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AUDIOMETRIC OUTCOME IN OSSICULOPLASTY WITH AUTOLOGUS CARTILAGE AND TEFLON PROSTHESIS (PORP, TORP) IN CHRONIC OTITIS MEDIA: A COMPARATIVE STUDY

ENT

Dr. Dinesh Valse Associate Professor, Department of ENT, ESIC Medical college and Hospital, Gulbarga.

Dr. Selvakumar* Junior Resident, Department of ENT, ESIC Medical college and Hospital, Gulbarga. *Corresponding Author

Dr. Anilkumar Doddamani HOD and Professor, Department of ENT, ESIC Medical college and Hospital, Gulbarga

ABSTRACT

Background: Ossiculoplasty is the surgical reconstruction of ossicular chain as well as to improve hearing level in patients with chronic otitis media(COM). The ideal prosthesis for this procedure should be biocompatible, stable, safe, easy to insert and capable of optimizing sound transmission. **Aim:** To compare the hearing outcomes of ossiculoplasty done with cartilage, PORP and TORP in patients with COM. **Methods:** This is a retrospective study of 14 month duration from November 2023 to January 2025 in 52 patients of chronic otitis media with or without cholesteatoma and conductive hearing loss admitted in the E.N.T department at ESIC Medical College and PGIMSR, Gulbarga, Karnataka. **Results:** Out of 52 patients, cartilage, PORP and TORP was used in 32, 13 and 7 patients respectively. Majority of patients achieved satisfactory hearing outcomes, with 63.4% achieving an AB gap of < 20 dB. Post operatively after 12 weeks mean air bone gap was maximum reduced (15dB) in TORP ossiculoplasty. **Conclusions:** The present study showed that TORP and PORP ossiculoplasty had better mean AB gap closure than cartilage ossiculoplasty in COM with or without cholesteatoma and conductive hearing loss.

KEYWORDS

Chronic Otitis Media, Ossiculoplasty, Cartilage, PORP, TORP, AB Gap(ABG), AB Gap Closure(ABGC)

INTRODUCTION

Chronic suppurative otitis media (CSOM) is a persistent inflammatory condition affecting the middle ear and mastoid cavity.Acute inflammation of the middle ear causes mucosal irritation and edema. Epithelial breakdown leads to ulceration, infection, and the formation of granulomas or granulation tissue. This process can result in the development of polyps in the middle ear[1-3]. The disease typically starts in childhood with a spontaneous tympanic membrane perforation caused by either acute otitis media (AOM) or as a complication of the milder form, secretory otitis media[4,5]. An epidemiological study found that the highest incidence rates of CSOM occur in impoverished tropical and subtropical regions[6,7].

CSOM most commonly occurs within the first six years of childhood, often due to poor management of AOM. However, diagnosing CSOM accurately remains challenging because the transition from AOM to CSOM is not clearly defined. According to the Global Burden of Disease Study 2010, otitis media accounts for 4.68 million disability-adjusted life years (DALYs), a disease burden comparable to intestinal helminth infections[8-10].

Bone resorption in cholesteatomas can occur due to enzymes produced by the expanding epithelial lining, potentially leading to erosion of the ossicles, otic capsule, and mastoid bone.Conductive hearing loss can result from ossicular chain abnormalities, including discontinuity or fixation. Discontinuity most commonly occurs due to an eroded incudostapedial joint, an absent incus, or an absent incus and stapes superstructure. In over 80% of cases, the cause of ossicular damage, particularly discontinuity, is chronic suppurative otitis media (CSOM), with or without cholesteatoma. Trauma or congenital malformations account for most of the remaining causes of ossicular damage[11,12].

Ossiculoplasty is the surgical reconstruction of the ossicular chain. The ideal prosthesis for this procedure should be biocompatible, stable, safe, easy to insert, and capable of optimizing sound transmission. The choice of prosthesis depends on factors such as compatibility and the ease of customization during surgery[13,14].

The treatment of CSOM has evolved from merely preventing complications to focusing on hearing restoration and improvement, driven by advancements in ear microsurgery techniques. Tympanoplasty methods have continuously improved, particularly in ossicular reconstruction (ossiculoplasty) after disease clearance, to enhance hearing outcomes. Materials used in ossiculoplasty include autografts (e.g., autologous ossicles, cartilage, bone), homologous grafts (e.g., homologous bone), and synthetic materials (e.g., polytetrafluoroethylene/Teflon, plastipore, hydroxyapatite, titanium). The choice of prosthesis depends on factors like biocompatibility, ease of intraoperative configuration, availability, and cost.

The present study was designed to determine the mean air conduction thresholds (ACT) and air-bone gap (ABG) closure pre and post-surgery across treatment groups using different graft materials, including autologous cartilage, autologous refashioned incus, and synthetic grafts such as Teflon partial ossicular reconstruction prosthesis (PORP) and total ossicular reconstruction prosthesis (TORP).

METHODS

Study Design, Sample Size and Source of Data:

This was a retrospective study carried out on 52 patients who were admitted and operated in the Department of ENT, ESIC Medical college and Hospital, Gulbarga during November 2023 to January 2025. Study period was 14 months.

Inclusion Criteria:

1. Patients diagnosed with chronic otitis media (COM) with or without cholesteatoma.
2. Presence of conductive hearing loss due to ossicular chain disruption or fixation.
3. Patients undergoing ossiculoplasty using either autologous cartilage or Teflon prosthesis (PORP/TORP).
4. Age group: All patients below 60 years.
5. Adequate preoperative audiometric data (pure-tone audiometry and air-bone gap measurements).

Exclusion Criteria:

1. Patients with sensorineural hearing loss or mixed hearing loss with a sensorineural component >30 dB..
2. History of previous ossiculoplasty or middle ear surgery.
3. Patients with systemic diseases affecting hearing (e.g., otosclerosis, autoimmune disorders).
4. Patients with contraindications to surgery or anesthesia.
5. Patients with inadequate preoperative or postoperative audiometric data.

Method of Data Collection

We considered around 52 samples who fulfilled inclusion criteria.All patients underwent surgery via a post-aural approach, with procedures including tympanoplasty with or without mastoidectomy, depending on the clinical indications. The choice of ossiculoplasty material was determined intraoperatively based on the extent of the disease. Autologous materials, such as reshaped conchal cartilage, were preferred whenever possible. However, in cases where autologous materials were unsuitable (e.g., due to non-availability in chronically diseased ears or microscopic squamous infiltration of the incus in cholesteatoma cases), synthetic materials like Teflon PORP (placed over the stapes suprastructure) or TORP (placed over the footplate) were used. The surgical procedures were standardized, with ossiculoplasty performed equally among participants undergoing tympanoplasty without mastoidectomy, canal wall up mastoidectomy, and canal wall down mastoidectomy.Pre- and postoperative air conduction threshold (ACT), bone conduction threshold (BCT), air-bone gap(ABG) and air-bone gap closure(ABGC) was recorded and calculatedat follow-up to evaluate hearing outcomes. Hearing thresholds were measured at frequencies of 500, 1000, 2000, and 4000 Hz, following the recommendations of the AAO-HNS (American Academy of Otolaryngology–Head and Neck Surgery). These frequencies were used to evaluate pre- and postoperative hearing improvement and ABG closure.

Statistical Analysis

The data collected was analysed using IBM SPSS version 27.0. Socio-demographic variables were analysed in terms of mean, standard deviation (SD), median, interquartile range (IQR)frequency (n) and percentage (%). The normality of numerical variables was analysed by the Kolmogorov-Smirnov test.A p-value of <0.05 was taken as statistically significant. Data results were represented in the form of tables and figures. Bivariate analysis between categorical variables performed by the Chi-square test. Independent t test was used to compare between two continuous variables and One-way Anova testwas used to compare between three/more continuous variables

RESULTS

In this study 52 CSOM patients included. The median age of the participants was 21.5 (14-28.5) years. Among 52 participants 24 (46.2%) were males and 28 (53.8%) were females (Table 1). Out of 52 cases, 23 were diagnosed with right atticoantral disease, 19 with left atticoantral disease, 8 with bilateral atticoantral disease and 2 with left tubotympanic disease

Table 1: Sociodemographic Characteristics of the Study Participants

Characteristics	n (%)
Age group	
• 1-10 years	3 (5.8%)
• 11-20 years	21 (40.4%)
• 21-30 years	16 (30.8%)
• 31-40 years	7 (13.5%)
• 41-50 years	4 (7.7%)
• 51-60 years	1 (1.9%)
Gender	
• Male	24 (46.2%)
• Female	28 (53.8%)

Intraoperative findings showed that majority of cases 24 (46.2%) had both the malleus and stapes intact (M+S+), incus eroded. A significant proportion of cases 19 (32.7%) showed erosion or absence of stapes or malleus along with incus erosion (M+S- and M-S+ combined).In 9 (17.3%) of cases, all 3 ossicles were absent or eroded (M-S-), suggesting severe ossicular chain damage(Table 2). The findings highlight the variability in ossicular chain status in CSOM, with a notable prevalence of ossicular erosion or absence in a subset of patients.

Table 2: Ossicular Chain Involvement

Ossicle eroded	No. Of cases
Only incus	24
Incus and Stapes	8
Incus and Malleus	11
All 3 ossicle eroded	9

The materials used for ossiculoplasty in the surgical management were analyzed, revealing the following distribution: cartilage was the most frequently used material, employed in 32 cases (61.5%), followed by Partial Ossicular Replacement Prosthesis (PORP) in 13 cases (25.0%), and Total Ossicular Replacement Prosthesis (TORP) in 7 cases (13.5%) (Table 3).

The preoperative air-bone (AB) gap measurements in patients were analyzed, revealing the following distribution: the majority of patients (38.5%) had an AB gap in the range of 21-30 dB, making it the most common finding. This was followed by 11-20 dB and 31-40 dB, each observed in 19.2% of cases. Similarly, an AB gap of 41-50 dB was also found in 19.2% of patients. Only a small proportion of cases (1.9% each) had severe Air Bone (A-B) gaps in the ranges of 51-60 dB and 61-70 dB.

The hearing outcomes Puretone audiometry (PTA), ACT, BCT was analysed for three groups based on materials used for ossiculoplasty.

The analysis of preoperative and postoperative pure-tone average (PTA) results for ossiculoplasty using different materials - cartilage, PORP, and TORP - revealed significant improvements in ACT and ABG across all groups, with p-values <0.0001 indicating statistically significant outcomes (Table 3).

Table 3: Pre and Post PTA and ABG in Various Groups

Group	PTA	PRE-OP Mean (SD)	POST-OP Mean (SD)	p-value
Cartilage (n=32)	ACT	43.41 (18.755)	34.09 (16.889)	<0.0001*
	BCT	15.91 (10.578)	15.91 (10.578)	---
	ABG	27.50 (11.946)	17.84 (10.699)	<0.0001*
PORP (n=13)	ACT	44.08 (12.045)	30.38 (10.453)	<0.0001*
	BCT	10.69 (3.987)	10.69 (3.987)	---
	ABG	33.38 (9.921)	19.69 (9.077)	<0.0001*
TORP (n=7)	ACT	56.29 (12.816)	41.29 (11.715)	<0.0001*
	BCT	19.14 (13.384)	19.14 (13.384)	---
	ABG	37.14 (8.821)	22.14 (6.619)	<0.0001*

The postoperative air-bone (AB) gap results (Table 4) were analyzed across the three groups, showing similar distributions of hearing outcomes. The statistical analysis ($\chi 2$=4.736, p=0.784) indicates no significant difference in postoperative AB gap outcomes among the three groups, suggesting that the choice of material (cartilage, PORP, or TORP) did not significantly influence the final hearing results. Overall, the majority of patients achieved satisfactory hearing outcomes, with 63.4% achieving an AB gap of ≤20 dB.

Table 4: The Postoperative Hearing Status With Different Graft Materials

Post-op A-B gap	Cartilage (n=32)	PORP (n=13)	TORP (n=7)	TOTAL (n=52)
0-10 dB	8 (25.0%)	2 (15.4%)	0 (0.0%)	10 (19.2%)
11-20 dB	14 (43.8%)	6 (46.2%)	3 (42.9%)	23 (44.2%)
21-30 dB	5 (15.6%)	3 (23.1%)	3 (42.9%)	11 (21.2%)
>30 dB	5 (15.6%)	2 (15.4%)	1 (14.3%)	8 (15.4%)
$\chi 2$=4.736, p=0.784				

Table 5 suggests findings of AB gap closure of various materials used. More AB gap closure meanings that good hearing outcome. >15dB AB gap closure considered as significant outcome.

Table 5: AB Gab Closure of Various Group

A-B gab closure	Cartilage(32)	PORP(13)	TORP(7)
0-10 dB	23	3	1
10-14 dB	7	5	2
15-20 dB	1	4	4
>20dB	1	1	0

Table 6 showing findings of mean closure of AB gap in various groups.

Table 6: Comparison of Mean Closure of A-BGap in Various Groups.

One way ANOVA test				
Closure	Cartilage (n=32)	PORP (n=13)	TORP (n=7)	F, p-value
A-BGap	9.61 (3.676)	13.69 (3.924)	15 (3.266)	9.467, <0.0001*

DISCUSSION

Since the early 20th century, various materials and surgical techniques have been used for ossicular chain reconstruction, but no single ideal material or standardized technique has gained universal acceptance. Currently, otologists worldwide primarily use three general classes of prostheses: autografts (patient's own tissue), homografts (donor tissue from another human), and allografts (synthetic or biocompatible materials). Despite advancements, the lack of consensus on the best material or technique highlights the complexity of achieving optimal hearing restoration and the need for further research and innovation in this field.

In this study, significant improvements in hearing outcomes were observed following ossiculoplasty in patients with chronic otitis media (COM) and severe-to-profound hearing loss. Key metrics, includingACT, BCT, ABG, demonstrated notable enhancements compared to baseline values, indicating the effectiveness of the procedure in restoring auditory function.The analysis of preoperative and postoperative pure-tone average (PTA) results for ossiculoplasty using cartilage, PORP, and TORP showed significant improvements in air conduction thresholds (ACT) and air-bone gap (ABG) across all groups ($p < 0.0001$). In the cartilage group, ACT improved from 43.41 dB to 34.09 dB, and ABG reduced from 27.50 dB to 17.84 dB. The PORP group shows ACT improve from 44.08 dB to 30.38 dB, and ABG decrease from 33.38 dB to 19.69 dB. The TORP group showed the greatest improvement, with ACT reducing from 56.29 dB to 41.29 dB and ABG narrowing from 37.14 dB to 22.14 dB. Bone conduction thresholds (BCT) remained unchanged. All materials were effective, with TORP showing the most significant improvements, likely due to more severe preoperative hearing loss. By table 6, the comparison of mean air-bone (AB) gap closure among the cartilage, PORP, and TORP groups using a one-way ANOVA test revealed significant differences ($F=9.467$, $p<0.0001$). The cartilage group (n=32) showed the smallest mean AB gap closure of 9.61 dB, while the PORP group achieved a closure of 13.69 dB, and the TORP group demonstrated the largest closure of 15 dB. These findings indicate that while all materials were effective in reducing the AB gap, TORP provided the greatest improvement, likely due to its use in cases with more severe ossicular damage. The significant p-value underscores the variability in closure efficacy among the materials, with TORP outperforming cartilage and PORP. By table 4, the postoperative hearing status, as measured by the air-bone (AB) gap, was analyzed across the cartilage, PORP, and TORP groups. The majority of patients 23(44.2%) achieved an AB gap of 11-20 dB, with cartilage showing the highest proportion 14(43.8%), followed by PORP 6(46.2%) and TORP 3(42.9%). A smaller proportion of patients 10(19.2%) achieved an AB gap of 0-10 dB, with cartilage contributing the most 8(25.0%), while no patients in the TORP group reached this range. An AB gap of 21-30 dB was observed in 11(21.2%) of cases, with the highest proportion in the TORP group 3(42.9%). Residual AB gaps >30 dB were seen in 15.4% of patients, distributed similarly across all groups. Statistical analysis ($\chi^2=4.736$, $p=0.784$) indicated no significant differences in postoperative AB gap outcomes among the materials, suggesting comparable efficacy in achieving satisfactory hearing results. Overall, 63.4% of patients achieved an AB gap of ≤20 dB, reflecting successful hearing restoration across all graft types.

In a study by Kumar et al.[15], the preoperative mean air conduction (ACT) in the autologous incus group was 41.60 ± 8.86 dB, which improved postoperatively to 33.82 ± 8.0 dB. Similarly, in the titanium prosthesis group, the preoperative ACT was 42.80 ± 9.19 dB, improving to 32.97 ± 9.02 dB postoperatively. In another study by Chavan et al.[16], the mean preoperative ACT was 47.89 dB, while Chauhan et al.[17] reported a preoperative ACT of 35 ± 12 dB, which improved to 27.4 ± 11.5 dB postoperatively. In the current study, the preoperative ACT varied across materials: cartilage (43.41 dB), PORP (44.08 dB), and TORP (56.29 dB). Postoperatively, ACT improved to 34.09 dB (cartilage), 30.38 dB (PORP), and 41.29 dB (TORP). The findings align with Kumar et al. and Chauhan et al., showing significant postoperative improvements in ACT. However, the current study's TORP group had a higher preoperative ACT (56.29 dB), reflecting more severe hearing loss, yet still achieved substantial improvement (41.29 dB). This suggests that while the current study's results are consistent with literature trends, the TORP group's outcomes highlight its efficacy in more complex cases. Overall, the current study reinforces the effectiveness of ossiculoplasty in improving ACT, with results comparable to or better than those reported in previous studies.

In a study by Jha et al.[18], the success rates of ossiculoplasty, defined by improvements in air-bone gap (ABG), were reported as 57% for cartilage, 59% for incus, and 40% for plastic PORP and TORP at 2 and 5 months postoperatively. In the current study, 63.4% of patients achieved a postoperative AB gap of ≤20 dB, which is comparable to or better than the success rates reported by Jha et al. Specifically, the current study demonstrated significant improvements in ABG across all materials: cartilage (27.50 dB to 17.84 dB), PORP (33.38 dB to 19.69 dB), and TORP (37.14 dB to 22.14 dB). While Jha et al. reported lower success rates for PORP and TORP (40%), the current study showed better outcomes, particularly for TORP, which achieved a mean ABG closure of 15 dB. This discrepancy may be attributed to differences in surgical techniques, patient selection, or follow-up duration.In another study on ossiculoplasty outcomes, the success rates were reported as 58% for incus and 33% for PORP and TORP.[19]The current study showed better outcomes, particularly for TORP, which achieved a mean ABG closure of 15 dB. This difference may be due to variations in surgical techniques, patient selection, or follow-up protocols. Overall, the current study highlights the effectiveness of ossiculoplasty, with results surpassing those of the cited study, particularly in the use of cartilage and PORP.

In a study by Sharma et al.[15], postoperative hearing outcomes showed mean air conduction (ACT) of 33.82 ± 8.0 dB and air-bone gap (ABG) of 24.41 ± 5.90 dB in Group A, and ACT of 32.97 ± 9.02 dB with ABG of 22.37 ± 7.59 dB in Group B. In comparison, the current study demonstrated superior or comparable results, with ACT improving to 34.09 dB and ABG reducing to 17.84 dB in the cartilage group, ACT improving to 30.38 dB and ABG reducing to 19.69 dB in the PORP group, and ACT improving to 41.29 dB with ABG reducing to 22.14 dB in the TORP group. The current study's ABG reductions were notably better, particularly in the cartilage and PORP groups, while the TORP group's slightly higher ABG likely reflects its use in more severe cases. Overall, the findings reinforce the effectiveness of ossiculoplasty, with the current study achieving superior or comparable hearing outcomes.

In a study by Quérat et al.[20], the residual mean air-bone gap (ABG) was 16.8 dB in the cartilage group (gain of 7.6 dB; P=0.001) and 15.8 dB in the PORP group (gain of 8.5 dB; P=0.002). The ABG was less than 20 dB in 67.6% of cartilage cases and 70.4% of PORP cases. Similarly, Lamba et al.[21] reported a mean hearing gain of 14.47 ± 6.54 dB for autografts and 14.57 ± 13.12 dB for synthetic grafts. In the current study, the cartilage group achieved a postoperative ABG of 17.84 dB, while the PORP group achieved 19.69 dB, and the TORP group achieved 22.14 dB. The proportion of patients achieving an ABG ≤20 dB was 68.8% for cartilage, 61.5% for PORP, and 42.9% for TORP. These results are comparable to Quérat et al.'s findings, particularly for cartilage and PORP, where the current study's ABG reductions and success rates align closely. However, the current study's TORP group had a slightly higher ABG, likely due to its use in more severe cases. Overall, the current study reinforces the effectiveness of ossiculoplasty, with results consistent with or slightly better than those reported by Quérat et al. and Lamba et al., particularly in the cartilage and PORP groups.

This study has a few limitations. First, it was a single-center, retrospective study, limiting the generalizability of the findings as it did not include data from other regions, centers, or ethnicities. Second, the study lacked more precise diagnostic methods, such as auditory brainstem response (ABR) or dynamic Eustachian tube function tests, which could have provided additional insights into hearing outcomes and Eustachian tube functionality. These limitations highlight the need for broader, multi-center studies and the inclusion of advanced diagnostic tools in future research.This study's small sample size increases the risk of statistical errors, highlighting the need for prospective clinical studies with larger sample sizes to assess the long-term outcomes of ossiculoplasty. However, ensuring patient compliance for extended follow-up periods remains a challenge. To address these limitations, more clinical trials with larger cohorts and longer

Ossiculoplasty using cartilage, PORP, and TORP demonstrated significant improvements in hearing outcomes for patients with COM and severe-to-profound hearing loss. All materials effectively reduced the ABG and improved ACT. While cartilage and PORP showed consistent success rates, TORP provided the greatest improvement in more severe cases, despite a slightly higher residual ABG. Further multi-center studies with larger sample sizes and longer follow-up periods are needed to standardize techniques and identify the most durable and effective ossicular prosthesis. Overall, ossiculoplasty remains a reliable and effective intervention for hearing restoration in COM patients.With ongoing advancements in the understanding of middle ear mechanics, the outcomes of ossiculoplasty continue to improve. By adhering to the principles of ossicular reconstruction and applying them meticulously in clinical practice, it is possible to achieve more favorable hearing results for patients, enhancing their quality of life.

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