

# A Prospective Randomized Study to Compare the Outcome of Tragal Perichondrium and Temporalis Fascia Grafting in Type 1 Tympanoplasty

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## Abstract

**Aim:** A Prospective randomized study to compare the outcome of tragal perichondrium and temporalis fascia grafting in Type 1 Tympanoplasty in cases of tubotympanic CSOM. CSOM causes significant morbidity in patients due to recurrent discharge, deafness, and various complications. Tympanoplasty is primary surgical treatment to treat CSOM and prevent further complications.

**Method:** This study involves the patient of tubotympanic type of CSOM presenting in OPD of ENT department in R.D.Gardi Medical College, Hospital & Research Centre, Ujjain from Feb 2020 to August 2021. Patients were divided randomly in two groups. One group was operated using temporalis fascia and another group with tragal perichondrium. Pre-operative pure tone audiometry was obtained in all the patients. This was compared post-operative pure tone audiometry conducted after 12 weeks. Hearing improvement along with other parameters as graft uptake, graft material used were also noted.

**Results:** Out of 60 cases 30 were operated using 'temporalis fascia graft' & rest were with 'tragal perichondrium'. On comparison of hearing improvement both the group had no statistical difference in hearing.

**Conclusion:** Tragal perichondrium & temporalis fascia are both comparable in terms of graft uptake & hearing improvement.

## 1. INTRODUCTION

Chronic otitis media is the chronic inflammation of the mucoperiosteal lining of the middle ear cleft which is characterized by ear discharge, permanent perforation of tympanic membrane and hearing impairment. It is one of the most common ear diseases encountered in developing countries due to poor socio-economic standards, poor nutrition, lack of health education and unhygienic habits<sup>[1]</sup>. It is a major cause for deafness in India. Tympanoplasty is now an established surgery for tympanic membrane perforations being carried out routinely by otorhinolaryngologists<sup>5</sup>. Autologous graft materials such as, temporalis fascia, tragal perichondrium, fat, cartilage, and fascialata have stood the test of time in the repairing of tympanic membrane perforations<sup>[2]</sup>. Such abundance of materials implies that there is no clear cut favourite and the choice of graft material depends on individual surgeon's preference. The concept of grafting tragal cartilage and perichondrium was introduced by Goodhill<sup>[3]</sup>.

However, due to its anatomic proximity, translucency, and suppleness, temporalis fascia and tragal perichondrium are the two most preferred grafting materials among the otologists. Failure rates are higher in larger perforations with temporalis fascia as a graft material<sup>[4]</sup>. Graft displacement, improper placement<sup>13</sup>, autolysis, infection, haemorrhage, Eustachian tube dysfunction are the known contributing factors for the failure of closure of perforation. Keeping all these factors in mind and in the light of good results, the present comparative study of different graft materials, that is, temporalis fascia and tragal perichondrium, in underlay type 1 tympanoplasty was undertaken<sup>[5]</sup>.

## AIM AND OBJECTIVES

### Aim:

A Prospective randomized study has been done with a sample size of 60 patients to compare the outcome of tragal perichondrium and temporalis fascia grafting in the patients with CSOM tubotympanic type undergoing type 1 tympanoplasty with underlay technique.

### Objectives:

1. To assess the outcome of tragal perichondrium and temporalis fascia grafting separately & assess the outcome of the surgery in respect with:
  - a.) Graft uptake.
  - b.) Hearing improvement.
  - c.) Complications.
2. To compare the results of both the procedures.

## 2. MATERIAL AND METHODS

Patients with tubotympanic type of chronic suppurative otitis media were selected from ENT outpatient department of R.D. Gardi medical college hospital and research centre between February 2020 to August 2021. This prospective study with randomization includes 60 patients out of which 30 were subjected to underlay Type I tympanoplasty using temporalis fascia and remaining 30 using tragal perichondrium. The results were analysed using following parameters:

### 1. Graft uptake

### 2. Donor site complications

### 3. Audiological outcome

- Closure of A-B gap

### 4. Late complications

- Re-perforation
- Retraction
- Adhesions
- Worsening of A-B gap

### Method of collection of data:

All cases were subjected to detailed history taking and clinical examination of ear, nose and throat with special reference to the ear. Routine haematological and radiological examination done for all cases. Septic foci in the nose and throat were treated prior to surgery.

**Inclusion criteria:**

1. Chronic suppurative otitis media, tubotympanic type.
2. Patients both male and female between age group 10 to 50 years.
3. Pure tone air bone gap between 15-45 dB hearing loss.
4. Ear to be operated should be dry, for at least 6 weeks prior to surgery.
5. Eustachian tube function normal.
6. Nonhealed traumatic perforations also included in the study.
7. Patients willing to give written informed consent.

**Exclusion criteria:**

1. Unsafe CSOM
2. Safe CSOM with sensorineural hearing loss.
3. Active discharging ear.
4. Patients <10 years and >50 years.
5. All ASOM cases.
6. Congenital hearing disorder.
7. Previous history of ear surgery.
8. Associated factors like uncontrolled hypertension, diabetes and severe anaemia.

**Follow up:**

Followed up after one month , third month and sixth month. For statistical analysis post-operative audiogram at 3 month follow up was used

**3. OBSERVATION AND RESULTS**

During the study, we have observed distribution of the age, sex, size of perforation, its relation to hearing loss and graft success rate.

For the purpose of analysis, these 60 patients selected for the study, having similar pathology (benign large, medium and small central perforations with conductive hearing loss with intact and mobile Ossicular chain) were divided into two groups according to the graft material used for tympanoplasty as per the consent obtained from the patient for the use of different graft materials. Thus in Group-I, 30 patients underwent tympanoplasty using temporalis fascia, in Group-II, 30 cases underwent tympanoplasty using tragal perichondrium.

**The data has been analyzed as follows:**

Table No.1 Age wise Distribution of patients in this study

Age (years)	Temporalis Fascia		Tragal Perichondrium		Total	
	No.	%	No.	%	No.	%
10-20	5	16	9	30.0	14	23
21-30	9	30.0	11	36	20	33
31-40	5	17	5	17	10	17
41-50	11	37	5	17	16	27
Total	30	100.0	30	100.0	60	100

The youngest patient in our study was 10 years old while the oldest patient in our study was 50 years old.

The mean age in the temporalis fascia graft group was  $33.5 \pm 12$  years, while in the tragal perichondrium graft group it was  $29.7 \pm 11$  years.

The overall male to female ratio was 22:38. Among the patients undergoing temporalis fascia grafting, 40% were males and 60% females. Among the patients undergoing tragal perichondrium grafting, 33 % males and 66 % females.

There was no statistically significant association seen between gender the graft group ( $P>0.05$ ), showing that the distribution of patients in both the groups is independent of the gender.

Table No. 2  
Association of size of TMP with type of graft

Size of TMP	Temporalis Fascia	Tragal Perichondrium	Total
LCP	14 47%	10 33%	24 40%
MCP	13 43%	16 53.0%	29 48%
SCP	3 10%	4 14%	7 12%
Total	30 100.0%	30 100.0%	60 100.0%

**Pearson Chi-Square = 1.120, DF = 2, P-Value = 0.571, Not significant**

Out of 30 cases with temporalis fascia graft the duration of disease is up to 5 years in 67% and more than 5 years in 33% and out of 30 cases with tragal perichondrial graft the duration of disease up to 5 years is 73% and more than 5 years is 26%.

Table No. 3  
Comparison of mean Preoperative and Postoperative A-B Gap  
between the two types of grafts

Parameter	Temporalis Fascia		Tragal Perichondrium		't' value	P value
	No.	[Mean $\pm$ SD]	No.	[Mean $\pm$ SD]		
Preop. A-B Gap	30	28.6 $\pm$ 6.8	30	27.8 $\pm$ 4.9	0.58, df=58	0.562, NS
Postop. A-B Gap	30	8.7 $\pm$ 2.90	30	8 $\pm$ 1.60	1.13, df=58	0.263, NS

**Unpaired 't' test applied. P value < 0.05 was taken as statistically significant**

The mean preoperative A-B gap in the Temporalis fascia group was 28.6  $\pm$  6.8, while in the tragal perichondrium group it was 27.8  $\pm$  4.90. The difference was found to be statistically not significant ( $P>0.05$ ), showing a comparable preoperative A-B gap between the two groups.

The mean postoperative A-B gap in the Temporalis fascia group was 8.7  $\pm$  2.90, while in the tragal perichondrium group it was 8  $\pm$  1.60. The difference was found to be statistically not significant ( $P>0.05$ ), showing a comparable postoperative A-B gap between the two groups.

Table No. 4

Comparison of mean improvement in A-B Gap between the two types of grafts

Parameter	Temporalis Fascia		Tragal Perichondrium		't' value	P value
	No.	[Mean±SD]	No.	[Mean±SD]		
Improve-ment in A-B Gap	30	17 ± 3.7	30	17.4 ± 3	-0.87, df=58	0.390, NS

*Unpaired 't' test applied. P value = 0.390, Not significant*

The mean improvement in the A-B Gap in the temporalis fascia group was  $17 \pm 3.7$ , while in the tragal perichondrium group it was  $17.4 \pm 3$ . The difference was found to be statistically not significant ( $P > 0.05$ ), showing that the improvement in both the groups was comparable. However, a highly significant difference was observed between preoperative and postoperative air-bone closures, indicating that most of the cases had air-bone closures and thus gain in hearing.

All the perforations were central perforations. In the present study, we have considered only large, medium and small central perforation of the tympanic membrane. The maximum number of cases, that is, 29 cases (48%) had medium central perforation, followed by large central perforation in 24 cases (40%), while 7 cases (12%) had small central perforation.

There was no significant statistical difference between these graft materials in relation to the improvement in A-B gap after tympanoplasty and the size of the perforation.

Table No. 5

Improvement in A-B gap in relation to graft material

Graft material	Improvement in A-B gap			
	Post operative A-B gap (within 10 dB)		Post operative A-B gap (within 11-20 dB)	
	Total no.	%	Total no.	%
Temporalis fascia	24	80	6	20
Tragal perichondrium	28	93	2	7

Table No. 6

Association of Postoperative Graft status with type of graft

Postoperative Graft Status	Temporalis Fascia	Tragal Perichondrium	Total
Normal	25 84%	27 90.00%	52 87%
Persistent Perforation	4 13%	3 10.00%	7 12%
Retracted	1 3%	0 0.00%	1 1%
Total	30 100.0%	30 100.0%	60 100.0%

*Pearson Chi-Square = 1.220, DF = 2 P value = 0.5434, Not significant*

In the temporalis fascia group, 25 (84%) were having normal postoperative graft status, 4 (13%) had persistent perforation postoperatively and in 1 (3%) had retracted graft postoperatively.

In the tragal perichondrium group, 27 (90.00%) were having normal postoperative graft status, 3 (10.00%) had persistent perforation postoperatively and none had retracted graft postoperatively.

A nonsignificant association was observed between the groups, i.e., temporalis fascia (Group-I), tragal perichondrium (Group-II), and the graft uptake. ( $P > 0.05$ ) revealing that the pattern of graft take-up was same statistically in the two groups showing that postoperative subjective hearing assessment is independent of the type of graft used.

Out of 60 cases, 3 patients of tragal perichondrial group had persistent perforation. 4 patients of temporalis group had persistent perforation.

In the temporalis fascia group, 27 (90.0%) patients had no complications, 1 (3%) had hematoma, 1 (3%) had persistent pain and 1 (3%) had seroma.

In the tragal perichondrium group, 30 (100.0%) patients had no complications.

The mean preoperative A-B gap was  $27.75 \pm 4.89$  and the mean 3 months postoperative A-B gap was  $7.98 \pm 1.61$ . The difference was found to be statistically significant ( $P < 0.05$ ), showing a significant decrease in the A-B gap postoperatively.

#### 4. DISCUSSION

The youngest patient in our study was 12 years old while the oldest patient was 50 year old. The average age incidence was 33.5 years for temporalis fascia cases and 29.7 years for tragal perichondrium. A study conducted by Jyothi Dhabolkar<sup>62</sup> also corresponded with the same age groups<sup>[6]</sup>.

The overall female to male ratio in our study was 38:22, temporalis fascia group male:female ratio 40:60, tragal perichondrium group has male:female ratio 33:66.67. The overall male:female ratio was consistent with other studies.

The results were analysed as per the international convention in reporting audiological outcomes as proposed by American association of otolaryngology protocol.

The possible predisposition of age towards disease was assessed and it was found that maximum number of patients, that is, 20 (33%) were from the age group of 21-30 years, followed by 16 (27%) in 41-50 years, 14 (23%) in 10-20 years, and 10 (17%) in 31-40 years<sup>[7]</sup>.

The mean age in the temporalis fascia graft group was  $33.5 \pm 12$  years, while in the tragal perichondrium graft group it was  $29.7 \pm 11$  years.

Similar findings were noted in the study of Singhet *al*, in which the mean age was 28.9 years (range: 13-48 year)<sup>73</sup> in which the mean age was 28 years (range: 9-57 years)<sup>[8]</sup>.

A nonsignificant association was observed between the two graft of graft material and the age groups ( $P = 0.205$ ).

#### Graft uptake:

The graft uptake rate in our study was 84% for temporalis fascia and 90% for tragal perichondrium. Graft take-rate was slightly better for tragal perichondrium than temporalis fascia. This marginal difference however is not statically significant. Various studies showed the graft uptake was in the range of 80% to 90%, for either temporalis fascia or tragal

perichondrium. The present study graft uptake rates are reasonable compared to other studies<sup>[9]</sup>.

Other studies described graft uptake rate as follows: Abraham Eviator<sup>59</sup> noted that the graft take up rate with tragal perichondrium by underlay technique was 90.47%. Goodhill reported a success rate of 100% in cases of primary myringoplasty with tragal perichondrium.

Quraishiet *al* reported a success rate of 94% in 32 cases of primary myringoplasty with tragal perichondrium.

Jyothi P. Dabholkar, Krishna Vora, AbhikSikdar reported that graft uptake rate in comparative study of underlay tympanoplasty with tragal perichondrium and temporalis fascia in a series of 50 cases with temporalis fascia and tragal perichondrium were 84% and 80% respectively<sup>[10]</sup>.

Patilet *al*(2009)reported in their study of 120 cases graft take up of 86.67% in temporalis fascia, for tragalperichondrium87.50% showed successful graft uptake.

BongaleKR(2010)in their comparative study withtemporalis fascia vstragal perichondrium in 80 patients in the age group 10 years to 50 years with history of safe perforation, myringoplasty was done, they found thatwith temporalis fascia graft uptake was 92.5% compared to 87.5% in tragal perichondrium<sup>[11]</sup>.

Shetty *et al*(2013). in a prospectiveanalysis of 50 patients with CSOM tubotympanic type reported a 96% graft take up rate of tragal perichondrium as compared to 92% in case of temporalis fascia.

Hameed *et al*(2015) included 20 patients of type 1 tympanoplasty. In 10 patients tragal perichondrium was used and in 10 patients temporalis fascia was used. They reported graft take up was achieved in 90% patients where temporalis fascia was used and in 80% patients where perichondrium was used as graft material.

Majeed J *et al*(2016) in their prospective randomized study of 60 patients reported the graft uptake rate of 88% for temporalis fascia and 83.33% for tragal perichondrium.

Swaminathanet *al*(2017).in their study of 19 patients between the age group of 15-45 years with tubotympanic CSOM reported90% of success in temporalis fascia group and 77.7% in the tragal perichondriumgroup.

### Hearing results:

The mean preoperative ABG for Group-I (temporalis fascia) was  $28.6 \pm 6.8$  dB, for Group-II(tragal perichondrium) was  $27.8 \pm 4.90$ . The mean postoperative ABG for Group-I (temporalis fascia) was  $8.7 \pm 2.90$  dB, for Group-II(tragal perichondrium) was  $8 \pm 1.60$ . The mean gain in hearing for Group-I (temporalis fascia) was  $17 \pm 3.7$  dB, for Group-II(tragal perichondrium) was  $17.4 \pm 3$  dB.

A nonsignificant association was observed between the graft materials (groups) and the Air-bone closure ( $P = 0.390 > 0.05$ ) revealing that the pattern of distribution of scores of different categories of air-bone closure was same in the two groups statistically. However, a highly significant difference ( $P < 0.05$ ) was observed between preoperative and postoperative air-bone closures, indicating that most of the cases had air-bone closures and thus gain in hearing. In our study mean gain in ABG was not significantly different between the temporalis fascia and tragal perichondrium. The mean gain for temporalis fascia was 17 dB with SD of 3.7, and for tragal perichondrium was 17.4 dB with SD of 3. Our findings were comparable to following studies<sup>[12]</sup>.

In studies conducted by Indorewalamean gain in ABG was 17 dB for temporalis fascia. Swaminathanet *al* reported an average of auditory gain of 10 to 15 dB in patients for both temporalis fascia and tragal perichondrium. In studies done by Shettyet *al* the mean gain in A-

B gap in patients using tragal perichondrium as graft material was  $16.5 \pm 7.27$  dB as compared to  $15 \pm 7.07$  dB in patients in whom temporalis fascia was used<sup>[13]</sup>.

In our study with temporalis fascia graft, good hearing results, that is, closure rate of ABG within 10 dB was found in 80% cases which is comparable to Herman and Tang (75%) and Dabholkar *et al* (76%), Strahan *et al* (82%), but is less than studies conducted by Gupta and Mishra (92%), and Alan Gibb (87.5%). Average hearing results, i.e., closure between 11 and 20 dB was found in 20% cases which is comparable to Dabholkar *et al* (24%). With tragal perichondrial graft, closure of ABG within 10 dB was found in 93% cases which is more than study conducted by Singh *et al* (55.5%), Dornhoffer (77%), Dabholkar *et al* (75%) and Gupta and Mishra (83%) and is comparable to Strahan *et al* (90%). The closure between 11 and 20 dB was found to be 6.7% which is less than Dabholkar *et al* (25%)<sup>[14]</sup>.

#### Donor site complications:

One patient had persistent pain while chewing for 3 months in case of temporalis fascia group. One patient in temporalis fascia group noted seroma formation which subsided later. Hematoma noted in one patient of temporalis group, which was drained later. All are treated with analgesics and antibiotics.

#### Failures:

Out of 60 cases, 2 patients of tragal perichondrial group had persistent perforation. 3 patients of temporalis group had persistent perforation and 1 patient had intact retracted drum.

### 5. SUMMARY AND CONCLUSION

From the present study we may conclude that:

- Temporalis fascia, tragal perichondrium grafts provide viable autograft material for tympanoplasty.
- These materials are mesodermal in origin which excludes the risk of iatrogenic cholesteatoma.
- They achieve comparable and excellent graft take up rate of 83.33% and 90% for temporalis fascia and tragal perichondrium respectively.
- They achieve comparable and good hearing restoration.
- The graft take-up rate and hearing improvement are similar for the two graft materials used.
- Size of the perforation doesn't significantly influence the success rate of tympanoplasty.
- Tragal perichondrium is thicker and stiffer than temporalis fascia and easier to manipulate in the middle ear as it does not get folded on itself, thus has ideal handling qualities.
- The results of myringoplasty with temporalis fascia were equal to that with tragal perichondrium, when graft uptake is concerned. Tragal perichondrium appears to be a better alternative to temporalis fascia as graft for tympanoplasty, taking hearing improvement and graft uptake together. Temporalis fascia and tragal perichondrium are excellent graft material for closure of perforation of tympanic membrane and hearing improvement.

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