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Title: Does The Diameter of The Prosthesis Affect The Outcome of Stapedotomy?

Running Title: The Diameter of The Prosthesis at Stapedotomy

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ABSTRACT

Objective: To compare the outcomes of the stapedotomies performed using Teflon prostheses with 0.4 mm and 0.6 mm diameters.

Materials and Methods: Pre- and postoperative audiograms of 52 participants, who had undergone stapedotomy, were evaluated retrospectively. Participants were divided into two groups according to the diameter of the prosthesis used for their surgery: Group 1 (0.4 mm) and Group 2 (0.6 mm). Air conduction (AC) pure tone thresholds at 250, 500, 1k, 2k, 4k and 6k Hz, and air-bone gaps (ABG) at 500, 1k, 2k, and 4k Hz, as well as pure tone averages (PTA), were compared within and between groups.

Results: The hearing gain, in terms of AC thresholds and ABGs, were statistically significant within both groups for each frequency ($p<0.05$). Pre- and post-operative PTAs and ABGs were similar between the groups ($p>0.05$). Whereas the preoperative AC thresholds were similar between the groups at all frequencies, postoperative AC thresholds of 0.6 mm group were better than 0.4 mm group at 2000 Hz ($p<0.05$). However, postoperative AC thresholds were similar between the groups at all frequencies other than 2000 Hz ($p>0.05$).

Conclusion: The outcomes of the stapedotomies with 0.4 and 0.6 mm Teflon prostheses were similar to each other in terms of postoperative hearing gain, pure tone averages, and air-bone gap. However, only at 2000 Hz, air conduction thresholds were found to be better in patients with 0.6 mm prosthesis, comparing to the ones with 0.4 mm.

Keywords: Stapedotomy, otosclerosis, prosthesis, diameter, hearing, outcome

Introduction

Otosclerosis is a common cause of conductive hearing loss in adults. It is characterized by bony resorption and replacement with new spongy bone, as a result of abnormal changes in bone metabolism in otic capsule. Dense and sclerotic new bony tissue may be located everywhere in otic capsule however is often localized to the anterior part of the oval window that restricts the movement of stapes resulting with progressive conductive hearing loss (1).

A curative treatment has not been defined for otosclerosis yet. However stapedotomy, in which the immobile stapes is replaced with a dynamic prosthesis, is a surgical option for restoration of the hearing in otosclerosis (2). By this method, annular ligament of stapes, which is the major factor for middle ear impedance, is by-passed leading the increase of the mobility of ossicular chain (3). The diameter of the prosthesis can affect maximum vibration amplitude (MVA) and speed of sound conduction (SSC). It has been shown that prostheses in lesser diameter increases MVA and decreases SSC (4). In addition to this, some clinical studies have shown better audiological results after stapedotomy with larger prosthesis (5-9), whereas the results of some others in the literature have not supported them (10-13). The controversy have been going on in the literature. This study aims to compare the outcomes of the stapedotomies with 0.4 mm and 0.6 mm prostheses.

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Material and Methods

Participants

This study was designed as a retrospective case-control study and included the patients who underwent stapedotomy at a university hospital between 2010 and 2015 with the diagnosis of otosclerosis. The data were collected from the patient files and the database of the hospital. Patients who had mixed hearing loss or conductive hearing loss because of an etiology other than otosclerosis or post-operative tympanic membrane perforation or lacking information regarding the postoperative follow-up were excluded. The study has been approved by local ethical committee. (Approval Number: 2018-421).

Surgery

All participants had underwent surgery with the same technique using surgical microscope under general anesthesia. The technique was consisted of the following steps: elevation of the tympanomeatal flap with endaural approach; partial removal of the scutum of ear canal for exposure of the pyramidal eminence and the vertical part of the facial nerve; examination of the mobility of ossicles to confirm the diagnosis of otosclerosis; measurement of the distance between the long process of the incus and the stapes footplate; separation of the incudostapedial joint; cut of the stapedius tendon; perforation of the footplate 0.1 mm wider than the diameter of the prosthesis using a hand drill; placement of the prosthesis in a position where the hook is secured around the long process of the incus, and 0.25 mm length of the tip is inserted into the vestibule; seal of the oval window with blood clot; repositioning of the tympanomeatal flap.

Outcome Measures

Pure tone audiometry (AC40 audiometer; Interacoustics, Middelfart, Denmark) had been performed pre-operatively, and 3rd month post-operatively. Pre- and post-operative audiograms were used for the comparisons. Air conduction (AC) pure tone thresholds at 250, 500, 1k, 2k, 4k and 6k Hz, and air-bone gaps (ABG) at 500, 1k, 2k, and 4k Hz were recorded for the ear that underwent surgery. Pure tone average (PTA) was calculated by averaging AC thresholds at 500, 1k, 2k and 4k Hz. Hearing gain in terms of AC thresholds and ABGs were calculated subtracting the postoperative values from preoperative ones at each frequency.

Groups and Statistical Analysis

Participants were divided into 2 groups according to the diameter of the prosthesis used for their surgery: Group 1: 0.4 mm (E2129; EON Meditech, Gujarat, India); Group 2: 0.6 mm (SPL 03.17.550; Audio Technologies, Gossolengo, Italy). Hearing gain for AC thresholds and ABGs were analyzed within the groups. Pre- and post-operative AC thresholds and ABGs as well as PTAs were compared between two groups.

The variance homogeneity assumption was assessed using Levene test which revealed that the variances are approximately equal for all data. Normality of the distribution of the data were analyzed using Shapiro-Wilk test. Paired-t test was used for normally distributed data and Wilcoxon test was used when data were not normally distributed for within group analysis. Student-t and Mann-Whitney U tests were used for normally and nonnormally distributed data, respectively, for the comparisons between the groups. p values less than 0.05 were considered statistically significant.

Results

Twenty-six in each group, 52 participants in total were included into the study. Average ages were 34.96±7.77 and 39.26±10.58 for Group 1 and 2, respectively ($p>0.05$). Twelve of the participants in Group 1, and 18 of the participants in Group 2 were females (Table 1).

The difference between pre- and post-operative AC thresholds and ABGs were statistically significant within both of the groups for each frequency ($p<0.05$). When pre- and post-operative PTAs and ABGs were compared between two groups, the differences were not significant ($p>0.05$) (Table 1). Whereas the preoperative AC thresholds were similar between the groups at all frequencies, postoperative thresholds of 0.6 mm group were better than 0.4 mm group at 2000 Hz ($p<0.05$). However, postoperative AC thresholds were similar between the groups at all frequencies other than 2000 Hz ($p>0.05$) (Figure 1). ABG gains were also similar between the groups at each frequency ($p>0.05$) (Figure 2).

Discussion

Stapedotomy is the standardized surgical method for restoration of hearing in patients having otosclerosis with good cochlear reserve since it provides successful outcome (14, 15). On the other hand, still there's no consensus on the diameter of the prosthesis used for this operation. Varying in material and diameter, many types of prostheses have been used. The most commonly used ones are Teflon prostheses with 0.4 and 0.6 mm diameters, in addition to the ones with 0.3, 0.5, and 0.8 mm diameters. Because of not only different opinions and practices among surgeons, but also the controversial results of regarding studies in the literature, the debate on the role of the diameter of the prosthesis on hearing outcome has been persisting.

Fisch (11) has reported that 0.6 mm prosthesis provides better outcome than 0.4 mm on 3rd week postoperatively, however on long term, both prostheses provide similar outcomes. Shabana et al. (12) also reported similar outcomes of prostheses with 0.4 and 0.6 mm diameter in terms of ABG.

On the other hand, some studies in which the prostheses with diameters other than 0.4 and 0.6 mm, such as 0.3 and 0.8 mm were evaluated, suggest that the diameter of the prosthesis has a role on the outcome of stapedotomy (6, 16-18). For instance, Sennaroglu et al. (6) reported that 0.8 mm prosthesis provides better hearing gain than 0.6 mm, particularly in lower frequencies. Gristwood et al. (16) attained the same conclusion by showing better hearing gain at lower frequencies with 0.8 mm prosthesis compared with 0.6 mm, as well. Grolman et al. (17) [and Karatas et al. (18) comparing 0.4 and 0.3 mm prostheses had also supported the opinion that larger prostheses provide better outcomes.

Marchese et al. (19) have evaluated the outcomes of 212 patients who underwent stapedotomy retrospectively, and shown that the hearing gain was better with 0.6 mm prosthesis than the 0.4 mm at all frequencies except 4 kHz. Bernardeschi et al. (9), also reported better hearing results with 0.6 mm prosthesis than 0.4 mm, especially at 125 and 250 Hz. A meta-analysis comparing the 0.4 and 0.6 mm prostheses also suggested that using 0.6 mm prosthesis results significantly better outcomes in terms of post-operative PTA and ABG (20). As opposed to this, a more recent meta-analysis by Wegner et al. (13) bring forward that the diameter of the

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prosthesis makes no difference on outcome of stapedotomy. We have found in our study that using 0.4 mm or 0.6 mm prostheses have not changed the outcomes of stapedotomies performed in our clinic, in terms of ABG and AC pure tone thresholds at all frequencies but 2000 Hz. The larger prosthesis provided better AC threshold only at 2000 Hz.

Using fresh cadaveric temporal bone Wegner et al. (8) have shown the correlation between larger prosthesis with higher round window velocity, and suggested that larger prostheses may provide moderately better hearing results than lesser. However, standing on the results of moderately better hearing gain, but substantially higher risk of inner ear damage with larger prostheses, Hüttenbrink (3) suggested usage of the prosthesis with 0.4 mm diameter for stapedotomy as a conclusion of his biomechanical study.

It is clear that regarding clinical studies have cons, such as comparing the outcomes of the surgeries performed by different surgeons, confounding factors that can affect hearing gain in study participants, and limited number of participants. Nevertheless, in overall, it seems that the differences between the audiological outcome of stapedotomies with different prosthesis are relatively small and not at the clinical significance level.

The results of this study are in accordance with the majority of the literature, relatively small sample size limits us to generalize our results, though.

Conclusion

We found that applying 0.4 or 0.6 mm teflon prostheses in stapedotomy makes no difference in audiological gain, post-operative pure tone averages or air-bone gap. However, air thresholds at 2000 Hz were better in patients with 0.6 mm prosthesis, comparing to the ones with 0.4 mm.

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Table 1. Comparison of the groups regarding age, sex, side of the operated ear, pre- and post-operative pure tone average and average air bone gap for the frequencies 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

	Group 1 (0.4 mm - n=26)		Group 2 (0.6 mm - n=26)		*p*
Age-years X±SD	34.96±7.77		39.26±10.58		0.101
Sex-female n (%)	12 (46.15)		18 (69.23)		0.092
Side-right n (%)	14 (53.85)		10 (38.46)		0.266
	Preoperative	Postoperative	Preoperative	Postoperative	
PTA-dBHL X±SD	60.96 ± 10^{A}	33.75 ± 9.08^{B}	54.90 ± 9.42^{a}	32.26 ± 9.94^{b}	$^{A-a}$: 0.059 $^{B-b}$: 0.575
Average ABG-dB X±SD	34.86 ± 7.07^{C}	15.87 ± 5.7^{D}	31.06 ± 7.37^{c}	15.05 ± 4.97^{d}	$^{C-c}$: 0.063 $^{D-d}$: 0.583

SD: standard deviation, PTA: pure tone average, dBHL: decibels hearing level, ABG: air-bone gap, dB: decibels

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Fig. 1. Distribution of preoperative and postoperative hearing levels at 250 Hz to 6000 Hz. (Panel A: Preoperative, Panel B: Postoperative; White: Group 1 [0.4 mm], Gray: Group 2 [0.6 mm], *: statistically significant difference between two groups)

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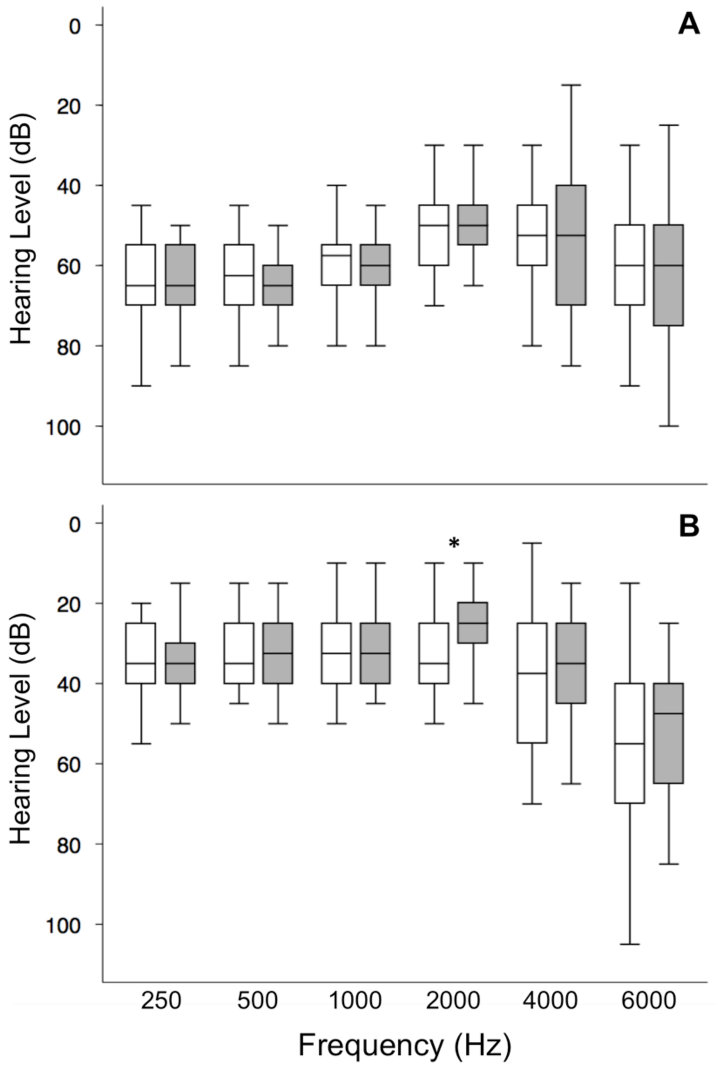
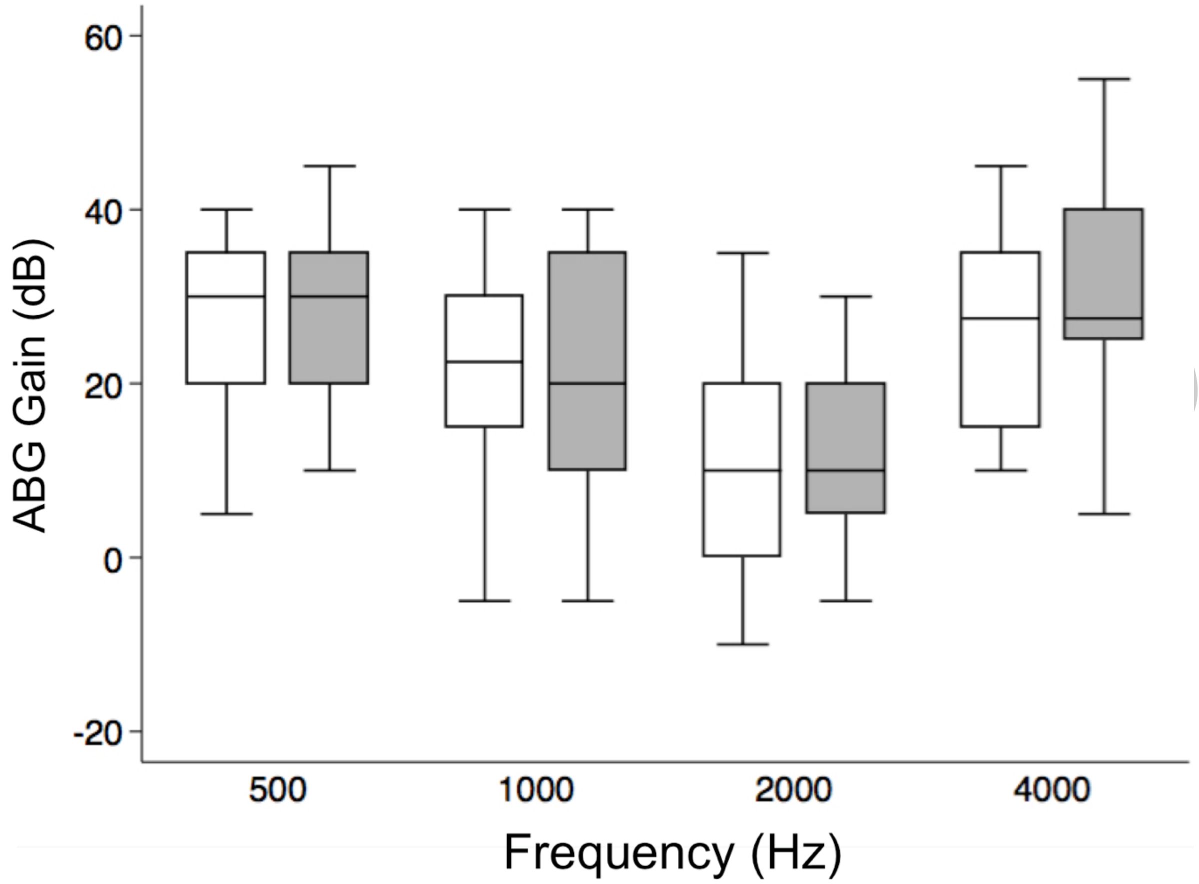


Fig. 2. Distribution of postoperative air bone gap (ABG) gain at 500 to 4000 Hz. (White: Group 1 [0.4 mm], Gray: Group 2 [0.6 mm])



60
40
20
0
-20
ABG Gain (dB)
500
1000
2000
4000
Frequency (Hz)