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# "TO EVALUATE PRE AND POST OPERATIVE HEARING OUTCOME AFTER TYMPANOPLASTY USING TEMPORALIS FASCIA GRAFT: A COMPARATIVE STUDY"

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**Abstract**
The purpose of this prospective comparative study is to evaluate the pre- and post-operative hearing outcomes in patients undergoing type I tympanoplasty with a temporalis fascia graft as well as to assess improvements in pure tone audiometric parameters, graft uptake rates, and overall surgical success. It was conducted on 30 patients diagnosed with CSOM, requiring only type 1 tympanoplasty with a mean age of 32.15 ± 3.60 years. Preoperative and postoperative audiometric assessments were performed at 3 and 6 months, evaluating pure tone average (PTA), air conduction thresholds, and air-bone gap (ABG). Data were analyzed using paired t-tests to determine statistical significance. The study demonstrated significant improvements in hearing outcomes. The mean PTA decreased from 35 ± 3.0 dB preoperatively to 22 ± 2.0 dB at 6 months postoperatively, and the ABG reduced from 20 ± 4.0 dB to 10 ± 2.5 dB ($p < 0.001$). Additionally, a high graft uptake rate of 93% was achieved with minimal intraoperative complications. The significant audiometric improvements and high graft uptake rate support its use as a reliable treatment option for restoring hearing function.

**Keywords:** Chronic Suppurative Otitis Media, Tympanoplasty, Temporalis Fascia, Hearing Outcome, Audiometry

## INTRODUCTION

Chronic Suppurative Otitis Media (CSOM) remains a significant public health concern, particularly in developing countries where its prevalence ranges from 2% to 15%, imposing a considerable burden on the quality of life and economic productivity of affected individuals [1]. This persistent inflammation of the middle ear, often accompanied by tympanic membrane perforation and recurrent infections, primarily leads to conductive hearing loss—a deficit that not only hampers communication but also impacts social integration and educational achievement [2]. Over the past several decades, tympanoplasty has evolved as a principal surgical intervention aimed at repairing the perforated tympanic membrane and restoring hearing function, thereby offering both anatomical and functional rehabilitation for patients with CSOM [3]. The procedure, initially conceptualized by pioneers such as Zollner and Wullstein, has undergone numerous refinements, with the incorporation of various graft materials to enhance the success rate of the repair [4]. Among these materials, temporalis fascia has emerged as a preferred graft owing to its close proximity to the surgical field, ease of harvest, and

favorable histological properties that promote graft take and integration [5]. Despite its widespread use, the outcomes of tympanoplasty using temporalis fascia graft have been subject to variability, largely influenced by factors such as patient demographics, the chronicity of the disease, the size and location of the perforation, and the surgical expertise [6]. Preoperative audiometric assessment, particularly through pure tone audiometry, serves as an essential baseline, quantifying the extent of the air-bone gap and establishing the degree of conductive hearing loss [7]. Such measurements are pivotal in determining candidacy for surgery as well as in setting realistic expectations for postoperative improvement [8]. In the context of tympanoplasty, the temporalis fascia graft is favored not only for its biocompatibility and ease of use but also for its mechanical properties that closely mimic those of the native tympanic membrane, thereby facilitating sound conduction and vibration [9]. In addition to the anatomical success indicated by graft uptake and an intact tympanic membrane, the functional outcome primarily measured by the improvement in pure tone thresholds and reduction of the air-bone gap is a critical determinant of surgical success [10]. Various studies have proposed criteria to objectively evaluate hearing improvement, such as achieving a postoperative air conduction threshold within 40 dB, a hearing gain of at least 15 dB, and an air-bone gap closure to within 20 dB [11]. The selection of patients based on strict inclusion criteria such as age above 18 years, the presence of a dry ear for a stipulated period, and the absence of extensive middle ear pathology ensures that the study findings are attributable primarily to the surgical intervention rather than confounding variables [12]. Tympanoplasty, by virtue of its dual role in eradicating infection and improving auditory function, represents an intervention that can yield substantial benefits in terms of quality of life and productivity [13]. Given the diverse clinical presentations and varying degrees of hearing impairment associated with CSOM, the present study has been designed as a prospective comparative analysis to evaluate the hearing outcomes before and after type I tympanoplasty using temporalis fascia graft [14]. The findings from this research are anticipated to contribute significantly to the body of knowledge on tympanoplasty, offering evidence-based recommendations that can enhance patient selection, surgical planning, and postoperative care, and ultimately lead to improved hearing outcomes and quality of life for patients suffering from CSOM [15].

## METHODOLOGY

The study was designed as a prospective comparative study involving patients who underwent type 1 tympanoplasty at the Department of Otorhinolaryngology & Head and Neck Surgery, Pacific Institute of Medical Sciences, Udaipur, India. for a period of one year from 1/08/2023 to 31/07/2024. The study was conducted after approval from Institutional Ethical Committee and taking written consent from the patient , the protocol adhered to the principles outlined in the Declaration of Helsinki. Patients of all gender with mucosal type chronic otitis media mucosal were included in the study.

The study utilized a simple random sampling technique to recruit eligible patients with age above 18 years diagnosed with chronic suppurative otitis media (CSOM) in whom ear had remained dry for at least one month and conductive hearing loss of not more than 40 dB, and who underwent type I tympanoplasty with temporalis fascia graft.

Patients who underwent tympanoplasty with graft materials other than temporalis fascia, requiring ossicular reconstruction or concurrent mastoidectomy or having cholesteatoma or with a history of revision tympanoplasty are excluded from study.

### Sample Selection

The sample size was calculated using a prior type of power analysis by G* Power Software Version 3.0.1.0 (Franz Faul, Universitat Kiel, Germany). The minimum sample size was calculated, following these input conditions: power of 0.80 and $P \leq 0.05$ and sample size arrived were 24 participants. Final sample achieved was 30.

The study parameters were comprehensive and included both clinical and audiometric variables. Detailed clinical histories were taken from all patients including duration of ear discharge, followed by thorough otological examinations including the size and location of the tympanic membrane

perforation. Routine preoperative investigations, including blood tests, chest X-rays, and mastoid imaging, were conducted to ensure surgical readiness. Pure tone audiometry was performed preoperatively to establish baseline hearing levels. Surgical intervention was carried out under local anesthesia via a post-auricular approach. During the operation, the temporalis fascia was meticulously harvested and used to reconstruct the perforated tympanic membrane. Following surgery, patients were scheduled for follow-up assessments on the 7th and 21th days for immediate postoperative evaluation and at 3 and 6 months for audiometric reassessment, ensuring a standardized follow-up protocol.

We used the criteria recommended by the Japan Clinical Otology Committee for calculation of the hearing improvement (Tai, 1998).[16]

• Using the proportion of patients with a post-operative hearing within 40 dB as the first criterion.
• Using hearing gain exceeding 15 dB as the second criterion.
• Using postoperative air-bone gap within 20 dB as third criterion.

**Statistical Analysis**

The data was coded and entered into Microsoft Excel spreadsheet. Analysis was done using SPSS version 20 (IBMSPSS Statistics Inc., Chicago, Illinois, USA) Windows software program. The variables were assessed for normality using the Kolmogorov Smirnov test. Descriptive statistics included computation of percentages, means and standard deviations. Level of significance was set at $p \leq 0.05$.

## RESULT AND ANALYSIS

**Table 1. Demographic Profile of Study Population**

| Parameter | Value |
|---|---|
| Number of Patients | 30 |
| Mean Age (years) ± SD | 32.15 ± 3.60 |
| Gender (Male/Female) | 13 / 17 |

A total of 30 patients were enrolled in the study. The mean age was 32.15 ± 3.60 years, with a slightly higher female representation (17 females vs. 13 males).

**Table 2. Distribution of Presenting Symptoms**

| Symptom | Frequency (n) | Percentage (%) |
|---|---|---|
| Otorrhea | 27 | 90 |
| Hearing Loss | 28 | 93 |
| Tinnitus | 13 | 43 |
| Vertigo | 4 | 13 |

Most patients presented with classical symptoms of chronic suppurative otitis media with Otorrhea in 90% of cases, hearing loss in 93%, vertigo in 13%, and tinnitus in 43%.

**Table 3. Pre and Postoperative Audiometric Data at 3 Months and 6 Months**

| Parameter | Pre-operative | Post-operative | |
|---|---|---|---|
| | Mean Value ± SD (dB) | Mean Value ± SD (dB) At 3 months | Mean Value ± SD (dB) At 6 months |
| Pure Tone Average (PTA) | 35 ± 3.0 | 25 ± 2.5 | 22 ± 2.0 |
| Air Conduction Threshold | 45 ± 4.5 | 35 ± 3.0 | 32 ± 2.8 |
| Bone Conduction Threshold | 25 ± 3.5 | 23 ± 2.5 | 22 ± 2.0 |
| Air-Bone Gap (ABG) | 20 ± 4.0 | 12 ± 2.5 | 10 ± 2.5 |

Preoperative evaluation showed a mean Pure Tone Average (PTA) of 35 ± 3.0 dB, an air conduction threshold of 45 ± 4.5 dB, and an air-bone gap (ABG) of 20 ± 4.0 dB. These baseline values confirmed the presence of moderate conductive hearing loss among the study participants. At 3 months after surgery, significant improvements were observed. The mean PTA decreased to 25 ± 2.5 dB, with the air conduction threshold improving to 35 ± 3.0 dB and the ABG reducing to 12 ± 2.5 dB. These early results indicate a beneficial impact of the tympanoplasty on hearing function. By 6 months postoperatively, further improvements were noted. The mean PTA was 22 ± 2.0 dB, and the ABG further reduced to 10 ± 2.5 dB, while the air conduction threshold continued to improve.

**Table 4. Distribution of Tympanic Membrane Perforation Size**

| Perforation Size | Frequency (n) | Percentage (%) |
|---|---|---|
| Small (<25%) | 12 | 40 |
| Medium (25–50%) | 14 | 47 |
| Large (>50%) | 4 | 13 |

The analysis of perforation sizes revealed that 40% of patients had small perforations (<25%), 47% had medium perforations (25–50%), and 13% had large perforations (>50%). This distribution helped in assessing the prognostic implications of perforation size on surgical outcomes.

**Table 5. Graft Uptake and Success Rate**

| Outcome | Frequency (n) | Percentage (%) |
|---|---|---|
| Successful Graft Uptake | 28 | 93 |
| Graft Failure | 2 | 7 |

The success rate of the graft uptake was very high, with 93% (28 out of 30) of patients showing successful graft integration. Only 7% experienced graft failure.

**Table 6. Distribution of Hearing Gain**

| Hearing Gain (dB) | Frequency (n) | Percentage (%) |
|---|---|---|
| 0–5 dB | 2 | 7 |
| 6–10 dB | 5 | 17 |
| 11–15 dB | 16 | 53 |
| >15 dB | 7 | 23 |

Analysis of hearing gain revealed that 53% of patients achieved an improvement of 11–15 dB, 23% had gains of more than 15 dB, 17% improved by 6–10 dB, and 7% showed minimal gain (0–5 dB). This variability demonstrates substantial functional improvement in most patients.

**Table 7. Paired t-test Analysis of Audiometric Parameters**

| Parameter | Mean Preoperative (dB) | Mean Postoperative (dB) | t-value(Hearing gain) | p-value |
|---|---|---|---|---|
| Pure Tone Average | 35 ± 3.0 | 22 ± 2.0 | 8.25 | <0.001 |
| Air-Bone Gap | 20 ± 4.0 | 10 ± 2.5 | 7.50 | <0.001 |

Statistical analysis using paired t-tests confirmed significant improvements in hearing. The mean PTA improved from 35 ± 3.0 dB to 22 ± 2.0 dB (t-value = 8.25, $p < 0.001$) and the ABG decreased from 20 ± 4.0 dB to 10 ± 2.5 dB (t-value = 7.50, $p < 0.001$). These results statistically validate the surgical intervention's effectiveness.

## DISCUSSION

In the present study, a total of 30 cases, aged above 18 years, with a demonstrable conductive deafness not more than 40 dB and consented to participate in the study procedure underwent tympanoplasty. The patients were followed for a period of 6 months to analyze audiometric outcome and hearing gains. The mean age of the patients is 32.15 ± 3.60 years. Female outnumbered male counterpart. This was found in agreement with previous studies documented in the literature.[17,18]

In the present study the commonest presenting complaints was Hearing loss (93.0%) and Vertigo (13.0 %), followed by Otorrhea (90.0 %) and Tinnitus in (43.0%) of patients. Similarly Shetty S. (2012) found commonest presenting complaints are ear discharge and hearing loss seen in all the (100%) patients. Tinnitus is found in 15%, pain in the ear in 33.3% and vertigo in 11.3% of patients.[19]

The graft success rate of 93% achieved in this study is comparable with other studies. Glasscock et al in his study of postauricular under surface tympanic membrane grafting, showed the graft take rate with autograft fascia to be 92.8%.(20) Similar results were published by Thakur et al who reported a graft uptake rate of 92.05% in 139 out of 151 ears that underwent type 1 tympanoplasty using temporalis fascia graft.(21)

Our 2 cases that failed to take up the graft were possibly because of unreported/untreated postoperative infection as the patients were non-compliant with follow-up.

The distribution of hearing gain further corroborated the functional benefits of the surgery. In our study, 53% of patients experienced an improvement in hearing by 11–15 dB, 23% achieved gains of more than 15 dB, 17% had gains between 6–10 dB, and a small subset (7%) exhibited only minimal gain (0–5 dB). This variation in hearing gain could be attributed to individual differences in disease chronicity, perforation size, and the intrinsic healing capacity of each patient. However, the majority of patients demonstrated substantial hearing improvement, underscoring the efficacy of the procedure in enhancing auditory function. Wasson et al after investigating the impact of perforation size and other variables on the success of myringoplasty concluded that perforation size was not a statistically significant determinant factor for successful myringoplasty.(22)

Preoperative pure tone audiometry (PTA) demonstrated a mean PTA of 35 ± 3.0 dB, an air conduction threshold of 45 ± 4.5 dB, and an average ABG of 20 ± 4.0 dB. These baseline audiometric values confirmed the presence of moderate conductive hearing loss in the study cohort. At 3 months postoperatively, there was a marked improvement in hearing parameters; the mean PTA decreased to 25 ± 2.5 dB, the air conduction threshold improved to 35 ± 3.0 dB, and the ABG was reduced to 12 ± 2.5 dB. These early postoperative findings provided encouraging evidence of the immediate benefits of the surgical intervention. By 6 months postoperatively, further improvements were noted with the mean PTA reaching 22 ± 2.0 dB, the air conduction threshold stabilizing at 32 ± 2.8 dB, and

the ABG further decreasing to $10 \pm 2.5$ dB. The sustained improvement over a 6-month period suggests that the tympanoplasty not only provided short-term relief but also resulted in lasting functional benefits. The reduction in the PTA by 13 dB and the significant decrease in the ABG by 10 dB were both statistically significant ($p < 0.001$), thereby reinforcing the efficacy of the temporalis fascia graft in restoring hearing function. The mean pre- and post-operative outcomes in terms Pure tone ($p<0.05$), Air-bone gap ($p<0.05$) and Hearing gain ($p<0.05$) were found comparable with the results of the studies conducted by Yadav et al.[23] and Haruqop et al.(24). Many studies on Tympanoplasty have found place in the literature with varying success rates.[25-27].

The overall discussion of the study results emphasizes that type I tympanoplasty using temporalis fascia graft resulted in significant and sustained improvements in auditory function of the patients.

Moreover, the study results have important clinical implications. The significant improvements in hearing thresholds not only enhance the quality of life for patients but also facilitate better communication and social integration. Additionally, the absence of a significant correlation between demographic variables and hearing improvement suggests that the procedure can be effectively applied across a broad spectrum of patients.

## CONCLUSION

In conclusion, the study demonstrated that type I tympanoplasty using a temporalis fascia graft significantly improved hearing outcomes by reducing the pure tone average and air-bone gap. The high graft uptake rate and minimal complications affirmed the safety and efficacy of the procedure. These findings support its use as a reliable treatment option for chronic suppurative otitis media, warranting further research with larger cohorts; as many studies did not look at hearing outcome, the technique used and the experience level of the surgeon.

**Conflict Of Interest:** No Conflict of Interest

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