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Does the Diameter of the Prosthesis Affect the Outcome of Stapedotomy?

ORIGINAL ARTICLE

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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, 1000, 2000, 4000, and 6000 Hz and air–bone gaps (ABGs) at 500, 1000, 2000, and 4000 Hz, as well as pure tone averages (PTAs), were compared within and between groups.

Results: Hearing gain, with regard to AC thresholds and ABGs, was statistically significant within both groups for each frequency ($p<0.05$). Pre- and postoperative 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 the 0.6 mm group were better than those of the 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 with regard to postoperative hearing gain, PTA, and ABG. However, only at 2000 Hz, AC thresholds were found to be better in patients with a 0.6 mm prosthesis than in those with a 0.4 mm prosthesis.

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

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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 the otic capsule. Dense and sclerotic new bony tissue may be located everywhere in the otic capsule; however, it is often localized to the anterior part of the oval window that restricts the movement of stapes, resulting in 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 hearing in otosclerosis (2). By this method, the annular ligament of stapes, which is the major factor for middle ear impedance, is bypassed, leading to an 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 increase MVA and decrease 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 other studies in the literature have not supported them (10-13). The controversy has been ongoing in the literature. The aim of the present study was to compare the outcomes of the stapedotomies with 0.4 mm and 0.6 mm prostheses.

MATERIALS and METHODS

Participants

This study was designed as a retrospective case–control study. Patients who underwent stapedotomy at a university hospital between 2010 and 2015 with a diagnosis of otosclerosis were included in the study. Data were collected from the patients' 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 postoperative tympanic membrane perforation or lacking information regarding the postoperative follow-up were excluded from the study. The study was approved by the local ethics committee (approval no.: 2018-421).

Surgery

All participants underwent surgery with the same technique using a surgical microscope under general anesthesia. The technique consisted of the following steps: elevation of the tympanomeatal flap using an endaural approach, partial removal of the scutum of the ear canal for exposure of the pyramidal eminence and the vertical part of the facial nerve, examination of the mobility of the 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, insertion of a 0.25 mm length of the tip into the vestibule, seal of the oval window with blood clot, and repositioning of the tympanomeatal flap.

Outcome Measures

Pure tone audiometry (AC40 audiometer; Interacoustics, Middelfart, Denmark) had been performed preoperatively and on month 3 postoperatively. Pre- and postoperative audiograms were used for comparisons. Air conduction (AC) pure tone thresholds at 250, 500, 1000, 2000, 4000, and 6000 Hz and air–bone gaps (ABGs) at 500, 1000, 2000, and 4000 Hz were recorded for the ear that underwent surgery. Pure tone average (PTA) was calculated by averaging AC thresholds at 500, 1000, 2000, and 4000 Hz. Hearing gain with regard to AC thresholds and ABGs was calculated by subtracting postoperative values from preoperative values at each frequency.

Groups and Statistical Analysis

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

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

RESULTS

A total of 52 participants, with 26 in each group, were included in the study. The average ages of the patients were 34.96±7.77 and 39.26±10.58 years for Groups 1 and 2, respectively (p>0.05). Of the 52 participants, 12 in Group 1 and 18 in Group 2 were females (Table 1).

The difference between pre- and postoperative AC thresholds and ABGs was statistically significant within both of the groups for each frequency (p<0.05). When pre- and postoperative 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 the 0.6 mm group were better than those of the 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) (Fig. 1). ABG gains were also similar between the groups at each frequency (p>0.05) (Fig. 2).

DISCUSSION

Stapedotomy is the standard surgical method for restoration of hearing in patients with otosclerosis with good cochlear reserve, since it provides a successful outcome (14, 15). On the other hand, there is still no consensus on the diameter of the prosthesis used for this operation. Many types of prostheses have been used with various materials and diameters. The most commonly used types 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. Owing to not only different opinions and practices among surgeons but also controversial results regarding studies in the literature, the debate on the role of the diameter of the prosthesis on hearing outcome has been ongoing.

Table 1. Comparison of the groups regarding age, sex, side of the operated ear, pre- and postoperative pure tone averages, and average air–bone gap for 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 (dB HL), X±SD	60.96±10^{A}	33.75±9.08^{B}	54.90±9.42^{a}	32.26±9.94^{b}	$^{A\text{-}a}$: 0.059
					$^{B\text{-}b}$: 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}	$^{C\text{-}c}$: 0.063
					$^{D\text{-}d}$: 0.583

SD: Standard deviation; PTA: Pure tone average; dB HL: Decibels hearing level; ABG: Air–bone gap; dB: Decibel

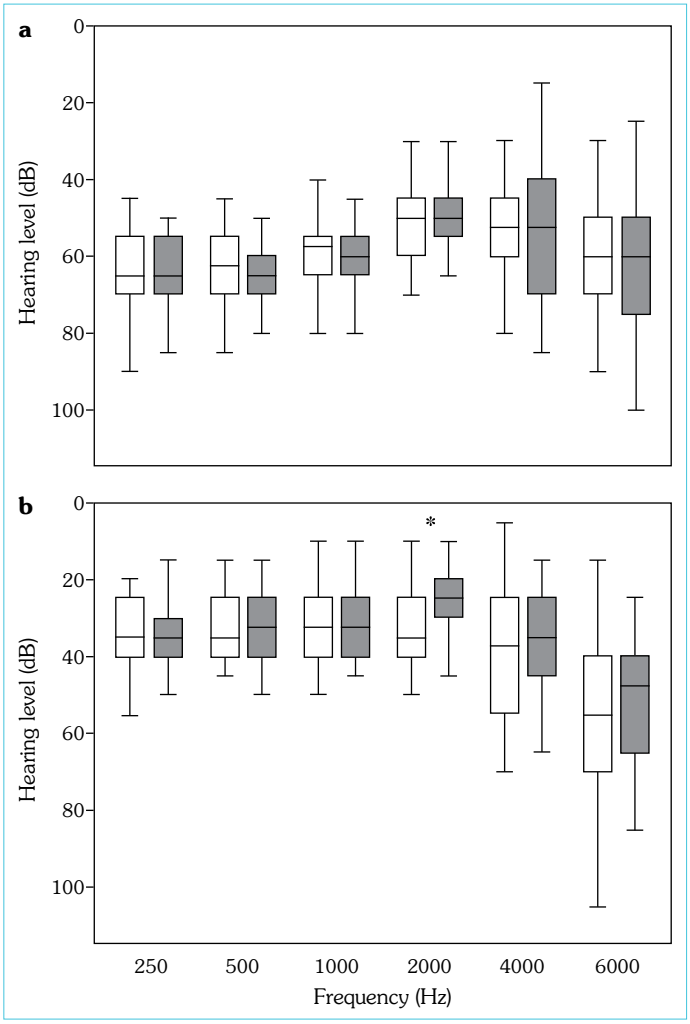

Figure 1. a, b. Distribution of preoperative and postoperative hearing levels at 250 Hz to 6000 Hz

Panel A: Preoperative, Panel B: Postoperative; White: Group 1 [0.4 mm], Gray: Group 2 [0.6 mm], *: statistically significant difference between two groups

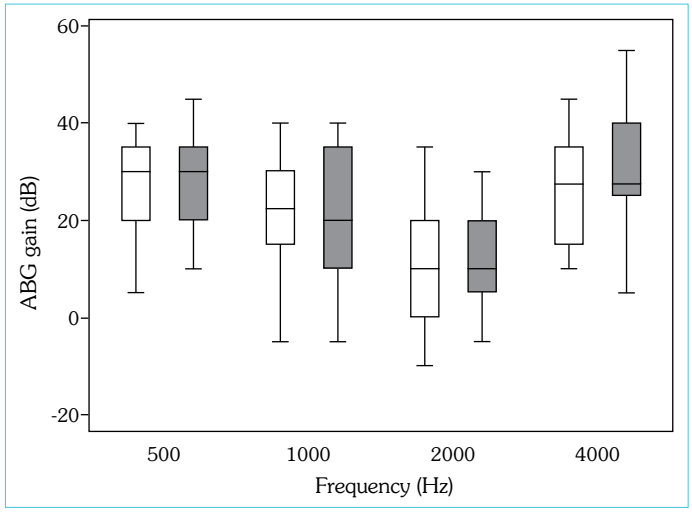

Figure 2. Distribution of postoperative air–bone gap gain at 500–4000 Hz

White: Group 1 (0.4 mm). Gray: Group 2 (0.6 mm)

Fisch (11) reported that a 0.6 mm prosthesis provides better outcome than a 0.4 mm prosthesis on week 3 postoperatively; however, in the long term, both prostheses provide similar outcomes. Shabana et al. (12) also reported similar outcomes of prostheses with 0.4 and 0.6 mm diameters with regard to 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 a 0.8 mm prosthesis provides better hearing gain than a 0.6 mm prosthesis, particularly in lower frequencies. Gristwood et al. (16) attained the same conclusion by showing better hearing gain at lower frequencies with a 0.8 mm prosthesis than with a 0.6 mm prosthesis, as well. Grolman et al. (17) and Karatas et al. (18) comparing 0.4 and 0.3 mm prostheses also supported the opinion that larger prostheses provide better outcomes.

Marchese et al. (19) evaluated the outcomes of 212 patients who underwent stapedotomy retrospectively and showed that hearing gain is better with a 0.6 mm prosthesis than with a 0.4 mm prosthesis at all frequencies except 4 kHz. Bernardeschi et al. (9) also reported better hearing results with a 0.6 mm prosthesis than with a 0.4 mm prosthesis, especially at 125 and 250 Hz. A meta-analysis comparing the 0.4 and 0.6 mm prostheses also suggested that using a 0.6 mm prosthesis results in significantly better outcomes with regard to postoperative PTA and ABG (20). As opposed to this, a more recent meta-analysis by Wegner et al. (13) reported that the diameter of the prosthesis makes no difference on the outcome of stapedotomy. In our study, we have found that using 0.4 mm or 0.6 mm prostheses have not changed the outcomes of stapedotomies performed in our clinic with regard to ABG and AC pure tone thresholds at all frequencies but 2000 Hz. The larger prosthesis provided better AC threshold only at 2000 Hz.

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

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

The results of the present study are in accordance with the majority of the literature. A 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, postoperative

PTAs or ABGs. However, air thresholds at 2000 Hz were better in patients with a 0.6 mm prosthesis than in those with a 0.4 mm prosthesis.

Ethics Committee Approval: The Institutional Review Board of the Erciyes University Faculty of Medicine approved the study protocol at 19.9.2018 (Approval No: 2018-421).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Designed the study: MİŞ, YÜ. Collected the data: DA, FŞ. Analyzed the data: MİŞ, DA, FŞ. Wrote the paper: MİŞ, DA, FŞ, İK, YÜ. All authors have read and approved the final manuscript.

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