medium	32	40	26 dB
Large	32	40	33 dB

All 16 cases (20%) of small perforation were initially conservatively managed, but they didn't improve so they were taken up for surgery. Perforations of tympanic membrane causes a conductive hearing loss that can range from negligible to 50 dB.

Perforation causes a loss that depends on perforation size and middle ear space volume. Perforation size is an important determinant of the loss, larger perforations result in larger hearing losses.<sup>3</sup> 80% of patients on our study was having moderate to large perforation which correspondence to degree of hearing loss.

Patients are randomly chosen and put in each group, so no bias is there. We had taken 44 patients for temporalis fascia and 36 were selected for fascia lata.

The success rate in achieving an intact tympanic membrane in expert hands is often quoted as around 95 percent.<sup>14</sup> In our study graft take up rate for fascia lata is 88.88% and for temporalis fascia it is 86.36%. Present

study shows that both temporalis fascia and fascia lata have almost equal graft uptake rate. For achieving a better comparative results we should be having larger number of patients in the study.

Table 3: Status of graft.

Status of graft	Temporais Fascia (%)	Fascia lata (%)	No. of cases (%)
Taken up	38 (86.36)	32 (88.88)	87.5
Rejected	6 (13.63)	4 (11.11)	12.5
Total	44	36	80

Table 4: Graft success rate with respect to size of perforation.

Size	Graft	Total	Success (%)
Small	Temporalis Fascia	6	6 (100)
	Fascia lata	10	8 (80)
Moderate	Temporalis Fascia	14	10 (71.42)
	Fascia lata	18	16 (88.88)
Large	Temporalis Fascia	24	22 (91.6)
	Fascia lata	8	8 (100)

Table 5: Total hearing gain in successful graft taken up case.

	Present stud	y		
Graft material Pre-op (dB) hearing loss		Postop (dB) hearing loss	Hearing gain (dB)	
Temporalis Fascia	39.96	28.49	11.46	
Fascia Lata	35.76	25.66	10.09	

In smaller perforation temporalis fascia has better graft uptake than fascia lata and in large perforation fascia lata has better graft uptake compared to temporalis fascia. And in case of moderate perforation also fascia lata has upper hand in terms of graft up take when compared with temporalis fascia.

**Table 5: Improvement in ABG.** 

	Present Study			
Graft	Mean Pre- op ABG (dB)	Mean Post-op ABG (dB)	Mean Gain in ABG (dB)	
Temporalis Fascia	24.9±6.28	16.45±3.74	8.45±5.13	
Fascia Lata	22.42±8.50	13.07±5.07	9.25±5.01	

Table 7: Comparison of taken up rate of graft material in different studies.

Author	Temporalis fascia (%)	Fascia lata (%)
Present study	86.36	88.88
Bhoopendra et al <sup>10</sup>	94.5	83.3
Kshitij et al <sup>7</sup>	86.67	85
Hardik et al <sup>8</sup>	96.66	93.33
Grishma et al <sup>11</sup>	84	96
Mohite et al <sup>15</sup>	96	96

In present study hearing gain in temporalis fascia is 11.46 dB and in fascia lata it is 10.09 dB. The study is comparable to Kshitij et al.<sup>7</sup> As per hearing is concerned, type of graft doesn't alter the outcome.

The mean gain in air bone gap (ABG) in temporalis fascia is 8.45±5.13 and in case of fascia lata is 9.25±5.01. Mean gain in ABG is better in fascia lata comparing to temporalis fascia though marginally so. Successful closure of the tympanic membrane may not give total improvement in hearing as it also depends on other factors.

Most tympanoplasty complications are preventable by comprehensive pre-operative planning, thorough knowledge of the temporal bone anatomy, applying meticulous surgical techniques and close post-operative follow-ups.<sup>5</sup> In our study post auricular wound gapping and graft rejection were main complications. Post auricular wound infection was seen in 4 cases and were treated conservatively with antibiotics and all cases did well after that.

#### DISSCUSSION

In present study 80 cases were included for type 1 tympanoplasty. For comparison, cases were divided in to two groups. 44 went for temporalis fascia and 36 went for fascia lata. All patients were operated by same post aural approach and all graft were put by inlay method to maintain uniformity. Patients selected were in age group between 15-60 years of age with mean age being 30.19 years. In our study male: female ratio is 1.5:1. The average age and sex ratio in present study is almost similar to other studies (Kshitij et al, Bhoopendra et al, Hardik et al).<sup>7,8,10</sup>

All the patients had history of ear discharge and among them 72.5% had decreased hearing while 25% had history of earache. Literature also states otorrhoea, hearing loss, otalgia are the main presenting symptoms.<sup>6</sup> 82.5% had unilateral ear pathology while 17.5% had bilateral pathology. In present study 60% of patients had duration of disease for more than 5 years while 40% had for less than 5 years. In our study 40% were having large perforation, 40% medium perforation and 20% small perforation. The mean hearing loss in relation to size of

perforation are as follows: small perforation is 20 dB, moderate perforation is 26 dB, large perforation is 33 dB which was similar to Hardik et al and Okafor et al.<sup>8,9</sup>

Overall graft uptake rate was 87.5%. Temporalis fascia contributing 86.36% whereas fascia lata contributing 88.88%. In smaller perforation temporalis fascia got better graft uptake (100%). In large perforation fascia lata has better graft uptake (100%). And in case of moderate perforation also fascia lata (88.88%) has upper hand. Post-operative hearing gain on an average with temporalis fascia was 11.46 dB while with fascia lata was 10.09 dB. Improvement in Air Bone Gap (ABG) temporalis fascia was 8.45±5.13 dB while with fascia lata is 9.25±5.01 dB which was comparable with Kshitij et al result (9.36±3.63). Graft rejection (12.5%) and wound gaping (10%) were the two most common complication in our study.

Here p>0.05 so there was no statistical significance. So material of graft is not affecting the uptake i.e. all the graft materials are analogous. Temporalis fascia and fascia lata available in large amount and have ease of handling. Temporalis fascia harvested from same incision while fascia lata needs separate incision. All materials have their merits and demerits but the final outcome remains almost same.

#### Limitations of study

The postoperative anatomical graft assessment was always subjective and there was always a chance of bias regarding oto-microscopic picture of graft uptake.

#### **CONCLUSION**

Both temporalis fascia and fascia lata provide viable autograft material. Each material is mesodermal in origin which excludes the risk of iatrogenic cholesteatoma. Each material achieve comparable and excellent graft uptake. Both materials attain comparable and good hearing restoration.

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Institutional Ethics Committee

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