

## Original Research Article

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# Comparative study showing relevance of prosthesis diameter and hearing outcome in stapes surgery

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## ABSTRACT

**Background:** Otosclerosis presents as conductive hearing loss, stapedotomy is the treatment for otosclerosis, and different sizes of piston diameter are available for the procedure. Aims and objectives were to study and compare hearing improvement between the 0.4 and 0.6 mm sizes of teflon piston in stapedotomy.

**Methods:** It was a prospective randomized controlled trial. Patients fulfilling inclusion criteria were subjected for small fenestra stapedotomy. Patients were divided into two groups after randomization into group A (with 0.4 mm piston diameter) and group B (with 0.6 mm piston diameter). The hearing outcome with standard audiological assessment was performed at one month and six months postoperatively.

**Results:** Comparison of 1 month AB gap among the patients with 0.4 mm piston and 0.6 mm piston showed that there was no statistically significant difference among both the groups of patients (independent t test p value=0.699). Comparison of 6 month AB gap among the patients with 0.4 mm piston and 0.6 mm piston showed that there was no statistically significant difference among both the groups of patients (independent t test p value=0.54).

**Conclusions:** There was no significant difference in hearing improvement among the individual methods (piston size 0.4 and 0.6) with each other both in 1 month post-operative and 6 month post-operative follow up. Hence, we conclude that there is no relevance of different diameter of teflon piston prosthesis (0.4 mm versus 0.6 mm) as far as hearing outcome is concerned.

**Keywords:** Otosclerosis, Piston diameter, Size of piston, Stapedotomy, Teflon piston

## INTRODUCTION

Otosclerosis is a hereditary localized disease of the bone derived from the otic capsule characterized by alternating phase of bone resorption and formation.<sup>1</sup>

Attempts to overcome the deafness due to stapedial ankylosis have been in the direction of bypassing stapes or mobilizing stapes or replacing stapes suprastructure with prosthesis.<sup>2</sup>

Small fenestra stapedotomy is one of the standard procedures for treatment of Otosclerosis.<sup>3</sup>

Shea introduced Stapes surgery in 1956, after that many developments have been made.<sup>4</sup> Different prosthesis of varying size, shape and type has been developed since then. Among the variables, diameter of prosthesis is one of the factors.<sup>5</sup> Different ranges of piston diameter from 0.3 to 0.8mm are available.<sup>6</sup> We conducted this study to know the effect of piston diameter of 0.4 and 0.6 mm and hearing outcome in our patients.

## Objective

To study and compare hearing improvement between the 0.4 and 0.6 mm sizes of teflon piston in stapedotomy.

## METHODS

A prospective randomized controlled trial study was conducted in the Department of ENT at Dr. Babasaheb Ambedkar Memorial Hospital, Mumbai, India.

Duration of study was from June 2016 to May 2018. An institute ethics committee clearance was obtained before the commencement of the study. All the patients suspected to have a diagnosis of otosclerosis were subjected to pure tone audiometry and tympanometry. A total of 42 patients were studied ranging from 20 to 60 years. These patients were randomized into two groups based on using table of random numbers into two Group A: 0.4 mm diameter piston (n=21) and Group B: 0.6 mm diameter piston (n=21). Every patient was subjected to detailed history and examination including otoscopic examination.

Patient selection was done according to the following criteria:

### Inclusion criteria

Conductive and mixed hearing impairment more than 30 dB air bone gap with intact tympanic membrane (with A or As type of curve on impedance audiometry); age group of 20 to 60 years.

### Exclusion criteria

Sensorineural hearing impairment; conductive hearing impairment less than 30 dB; fluctuating hearing loss; history of any previous ear surgery; history of chronic suppurative otitis media; tympanosclerosis; history of trauma/ pre-existing ear perforation.; B or C or Ad type of curve on impedance audiometry; current vertigo or balance problems such as active meniere disease or especially in the case of superior semicircular canal dehiscence, in which the corresponding air-bone gap can potentially mimic otosclerosis; active external or middle ear infection.

After fulfilling the inclusion and exclusion criteria, all the patients were subjected to a standard small fenestra stapedotomy technique by endomeatal approach performed by a single surgeon. All the patients had the insertion of teflon prosthesis of either 0.4 or 0.6 mm prosthesis. The patients were evaluated subjectively for hearing improvement and objectively with post-operative audiogram done at 1 month and 6 months. Post-operative air bone gap closure was calculated by analyzing the postoperative air conduction and best preoperative bone conduction thresholds. Regarding the reporting of hearing results we followed the guidelines of committee on

hearing and equilibrium guidelines for the evaluation of results of treatment of conductive hearing loss. American Academy of Otolaryngology-Head and Neck Surgery Foundation.<sup>7</sup>

### Surgical technique

Surgery was performed under intravenous sedation with monitoring. The patient was placed in supine position with the head partially tilted to the opposite side and neck slightly extended with 30 degree elevation of head end of table. Local anesthetic blockage of the ear with 2% xylocaine and 1:200,000 adrenaline was given. We used endomeatal approach with adequate size ear speculum. Endomeatal Rosen's incision was taken in all cases and a tympanomeatal flap was raised medially. Posterosuperior bony overhang was curetted out till exposure of lower 2/3<sup>rd</sup> of long process of incus, base of pyramid and tympanic segment of facial nerve. After adequate exposure ossicles palpated from lateral to medial to rule out Malleus head fixation. Foot plate fixation confirmed. The distance between the oval window and the long process of the incus was determined and trial of piston done to assess length of piston required. If posterior crura found thick, partial drilling was done for adequate exposure of posterior half of footplate. Fenestration was made in footplate of stapes by gradually increasing size of perforators. The incudo stapedial joint was disarticulated. The stapedial tendon was cut. Cruras of the stapes were fractured and then stapes suprastructure removed. Teflon prosthesis with a diameter of 0.4 mm or 0.6 mm were used in the respective divided groups and crimped to the long process of the incus and the oval window sealed with small pieces of gelfoam. The tympanomeatal flap was repositioned back and subjective hearing improvement on the operating table confirmed.

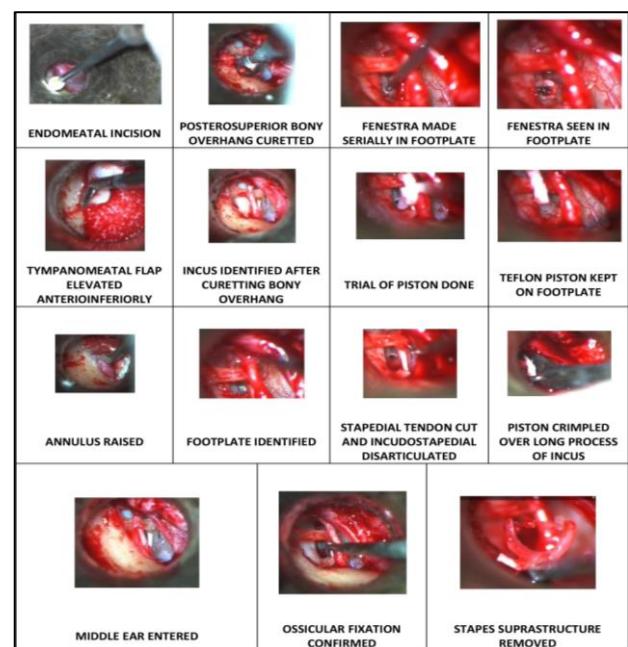


Figure 1: Steps of stapedotomy.

### *Statistical analysis*

*Qualitative data:* Pearson's chi square test was applied to test the relationship of categorised independent and dependent variable. A p value (significance) of  $<0.05$  was deemed statistically significant.

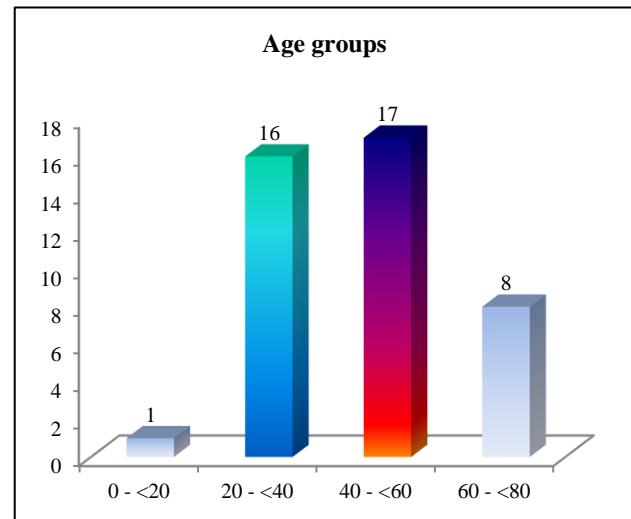
**Quantitative data:** Normality of the quantitative variables were assessed by Q-Q plots. Mann Whitney U test and Kruskal Wallis test was used to test independent quantitative variables that were not normally distributed with dichotomous and multiple grouping variables respectively.

## RESULTS

Among all the patients included in the study (n=42), mostly common patients were belonging to age group of 40-60 years, 17 (42.5%) followed by 16 (37.5%) belonged to age group of 20-40 years of age group, 8 (17.5%) belonged to 60-80 years age and only 1 patient was less than 20 years. The mean age of the patients was  $44.5 \pm 12.85$  years. Hence the study population belonged to mostly a late middle age group.

Among the patients selected for the final study and analysis 26 (65%) were males and 16 (35%) were females. Higher male preponderance may be due to fitness for duty in our organization.

The mean air bone gap after implantation of 0.4 Teflon piston, 1 month post-operative mean air bone gap was 26.42 as compared to 39.28 preoperative AB gap. The air bone gap was 17.4 after 6 months post operatively. There was significant decrease in AB gap after the implantation (ANOVA p value<0.001). Hence it can be concluded that there was significant improvement after 0.4 mm Teflon piston implant (Table 1).



**Figure 2: Age distribution of the patients.**

**Table 1:** Difference of AP gap pre op and post-operatively in patients with implant piston size 0.4 mm.

A-B gap piston size (0.4 mm)	Observation	Mean	Variance	Std. deviation	P value
<b>Pre-operative</b>	21	39.2857	81.9643	9.0534	
<b>Post-operative period- 1 month</b>	21	26.4286	104.1071	10.2033	<0.001
<b>Post-operative period- 6 months</b>	21	17.4048	51.0655	7.146	

**Table 2: Difference of AB gap pre op and post operatively in patients with implant piston size 0.6mm.**

A-B gap (piston size 0.6 mm)	Observation	Mean	Variance	Std. deviation	P value
Pre-operative	21	41.1842	89.1447	9.4416	
Post-operative period- 1 month	21	26.7105	88.9254	9.43	<0.001
Post-operative period- 6 months	21	17.7632	56.1769	7.4951	

**Table 3: Comparison of pre-operative AB gap with 0.4 mm and 0.6 mm piston.**

Pre-operative A-B gap	Observation	Mean	Variance	Std. deviation	P value
0.4	21	39.2857	81.9643	9.0534	0.32
0.6	21	42.1429	93.3036	9.6594	

**Table 4: Comparison of 1 month post-operative AB gap with 0.4 mm and 0.6 mm piston.**

Post-operative AB gap at 1 month	Observation	Mean	Variance	Std. deviation	P value
0.4	21	26.428	104.107	10.203	0.699
0.6	21	27.619	92.172	9.600	

**Table 5: Comparison of 6-month post-operative AB gap with 0.4 and 0.6 mm piston.**

Post-operative AB gap at 1 month	Observation	Mean	Variance	Std. deviation	P value
0.4	21	17.4048	51.0655	7.146	
0.6	21	18.8095	62.8869	7.9301	0.54

The mean air bone gap after implantation of 0.6 mm Teflon piston, 1 month post-operative mean air bone gap was 26.71 as compared to 41.18 preoperative AB gap. The air bone gap was 17.76 after 6 months post operatively. There was significant decrease in AB gap after the implantation (ANOVA p value<0.001). Hence it can be concluded that there was significant improvement after 0.6 mm Teflon piston implant (Table 2).

Comparison of preoperative AB gap among the patients with 0.4 mm piston and 0.6 mm piston showed that there was no statistically significant difference among both the groups of patients (Independent t test p value=0.32). Hence it can be concluded that the patients were comparable on the basis of preoperative AB gap.

Comparison of 1 month AB gap among the patients with 0.4mm piston and 0.6 mm piston showed that there was no statistically significant difference among both the groups of patients (Independent t test p value=0.699). Hence it can be concluded that the improvement of patients were similar on the basis of 1 month post-operative AB gap and not one procedure had better effectiveness than other (Table 4).

Comparison of 6 months AB gap among the patients with 0.4mm piston and 0.6 mm piston showed that there was no statistically significant difference among both the groups of patients (independent t test p value=0.54). Hence it can be concluded that the improvement of patients was similar on the basis of 6-month post-operative AB gap and not one procedure had better effectiveness than other.

Finally comparing the mean AB gap in preoperative patients, 1 month post-operative part and 6 month post-operative, it can be concluded that, both the methods are effective in terms of decreasing AB gap. But there was no significant difference among the individual methods (piston size 0.4 and 0.6) with each other both in 1 month post-operative and 6 month post-operative follow up.

## DISCUSSION

We conducted this study to know the relevance different size of stapes piston diameter and its implication on hearing outcome.

To reduce the risk of bias, we conducted prospective randomized study involving 42 patients, the audiologist who performed the audiological test was blinded, and we followed strict recommendations of the committee on hearing and equilibrium for evaluation of the results.<sup>7</sup> All

the surgeries was performed by a single surgeon, using a standard surgical technique (small fenestra stapedotomy), and with same piston manufacturer. We followed the patients at one and six months to reduce the loss of patients during follow up.

Hearing gain was assessed by comparing pre and post op audiogram at 1 month postop and 6 months post op.

In our study, patients who received piston diameter of 0.4 mm and 0.6 mm showed no significant advantage of one over the other.

In our study, there were more number of male patients than female patients (1.6:1) this is contrary to previous studies Gupta et al.<sup>8,9</sup> This was probably due to fitness for duty in our organization.

Most of the patients were in the age group of 40-60 years.<sup>10,11</sup> This was in accordance with that reported earlier.

The mean air bone gap at speech frequencies were calculated in both the groups in preoperative and 1 month post-operative and 6 month post-operative periods, both the methods were effective in terms of decreasing AB gap. The difference in the two groups was statistically insignificant (p>0.005).

Some studies had similar findings as our study (suggesting there is no significant difference in outcome with use of different diameter of prosthesis), Gupta et al, Gristwood et al, Cavaliere et al, Faranesh et al, Wegner et al and other studies had findings contrary to our study.<sup>6,8,12-14</sup>

They preferred use of larger diameter of piston over smaller, these include Bernardschi et al, Laske et al, Conrad et al, Shea, Sennaroglu et al, Grolman et al, Marchese et al.<sup>5,15-20</sup>

The better result with larger diameter was assumed on basis of mathematical models on mechanical and acoustic analysis middle ear reconstruction (and on the biomechanics of stapedotomy), which seemed to indicate that a larger diameter piston is associated with better sound transmission to the inner ear.<sup>21,22</sup>

Experimental study on temporal bone model by Sim et al, demonstrated that a larger diameter prosthesis increased the round window velocities, had better volume displacement at round window and better sound transmission slightly improving hearing results.<sup>6,23</sup> Wegner et al confirmed the higher round wound

displacement when using larger prosthesis.<sup>6</sup> But in our study, we did not find any such improvement with larger diameter of piston.

The greater improvement in hearing especially at lower frequency from studies done by Sennaroglu et al, Grolman et al, Marchese et al, could be explained by experimental model of Rasowski and Merchant, which showed a high relationship between the prosthesis diameter and oval window surface, which gives the system better compliance at low frequencies.<sup>18-21</sup> They also noted that these improvements were present in initial few weeks after surgery and during subsequent follow up the hearing improvement for the two prosthesis were practically identical Fisch.<sup>24</sup> We had similar results in our study on follow up to 6 months. This study proves that hearing outcome is not affected by diameter of piston.

## CONCLUSION

There was no significant difference in hearing improvement among the individual methods (piston size 0.4 and 0.6 mm) with each other both in 1 month post-operative and 6 month post-operative follow up. Hence, we conclude that there is no relevance of different diameter of Teflon piston prosthesis (0.4 mm versus 0.6 mm) as far as hearing outcome is concerned.

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