

Original Research Article

Reinforced temporalis fascia with conchal cartilage versus exclusive temporalis fascia grafting in type 1 tympanoplasty: a comparative study

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ABSTRACT

Background: Various grafting materials have been used for the repair of a tympanic membrane perforation over the years, with temporalis fascia and conchal cartilage being the most widely used. Our study is an attempt to compare and analyse the use of exclusive temporalis fascia as grafting material against a reinforced graft consisting of temporalis fascia and conchal cartilage.

Methods: This was a prospective study of 100 patients having inactive mucosal chronic otitis media with a dry central perforation with moderate conductive hearing loss, undergoing type 1 tympanoplasty using underlay technique. 50% of the subjects were grafted with temporalis fascia alone while a reinforced temporalis fascia graft along with conchal cartilage was used in the remaining 50% of the cases. The results were evaluated at an interval of 24 weeks after surgery on the basis of graft uptake and hearing restoration (closure of air-bone gap <10 dB).

Results: Graft uptake in exclusive temporalis fascia grafting was 86% while it was 94% when a reinforced graft was used; the hearing restoration rates in both the groups were 82% and 80% respectively.

Conclusions: Reinforced temporalis fascia grafting along with conchal cartilage gives better results than grafting with temporalis fascia alone as regards to graft uptake, while the audiometric results are comparable in both the groups.

Keywords: Tympanoplasty, Temporalis fascia, Conchal cartilage, Reinforced temporalis fascia with conchal cartilage

INTRODUCTION

The tympanic membrane (TM) plays a significant role in the physiology of hearing as well as in the pathophysiology of chronic inflammatory middle ear diseases, perforations of which may significantly impair the quality of life in millions of patients.

A tympanic membrane perforation, irrespective of the cause, will require surgical closure, if it fails to heal on its own with supportive conservative treatment. Repairing of tympanic membrane perforation helps to restore the vibratory surface area of the tympanic membrane and also affords round window protection, which is expected

to cause an improvement in hearing. Additionally, the repaired drum would prevent an exposure of the middle ear to external infections and allergens.

Various materials have been tried and used successfully in the closure of these tympanic membrane perforations. These include temporalis fascia, conchal and tragal cartilage, perichondrium, skin, fascia lata, dura and vein graft.¹⁻⁷ In addition; these can be reinforced with one another and used in various combinations in middle ear surgery.

The basic principle in using any biological autologous graft material is that it acts as a scaffold of tissue matrix,

when applied to seal the perforation and this subsequently re-vascularises and stimulates migration of fibroblasts and epithelium. Abundance of various materials used for grafting shows that there is no clear favourite and it depends on the individual surgeon's preference.

Considering its site, ease of harvest and most importantly, the biological similarity to the normal tympanic membrane, the temporalis fascia is the most commonly used graft material worldwide. Use of cartilage, conchal or tragal, is also favoured by a lot of surgeons. The greatest advantage of the cartilage graft has been thought to be its very low metabolic rate. It receives its nutrients by diffusion, is easy to work with because of its pliability, and it can resist deformation from pressure variations.⁸

Different techniques of graft placement may be used by surgeons but the underlay technique is the most preferred method where the graft is placed medial to both, the fibrous and mucosal layers of the tympanic membrane. Temporalis fascia may be used alone or in combination with a cartilage graft. A cartilage graft may be placed medial to the placement of temporalis fascia in reinforced fascia-cartilage technique. Use of conchal cartilage over tragal cartilage is preferred in our institute, as it can be harvested from the same post-aural incision as temporalis fascia.

The objective of performing this study was to compare and analyse the graft uptake and hearing restoration levels between two sets of patients, one which were grafted with temporalis fascia alone and another in which a reinforced temporalis fascia graft with conchal cartilage was used. By using graft uptake and hearing restoration as parameters, this study aims at conclusively finding the better grafting material or materials in patients undergoing a type 1 tympanoplasty for a central perforation with moderate conductive hearing loss.

METHODS

This was a prospective study involving 100 patients, carried out over a period of 18 months from August 2018 to January 2020, at Sanjeevan Medical Foundation ENT Post-Graduate Training Institute, Miraj, Maharashtra, India. The study has been granted the requisite approval by the ethics committee of the institute.

The study includes a detailed comparative analysis of 50 patients who underwent type 1 underlay tympanoplasty by using a reinforced temporalis fascia graft along with conchal cartilage against 50 patients having a similar profile of disease, who underwent a similar procedure but with use of temporalis fascia alone as grafting material (Tables 1 and 2).

The study group includes patients in the age group of 16-50 years with no sex predilection, having unilateral or bilateral inactive mucosal chronic otitis media with a dry central perforation and moderate conductive hearing loss.

Only those patients who had an intact ossicular chain finding intra-operatively were selected for the purpose of this study. Patients with active mucosal otitis media i.e. those having a discharging ear were first treated conservatively and operated only when the ear was dry for a period of at least six weeks.

Table 1: Demographic distribution.

Variables	Number of patients	Percentage (%)
Male	41	41
Female	59	59
Total	100	100

Table 2: Type of graft material used.

Graft material used	Number of patients	Percentage (%)
Temporalis fascia	50	50
Temporalis fascia with conchal cartilage	50	50
Total	100	100

Inclusion criteria

Inclusion criteria were unilateral or bilateral safe (inactive mucosal) COM with a dry central perforation, moderate conductive hearing loss (41-55 dB) and intact ossicular chain (intra-operative finding).

Exclusion criteria

Exclusion criteria were patients having active mucosal otitis media (discharging ear), not responding to medical line of management, patients having atticointral (squamosal COM) disease, patients with sensorineural or mixed hearing loss, patients with moderately severe to severe conductive hearing loss (suggestive of ossicular discontinuity), patients with history of previous ear surgery, patients having ossicular discontinuity or fixation (intra-operative finding), patients showing signs of tympanosclerosis pre-operatively or intra-operatively, and uncontrolled hypertension, diabetes mellitus or any form of immunocompromised status.

Pre-operative evaluation

It was extremely important to keep the preoperative findings of all the patients as similar as possible to rule out any chances of false results. For this very purpose, only those patients were chosen who were having a dry central perforation with moderate conductive hearing loss. An attempt was made to keep the size and site of the perforations identical in both the groups. The tympanic membrane was evaluated by oto-endoscopy and microscopy after thorough cleaning of the external auditory canal. The hearing assessment was done by

tuning fork tests clinically and the same was confirmed on pure tone audiometry. A detailed medical and surgical history of all the subjects was also taken to rule out any other causes which could have interfered with our results.

Statistical analysis

The study design is a hospital based prospective study with quantitative data presented as simple percentage. Hearing assessment has also been summarised in mean and standard deviation along with test of significance being done using standard statistical methods in both groups.

RESULTS

All patients underwent a type 1 tympanoplasty by underlay technique using a post-aural approach. Only those patients who had an intact and mobile ossicular chain (confirmed intra-operatively) were selected.

These patients were assessed post-operatively at 6, 12 and 24 weeks and were evaluated on two main parameters - namely, the graft uptake and hearing improvement. The graft uptake was evaluated visually by oto-endoscopy and microscopy. Hearing assessment was assessed by tuning fork tests and pure tone audiometry. For sake of eliminating subjective error and quantifying our findings, only pure tone audiometry results were taken into consideration for the purpose of this study.

Observation and results only at the end of 24 weeks after surgery were considered as final. At the end of 24 weeks, it was observed that graft uptake was 86% in those grafted exclusively with temporalis fascia while it rose significantly to 94% in those subjects who were grafted with a reinforced temporalis fascia with conchal cartilage (Figures 1 and 2). This success of graft uptake was more than the average of 90% when all the 100 patients were considered together (Table 3).

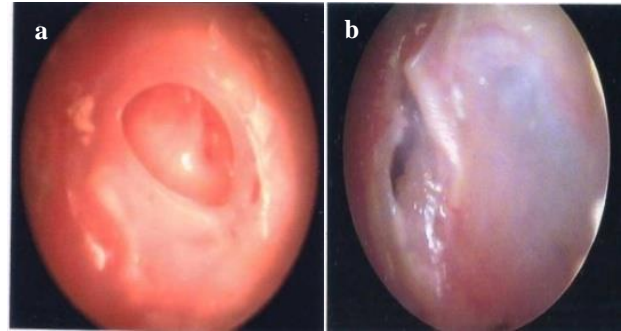


Figure 1 (a and b): Left ear dry central perforation preoperatively and temporalis fascia grafting in the same, seen at 24 weeks.

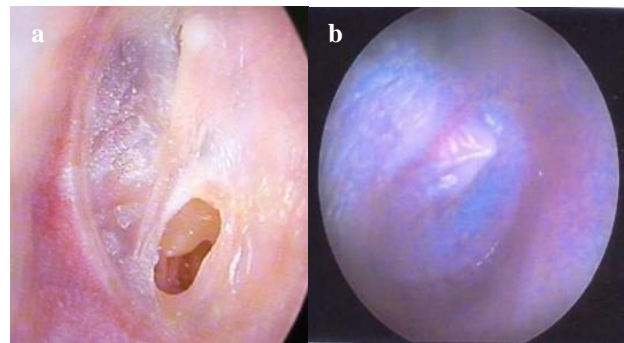


Figure 2 (a and b): Right ear dry central perforation pre-operatively and reinforced temporalis fascia grafting with conchal cartilage in the same, seen at 24 weeks.

Hearing improvement after surgery was assessed in terms of closure of the air-bone gap to less than 10db, which if attained was considered successful. It was found that 82% of those grafted with temporalis fascia showed this improvement while it was 80% in whom a reinforced graft was used (Table 4).

Table 3: Comparative analysis of graft uptake between the two study groups 24 weeks after surgery.

Graft material used	Graft uptake	Residual perforation	Total	Percentage of success	Percentage of failure
Temporalis fascia	43	7	50	86	14
Temporalis fascia with conchal cartilage	47	3	50	94	6
Total	90	10	100	90	10

Table 4: Comparative analysis of hearing restoration 24 weeks after surgery.

Graft material used	Post-operative air-bone gap <10 dB	Post-operative air-bone gap >10 dB	Total	Percentage of successful hearing restoration
Temporalis fascia	41	9	50	82
Temporalis fascia with conchal cartilage	40	10	50	80
Total	81	19	100	81

Mean air bone gap in patients grafted with temporalis fascia was 9.70dB with standard deviation of 4.29 dB whereas the mean and standard deviation in reinforced temporalis fascia with conchal cartilage were 9.72 dB and 4.24 dB respectively. P value calculated using unpaired T-test was 0.98 (p=0.98) indicating that the difference in the hearing improvement outcomes in both groups was statistically not significant.

DISCUSSION

Otitis media is a general term used to describe any inflammatory disease of the mucous membrane lining the middle ear cleft. It is an important disease in both, children and adults and is caused by multiple interrelated factors including nose and sinus infections, poor personal hygiene, Eustachian tube dysfunction, allergies and barotraumas. Chronic otitis media is the most advanced disease state in the spectrum of otitis media and is associated with one or more forms of irreversible pathological conditions in the middle ear such as granulation tissue, ossicular chain discontinuity, tympanosclerosis, tympanic membrane perforation or cholesteatoma.

Traditionally chronic otitis media is classified into tubotympanic disease characterized by the presence of a central perforation and atticotympanic disease characterized by the presence of a cholesteatoma. Modern terminologies for the same include mucosal and squamous types of chronic otitis media respectively, which maybe inactive or active.

Tympanoplasty is the main surgical treatment for mucosal type of disease. It is defined as an operation performed to eradicate the disease in the middle ear and to reconstruct the hearing mechanism, with or without tympanic membrane grafting.⁹ The ideal tympanoplasty restores sound protection for the round window by constructing a closed, air containing middle ear against the round window membrane and also restores sound pressure transformation for the oval window by connecting a large tympanic membrane or a substitute membrane with the stapes footplate via either an intact or a reconstructed ossicular chain.¹⁰

To accomplish the two physiological principles of tympanoplasty, sound protection for the round window must first be provided by means of a tissue graft to repair the tympanic membrane defect, and the middle ear must be lined by mucosa with adequate ventilation. Also, the sound pressure transformation to the oval window must be provided by a mobile ossicular continuity between the larger tympanic membrane and the smaller oval window.¹⁰

Over the years, different grafting materials have been introduced right from a pig's bladder membrane by Benzer in 1640 to canal wall skin by William House in 1958 to temporalis fascia in 1964 by Ned Chalet. Conchal

cartilage was first used by Allesandro Trombetta in 1963. Since then, skin as a grafting material has been discarded due to its desquamation formation properties with chances of cholesteatoma formation. Vein grafts while quite popular in surgery for otosclerosis, have not proven to be as efficacious in surgery for chronic otitis media. To date, temporalis fascia and conchal cartilage have been the two most commonly used grafting materials.¹¹

In this study, we have compared the results of temporalis fascia with conchal cartilage reinforced grafts used for the repair of the perforated tympanic membrane using underlay technique to those in which exclusive temporalis fascia was used as grafting material. Both conchal cartilage and temporalis fascia are accessible near the operative site and are available in adequate amount. Also, both have a low basal metabolic rate and hence require lesser amounts of oxygen which in turn ensures better graft survival. The thickness of both temporalis fascia and conchal cartilage is nearly the same as that of the tympanic membrane. Thus, they are the nearest possible thing to an ideal graft tissue, while both being mesodermal in origin, are free from the possibility of post-operative cholesteatoma formation.

In our series of 100 patients, we used temporalis fascia in 50 patients and the other 50 patients were operated using reinforced temporalis fascia with conchal cartilage as graft material. Temporalis fascia in all cases was prepared by spreading it over an inverted bowl, which was placed over another hot water bowl to dry it completely (Figure 3). Before drying, care was taken to shave off all the excess muscle/ fat from the surface of the temporalis fascia. The conchal cartilage which was used in 50 cases was prepared by thinning it adequately to fit into the middle ear space and all the perichondrium over it was also shaven off.



Figure 3: Temporalis fascia dried and spread over an inverted bowl along with an ovoid piece of conchal cartilage.

All the cases were operated under local anesthesia with sedation, using a post-aural approach. The youngest patient in our series was 18 years old while the oldest was 47 years old with females outnumbering the males by a

ratio of 1.4:1. While a routine underlay technique for placement of temporalis fascia was used in all the cases; in reinforced grafts, an adequately shaped conchal cartilage piece was placed in the middle ear space medial to the temporalis fascia.

Though temporalis fascia is considered the most ideal of the graft materials used to reconstruct a tympanic membrane perforation, reinforcing it with a conchal cartilage was found to improve the chances of graft uptake by a considerable margin in our study (86% success for temporalis fascia alone as opposed to 94% for a reinforced graft). Strahan achieved a graft uptake success rate for temporalis fascia upto 87% by underlay technique.¹² Dabholkar et al achieved a 84% success rate for temporalis fascia grafting in 2007, while Rout et al and SP Singh et al achieved a 82.6% and 85% success respectively for the same in 2018.^{11,13,14} Our success rate of 86% by using temporalis fascia alone was comparable to all these studies.

Present study achieves almost 94% graft uptake by using a temporalis fascia together with conchal cartilage, which is a significant improvement over the graft success rates of the other group in our study as well as other studies, when temporalis fascia has been used in isolation. Rout et al and Singh et al both achieved a success of 95% when using a temporalis fascia with conchal cartilage which again is a comparable success rate to our study.^{13,14} Further, our results compared favorably to the use of perichondrium (80% success - Dabholkar et al) or cartilage alone (92% - Iacavou et al and Yu et al) by others.^{11,15,16} Thus a reinforced temporalis fascia graft with conchal cartilage was proven to be more reliable as regards to graft uptake, when compared to either of the two entities used in isolation or any other grafting material such as perichondrium.

One distinct advantage of using a conchal cartilage is in cases having a central perforation with an attic or posterosuperior retraction pocket in which it can be used to obliterate the retraction pocket. Another major advantage is that it can be used in reconstruction of the ossicular chain in cases of ossicular discontinuity. However, our case series focused exclusively on central perforations and hence, both these pathologies were not considered.

Disadvantage of using a cartilage in the middle ear is that it is considered to obliterate the middle ear space, thereby compromising the vibratory characteristics of the tympanic membrane and thus contributing to less than desired improvement in hearing. However according to the study by Yung, concerns that the stiffness and mass of cartilage grafts may adversely affect hearing have not been substantiated in clinical reports thus far.⁸

The hearing restoration rate (closure of air-bone gap to less than 10 dB) for temporalis fascia graft was 82% in the study conducted by Strahan et al while it was 83.8%

in the study by Rout et al. The present study achieves a hearing restoration rate of 82% when using a temporalis fascia graft alone (comparable to Strahan and Rout), while it is 80% when a reinforced graft is used (Rout achieved 81.1% success for the same).^{12,13} Thus, almost similar hearing restoration success was achieved irrespective of whether only temporalis fascia or a reinforced graft was used. This was further in line with the findings of Dabholkar and Pradhan, who despite having varying percentage levels (76% and 75% for the former using a temporalis fascia and tragal perichondrium respectively, 90% and 88% for the latter using temporalis fascia and conchal/tragal cartilage respectively), concluded that the hearing restoration rates were similar, irrespective of the type of graft material used.^{11,17}

To summarize, the present study achieved graft uptake in 90% of all the cases, which can be considered more than satisfactory. The number is boosted by higher graft uptake success rates in reinforced grafts (94%) as compared to solitary temporalis fascia grafts (86%), although the later numbers are comparable to other studies in which temporalis fascia was used alone. Hearing restoration is almost the same in both our study groups with use of temporalis fascia alone (82%) doing only slightly better than the reinforced grafts (80%). Statistical analysis also confirmed that the differences in hearing restoration levels in both groups were not significant ($p=0.98$).

Therefore, we advocate the use of a reinforced temporalis fascia graft with a conchal cartilage in almost all cases of inactive mucosal chronic otitis media, having a dry central perforation and moderate conductive hearing loss, as it tends to have higher chances of graft uptake and comparable hearing restoration levels as compared to temporalis fascia graft used in isolation.

CONCLUSION

The basic aim of the study was to compare and analyse whether use of a reinforced temporalis fascia with conchal cartilage gives better post-operative results as regards to graft uptake and hearing improvement as opposed to solitary use of temporalis fascia as grafting material. And we can conclude that while the graft uptake is definitely better when a reinforced graft is used, the post-operative audiometric results are comparable in both the groups. Hence, we advocate the use of a reinforced temporalis fascia with conchal cartilage when performing a type 1 tympanoplasty in all cases of inactive mucosal chronic otitis media, having a dry central perforation and moderate conductive hearing loss.

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Conflict of interest: None declared

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

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