International Journal of Otorhinolaryngology and Head and Neck Surgery
Kumar P et al. Int J Otorhinolaryngol Head Neck Surg. 2026 Aug;12(4):550-555
https://www.ijorl.com
pISSN 2454-5929 | eISSN 2454-5937
DOI: https://dx.doi.org/10.18203/issn.2454-5929.ijohns20262376

Original Research Article

Randomized control trial for comparison of teflon and titanium piston in stapedotomy

Pankaj Kumar, Moudipa Chatterjee*, Ajay Kumar Gupta, Nitin Kumar

Department of ENT, Dr. Baba Saheb Ambedkar Medical College and Hospital, Delhi, India

Received: 09 February 2026
Revised: 19 July 2026
Accepted: 21 July 2026

***Correspondence:**
Dr. Moudipa Chatterjee,
E-mail: moudipa17@gmail.com

ABSTRACT

Background: This study aims to compare the improvement in hearing after stapedotomy using Titanium versus Teflon pistons in patients with otosclerosis, and to assess postoperative auditory and vestibular symptoms, such as tinnitus and vertigo, in both groups.
Methods: A randomized controlled trial was carried over a period of 12 months.44 patients aged 18-60 with otosclerosis were divided into 2 groups by random allocation. Group A was subjected to stapedotomy with Teflon piston and group B received Titanium piston. All patients were followed up post operatively at 3, 6 and 12 weeks, to assess audiological outcomes and post-operative symptoms.
Results: The mean pre-operative air-bone gap (ABG) was 32.95±4.83 dB in the Teflon group and 33.23±5.19 dB in the Titanium group, with no significant difference. At 3 and 6 weeks post operatively, mean ABG further improved parallelly in both groups. At 12 weeks, final mean ABG was 9.68±3.03 dB in the Teflon group and 11.05±3.86 dB in the Titanium group, with no statistically significant difference. Excellent ABG closure (≤10 dB) was achieved in 72.7% of Teflon patients and 59.1% of Titanium patients. Post op tinnitus and vertigo were also comparable in both groups.
Conclusions: Stapedotomy using either Teflon or Titanium piston prostheses results in significant and clinically meaningful improvement in hearing among patients with otosclerosis. Thus, both pistons can be effectively used based on availability and practical considerations to achieve excellent functional hearing outcomes when meticulous surgical technique is employed.

Keywords: Otosclerosis, Stapedotomy, Teflon piston, Titanium piston

INTRODUCTION

Otosclerosis is a primary disorder of bone remodelling that uniquely involves the otic capsule and most often leads to fixation of the stapes footplate, producing a slowly progressive conductive hearing loss with a characteristically normal-looking tympanic membrane.[1,2] Epidemiologically, the "clinical" disease represents only a fraction of "histologic" otosclerosis discovered on temporal-bone examination.[3] The condition typically manifests in early to mid-adulthood, most often presenting in the third or fourth decade of life, and tends to worsen gradually over subsequent years.[4] Surgery remains the mainstay treatment for otosclerosis. Surgery on the stapes has evolved through a long arc of trial, refinement, and standardization. Stapes surgery dates back to 1956 when Shea performed the first modern stapedectomy using a Teflon stapes replacement prosthesis.[5,6] From there, "stapedectomy" gradually gave way to "small-fenestra stapedotomy," a technique designed to preserve inner-ear integrity by creating a controlled fenestra in the fixed footplate and coupling a

piston prosthesis to the long process of the incus, thereby re-establishing efficient energy transfer to the vestibule while minimizing perilymph disturbance.[7,8] There are numerous types of prostheses and materials available for stapes surgery, for instance, big easy piston, Titanium soft clip, nitinol, and smart prostheses.[9,10] Teflon piston is the most commonly used prostheses in stapedotomy. Titanium implants are relatively new in the evolution of stapes prosthesis.[11] Optimally, patients undergoing stapes surgery receive long term hearing improvement. However, with traditional stapes prostheses that attach to the long process of the incus, there is always the risk of incus necrosis. Thus, the prosthesis is an engineered interface that must transmit sound efficiently, minimize the risk of incus necrosis, remain stable in a dynamic middle-ear environment, and do so with minimal biological or mechanical harm.[12]

This is where the choice between Teflon (fluoroplastic/ polytetrafluoroethylene-PTFE) and Titanium pistons becomes clinically meaningful rather than merely preferential. Fluoroplastic pistons gained popularity because they are inert, stable, and have a long track record, and many classic designs pair a PTFE shaft with a metal loop that is manually crimped onto the incus. Titanium pistons, in contrast, are valued for their high strength-to-weight ratio, corrosion resistance, and favourable biocompatibility profile in middle-ear environments, and they have enabled design families that aim to make fixation more consistent—either by refined crimp geometries or clip/"soft-clip" mechanisms intended to reduce the technical variability of manual crimping.[13,14] Evidence comparing fluoroplastic and Titanium-based options suggests that, in many settings, both families can deliver strong average hearing gains, but subtle differences appear depending on prosthesis design, frequency range, and how "attachment security" is operationalized. A randomized clinical study by Shiraz et al compared a Titanium soft-clip prosthesis with a fluoroplastic Causse loop piston and reported broadly similar short-term postoperative hearing outcomes overall, while noting frequency-specific differences (with the fluoroplastic piston showing better short-term ABG improvement at some low frequencies in that cohort).[15] Retrospective matched comparisons of Titanium and fluoroplastic designs also tend to show close overall performance in speech frequencies, with occasional advantages appearing at specific frequencies.[16] Surgeons see excellent closures with both options, yet small differences in ABG distribution, low-frequency performance, operative handling, and longer-term stability can translate into different patient experiences and different revision burdens. Mangham et al performed a retrospective study comparing Titanium and Teflon piston. Comparing 2 pistons designated 0.6 mm in diameter, the Teflon piston produced better hearing results. Although, actual piston diameter differed between devices that contributed to the superior results with the larger Teflon piston. Also, the titanium piston performed better with a small stapes fenestra diameter that suggests an advantage for Titanium over Teflon in certain conditions.[17] Hence it is important to identify whether one material/design combination offers more consistent ABG closure, better low-frequency performance, and comparable (or improved) safety and durability, thereby guiding prosthesis selection with evidence rather than habit.

METHODS

A randomized controlled trial was carried out in the Department of Otorhinolaryngology (ENT) at a tertiary care teaching hospital in New Delhi, over a period of 12 months, from January 2025 to December 2025, following approval from the Institutional Ethics Committee. This duration included patient recruitment, preoperative evaluation, surgical intervention, postoperative follow-up, and data collection. 44 patients, aged 18-60 years, irrespective of gender, diagnosed with otosclerosis were recruited as study subjects. All the subjects presented with conductive hearing loss and normal tympanic membrane with Impedance audiometry showing 'as' type tympanogram and absent stapedial reflex, along with an air–bone gap of at least 25 dB on pure tone audiometry. Patients who were excluded from the study were those with pure sensorineural hearing loss or mixed hearing loss, only hearing ear, congenital or acquired inner ear malformations, previous vertigo or balance disorders, active stage of otosclerosis, and history of chronic middle ear infection. Each enrolled patient was followed up postoperatively at 3 weeks, 6 weeks, and 12 weeks, as per the study protocol, to assess audiological outcomes and postoperative symptoms.

Patients were randomly allocated into two groups:

Group A

Patients undergoing endoscopic stapedotomy using Teflon piston (diameter approximately 0.4–0.6 mm).

Group B

Patients undergoing endoscopic stapedotomy using Titanium piston (length 4.0–4.75 mm, diameter 0.5 mm).

All patients underwent detailed preoperative evaluation including history taking and thorough ENT examination. Audiological assessment was performed using pure tone audiometry and impedance audiometry. Stapedial reflex testing was also performed. Following routine investigations and pre-anaesthetic clearance, patients underwent endoscopic stapedotomy. Group-specific prostheses were used according to randomization. Intraoperative findings, piston length, operative time, and perioperative complications were documented. Patients were discharged as per institutional protocol and advised regular follow-up. Audiological evaluation was performed preoperatively and postoperatively at 3 weeks, 6 weeks, and 12 weeks. Each follow-up visits included

otoscopic examination, pure tone audiometry, and assessment of tinnitus and vertigo. All findings were recorded systematically.

Ethical considerations

Ethical clearance was obtained from the Institutional Ethics Committee prior to initiation of the study. Informed written consent was obtained from all participants. Confidentiality of patient information was maintained throughout the study. Participation was voluntary, and patients were free to withdraw at any stage without affecting their standard medical care. No additional financial burden was imposed on the participants.

RESULTS

A total of 44 subject was included in the study, 22 in each group on the basis of the type of piston used for stapes surgery. Figure 1 shows a Titanium and Teflon prosthesis in situ.

Mean age of patients in the Teflon group was 42.45±8.92 years, while in titanium group it was 33.05±9.78 years.

The primary parameter that was tested among the patients was the change seen in AB gap from pre-operative period to subsequent follow up visits at 3,6 and 12 weeks after the surgery. The mean pre-operative ABG was comparable between Teflon (32.95±4.83 dB) and Titanium (33.23±5.19 dB) groups. Table 1 presents the post-operative ABG at 3, 6- and 12-week follow-up, representing the primary outcome measure. Both groups showed substantial improvement from baseline. At 12 weeks post op the Teflon group achieved a mean ABG of 9.68±3.03 dB compared to 11.05±3.86 dB in the Titanium group. The difference was not statistically significant (p=0.200), indicating comparable hearing outcomes with both prostheses.

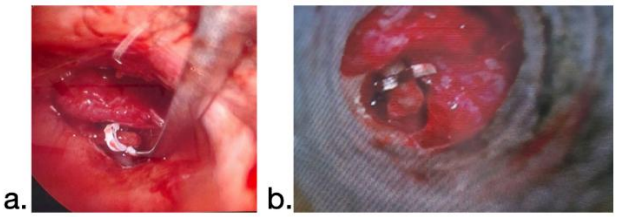

Figure 1: (a) Teflon prosthesis in situ and (b) Titanium piston in situ.

Table 1: Mean air-bone gap measured in both groups over the follow up period.

Time points	Teflon mean (dB)	Teflon SD	Titanium mean (dB)	Titanium SD
Pre-operative	32.95	4.83	33.23	5.19
3 weeks	14.68	3.03	16.05	3.86
6 weeks	11.68	3.03	13.05	3.86
12 weeks	9.68	3.03	11.05	3.86

Both groups showed progressive improvement over follow-up period.

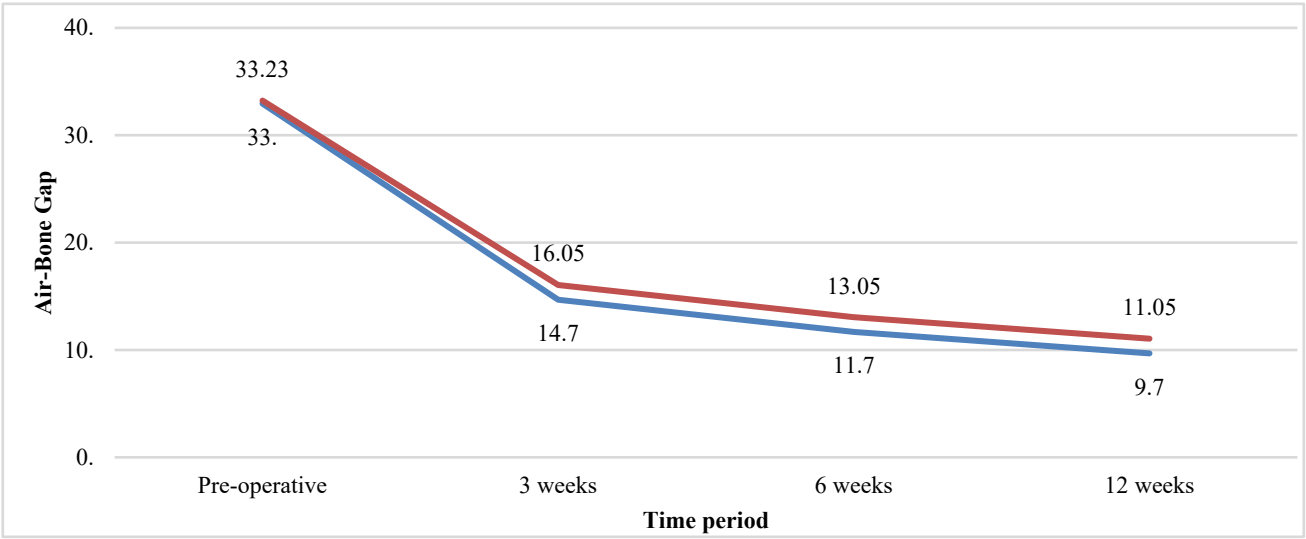

Figure 2: Trend of air-bone gap over time.

Figure 2 illustrates the trend of air-bone gap over the follow-up period. Both groups demonstrated progressive and parallel improvement from pre-operative values to 12 weeks post-operatively. The similar trajectory of improvement indicates that both Teflon and Titanium prostheses provide comparable functional outcomes over time.

Table 2: Comparison of ABG improvement between groups.

Groups	Mean Improvement (dB)	SD	Range (dB)
Teflon (n=22)	23.27	4.51	15-31
Titanium (n=22)	22.18	4.34	15-30

t=0.818, p=0.418.

Table 3: Distribution of patients according to ABG closure categories.

ABG closures	Teflon (n=22)	%	Titanium (n=22)	%
Excellent (≤10 dB)	16	72.7	13	59.1
Good (11-20 dB)	6	27.3	9	40.9

χ^2=0.405, df=1, p=0.525.

Table 4: Distribution of patients according to post-operative tinnitus status.

Tinnitus statuses	Teflon (n=22)	%	Titanium (n=22)	%
Improved	12	54.5	12	54.5
Unchanged	2	9.1	3	13.6
Worsened	2	9.1	2	9.1
Absent pre-op	6	27.3	5	22.7

Similar tinnitus outcomes in both groups.

Table 5: Distribution of patients according to pre and post-operative vertigo.

Vertigo statuses	Teflon (n=22)	%	Titanium (n=22)	%
Preoperative	2	9.1	2	9.1
Postoperative	2	90.9	4	18.2

Fisher's Exact Test, p=0.664.

Table 2 compares the magnitude of ABG improvement between groups. The Teflon group showed a mean improvement of 23.27±4.51 dB while the Titanium group achieved 22.18±4.34 dB improvement. Both groups demonstrated substantial hearing gain with no statistically significant difference (p=0.418).

Table 3 shows the distribution of ABG closure categories at 12 weeks. Excellent closure (≤10 dB) was achieved in 72.7% of Teflon patients and 59.1% of Titanium patients. Good closure (11-20 dB) was observed in the remaining patients. The difference was not statistically significant (p=0.525), indicating similar categorical outcomes.

Table 4 describes the pre and post-operative tinnitus outcomes. Tinnitus was present in the majority of patients in both groups preoperatively (Teflon: 72.7%, Titanium: 77.3%). Tinnitus improvement was observed in 54.5% of patients in both groups. Tinnitus worsened in only 9.1% of patients in each group. The similar distribution of tinnitus outcomes suggests that prosthesis material does not significantly influence post-operative tinnitus status.

Pre-operatively vertigo was uncommon in both groups, being present in only 9.1% of patients in each group. Post-operative vertigo was present in 9.1% of Teflon patients and 18.2% of Titanium patients. This difference was not statistically significant (p=0.664), indicating that both prosthesis types have comparable vestibular safety profiles (Table 5).

DISCUSSION

The aim of this study was to compare the audiological outcomes and safety profiles of Teflon and Titanium piston prostheses following stapedotomy in patients with otosclerosis-induced conductive hearing loss. The primary objective was to evaluate and compare postoperative air-bone gap closure achieved with each prosthesis over a defined follow-up period. Secondary objectives included assessment of the magnitude of hearing improvement, categorical hearing outcomes, and postoperative auditory and vestibular symptoms such as tinnitus and vertigo, as well as prosthesis-related complications. Pre-operative audiological assessment demonstrated comparable severity of conductive hearing loss between the two study groups. Early postoperative audiological outcomes demonstrated substantial improvement in both prosthesis groups. At 3 weeks following stapedotomy, the mean air-bone gap (ABG) reduced from pre-operative values of approximately 33 dB to 14.68±3.03 dB in the Teflon group and 16.05±3.86 dB in the Titanium group. Although the Teflon group showed numerically lower ABG values, the intergroup difference was not statistically significant (p=0.200), indicating comparable early hearing restoration. These findings closely parallel those reported by Velankar et a

al, who assessed hearing outcomes at 3 weeks post-stapedotomy and observed nearly identical ABG closure between Teflon and titanium prostheses, with no statistically significant difference.[18] At 6 weeks post-operatively, continued improvement in hearing thresholds was observed in both groups. Ghonem et al, also evaluated postoperative ABG at multiple intervals and found no significant difference between Teflon and titanium prostheses at 1 and 3 months follow-up.[19] Final audiological evaluation at 12 weeks demonstrated excellent hearing restoration in both groups. The mean ABG at this time point was 9.68±3.03 dB in the Teflon group and 11.05±3.86 dB in the Titanium group, with no statistically significant intergroup difference (p=0.200). These values represent clinically meaningful closure of the conductive component of hearing loss. Ataide et al similarly reported a mean postoperative ABG of 9.1 dB using a titanium Fisch-type prosthesis, with 96.9% of patients achieving ABG ≤20 Db.[20] Faramarzi et al (2020) also demonstrated similar final ABG closure between fluoroplastic and titanium pistons, despite minor frequency-specific differences.[21] The present study's findings reinforce the conclusion that both Teflon and Titanium pistons achieve equivalent and satisfactory final hearing outcomes.

Categorical assessment of postoperative hearing outcomes at 12 weeks demonstrated excellent ABG closure (≤10 dB) in 72.7% of patients in the Teflon group and 59.1% in the Titanium group, while the remaining patients achieved good closure (11–20 dB). The difference was not statistically significant (χ^2=0.405, p=0.525). Importantly, 100% of patients in both groups achieved ABG ≤20 dB, indicating universal surgical success. Comparable success rates have been reported in previous studies. Ataide et al documented ABG ≤20 dB in 96.9% of patients using titanium prostheses.[20] Immordino et al reported mean ABG closure of approximately 21 dB with different titanium prosthesis designs, confirming high success rates.[22] The absence of significant differences in success rates reinforces that prosthesis selection should be guided by surgical preference and long-term considerations rather than expectations of differential hearing improvement.

Post-operative tinnitus outcomes were comparable between both study groups. Improvement in tinnitus was observed in 54.5% of patients in both the Teflon and Titanium groups, while tinnitus worsened in 9.1% of patients in each group. The remaining patients had either unchanged tinnitus or were asymptomatic pre-operatively. Similar observations were reported by Ghonem et al, who found no statistically significant difference in tinnitus improvement between titanium and Teflon prosthesis groups despite substantial hearing restoration.[19] Faramarzi et al also documented comparable postoperative auditory symptom outcomes, including tinnitus, between both prosthesis materials.[15] The consistency of tinnitus outcomes across multiple studies reinforces the understanding that tinnitus improvement is secondary to hearing gain and is not materially affected by prosthesis composition.

Evaluation of postoperative vestibular symptoms demonstrated low and comparable vertigo rates between the two groups. Post-operative vertigo was reported in 9.1% of patients in the Teflon group and 18.2% of patients in the Titanium group, with no statistically significant difference (p=0.664). Ghonem et al similarly reported transient postoperative vertigo in a small proportion of patients, with no significant difference between prosthesis groups.[19] The systematic review by Wegner et al emphasized that vestibular outcomes are more strongly influenced by surgical handling of the inner ear than by prosthesis characteristics.[23] The absence of severe or persistent vertigo in the present study supports the vestibular safety of both materials.

The demonstration of comparable hearing outcomes and safety profiles with both Teflon and Titanium pistons suggests that prosthesis material does not significantly influence short-term audiological success following stapedotomy. This equivalence allows surgeons greater flexibility in prosthesis selection based on availability, cost considerations, and personal surgical experience rather than perceived differences in hearing outcomes.

Limitations

Despite the strengths of the present study, the relatively small sample size may limit the statistical power to detect subtle differences between prosthesis groups. The short duration of follow-up also restricts assessment of long term hearing stability and delayed complications such as late piston displacement. Thus, future research should focus on multicenter randomized controlled trials with larger sample sizes to validate and extend the findings of the present study.

CONCLUSION

This randomized controlled trial showed that stapedotomy with either Teflon or Titanium piston prostheses significantly improves hearing in patients with otosclerosis-related conductive hearing loss. Both prostheses reduced the air-bone gap from comparable pre-operative values with sustained improvement observed throughout follow-up. Although the Teflon group demonstrated slightly better audiological outcomes, differences were not statistically significant, indicating comparable effectiveness. Hearing gain exceeded 22 dB in both groups. Tinnitus improvement, low rates of transient vertigo, and absence of major complications confirmed similar complication profile. Prosthesis choice may therefore depend on surgeon preference and availability. Thus, Stapedotomy remains a highly effective surgical procedure for otosclerosis, and both Teflon and Titanium pistons can be confidently utilized to achieve excellent functional hearing outcomes when appropriate patient selection and meticulous surgical technique are employed.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kumar P, Chatterjee M, Gupta AK, Kumar N. Randomized control trial for comparison of teflon and titanium piston in stapedotomy. Int J Otorhinolaryngol Head Neck Surg 2026;12:550-5.