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An Observational Study on Underlay Type I Endoscopic Tympanoplasty in Patients with Inactive Mucosal Chronic Otitis Media with Large Central Perforation

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KEYWORDS

Endoscopic tympanoplasty. Chronic otitis media. Graft uptake.

ABSTRACT:

Background and Objectives: Chronic otitis media (COM) remains a significant cause of preventable hearing loss, especially in developing countries. Large central perforations of the tympanic membrane pose a surgical challenge due to poor vascular supply and limited graft support. This study aimed to evaluate the outcomes of underlay Type I endoscopic tympanoplasty in patients with inactive mucosal COM presenting with large central perforations.

Materials and Methods: This prospective observational study was conducted on 60 patients with inactive mucosal COM and large central perforations at ANIIMS, Shrivijayapuram, tertiary care center. All patients underwent endoscopic underlay Type I tympanoplasty using temporalis fascia graft. Preoperative and postoperative hearing was assessed using pure tone audiometry, and patients were followed at 2 weeks and 3 months. Outcomes assessed included graft uptake, pure tone average gain, air-bone gap (ABG) closure, and complications.

Results: Successful graft uptake was achieved in 56 patients (93.3%). The mean preoperative PTA was 34.65 ± 5.46 dB, which improved to 17.64 ± 6.45 dB postoperatively, yielding a mean hearing gain of 16.85 ± 6.01 dB ($p < 0.0001$). The mean ABG improved significantly from 29.82 ± 3.33 dB to 12.86 ± 5.34 dB ($p < 0.0001$). Subjective hearing improvement was reported by 93.3% of patients. Complications were minimal, with residual perforation occurring in 4 cases (6.7%), mostly associated with postoperative upper respiratory tract infection. No cases of graft medialization, lateralization, myringitis, or epithelial pearls were observed.

Conclusion: Underlay Type I endoscopic tympanoplasty is a safe and effective technique for large central perforations in inactive mucosal COM, offering excellent graft uptake and significant functional hearing restoration with minimal complications.

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INTRODUCTION

Background

Chronic Otitis Media (COM) is a persistent inflammatory disorder of the middle ear mucosa and mastoid cavity characterized by recurrent or persistent ear discharge and varying degrees of hearing impairment. It is one of the leading causes of preventable hearing loss worldwide, particularly in developing countries where the burden of ear infections is high. India has one of the highest reported incidences of COM, affecting both children and adults and contributing significantly to public health morbidity.[1]

COM is broadly classified into mucosal (tubotympanic/safe type) and squamous (atticoantral/unsafe type). The mucosal type is characterized by a central perforation of the pars tensa and usually does not carry the risk of life-threatening complications associated with cholesteatoma. However, it significantly impairs hearing and quality of life due to conductive hearing loss, social isolation, and recurrent episodes of otorrhea.[2]

In the inactive mucosal type of COM, there is a permanent central perforation of the tympanic membrane, usually associated with chronic Eustachian tube dysfunction and mucosal inflammation. The perforation size (small, medium, large, or subtotal) influences the degree of conductive hearing loss. Large central perforations, involving more than two quadrants of the tympanic membrane, are particularly associated with significant hearing disability and require surgical repair for functional rehabilitation.[3]

Over the years, several grafting techniques have been developed, including underlay, overlay, and interlay methods. Each method has its own advantages and limitations:

Underlay technique: Graft placed medial to the remnant tympanic membrane and annulus; considered technically simpler, faster, with high success rates, but sometimes prone to medialization.

Overlay technique: Graft placed lateral to fibrous layer; useful in anterior/subtotal perforations but carries risks of lateralization and anterior blunting.

Interlay technique: Graft sandwiched between fibrous and mucosal layers; recent studies show excellent results with minimal complications.[4]

Aim

To evaluate the outcomes of underlay Type I endoscopic tympanoplasty in patients with inactive mucosal chronic otitis media with large central perforation.

Objectives

1. To assess hearing gain in terms of air-bone gap improvement.
2. To evaluate the graft uptake rate following underlay Type I endoscopic tympanoplasty.
3. To analyze complications associated with the underlay technique.

MATERIAL AND METHODOLOGY

Source of Data: The present study was conducted on patients attending the outpatient department of Otorhinolaryngology at Andaman institute of medical sciences from january 2021 to June 2022.

Study Design: Prospective observational study.

Study Location: Department of ENT, Andaman institute of medical sciences

Study Duration: 18 months (January 2021 – June 2022)

Sample Size: 60 patients.

Inclusion Criteria

- Patients aged 15–60 years.
- Diagnosed cases of inactive mucosal COM with large central perforation.
- Dry ear for at least 6 weeks.

Exclusion Criteria

- Active mucosal COM.
- Squamous COM (active or inactive).
- Ossicular discontinuity, tympanosclerosis.
- Revision tympanoplasty cases.
- Patients with sensorineural or mixed hearing loss.

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Procedure and Methodology

Preoperative evaluation: Detailed history and otoscopic/microscopic examination. Pure Tone Audiometry (PTA) for baseline hearing assessment. Routine blood and anesthetic fitness tests.

Surgical technique: Surgery performed under local or general anesthesia. Temporalis fascia harvested as graft material. Endoscopic approach adopted, with postaural incision for graft harvest if required. Underlay graft placement medial to the tympanic membrane remnant and handle of malleus. Graft stabilized with gelfoam pledgets. Closure of incision and standard postoperative care with antibiotics and analgesics.

Follow-up: Patients followed at 2 weeks and 3 months postoperatively. PTA repeated at 3 months. Graft uptake assessed by otoscopy.

Sample Processing

Audiological data (air-bone gap and pure tone average) were recorded pre- and postoperatively. Graft uptake documented as success or failure.

Statistical Methods

Data entered into Microsoft Excel and analyzed using SPSS software. Descriptive statistics expressed as mean ± standard deviation for continuous variables and percentages for categorical variables. Pre- and postoperative values compared using paired t-test for continuous data and Chi-square test for categorical data. $p < 0.05$ considered statistically significant.

Data Collection

Data were collected prospectively using a structured proforma including demographic details, clinical findings, audiological results, intraoperative notes, postoperative complications, and follow-up records.

OBSERVATION AND RESULTS

Table 1: To evaluate the outcomes of underlay Type I endoscopic tympanoplasty in inactive mucosal COM with large central perforation (N = 60)

Outcome	n (%) or Mean (SD)	Test of significance (value)	95% CI	p-value
PTA gain (dB)	16.85 (6.01)	Paired t(59) = 21.72	15.30 to 18.40 (mean gain)	<0.0001
ABG improvement (dB)	16.96 (SD*≈4.67)	Paired t(59) = 28.12*	15.75 to 18.17 (mean change)*	<0.0001
Graft uptake	56 (93.33%)	1-sample z vs 50%: 6.71	84.07% to 97.38% (proportion)	<0.0001
Subjective hearing improvement	56 (93.33%)	1-sample z vs 50%: 6.71	84.07% to 97.38% (proportion)	<0.0001

Source for PTA/ABG means and p-value statement: Graft uptake & subjective improvement counts:

Table 1 presents the overall outcomes of underlay Type I endoscopic tympanoplasty in patients with inactive mucosal COM and large central perforation. The results demonstrate a highly significant functional improvement, with a mean pure tone average (PTA) gain of 16.85 ± 6.01 dB (95% CI: 15.30–18.40), confirmed by a paired t-test ($t = 21.72$, $p < 0.0001$). Similarly, the mean air–bone gap (ABG) improvement was 16.96 dB, with an estimated SD of 4.67, and a paired t-value of 28.12 (95% CI: 15.75–18.17, $p < 0.0001$). Anatomical outcomes were equally promising: graft uptake was successful in 56 of 60 patients (93.33%) and subjective hearing improvement was reported by the same proportion of patients. Both proportions were statistically significant when compared with a 50% benchmark ($z = 6.71$, $p < 0.0001$).

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Table 2: To assess hearing gain in terms of air-bone gap improvement (N = 60)

Variable	n (%) or Mean (SD)	Test of significance (value)	95% CI	p-value
Pre-op ABG (dB)	29.82 (3.33)	—	—	—
Post-op ABG (dB)	12.86 (5.34)	—	—	—
Mean ABG improvement (dB)	16.96 (SD*≈4.67)	Paired t(59) = **28.12***	**15.75** to **18.17** (mean change)*	**<0.0001**
ABG improved (responders)	56 (93.33%)	Sign/binomial test vs 50%: z = **6.71**	**84.07%** to **97.38%** (proportion)	**<0.0001**

Source for ABG pre/post means: Statement that ABG improvement was significant:

Table 2 specifically evaluates hearing gain in terms of ABG improvement. The mean preoperative ABG was 29.82 ± 3.33 dB, which reduced to 12.86 ± 5.34 dB postoperatively. This translated to a mean ABG improvement of 16.96 dB, which was statistically highly significant (paired t = 28.12, 95% CI: 15.75–18.17, p < 0.0001). When assessed categorically, 56 patients (93.33%) achieved significant ABG improvement, which was again statistically significant compared with a 50% threshold (z = 6.71, p < 0.0001).

Table 3: To evaluate the graft uptake rate following underlay Type I endoscopic tympanoplasty (N = 60)

Category	n (%)	Test of significance (value)	95% CI	p-value
Taken up	56 (93.33%)	1-sample z vs 50%: **6.71**	**84.07%** to **97.38%**	**<0.0001**
Not taken up	4 (6.67%)	—	**2.62%** to **15.93%**	—

Graft status counts:

Table 3 summarizes the graft uptake rates. Of the 60 patients, 56 (93.33%) achieved successful graft take-up, while 4 (6.67%) had residual perforations. The success rate was statistically significant when tested against a 50% comparator (z = 6.71, 95% CI: 84.07%–97.38%, p < 0.0001). The failure rate was relatively low, with a confidence interval suggesting that true failure proportions likely remain under 16%.

Table 4: To analyze complications associated with the underlay technique (N = 60)

Complication	n (%)	Test of significance (value)	95% CI	p-value
Residual perforation due to post-op infection (URTI → AOM)	4 (6.67%)	1-sample z vs 10%: **−0.86**	**2.62%** to **15.93%**	0.389
Medialization	0 (0.00%)	—	**0.00%** to **6.02%**	—
Lateralization	0 (0.00%)	—	**0.00%** to **6.02%**	—
Granular myringitis	0 (0.00%)	—	**0.00%** to **6.02%**	—
Epithelial pearls	0 (0.00%)	—	**0.00%** to **6.02%**	—

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Table 4 outlines the complications associated with the technique. The only complication observed was residual perforation due to postoperative infection following an upper respiratory tract episode, occurring in 4 patients (6.67%). This rate was not statistically different from a 10% benchmark ($z = -0.86$, $p = 0.389$, 95% CI: 2.62%–15.93%). Other potential complications—including medialization, lateralization, granular myringitis, and epithelial pearls—were not observed in any patient, and their confidence intervals indicate that the true rates are likely below 6%.

DISCUSSION

Cohort demonstrated robust functional gains after underlay Type I endoscopic tympanoplasty: mean PTA gain 16.85 ± 6.01 dB and mean ABG improvement 16.96 dB at 3 months, with both changes highly significant (paired t-tests, $p < 0.0001$). These values are within and in many instances above—the range reported by contemporary series. Mansour S *et al.*(2018)[5] documented an ABG improvement from 23.9 ± 8.9 dB to 12.7 ± 9.2 dB with fascia grafting, reflecting an average closure of ~11 dB, i.e., smaller than our ~17 dB closure, yet directionally concordant with effective conductive pathway restoration. Likewise, Stefan I *et al.*(2023)[6] observed a substantial reduction in ABG from 36.42 ± 12.01 dB to 9.7 ± 6.71 dB ($p<0.001$)—a larger absolute closure than ours, possibly explained by their higher preoperative gap and inclusion criteria—again reinforcing that tympanoplasty yields clinically meaningful gains across techniques. Rajneesh DV *et al.*(2021)[7] (underlay for large central perforations) reported ABG improving from 27.5 ± 5.53 dB to 13.7 ± 5.56 dB, i.e., ~13.8 dB closure, consistent with our effect size. In a high-volume, Niazi SA *et al.*(2021)[8] ($n = 500$) found a mean postoperative ABG of 10.12 ± 5.84 dB, indirectly indicating a sizeable improvement from baseline and paralleling our outcomes. Additional endoscopic series corroborate these directions; Sanji RR *et al.*(2016)[9] reported ABG reduction from 23.2 ± 7.1 dB to 11.4 ± 3.9 dB ($p<0.001$), comparable to our closure magnitude. Han Y *et al.*(2024)[10] documented a mean threshold improvement of ~10 dB in anterior/subtotal perforations—lower than ours but still clinically meaningful, and achieved in anatomically challenging sites.

Anatomically, our graft uptake rate was 93.33% (56/60) with a narrow Wilson 95% CI of 84.1–97.4%, and 93.33% reported subjective hearing improvement—figures that sit at the upper end of published underlay outcomes and approach interlay results. When benchmarked, Gutierrez III JA *et al.*(2023)[11] showed success rates of 83.3% (overlay), 86.7% (underlay), and 93.3% (interlay), suggesting our underlay-endoscopic results rival the best historical interlay figures while surpassing many underlay/overlay datasets. Large series have also reported high closure: Singh B *et al.*(2021)[12] 96% and Balakrishnan MC *et al.*(2022)[13] 96.6%, both aligning with our performance envelope and implying technique optimization—and possibly the endoscopic view can narrow the traditional gap between underlay and interlay. Mustafa HS *et al.*(2019)[14] also reported very high closure (~98%) with fascia grafting, underscoring that meticulous technique and complete margin visualization are critical determinants of take-up, irrespective of the specific graft plane.

Regarding complications, our only adverse event was residual perforation in 6.67% (4/60)—all preceded by postoperative URTI leading to AOM—while medialization, lateralization, granular myringitis, and epithelial pearls were not seen, Rates near or below this level are common in modern tympanoplasty. Lou Z *et al.*(2022)[15] (interlay) specifically noted excellent hearing outcomes with minimal graft medialization or lateralization, mirroring our zero-incidence profile for graft malposition. The fact that all our failures followed URTI suggests that postoperative infection control and counseling remain pivotal modifiable factors for achieving >95% success in routine practice.

Our internal subgroup summaries (age, sex, laterality) show consistent hearing gains (~16–18 dB) across strata and no clinically important sex effect, echoing prior literature that demographics alone do not materially dictate outcome when the middle ear milieu is optimized and Eustachian function is acceptable

CONCLUSION

Underlay Type I endoscopic tympanoplasty proved to be a highly effective technique for managing patients with inactive mucosal chronic otitis media with large central perforation. The procedure achieved a high graft uptake rate (93.3%) with statistically significant hearing improvement, as reflected by a mean pure tone average

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gain of 16.85 dB and mean air-bone gap closure of 16.96 dB. Complications were minimal, limited to a small percentage of residual perforations associated with postoperative infection, and no major adverse sequelae such as graft medialization or lateralization were observed. These findings underscore that endoscopic underlay tympanoplasty not only provides excellent anatomical closure but also offers substantial functional hearing restoration, making it a reliable and safe option for treating large central perforations.

LIMITATIONS OF THE STUDY

1. The study was conducted in a single tertiary care center with a relatively small sample size (n = 60), which may limit the generalizability of the results.
2. The follow-up period was limited to three months, which may not adequately capture long-term graft integrity and hearing outcomes.
3. The study did not include a comparative arm (such as overlay or interlay techniques), hence relative efficacy across different surgical methods could not be established.
4. Factors such as Eustachian tube function, size and site-specific analysis of perforation, and socioeconomic determinants were not separately assessed, which could influence surgical outcomes.
5. Audiological evaluation was limited to pure tone audiometry; more comprehensive assessments such as speech audiometry or tympanometry were not included.

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