



## A Comparative Study on Morphological and Audiological Outcome in Type I Tympanoplasty for Chronic Otitis Media Mucosal Disease Using Temporalis Fascia versus Cartilage Graft

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### Abstract

**Objective:** To compare the morphological and audiological outcome of Type I tympanoplasty in Chronic otitis media mucosal disease using temporalis fascia and cartilage graft.

**Materials and Methods:** A prospective comparative study among 110 patients with complaints of ear discharge and hearing loss due to Chronic otitis media mucosal disease who underwent Type I tympanoplasty. There were 52 patients where cartilage graft was used and 58 patients where temporalis fascia graft was used. The pre-operative clinical and audiological findings of the study subjects were noted using a proforma. In the post-operative period, they were followed up after 3 months and 6 months. At 3<sup>rd</sup> month, patients were assessed for perforation closure and audiological evaluation by Tuning Fork Test and Pure Tone Audiometry. At 6<sup>th</sup> month patients were subjected to clinical examination for integrity of tympanic membrane, PTA and Tympanometry.

**Results:** Otorrhea was the commonest presenting complaint and majority had a large central perforation. The preoperative hearing loss was between 25dB to 45 dB. Majority of the cases had post aural approach for surgery. Tympanosclerosis was seen in 24 patients. Temporalis fascia graft was used in 58 patients, and cartilage graft in 52 patients. Among the temporalis fascia group graft failure was seen in 19 cases while in cartilage graft group there was only 3 cases. The AB gap closure of more than or equal to 10 dB in temporalis fascia was 82.8% while that in cartilage graft was 94.2%. The tympanometry curve of A or C was considered as a successful outcome. In 53% of patients with cartilage graft A or C was obtained, while in temporalis fascia graft group it was 47%. In the short term follow up of 6 months it was found that cartilage graft had reduced chance of re-perforation and better hearing outcome

**Keywords:** Cartilage graft, Temporalis fascia, Type I Tympanoplasty.

### Introduction

Chronic otitis media causes permanent pathologic damage to the tympanic membrane and other

middle ear structures. The global burden of the disease involves 65-330 million individuals with draining ears and more than half suffering

significant hearing impairment.<sup>1</sup>Perforation can result in relapsing infection and deafness which hampers productivity in many individuals.

Tympanoplasty aims to reproduce the natural characteristics of the tympanic membrane in terms of the conduction of the sound and vibration, resistance to negative middle ear pressure and maintenance of structures and middle ear spaces by avoiding long term resorption. Since early days, various graft materials have been tried for the closure of the tympanic membrane perforation. Temporalis fascia has been used commonly with good results. However cartilage grafts are now coming up as a primary alternative. Fascia has the advantage of being thin and transparent in nature with ease of harvesting and is readily available. Whereas the cartilage graft offers good tensile strength with a high elastic modulus, thus making it a versatile graft.<sup>2</sup>

Audiological evaluation including Pure Tone Audiogram (PTA) and Impedence audiometry in the post-operative period helps to assess the graft material. The change of the tympanometric curve from B to A or C, indicate the closure of the perforation. The gain in Air-Bone Gap in the PTA gives an idea of the acoustic transfer allowed by different grafts used. The goal of improving the results of tympanoplasty is important for the ENT surgeon to ensure a dry ear with good hearing outcome. The success rate of tympanoplasty for Chronic otitis media mucosal disease has not been uniformly evaluated in literature. This study was aimed to evaluate the functional and audiological outcomes of type I tympanoplasty performed with temporalis fascia graft and cartilage graft.

### Aim

The aim of this study was as follows:

- To compare the morphological and audiological outcome in Type I Tympanoplasty using temporalis fascia graft and cartilage graft in patients with Chronic Otitis Media mucosal disease

### Materials and Methods

**Study Design:** Prospective comparative study

**Study Setting:** Department of Otorhinolaryngology, Government Medical College, Thiruvananthapuram, Kerala

**Study Subjects:** Patients with Chronic Otitis Media mucosal disease posted for Type I Tympanoplasty with or without cortical mastoidectomy in the Department of ENT, Government Medical College, Thiruvananthapuram.

**Study Period:** January 2017 to June 2018

### Sample Size

Sample size calculated using the formulae

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2(P_1Q_1 + P_2Q_2)}{(P_1 - P_2)^2}$$

$Z_{1-\alpha/2}$  - power of study

$Z_{1-\beta}$  - confidence of study

$P_1$  - success rate with temporalis fascia graft

$P_2$  - success rate with cartilage graft

$Q_1$  is  $1 - P_1$

$Q_2$  is  $1 - P_2$

Sample size was derived from the previous study, Temporalis fascia graft vs. Cartilage graft in myringoplasty conducted by Haitham A. Alnori and Ali A. Muttalib<sup>3</sup>

$Z_{1-\alpha/2} = 1.96$  with confidence interval of 95%

$Z_{1-\beta} = 0.82$

And the sample size was found to be 50 for each group

### Inclusion Criteria

- Patients with Chronic otitis media mucosal disease posted for type 1 Tympanoplasty with or without cortical mastoidectomy who are willing to give consent for participation in the study
- Patients more than 12 years and less than 60 years.

### Exclusion Criteria

- Patients who have sensorineural hearing loss.
- Patients with small central perforation with no significant hearing loss.

**Data Collection Tools**

1. Proforma
2. Otoscope Findings
3. Tuning Fork Test
4. Pure Tone Audiometry
5. Tympanometry

**Method**

All patients posted for Type I Tympanoplasty with or without cortical mastoidectomy for Chronic Otitis Media Mucosal Disease were included in the study after obtaining consent for participation in the study. The data regarding preoperative disease, size and site of perforation, middle ear status, ossicular status, surgical approach, graft material used, adjunctive procedures, pre and postoperative morphological (otoscopy) and audiological (hearing evaluation by Tuning Fork Test and Pure-Tone Audiogram) results were taken and analysed. The Tuning fork tests- Rinne test, Weber test and Absolute bone conduction test were performed with tuning forks of 256 Hz, 512 Hz and 1024 Hz. The size of perforation was classified into small, moderate or large depending on the involvement of one quadrant, two quadrants and three or more than three quadrants respectively.<sup>4</sup>Subtotal perforation has only a rim of pars tensa. Tragal, conchal or preserved nasal septal cartilage was used as cartilage graft in the study. It was sliced to make an approximate thickness of 0.5mm using the cartilage slicer. Postaural and transcanal approaches were used. The cases were done using operating microscope or 0 degree endoscopes.

A week following the procedure, patients were assessed for any postoperative complications. They were also followed up after 3 months and 6 months. At 3<sup>rd</sup> month, patients were assessed for perforation closure and audiological evaluation by Tuning Fork Test and Pure Tone Audiometry. At 6<sup>th</sup> month patients were subjected to clinical examination for integrity of tympanic membrane and PTA & Tympanometry to assess the audiological outcome following the procedure. A successful outcome was defined as an

improvement in Air-bone gap of 10 dB in Pure Tone Audiogram and closure of tympanic membrane perforation. Tympanometric curve of A or C defines success.

**Ethical Considerations**

1. Written informed consent was obtained from all study participants.
2. Confidentiality was maintained regarding data given by the participants.
  - Approval from Hospital authorities obtained
  - Clearance from Ethics Committee obtained

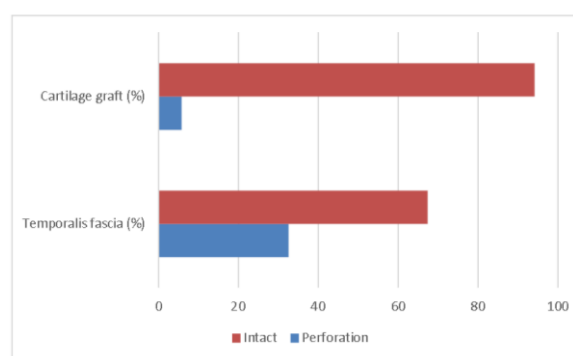
**Results**

A total of 110 patients were included in the study. Post operatively they were evaluated till the 6<sup>th</sup> month.

- Morphological success rate as intact tympanic membrane was significantly higher with cartilage graft (94.2%) as compared to temporalis fascia (67.2%)(fig.1)

**Table 1** Status of graft

Status of graft(Otoscopy)	Temporalis fascia		Cartilage graft	
	No.	Percent	No.	Percent
Perforation	19	32.8	3	5.8
Intact	39	67.2	49	94.2



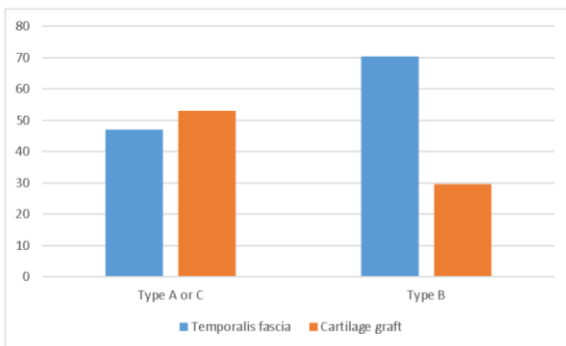
**Figure 1** Status of graft

An intact tympanic membrane was seen in 94.2% of patient in whom cartilage graft was used and only in 67.2% of patients with temporalis fascia. Hence cartilage graft has significantly higher uptake compared to temporalis fascia. The significance was proved with p<0.001.

- Significant difference was found in tympanometric outcome between temporalis fascia and cartilage grafts. 53% patients with cartilage graft and 47% with temporalis fascia had Type A or C curve in tympanometry. (fig.2)

**Table 2.** Tympanometric outcome

Tympanometric curve	Temporalis fascia		Cartilage graft	
	No:	Percent	No:	Percent
Type A or C curve	39	47	44	53
Type B curve	19	70.4	8	29.6



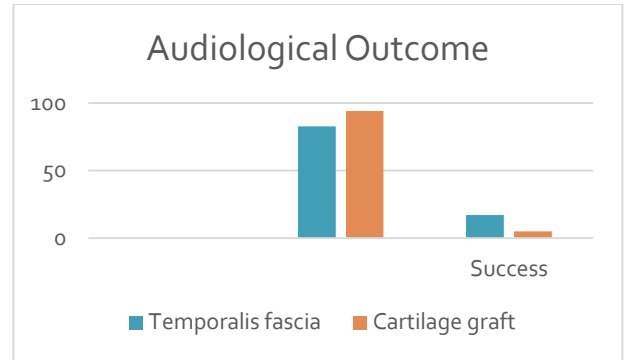
**Figure 2.** Tympanometric outcome

39 cases with temporalis fascia had type A or C curve and 19 cases had type B curve. 44 cases with cartilage graft had type A or C curve and 8 cases had B curve. This was found to be statistically significant using Chi Square test with  $p = 0.035$ .

- Audiological outcome was better with cartilage graft than with temporalis fascia. It could probably be due to the fact that thin sliced graft was used in the study giving a better acoustic transfer.(fig.3)

**Table 3** Audiological outcome

Graft	Success		Failure	
	No.	Percent	No.	Percent
Temporalis fascia	48	82.8	10	17.2
Cartilage	49	94.2	3	5.8



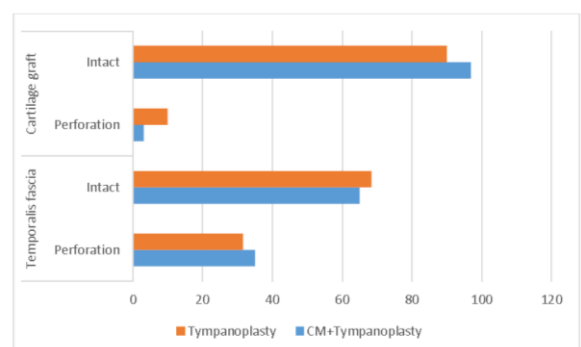
**Figure 3.** Audiological outcome

Cartilage graft showed significant improvement in post-operative AB gap gain. (94.2%) which includes all patients with AB gap gain more than 10 dB. Audiological success rate with temporalis fascia graft was 82.8%. Statistical significance was proved with  $p=0.012$  with Chi-square test

- The role of tympanoplasty alone and tympanoplasty done along with cortical mastoidectomy in chronic otitis media in terms of graft uptake was also analysed .(fig.4)

**Table 4** Type of surgery and morphological outcome

	Temporalis fascia				Cartilage graft			
	Perforation		Intact		Perforation		Intact	
	No.	Percent	No.	Percent	No.	Percent	No.	Percent
Cortical mastoidectomy+ tympanoplasty	7	35	13	65	1	3.1	31	96.9
Tympanoplasty alone	12	31.6	26	68.4	2	10	18	90



**Figure 4** Type of surgery and morphological outcome

There is no significant difference in the morphological outcome when tympanoplasty

alone was done versus cortical mastoidectomy with tympanoplasty with cartilage graft and temporalis fascia graft.

- Tympanosclerosis causes conductive hearing loss. When audiological outcome was assessed, failure rate was more in cases with tympanosclerosis (20.8%) than without tympanosclerosis (16.4%).

### Discussion

Chronic otitis media is clinically diagnosed from history of long standing discharging ear with associated hearing loss. In mucosal disease, there is perforation of pars tensa with or without inflammation of the middle ear. The surgical management is by tympanoplasty with or without mastoidectomy. Various materials are used as graft for tympanic membrane repair. In this study, an attempt was made to compare the audiological and morphological success of type 1 tympanoplasty with or without mastoidectomy using temporalis fascia and cartilage graft.

42 males and 68 females were included in the study with a male: female ratio of 0.6:1. A similar female preponderance was noticed in the study conducted by Kazikdas et al<sup>5</sup> with 33 females and 18 males. The mean age of patients in this study was 30 years which was also similar to the study conducted by Kazikdas et al<sup>5</sup> where the mean age was 27.6 years. The commonest presenting complaint was otorrhea (100%) followed by hearing loss (69.1%) 12.7% of patients had ringing sensation of the ear, 4.5% had vertigo and 5.4% had associated ear ache. In the study conducted by Sharma N et al<sup>6</sup> the commonest presenting complaint was ear discharge (100%) followed by hearing loss (95%), tinnitus (6.25%) and earache (3.75%), none had vertigo. Majority of the patients had a long standing disease with duration ranging from 3 months to 40 years.

In this study the tympanic membrane findings were divided as moderate central perforation, large central perforation and subtotal perforation based on the otoscopic examination. Large central perforation was the commonest (48.2%) followed

by moderate central perforation (28.2%). Similar finding has been described in study conducted by VV Harkare et al.<sup>7</sup>

All the patients were evaluated pre operatively by Pure Tone Audiogram. The degree of hearing loss was categorized into three different groups based on Pure tone average i.e. 0-20 dB, 21-40 dB and 41-60 dB. In this study 6.4%, 52.7 % and 40.9 % of the patients had hearing loss ranging from 0-20 dB, 21-40 dB and 41-60 dB respectively. 58 cases underwent tympanoplasty with temporalis fascia graft while 52 cases underwent tympanoplasty using cartilage graft.

Out of the 110 patients, 52 underwent cortical mastoidectomy with tympanoplasty and 58 underwent tympanoplasty alone. In patients who underwent cortical mastoidectomy with tympanoplasty, 20 (38.5 %) had temporalis fascia as graft and 32 (61.5%) had cartilage graft. Intra-operatively 24 out of 110 patients (21.8 %) had tympanosclerosis. Association of tympanosclerosis has been mentioned in the study by Batni G et al<sup>8</sup> in which 4 cases out of 88 had tympanosclerosis.

The success in this study was defined by audiological and morphological criteria. Audiological success is defined as an improvement in AB gap of at least 10 dB in PTA.<sup>9</sup> The AB gap is calculated in speech frequency i.e. 500 Hz, 1 KHz and 2 KHz. Morphological success was defined as an intact tympanic membrane and A or C curve on Tympanometry at the end of 6 months after surgery. Various associations with the morphological and audiological outcomes have been studied. The tympanometric outcome on using Cartilage graft and Temporalis fascia was compared. 47% with temporalis fascia graft, had a successful outcome by having an A or C curve while 70.4% had a B curve. In patients whom a cartilage graft was used, 53% had a successful outcome in terms of having A or C curve, while 29.6 % had a B curve. Significance was found (p=0.035) using Chi Square test. Of the patients in whom cartilage graft was used, 94.2% had an intact tympanic membrane at the end of 6



months, while 67.2% of the patients grafted with temporalis fascia had an intact membrane. This parameter was statistically significant ( $p=0.00$ ). Here 32.8% of those with temporalis fascia graft and 5.7% of those with cartilage graft had perforation. It is similar to the result obtained by Yegin Y et al<sup>10</sup> where graft success with cartilage graft was 91.3% with  $p=0.01$ . In the study conducted by Aneesa A M et al<sup>4</sup> cartilage graft had an uptake of 92.4% whereas temporalis fascia had 80% uptake at 6 months of follow up. According to Lacovou E et al<sup>11</sup>, there was significant success in hearing results with cartilage graft here the mean graft integration rate was 92.4% in cartilage group and 84.3% in temporalis fascia group.

The successful audiological outcome is a gain in AB gap of 10 dB.<sup>9</sup> Statistically cartilage graft had good audiological outcome (94.2%) compared to temporalis fascia (82.8%) ( $p= 0.012$ ) in this study. In the study conducted by Yegin Y et al., AB gap gain in cartilage group (7.51) was more than the gain in the temporalis fascia graft group (4.68), it was significant ( $p=0.046$ )<sup>43</sup>. Alnori H et al. study showed the percent improvement in mean AB gap was more for fascia than cartilage graft ( $p= 0.001$ ). An improvement of 19.6 dB was noted in temporalis fascia and that of cartilage graft was 15.7 dB. In the study conducted by Aneesa AM et al.<sup>4</sup> Air-bone gap in fascia group showed a closure to 10 dB in 17.5% of patients and in the cartilage group, 10 dB AB gain was seen in 25% of patients.<sup>4</sup>

In study conducted by Ulku et al<sup>12</sup> 91.3% success rate of graft uptake in cartilage vs. fascia 88.2% and hearing gain of 12.3% in cartilage and 12.7% in fascia in cases of type 1 tympanoplasty. Albirmawy et al<sup>13</sup> has reported a case series in type 1 tympanoplasty where the morphological success rate in cartilage 95% vs. fascia 76.2%. Mean postoperative air bone gap 10.95 $\pm$ 2.12 dB in cartilage versus 12.73 $\pm$ 8.97 in fascia. No significant difference in hearing between two groups. Chabra et al<sup>14</sup> showed 90% of patients with cartilage shield tympanoplasty and 88% with

temporalis fascia had significant improvement in hearing ABG>10 dB)

The relationship between the duration of disease and hearing loss was assessed. It showed that the longer the duration of the disease, more is the AB gap in the Pure Tone Audiogram. The relationship between duration of the disease with graft used have also been assessed and comparable results were obtained. Both the grafts were used for long standing disease.

The evaluation of tympanosclerosis with pre-operative hearing loss was done. But since the number of patients with tympanosclerosis was limited no association could be made. The association of tympanosclerosis with post-operative improvement in AB gap was also assessed. The improvement in AB gap was comparable but failure was more in patients with tympanosclerosis (20.8%). The failure in cases without tympanosclerosis was 16.3%. Tsuzuki K et al<sup>15</sup> showed significantly improved hearing results after removal of tympanosclerosis in Tympanoplasty.

The morphological outcome of tympanoplasty alone and cortical mastoidectomy with tympanoplasty for cartilage graft and temporalis fascia graft was compared. Morphological outcome with temporalis fascia was comparable in both surgeries, success rate was 65% for Tympanoplasty with Cortical Mastoidectomy and 68.4% for Tympanoplasty. Success rate with cartilage graft for Tympanoplasty with Cortical Mastoidectomy was 96.9% and Tympanoplasty alone was 95%.

### Conclusion

Cartilage graft is superior to temporalis fascia graft with regard to good morphological and audiological outcomes. It has better graft uptake and improved hearing.

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