

Original Research Article

**COMPARATIVE STUDY BETWEEN HEARING
OUTCOME OF TEMPORALIS FASCIA VERSUS
TRAGAL CARTILAGE GRAFT IN TYPE 1
TYMPANOPLASTY**

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Abstract

Introduction: Chronic suppurative otitis media is highly prevalent middle ear disease. Different graft materials have been used for repair of tympanic membrane perforation by different surgeons in their own choice with variable outcomes. To the best of our knowledge there is no protocol-based study conducted in our country regarding reinforcement cartilage tympanoplasty. This study had compared the hearing outcome of temporalis fascia versus Tragal cartilage graft in Type 1 Tympanoplasty.

Material and Method: The present study was conducted among 50 patients of chronic suppurative otitis media (CSOM), admitted for tympanoplasty and were randomized into 2 groups of 25 patients in each group, group A and group B, to be reconstructed using temporalis fascia or tragal cartilage- perichondrium graft respectively. Objective hearing improvement and subjective improvement in hearing was also noted. The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 21.0 statistical analysis and p value <0.05 is considered as significant. **Results:** The majority of the studied cases were males (i.e., 52.0% in group fascia and 56.0% in cartilage group). The Anthropometric data was also comparable between the groups ($p>0.05$). We recorded post-operative graft status and it was found that intact was achieved in 88.0% cases of fascia group and in 96.0% cases of Cartilage group but the difference was statistically insignificant ($p>0.05$). In fascia group, majority 15 (60.0%) patients were having perforation size >3 mm and 10 (40.0%) patients were ≤ 3 mm perforation size. In Cartilage Group B, majority 13 (52.0%) patients were >3 mm perforation size and 12 (43.0%) patients were <3 mm perforation size. Correlation of both groups was found to be statistically non-significant ($p>0.05$). **Conclusion:** The present study revealed that as per the post-operative graft status, it was found that intact was achieved in 88.0% cases of fascia group and in 96.0% cases of Cartilage group but the difference was statistically insignificant ($p>0.05$). Thus, to conclude, both temporalis fascia and tragal cartilage with perichondrium are acceptable graft materials for successful closure of tympanic membrane perforations. The overall graft uptake and

hearing improvement were better with cartilage, than temporalis fascia. However, none of the results were statistically significant.

Keywords: **Temporalis fascia; Tragal cartilage graft; Tympanoplasty**

Introduction

Chronic suppurative otitis media is highly prevalent middle ear disease. It is a persistent disease affecting the mucoperiosteal lining of middle ear cleft for more than 3 months which is insidious in onset and capable of causing destruction and some irreversible sequela.¹ Temporalis fascia and tragal cartilage are the two most commonly used grafting materials due to its close proximity to the operative field.²

Tympanoplasty was introduced by Wullstein³ in 1952 and Zollner⁴ in 1955. Since then numerous graft materials such as skin, fascia, vein, perichondrium and dura matter have been used to reconstruct the tympanic membrane (TM). Temporalis fascia and perichondrium remain the most employed materials for closure of TM perforation till date. In the last decade, it had shown a renewed interest an increasing use of cartilage graft as an alternative to more traditional grafting materials for TM reconstruction. Cartilage is like fascia in that it is mesenchymal tissue. Besides that, it has more rigid quality to resist resorption and retraction, even in the milieu of continuous eustachian tube dysfunction.⁵ Therefore, graft materials that are more rigid than fascia (i.e., cartilage) and more resistant to infection, resorption, and retraction have been proposed as more appropriate for TM reconstruction.⁶

Cartilage material has been criticized because of concerns regarding hearing results. The thickness and composition of cartilaginous TM should represent a compromise between sufficient stability and adequate acoustic sensitivity. Various authors have shown that following cartilage tympanoplasty, hearing outcome is poor as compared to temporalis fascia or perichondrium.^{7,8} It is assumed that when a large portion of the tympanic membrane is replaced with cartilage, tympanic membrane becomes more stiff and adds mass.⁹ In contrast, Ozbek et al¹⁰ reported that cartilage grafts had significantly higher success rates in comparison with temporalis fascia grafts and the comparison of audiological results between groups revealed no significant difference. In a meta-analysis including 37 studies to compare of cartilage with temporalis fascia tympanoplasty, the authors reported that ABG closure of <10 dB did not differ between cartilage (53.0%) and fascia (54.0%) groups.¹¹

Different graft materials have been used for repair of tympanic membrane perforation by different surgeons in their own choice with variable outcomes. To the best of our knowledge there is no protocol-based study conducted in our country regarding reinforcement cartilage tympanoplasty. This study had compared the hearing outcome of temporalis fascia versus Tragal cartilage graft in Type 1 Tympanoplasty.

Material and Method

The present prospective observational study was carried out in the Department of oto- rhinolaryngology, Career Institute of Medical Sciences and Hospital, Lucknow U.P among 50 patients of chronic suppurative otitis media (CSOM), admitted for tympanoplasty with or without cortical mastoidectomy for duration of two years. Inclusion Criteria comprised of patients with safe type of CSOM with central perforation, pure conductive hearing loss, adequate cochlear reserve, patent Eustachian tube and patient fit for surgery. Exclusion Criteria comprised of ossicular discontinuity, external ear pathology, children below 10 years, unsafe CSOM and SNHL/mixed hearing loss.

All the patients falling in sampling frame and fulfilling the inclusion and exclusion criteria of study were enrolled in the study. Demographic information like age and gender was gathered, body weight and height of the patients were measured and body mass index was calculated. Laboratory evaluations (routine blood and urine investigation microscopy, radiology X-Ray

Paranasal Sinuses Waters view) were recorded.

Bilateral x-ray mastoids in Schuller lateral oblique view were done in all cases to know the pneumatization/sclerosis of mastoids, status of sinus plate and the dural plate. Pre-operatively all the patients with discharging ears were routinely treated by suction clearance, instillation of antibiotic ear drops. It was made sure that ear to be operated was dry for at least 6 weeks pre-operatively for all cases.

After the approval of Institutional Review Board and written informed consent from the patient, these patients were randomized into 2 groups of 25 patients each into Group A and Group B, to be reconstructed using temporalis fascia or tragal cartilage- perichondrium graft respectively. Pre operative assessment included a detailed history, clinical and audiological evaluation, supplemented with suitable radiological investigations when indicated to exclude squamous otitis media, suspected ossicular pathology, eustachian tube dysfunction, and sensorineural hearing loss. Patients with history of previous surgery were excluded.

Patients were operated under general or local anaesthesia. The decision between choosing transcanal approach or post- auricular approach was made based on the preoperative examination with a microscope. Temporalis fascia was harvested by a standard post auricular approach.

The cartilage graft was placed by either the cartilage shield or butterfly technique. In the underlay butterfly technique, the graft size taken 2 mm wider in diameter than the perforation and a 1mm deep groove created along the circumferential border of the cartilage disc allowing the cartilage flanges to spring open.

This groove is engaged with the anterior rim of the perforation so that the medial flange which is medial to the tympanic membrane with the perichondrium facing laterally and the rest of the graft manipulated into place with a dissector or needle and the.

In the cartilage shield technique, a V- shaped notch is created in the cartilage to accommodate the malleus handle and the graft was placed medial to tympanic membrane remnant. In both techniques of cartilage tympanoplasty, the perichondrium was draped onto the lateral bony canal wall to be covered by the tympanomeatal flap.

For follow-up, the following parameters were evaluated: graft uptake, subjective improvement in hearing, and air-bone gap (AB Gap) closure. Successful graft uptake is defined as full intact healing of the graft without residual perforation. Objective hearing improvement is assessed by the A-B gap closure. For this, the A-B Gap is first calculated by noting the mean air-bone gap at 500, 1,000, 2,000 Hz for each patient. The A-B gap closure i.e., the difference in the pre-operative and post-operative AB gap is then calculated for each patient individually at second month.

Subjective improvement in hearing was also noted. Post operative care and follow-up Patients was given water precautions and cautioned against vigorous nose blowing. Sutures removed one week after surgery. Antibiotic steroid-containing drops were started on 5th postoperative day after ear pack removal. For the first month, the patient followed up weekly, then at second month for clinical examination. Tuning fork tests (Rinne's, Weber's and A.B.C) using 256, 512 and 1024 Hz tuning forks and pure tone audiometry.

The data was collected on a semi-structured questionnaire. Records of all the test reports were maintained. Representative photographic record was made. All observations were made under direct supervision of the supervisor.

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 21.0 statistical analysis and p value <0.05 is considered as significant.

Results

It was observed that in the Fascia Group, the majority 13 (52.0%) patients were male and 12 (48.0%) patients were female. In the Cartilage Group, the majority 14 (56.0%) patients were male and 11 (44.0%) patients were female. The correlation of both groups was found to be statistically non-significant ($p>0.05$) (table 1).

Table 1: Distribution of the studied patients based on gender

Gender	Fascia Group (n=25)	Cartilage Group (n=25)	P value
Male	13 (52.0%)	14 (56.0%)	0.777
Female	12 (48.0%)	11 (44.0%)	

The table 2 shows the distribution of studied patients based on the pre-operative AB Gap group and it was observed that in the Fascia Group, the majority 17 (68.0%) patients belonged to <25 pre-operative AB Gap group and 8 (32.0%) patients belonged to ≥ 25 pre-operative AB Gap group respectively. The correlation of both groups was found to be statistically non-significant ($p>0.05$).

Table 2: Distribution of studied patients based on pre-operative AB Gap group

Pre-Operative Gap Group	Fascia Group (n=25)	Cartilage Group (n=25)	P value
<25	17 (68.0%)	16 (64.0%)	0.765
≥ 25	8 (32.0%)	9 (36.0%)	

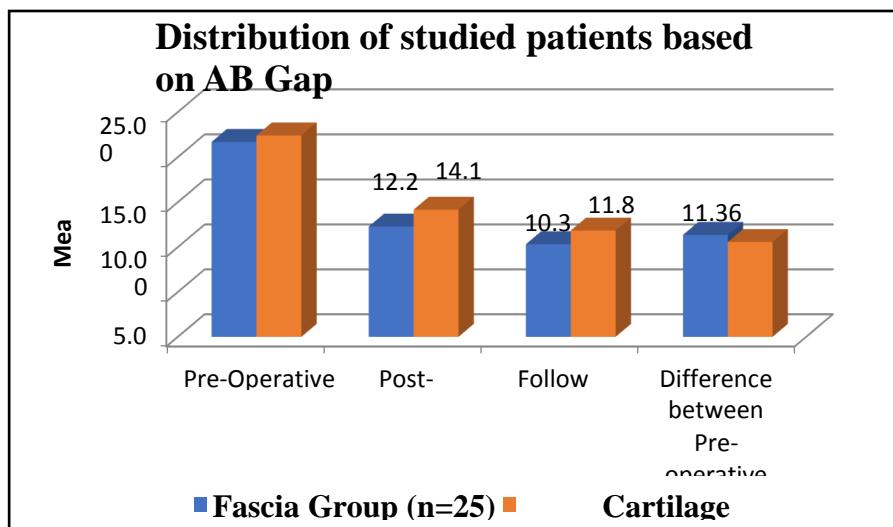
The table 3 and graph 1 shows the distribution of studied patients based on AB Gap. It was observed that in the Fascia Group, the mean AB Gap in Pre-Operative, Post-Operative, at follow up and the Difference between Pre-operative and Follow up was 21.68, 12.28, 10.32 and 11.36 respectively. In the cartilage group, the mean AB gap in pre-operative, post-operative, at follow up and the difference between pre-operative and follow- up was 22.40, 14.16, 11.84 and 10.56 respectively. The correlation of both groups was found to be statistically non-significant ($p>0.05$).

Table 3: Distribution of studied patients based on AB Gap

AB Gap	Fascia Group (n=25)	Cartilage Group (n=25)	P value
Pre-Operative	21.68 \pm 8.01	22.40 \pm 7.26	0.741
Post-Operative	12.28 \pm 4.27	14.16 \pm 4.98	0.158
Follow up	10.32 \pm 3.81	11.84 \pm 3.79	0.165
Difference between Pre- operative & Follow up	11.36 \pm 5.88	10.56 \pm 7.04	0.665

Table 4: Distribution of studied patients based on post-operative Graft status

Post-operative Graft status	Fascia Group (n=25)	Cartilage Group (n=25)	P value
Intact	22 (88.0%)	24 (96.0%)	0.297
Failure	3 (12.0%)	1 (4.0%)	

Graph 1: Distribution of studied patients based on AB Gap

The table 4 shows the distribution of studied patients based on post-operative Graft status and it was observed that in the Fascia Group, the majority 22 (88.0%) patients belonged to Intact status and 3 (12.0%) patients belonged to Failure status respectively. In the Cartilage Group, the majority 24 (96.0%) patients belonged to Intact status and 1 (4.0%) patient belonged to Failure status respectively. The correlation of both groups was found to be statistically non-significant ($p>0.05$).

Discussion

Type 1 tympanoplasty is one of the most commonly performed procedures in otorhinolaryngology. With advanced microsurgical techniques and equipment, the graft uptake success rates of 90.0% to 97.0% have been reported.¹² Various factors influencing the success rate of tympanoplasty have been discussed in literature. Persistent perforation of the tympanic membrane causes recurrent ear discharge and hearing loss of varying degrees. Cartilage supported myringoplasty with palisade technique has good result of graft uptake rate ranging from 86.0 to 100.0%.^{13,14} This technique brings very good functional and better long-term results.¹⁵

In the present study the AB gap was compared pre and post operatively and it was found that the AB gap was higher in cartilage group than fascia group but the difference was insignificant ($p>0.05$). Our findings were supported by Sood AS et al¹⁶ who found that the mean was taken for the difference in AB gap i.e., the AB gap closure. In their study, 47.5% (19 out of 40) patients showed a post operative AB gap of less than or equal to 10 dB. The AB gap closure at 2 months post operative was 11.55 ± 8.173 dB for the Tragal cartilage- perichondrium group, as compared to 10.49 ± 9.069 dB for the Temporalis fascia group. At 6 months, the AB gap closure was 14.98 ± 9.915 dB for Tragal cartilage- perichondrium as compared to 11.41 ± 8.288 dB for Temporalis fascia group. Thus, the hearing improvement was better for Tragal cartilage group both at 2 months and 6 months as compared to Temporalis fascia group. The comparison of the AB gap and the pure tone average scored between both techniques also showed no significant differences.

It should be pointed out that in our study the hearing improvement increased with time, which can be explained by the gradual process of healing and post operative stabilisation of the neotympanic membrane. Most studies arbitrarily define the improvement of hearing as cut-off point or mean of audiometric parameters with very different values and times. Therefore, we must be careful when assessing these figures. Contrary to our results, some authors suggest that though cartilage may be good for graft stabilisation, hearing results are often inferior to those with temporalis fascia.¹⁷ Zahnert T et al¹⁸ had postulated that the thickness of the cartilage graft in

cartilage tympanoplasty should be less than 0.5 mm for it to achieve acoustic properties similar to the normal tympanic membrane.¹³ However, the thinning of the cartilage graft, normally in the range of 0.7 to 1 mm, results in inevitable twisting of the cartilage making reconstruction more difficult.

Recent studies have however showed promising results with full-thickness cartilage tympanoplasty, similar to our results.^{14,15} A study by Chen XW et al¹⁹ conducted on 102 patients using cartilage-perichondrium composite graft in 79 patients undergoing tympanoplasty showed the preoperative AB gap to be 41.66 ± 10.22 dB and postoperative AB gap to be 26.86 ± 8.92 dB. In a study by Zhang ZG et al²⁰ though early hearing improvements in temporalis fascia group were better than that of cartilage– perichondrium composite grafts, there was no significant difference 1 year after surgery. Parida PK et al²¹ reported that measurement of AB gap closure was taken as a guide to study the degree of hearing improvement. The postoperative AB gap was categorized into 2 groups; C10 and B10 dB. There was no significant difference in graft uptake, hearing improvements and degree of improvement between the two groups. in a study done by Wu PW et al²² comparing the short- and long-term hearing outcomes of patients with small and large eardrum perforations who underwent successful inlay cartilage Tympanoplasty, no differences were apparent between the short- and long-term air bone gap closure ($p=0.689$) of small perforations. Khan MM et al²³ reported the mean ABG preop as 31.47 ± 3.98 and 30.98 ± 3.54 for cartilage and fascia group respectively whereas 7.19 ± 2.99 and 6.86 ± 2.39 post-op for cartilage and fascia group respectively and the difference was insignificant between the groups similar to the present study. In our study we recorded post-operative graft status and it was found that intact was achieved in 88.0% cases of fascia group and in 96.0% cases of Cartilage group but the difference was statistically insignificant ($p>0.05$). Our findings were concordance with Poonam KC²⁴ who reported that graft uptake rate was 41 (91.1%). The mean pre- and post-operative pure tone average were 26.88dB and 8.44dB respectively. The post- operative hearing gain was 18.36dB. Hearing improvement after surgery was found to be statistically highly significant with $P<0.001$. According to Khan MM et al²³ in the anatomical evaluation of the tympanic membrane, the criterion for success is an absence of re-perforation. In our study, the graft take-up rate was 98.20% in the sliced cartilage group and 87.42% in the temporalis fascia group. There were 2 residual perforations in each group, 2 recurrent perforations in the cartilage group and 19 recurrent perforations in the temporalis fascia group at the 2-year follow up.¹⁰⁵ At the 4-year follow up, graft take-up was 97.75% and 82.63% in the cartilage and temporalis fascia groups, respectively, with 3 recurrent perforations in the cartilage group and 27 in the temporalis fascia group.

Sandhu KS et al¹² found that complete graft uptake was present in 88.0% of the patients in group I and 84.0% patients in group II. 12.0% patients in group I and 16.0% patients in group II did not have complete graft uptake. The difference in the two groups was statistically insignificant ($p>0.05$). Nagle SK et al²⁵ observed that in dry ear primary closure rate was 88.0% while in wet ear it was 74% giving statistically insignificant p value (0.07). They concluded that the presence of discharge in the ear at the time of operation does not interfere with the results of type 1 tympanoplasty, but it should be mucoid and sterile. Dhar G et al²⁶ who inferred with graft uptake of 90.0% in dry ears compared to 84.0% in wet ears after myringoplasty ($p=-0.0956$) that presence of mucoid discharge which is culture negative at the time of surgery is not a contraindication for surgery. Shishegar M et al²⁷ performed palisade cartilage tympanoplasty in 27 patients and found Graft uptake rate 100.0% for cartilage.

Conclusion

The present study revealed that as per the post-operative graft status, it was found that intact was achieved in 88.0% cases of fascia group and in 96.0% cases of Cartilage group but the difference was statistically insignificant ($p>0.05$). Thus, to conclude, both temporalis fascia and tragal

cartilage with perichondrium are acceptable graft materials for successful closure of tympanic membrane perforations. The overall graft uptake and hearing improvement were better with cartilage, than temporalis fascia. However, none of the results were statistically significant.

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