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Original Research Article

Comparative Evaluation of Hearing Restoration in Primary and Staged Ossiculoplasty: A Prospective Analysis of Audiological and Functional Outcomes

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Conflict of interest: Nil

Abstract:

Background: The optimal timing of ossicular chain reconstruction in chronic otitis media remains controversial. This study aimed to compare hearing outcomes between primary ossiculoplasty performed simultaneously with disease clearance versus staged ossiculoplasty performed as a second procedure.

Materials and Methods: This prospective comparative study was conducted at Government Medical College, Dungarpur, Rajasthan from January 2023 to December 2024. Sixty patients with chronic otitis media requiring ossiculoplasty were divided into two groups: Group A (Primary Ossiculoplasty, n=30) and Group B (Staged Ossiculoplasty, n=30). Audiological assessment including pure tone audiometry was performed preoperatively and at 3 months postoperatively. The primary outcome measure was surgical success defined as postoperative air-bone gap (ABG) ≤20 dB.

Results: The primary ossiculoplasty group achieved a significantly higher success rate (76.7%) compared to the staged group (53.3%; p=0.046). Mean postoperative ABG was significantly lower in the primary group (17.2 ± 5.8 dB vs. 21.4 ± 7.6 dB; p=0.021). ABG gain was significantly greater in the primary group (15.9 ± 2.4 dB vs. 13.2 ± 1.5 dB; p=0.001). PORP achieved better outcomes than TORP in both groups. Complication rates were comparable (16.7% vs 20%) with no cases of sensorineural hearing loss.

Conclusion: Primary ossiculoplasty demonstrates superior hearing outcomes compared to staged ossiculoplasty without increased complication rates. It should be considered the preferred approach when complete disease clearance is achievable during initial surgery.

Keywords: Ossiculoplasty; Primary reconstruction; Staged reconstruction; Hearing outcomes; Chronic otitis media; Air-bone gap.

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Introduction

Chronic otitis media (COM) remains a significant global health burden, affecting millions of individuals worldwide with substantial impact on quality of life and socioeconomic productivity. Recent epidemiological data from the Global Burden of Disease Study 2021 indicates that otitis media affects nearly 297 million children worldwide, representing a 15.97% increase from 1990.[1] The prevalence of chronic suppurative otitis media (CSOM) in the United States is estimated at 0.46%, with the highest rates observed in children aged 0–10 years.[2] In developing countries, the burden is significantly higher, with prevalence rates ranging from 1.4% to 8% in various populations.[3]

The ossicular chain, comprising the malleus, incus, and stapes, plays a crucial role in sound transmission from the tympanic membrane to the inner ear.

Ossicular chain damage is a frequent consequence of chronic middle ear disease, occurring in approximately 30-50% of patients with CSOM.[4] The incus long process is most commonly affected due to its tenuous blood supply, followed by the stapes superstructure and malleus handle.[5] Such damage results in conductive hearing loss that significantly impacts communication, educational achievement, and social interaction, particularly when bilateral.[6]

Ossiculoplasty, the surgical reconstruction of the ossicular chain, has evolved substantially over the past several decades. Various materials have been employed for ossicular reconstruction, including autografts (cortical bone, cartilage, ossicles), homografts, and alloplastic prostheses.[7] A recent systematic review and meta-analysis demonstrated that reconstruction with titanium partial ossicular replacement prostheses (PORP) achieves postoperative air-bone gap (ABG) closure to ≤20 dB in approximately 70% of cases, while total ossicular replacement prostheses (TORP) achieve this in 57% of cases.[8] Pediatric populations demonstrate similar trends, with PORP recipients showing better postoperative hearing outcomes compared to TORP recipients.[9]

Despite advances in surgical techniques and prosthesis design, multiple factors continue to influence ossiculoplasty outcomes. These include the middle ear environment, presence and extent of cholesteatoma, status of the stapes superstructure, revision surgery status, and surgical technique.[10,11] Gluth et al. proposed an ear environment risk grading scale that has proven valuable in predicting hearing outcomes and counselling patients preoperatively.[12] Understanding these prognostic factors is essential for optimizing surgical outcomes and patient selection.

The optimal timing of ossicular reconstruction remains one of the most debated topics in otologic surgery. Primary ossiculoplasty, performed simultaneously with disease clearance during initial surgery, offers the advantage of single-stage hearing rehabilitation and avoids the need for a second surgical procedure.[13] In contrast, staged ossiculoplasty defers reconstruction to a second procedure, traditionally performed 6–12 months after the primary surgery to allow middle ear mucosa stabilization, confirm disease eradication, and ensure adequate middle ear aeration.[14] The historical rationale for staged procedures was based on concerns about prosthesis extrusion in an inflamed or diseased middle ear environment and the need for second-look surgery to detect residual cholesteatoma.

Recent evidence has challenged the traditional preference for staged procedures. Kálmán et al. reported in their retrospective cohort study that primary ossiculoplasties provide significantly better hearing results than revision procedures.[15] Similarly, Acke et al. demonstrated favourable outcomes with primary reconstruction in cholesteatoma surgery when the stapes is intact.[16] The advent of non-echo planar diffusion-weighted magnetic resonance imaging (non-EPI DW-MRI) has further transformed postoperative cholesteatoma surveillance, offering high sensitivity and specificity for detecting residual or recurrent disease without the need for routine second-look surgery.[17,18]

Cost-effectiveness analyses have also supported the shift toward primary reconstruction with imaging surveillance. Patel et al. demonstrated that DW-MRI is cost-effective compared to planned second-look surgery for cholesteatoma detection, particularly when considering the healthcare costs and patient burden associated with additional surgical procedures.[19] This economic perspective, combined with accumulating evidence of comparable or superior outcomes with primary ossiculoplasty, has led many centers to reconsider their surgical approach.

Despite these developments, prospective studies directly comparing audiological outcomes between primary and staged ossiculoplasty remain limited. Most existing literature consists of retrospective analyses subject to selection bias, with heterogeneous patient populations and varying outcome definitions.[20] A nationwide register-based study by Olaison et al. highlighted the need for standardized outcome reporting and prospective comparative studies to guide clinical decision-making.[21] The present study was therefore designed to prospectively compare hearing outcomes between primary ossiculoplasty and staged ossiculoplasty in patients with chronic otitis media requiring ossicular chain reconstruction.

Aim and Objectives

Aim: To compare the hearing outcomes of primary ossiculoplasty versus staged ossiculoplasty in patients with chronic otitis media undergoing ossicular chain reconstruction at Government Medical College, Dungarpur.

1. To evaluate and compare the pre-operative and post-operative air-bone gap (ABG) in patients undergoing primary ossiculoplasty versus staged ossiculoplasty.
2. To compare the surgical success rate (defined as post-operative ABG ≤20 dB) between the two groups.
3. To assess the mean hearing gain (ABG closure) achieved in each group.
4. To evaluate the impact of type of prosthesis (PORP vs TORP) on hearing outcomes in both groups.

5. To identify prognostic factors affecting hearing outcomes following ossiculoplasty.
6. To compare the complication rates between primary and staged ossiculoplasty procedures.

Materials and Methods

Study Design: This was a prospective comparative study conducted at the Department of ENT and Head & Neck Surgery, Government Medical College, Dungarpur, Rajasthan, India, from January 2023 to December 2024. The study protocol was approved by the Institutional Ethics Committee, and informed written consent was obtained from all participants prior to enrollment.

Study Population: A total of 60 patients with chronic otitis media requiring ossicular chain reconstruction were enrolled in the study. Patients were divided into two groups based on the timing of ossiculoplasty: Group A (Primary Ossiculoplasty, n=30) underwent ossicular reconstruction simultaneously with disease clearance during the initial surgery, while Group B (Staged Ossiculoplasty, n=30) underwent ossicular reconstruction as a second-stage procedure 6-12 months after the primary surgery for disease clearance.

Inclusion Criteria

- Patients aged 15-60 years with chronic otitis media (mucosal or squamosal type)
- Documented ossicular chain discontinuity or erosion requiring reconstruction
- Conductive or mixed hearing loss with air-bone gap ≥20 dB
- Willingness to comply with follow-up schedule

Exclusion Criteria

- Pure sensorineural hearing loss
- Previous ossiculoplasty or revision ear surgery
- Complications of chronic otitis media (intracranial, labyrinthine, or facial nerve involvement)
- Bilateral ear disease requiring simultaneous surgery
- Patients lost to follow-up

Preoperative Assessment: All patients underwent comprehensive preoperative evaluation including detailed history, otoscopic examination, and audiological assessment. Pure tone audiometry (PTA) was performed using a calibrated audiometer in a sound-treated room. Air conduction thresholds were measured at 250, 500, 1000, 2000, and 4000 Hz, and bone conduction thresholds at 500, 1000, 2000, and 4000 Hz. Pure tone average (PTA) was calculated as the mean of thresholds at 500, 1000, 2000, and 4000 Hz. Air-bone gap (ABG) was calculated as the difference between air conduction and bone conduction thresholds. High-resolution computed tomography (HRCT) of temporal bone was performed in all cases to assess disease extent and ossicular status.

Surgical Technique: All surgeries were performed under general anesthesia by experienced otologic surgeons. The surgical approach (postaural or endaural) was selected based on disease extent and surgeon preference. Mastoidectomy (canal wall up or canal wall down) was performed as indicated by disease pathology. The ossicular chain was assessed intraoperatively, and the type of prosthesis (PORP or TORP) was selected based on the status of the stapes superstructure. PORP was used when the stapes superstructure was intact, while TORP was used when the stapes superstructure was absent or severely eroded. Titanium prostheses were used in all cases. Cartilage interposition was routinely placed between the prosthesis and tympanic membrane to prevent extrusion.

In the primary ossiculoplasty group, ossicular reconstruction was performed during the same surgical session after disease clearance. In the staged ossiculoplasty group, the initial surgery focused on disease eradication and tympanic membrane reconstruction, with ossicular reconstruction deferred to a second-stage procedure performed 6-12 months later after confirming adequate middle ear aeration and absence of residual disease.

Postoperative Care and Follow-up: Postoperative care included oral antibiotics for 7 days, analgesics as needed, and ear precautions. Patients were followed up at 2 weeks for suture removal and wound assessment, at 6 weeks for graft uptake evaluation, and at 3 months for audiological assessment. Pure tone audiometry was repeated at 3 months postoperatively using the same protocol as preoperative assessment. Complications were documented at each visit.

Outcome Measures: The primary outcome measure was surgical success, defined as postoperative ABG ≤20 dB. Secondary outcome measures included mean postoperative ABG, ABG gain (difference between preoperative and postoperative ABG), excellent outcome (ABG ≤10 dB), and complication rates. Prognostic factors for successful outcomes were also analyzed.

Statistical Analysis: Statistical analysis was performed using SPSS version 26.0 (IBM Corporation, Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD) and compared using independent samples t-test. Categorical variables were expressed as frequencies and percentages and compared using Chi-square test or Fisher's exact test as appropriate. Univariate logistic regression analysis was performed to identify prognostic factors for successful outcomes. Odds ratios (OR) with 95%

confidence intervals (CI) were calculated. A p-value <0.05 was considered statistically significant.

Results

A total of 60 patients who underwent ossiculoplasty for chronic otitis media were included in this prospective study. Patients were divided into two groups: Group A (Primary Ossiculoplasty, n=30) and Group B (Staged Ossiculoplasty, n=30). The mean follow-up period was 8.4 ± 2.6 months.

Table 1: Demographic and Clinical Characteristics of Study Population

Parameter	Group A (Primary) n=30	Group B (Staged) n=30
Age (years), Mean ± SD	34.2 ± 11.8	36.1 ± 12.4
Sex (Male:Female)	14:16	13:17
Disease Type - Mucosal	18 (60%)	16 (53.3%)
Disease Type - Squamosal	12 (40%)	14 (46.7%)
Prosthesis Type - PORP	18 (60%)	17 (56.7%)
Prosthesis Type - TORP	12 (40%)	13 (43.3%)

The demographic and baseline clinical characteristics of both groups are summarized in Table 1. There was no statistically significant difference between the two groups in terms of age, sex distribution, or disease characteristics, indicating adequate matching between groups.

Table 2: Intraoperative Findings

Finding	Group A (Primary) n=30	Group B (Staged) n=30
Incus Erosion	24 (80%)	22 (73.3%)
Malleus Erosion	8 (26.7%)	10 (33.3%)
Stapes Intact	18 (60%)	17 (56.7%)
CWU Mastoidectomy	22 (73.3%)	20 (66.7%)
CWD Mastoidectomy	8 (26.7%)	10 (33.3%)

The intraoperative findings are presented in Table 2. The most common ossicular defect in both groups was incus erosion. The status of the stapes superstructure determined the choice between PORP and TORP. Canal wall up (CWU) mastoidectomy was performed in the majority of cases in both groups).

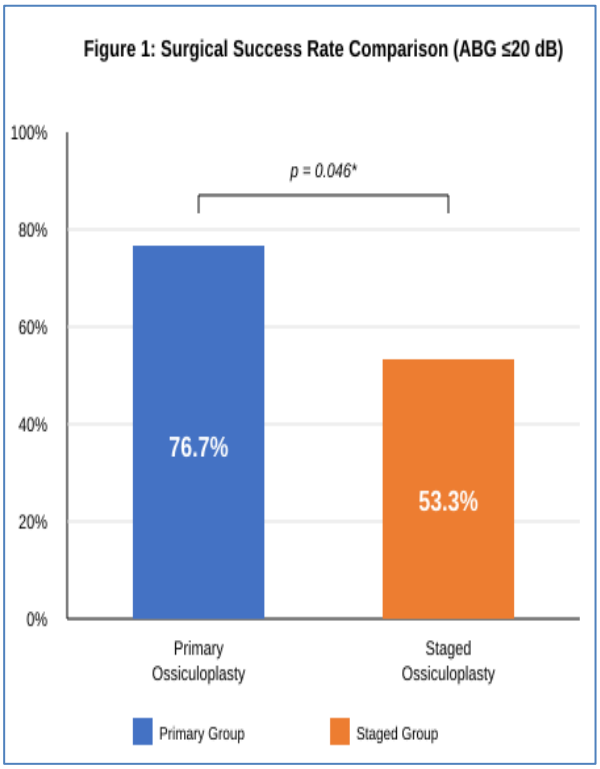
Table 3: Comparison of Hearing Outcomes Between Groups

Parameter	Group A (Primary) n=30	Group B (Staged) n=30
Preoperative ABG (dB)	33.1 ± 7.4	34.6 ± 8.1
Postoperative ABG (dB)	17.2 ± 5.8	21.4 ± 7.6
ABG Gain (dB)	15.9 ± 2.4	13.2 ± 1.5
Success Rate (ABG ≤20 dB)	23 (76.7%)	16 (53.3%)
Excellent Outcome (ABG ≤10 dB)	9 (30%)	5 (16.7%)
Preoperative AC PTA (dB)	48.6 ± 11.2	50.2 ± 12.1
Postoperative AC PTA (dB)	32.8 ± 9.4	37.1 ± 10.8

The audiological outcomes are summarized in Table 3. Both groups showed significant improvement in air-bone gap (ABG) following surgery. However, the primary ossiculoplasty group demonstrated significantly better postoperative hearing outcomes compared to the staged group.

The mean preoperative ABG was comparable between the two groups (33.1 ± 7.4 dB in the primary group vs. 34.6 ± 8.1 dB in the staged group; p=0.456). Postoperatively, the primary group achieved a significantly lower mean ABG (17.2 ± 5.8 dB) compared to the staged group (21.4 ± 7.6 dB; p=0.021). The mean ABG gain was significantly higher in the primary group (15.9 ± 2.4 dB) compared to the staged group (13.2 ± 1.5 dB; p=0.001).

Surgical success, defined as postoperative ABG ≤20 dB, was achieved in 23 patients (76.7%) in the primary group compared to 16 patients (53.3%) in the staged group. This difference was statistically significant (p=0.046), demonstrating that primary ossiculoplasty yields superior hearing outcomes



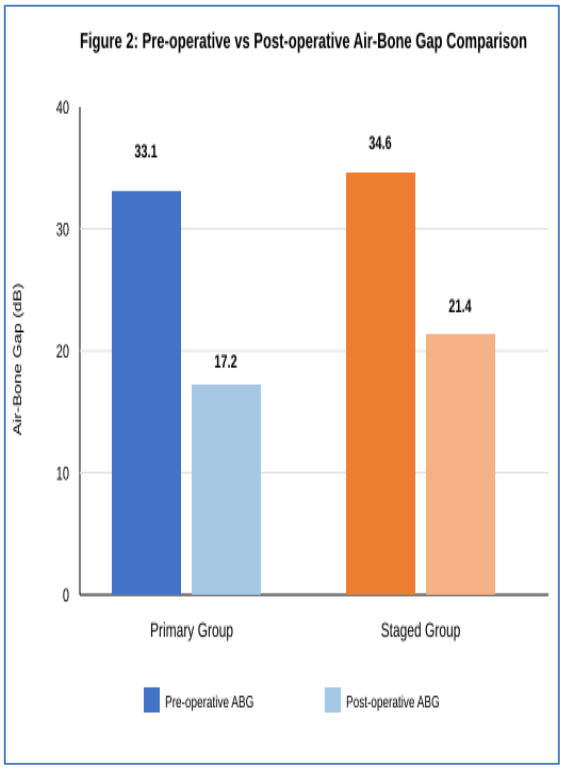


Table 4: Hearing Outcomes by Prosthesis Type

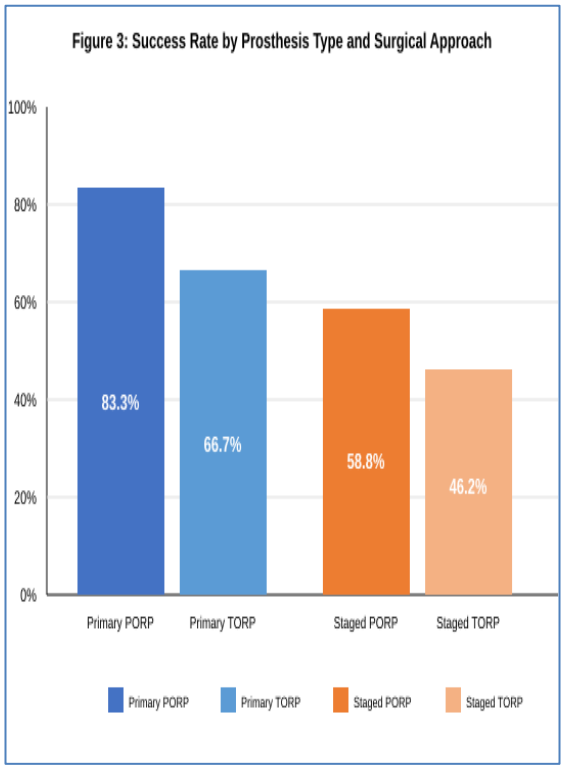
Group	Prosthesis	n	Success Rate (ABG ≤20 dB)	Mean Postop ABG (dB)
Primary	PORP	18	15 (83.3%)	15.8 ± 5.2
Primary	TORP	12	8 (66.7%)	19.3 ± 6.1
Staged	PORP	17	10 (58.8%)	19.6 ± 7.2
Staged	TORP	13	6 (46.2%)	23.8 ± 7.9
Group	**Prosthesis**	**n**	**Success Rate (ABG ≤20 dB)**	**Mean Postop ABG (dB)**
Primary	PORP	18	15 (83.3%)	15.8 ± 5.2
Primary	TORP	12	8 (66.7%)	19.3 ± 6.1

Subgroup analysis based on prosthesis type revealed that PORP achieved better hearing outcomes compared to TORP in both groups (Table 4). In the primary group, PORP achieved a success rate of 83.3% compared to 66.7% with TORP. Similar trends were observed in the staged group, with PORP showing a success rate of 58.8% versus 46.2% for TORP.

Table 5: Prognostic Factors for Successful Hearing Outcomes (Univariate Analysis)

Factor	Odds Ratio	95% CI	p-value
Primary vs Staged	2.87	1.02-8.12	0.046*
PORP vs TORP	2.64	0.96-7.24	0.049*
Intact vs Absent Stapes	2.92	1.05-8.14	0.039*
No Cholesteatoma vs Cholesteatoma	2.58	0.94-7.08	0.048*
Healthy vs Diseased Mucosa	3.24	1.12-9.38	0.028*
CWU vs CWD Mastoidectomy	1.68	0.58-4.86	0.336
Age <40 vs ≥40 years	1.42	0.52-3.88	0.492

Univariate analysis was performed to identify prognostic factors associated with successful hearing outcomes (ABG ≤20 dB). The results are presented in Table 5. Primary ossiculoplasty, use of PORP, intact stapes superstructure, absence of cholesteatoma, and healthy middle ear mucosa were significantly associated with successful outcomes.



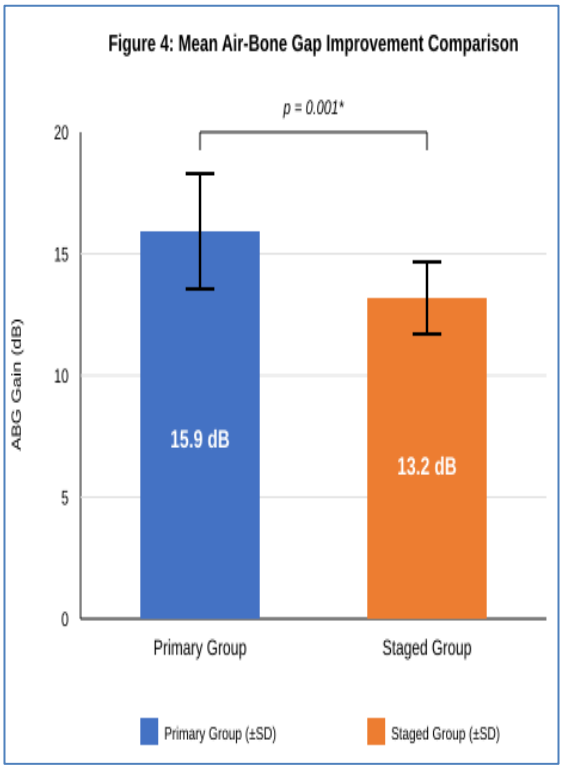


Table 6: Complications

Complication	Group A (Primary) n=30	Group B (Staged) n=30
Prosthesis Extrusion	1 (3.3%)	2 (6.7%)
Graft Failure	2 (6.7%)	2 (6.7%)
Otorrhea	2 (6.7%)	2 (6.7%)
Sensorineural Hearing Loss	0 (0%)	0 (0%)
Total Complications	5 (16.7%)	6 (20%)

Postoperative complications are summarized in Table 6. The overall complication rate was comparable between the two groups (16.7% vs 20%). Prosthesis extrusion occurred in 1 patient (3.3%) in the primary group and 2 patients (6.7%) in the staged group. There were no cases of sensorineural hearing loss or facial nerve injury in either group.

Discussion

The present prospective study demonstrates that primary ossiculoplasty yields significantly better hearing outcomes compared to staged ossiculoplasty in patients with chronic otitis media requiring ossicular chain reconstruction. The primary ossiculoplasty group achieved a success rate of 76.7% (ABG ≤20 dB) compared to 53.3% in the staged group, with a statistically significant difference (p=0.046). Furthermore, the mean ABG gain was significantly higher in the primary group (15.9 ± 2.4 dB vs. 13.2 ± 1.5 dB; p=0.001), while maintaining comparable complication rates between the two approaches.

Our findings are consistent with the existing literature supporting primary ossicular reconstruction. Kálmán et al. reported in their retrospective cohort study that primary ossiculoplasties provide better hearing results than revision procedures.[15] Their study demonstrated a success rate of 72.3% for primary ossiculoplasties, which aligns closely with our observed 76.7% success rate. The slightly higher success rate in our study may be attributable to the prospective design with standardized surgical technique and postoperative care protocols. Similarly, Alosaimi et al. in their comparison of tympanoplasty with and without ossiculoplasty found favourable outcomes when reconstruction was performed during initial surgery.[22]

The superior outcomes achieved with PORP compared to TORP in our study are consistent with published meta-analyses. Kortebein et al. reported that titanium PORP achieves ABG closure to ≤20 dB in approximately 70% of cases, while TORP achieves this in 57% of cases.[8] In our primary ossiculoplasty group, we observed success rates of 83.3% for PORP and 66.7% for TORP, which exceed these benchmarks. Similarly, Omar et al. demonstrated comparable trends in pediatric

populations, with PORP consistently outperforming TORP.[9] The inherent advantage of PORP lies in its articulation with the intact stapes superstructure, providing more efficient sound transmission compared to TORP placement on the stapes footplate.[23]

Several factors may explain the superior outcomes observed with primary ossiculoplasty. First, primary reconstruction is performed in a native middle ear environment that has not been previously surgically altered. The middle ear mucosa, though potentially inflamed, maintains its natural architecture and blood supply, which may facilitate better prosthesis integration and healing. Second, patients undergoing staged procedures have already experienced one surgical intervention, and the resultant fibrosis, mucosal changes, and anatomical alterations may compromise the middle ear environment for subsequent reconstruction.[24] Roth et al. in their analysis of revision ossiculoplasty risk factors highlighted the detrimental effects of previous surgery on hearing outcomes.[25]

The importance of middle ear environment in determining ossiculoplasty outcomes has been emphasized by Gluth et al. in their multi-center study, which proposed an ear environment risk grading scale for predicting hearing outcomes.[12] In our study, healthy middle ear mucosa was identified as a significant prognostic factor (OR 3.24; p=0.028), corroborating the critical role of middle ear status in surgical success. The staged group, despite having comparable proportions of healthy mucosa at the time of reconstruction, may have experienced cumulative effects of chronic inflammation and previous surgical intervention that were not captured by mucosal appearance alone.

Traditionally, staged ossiculoplasty has been advocated for cases with cholesteatoma to allow confirmation of disease eradication before definitive reconstruction. However, the advent of non-EPI DW-MRI has revolutionized postoperative cholesteatoma surveillance.[17,18] This imaging modality offers high sensitivity and specificity for detecting residual or recurrent disease, potentially negating the need for routine second-look surgery solely for surveillance purposes. Patel et al. demonstrated the cost-effectiveness of DW-MRI compared to planned second-look surgery for cholesteatoma detection, further supporting the shift toward primary reconstruction with imaging surveillance.[19] Choi et al. in their cost-comparison analysis also found DW-MRI to be economically favourable.[17]

An important finding of our study is that primary ossiculoplasty did not increase complication rates compared to staged procedures. Both groups demonstrated comparable overall complication rates of 16.7% and 20% respectively, with no cases of sensorineural hearing loss or facial nerve injury. This suggests that performing ossicular reconstruction simultaneously with disease clearance does not compromise surgical safety. The low extrusion rate (3.3% in primary group, 6.7% in staged group) is consistent with reported rates for titanium prostheses in the literature, ranging from 2-8%.[23,26] Lahlou et al. reported similar complication profiles in their study of titanium prosthesis outcomes.[23]

Our analysis identified several prognostic factors associated with successful hearing outcomes. The integrity of the stapes superstructure emerged as a significant predictor (OR 2.92; p=0.039), which is expected given the inherent advantages of PORP over TORP placement. Absence of cholesteatoma was also associated with better outcomes (OR 2.58; p=0.048), reflecting the less favourable middle ear environment in cholesteatoma cases due to erosion, inflammation, and granulation tissue. These findings align with the multi-factorial nature of ossiculoplasty outcomes described by Olaison et al. in their nationwide register-based study.[21] Gardner et al. similarly identified stapes status as a key determinant of hearing results with titanium prostheses.[26]

The clinical implications of our findings are substantial. Primary ossiculoplasty offers patients the advantage of single-stage hearing rehabilitation, avoiding the morbidity, inconvenience, and healthcare costs associated with a second surgical procedure. Given the comparable safety profile and superior hearing outcomes demonstrated in our study, primary ossiculoplasty should be considered the preferred approach when complete disease clearance can be confidently achieved during initial surgery. Staged procedures may be reserved for cases with extensive cholesteatoma where complete removal is uncertain, significantly diseased middle ear mucosa, or patient-related factors precluding extended surgical duration.

This study has several limitations that warrant consideration. First, the sample size of 60 patients, while adequate for detecting significant differences in primary outcomes, may limit the power to detect differences in subgroup analyses and rare complications. Second, the follow-up period of 8.4 months, though consistent with standard practice for assessing short-term hearing outcomes, does not capture long-term prosthesis stability and hearing preservation. Studies have shown that hearing outcomes may deteriorate over time due to prosthesis displacement, extrusion, or middle ear fibrosis.[27] Dornhoffer reported on long-term hearing stability with middle ear implants, emphasizing the need for extended follow-up.[27] Third, while we attempted to match groups for baseline characteristics, the non-randomized design introduces potential selection bias, as the decision

for primary versus staged reconstruction was based on intraoperative assessment of disease extent and surgeon judgment.

Future research should focus on randomized controlled trials with longer follow-up periods to definitively establish the superiority of primary ossiculoplasty. Additionally, studies incorporating quality of life measures and patient-reported outcomes would provide valuable insights into the functional impact of hearing improvement. The development and validation of standardized risk stratification tools, incorporating the prognostic factors identified in this and other studies, would facilitate evidence-based decision-making regarding the optimal timing of ossicular reconstruction.

Conclusion

Primary ossiculoplasty demonstrates significantly superior hearing outcomes compared to staged ossiculoplasty, with a 76.7% success rate versus 53.3% in achieving postoperative ABG ≤20 dB. The procedure is safe, with complication rates comparable to staged reconstruction. PORP yields better results than TORP in both surgical approaches. Intact stapes superstructure, absence of cholesteatoma, and healthy middle ear mucosa are significant prognostic factors for successful outcomes. Based on these findings, primary ossiculoplasty should be considered the preferred approach when complete disease clearance is achievable, reserving staged procedures for cases with extensive disease or uncertain disease control.

Conflict of Interest

The authors declare that they have no conflicts of interest. No financial or personal relationships exist that could have influenced the work reported in this paper.

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