The Journal of International Advanced Otology

J Int Adv Otol 2017; 13(2): 162-70 • DOI: 10.5152/iao.2017.3378

Original Article

Hearing and Otoacoustic Emissions Outcome of Stapedotomy: Does the Prosthesis Diameter Matter?

Nabil Faranesh, Ebrahim Magamseh, Suliman Zaaroura, Reem Zeidan, Avi Shupak

Department of Otolaryngology, Head and Neck Surgery, French Hospital, Nazareth, Israel (NF, EM, SZ)
Unit of Otoneurology, Lin Medical Center, Haifa, Israel (RZ, AS)
The Bruce Rappaport Faculty of Medicine, The Technion, Haifa, Israel (AS)
Department of Otolaryngology, Head and Neck Surgery, Carmel Medical Center, Haifa, Israel (RZ, AS)

Cite this article as: Faranesh N, Magamseh E, Zaaroura S, Zeidan R, Shupak A. Hearing and Otoacoustic Emission Outcome of Stapedotomy: Does the Prosthesis Diameter Matter? J Int Adv Otol 2017; 13: 162-70.

OBJECTIVE: To compare the hearing and otoacoustic emissions (OAE) outcome of stapedotomy employing 0.4 and 0.6 mm diameter prostheses.

MATERIALS and METHODS: In total, 18 patients with otosclerosis participated in a prospective, double-armed, randomized cohort study. All the patients underwent small fenestra drill stapedotomy employing the Causse fluroplastic large loop piston prostheses. The patients were randomly assigned to groups of 0.4 mm (n=9) and 0.6 mm (n=9) diameter prostheses. The results of pure tone air and bone audiometries, speech audiometry, and OAE conducted 12 months post operatively were compared within and between the groups.

RESULTS: The within-group analysis showed significant post-stapedotomy improvements in the average air conduction pure tone thresholds in both groups (52.9±9.6 vs. 25.6±5.2 dB HL; p<0.0001 and 54.6±10.4 vs. 22.2±8.2 dB HL; p<0.0001 for the 0.4 and 0.6 mm groups, respectively) and average air-bone gap (ABG; 37.1±8.5 vs. 8.1±3.9 dB HL; p<0.0001 and 38.3±7.5 vs. 9.9±4.5 dB HL; p<0.0001 in the 0.4 and 0.6 mm groups, respectively). No significant differences were found between the groups in these outcome measures, as well as in the rate of ABG closure within 10 dB HL and the word recognition scores. Favorable outcome in the post-stapedotomy bone conduction (BC) was found for the 0.6 mm prosthesis group, reflecting superior cancellation of the Carhart phenomenon for the 500–3000 Hz pure tone thresholds average (−1.7±3.7 vs. 3.9±6.2 dB HL for the 0.4 and 0.6 mm groups, respectively; p<0.04) and 1000, 2000, and 4000 Hz average (−2.6±4.33 vs. 3.9±7.8 dB HL for the 0.4 and 0.6 mm groups, respectively; p<0.05). Small signal-to-noise ratio (SNR) values of the transient-evoked OAE (TEOAE) and distortion product OAE (DPOAE) were found at baseline and follow-up evaluation with no consistent changes post stapedotomy.

CONCLUSION: Similar post-stapedotomy hearing results were found for the 0.4 and 0.6 mm prostheses with small but statistically significant advantage in BC gain and the overclosure parameter for the 0.6 mm prosthesis. OAE testing was not found to be of clinical value in the evaluation of stapedotomy hearing outcome.

KEYWORDS: Stapes surgery, audiometry, otoacoustic emissions, outcome measures

INTRODUCTION

Otosclerosis is a unique otic capsule bone disease. Patients mainly experience conductive hearing loss due to fixation of the stapes footplate within the oval window niche but some may have sensorial or mixed hearing loss secondary to cochlear involvement [1]. Surgical treatment aiming to restore otosclerosis-induced conductive hearing loss include partial or complete removal of the stapes (stapedotomy and stapedectomy, respectively) and its replacement by prosthesis. Nowadays, the most often-practiced stapes surgery is stapedotomy employing the small fenestra technique. The reported advantages of this technique include lower risk for inner ear damage, high tone hearing preservation, and reduced occurrence of perilymphatic fistula [2-6]. These were achieved without affecting the success rates of hearing restoration when compared to the previously employed stapedectomy procedures [7-9].

The characteristics of the stapes prosthesis might have a crucial role toward hearing outcome. Recent research efforts have focused on different aspects of the prosthesis, including the fixation mechanism and shape, materials, and diameter of the piston shaft [10, 11].

The optimal prosthesis diameter required for maximal hearing gain is still controversial. A large diameter is closer to the size of the sound transmitting area of the stapes footplate. Nevertheless, a smaller diameter might be compensated by larger amplitude of the prosthesis movement to ensure equal volume of the displaced perilymphatic fluid. A larger prosthesis diameter requires a wider

Corresponding Address: Avi Shupak E-mail: shupak@012.net.il
Submitted: 13.12.2016 **Revision received:** 21.04.2017 **Accepted:** 06.07.2017

fenestra that may increase the risk for inner ear trauma. However, the heavier prosthesis theoretically produces better results in the lower frequencies, which are important for speech comprehension [12-16].

A recent systematic review could not find sufficient evidence for the superiority of larger diameter or smaller diameter pistons [17]. The authors identified several confounding parameters in most previous studies, including the variety of prosthesis type employed in the treatment groups, lacking information about the fenestration size, insufficient reporting of the preoperative hearing thresholds or missing comparison of preoperative hearing between the treatment groups, and heterogeneous reporting of hearing outcome that many times did not adhere to recommended guidelines [18, 19]. Also, randomization was carried out only in one of the studies, and blinding of the hearing outcome assessors was mostly deficient.

The most commonly used stapes prostheses are of 0.4 mm and 0.6 mm in diameter [20].

A previous meta-analysis comparing these 2 prostheses diameters included 5 controlled studies with a total of 590 patients. The review showed favorable results for the 0.6 mm over the 0.4 mm prosthesis when closure of the air-bone gap (ABG) within 10 dB HL was considered. However, the authors could not compare other hearing outcome parameters including the postoperative ABG and word recognition scores due to deficient reporting [20].

Otoacoustic emissions (OAE) are an objective neurophysiological measure reflecting the function of the inner ear outer hair cells (OHCs). The evoked Otoacoustic emissions (OAE), which include the transient evoked OAE (TEOAE) and the distortion products OAE (DPOAE), are both commonly used in clinical practice [21]. The TEOAE are measured in response to a broadband click stimulus and reflect the OHC activity at the threshold level. The DPOAE originate from the cochlea when 2 pure tones (f1, f2) are simultaneously presented and are thought to reflect the OHCs activity at the supra-threshold level. Thus, although both evoked OAE measure the OHCs function, they reflect different ranges of their activity [22]. The presence of OAE is highly dependent on middle ear function and ossicular chain mobility as the recording requires sound transmission both toward and from the cochlea. This is the reason why the detection of OAE is not anticipated in the presence of ABG greater than 15 dB HL [23]. In otosclerosis, OAE detection is usually hampered due to increased middle ear stiffness significantly reducing the transmission of emissions from the cochlea to the external ear canal [24]. Restoration of the ossicular chain mobility with ABG closure might improve the detectability of OAE on the condition of preserved sensorineural hearing. This might provide a fast and objective method for post-stapes surgery hearing evaluation as an adjunct to conventional audiometry.

Aims

The objective of our study was to compare the hearing results and OAE outcome of otosclerosis patients, which had small fenestra stapedotomy employing either 0.4 or 0.6 mm diameter stapes prostheses.

MATERIALS and METHODS

Study Design

Eighteen patients who underwent stapedotomy due to otosclerosis-induced conductive hearing loss were included in a prospective 2-arm randomized study.

All operations were carried out by a single surgeon (EM) using the same surgical technique. The study participants were randomized into 2 groups of 9 patients each using computerized randomization [25]. The Causse fluroplastic large loop stapes piston prosthesis (Medtronic Xomed, Inc., Jacksonville, Florida, USA) with a shaft diameter of 0.4 mm was used in one study group (0.4 mm group) and the 0.6 mm diameter prosthesis in the second group (0.6 mm group).

Prior to the stapedotomy and 12 months postoperatively, all patients had audiological and OAE evaluations. The interval of 12 months for the follow-up testing was in accordance with the American Academy of Otolaryngology-Head and Neck Surgery guidelines for the evaluation of the results of treatment of conductive hearing loss emphasizing that results on 1 year provide a more realistic guide than shorter-term results [19].

The audiological evaluation included pure tone air (AC) and bone conduction (BC) audiometry over the frequency range of 0.25–8 kHz and 0.5–4 kHz, respectively, and speech audiometry. Single tone tympanometry and ipsilateral stapedial reflex testing were done preoperatively only as part of the diagnostic evaluation of otosclerosis with stapes fixation.

Audiometry was performed using the clinical audiometer AC 33, Interacoustics, Denmark. Tympanometry and stapedial reflex testing were conducted by employing the 39 AUTO TYMP, GSI, Denmark.

Transient evoked optoacoustic emissions TEOAE were recorded in response to 256 noise-free repetitions of 80 dB SPL, 0.1 ms duration non-linear click stimulus in a half octave band over the frequency range of 700 to 3700 Hz (700, 1500, 2200, 3000, and 3700 Hz). The signal-to-noise ratio (SNR), which is the ratio between the OAE amplitude and the associated noise floor in the same frequency, was calculated.

For the DPOAE, 2 primary tones (f1, f2) were used, $f2 > f1$, with constant frequency ratio of $f2/f1 = 1.22$; f2 varied from 1001 to 6348 Hz. The L1 and L2 intensities of the f1 and f2 tones were 70 and 65 dB SPL, respectively. DPOAE measures included the amplitude at the frequency 2f1-f2 and the noise floor in the respective f2. DPOAE SNR values corresponding to the frequency 2f1-f2 were plotted as a function of f2 frequency (DP-grams).

Transient evoked optoacoustic emissions TEOAE and DPOAE were conducted using the ILO292 analyzer, OAE system (Otodynamics Ltd., UK).

All audiological and OAE evaluations were carried out in a soundproof audiometry booth by the same certified clinical audiologist (RZ)

The patients and the clinical audiologist performing the pre and post-stapedotomy hearing and OAE evaluations were blinded to the patients' study group allocation.

The study protocol and procedures were approved by the local ethic committee institutional review board. All subjects signed informed consent form describing the purpose of the research and the subject's role.

Inclusion Criteria
All study participants were older than 18 years, who understood and signed the informed consent. All patients had normal preopreoperative tympanic membrane on otomicroscopy, A or As type tympanometry, and missing ipsilateral stapedial reflex. Their history ruled out possible other etiologies for conductive hearing loss, and stapes fixation on surgery verified the diagnosis of otosclerosis.

Before the baseline hearing and OAE evaluation and on the 12 months follow-up, otomicroscopy and tympanometry were carried out to assure clean external ear canal and normal middle ear pressure equivalents (within −100 and +100 daPa).

Surgical Technique
Stapedotomy was conducted under local or general anesthesia according to the patient and surgeon preference. Transcanal or endaural approaches were used to elevate a tympanomeatal flap. Using a curette, part of the bony posterior wall of the external ear canal wall was removed to allow exposure of the pyramidal eminence and the vertical part of the facial nerve and to assure complete visualization of the oval window niche. The ossicular chain mobility was examined to confirm stapes fixation. The distance between the long process of the incus and the stapes footplate was measured employing a measuring rod, and prosthesis long enough to assure 0.25 mm insertion beyond the footplate plane was selected. The incudostapedial joint was separated, the stapedius tendon was cut, and the stapedial suprastructure was removed. Using a hand drill a footplate perforation 0.1 mm wider than the prosthesis diameter was done. The prosthesis was inserted into the vestibule and was secured around to the long process of the incus. The oval window niche was sealed using a blood drop. The ossicular mobility was re-examined to insure adequate results and the tympanomeatal flap repositioned to the canal wall and held in place with small gelfoam strips [26]. The patients were hospitalized for at least one night for observation and a follow-up visit was scheduled 1 week after discharge during which the external ear canal packing was removed. None of the patients had any complications during or after surgery.

Outcome Measures
Behavioral audiometry
The audiological outcome measures were adopted from the American Academy of Otolaryngology-Head and Neck Surgery guidelines for the evaluation of results of treatment of conductive hearing loss [19] and the recommended presentation format of pure tone threshold–word recognition scattergrams [18].

The following parameters were calculated from the patients' evaluation results on presentation and 12 months post-stapedotomy:

Air conduction pure tone average (AC-PTA): The average air conduction pure tone thresholds in dB HL for 500, 1000, 2000, and 3000 Hz

Air conduction gain (GAINac): The difference in dB HL between the preoperative and postoperative AC-PTA

Bone conduction BC pure tone average (BC-PTA): The average BC pure tone thresholds in dB HL for 500, 1000, 2000, and 3000 Hz

Bone conduction gain (GAINbc): The difference in dB HL between the preoperative and postoperative BC-PTA

Air-bone gap (ABG): The difference in dB HL between AC-PTA and BC-PTA

Stapedotomy outcome was categorized according to the magnitude of ABG closure measured on 12 months follow-up: ABG<10 dB HL - excellent; 10 dB HL<ABG<20 dB HL - good; 20 dB HL<ABG<30 dB HL–fair; and ABG-PTA>30 dB HL- failure. The stapedotomy success rate was defined as the percentage of patients having air-bone gap closure within 10 dB HL [18].

Air-bone gap gain (GAINabg): The difference in dB HL between the preoperative and postoperative ABG.

Overclosure in stapes surgery refers to the apparent improvement in bone conduction due to the Cahart's phenomenon [27]. The average pure tone BC thresholds for 1000, 2000, and 4000 Hz (BC high) was calculated and compared between the baseline and 12 months follow-up audiograms. The difference between the pre- and postoperative BC high values was defined as the overclosure parameter. This parameter indicates changes in post-stapedotomy sensorineural hearing when a positive result indicates overclosure and negative result indicates possible inner ear damage.

Word recognition score (WRS, %): The percentage of 50 monosyllabic words presented at 40 dB sensation level or maximum comfortable loudness, whichever is less, that are correctly identified

Word recognition score gain (GAINwrs%): The difference between the preoperative and postoperative WRS%.

Otoacoustic emissions:
TEOAE were considered as detectable for SNR values ≥3 dB SPL in the presence of at least 60% signal reproducibility.

DPOAE were considered as detectable for SNR values ≥3 dB SPL.

For the purpose of the present study, TEOAE and DPOAE were considered present when detectable in at least one frequency [28].

The average TEOAE SNR was calculated for the total click response over 700–3700 Hz. For the DPOAE the SNR values for the f2 frequencies, 1001–3174 and 4004–6348 Hz frequencies were separately averaged to represent the low and middle frequencies and the high frequency emissions.

Statistical Analysis
Differences in the proportions of detectable TEOAE and DPOAE responses and stapedotomy success categories were compared by the Fisher exact test. The continuous variables AC-PTA, GAINac, BC-PTA, GAINbc, ABG, GAINabg, BChigh, Overclosure, Disc%, GAINdisc%, and SNR values of the OAE were first determined to follow Gaussian distribution employing the Kolmogorov–Smirnov test. Comparisons between the study groups were made using 2-tailed unpaired t test and within the groups by 2-tailed paired t test. When the Kolmogorov–Smirnov test did not indicate normal distribution of the data, the nonparametric 2-tailed Mann–Whitney test was employed for

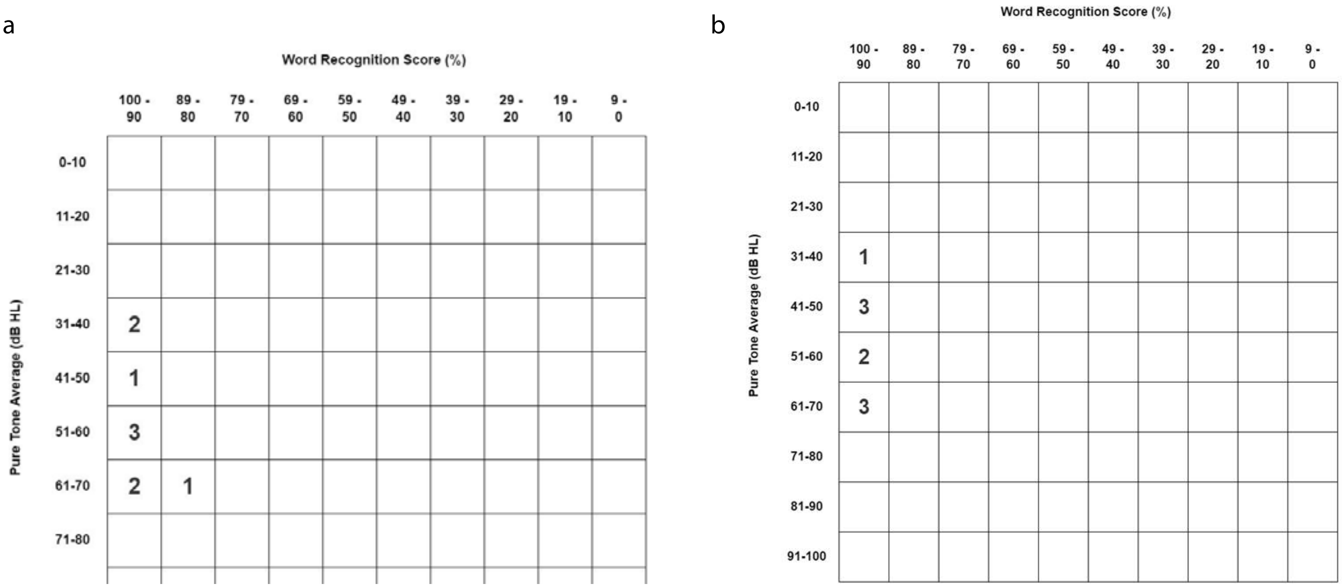

Figure 1. a, b. Scattergrams of the baseline averages of the air conduction pure tone thresholds in dB HL for 500, 1000, 2000, and 3000 Hz and WRS in % for the 0.4 mm (a) and 0.6 mm (b) prostheses groups.

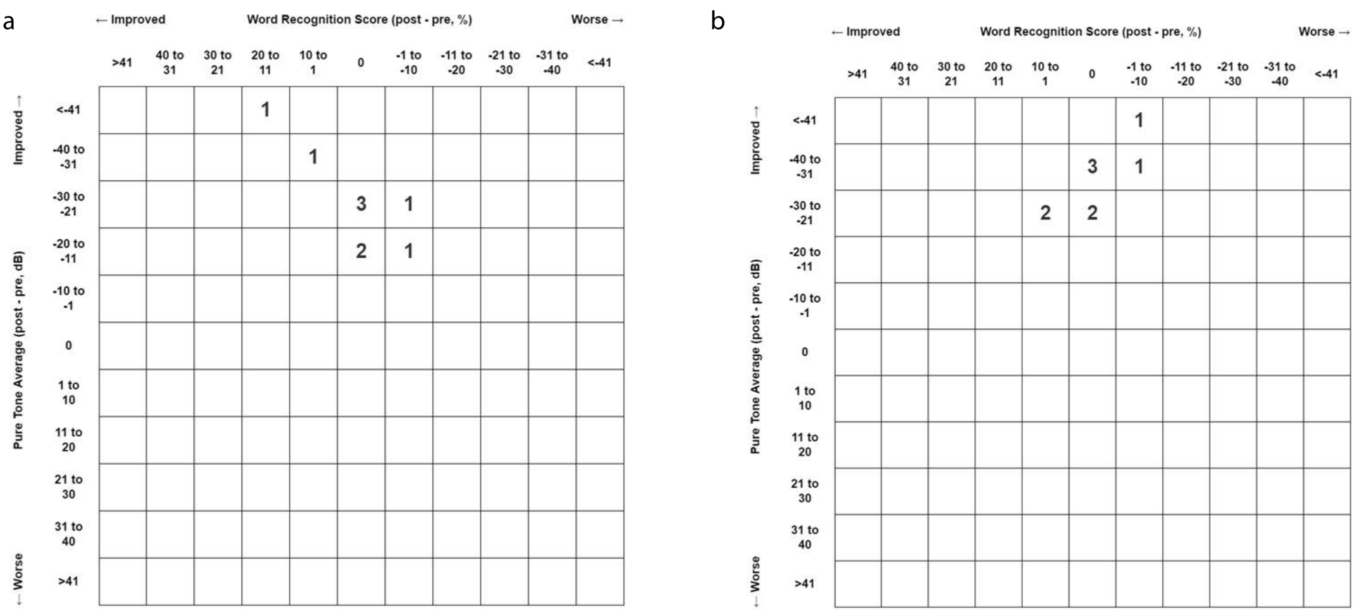

Figure 2. a, b. Scattergrams of the 12 months post-stapedotomy pure tone air conduction averages in dB HL for 500, 1000, 2000, and 3000 Hz and WRS in % for the 0.4 mm (a) and 0.6 mm prostheses (b) groups. Decreased and increased WRS scores in 10% intervals are to the right and left of the "0" column, respectively. Decreased and increased pure tone air conduction averages in 10 dB HL intervals are below and above the "0" raw, respectively.

between the group comparisons and the 2-tailed Wilcoxon matched-pairs signed-ranks test for within the group's comparisons. P values <0.05 were considered statistically significant.

RESULTS

Figures 1 and 2 are scattergrams of the baseline and post-stapedotomy evaluations of the AC-PTA and WRS% of the study groups. Table 1 summarizes the hearing results.

Air bone gap ABG closure within 10 dB HL was achieved on the 12 months follow-up evaluation in 5 patients (56%) in each of the study groups. No significant differences in the proportions of the stapedotomy outcome categories were found.

The baseline evaluation did not show statistically significant differences between the study groups in AC-PTA, BC-PTA, ABG, BChigh, and WRS%. Between the groups analysis of the post-stapedotomy results did not reveal an advantage for the 0.4 mm or 0.6 mm prosthesis in any of these parameters. In addition, the GAINac, GAINabg, and GAINwrs% values were similar in both study groups.

The 0.6 mm group showed significantly better results in the improvement of post-stapedectomy BC pure tone hearing averaged over 500, 1000, 2000, and 3000 Hz (GAINbc) (p=0.035, t test; Figure 3), and in the Overclosure parameter representing the difference in the bone conduction pure tone hearing averaged over 1000, 2000, and 4000 Hz (p=0.044, t test; Figure 4).

Table 1. Hearing outcome

		0.4 mm prosthesis	0.6 mm prosthesis	Statistics
Post-stapedotomy ABG within 10 dB HL (number of patients)		5	5	p=1
AC - PTA (dB HL)	Baseline	*52.9+9.6	#54.6+10.4	p=0.73
	Post-stapedotomy	*25.6+5.2	#22.2+8.2	p=0.31 *p<0.0001 #p<0.0001
GAINac (dB HL)		27.4+9.1	32.4+6.4	p=0.197
BC - PTA (dB HL)	Baseline	*15.8+6.4	#16.3+9.29	p=0.91
	Post-stapedotomy	*17.5+5.39	#12.4+7.38	p=0.12 *p=0.25 #p=0.067
GAINbc (dB HL)		-1.7±3.75	3.9±6.2	p=0.035
ABG (dB HL)	Baseline	*37.1±8.5	#38.3±7.53	p=0.75
	Post-stapedotomy	*8.1±3.96	#9.9±4.57	p=0.38 *p<0.0001 #p<0.0001
GAINabg (dB HL)		29±8.86	28.5±9.05	p=0.89
BChigh (dB HL)	Baseline	*17±7.84	#17.2±9.57	p=0.96
	Post-stapedotomy	*19.6±8.45	#13.3±7.76	p=0.12 *p=0.22 #p=0.15
Overclosure (dB HL)		-2.6±4.33	3.9±7.84	p=0.044
WRS%	Baseline	*96±4.9	#94.7±2	p=0.45
	Post-stapedotomy	*96.9±3.33	#94.7±2	p=0.15 *p=0.16 #p=1
GAINwrs%		0.9±4.81	0±2.83	p=0.96

BC: bone conduction; PTA: pure tone average; AC: air conduction; ABG: air-bone gap; WRS: word recognition score

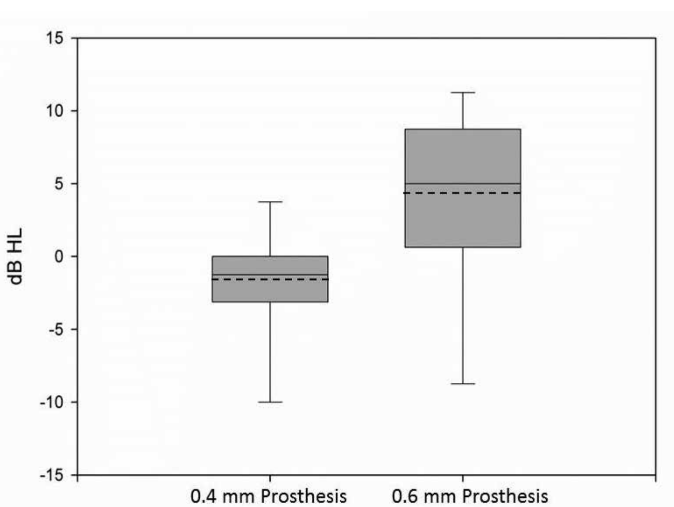

Figure 3. Box plot of the GAINbc. The GAINbc was significantly higher in the 0.6 mm prosthesis group (p=0.035, Student unpaired 2-tailed t test). The boundary of the box closest to zero indicates the twenty-fifth percentile, the solid line within the box marks the median, the dashed line marks the mean, and the boundary of the box farthest from zero indicates the seventy-fifth percentile. Whiskers above and below the box indicate the ninetieth and tenth percentiles.

Within the groups analysis revealed a significant improvement in AC-PTA and ABG in both groups. BC averages for 500, 1000, 2000, and 3000 Hz (BC-PTA), BC averages for 1000, 2000, and 4000 Hz (BChigh) and the WRS% did not differ between the baseline and post-stapedotomy evaluations.

Table 2 summarizes the OAE evaluations of the study groups.

On the baseline testing, DPOAE were detected in 1 (11%) and 3 (33%) patients of the 0.4 and 0.6 mm groups, respectively. On 12 months follow-up, 4 (44%) and 7 (78%) patients, respectively, had recordable emissions. TEOAE responses were found in 1 (11%) and 2 (22%) subjects preoperatively and 7 (78%) and 5 (55%) subjects postoperatively. The proportion of patients having recordable TEOAE and DPOAE pre and post-stapedotomy did not differ between the groups.

No significant differences were found between the study groups in the average SNR values of the DPOAE and TEOAE protocols on the baseline and follow-up evaluations.

Within the groups analysis showed significantly higher proportion of patients having detectable TEOAE after the stapes surgery in the 0.4

Table 2. OAE results

DPOAE		0.4 mm prosthesis	0.6 mm prosthesis	Statistics
Detectable (no of patients)	Baseline	*1	#3	p=0.57
	Post-stapedotomy	*4	#7	p=0.33 *p=0.29 #p=0.15
SNR 1001–3174 Hz (Average+SD)	Baseline	*-5.88+1.6	#-4+2.8	p=0.1
	Post-stapedotomy	*-4.01+2.71	#-2.39+4.28	p=0.35 *p=0.14 #p=0.41
SNR 4004–6348 Hz (Average+SD)	Baseline	*-4.94+1.65	#-5.74+4.76	p=0.64
	Post-stapedotomy	*-3.31+3.25	#-2.75+3.62	p=0.73 *p=0.045 #p=0.21
TEOAE				
Detectable (No of patients)	Baseline	*1	#2	p=1
	Post-stapedotomy	*7	#5	p=0.62 *p=0.015 #p=0.33
SNR 700–3700 Hz (Average+SD)	Baseline	-1.21+2.58	#-2.79+1.22	p=0.13
	Post-stapedotomy	1.83+2.68	#2.02+2.84	p=0.88 *p=0.06 #p=0.002

DPOAE: distortion product otoacoustic emissions; SD: standard deviation; SNR: signal-to-noise ratio; TEOAE: transient-evoked otoacoustic emissions

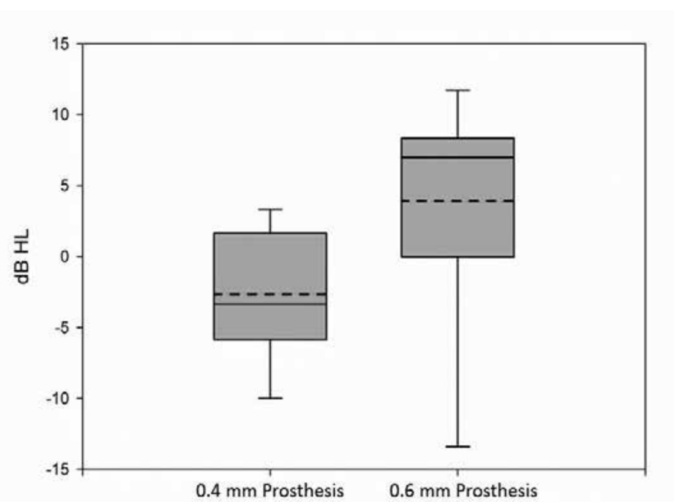

Figure 4. Box plot of the overclosure parameter. The post-stapedotomy improvement in the averaged bone conduction for 1000, 2000, and 4000 Hz was significantly higher in the 0.6 mm prosthesis group (p=0.044, Student unpaired 2-tailed t test).

mm but not in the 0.6 mm prosthesis group (p=0.015, Fisher's exact test). Also, significantly higher post-stapedotomy DPOAE SNR average for the high frequencies responses (f2 –4004–6348 Hz) was found in this group (p=0.045, paired t test). For the 0.6 mm group, significantly higher TEOAE SNR average was found on the post-stapedotomy follow-up when compared to the baseline evaluation (p=0.002, paired t test).

In all ten patients having post-stapedotomy ABG smaller than 10 dB HL, the AC-PTA was within 31 dB HL (range: 10–31 dB HL, average±-standard deviation: 23.13±8.28). TEOAE are most of the time recordable when the pure tone thresholds are lower than 30 dB HL, and DPOAE can be detected when the pure tone thresholds are lower than 40–50 dB HL [29, 30]. Thus, for these patients with preserved sensorineural hearing and minimal ABG, measureable OAE might have been expected. However, only 7 of these 10 patients had detectable TEOAE and DPOAE responses. The sensitivity of TEOAE and DPOAE testing toward the prediction of ABG <10 dB HL was 70% for both protocols and the specificities were 37.5% and 50% for TEOAE and DPOAE, respectively (Table 3).

DISCUSSION

Stapedotomy employing either the 0.4 or 0.6 mm prostheses resulted in comparable hearing in the main outcome measures recommended for the evaluation of surgical treatment of conductive hearing loss [18, 19]. Within the groups analysis showed significant post-stapedotomy improvement in AC-PTA and closure of the ABG with preserved WRS%, while no advantage was demonstrated for one of the study groups in neither of these parameters nor the number of decibels closure of the ABG. Also, in identical percentage of patients the post-operative ABG diminished to less than 10 dB HL.

The comparisons between the 0.4 and 0.6 mm groups revealed statistically significant advantage for the larger diameter prosthesis in the GAINbc and overclosure measures indicating better post-stapedotomy sensorineural hearing both in the low- and high-frequency

Table 3. Prediction analysis of post-operative OAE results toward stapedotomy success

	ABG<10 dB	ABG>10 dB
DPOAE		
Detected	7	4
Non recordable	3	4
Sensitivity 70% (95% Confidence interval: 0.34–0.93)		
Specificity 50% (95% Confidence interval: 0.16–0.84)		
TEOAE		
Detected	7	5
Non recordable	3	3
Sensitivity 70% (95% Confidence interval: 0.34–0.93)		
Specificity 37.5% (95% Confidence interval: 0.08–0.75)		

ABG: air-bone gap; OAE: otoacoustic emissions; TEOAE: transient-evoked otoacoustic emissions

bands. We attribute the observed improvement in BC hearing to Carhart phenomenon as reduction in otosclerosis-induced BC sensitivity was previously demonstrated in 500 to 4000 Hz, although the maximal notch is centered at 2000 Hz [31]. As the cochlear reserve is not expected to improve secondary to the stapedotomy procedure *per se*, these results might be explained by superior coupling of the 0.6 mm prosthesis with the vestibule as compared to the 0.4 mm prosthesis. Also, changes in the ossicular chain resonance secondary to the replacement of the fixated stapes by the 0.6 mm prosthesis might better contribute to the restoration of the middle ear resonance toward its natural characteristics of 800–1200 Hz [32]. The negative values of GAINbc and overclosure observed in the 0.4 mm group might point to inferior sealing of the oval window niche or inner ear damage secondary to transient post-operative perilymph leakage.

A previous meta-analysis of 5 controlled studies, which were not randomized, have reported favorable results for the 0.6 over the 0.4 mm prosthesis in achieving <10 dB HL ABG closure [20]. Pooled data regarding the performance of the 2 prostheses extracted from these and additional 57 uncontrolled studies with variable characteristics of the pistons, different surgical techniques, and diverse follow-up periods and study designs showed better results for the 0.6 mm prosthesis in the post-operative AC-PTA, ABG, and ABG improvement (GAINabg) [20]. We could not find significant differences between the study groups in any of these parameters. This discrepancy might be explained by the present study better results. In AC-PTA and GAINabg for both prostheses over those reported for the pooled data of the better performing 0.6 mm prosthesis. Also, lacking randomization in the included studies might have biased patients allocation: smaller diameter prostheses are preferred whenever risky anatomic conditions, such as dehiscent or overhanging facial nerve and persistent stapedial artery, might compromise surgical success. If the 0.4 mm prosthesis was more often employed for such cases the better outcome found for the 0.6 mm prosthesis might have been resulted from unbalanced allocation of the more challenging cases in the smaller diameter prosthesis groups.

Corroborating our results a recently published systematic review of 12 studies could not find sufficient evidence to support the superiority of the use of a larger diameter piston compared to a smaller diameter piston neither in the stapedotomy success rate nor in the post-operative ABG [17].

A prior review of theoretical models and temporal bone studies discussed that a lower mass prosthesis might result in better transmission of higher frequencies whereas heavier prostheses could perform better in the lower frequencies [12]. In contrary to this suggestion significantly better hearing results in the lower frequencies were reported in a clinical study for the 0.4 mm prosthesis as opposed to the 0.6 mm prosthesis [33]. Our data do not show a frequency-specific advantage for one of the prosthesis as the post-stapedotomy air conduction and ABG results were similar across all frequencies in both groups.

The recording of OAE requires both adequate transmissions of the sound stimuli to the cochlea and that of the evoked emission back to the external auditory canal. Middle ear dysfunction resulting in ABG would hamper OAE detection while recovery of the air conduction mechanism might facilitate their recordings. This reasoning is supported by previous studies reporting reoccurrence of OAE in children suffering from otitis media with effusion after insertion of ventilation tubes [34, 35] and post myringoplasty [36]. However, varying OAE results were found after stapes surgery: TEOAE were recorded only in 4 out of 37 ears following stapedectomy [36]. DPOAE were detected in 24 of 45 (53%) otosclerotic ears preoperatively and in 10 out of 18 ears (58%) post successful stapes surgery [37], and in another study in 30%–35% of 40 patients preoperatively and in 88%–91% postoperatively [38]. In contrary to these results, other groups could not find measurable DPOAE preoperatively among any of their otosclerosis patients to be recorded in 4 of 15 subjects (27%) [39] and in 23 of 34 subjects (68%) at 1 and 4 months, respectively, after the stapes surgery [40]. In another study, none of 34 otosclerosis patients had detectable TEOAE or DPOAE preoperatively. Thirty of 31 patients from this cohort, having partial stapedectomy or stapedotomy, had no measureable emissions 3 months post-surgery, while the 6 months follow-up evaluation conducted on 14 of these patients showed detectable emissions in the single patient having positive results on the 3 months follow-up [41]. Yet, others reported improvement of TEOAE and DPOAE responses mainly in the low frequency band [42, 43].

The follow-up intervals reported in these previous studies all fell short of the 12 months period which is recommended for the follow-up evaluation of conductive hearing loss middle ear surgery results [36-43]; pre-operative OAE testing was not carried out or done on different group of patients [36, 37], and various stapes surgery techniques and prostheses types were used [38, 41, 42].

In the present study, the DPOAE average SNR for 4004–6348 Hz significantly increased in the 0.4 mm prosthesis group, while the TEOAE average SNR for 700–3700 Hz was significantly higher in the 0.6 mm group. Also, higher proportion of subjects in which the 0.4 mm prosthesis was implanted had positive TEOAE response when compared to the preoperative evaluation. However, no consistent patterns of TEOAE and DPOAE presence were found for both study groups on the 12 months follow-up evaluation, and the presence of OAE responses did not correlate with the stapedotomy hearing outcome.

A possible explanations for lacking OAE in the face of corrected ABG and sensorineural hearing within the measurable range for TEOAE and DPOAE [29, 30] is an increase in middle ear stiffness secondary to the cutting of the stapedial tendon, removal of the crural arch, and use of the piston prosthesis while the elastic properties of the annular ligament are not restored. Also, the sound transmission characteristics in the middle ear might have been affected by the change in the resonance frequency of the reconstructed ossicular chain and incomplete sealing of the vestibulum by the stapes prosthesis [42, 44]. In addition, otosclerosis involvement of the cochlea is associated with decreased counts and depressed motility of the outer hair cells [45, 46]. Limited derangement of the outer hair cells might attenuate and ablate OAE response before sensorineural hearing loss becomes apparent in behavioral audiometry [47].

The main limitation of the present study is the relatively small number of patients that could have been recruited resulting in probable statistical under-power of some of the between the groups comparisons.

CONCLUSION

Small fenestra stapedotomy employing either the 0.4 or 0.6 mm diameter prostheses resulted in similar hearing outcome in the main outcome measures recommended for the evaluation of surgical treatment of conductive hearing loss. The use of the 0.6 mm prosthesis showed small but statistically significant advantage toward the cancellation of the Carhart phenomenon. While OAE testing might provide interesting research insights about sound transmission into and from the inner ear, it was not found to be of clinical value in the evaluation of stapedotomy hearing outcome.

Ethics Committee Approval: Ethics committee approval was received for this study from the local ethics committee of the French hospital Nazareth, Israel.

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

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - N.F., E.M.; Design - A.S., N.F.; Supervision - A.S., S.Z.; Data Collection and/or Processing - N.F., R.Z.; Analysis and/or Interpretation - N.F., A.S., R.Z., S.Z., E.M.; Literature Search - N.F., A.S.; Writing Manuscript - N.F., A.S.; Critical Review - E.M., R.Z., S.Z.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study has received no financial support.

REFERENCES

1. Menger JD, Tange RA. The etiology of otosclerosis: a review of the literature. Clin Otolaryngol Allied Sci 2003; 28: 112-20. [CrossRef]
2. Pedersen CB, Elbrond O. Comparative investigation of House and Fisch prostheses in stapedectomy. Acta Otolaryngol 1982; 386: 84-7. [CrossRef]
3. Sennaroglu L, Unal O, Sennaroglu G, Gursel B, Belgin E. Effect of teflon piston diameter on hearing result after stapedotomy. Otolaryngol Head Neck Surg 2001; 124: 279-81. [CrossRef]
4. Colletti V, Sittoni V, Fiorino FG. Stapedotomy with and without stapedius tendon preservation versus stapedectomy: long-term results. Am J Otol 1988; 9: 136-41. [CrossRef]
5. Kursten R, Schneider B, Zrunek M. Long-term results after stapedectomy versus stapedotomy. Am J Otol 1994; 15: 804-6.
6. Spandow O, Söderberg O, Bohlin L. Long-term results in otosclerotic patients operated by stapedectomy or stapedotomy. Scand Audiol 2000; 29: 186-90. [CrossRef]
7. Fish U. Stapedectomy versus stapedotomy. Am J Otol 1982; 4: 112-7.
8. Herzog JA. 0.4 mm stapedotomy: a consistent technique for otosclerosis. Am J Otol 1991; 12: 16-9.
9. Marquet J. Otosclerosis small hole technique. J Laryngol Otol 1983; 8: 78-80.
10. Marchese MR, Cianfrone F, Passali GC, Paludetti G. Hearing results after stapedotomy: role of the prosthesis diameter. Audiol Neurotol 2007; 12: 221-5. [CrossRef]
11. Fritsch MH, Naumann IC. Phylogeny of the stapes prosthesis. Otol Neurotol 2008; 29: 407-15. [CrossRef]
12. Huttenbrink KB. Biomechanics of stapesplasty: a review. Otol Neurotol 2003; 24: 548-57. [CrossRef]
13. Rosowski JJ, Merchant SN. Mechanical and acoustic analysis of middle ear reconstruction. Am J Otol 1995; 16: 486-97.
14. Bohnke F, Arnold W. Finite element model of the stapes-inner ear interface. Adv Otorhinolaryngol 2007; 65: 150-4.
15. Arnold W, Bohnke F, Scherer E. Influence of the area of stapes footplate prostheses in perilymphatic pressure and basilar membrane displacement. Otorhinolaryngol Nova 1999; 9: 81-6. [CrossRef]
16. Sim JK, Chatzimichalias M, Roosli C, Laske RD, Huber AM. Objective assessment of stapedotomy surgery from round window motion measurement. Ear Hear 2012; 33: 24-31. [CrossRef]
17. Wegner I, Verhagen JJ, Stegeman I, Vincent R, Grolman W. A systematic review of the effect of piston diameter in stapes surgery for otosclerosis on hearing results. Laryngoscope 2016; 126: 182-90. [CrossRef]
18. Gurgel R, Jackler R, Dobie R, Popelka G. A new standardized format for reporting hearing outcome in clinical trials. Otolaryngol Head Neck Surg 2012; 147: 803-7. [CrossRef]
19. Monsell E, Balkany T, Gates G, Goldenberg RA, Meyerhoff WL, House JW. Committee on Hearing and Equilibrium guidelines for the evaluation of results of treatment of conductive hearing loss. American Academy of Otolaryngology–Head Neck Surgery Foundation Inc. Otolaryngology Head Neck Surg 1995; 113: 186-7. [CrossRef]
20. Laske RD, Röösli C, Chatzimichalis MV, Sim JH, Huber AM. The influence of prosthesis diameter in stapes surgery: a meta-analysis and systematic review of the literature. Otol Neurotol 2011; 32: 520-8. [CrossRef]
21. Hall JW. Handbook of Otoacoustic Emissions. San Diego, CA: Singular Publishing Group, 2000: 1-365.
22. Robinette MS, Glattke TJ. Otoacoustic Emissions: Clinical Applications. New York: Thieme Publishers, 2007: 1-436.
23. Hall JW. Distortion product and transient evoked OAEs: effect of peripheral auditory dysfunction and hearing loss. In: Hall JW, ed. Handbook of Otoacoustic Emissions. San Diego, CA: Singular Publishing Group, 2000: 223-68.
24. Probst R. Audiological evaluation of patients with otosclerosis. Adv Otorhinolaryngol 2007; 65: 119-126. [CrossRef]
25. Available from: http://www.random.org/sequences
26. House JW, Cunnigham III CD. Otosclerosis. In: Flint PW, Haughey BH, Lund VJ, Niparko JK, Richardson MA, Robbins KT, et al eds. Cummings otolaryngology head and neck surgery 5th ed. Canada: Elsevier, 2014: 2211-9.
27. Carhart R. Clinical application of bone conduction audiometry. Arch Otolaryngol 1950; 51: 798-808. [CrossRef]
28. Shupak A, Zeidan R, Shemesh R. Otoacoustic emissions in the prediction of sudden sensorineural hearing loss outcome. Otol Neurotol 2014; 35: 1691-7. [CrossRef]
29. Probst R, Lonsbury-Martin BL, Martin GK. A review of otoacoustic emissions. J Acoust Soc Am 1991; 89: 2027-67. [CrossRef]
30. Gorga MP, Neely ST, Ohlrich B, Hoover B, Redner J, Peters J. From laboratory to clinic: a large scale study of distortion product otoacoustic emissions in ears with normal hearing and ears with hearing loss. Ear Hear 1997; 18: 440-55. [CrossRef]

31. Carhart R. Effects of stapes fixation on bone-conduction response. In Ventry IM, Chailkin JB, Dixon RF, eds. Hearing measurement: New York, NY: Appleton-Century-Crofts, 1971: 116-129.
32. Margolis RH, Van Camp J, Wilson RH, Creten WL. Multifrequency tympanometry in normal ears. Audiology 1985; 24: 44-53. [CrossRef]
33. Teig E, Lindemann H. Stapedotomy piston diameter: is bigger better? Otorhinolaryngol Nova 1999; 9: 252-6. [CrossRef]
34. Owens JJ, McCoy MJ, Lonsbury-Martin BL, Martin GK. Otoacoustic emissions in children with normal ears, middle ear dysfunction and ventilation tubes. Am J Otol 1993; 14: 34-40.
35. Tilanus SC, Van Stenis D, Snik AF. Otoacoustic emission measurements in evaluation of immediate effect of ventilation tube insertion in children. Ann Otol Rhinol Laryngol 1995; 104: 297-300. [CrossRef]
36. Lieberum B, Held B, Schrader M. Otoacoustic emissions (TEOAE and DPOAE) after middle ear operation. Laryngorhinootologie 1996; 75: 18-22. [CrossRef]
37. Ralli G, Cianfrone G, Fabbricatore M, Altissimi G. Analysis of otoacoustic distortion products in a group of otosclerotic patients. Acta Otorhinolaryngol Ital 1996; 16: 485-91. [CrossRef]
38. Migirov L, Wolf M. Distortion product otoacoustic emissions following stapedectomy versus stapedotomy. J Laryngol Otol 2010; 124: 16-8. [CrossRef]
39. Filipo R, Attanasio G, Barbara M, Viccaro M, Musacchio A, Cappelli G, et al. Distortion product otoacoustic emissions in otosclerosis: intraoperative findings. Adv Otorhinolaryngol 2007; 65: 133-6.
40. Gierek T, Smolka W, Zbrowska-Bielska D, Klimczak-Golab L, Maizl K. The evaluation of distortion product otoacoustic emissions after stapedotomy. Otolaryngol Pol 2004; 58: 817-20.
41. Herzog M, Shehata-Dieler WE, Dieler R. Transient evoked and distortion product otoacoustic emissions following successful stapes surgery. Eur Arch Otorhinolaryngol 2001; 258: 61-6. [CrossRef]
42. Mantzari E, Maragoudakis P, Kandiloros D, Ferekidis E, Korres SG. The profile of otoacoustic emissions and multifrequency tympanometry in otosclerotic patients undergoing two types of stapes surgery: small fenestra and microtraumatic stapedotomy. Med Sci Monit 2014; 20: 1613-20. [CrossRef]
43. Singh PP, Gupta N, Verma P. Transient evoked and distortion product otoacoustic emission profile in patients of otosclerosis: a preliminary report. Indian J Otolaryngol Head Neck Surg 2012; 64: 25-30. [CrossRef]
44. Wada H, Ohyama K, Kobayashi T, Koike T, Noguchi S. Effect of middle ear on otoacoustic emissions. Audiology 1995; 34: 161-76. [CrossRef]
45. Kwok OT, Nadol JB. Correlation of otosclerotic foci and degenerative changes in the organ of Corti and spiral ganglion. Am J Otolaryngol 1989; 10: 1-12. [CrossRef]
46. Sziklai I. Human otosclerotic bone-derived peptide decreases the gain of the electromotility in isolated outer hair cells. Hear Res 1996; 95: 100-7. [CrossRef]
47. Shupak A, Tal D, Sharoni Z, Oren M, Ravid A, Pratt H. Otoacoustic emissions in early noise-induced hearing loss. Otol Neurotol 2007; 28: 745-52. [CrossRef]