

Original Research Article

Cartilage palisades versus temporalis fascia: a randomised control trial

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ABSTRACT

Background: Tympanic membrane perforation is a common cause of hearing loss. Various surgical techniques with different graft materials have been described for the treatment of perforations. The most widely used graft materials are the cartilage and temporalis fascia.

Methods: We conducted a prospective randomised control longitudinal study to document the post operative hearing outcomes of type 1 tympanoplasty in patients with inactive mucosal chronic otitis media (n=120) using the cartilage palisades tympanoplasty technique (n=60) and temporalis fascia (n=60).

Results: It was found that the mean AB (air-bone) gap at 5 months post operatively was 12.35 ± 7.17 dB with temporalis fascia and 11.39 ± 7.907 dB in cartilage palisades tympanoplasty. At 12 months the AB gap was 14.98 ± 9.915 dB in temporalis fascia group as compared 11.41 ± 8.288 dB for cartilage palisades group. Thus, hearing improvement was better in cartilage palisades group, but interestingly the comparison of the air conduction gain and subjective improvement at the end of 5 and 12 months between the two techniques was not statistically significant and parallels the above findings.

Conclusions: Hence we conclude that both temporalis fascia and cartilage palisades were acceptable graft material for successful closure of tympanic membrane perforation.

Keywords: Temporalis fascia, Cartilage, Tympanoplasty, Longitudinal study, Tympanic membrane, Air conduction

INTRODUCTION

Persistent perforation of tympanic membrane can impair the patients hearing due to effect on sound conducting mechanism of middle ear.¹

In most cases with persistent perforation, medical treatment is not sufficient and such patients need to undergo surgical correction, involving myringoplasty or tympanoplasty depending on the type of pathological process. tympanoplasty or tympanic membrane (TM) repair is one of the most commonly performed surgeries in otolaryngology.²⁻⁴ Different surgical techniques and grafts are in practice. Since the first description of tympanoplasty in 1952 by Wullstein and Zollner, some grafting material such as temporalis, fascia lata, perichondrium, periosteum, vein, duramater and cartilage

have been used for perforation closure. Temporalis graft is generally considered to be a superior graft with respect to take up rate probably due to its low metabolic rate, and its easy availability in sufficient quantity as separate incision is not required.

On the other hand, in large perforations, atelactatic drums or adhesive otitis media or retraction pockets due to middle ear ventilation problems, cartilage grafts are better options.⁴⁻⁶ Since Utech in 1959 and then Heermann Jansen in the early 1960 reported their experience with cartilage graft tympanoplasty, many authors described their use as palisade, perichondrium /cartilage island flap or cartilage shield for cases of high risk failure.⁷⁻⁹ Conchal and tragal cartilage are two most frequently used cartilaginous grafts. Conchal cartilage is preferred due to its increased stability, pliability, and resistance to

negative middle ear pressure, even in cases of Eustachian tube dysfunction.⁴⁻⁶ Its increase usage are due to the reasons that it is easy to harvest, decreased time consumption, minimal scarring and no significant post operative morbidity especially in cases of large perforation, anteriorly placed perforations, adhesive otitis media and recurrent infections. Various authors have shown that the hearing results are good with cartilage regardless the thickness of the graft. TosM, reviewed 23 different cartilage tympanoplasty methods and grouped them into six categories from A-F.^{8,10} Palisade technique is considered a form of group A cartilage tympanoplasty. Palisade technique specifically involves placement of 0.5-3 mm thick pieces of cartilage placed side by side and often overlapping, under remnant tympanic membrane until defect is covered.⁷ Post operative hearing depends on functioning ossicular chain and aerated middle space, assuming that intact tympanic membrane has been reconstructed. Taking abovementioned facts, this study taken to compare hearing improvement of patients undergoing type 1 tympano-plasty with temporalis fascia and cartilage palisades.

METHODS

This prospective randomized controlled longitudinal trial was carried out in a tertiary care centre from December 2019 to December 2021 study the post operative hearing outcomes of type 1 tympanoplasty in patients of inactive mucosal chronic otitis media (n=120) using the cartilage palisades (n=60) and temporalis fascia (n=60). Necessary permission and approval from ethics committee and authority prior to start of the study was taken. Informed written consents were obtained from patients according to the protocol approved by ethics committee of our institution and patient's confidentiality was maintained. Simple Random sampling was used and patients undergoing type 1 tympanoplasty were simply randomized into two groups. Randomisation was done by odd and even numbers. Even number patients underwent tympanoplasty with temporalis fascia, while odd number patients underwent tympanoplasty by cartilage palisades.

The group 1 (Temporalis fascia group) included sixty patients in whom temporalis fascia was used as a graft material. In the second group (Cartilage palisades group) sixty patients in whom cartilage palisades were used as a graft material were included. All the participants had safe type of CSOM with central perforation, pure conductive hearing loss, adequate cochlear reserve, patent Eustachian tube and were fit for surgery. The study didn't include participants who had Ossicular discontinuity, external ear pathology, children below ten years, unsafe CSOM, SNHL /mixed hearing loss and had history of other associated middle ear surgery excluded.

Preoperative assessment

A detailed history was taken. Thereafter, detailed examination of both ears was done. Any focus of

infection in nose and throat was excluded. Eustachian tube function evaluated using Valsalva manoeuvre and Siegelisation. Hearing assessment using tuning forks followed by pure tone audiometry was done. Pure tone air conduction, bone conduction and air-bone gap averages were calculated at frequencies of 500, 1000, 2000 and 4000 Hz.

Radiology-bilateral X ray mastoids in Schuller lateral oblique view was done in all cases to know the pneumatisation /sclerosis of mastoids, status of sinus plate and the dural plate. It was made sure that the ear to be operated was dried for at least 6 weeks pre operative for all cases. Routine blood examination was done for anaesthesia. All patients were operated under general anaesthesia by a single surgeon to avoid surgeon to surgeon discrepancy. Antibiotic prophylaxis was given postoperatively for 3 weeks. In sixty cases temporalis fascia was used and other sixty cases conchal cartilage palisades were used as a graft material. Three semi-lunar shaped full thickness palisades were made from the conchal cartilage. Perichondrium was removed from the side that was placed towards the middle ear while it was retained towards the side that was supposed to be towards the remnant tympanic membrane. The palisades were supported in the middle ear using gel foam pledgets. Thereafter the tympanomeatal flap was carefully repositioned on the palisade assembly for early epithelialisation of the palisades. The external auditory canal was packed with medicated gel foam.

All patients were followed up in ENT OPD for aural cleaning, otoscopy and postoperative hearing assessment. Tuning fork tests using 256, 512, 1024 tuning forks were used and pure tone audiometry was done at 5 months and 12 months post operatively. Pure tone air conduction, bone conduction and air-bone gap averages were calculated at frequencies of 500, 1000, 2000 and 4000 Hz. Ear findings and pure tone audiometry reports were recorded. At the end of study, decoding of the groups was done and results were statistically analysed.

RESULTS

The mean age of the patients was 27.46 years with 68% males and 32% females. 120 patients were selected for the study and were randomised into two groups of 60 each. Ten patients (7 of group-1 and 3 of group-2) had residual perforation postoperatively and were excluded from the study. 8(3 of group-1 and 5 of group-2) patients were lost to follow up at the end of 12 months of the study and hence had to be excluded from the study group. Thus, we were left with a total of 102 patients (50 patients in group-1 and 52 in group-2). In group-1 the preoperative mean air conduction (AC) was 39.68±11.29 dB and preoperative mean AB gap was 28.20±9.16 dB. After 5 months postoperatively the mean AC levels were reduced to 28.13±9.259 dB and hence there was a postoperative mean gain of 11.55±8.173 dB. The postoperative mean AB gap at 5 months was 12.35±7.17 dB. The

postoperative mean AC levels at 12 months were further reduced to 24.70 ± 8.383 dB, hence there was a gain of 15.98 ± 9.915 dB (further gain of 4.78 ± 8.69 dB). The mean AB gap at 12 months was 14.98 ± 9.915 dB. About 88% (44 out of 50) patients showed subjective improvement in hearing (Table 1 and 2). When the preoperative and the postoperative values of the hearing profile of group-1 compared the p value was significant ($p < 0.01$)

In group 2 the preoperative mean air conduction (AC) was 32.91 ± 11.848 dB and preoperative mean AB gap was 24.63 ± 9.903 dB. After 5 months postoperatively the mean AC levels were reduced to 22.43 ± 14.153 dB and hence there was a postoperative mean AC gain of 10.49 ± 9.069 dB. The postoperative mean AB gap at 5 months was 11.39 ± 7.90 dB. The postoperative mean AC

levels at 12 months were further reduced to 20.51 ± 13.807 dB; hence there was a gain of 12.01 ± 3.18 dB (further gain of 2.69 ± 3.64 dB). The mean AG gap at 12 months was 11.41 ± 8.228 dB. About 80.7% (42 out of 52) patients showed subjective improvement in hearing (Table 1 and 2). The p value was significant ($p < 0.01$) when the preoperative values were compared with the postoperative hearing profile values in case of the group-2.

Thus, hearing improvement was better for conchal cartilage group both at 5 and 12 months, but the comparison of the AC gain and AB gap at the end of 5 as well as 12 months and subjective improvement in hearing between the two techniques (Group 1 and 2) was not statistically significant ($p > 0.05$).

Table 1: Hearing profile 5 months after postoperative period.

Variables	Pre-op, mean AC levels	Post-op, mean AC levels	Post-op, mean AC gain	Pre-op, mean AB gap	Post-op, mean AB gap	Pre post, significance
Temporalis fascia	39.68 ± 11.29	28.13 ± 9.25	11.55 ± 8.17	28.20 ± 9.16	12.35 ± 7.173	< 0.01
Conchal cartilage palisades	32.91 ± 11.848	22.43 ± 14.153	10.49 ± 9.069	24.63 ± 9.903	11.39 ± 7.907	< 0.01

Table 2: Hearing profile 12 months after postoperative period.

Variables	Pre-op, mean AC levels	Post-op, mean AC levels	Post-op, mean AC gain	Pre-op, mean AB gap	Post-op, mean AB gap	Pre post, significance
Temporalis fascia	39.68 ± 11.29	24.7 ± 8.38	15.01 ± 9.915	28.20 ± 9.16	14.98 ± 9.915	< 0.01
Conchal cartilage palisades	32.91 ± 11.848	20.51 ± 13.807	12.01 ± 3.18	24.63 ± 9.903	11.11 ± 8.228	< 0.01

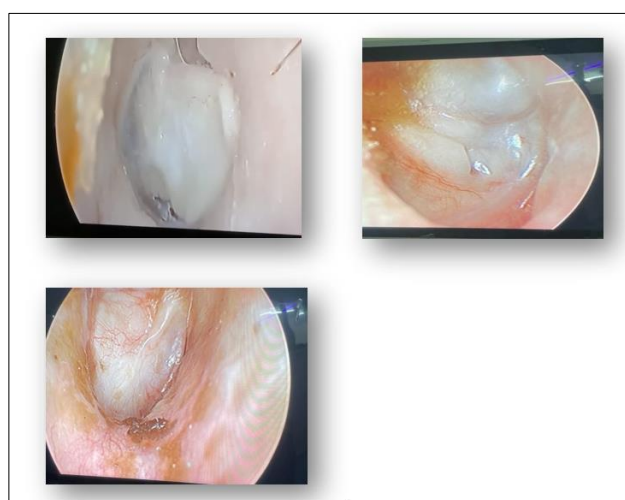


Figure 1: Postoperative endoscopic images of patients post 5 months of cartilage palisade graft.

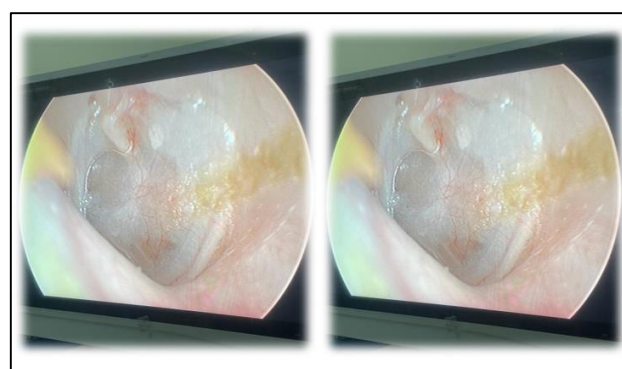


Figure 2: Postoperative endoscopic images of patients post 5 months of temporalis fascia grafts

DISCUSSION

The present study was designated to evaluate hearing improvement while using temporalis fascia and conchal cartilage palisades as graft material in type 1

tympaanoplasty. Pre-op mean AB gap was 28.20 ± 9.161 dB in group 1 while it was 24.63 ± 9.903 dB in group-2 (intergroup $p > 0.05$ non-significant). Post-op mean AB gap at 5 months was 12.35 ± 7.713 dB for group-1 while it was 11.39 ± 7.907 dB for group 2 (intergroup $p > 0.05$ non-significant). Mean AB gap at 12 months was 14.98 ± 9.915 dB in group 1, while it 11.41 ± 8.2885 dB for group 2 (intergroup $p > 0.05$ non-significant).

Thus, hearing improvement was better for conchal cartilage group both at 5 and 12 months, but the comparison of the AC gain and AB gap at the end of 12 months and subjective improvement in hearing between the two techniques was not statistically significant thus proving that the hearing outcomes were comparable when either of the two graft materials were used.

In our study 47.5% showed a post operative AB gap of less than or equal to 10dB. In this study though only single method of doing tympanoplasty was under taken i.e., post aural underlay and study was limited to only central perforations with mild to moderate conductive hearing loss, however the strength of this trial was randomisation, data collection and analysis which were performed centrally. This was in contrast to most studies which arbitrarily define the improvement in hearing as cut off or mean of audiometric parameters with very different values and time. In present study hearing improvement increased gradually with time which explained gradual process of healing as well as post operative stabilization of graft of the neo tympanic membrane.

According to some authors, cartilage may be good for graft stabilization but not for hearing results.^{11,12} Cartilage palisades were first used by Heermann to reconstruct the tympanic membrane to avoid the torsion caused by large slice of cartilage.¹³ Cartilage palisade usage has been recommended in literature in posterosuperior retraction pockets since long.^{14,15} Zahnert and colleagues have postulated that the thickness of cartilage graft in cartilage tympanoplasty should be less than 0.5 mm for it to achieve acoustic properties similar to normal tympanic membrane, however thinning of the cartilage graft, normally in the range of 0.77 mm to 1mm, results in inevitable twisting of the cartilage making reconstruction more difficult. His study showed no significant differences in hearing improvement after full thickness cartilage was used as compared to temporalis fascia tympanoplasty, similar to our results.¹⁶ In our study, we used full thickness conchal cartilage palisades with attached perichondrium (facing the remnant tympanic membrane) for better resistance to retraction and encountered no problems with curling. Perichondrium on adjacent palisades helped in their early union because of tissue fluid and promoted early epithelialization. A study conducted on 102 patients using perichondrium /cartilage composite graft, in 79 patients undergoing palisade tympanoplasty showed significant closure of the AB gap.¹⁷ In another study, early improvement of hearing in

temporalis fascia were seen than in cartilage composite graft, but there was no significant difference after 1 year.¹⁸ An overall hearing improvement with an AB gap difference of less than twenty dB, was seen approximately in 56% cases after 2 years of follow up in a study by Pesce et al.¹⁹ Vashishth et al examined outcomes of cartilage palisades over temporalis fascia at six months and 1 year in children and adult patients. The authors demonstrated excellent results in the palisade group.²⁰ These results are very similar to the results of our study. Khan et al in his study of 390 patients, 223 patients, underwent cartilage palisade tympanoplasty by single surgeon showed good closure of the AB gap, but in their study non-randomized, selection bias remained an issue, while the main strength of our study was that, it was a prospective randomised controlled longitudinal trial.²¹

Although our study shows that both the technique gave same outcome while in terms of getting the longitudinal follow up advocated good hearing outcome in conchal cartilage palisades surgery, still-more number of data would be the beneficial in future studies.

CONCLUSION

Although both temporalis fascia and conchal cartilage palisades are acceptable graft material for successful closure of tympanic membrane perforation however hearing improvements was better when the conchal cartilage palisades were used in the type 1 tympanoplasty.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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