

## ORIGINAL ARTICLE

**An Investigation on the Fibrin Glue's Impact on Myringoplasty's Success Rate: A Randomized Controlled Study**AHSAN QURESHI<sup>1</sup>, NISAR AKBER KHAN<sup>2</sup>, MUHAMMAD SALEEM<sup>3</sup>, RAMZAN ALI<sup>4</sup>, SULTAN BADAR MUNIR<sup>5</sup>, ALI HUSNAIN SHEIKH<sup>6</sup>, KHURRAM SHAHZAD<sup>7</sup><sup>1</sup>Assistant Professor, Women Medical College and Jinnah International Hospital Abbottabad<sup>2</sup>Assist. Professor ENT, Faisalabad Medical University (Allied Hospital Fsd),<sup>3</sup>Associate Professor of ENT Aziz Fatima Medical and Dental Collage Faisal Abad<sup>4</sup>Assistant Professor Paediatric ENT, Children Hospital And University of Child Health Sciences Lahore<sup>5</sup>Senior Medical Officer, Paediatric ENT Department, The University of Child Health Sciences, The Children Hospital, Lahore<sup>6</sup>Associate Professor Akhtar Saeed Medical and Dental College/Akhtar Saeed Trust Hospital Lahore<sup>7</sup>HISS, Hamdard University, Karachi, PakistanCorrespondence to: Ahsan Qureshi, Email: [wllartist@yahoo.com](mailto:wllartist@yahoo.com)**ABSTRACT****Objective:** The study's goal is to evaluate the success rates of graft uptake in platelet-rich fibrin-assisted underlay myringoplasties employing temporalis fascia grafts to those in traditional underlay myringoplasties.**Methods:** This study was conducted in Mayo Hospital in Lahore's ENT department carried out this double-blind, randomized, controlled trial investigation. We recruited 60 individuals with dry central tympanic membrane perforations. Patients with comorbidities such as diabetes and sensorineural hearing loss were not included. Probability basic random sampling was used. The patients were split into two groups using a lottery system. With the help of SPSS version 26, statistical analysis was carried out. The P-value was calculated using the chi-square test.**Results:** There were 60 patients, of whom 38 were males and 22 were women. The control group's average age was 27.53 ± 11.41 years, but the study group's average age (Fibrin) was 31.77 ± 12.43 years. At the 2-month follow-up, the grafts were successfully absorbed by every patient in the platelet-rich fibrin group. 23 out of 30 patients in the control group who underwent the conventional method successfully absorbed their grafts, however, the remaining 7 patients had different issues that led to graft rejection.**Practical Implication:** The tympanic membrane would mend more quickly if platelet-rich fibrin was used after ear procedures. Fibrin glue in tympanoplasty has been tried in several locations throughout the globe. [7,8] When concentrated fibrinogen solutions are combined with thrombin, fibrin glue is created. It may also be made from platelet-rich plasma. Our research compares platelet-rich fibrin-assisted underlay myringoplasties employing temporalis fascia grafts to traditional underlay myringoplasties to see which has a higher graft uptake success rate.**Conclusions:** The use of platelet-rich fibrin on the anterior ligament grafting line and perforation edges during underlay myringoplasty has greatly increased the success rate of the graft.**Keywords:** platelet-rich fibrin, temporal fascia graft, myringoplasty**INTRODUCTION**

Acute suppurative otitis media is fairly common, with a rate of 4% to 11% in underdeveloped nations. For both attic antral and tub tympanic diseases, central perforation is a frequent symptom. Repair of the ruptured tympanic membrane in tub tympanic disease is often accomplished with myringoplasty. In safe varieties of acute suppurative otitis media, it is the most often utilized surgical technique for perforation repair (central pars tensa perforations). Allogenic anterior fascia has demonstrated the most effective absorption among the variety of graft materials utilized in myringoplasty. Myringoplasty may be performed using either the overlay method or the underlay technique, both of which provide acceptable outcomes; however, the underlay approach performs somewhat better. Because it is technically straightforward, the underlay approach should be favored; nevertheless, the choice of technique will ultimately rely on the surgeon's preferences and the location of the hole<sup>(1,2)</sup>. The kind of graft material utilized in myringoplasties was another deciding factor. Since many years ago, the temporalis fascia is often employed. The temporalis graft closes holes in chronic otitis media of the inactive mucosal type with a central perforation better than the conchal perichondral graft, according to recent research. According to the post-operative findings, the research group who received temporalis fascia as the graft material for their ears improved their hearing more than the group that received conchal perichondrium<sup>(3-5)</sup>. Different variables lead to different graft uptake outcomes. Quite often, residual perforation, graft lateralization, re-perforation, and lack of vascularization of grafts have been observed. Statistically, the risk of recurring perforations in tympanoplasty was reduced by human fibrin tissue adhesive (n=1051)<sup>(6)</sup>. Platelet concentrates have shown encouraging results when utilized to speed up wound healing in several parts of the globe. As a result, the tympanic membrane would mend more quickly if platelet-rich fibrin was used

after ear procedures. Fibrin glue in tympanoplasty has been tried in several locations throughout the globe<sup>(7,8)</sup>. When concentrated fibrinogen solutions are combined with thrombin, fibrin glue is created. It may also be made from platelet-rich plasma<sup>(9,10)</sup>.

Our research compares platelet-rich fibrin-assisted underlay myringoplasties employing temporalis fascia grafts to traditional underlay myringoplasties to see which has a higher graft uptake success rate.

**MATERIAL AND METHODS**

From July to December 2022, this was conducted at the Mayo Hospital in Lahore's ENT department. The hospital's bioethical committee has given its clearance to this project. In our area, 4% of people have chronic suppurative otitis media tubotympanic illness. We used 60 cases after using the sample size calculation method developed by the WHO based on prevalence. Following sufficient informed written permission, the sixty instances of dry central tympanic membrane perforations were enlisted. Each puncture affected three or four quadrants of the pars tensa. All of the patients were over 15 in age, had conductive deafness, and there was no evidence of infection or cholesteatoma. Patients with co-morbid conditions including diabetes or hypertension, visual-spatial loss of hearing, severe neurological traumas, tinnitus, and known allergies to any medication or chemical biological substance were excluded from the research.

Probability basic random sampling was used. Both the patients and the operating surgeon were unaware of their group assignments since the patients were split into two groups by lottery. In a performance, the patient's demographic information was gathered, and the assigned group was mentioned. Myringoplasty was performed on all 30 patients in the study and control groups. The post-aural approach and underlay method was employed to conduct myringoplasty on all patients, and temporalis

fascia was used as a graft in each procedure. By utilizing a centrifuge to generate platelet-rich fibrin from each patient's blood in the research group, we were able to employ it as a plug over a temporalis fascia graft and a piece of the tympanic membrane to close perforations. Gel foam was retained over the sealed hole in the control group. Both groups performed two-layer wound closure, and BIPP dressing was used to pack the external auditory canal. One senior ENT surgeon completed each procedure.

After one week after surgery, the ear packing was removed. Following surgery, photo microscopy and graft uptake were evaluated at 2 weeks and again at 2 months. Before the operation and two months after the operation, pure tone audiometry was performed. Tympanic membrane healing, graft lateralization, anterior blunting, or graft refection were examined postoperatively to compare the two groups. A blinded observer used to microscopic to validate the outcome (ENT consultant). The demographic information of the patient's age, gender, and right and left ear distribution between the two groups were statistically analyzed. The confounding effects of these factors were examined when the statistical significance of a p-value of less than 0.05 was determined. To see whether there was a statistically significant difference between the two groups, an independent sample t-test was performed to calculate the averages and standard deviations of the two groups for the patient age data. The chi-square test was used to determine the statistical significance of the right and left ear ratios in the two groups. The graft uptake at two months after surgery, the major outcome variable, was compared between the two groups using the chi-square test to determine whether a statistically significant difference could be detected to show that the study group had seen greater success.

**RESULTS**

60 patients in all, 38 of them were men and 22 of whom were women. It was not statistically significant that one group's gender distribution differed from the other (p-value 0.754). Age-wise, the control group (Conventional) had a mean age of 27.53 11.41 years, while the study group (Fibrin) had a mean age of 31.77 12.43 years. When the age difference between the two groups was evaluated using an independent sample t-test, no statistically significant difference was detected (p-value 0.587). There were 13 left ears and 17 right ears in the fibrin study group. 16 left ears and 14 right ears were operated on in the control group (conventional). The Pearson chi-square test was used to assess the difference in this random distribution, and it was determined that the difference was not significant as p- the value is equal to 0.438.

At the 2-month follow-up, all of the study group patients who received platelet-rich fibrin had satisfactory graft uptake. In contrast, 23 out of 30 patients in the control group who had conventional surgery without the use of fibrin had effective graft uptake, and the other 7 patients experienced various problems that resulted in partial or total graft rejection, as shown in Figure 1.

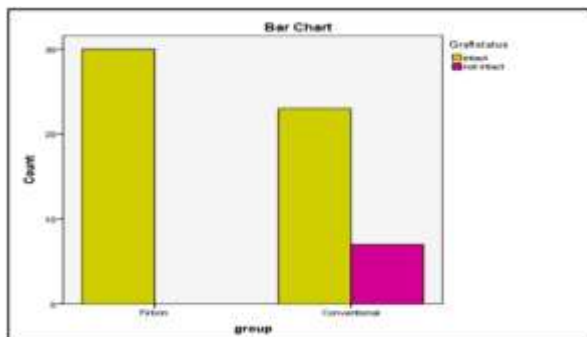


Figure 1: A comparison of two groups' results for intact grafts

Two patients' anterior blunting and one patient's lateralization of the graft were the results of graft rejection in four

individuals. By using the chi-square test to assess this difference, it was determined that it was statistically significant as the chi-square test shows a p-value of 0.005, and Fisher's exact test depicts a p-value of 0.011.

Table 1: Comparison of fibrin-based graft uptake success rates across several studies

Sample size	Success (%)	Follow-up	p-value	References
60	100	2 months	0.011	This study
55	94.4	6 months	0.031	[14]
86	97.7	3 months	0.012	[17]
64	100	6 months	0.02	[18]
32	64.3	1 month	<0.05	[20]
60	80	10 days	<0.05	[21]

**DISCUSSIONS**

The table provides a comparison of this study to other ones of a similar nature. Gur et al. evaluated the effectiveness of platelet-rich fibrin membranes in patients who had traumatic ear drum perforations repaired by using recovery rates, curing times, and reductions in mean air-bone gaps as indicators. These findings were also contrasted with those obtained from individuals undergoing the paper patch procedure employing platelet-rich fibrin membranes, using roughly the same markers as previously described (11,12). The study investigated the effects of Choukroun's platelet-rich fibrin (PRF) on newly formed traumatic ear drum perforation without utilizing traditional myringoplasty techniques. The study group (PRF) had better results after one month, but there was no statistically significant difference between the two groups after two months (p>0.05) following surgery. It was shown that platelet-rich fibrin (PRF) is an autogenous, useful, and comparatively simple-to-fix biomaterial that aids the tympanic membrane's healing process (12-14). Another research looked at the effectiveness of topically using autologous platelet-rich plasma (PRP) to improve the success rates of myringoplasty. The topical administration of autologous PRP during myringoplasty is safe, highly effective, and successful, with no known complications, according to outcomes that were evaluated at 6 months. PRP helps chronic TM perforations heal more quickly, but it also prevents infection and eliminates the need for an inner EAC pack (15). Table-I displays a comparison of various studies. Similar to the previous study, another one concluded that platelet-rich fibrin, which is autologous material, is safe for patients after watching 86 patients over the course of two years (16).

When platelet-rich fibrin was employed, the rate of postoperative graft uptake was higher. The same group also had a decreased post-operative infection rate (17,18).

In this context, a study examined how platelet-rich fibrin therapy affected the uptake of the graft and the thresholds for frequency-specific squeals in hearing after myringoplasty (19). At one, three, and six months after the treatment, the research found that platelet-rich fibrin-assisted temporalis fascia graft survival rates had more telling outcomes than temporalis fascia alone. A meaningful difference between the two groups' hearing threshold gains, however, was not seen (20). Additionally, our investigation of 60 patients demonstrated that platelet-rich fibrin combined with temporalis fascia resulted in noticeably better outcomes than temporalis fascia alone.

25 individuals with central perforations were chosen for a pilot trial. The PTA evaluation, TCA (50%), and autologous platelet-rich fibrin (PRF) Plug Myringoplasty method were performed on all 25 patients, and they were all monitored for 6 months after surgery. According to this research, the PRF Plug Myringoplasty procedure had a 92% closure rate for traumatic tympanic membrane perforations, whereas TCA had a 50% closure rate. There was also a statistically significant improvement in hearing (88%) (18). Another investigation applied a thin layer of fibrin glue to the perforation's lateral border. They discovered that this approach may be used for entire membrane perforations as well as big holes without a posterior edge or minor perforations (21).

A study showed that platelet-rich plasma, which has enhanced growth factors, is a cheap and efficient platelet concentrate. After myringoplasty, it speeds up the tympanic membrane closure<sup>(22)</sup>. In a few other head and neck procedures, according to another research, this substance was helpful. This tissue adhesive method was used for oral, chylous, tympanoplasty, pharyngeal fistulas, perilymphatic closure, closure of cerebrospinal fluid leaks, and implantation of local skin flaps and split-thickness skin grafts in hereditary hemorrhagic telangiectasia. Tissue glue is useful for local hemostasis and tissue healing makes the surgeon's job easier, and may save more involved surgical procedures<sup>(23,24)</sup>. While there was no discernible detrimental difference in the repair of skeletal tissue between the two groups, soft tissue healing showed significantly superior outcomes in the experimental group using the pain score scale. In dentistry, PRF has been demonstrated to enhance the development of soft tissue and restrict post-extraction dimensional alterations<sup>(25,26)</sup>. The most popular moniker for the platelet concentrates utilized in several surgical operations is "platelet-rich plasma." Despite being so gerund and comprehensive, this phrase has raised mystifications in scientific databases.

It is important to note that these recently created platelet concentrates need comparison testing by more substantial studies. Such goods must be put to the test in all treatments where soft tissue repair and angiogenesis are necessary to provide acceptable results, with the consent of both patients and regulatory authorities. To establish the efficacy of PRF on anteriorly tissue graft myringoplasty, more clinical trials with bigger sample numbers and prolonged surgical follow-up are required.

## CONCLUSIONS

The success rate of the temporalis fascia graft has been much improved when an underlay myringoplasty is performed by adding platelet-rich fibrin to the margins of the graft and the perforation edges.

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