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ORIGINAL RESEARCH ARTICLE

Surgical and Audiological Outcome of Tympanoplasty Type I with use of Gelfoam Soaked in Platelet Rich Plasma: A Novel technique

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ABSTRACT

Introduction: Chronic otitis media is a disease commonly presented in ENT clinics. Gelfoam is a commonly used agent for packing the middle ear and external auditory canal during tympanoplasty. The aim of the study is to observe and document the surgical and audiological outcomes of tympanoplasty type I with the use of Gelfoam soaked in platelet-rich plasma (PRP).

Material and methods: This study included 30 patients aged between 15 to 50 years of age who were diagnosed with Inactive COM mucosal type undergoing type I tympanoplasty. Pre-operative otoscopy and pure tone audiometry were done and compared with post-operative otoscopy and pure tone audiometry at 6 weeks.

Results: All 30 (100%) patients showed uptake of graft at the end of 6 weeks. In a comparison of pre-operative and post-operative AB gap at 6 weeks, there was a significant improvement (*p-value* 0.00). The AB gap average at individual frequencies:500, 1000, and 2000 Hz was measured, and maximum AB gap improvement was seen at 1000 Hz, of 11.3 ± 6.0 dB.

Conclusion: All the patients in the study group showed complete graft healing and significant improvement on audiogram post-operatively at 6 weeks, signifying that the use of PRP with Gelfoam enhances the overall outcome of TM perforation repair.

Keywords: Type I Tympanoplasty, Gelfoam, PRP, Audiology, Graft uptake.

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INTRODUCTION

Chronic otitis media is a disease commonly presented in ENT clinics, defined as an inflammatory condition of the middle ear cleft. The hallmark of COM is a persistent tympanic membrane perforation with pus discharge.

The standard treatment of COM after medical management of infection is surgery, i.e., tympanoplasty, with or without cortical mastoidectomy. After making sure the middle ear cleft has adequate functional ventilation, the surgeon repairs the tympanic membrane perforation using a graft material. The middle ear and/or EAC are then packed to ensure that the graft remains in place and the TM flap is reposited.[1,2]

Gelfoam is a commonly used agent for packing the middle ear. It achieves hemostasis, supports the graft initially, and provides aeration to the middle ear cavity as it gradually dissolves. However, few authors have also postulated and reported its detrimental effects, like adhesions, fibrosis, ossicular fixation, and even osteogenesis, thus bringing suboptimal hearing outcomes.[3]

Various packing agents and materials have been used in ear surgery, with both positive and detrimental outcomes. A newer modality, i.e., platelet-rich plasma, has been part of management in many fields, including orthopaedics, neurosurgery, dermatology, plastic surgery and oromaxillofacial surgery. Platelet-rich plasma consists of many growth factors, including PDGF, TGF-α, TGF-β, EGF, FGF, IGF, and PDAF, as well as white blood cells, phagocytic cells, a high concentration of native fibrinogen, and chemicals that can affect blood vessels and attract cells. Specifically, PDGF and TNF-β expedite the process of wound healing and blood clotting and reduce the formation of scars.[4] Hence, this present study has been undertaken to evaluate and compare the outcome of Tympanoplasty Type I in terms of hearing outcome and graft uptake by using Gelfoam soaked in platelet-rich plasma in our tertiary hospital setup.

MATERIAL AND METHODS

This observational prospective study was conducted in the Department of Otorhinolaryngology of the tertiary care center in Western UP from August 1, 2022, to January

31, 2024. This study included 30 patients aged between 15 to 50 years of age who were diagnosed with Inactive COM mucosal type, undergoing Type ITympanoplasty and meeting the inclusion criteria, i.e., patients with medium central, large central, and subtotal perforation, mild to moderate conductive hearing loss and patent eustachian tubes on Valsalva maneuver. Patients with evidence of active upper respiratory tract infection, severe conductive hearing loss, mixed hearing loss, sensorineural hearing loss, small central and total perforation of the tympanic membrane, and squamous COM were excluded from the study.

About 30 randomly selected patients with the abovementioned inclusion criteria were planned for operation after due consent. Intraoperatively, 2 mL of PRP was used to soak the gelfoam, which in turn was used to create a middle ear bed for graft support.

Preparation of PRP: For Platelet-rich Plasma preparation, a platelet-concentrating cell separator, Remi PRP Centrifuge Machine, Model 8C, was used: 5ml venous blood of the patient was taken into an ACD vial. The first centrifugation i.e soft spin was done at 1500 rpm for 15 min which separated blood into three layers, a bottom-most layer containing RBC (55% of total volume), a topmost acellular layer called Platelet Poor Plasma (40% of total volume), and an intermediate Platelet Rich Plasma layer (5% of total volume) called the Buffy coat. Using a syringe, PPP, PRP, and some RBCs were transferred into an EDTA vial without an anticoagulant. This vial underwent a second centrifugation, called hard spin for 30 min at 3000 rpm. This allowed the PRP to settle at the bottom of the vial with very few RBCs. The acellular plasma (80% of the volume) found at the top and PPP was removed with a syringe and discarded; the remaining PRP was incorporated into the gelfoam of the allotted patients.

Pre-operative otoscopy and pure tone audiometry were done and compared with post-operative otoscopy and pure tone audiometry at 6 weeks. Perforation on otoscopy was assessed and classified into medium (25-50% of total TM area), large (50–75%), and sub-total (75–99). Hearing acuity was assessed and recorded by measuring air conduction and bone conduction thresholds by Pure Tone Audiometry at 500 Hz, 1000 Hz, and 2000 Hz. The data was collected, tabulated and analysed using Microsoft Excel 2019 and Paired t-test was applied.

RESULTS

Out of 30 patients included in the study, 13 were male and 17 patients were female, giving a male-to-female ratio of 1:1.76 (43% males vs 57% females). The majority of the patients(10) were in the age group of 15-25 years of age (41%), followed by 8 patients in the 26 to 35 years of age group (27%), 5 patients were in age group 36-45 years (15%) and 7 patients in 46 to 50 years age group (17%).

The majority of the patients presented with a discharge of 1 to 5 years duration (63.33%), followed by a duration of discharge for 6 to 10 years (34.45%), with only 1 (1.11%) patient with 5 months of duration of discharge and 1 (1.11%) patient with 14 years of discharge. In 24 (80%) patients presented with 1 to 5 years of decreased hearing, 3 (10%) patients with a duration of less than 1 year and 3(10%) with 6-10 years of decreased hearing.

All 30 patients included in the study underwent otoscopic examination and hearing assessment by Pure Tone Audiometer (PTA). The majority of patients had Large central perforation (13,43%), Medium perforation in 12 patients (40%) and Subtotal perforation in 5 patients (17%). On PTA, the majority had Moderate conductive hearing loss (29,97%) and only 1patient had Mild conductive hearing loss (3%).

All the patients in the study group underwent Type I Tympanoplasty and graft uptake on otoscopy and hearing outcome on PTA was assessed and documented.

All 30 (100%) patients showed uptake of graft at the end of 6 weeks.

In a comparison of pre-operative and post-operative AB gap at 6 weeks, there was a significant improvement of 8.16 ± 0.04 dB and the result was statistically significant (*p-value*-0.00). The AB gap average at individual frequencies namely 500, 1000, and 2000 Hz was measured, and improvement at all speech frequencies were observed. Maximum AB gap improvement was seen at 1000 Hz, of 10.0 ± 8.9 dB. When comparing the pre-operative and post-operative AB gap based on perforation size, significant improvement was observed; *p-value* of 0.01. Majority of patients (13) had an AB gap of 31 to 40 dB. Six weeks following Type I Tympanoplasty, PTA was performed in all operated COM patients and majority of the patients (20) showed improvement in AB gap ranging between 20 to 30 dB (Table 1).

Table 2 shows that there was improvement noticed in respect to AB gap on all the 3 speech frequencies, which was statistically significant (0.00). Maximum improvement in AB gap was observed on 1000 Hz of 10.0 ± 8.9. When comparing the pre-operative and post-operative AB gap based on perforation size, significant improvement was observed (*p-value*- 0.01) (Figures 1 and 2). Figure 3 (A-C) shows otoscopic examination. Audiometric analysis and post-operative PTA of the left ear of the patient at 6 weeks.

DISCUSSION

For ages, chronic otitis media has been an important middle ear disease. COM is characterized by symptoms

Table 1: Distribution of the number of patients according to Air-Bone gap in pre-operative and post-operative period

AB gap average (in dB)	*Pre-operative*	*Post operative*
<20	0	0
20–30	5	20
31–40	13	8
>40	12	2

like perforated tympanic membrane and middle ear discharge caused by persistent inflammation of the middle ear.

AOM is the most common prequel to COM, though a majority of AOM shows spontaneous resolution. But when the perforation doesn't heal within 3 months, its spontaneous closure is unlikely and at this point, a chronic perforation is considered for surgical repair.

The treatment of COM primarily involves the procedure of tympanoplasty, which is the repairing of tympanic membrane perforation. Temporalis fascia graft used to repair the perforation is supported with certain packing agents like gelfoam provides aeration to the middle ear cavity as it gradually dissolves, supports the graft initially. However, few authors have also postulated and reported its detrimental effects like adhesions, fibrosis, ossicular fixation, retraction of the tympanic membrane, slower healing process with delayed epitheliasation thus bringing suboptimal hearing outcomes.[3] Recent research explores combining Gelfoam with agents, like blood products like platelet-rich plasma, to optimize healing and hearing outcomes in COM management.

In our study, we assessed and compared the surgical and audiological outcomes of Type I Tympanoplasty with gelfoam soaked in platelet-rich plasma.

This prospective study included more female patients. The female-to-male patient ratio was 1.76:1 in our study. Similarly in studies by Pilai *et al.* and Fad *et al.*, the male-to-female ratio was on the higher side for females at 1:1.72 and 1:1.4 simultaneously.[5,6] One of the reasons that can be accountable is thatover the years females have also become aware of their health.[7]

Our study included patients ranging from the age of 15 years to 50 years. Majority of the patients were in the age group of 15-25 years of age (41%), Malick *et al.* observed that the largest proportion of their study population, approx. 40%, were aged between 20 and 30

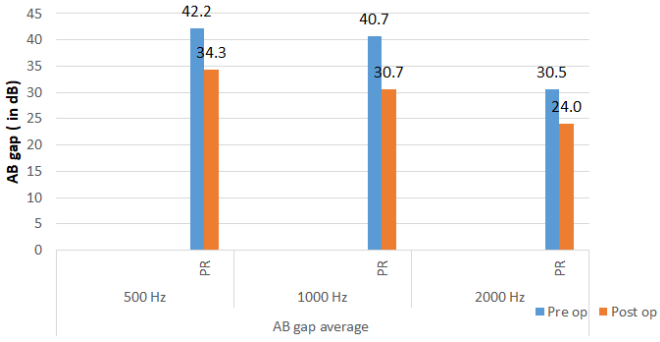


Figure 1: Pre-operative *versus* post-operative air-bone gap at individual frequency

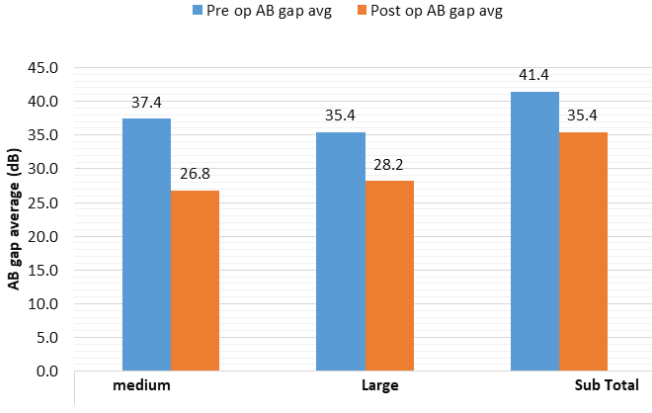
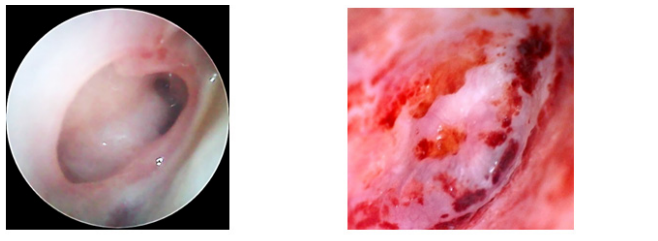


Figure 2: Pre-operative AB gap versus post-operative AB gap at 6 weeks comparable with perforation size



Pre operative perforation **6 weeks Post operative graft uptake**

Figure 3A: Otoscopic examination

years.[8] This age-specific prevalence suggests a notable incidence of COM in the younger adult population. The cause of such a pattern can be multifactorial; bacterial or viral infection of the middle ear, eustachian tube dysfunction, and allergic rhinitis or URTIcommonly affectingthe younger population.

In our study, 63% patients reported ear discharge duration of 1-5 years and 80% decreased hearing for 1 to

Table 2: Pre-operative versus post-operative air-bone gap at individual frequency

Individual frequency	*500 Hz*	*1000 Hz*	*2000 Hz*	*Average*	*p-value (paired T-test)*
Pre-operative (dB)	42.2 ± 7.8	40.7 ± 8.4	30.5 ± 7.7	37.74 ± 5.95	
Post-operative (dB)	34.3 ± 6.8	30.7 ± 7.8	24.0 ± 7.4	29.58 ± 5.78	0.00
Improvement (dB)	7.9 ± 7.3	10.0 ± 8.9	6.5 ± 8.5	8.16 ± 0.04	

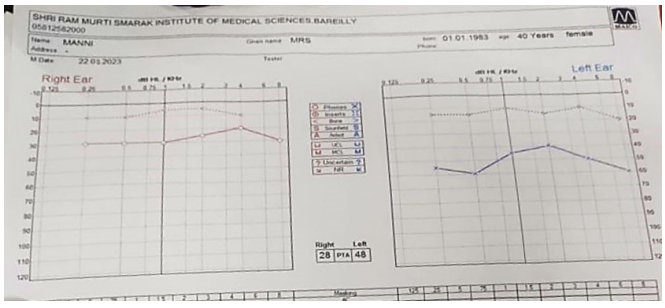


Figure 3B: Audiometric analysis

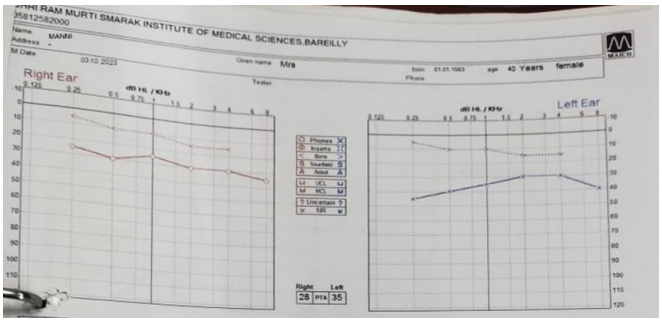


Figure 3C: Pre-operative PTA of the left ear of a patient

5 years. The findings of our research are consistent with the results reported in studies by Sarkar *et al*.and Malick *et al*., indicating similar trends in the demographic and clinical characteristics of patients with COM.[8,9] Some studies, as done by Brennan *et al*., suggest that varied periods of symptoms can be addressed by the fact that many people do not have good access to modern primary health care, hence they present with prolonged history whereas those who acquire early access to health services have a shorter period of symptomatology.[10]

43% of the patients had large-sized perforations, making it a common occurrence, followed by 40% of cases with medium central perforations. This indicates that a significant portion of the patients had substantial damage to the tympanic membrane.The findings of our study were also almost similar to Faramarzi *et al*., who reported that 51% of the participants had medium-sized perforations and 22% had large-sized perforations.[12] While a study by Kranti Bhawana *et al.* shows a huge difference in the type of perforation presentation, 78% being medium and only 22% large central perforation, though its cause was not explicitly explained in the study.[13]

All the perforations in our study showed complete graft healing at the end of 6 weeks post-operatively. In another study by Sahoo S R *et al.* success of Tympanoplasty type I in terms of graft uptake at the end of 30 days was observed in 97.5% of patients.[14]Another study by S Gökçe *et al.* showed that graft survival rates were significantly higher in the temporal fascia graft plus platelet rich fibrin therapy group than in the temporal fascia graft alone group at 1 month (100.0 vs 85.5%).[15]

Though it has not been studied in our study, it is safe to say that graft uptake can depend on factors ranging from the expertise of the performing surgeon, environmental factors to post-operative care being taken by the patient himself.[12,13]

Audiological assessments in our study revealed that most patients had moderate conductive hearing loss, observed with large central perforation. Pre-operative audiological tests showed an Air-Bone (AB) gap of 31 to 40 dB in a significant number of patients. A study by Satinder Pal Singh *et al.* shows a similar pre-operative mean AB gap of 37.65 ± 6.40.[11] Another study by Gupta *et al.* observed a mean AB gap of 38.56 ± 1.99.[16] Such presentation of conductive hearing loss can be because when patients' day-to-day activities start getting, where the patient is socially handicapped, only then they seek health care and advice.

Six weeks post-operatively, the majority of patients showed an air-bone gap narrowing to 20 to 30 dB, indicating audiological improvement. The findings from our research align closely with those reported in the study conducted by Blake *et al*.[17] In their research, it was noted that a majority of the patients exhibited moderate conductive hearing loss, alongside large-sized tympanic membrane perforations. The pre-operative audiological assessment revealed an Air-Bone (AB) gap ranging between 31 to 40 decibels (dB). Six weeks following the surgical intervention, a significant improvement was noted, measuring between 20 to 30 dB. This shift not only signifies audiological improvement but also parallels the trajectory of recovery noted in our study. Additionally, a study by S Gökçe *et al.* showed that the temporalis fascia graft with platelet-rich fibrin(PRF) had an improvement of 19.30 ± 3.16 dB at 1 month post-operatively.[15] This consistency in the AB gap range across different studies highlights a common audiological characteristic in patients suffering from similar ear pathologies.

In our study, we reported hearing thresholds across different speech frequencies, namely at 500, 1000, and 2000 Hz, both pre-operatively and post-operatively at 6 weeks. The best result in improvement in AB gap was seen at 1000 Hz, i.e., 10.0 ± 8.9 dB. Parallel to our study, a study by Karaman *et al*.where 74 patients underwent Tympanoplasty Type I, found that ABG improvement was 20.2 dB at 500 Hz, 23.6 dB at 1000 Hz, and 22.2 dB at 2000 Hz, depicting maximum improvement at 1000 Hz.[18] Study by S Gökçe *et al.* showed improvement with PRF on all speech frequencies but it was statistically insignificant (500 Hz–0.175; 1kHz-0.143; 2 kHz-0.02).[15] Whereas, in a study by Yilmaz *et al.* and Salvador *et al*., the most improvement in AB gap was present for 500

Hz- 13.1 and 11.58, followed by 1000 Hz- 11 and 7.25 and, at 2000 Hz-10.6 and 3.96 simultaneously, in that order.[19] The reasoning for such a result could not be inferred from our study, also no proper explanation could be extracted from any other study.

There was a statistically significant improvement between pre-operative and post-operative air-bone gap on audiometry (*p-value* 0.00). Similar results were reported by Singh S P *et al.*, who reported significant improvement in the air-bone gap.[11]

Variable improvement in AB gap with use of PRP across various studies done, either significant or insignificant, still shows that better audiological outcomes are expected with tympanoplasty done with PRP as packing agent with gelfoam.

CONCLUSION

In our study, all the patients showed complete graft healing and significant improvement on audiometry post-operatively at 6 weeks, signifying that the use of PRP with gelfoam enhances the overall outcome of TM perforation repair and can be used as a measure to enhance early graft uptake.

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