

## Myringoplasty with and without Fibrin Sealant use in Large Size Tympanic Membrane Perforation - A Comparative Study

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### ABSTRACT

**Background:** The powerful elastic fibers of platelet-rich fibrin, which are rich in growth components, make it the ideal patch material for tympanic membrane perforation. On this basis, this study set out to assess the efficacy of fibrin in myringoplasty in terms of the success rate of temporalis fascia graft uptake, as well as its safety.

**Methods:** This randomized controlled trial was conducted in the department of ENT in a tertiary care teaching hospital among patients who attended ENT department with large tympanic membrane perforation. A total of sixty six participants with COM were included in the study and all were included in the post treatment assessment. Cases were divided in two groups A (control group without fibrin sealant) and group B (fibrin sealant) using computer generated random numbers with 33 cases in each group. Ethical committee approval was obtained for this study. Data was analyzed using statistical package for social sciences.

**Results:** On comparing the groups – Myringoplasty with temporalis fascia graft using fibrin glue and Myringoplasty with temporalis fascia graft without using fibrin glue both the groups were similar in demographic and ontological findings. Notably the graft up-take was reported to be high in the group - Myringoplasty with temporalis fascia graft using fibrin glue compared to non fibrin glue group. However, postop grading of hearing loss, and postop mean ABG were similar in both Myringoplasty with temporalis fascia graft using fibrin glue and Myringoplasty with temporalis fascia graft without using fibrin glue. Additionally, in both groups, on comparing pre and postop hearing loss, pre and postop mean ABG, the post op hearing and ABG were improved significantly.

**Conclusion:** By applying fibrin glue to the graft's borders and the perforation edges during myringoplasty, we may conclude that the temporalis fascia graft's success rate has significantly increased. Successful audiological outcomes and improved graft uptake following TM perforation are provided by the application of fibrin glue.

**Key words:** Perforation in ear, otitis media, surgical repair, fibrin glue

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### Introduction

An inflammation of the middle ear cleft mucoperiosteum, chronic otitis media (COM) typically manifests as purulent otorrhea lasting more than six weeks, otalgia, or hearing loss [1]. An estimated 65 to 300 million people worldwide suffer from COM, with 60% of them suffering from severe hearing loss. About 6% of Indians suffer from chronic ear illness, and COM is more common in underdeveloped nations [2].

In both mucosal chronic otitis media and squamosal chronic otitis media, central perforation is frequently seen. Myringoplasty is frequently performed to repair ruptured tympanic membranes in mucosal chronic

otitis media illness. For safe forms of COM (central pars tensa perforations), it is the most often utilized surgical technique for perforation repair. Autologous temporalis fascia has demonstrated the most favorable outcomes in terms of effective uptake among the list of graft materials utilized in myringoplasty. Although both myringoplasty overlay and underlay procedures produce good outcomes, the underlay approach performs somewhat better than the overlay technique. As a result, the underlay approach should be chosen since it is technically straightforward; nonetheless, the surgeon's preference and the perforation site will ultimately determine which technique is used [3]. The

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selection of graft materials for myringoplasties was an additional consideration. For many years, temporalis fascia has been utilized extensively. According to a recent study, the temporalis graft is superior to the conchal perichondrial graft for closing holes in chronic otitis media that is inactive mucosal and has a central perforation in the Tympanic Membrane (TM).

According to the post-operative findings, the study group that received temporalis fascia as graft material saw a greater improvement in hearing than the group that received conchal perichondrium [4]. There are several reasons why graft uptake results differ. Graft lateralization, re-perforation, residual perforation, and vascularization failure have all been often observed. Strauss conducted research on the use of human tissue adhesives in guinea pigs. On a statistical background, the rate of recurring holes in tympanoplastic was reduced by human fibrin tissue adhesive [5]. Platelet extracts are being utilized with encouraging results to promote wound healing in several parts of the world. Therefore, the tympanic membrane healing would likewise be enhanced by the use of platelet-rich fibrin in ear procedures. Numerous facilities worldwide have tried using fibrin glue for tympanoplasty [6,7]. Platelet rich plasma (PRP) or a combination of concentrated fibrinogen solutions and thrombin can be used to make fibrin glue [8].

The tympanic membrane is protected from inflammation and mechanical stress by platelet-rich fibrin, a resorbable membrane. It speeds up matrix remodeling and cell division. Since it is an autologous biomaterial, no unfavorable tissue responses are triggered [9]. Additionally, it may be readily controlled during surgical operations and is simple, rapid, and inexpensive to make. Research has also been done on the function of platelet-rich fibrin in healing traumatic tympanic membrane perforations [10,11]. It is regarded as the perfect patch material for tympanic membrane perforation because of its robust elastic fibers that are abundant in growth ingredients. Additionally involved in growth factor release, immunological control, antimicrobial response, and matrix remodeling during wound healing are leukocytes embedded in the platelet-rich fibrin scaffold [12]. The purpose of this study was to evaluate the safety of using fibrin in myringoplasty as well as its effectiveness in terms of the success rate of temporalis fascia graft uptake.

### **Methods**

This randomized controlled trial was conducted in the department of ENT in a tertiary care teaching hospital among patients who attended ENT department with large tympanic membrane perforation during November 2023 to January 2025. Cases with large central perforation, dry middle ear cavity and no active disease of nose and throat were included. However, cases with sign of cholesteatoma or ossicular necrosis, anaemia, chronic kidney disease, haemodynamic instability, diabetes, fluctuating hypertension, hypofibrinogenemia, and platelet dysfunction

were excluded. A total of sixty six participants with COM were included in the study and all were included in the post treatment assessment. Cases were divided in two groups A (control group without fibrin sealant) and group B (fibrin sealant) using computer generated random numbers with 33 cases in each group. Ethical committee approval was obtained for this study from the appropriate Institutional Ethics Committee.

Patients attending ENT department with large tympanic membrane perforation during the study period were included in the study. The individual participants were explained about the study in detail and they were also assured that, their identity would be kept strictly confidential and they have the option to refuse participation in the study. Written informed consent was obtained from the study participants prior to the interview. After taking the written informed consent, participants were allotted to group A and group B and assessed for the demographic and clinical presentation by the principal investigator using a pre structured proforma. Following which the principal investigator assessed the detailed history of the participants and clinically examined the patients and diagnosis of tympanic perforation was confirmed.

The blood was obtained from antecubital vein using 16/18 number scalp vein set in specific tube having 1 ml of anticoagulant, 9.0 ml of blood was collected. Immediately centrifugation of blood was done at automatic centrifugation machine using 1500 rpm for 15 min. This resulted in two layers upper one yellowish and lower one dark red. By using a sterile pipette supernatant plasma was transferred to another sterile tube for hard spin. Second centrifugation was done at 3000 rpm for 15 min, upper supernatant fibrin glue (platelet poor plasma) was sucked gently with pipette after leaving 1 ml of fluid and pellet at the bottom. Using another sterile pipette gently mixed the pellet in the fluid, preserved to be used during surgery. Immediately before use 0.1 ml of calcium gluconate was added to activate the release of growth factor.

This fibrin glue was added to just sufficient quantity of gel foam going to be used in surgery two drops of fibrin glue was installed on each side of dried temporal fascia graft. The graft was placed medial to handle of malleus after lifting 360° tympanomeatal flap. Repositioning of anterior segment was done meticulously to prevent anterior blunting. Fibrin glue wet gel foam placed over the graft pressing the graft to squeeze out any air or blood between the graft and bone. Thin ribbon pack was placed in cartilaginous portion external auditory canal. Pack was observed on alternate days and gentle suction done over it. Ribbon pack removed on 7<sup>th</sup> day and condition of gel foam observed. The postoperative medication protocol, including antibiotics and vitamin C and D, was administered according to the standardized institutional recovery protocol to optimize wound healing and prevent secondary infection.

*Data analysis*

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The data was entered in excel sheet and analyzed using Statistical Package for Social Sciences (SPSS) - Version 19. Descriptive statistics with mean, standard deviation and proportions (%) were calculated for quantitative variables. To test the hypothesis Chi Square test, paired t test and independent sample t tests were used. p value of <0.05 was considered as statistically significant.

### Results

In this study among Group A participants 6.1%, 21.2%, 16.7% and 7.6% of the participants were in the age group of ≤ 20 years, 21-30 years, 31-40 years and > 40 years of age whereas in Group B 3%, 21.2%, 19.7% and 7.6% of the participants were between the age group of ≤ 20 years, 21-30 years, 31-40 years and > 40 years. There was no statistical significance noted between group A and group B participants for age. The mean age among group A and group B cases were 28.7±9.6 years and 29.5±8.9 years respectively with no statistically significant difference.

Based on the gender 31.8% of the participants were males and 18.2% of the participants were females in group A while 27.3% of the participants were males and 22.7% of the participants were females in group B. there was no significant association recorded between the groups based on gender. BMI was recorded to be normal among 30.3% of the cases, overweight among 15.2% of the cases and obese among 4.5% of the cases in group A while it was found to be normal among 36.4% of the cases, overweight among 10.6% of the cases and obese among 3% of the cases in our study. The association between group A and B for BMI was statistically not significant. The mean BMI among group A participants were 26.9±2.7 whereas among group B participants was 26.1±2.1, with no statistical difference between group A and B cases for BMI. Different ontological findings were compared between two groups and all parameters were similar in both groups without any significant difference (Table1).

**Table 1: Otological findings**

Variables	Group A	Group B	Total	p value
<b>Duration of ear complaints</b>				
< 1 month	8 (12.1)	9 (13.6)	17 (25.8)	0.7462
1-2 months	14 (21.2)	11 (16.7)	25 (37.9)	
> 2 months	11 (16.7)	13 (19.7)	24 (36.4)	
<b>Side of Pathology</b>				
Left	14 (21.2)	16 (24.2)	30 (45.5)	0.6210
Right	19 (28.8)	17 (25.8)	36 (54.5)	
<b>Duration of dry ear</b>				
< 2 weeks	2 (3.0)	3 (4.5)	5 (7.6)	0.6027
2-4 weeks	21 (31.8)	17 (25.8)	38 (57.6)	
> 4 weeks	10 (15.2)	13 (19.7)	23 (34.8)	
<b>No. of quadrants involved by perforation</b>				
Two	6 (9.1)	8 (12.1)	14 (21.2)	0.8329
Three	11 (16.7)	10 (15.2)	21 (31.8)	
Four	16 (24.2)	15 (22.7)	31 (47.0)	

On assessing the Pre op Grading of Hearing loss in group A participants 4.5%, 21.2%, 15.2%, 7.6%, 1.5% were found to have normal, mild, moderate, moderately severe and severe hearing loss respectively. Likewise in group B the Pre op Grading of Hearing loss was noted among 6.1%, 19.7%, 12.1%, 9.1% and 3% of the patients who had normal, mild, moderate, moderately severe and severe hearing loss respectively (Table 2).

**Table 2: Pre op Grading of Hearing loss between groups**

Pre op Grading of Hearing loss	Group A	Group B	Total	p value
Normal	3 (4.5)	4 (6.1)	7 (10.6)	0.9753
Mild	14 (21.2)	13 (19.7)	27 (40.9)	
Moderate	10 (15.2)	8 (12.1)	18 (27.3)	
Moderately severe	5 (7.6)	6 (9.1)	11 (16.7)	
Severe	1 (1.5)	2 (3.0)	3 (4.5)	
Profound	0 (0)	0 (0)	0 (0)	

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Based on the post op grading of hearing loss 15.2%, 16.7%, 12.1%, 4.5% and 1.5% of the participants in group A had normal, mild, moderate, moderately severe and severe hearing loss respectively. However in group B 25.8%, 15.2% and 9.1% of the participants were found to have normal, mild and moderate hearing loss respectively. Moderately severe to profound hearing loss was not noted among group B patients. The association between both the groups for post op grading of hearing loss was insignificant (Table 3).

**Table 3: Post op Grading of Hearing loss between groups**

Post op Grading of Hearing loss	Group A	Group B	Total	p value
Normal	10 (15.2)	17 (25.8)	27 (40.9)	0.2921
Mild	11 (16.7)	10 (15.2)	21 (31.8)	
Moderate	8 (12.1)	6 (9.1)	14 (21.2)	
Moderately severe	3 (4.5)	0 (0)	3 (4.5)	
Severe	1 (1.5)	0 (0)	1 (1.5)	
Profound	0 (0)	0 (0)	0 (0)	

Based on the grading of hearing loss pre- operative and post-operative, among group A patients there was significant association recorded (Table 4).

**Table 4: Comparison of Pre and post op grading of hearing loss in group A**

Grading of Hearing loss	Group A		Total	p value
	Pre Op	Post Op		
Normal	3 (4.5)	10 (15.2)	13 (19.7)	0.0231*
Mild	14 (21.2)	11 (16.7)	25 (37.9)	
Moderate	10 (15.2)	8 (12.1)	18 (27.3)	
Moderately severe	5 (7.6)	3 (4.5)	8 (12.1)	
Severe	1 (1.5)	1 (1.5)	2 (3.0)	
Profound	0 (0)	0 (0)	0 (0)	

**\*Significant**

Based on the grading of hearing loss pre- operative and post-operative procedure, among group B patients there was significant association recorded (Table 5).

**Table 5: Comparison of Pre and post op grading of hearing loss in group B**

Grading of Hearing loss	Group B		Total	p value
	Pre Op	Post Op		
Normal	4 (6.1)	17 (25.8)	21 (31.8)	0.0343
Mild	13 (19.7)	10 (15.2)	23 (34.8)	
Moderate	8 (12.1)	6 (9.1)	14 (21.2)	
Moderately severe	6 (9.1)	0 (0)	6 (9.1)	
Severe	2 (3.0)	0 (0)	2 (3.0)	
Profound	0 (0)	0 (0)	0 (0)	

**\*Significant**

The mean pre op ABG among group A patients was 20.3±9.4 and in group B patients was 19.6±10.2, with no difference between group A and Group B patients (p value =0.6825). The mean post op ABG among group A patients was 11.5±8.4 while the mean post op ABG among group B patients was 9.8±9.1. There was no difference noted between group A and group B cases based on post op ABG. The mean ABG among group A participants during pre op was 20.3±9.4 whereas at post op therapy was 11.5±8.4. The difference in mean ABG among group A cases based on pre op and post op procedure was highly significant. The mean ABG among group B participants during pre op procedure was 19.6±10.2 whereas at post op procedure it was 9.8±9.1. The difference in mean ABG among group B cases based on pre op and post op procedure was highly significant (Table 6).

**Table 6: Comparison of ABG between groups at pre and post op periods**

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Parameter	Group A	Group B	p value
Pre op Mean ABG	20.3±9.4	19.6±10.2	0.6825
Post op Mean ABG	11.5±8.4	9.8±9.1	0.2668
<b>p value</b>	<0.0001*	<0.0001*	-

\*Significant

In this current study, Intra op Middle ear inflammation was present among 7.6% and 6.1% of the cases in group A and B respectively with insignificant p value of 0.7198. In this study post op infection was present among 3% of the cases in group A while no cases had post op infection in group B, but the association between the groups for post op infection was statistically insignificant (p value =0.1509). Post op graft was not taken up among 10.6% of the cases in group A while only 1.5% of the cases in group B were noted for whom post op graft was not taken up. There was significant association recorded between group A and group B participants for post op graft status (p value =0.0236).

**Discussion**

In consistent with this study, Habesoglu M et al [13] reported that the research group's mean area of perforation in the initial inspection was 10.9 mm<sup>2</sup>, whereas the control group's was 10 mm<sup>2</sup>. The study group's mean perforation area at completion of first month was 1.3 mm<sup>2</sup>, whereas the control group's was 4.4 mm<sup>2</sup>. At the conclusion of the first month, the study group's overall tympanic closure rate was 64.3%, whereas the control group's was 22.2%. One patient in the experimental group and four in the control group had perforations at completion of second month. They came to the conclusion that there is currently little information available on the use of PRP in otology and that its application in otologic therapies is a novel topic. According to their research, PRP is an autogenous, practical, and simple-to-make biomaterial that speeds up the TM's healing process. Also Habesoglu M et al [14] showed the benefits of platelet rich plasma (PRP) for acute ear drum perforation healing. Perforation diameters were measured at first examination to be 10.9 mm<sup>2</sup> in the PRP group and 10 mm<sup>2</sup> in the non-PRP group. Perforation diameters were 1.4 mm<sup>2</sup> in the PRP group and 4.4 mm<sup>2</sup> in the non-PRP group after a month. Ear drum closure rates were 64.3% in the study group and 22.2% in the control group. Thus, they discovered that PRP is a biomaterial that is easily manufactured and autogenous, which speeds up the repair of the ear drum.

In another study, Hosam M et al [15] reported that with remarkable mean difference between the two groups, group A's total graft take rate was 96% whereas group B's was 76%. The hearing outcomes were acceptable and in line with earlier research findings in the literature. There were no documented postoperative problems. They asserted that a straightforward method for fixing small-to-medium-sized TM perforations is

inlay butterfly cartilage myringoplasty. When PRP is used topically, the technique's success rate has increased. The autologous PRP shields the transplant from infection while also promoting recovery. Ensari N et al [16] discovered that the mean healing period for the TM perforation was 17.3 days in the control group and 10.3 days in the research group that received PRP. The research group had higher levels of fibrosis and neovascularization. They asserted that PRP membrane may be effectively applied to wound healing and TM perforation repair. Nair NP et al [17] discovered that the study group's postoperative infection rate was 4.7%, whereas the control group's rate was 19%. The study group's graft absorption success rate was 97.7%, whereas the control group's was 81%. There was statistical significance in the results. By comparing the groups, they came to the conclusion that PRP is safe for patients since it is autologous in nature. When PRP is employed, the postoperative graft absorption rate is higher. The same group also had a decreased risk of postoperative infection.

However, Shindy MF et al [18] found that PRP, an autologous simple graft technique, offered higher healing rates, superior audiological results, minimal costs, and no problems as compared to conservative care. Aslam S et al [19] compared to traditional underlay myringoplasties, the graft acceptance success rate in PRP-assisted underlay myringoplasties was evaluated using TFG. Of the 60 patients in all, 38 were men and 22 were women. The mean age of the study group (Fibrin) was 31.7 years, whereas the mean age of the control group was 27.5 years. At the 2-month follow-up, every patient in the PRP group had successfully undergone graft uptake. Twenty-three of the thirty patients in the control group who received the traditional method had satisfactory graft uptake, whereas the remaining seven patients experienced various problems that resulted in graft rejection. Applying PRP to the TFG and perforation edges during an underlay myringoplasty operation has greatly increased the graft's successful absorption rate. Similarly, Riaz N et al [20] reported that graft uptake was found to be 78% in patients and 52% in controls after a three-month follow-up. In cases, the average hearing restoration was 18 dB, whereas in controls, it was 6 dB. 32% of the controls and 8% of the patients had postoperative infection. According to their findings, using PRP topically during myringoplasty improves graft absorption, enhances hearing, and significantly lowers infection and hole sizes. Huang J et al [21] discovered that the chronic subgroup's OR was 5.4 and the acute perforation closure rate's OR was 4.3. The use of PRP can improve the closure of both

acute and chronic perforations, as seen by the completed closure rate's total OR value of 5.1. PRP usage did not result in better hearing outcomes, according to the qualitative review. PRP can lower the rate of infections while also encouraging closure. There was no influence from the literature in this analysis, and the sensitivity analysis had no effect on the final findings. They asserted that PRP can lower the frequency of infections, improve the rehabilitation rate of autografts in TM operations, and raise the repair rate of acute perforations. Nonetheless, research suggests that PRP has little effect on hearing results. This study demonstrates the efficacy of PRP as a TM regeneration agent.

In contrast, Awady MK et al [22] evaluated the present-day use of autologous PRP in order to increase the success rate of myringoplasty. Patients were split into two groups: 20 patients in group A underwent myringoplasty surgery with PRP added from the same patient, and 20 patients in group B underwent myringoplasty surgery without PRP added. At six months after surgery, case group A's success rate (graft taking) was noticeably greater than the control group's. In 95% of instances in case group A, the air-bone gap's hearing gain was greater than 10 dB, while 70% of cases in control group B had no significant difference. Since hearing gain is correlated with TM closure, PRP usage had no influence on hearing gain in graft-taken instances. During myringoplasty, they asserted that topical PRP treatment over tragal perichondrial graft is safe, effective, and free of problems. PRP reduces the risk of surgical infection and promotes the repair of chronic TM perforations. Aboelnaga HA et al [23] examined the function of autologous PRP as a myringoplasty adjuvant for closing central TM holes. Group A's success rate (graft taking) at 6 months after surgery was 90%, which was much greater than group B's 70%. Success in closing the air-bone gap showed that 78% of cases in group A were successful, a substantially greater percentage than 54% of instances in group B. At six months after surgery, the air-bone gap was significantly greater in the case group's graft-taken patients than in the control group. Graft uptake and either hemoglobin or platelet levels in both groups did not significantly correlate. Furthermore, in both groups, there was no significant relationship between the extent of the hole and graft uptake. They asserted that PRP is an entirely autologous platelet levels with increased growth factors that is inexpensive and economical. With no discernible adverse effects, it raises the total myringoplasty success rate. Qureshi A et al [24] reported that the average age of the study group (Fibrin) was 31.8 years, whereas the average age of the control group was 27.5 years. All of the patients in the PRP group had effectively absorbed the grafts at the 2-month follow-up. In the control group, 23 of 30 patients who had the traditional procedure successfully absorbed their grafts; the other 7 patients experienced various problems that resulted in graft rejection. They said that the success rate of the graft has significantly

enhanced when PRP is applied to the front ligament grafting line and perforation margins during underlay myringoplasty.

Notably, Tiple C et al<sup>82</sup> discovered that the PRP group had a greater rate of graft survival than the non-PRP group at postop follow-up at 1, 3, 6, and 12 months. At the 12-month point, 95% of patients in PRP group had a good result, compared to 70.4% in non PRP group. Postop hearing threshold level was 18.4 dB for the PRP group and 27.6 dB for the non-PRP group, which was statistically substantially lower. There was a larger improvement in the PRP group even though there was no significant difference in the postop air-bone gap value between the groups. The incisions healed flawlessly, and PRP was well tolerated. They said that PRP membrane is an efficient treatment for patients with chronic TM perforations because it raises the autograft survival rate.

### Conclusion

By applying fibrin glue to the graft's borders and the perforation edges during myringoplasty, we may conclude that the temporalis fascia graft's success rate has significantly increased. Successful audiological outcomes and improved graft uptake following TM perforation are provided by the application of fibrin glue. Growing interest in tissue engineering and cellular therapies is being fueled by the potential biotechnology known as fibrin glue. This method would be applied as a successful therapy for massive TM perforations.

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