

Comparative Study of Outcome of Platelet-Rich Plasma (PRP) and Temporalis Fascia in Myringoplasty

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Abstract

Aim: this study aims to evaluate the efficacy of a PRP hourglass graft compared with the conventional method employing a temporalis fascia underlay graft in treating tympanic membrane perforation.

Materials and methods: this randomized controlled trial randomized was conducted in the period from October 2018 to December 2020 on forty patients with chronic otitis media safe dry mucosal disease presented to department of otorhinolaryngology, Beni Suef University. They were randomly assigned into two groups (the first group underwent myringoplasty using autologous PRP graft and the 2nd group underwent myringoplasty using autologous temporalis fascia graft only (20 in each)).

Results: Though all post-operative A-B gaps at 500, 1000 and 2000 Hz seemed to be to be lower with temporalis fascia graft, yet not significant. However, the average A-B gap was statistically higher in PRP group than temporalis fascia, P-value = 0.035. Myringoplasty with temporalis fascia graft showed significant reduction in A-B gaps at 500, 1000 and 2000 Hz. While PRP showed no significant improvement was shown at low frequencies (500 Hz), with significant improvement at higher frequencies (1000 & 2000 Hz). Both methods showed an improvement in average A-B gaps, P-value =0.001 in temporalis fascia group and 0.034 in PRP group. Post-operative full healing after 3 months, complications, graft lateralization, and displacement into the middle didn't differ significantly in both groups.

Conclusion: After a successful myringoplasty treatment, patients with PRP grafts had comparable hearing results to those with fascial grafts, as shown by significant reductions in the mean air-bone gap from pre-operative to post-operative.

Keywords: CSOM, PRP, Myringoplasty, AB gap

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Introduction

A persistent infection of the middle ear cleft known as chronic suppurative otitis media (CSOM) is characterized by tympanic membrane rupture and drainage from the ears. Poor socioeconomic status, inadequate nutrition, and a lack of health knowledge among rural residents all contribute to a greater incidence of CSOM.¹

Surgery to treat CSOM is still debatable. It is well acknowledged that the major goals of surgery are to permanently dry up the ear and seal the hole. A well-known method for treating tympanic membrane perforations is myringoplasty. But now the race is on to enhance the outcome even more by researching the many impacting components.^{2,3}

Middle ear surgery reconstructs the tympanic membrane using fascia, perichondrium, and cartilage. Temporalis fascia is the most common, conventional and ideal nowadays because of its low baseline metabolic rate, normal tympanic membrane shape, and good graft take-up rate and hearing outcome. But temporalis fascia grafts may cause complications. The graft pulls off the malleus handle and blunts the anterior sulcus. This thickens the tympanic membrane in this location, causing malleus fixation to the anterior canal wall. Placement of the graft beneath the malleus handle may help.⁴

PRP was originally employed in a clinical setting by Ferrari et al. in the middle of the 1980s during open-heart surgery. Since then, it has been used safely and efficiently in a variety of sectors.⁵ **Erkilet et al.** in otolaryngology reported in 2009 that autologous platelet-rich plasma significantly improved rat tympanic membrane perforation repair.⁶

Platelet-rich plasma (PRP) exhibits chemotactic and mitogenic qualities and functions as a growth factor agonist. It serves as an adhesive surgical hemostatic agent and tissue sealer. PRP is effective, safe, and biocompatible. It quickens the regeneration of the epidermal, endothelial, and cellular layers. By reversing the glucocorticoids that mediate the suppression of wound healing, it improves collagen production, angiogenesis, soft tissue repair, and reduces dermal scarring.⁷

PRP can be made quickly (in 12 minutes), easily (start during anesthesia induction and ready before step of its application so, its preparation is not a burden on the length of surgery), safely (from patient's blood without fear of infectious diseases), cheaply (syringe, vacuum tube), without additives (no anticoagulants or toxic materials), and it protects against infection. These platelets' in vivo half-life is around 7 to 10 days, which is long enough for healing.^{7,8}

To our knowledge, there are only a small number of research have evaluated the clinical effectiveness of PRP graft alone in treating tympanic membrane perforation. So, this study aims to evaluate the efficacy of a PRP hourglass graft compared with the conventional method employing a temporalis fascia underlay graft in treating tympanic membrane perforation.

Materials and methods

A randomized, controlled clinical trial was conducted on forty patients with chronic otitis media safe dry mucosal disease presented to department of otorhinolaryngology, Beni Suf University. They were randomly divided into two groups. Each group consists of twenty patients in the period from October 2018 to December 2020.

The 1st group underwent myringoplasty using autologous PRP graft and the 2nd group underwent myringoplasty using autologous temporalis fascia graft. Patients in the 1st group underwent myringoplasty using hourglass PRP graft trans canal trans-perforation but patients in the 2nd group underwent myringoplasty by the traditional method of postauricular underlay graft using deep temporalis fascia. The results were evaluated with regards to postoperative graft taking, hearing improvement and complications.

Inclusion criteria

Patients with dry central perforation of tympanum and obviously healthy middle ear mucosa for at least 2 months before the procedure with small-sized perforation less than or equal 25% of TM (less than one quadrant of TM) were included in the study.

Exclusion criteria

Patients with cholesteatoma or active ear discharge, attic and marginal perforations, suspected ossicular pathology (more than or equal 30 dB air-bone gap) were excluded from the current study. In addition to any clotting disorders or use of anticoagulants 10 days preoperatively, history of any previous otological surgery were not eligible for enrollment in the study.

Pre-operative assessment

All patients gave a complete medical history and received a general and local examination, which included an otoscopic ear examination and an audiological test using pure tone audiometry (PTA) to determine hearing level. Patients also underwent measurements of their coagulation and complete blood count parameters to determine if any contraindications to platelet-rich plasma use existed as blood diseases blood or coagulopathies.

Preparation of the platelet-rich plasma (PRP)

To prevent damaging of the platelets, 10 ml of peripheral venous blood from each patient was used to create platelet-rich plasma. The collected blood was immediately centrifuged for 12 minutes at 3,200 rpm in two 5-ml plain vacuum tubes (without calcium or anticoagulant).

The blood was divided into three layers of varying densities as a result of the centrifugation. Red blood cells made up the bottom layer, platelet-rich plasma (approximately 1.5 ml³) including platelets and white blood cells (buffy coat) made up the middle layer, and platelet-poor plasma made up the top layer. Within an hour of centrifugation, a needle was used to remove the platelet-rich plasma layer and pull it away from the surrounding red cell layer. This was done following syringe suction of the top layer.

Surgical technique

In both groups, general anesthesia was used for myringoplasty. The margins of each hole were cleaned, and all patients were positioned supine with their heads moved to the other side such that the perforated ear was up.

A single piece of platelet-rich plasma that was about twice the size of the hole was created for the first group. The platelet-rich plasma bulge was injected through the hole using a trans canal technique, and it was positioned in the shape of an hourglass, with almost equal sections lying medial and lateral to the perforation. To prevent graft displacement medially, gel foam was put into the middle ear in accordance with the available space. The hourglass piece was then covered with a second, bigger piece of platelet-rich plasma that was injected into the external auditory canal. After sealing the external canal with a pack soaked in antibiotic ointment and wearing ear plugs for a week, the external auditory canal was filled with gel foam (soaked in platelet-poor plasma).

The second group had an autologous temporalis fascia graft myringoplasty. The deep fascia had separated from the muscle before it was collected via a postauricular incision. After elevating the posterior tympano-meatal flap and filling the middle ear with a layer of gel foam to prevent graft drop within the middle ear, the fascia had been placed in the underlay method. The graft was evenly dispersed, and gel foam, a pack of antibiotic ointment, and an ear dressing were used over the graft for a week.

Post-operative assessment

After the surgery, patients were released with postoperative drugs such as broad-spectrum oral antibiotics, analgesics, and antibiotic-steroids ear drops to be given twice daily for three weeks after the withdrawal of the pack. After one week, the dressing, pack, and post-auricular sutures were removed at the ENT clinic. Three months after surgery, the patients were examined clinically and audiometrically during a follow-up consultation. A successful myringoplasty was defined as complete graft acceptance, relief of preoperative symptoms as discharge, and complete healing of the TM without residual perforation, retraction, or lateralization over a three-month follow-up period following surgery. The auditory results were examined using an audiogram of pure tones. On the basis of the patients' preoperative and postoperative audiograms, audiological data was collected. Changes in the pre- and postoperative air-bone gaps (ABG), defined as the difference between the preoperative and 3-months postoperative air-

bone gaps at 500, 1000, and 2000 Hz with the average ABG, were examined in the patients' data.

Statistical methods:

SPSS version 23.0 was used for data handling. The normality of the data was examined by Shapiro-Wilk test. Mean, standard deviation, or median and range were used to describe the data. Non-parametric The Mann Whitney test was used to compare independent groups, while the Wilcoxon signed-rank test was employed to compare pre- and post-test data within each research group. The drop or improvement in A-B gap was calculated as absolute difference between pre- and post-operative values. Chi-square and Fisher Exact test were used for comparing proportions. P-value was always two tailed and significant when ≤ 0.05 .

Ethical considerations

All participants were given an explanation of the research, and signed informed permission was acquired from all patients or parents of enrolled children. We got an ethical approval from the research ethics committee in the faculty of medicine of Beni-Suef university.

Results

Table (1) there was no statistically significant difference between the two groups regarding the age and sex distribution (P-value>0.05).

Table 1: Baseline characteristics of the studied groups:

Baseline characteristics	PRP group N=20 (%)	Temporalis fascia group N=20(%)	P-value
Age			
Mean±SD	29.6±5.1	25.9±8.8	0.117
Range(min-max)	(20-40)	(15-40)	
Sex			
Males	12 (60)	10 (50)	0.530
Females	8 (40)	10 (50)	

Pre-operative values of air-bone gaps were comparable among both study groups with no statistically significant difference, all P-values are >0.05.

Table 2: comparison of pre-operative air-bone gaps at 500, 1000 and 2000 Hz with average air-bone gap in both study groups:

Pre-operative A-B gaps (Mean±SD)	PRP N=20	Temporalis fascia N=20	P-value*
At 500 Hz	19.25±5.68	20.25±5.50	0.602
At 1000 Hz	17.95±4.03	18.15±4.82	0.989
At 2000 Hz	13.95±4.05	13.00±4.70	0.414
Average air-bone gap	17.15±3.42	17.10±4.17	0.989

SD = Standard deviation

Though all post-operative A-B gaps at **500, 1000 and 2000 Hz** seemed to be lower with temporalis fascia graft, yet not significant. However, the average

A-B gap was statistically higher in PRP group than temporalis fascia, P-value = 0.035 (table 3).

Table 3: Comparison of post-operative air-bone gaps at 500, 1000 and 2000 Hz with average A-B gap in both study groups:

Post-operative A-B gaps (Mean±SD)	PRP N=20	Temporalis fascia N=20	P-value
At 500 Hz	15.25±8.50	10.50±8.26	0.086
At 1000 Hz	13.25±6.74	10.25±8.35	0.086
At 2000 Hz	10.75±5.68	8.00±6.37	0.081
Average air-bone gap	12.95±6.53	9.55±7.54	0.035*

*P-value is significant ≤ 0.05 , SD = Standard deviation

Myringoplasty with temporalis fascia graft showed significant reduction in A-B gaps at 500, 1000 and 2000 Hz with highly significant P- values (table 4). With PRP hourglass graft, no significant improvement was shown at low frequencies (500 Hz), with significant

improvement at higher frequencies (1000 & 2000 Hz, P-values 0.028 and 0.049 respectively) and overall, both methods showed an improvement in average A-B gaps, P-value =0.001 in temporalis fascia group and 0.034 in PRP group (table 4).

Table 4: Comparison of pre- and post-operative values of air-bone gaps at 500, 1000 and 2000 Hz with average A-B gap in each group separately:

A-B gap Mean±SD	PRP		P-value	Temporalis fascia		P-value
	Before	After		Before	After	
At 500 Hz	19.25±5.68	15.25±8.50	0.155	20.25±5.50	10.50±8.26	<0.001*
At 1000 Hz	17.95±4.03	13.25±6.74	0.028*	18.15±4.82	10.25±8.35	0.002*
At 2000 Hz	13.95±4.05	10.75±5.68	0.049*	13.00±4.70	8.00±6.37	0.002*
Average A-B gap	17.15±3.42	12.95±6.53	0.034*	17.10±4.17	9.55±7.54	0.001*

*P-value is significant ≤ 0.05 , SD = Standard deviation

Absolute reduction in air-bone gaps at 500, 1000, 2000 Hz and average values of A-B gap were not significantly different between the two study groups.

In spite of the non-statistical difference, it may be of clinical importance as absolute reduction of post-operative gaps is more in temporalis fascia group than PRP group (table 5).

Table 5: Comparison of absolute reduction in air-bone gaps at 500, 1000 and 2000 Hz with average A-B gap between both study groups:

Absolute reduction of post-operative gaps		PRP N=20	Temporalis fascia N=20	P-value
At 500 Hz	Mean±SD	4.00±11.42	9.75±7.16	0.060
	Median (range)	2.5 (-15 - 25)	10 (-10 - 20)	
At 1000 Hz	Mean±SD	4.70±8.63	7.90±7.52	0.289
	Median (range)	3.5 (-10 - 20)	10 (-10 - 20)	
At 2000 Hz	Mean±SD	3.20±7.01	5.00±5.62	0.478
	Median (range)	3.5 (-5 - 15)	5 (-5 - 15)	
Average A-B gap	Mean±SD	4.20±8.06	7.55±6.09	0.221
	Median (range)	4 (-10 - 15)	8 (-9 - 16)	

*p value is significant ≤ 0.05 , SD = Standard deviation,

Values with negative signs indicates an increase in A-B gaps (deterioration of hearing)

Table (6) showed that there was no statistically significant difference between the two groups regarding the full healing after 3 months (P-value>0.05).

Post-operative complications showed statistical significance in pain post-operatively in PRP group than temporalis fascia group, P-value=0.028. Only one case of chorda tympani injury in temporalis fascia group. 2 cases of post-operative otorrhea in PRP group while 3 cases in temporalis fascia group with no statistical significance.

Table 6: Comparison between both groups regarding the post-operative outcomes:

Post-operative outcomes	PRP N=20 (%)	Temporalis fascia N=20 (%)	P-value
3 months full healing	12 (60)	16 (80)	0.173
Complications			
Chorda tympani injury	0 (0)	1 (5)	0.317
Otorrhea	2 (10)	3 (15)	1.00
Post-operative pain	2 (10)	8 (40)	0.028*

*P-value is significant ≤ 0.05

In neither group did the graft become lateralized or moved into the middle ear, nor was a retraction pocket identified throughout the follow-up period.

Discussion

Persistent suppurative otitis media is mucoperiosteal chronic inflammation of the lining of the cleft of the middle ear. The perichondrium, temporalis fascia, and cartilage are among the numerous viable closure materials and the most common approach for mending tympanic membrane holes is the underlay technique.⁹

PRP is a minimally invasive technique for obtaining a high concentration of autologous growth factors (GFs) that may be injected directly into the lesion site.¹⁰

Concerning the efficacy of PRP and temporalis fascia grafts, we found no statistically significant difference between the two groups concerning pre-operative and post-operative A-B gaps at 500, 1000, 2000 Hz although lower in temporalis fascia than PRP post-operatively (All P-values > 0.05). But post-operative mean A-B gap was statistically higher in PRP group compared with temporalis fascia group (P-value=0.035).

Comparison of pre- and post-operative values showed that temporalis fascia group had significant

reduction in A-B gaps at 500, 1000 and 2000 Hz with P-values (0.001, 0.002 and 0.002 respectively) while in PRP group had no significant improvement at low frequencies (500 Hz), P-value=0.155 but at higher frequencies (1000, 2000 Hz) there was significant improvement, P-values 0.028 and 0.049 respectively. Both groups showed improvement in mean A-B gaps, P-value=0.001 in temporalis fascia group and 0.034 in PRP group.

Besides, there was statistically insignificant difference between the studied groups concerning the absolute reduction at 500, 1000, 2000 Hz with average A-B gaps (P-value >0.05). Despite absence of statistical significance, still there was a clinical importance as absolute reduction in values was higher in temporalis fascia than PRP groups.

There was statistically insignificant difference between both groups regards the full healing after 3 months (P-value >0.05) and post-operative complications except in post-operative pain is more in temporalis fascia group due to skin incision than PRP group as showed statistical significance (P-value=0.028).

In concordance with our findings, **Refaat (2020) limited anterior margin, poor visualization, and inadequate graft stabilization. Platelet Rich Plasma (PRP**¹¹ evaluated the effect of adding PRP on

healing of anterior tympanic membrane perforation (ATMP) by using underlay technique myringoplasty. Between June 2015 and August 2016, 40 patients with chronic dry ATMP attending the ENT outpatient clinics at Al-Azhar University Hospitals participated in a prospective, randomized trial. The participants were randomly assigned into two equal groups: the study group received underlay myringoplasty by temporalis fascia graft with the addition of platelet-rich plasma (PRP), and the control group got underlay myringoplasty with temporalis fascia graft alone. There was statistically insignificant difference between the two groups with respect to the rate of reduction of the air-bone gap at 500, 1000, and 2000 Hz, or the mean air-bone gap (P -value >0.05).

Yadav and colleagues (2018) aimed to determine the efficacy of PRP during underlay myringoplasty which included 40 patients with medium, large and subtotal perforations and air-bone gaps more than 25 dB on PTA. PRP was added to the temporalis fascia graft during underlay myringoplasty (group 1) and compared to another control group without PRP and followed up for 3 months. In both groups, there was a significant improvement of air-bone gap post-operatively ($p < 0.001$). However, on the contrary, the mean hearing threshold gain was 18.62 dB in PRP group and 13.15 dB in control group.⁷

The same findings of promising results of PRP were observed when used as an office procedure in 25 patients with small, dry, unilateral TM perforation by **El-Anwar and colleagues (2015)**¹². With topical anesthesia for 20 minutes, PRP was inserted via trans canal approach in an hourglass configuration through the perforation with a second, larger piece of PRP put in the external auditory canal over the hourglass piece. Complete repair was reached in 21 ears (84%). No reported cases with infection, tinnitus, hearing impairment, bleeding, taste disturbance, vertigo, or hyperkeratosis. The mean air-bone gap at speech frequencies improved significantly from 16 ± 3.83 dB preoperatively to 7 ± 2.9 dB postoperatively ($p < 0.001$). The mean duration of the technique was 4.0 ± 1.5 minutes with no need for general anesthesia. In addition, there was no need to preoperative oral anxiolytics or conscious sedation intraoperatively. Pain postoperatively was tolerable and there was no need for analgesic in all patients.

As our results, **Fawzy and colleagues (2018)** examined the effect of adding the PRP to the fat graft in myringoplasty procedures in patients with dry perforation of tympanic membrane secondary to tubo-tympanic CSOM. PRP was added to the fat graft and the other group was done without PRP. There was statistically insignificant difference between the two groups concerning all rate of decline of mean air-bone gap and air-bone gap at 500, 1000, 2000 Hz (P -value >0.05).¹³

With regard to the successful healing of perforation, we found that 60% and 80% in the PRP and temporalis fascia groups had successful myringoplasty respectively. There was no statistically significant difference between the two groups regarding the full healing after 3 months, although post-operative pain is more in temporalis fascia than PRP groups with statistical significance ($P = 0.028$).

Similarly, **Refaat (2020)** limited anterior margin, poor visualization, and inadequate graft stabilization. Platelet Rich Plasma (PRP) reported that in the study group, full perforation healing was 85%, whereas in control group it was 75%.¹¹

On the contrary, **Yadav and colleagues (2018)** showed that the graft uptake was 95 percent in PRP group and 85 percent in the control group ($P < 0.05$).⁷

Different epidemiological features might be the precise reason of this disparity., different sample sizes and use of other grafts in combination with PRP graft.

We did two cases with medium-sized perforations not included in the study using tragal perichondrium in combination with PRP; the results were good with complete faster healing. So PRP can be used in combination with another graft material to improve results.

Conclusion and recommendations

In conclusion, patients who had PRP grafts showed similar hearing outcomes to those who had fascial grafts after a successful myringoplasty procedure as evidenced by marked decreases in the mean air-bone gap from pre-operative to post-operative. We believe that PRP graft, with its availability, ease of preparation technique, autologous

nature, low cost, and good graft uptake rate justifies its use in myringoplasty procedures. However, more research with a rigorous design, a large sample size, and multiregional collaboration is necessary.

According to this study, we recommend utilization of PRP in small-sized perforations but should be tested for larger perforations. With more training, PRP myringoplasty can be used with local anesthesia as an office procedure later on. In addition, because platelet-rich plasma is autologous, it includes no chemicals such as anticoagulant or calcium, ensuring that it has no deleterious impact on the inner ear.

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