https://doi.org/10.29309/TPMJ/2026.33.03.10101 www.theprofesional.com

ORIGINAL ARTICLE

Evaluation of hearing outcomes in ossicular chain reconstruction: A comparison between total and partial ossicular replacement prostheses.

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ABSTRACT… Objective: To evaluate and compare postoperative hearing outcomes in patients who have undergone ossicular chain reconstruction using partial and total ossicular replacement prostheses. **Study Design:** Prospective Non-randomized Clinical study. **Setting:** Department of Otorhinolaryngology, Shifa International Hospital, Islamabad. **Period:** April 2024 to April 2025. **Methods:** Patients undergoing ossiculoplasty were enrolled consecutively and categorized into two groups based on prosthesis used: total ossicular replacement prosthesis (TORP) and partial ossicular replacement prosthesis (PORP). The selection of prosthesis was determined intraoperatively based on extent of ossicular chain damage. All patients were followed post-operatively. Pre-operative and post-operative hearing thresholds were assessed using pure tone audiometry. **Results:** The TORP group had a higher preoperative air-bone gap (ABG) at 31.77 ± 10.05 dB, compared to the PORP group at 26.31 ± 10.67 dB. After surgery, ABG improved in both groups, reaching 17.54 ± 10.83 dB in the TORP group and 19.69 ± 10.34 dB in the PORP group. Both results met the criteria for successful ossiculoplasty. The analysis within the TORP group showed significant hearing improvement, with a p-value of less than 0.01. This group had a mean ABG gain of 14.23 dB and a large effect size. In contrast, the PORP group showed a moderate improvement of 6.62 dB, with a p-value of 0.05. However, the differences between the two groups were not statistically significant, with a p-value of 0.185 and a Hedges' g effect size of -0.519 favoring TORP. **Conclusion:** Both TORP and PORP effectively treat conductive hearing loss. TORP may provide more benefit for patients with severe preoperative hearing loss or significant ossicular damage. Choosing a prosthesis should depend on what is found during the operation instead of past practices.

Kew words: Chronic Suppurative Otitis Media (CSOM), Conductive Hearing Loss, Ossiculoplasty, Partial Ossicular Replacement Prosthesis (PORP), Total Ossicular Replacement Prosthesis (TORP).

Article Citation: Saqib M, Aslam MA, Khan RM, Wali H. Evaluation of hearing outcomes in ossicular chain reconstruction: A comparison between total and partial ossicular replacement prostheses. Professional Med J 2026; 33(03):466-471. https://doi.org/10.29309/TPMJ/2026.33.03.10101

INTRODUCTION

Ossicular chain disruption results in conductive hearing loss, which may be secondary to a number of aetiologies, including chronic suppurative otitis media (CSOM), cholesteatoma, malignancies, trauma, and congenital diseases (Deklerck et. al, 2014).[1] For those patients where the incus is completely absent, synthetic ossicular prostheses can be useful. There are two main options – total ossicular replacement prosthesis (TORP) and partial ossicular replacement prosthesis (PORP), both of which are commonly used in the conditions mentioned above (Vassbotn et. al, 2007).[2] The choice of which of the two surgeries to perform is generally down to whether the stapes is intact – in which case a PORP is more suitable – or if there is only a footplate, so that a TORP is a better option (Schmerber et. al, 2006).[3] However, the option of TORP with intact stapes suprastructure has been shown to be an effective alternative with good hearing results (Baker et. al, 2015).[4]

As regards the effectiveness of both types of surgeries, results have varied greatly and have often been conflicting. Better results of TORP have been reported in some studies (Murugasu et. al, 2005; Vincent et. al, 2011)[5,6] while PORP has been more effective in others (Brackmann, 1993; Yu et. al, 2013).[7,8] PORP has also been reported to be more stable in long term follow-up (Yu et. al, 2013).[8] There have even been studies where no significant difference was found in efficacy (Faramarzi et. al, 2023).[9] It has also been seen that staged ossicular reconstruction yields the best results as opposed to unstaged (Kim et. al, 2006; Shelton & Sheehy, 1990).[10,11]

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Article received on:
30/09/2025
Date of revision:
10/11/2025
Accepted for publication:
11/12/2025

The purpose of this research is to compare the effectiveness of PORP and TORP in the Pakistani population, which has not been explored in detail before. The global literature on the subject is obviously quite controversial, and we aim to add our latest findings to shed more light on the matter. Our objective was to evaluate improvement in conductive hearing levels in an equal number of patients who had undergone either TORP or PORP.

METHODS

This non-randomised clinical trial was conducted at Department of Otorhinolaryngology, Shifa International Hospital, Islamabad from April 2024 to April 2025 after approval from the ethical committee (IRB. No. 141-24). Patients who underwent ossicular chain reconstruction at our centre were enrolled in the prospective database. All patients with chronic suppurative otitis media (CSOM), regardless of the presence of cholesteatoma or history of previous ear surgery, were included in our study. Demographic information and baseline clinical characteristics including patient sex, laterality, stapes status, malleus status, indication of surgery, staged vs unstaged, revision ear surgery, extrusion of prosthesis and surgical technique were recorded.

The pre-operative and post-operative pure tone audiometric data were recorded. Guidelines issued by American Academy of otolaryngology - Head and Neck Cancer Surgery (AAO-HNS)[12] were followed. Pre-operative and post-operative air conduction threshold (AC) and bone conduction threshold (BC) were recorded as the average of four-tone pure-tone at 0.5, 1, 2 and 3 kHz. Pre-operative and post-operative air bone gap (ABG) was reported as air conduction (AC) threshold minus bone conduction threshold (BC). Closure of the air-bone gap (Δ ABG) was calculated as pre-operative ABG minus post-operative ABG.

The main outcome of interest was air bone gap and change in air bone gap. AAO-HNS recommend documenting mean and standard deviation of post operative air-bone gap and number of decibels of change in air bone gap (Δ ABG). The number of patients achieving post-operative air bone gap < 20 dB was also recorded.

Surgical approaches whether trans-canal or combined approach tympanoplasty were included. After disease clearance in CSOM usually for hearing reconstruction a TORP is used when supra-structure is absent and a PORP is used when supra-structure is present. All of our patients had a footplate present and mobile confirmed pre-operatively. In both TORP and PORP the length of the prosthesis is adjusted so it just touches the tympanic membrane. Cartilage augmented tympanoplasty is then done with a piece of cartilage placed in between the head of titanium prosthesis and tympanic membrane. Gel foam is placed within the middle ear cleft and over the tympanic membrane to stabilize the prosthesis, graft and flap.

Statistical analysis using IBM SPSS 23.0 (IBM Corporation, Armonk, NY, U.S.A). The categorical variables were summed together using percentages and frequency. The range and mean +/- standard deviation were used to describe continuous variables as needed. The data was parametric, and the Shapiro-Wilk test was used to evaluate the normality of all continuous variables. The t-test was used for group comparison. Paired sample t-test when comparing pre-operative and post-operative air bone gap within one group and independent sample t-test when comparing two groups. A p-value of less than 0.05 was deemed significant for statistical analyses. This study was authorized by Shifa International Hospital's Institutional Review Board.

RESULTS

A total of 36 ossiculoplasties were done by the senior author. Out of which 26 fulfilled the inclusion criteria, came for routine follow ups, and had adequate pre & post operative pure tone audiogram data. Out of 26 patients included, 13 patients underwent TORP and 13 underwent PORP. Baseline clinical characteristics and demographic data is summarized in Table-I. The mean age of patients in the TORP group was 39.2 while it was 37.6 in the PORP group. For gender and laterality, an equal half and half split between male-female and right-left. Diagnoses were categorized as mucosal disease with presence of tympanic membrane perforation (46.2%), squamous disease with presence of cholesteatoma (50%) and tympansclerosis (3.8%). The percentage of staged

ossiculoplasties was higher in the TORP group as compared to the PORP group (23.1% and 7.7% respectively). In contrast, the percentage of revision cases was higher in the PORP group as compared to the TORP group (15.4 % and 7.7 % respectively). The percentage of presence of malleus at the time of ossiculoplasty in the TORP group was 84.6 % while 61.5 % in the PORP group. The percentage of prosthesis extrusion in both the groups was similar i.e. 7.7 %.

The preoperative air-bone gap (ABG) was higher in the TORP group than in the PORP group, i.e. measuring 31.77 ± 10.05 dB in TORP group compared to 26.31 ± 10.67 dB in the PORP group. Postoperatively, the mean ABG improved to 17.54 ± 10.83 dB in the TORP group and 19.69 ± 10.34 dB in the PORP group. Both groups achieved a mean postoperative ABG below 20 dB, which meets common criteria for successful ossiculoplasty.

Within-group analysis showed that TORP significantly improved conductive hearing loss (p value < 0.01) with a large effect size. The PORP group also showed improvement that was close to statistical significance (p = 0.05), linked with a moderate effect size. The mean ABG improvement was 14.23 dB in the TORP group and 6.62 dB in the PORP group. This finding indicates a greater gain in hearing after TORP placement.

Table-III shows results of an independent sample t-test run to compare effectiveness of TORP vs PORP. Results were not found to be significantly different in-terms of effectiveness (p=0.185). Hedges'g effect size was -0.519 for TORP vs PORP.

TABLE-I

Characteristic of demography in both groups.

Characteristic		All Patients (n = 26)	TORP (n = 13)	PORP (n = 13)
Age yrs [mean (range)]		38.4 (12-65)	39.2 (12-65)	37.6 (17-65)
Sex	Male	13 (50%)	7 (53.8%)	6 (46.2%)
	Female	13 (50%)	6 (46.2%)	7 (53.8%)
Side	Right	13 (50%)	7 (53.8%)	6 (46.2%)
	Left	13 (50%)	6 (46.2%)	7 (53.8%)
Surgery indication	Mucosal disease	12 (46.2%)	4 (30.8%)	8 (61.5%)
	Squamous disease	13 (50%)	8 (61.5%)	5 (38.5%)
	Tympanosclerosis	1 (3.8%)	1 (7.7%)	0
Malleus status	Present	19 (73.1%)	11 (84.6%)	8 (61.5%)
	Absent	7 (26.9%)	2 (15.4%)	5 (38.5%)
Staged	Yes	4 (15.4%)	3 (23.1%)	1 (7.7%)
	No	22 (84.6%)	10 (76.9%)	12 (92.3%)
Revision surgery	Yes	3 (11.5%)	1 (7.7%)	2 (15.4%)
	No	23 (88.5%)	12 (92.3%)	11 (84.6%)
Prosthesis extrusion	Yes	2 (7.7%)	1 (7.7%)	1 (7.7%)
	No	24 (92.3%)	12 (92.3%)	12 (92.3%)

TABLE-II

Surgery	Timepoint	Mean ABG (SD)	Mean Difference	t (df)	p-value	Effect size (Hedges' g)
TORP	Pre-op	31.77 (10.05)				
	Post-op	17.54 (10.83)				
			14.23	3.42 (12)	0.003	0.889
PORP	Pre-op	26.31 (10.67)				
	Post-op	19.69 (10.34)				
			6.62	1.78 (12)	0.05	0.462

TABLE-I				
Group	Mean Difference (SD) [Post – Pre]	t (df)	P-value (two-sided)	Effect Size (Hedges' g)
TORP	14.23 (14.98)	3.42 (12)		
PORP	6.62 (13.41)	1.78 (12)		
TORP - PORP	-7.62 (5.58)	-1.37 (24)	0.185	-0.519

DISCUSSION

For many years, ossiculoplasty has been carried out using various materials and techniques. Titanium's low mass, dependability, and biocompatibility have made it a popular material. Numerous studies showing the results of these titanium prosthesis have been published. No research articles comparing the effectiveness of TORP and PORP in the Pakistani population have yet been published.

The present study evaluated hearing outcomes following ossiculoplasty using PORP and TORP prostheses, with particular emphasis on postoperative air–bone gap (ABG) closure. Both prosthesis types resulted in a mean postoperative ABG below 20 dB (TORP: 17.54 ± 10.83 dB; PORP: 19.69 ± 10.34 dB), meeting the widely accepted benchmark for surgical success. These findings are consistent with previously published literature, where mean ABG closures typically ranged between 10–20 dB following ossiculoplasty (Dornhoffer, 1998[13]; Yung, 2006.[14]

Interestingly, while some studies (e.g., Dornhoffer, 1998[13] reported 69% of PORP cases and 35% of TORP cases had excellent hearing results (< or = 10 dB PTA-ABG), whereas 31% and 50% of PORP and TORP cases had good results (11 to 20 dB PTA-ABG), our results suggest that TORP can be equally or more effective, particularly in patients with larger preoperative ABGs — a trend observed in our study where the TORP group had a higher baseline ABG (31.11 ± 1.05 dB) than the PORP group (26.31 ± 1.67 dB). This difference may account for the greater hearing gain observed in the TORP group, as patients with more severe conductive deficits may benefit more from total ossicular replacement.

The most recent meta analysis published in February 2023 on this subject concludes an average improvement in air-bone gap (ABG) of about 12 dB following titanium PORP placement and 17 dB with TORP placement. It also states that a greater proportion of patients receiving PORP placements achieve a "successful" postoperative ABG of less than 20 Db.[15] Our results are comparable with an average improvement in ABG in the PORP group of 6.62 dB and in the TORP group of 14.23 dB. All our patients fall under the 20 dB ABG window post operative. It is important to note here that our PORP patients had a lower pre-operative air bone gap of 26.31 as compared to 31.77 of the TORP group, reflecting less room for improvement.

In our study TORP significantly improved conductive hearing loss (p value < 0.01). Although the difference between TORP and PORP did not reach statistical significance, the moderate effect size (Hedges' g = -0.519) suggests that TORP may be more effective in reducing the air–bone gap. This trend might become statistically significant with a larger sample size, warranting further investigation in larger, prospective studies.

Several studies have evaluated hearing outcomes following ossiculoplasty, with particular focus on air-bone gap (ABG) closure and post-operative air-bone gap less than 20 dB as an indicator of surgical success. The type of prosthesis used, integrity of the middle ear structures, and surgical technique are all key factors affecting outcomes. In our study, both TORP and PORP achieved mean post-operative ABG values below 20 dB, but TORP showed a larger mean ABG improvement with 14.2 dB.

Our study possesses notable strengths that enhance the reliability of our results and conclusions drawn from them, particularly as it adds to the limited literature available in this area of clinical practice. Along with being one of the first comparisons between the two prostheses in Pakistan and providing novel regional data, it also contributes on the global scale by utilizing standardized, internationally accepted ways of outcome measures. While other similar

studies have cited high variability in the surgical procedures as a limitation, our study minimized variability by having all the procedures performed by the same senior surgeon. This aimed to maintain uniformity in the surgical technique and handling of the prosthesis while reducing inconsistencies introduced by differing levels of surgical expertise. This approach allowed a more thorough comparison of the outcomes with minimal influence of external factors that could have brought forth unanticipated differences in hearing results.

Despite having several strengths, one of the limitations worth noting is that, as a single-center study, our results may not be a complete representation of the outcomes across other surgical settings in Pakistan. Nevertheless, a controlled environment with unvarying surgical and audiometric protocol was crucial to conduct our research to adequately compare TORP and PORP. Another limitation was keeping the follow-ups limited to short-term, which may have not allowed us to record long-term complications but it was necessary in our case. This was primarily due to limitations relating to the academic timeline of the degree program, which required the studies and the manuscript to be completed and submitted within a certain timeframe. As a result, the long-term outcomes were not able to be assessed. Future research with longer follow up periods are necessary to better understand the long-term effects and sustainability of the results.

This study lays a foundation for future research to further expand through multi-center trials and longer follow-up periods. Such studies would better satisfy the demands to represent general surgical settings across Pakistan and lead to a more comprehensive evaluation of long-term outcomes. The insights from our work may eventually allow evidence-based refinement in ossicular reconstruction, aiming to reduce complication rates and improve the patients' postoperative quality of life.

CONCLUSION

As our research indicates, both procedures improve conductive hearing loss, though in select patients, primarily those with more severe preoperative hearing loss, TORP appears to be, on average, more advantageous.

According to this study, both PORP and TORP are viable ossicular reconstruction options, though the latter seems especially beneficial in patients with substantial ossicular chain damage.TORP seems especially beneficial in patients with advanced ossicular chain damage. We recommend that the choice of prosthesis be made based on the operative findings on the continuity of the ossicular chain, stapes mobility, and the middle ear anatomy, rather than on the historical biases pertaining to PORP and TORP. Surgeons must take preoperative hearing loss into account and should provide patients with realistic expectations based on the anticipated outcomes of surgical intervention for their specific middle ear disease.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

SOURCE OF FUNDING

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Muhammad Saqib:** Writing, data collection.
2	**Muhammad Azeem Aslam:** Data entry.
3	**Ramla Mehak Khan:** Data collection.
4	**Hadia Wali:** Proof reading.