

ORIGINAL ARTICLE

Objective Evaluation of the Prosthesis Diameter on Hearing Results after Stapedotomy

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Objective: To evaluate objectively the Teflon piston diameters on hearing results in otosclerosis patients undergone stapedotomy.

Materials and Methods: The diameters of prostheses used were 0.3 mm and 0.6 mm in two groups of ten patients. and 10 healthy patients as control group were included. Transient evoked otoacoustic emissions (TEOAE), Distortion product otoacoustic emissions (DPOAE) and DPOAE I/O functions were recorded.

Results: Significant changes were detected at 2000-3000 Hz ($p<0.001$) and 4000-6000 Hz ($p<0.05$) for 0.6 mm prostheses in TEOAE statistically. Also 3000-4000 Hz for 0.6 mm prostheses ($p<0.05$) for DPOAE and with 65 dB at 2000 Hz ($p<0.05$), with 60 dB and 45 dB at 3000 Hz ($p<0.05$) for DPOAE I/O were found statistically.

Conclusions: OAE measurements are advisable for follow-up examinations in otosclerosis patients with stapedotomy. An increase in prosthesis diameter for stapedotomy gives better hearing results, not only at lower frequencies, but also at higher.

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Introduction

Stapedectomy and stapedotomy are widely used surgical procedures capable of restoring hearing to individuals with hearing loss caused by otosclerosis. In general stapes surgery can be divided into the large fenestra technique "stapedectomy" and the small fenestra technique" stapedotomy^[1]. When performing stapedotomy, prostheses with different size, shape and material have been used.

Several different prostheses with different widths have also been used, but there is no unanimous opinion about the advantages of a smaller or a larger prosthesis. A few publications report the functional results obtained after stapedotomy according to the size of the piston with subjective audiological tests^[2-4]. There is no literature for evaluation of prosthesis diameter on hearing results with objective audiological tests including otoacoustic emissions (OAE).

Patients with otosclerosis suffer from a conductive hearing loss due to a fixation of the stapedial footplate within the oval window niche so that stapedial reflexes or OAE seem not useful before stapes surgery. Transient evoked otoacoustic emissions (TEOAE) were detected in only a small number of patients after stapes surgery while distortion product otoacoustic emissions (DPOAE) have been reported to be more frequently evident after successful stapedectomy^[5].

The aim of this study is to determine by TEOAE and DPOAE if the diameter of the prosthesis could affect the successful hearing results of stapedotomy using 0.3mm and 0.6mm diameter teflon prostheses.

Materials and Methods

Twenty consecutive patients underwent stapedectomy with teflon prosthesis was allocated for this study. A group of 10 healthy persons included in the study as a control group. This study has been performed in

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comply with the ethical principles of the assigned institutional board. All patients underwent a standardized intake assessment including a full history and otoscopic examination by an otolaryngologist and subjective audiological tests including pure tone audiometry (Interacoustics AC 40, Clinical Audiometer, Assens, Denmark) and tympanometry (Interacoustics AZ T, Impedance Audiometer, Denmark, calibrated to ANSI S3.39-1987 standards). The mean age of the included subjects was 34.3 years (range 28-45), and there were 9 females and 11 males. The right ear was operated in 8, the left in 12 cases.

The inclusion criteria for the study were a normal otoscopic examination, a hearing level better than 45 dB in pure-tone audiometry, a type A tympanogram, time of the audiological examination at least one year later after surgery. Sensorineural hearing loss worse than 50 dB, non type A tympanogram, middle or external ear problems, time of the audiological examination less than 12 months postoperatively were excluded from this study. The study protocol was approved by Institutional Review Board.

All patients were operated using the transcanal approach, under local anaesthesia. After removing the stapes suprastructure, the footplate was perforated using a manual perforator or a skeeter. Teflon wire prostheses of differing lengths (0.3–0.6 mm) were used for the stapedotomy cases. The study groups consisted of 10 patients with 0.3 mm diameter prostheses (Group A), 10 patients with 0.6 mm diameter prostheses (Group B) and 10 patients with control group (Group C) included 10 volunteers aged 20–45 years with normal hearing and normal otoscopic findings.

Recording of OAE including TEOAE and DPOAE were measured for the operated ear in Group A, B and for the normal ear in control group (Capella Cochlear Emission Analyzer, Madsen, Denmark). All groups passed an otomicroscopic check to clean the outer ear canal and to verify a normal tympanic membrane before each testing. All subjects were instructed to be immobile during the OAE recordings. Adequate positioning of the measurement probe in the external ear canal was monitored carefully at the beginning of the test by observing the ear canal response on the monitor.

The TEOAEs were obtained with stimuli consisting of a click of 80 μ s duration. The stimulus level in outer air was set at 80 ± 2 dB SPL. The click rate was 50/s, and post stimulus analysis was in the range of 2–20 ms. A total of 260 sweeps was averaged above the noise rejection level of 47 dB. Stimuli were presented in the nonlinear mode, in which every fourth click stimulus is inverted and three times greater in the amplitude than the three preceding clicks. A TEOAE was defined as a response if its amplitude was ≥ 3 dB above the level of the noise. Reproducibility percentages ≥ 60 % were taken into account as acceptable for analysis at five successive frequency bands from 1000 to 5000 Hz.

The DPOAE at $2f_1 - f_2$ were elicited. Two equilevel ($L_1 = L_2 = 65$ dB) primary signals (f_1 and f_2) were generated while $f_2/f_1 = 1.21$. The intensities for DPgram were set as equilevel at 65 dB. DPOAE were plotted as a function of f_2 . The frequencies examined for DPgram were ranged from 750 to 8,000 Hz (750, 1000, 1500, 2000, 3000, 4000, 6000 and 8000 Hz). Detection threshold and suprathreshold measures in the form of I/O functions were obtained by decreasing the primary tones from 65 to 47 dB SPL, in 3-dB steps. The DPOAE I/O amplitude thresholds were estimated manually on the OAE screen for each patient. The DPOAE were measured and recorded as an average of four separate spectral averages of each stimulus condition. The level of the noise floor was measured at the frequency that was 50 Hz above the DPOAE frequency, using similar averaging techniques. An emitted response was accepted if the DPOAE at $2f_1 - f_2 \geq 3$ dB above the noise-floor level at the $2f_1 - f_2 + 50$ Hz frequency for both type of testing methods (DPgram and I/O functions). Mann Withney U test was performed for statistical evaluation. Cochlear microphonic amplitudes of group A, B and C were compared statistically. Difference was considered to be statistically significant at a p value of less than 0.05.

Results

Twenty patients (9 women, 11 men) mean age 34.3 years (ranging between 28 and 45) undergone stapes surgery were included for this study. Demographic data of each group was shown in Table 1.

Table 1. Demographic data of patients

GROUP	Age (year)*	n**: Female	n: Male	n: Right ear	n: Left ear	n: Total
A	36.8	4	6	3	7	10
B	33.9	5	5	5	5	10
C	32.1	5	5	5	5	10

*: Mean value, **: Number of patients

A: Patients with 0.3 mm diameter prostheses (Group A)

B: Patients with 0.6 mm diameter prostheses (Group B)

C: Control group

Response of TEOAE at 2000, 3000, 4000 and 6000 Hz frequencies were statistically significant for Group C compared to Group A and B ($p < 0.05$). Statistically significant changes were detected at 2000-3000 Hz

($p < 0.001$) and at 4000 and 6000 Hz ($p < 0.05$) for Group B to Group A. There was no statistically changes at 1000 Hz for each groups ($p > 0.05$) (Figure 1).

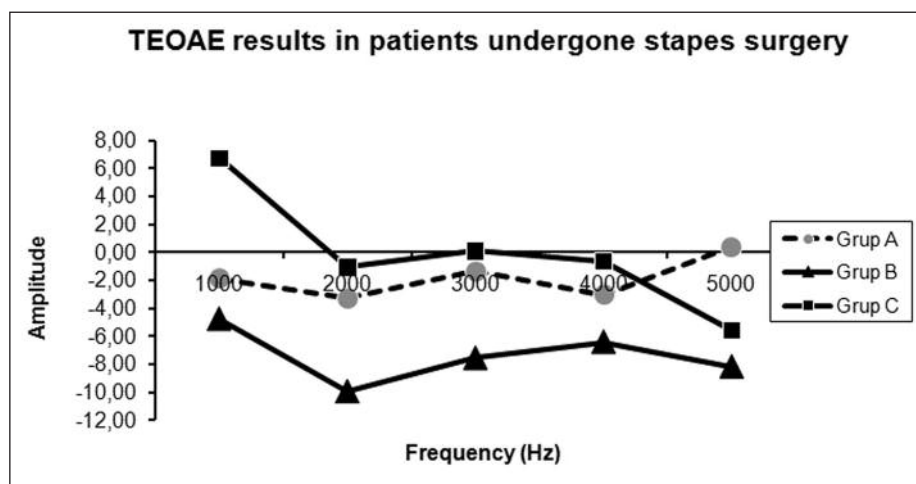


Figure 1. Statistically significant changes were detected at 2000-3000 Hz ($p < 0.001$) and at 4000 and 6000 Hz ($p < 0.05$) for Group B to Group A.

(Group A: Patients with 0.3 mm diameter prostheses Group B: Patients with 0.6 mm diameter prostheses Group C: Control group)

For DPOAE results, there were no statistically significant difference between Group A and Group B at 1000 Hz, 2000 Hz and 6000 Hz frequencies ($p > 0.05$). Statistically significant difference was obtained for repeated measurements at 3000 Hz and 4000 Hz for Group B to A ($p < 0.05$) (Figure 2). DPOAE I/O functions were statistically insignificant at 1000, 4000 and 6000 Hz frequencies ($p > 0.05$), whereas measurements with 65 dB at 2000 Hz ($p < 0.05$) (Figure 3), with 60 dB and 45 dB at 3000 Hz ($p < 0.05$) for Group B to A (Figure 4).

Discussion

Nowadays the stapedectomy has been often performed using the small-fenestra technique that has been advocated in order to reduce inner ear damage caused by operative trauma to the cochlea. During the evolution of otosclerosis surgery many stapes replacement prostheses have been developed [6]. All these implants differ in size, shape, and weight. The available prostheses are most commonly composed of three materials: fluoroplastic (Teflon-type polymer),

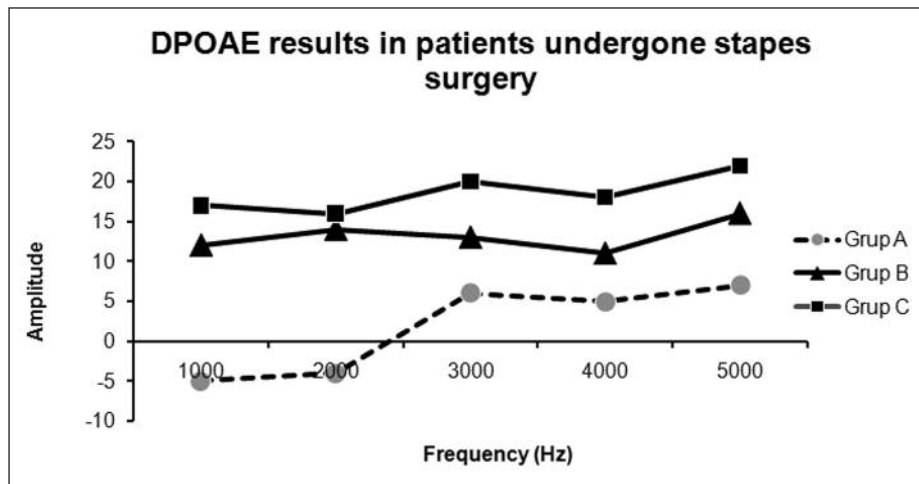


Figure 2. Statistically significant difference was obtained for repeated measurements at 3000 Hz and 4000 Hz for Group B to A ($p < 0.05$) (**Group A:** Patients with 0.3 mm diameter prostheses **Group B:** Patients with 0.6 mm diameter prostheses **Group C:** Control group)

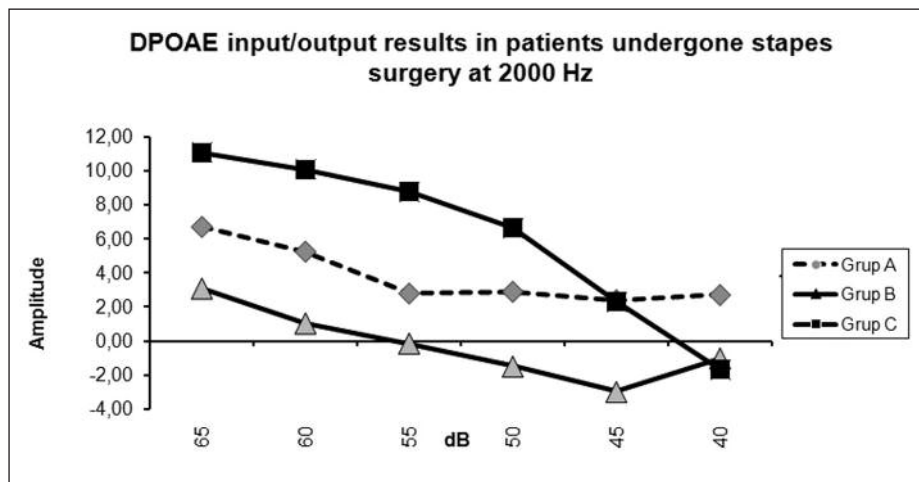


Figure 3. DPOAE I/O functions were statistically significant with 65 dB at 2000 Hz ($p < 0.05$). (**Group A:** Patients with 0.3 mm diameter prostheses **Group B:** Patients with 0.6 mm diameter prostheses **Group C:** Control group)

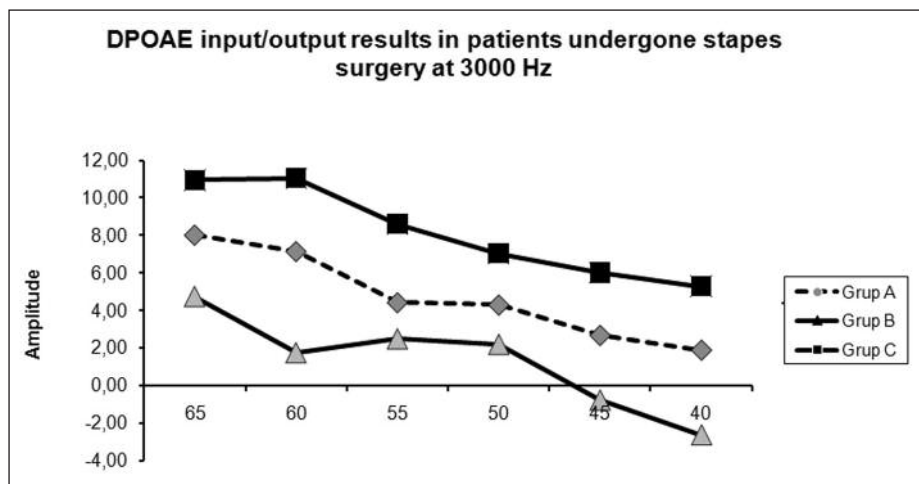


Figure 4. DPOAE I/O functions were statistically significant with 60-45 dB at 3000 Hz ($p < 0.05$). (**Group A:** Patients with 0.3 mm diameter prostheses **Group B:** Patients with 0.6 mm diameter prostheses **Group C:** Control group)

stainless steel or platinum. Of these materials, Teflon remains the most frequently used material placed into the oval window as a stapes prosthesis. Teflon is well-tolerated in the middle ear because it is not reactive with tissue [6,7].

Because the ear works as a pressure receptor, a prosthesis will modify the sound pressure transmission and then interfere with hearing gain. Therefore, the choice of the prosthesis diameter represents an important aspect of stapes surgery. Nowadays it is still object of a wide discussion. There is no single 'optimum' piston diameter, and there is variation on whether larger or smaller piston diameters give better acoustic results after stapedotomy. Consequently, the opinions on the role of the prosthesis thickness are not unanimous [4,8,9].

Tange et al. [8] and Cotulbea et al. [9] were found no influence for the different shape and material of prosthesis on the results of stapes surgery. Fisch pretended that the diameter of the prosthesis has no effect on hearing gain [10]. Fisch found that there was no difference statistically between 0.3 and 0.6 mm prostheses after 1 year, although in the short run, 0.6 mm gave a better result at the low frequencies [10]. Huttenbrink concluded that the 0.3mm stapes piston is optimum and that pistons with smaller and larger diameter have their disadvantages [11]. Donaldson and Snyder [12] suggested that increase in diameter resulted in better gain in lower frequencies and decrease in diameter gave better results in higher frequencies. Gristwood [13] compared between 0.6 and 0.8 mm prostheses and revealed that the decrease of diameter gives poor results at low frequencies. Grolman et al. found the same result comparing 0.3 and 0.3 mm prostheses. [14]

Sennaroglu et al. compared 0.6 and 0.8 mm prostheses and concluded that the improvement in the hearing level was better with the use of 0.8 than with 0.6 mm Teflon pistons, particularly at the lower frequencies [3]. Shabana et al. found that there was no statistically significant difference in closure of the ABG using 0.4 and 0.6 mm prostheses, indicating that both diameters do not affect the cochlear reserve in stapes surgery for otosclerosis [2]. However, the raw data showed a trend toward better results for the 0.6 mm piston. This may be due to a larger surface area of transmission created

in the footplate. The ratio of the base area of the prosthesis to the stapes footplate is highest using a 0.6 mm piston. The increased portion of the cochlea stimulated by this higher ratio could explain the better results of pistons with a higher diameter.

There is no literature for the evaluation of prosthesis diameter on hearing results with objective audiological tests in stapes surgery. Therefore we have performed to study the diameter of the prosthesis could affect the successful hearing results of stapedotomy with OAE. In TEOAE measurements, statistically significant changes were detected at 2000-3000 Hz ($p<0.001$) and at 4000 and 6000 Hz ($p<0.05$) for 0.6 mm prostheses to 0.3 mm (Figure 1). For DPOAE results, statistically significant difference was obtained for repeated measurements at 3000 Hz and 4000 Hz for 0.6 mm prostheses to 0.3mm ($p<0.05$) (Figure 2). DPOAE I/O functions were statistically significant with 65 dB at 2000 Hz ($p<0.05$) (Figure 3), with 60 dB and 45 dB at 3000 Hz ($p<0.05$) for 0.6 mm prostheses to 0.3 mm (Figure 4). The improvement in the hearing level level was better with the use of 0.6 than with 0.3 mm teflon pistons, particularly not only at the lower frequencies, but also 4000 Hz and 6000 Hz frequencies.

On the basis of the present results, TEOAE or DPOAE measurements are fast, objective and non-invasive methods to evaluate the benefit of successful stapes surgery can be recommended only as an adjunct to clinical follow-up examinations and conventional pure-tone audiometry, but they cannot replace behavioral threshold testing [5]. However, in those patients with postoperatively present OAE, TEOAE or DPOAE measurements are advisable for follow-up examinations because of their established low intra-subject variability. The hearing levels of patients in these study were better for the measurements reflect outer hair cell function, and greatly depend upon both inward and outward transmission of acoustic energy through the middle ear.

Conclusion

To the best of our knowledge, this is the first report to compare objectively prosthesis diameter on hearing results using OAE in otosclerotic patients who underwent stapedotomy. OAE, TEOAE or DPOAE measurements are advisable for follow-up examinations

in otosclerosis patients with stapedotomy. It was found that transmission of acoustic energy through the middle ear postoperatively was better with the use of larger piston diameter (0.6 mm) particularly not only at lower frequencies, but also at higher frequencies in this study. An increase in prosthesis diameter for stapedotomy gives better hearing results, especially at lower frequencies.

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