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ORIGINAL PAPER

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A retrospective study of the hearing results obtained after stapedotomy by the implantation of two Teflon pistons with a different diameter

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Abstract This study reports the evaluation of hearing results after implantation of a Teflon piston of a different diameter in cases of otosclerosis requiring stapedotomy. By random selection, a Teflon piston with a shaft diameter of 0.3 mm was inserted in 34 cases and a piston with a shaft diameter of 0.4 mm in 26 cases. A retrospective analysis of the pre- and postsurgery audiological results of these two patient groups was carried out by microcomputer. A repeated statistical measures analysis of variance was used to test and estimate the air-conduction frequency-specific differences between the two prostheses with respect to changes in pre- and postoperative hearing. The results of this comparative study of the two Teflon pistons with different diameters indicate statistically a greater hearing gain for the 0.4-mm prosthesis, especially in the lower frequencies.

Key words Hearing loss · Otosclerosis · Stapedectomy · Teflon ossicular implant · Audiometry

Introduction

Since Shea [11] introduced clinically the procedure of stapedectomy with interposition of a stapes prosthesis in 1958, many different prostheses have become available. At present, the Teflon piston is the most widely employed prosthesis for reconstruction of the ossicular chain in cases of otosclerosis [1]. The initial surgical technique of removal of the complete stapes (i.e. stapedectomy) has

been altered in the so-called small fenestra method [7, 9]. This technique has been further refined during the past decade [4] and there has been considerable development in the prostheses used. Enhancement of these prostheses has mainly focused on shape, size, and material type.

There is a tendency to reduce the diameter of the inserted shaft of the prosthesis through the stapes footplate fenestra. The shaft diameter of the prosthesis ranges from 0.8 mm down to 0.3 mm. Although there is a wide variety of stapes prostheses available there are only a few reports on comparative results obtained with the different devices [5, 13]. We report a retrospective analysis of pre- and postsurgery audiological results of two patient groups that underwent stapedotomies using two Teflon prostheses having different shaft diameters (0.4 mm and 0.3 mm respectively).

Patients and methods

From 1991 to 1994, 60 implantations with full Teflon stapes pistons were placed in patients with otosclerosis after removal of the stapes superstructure. The group consisted of 44 women and 16 men (age range 18–62 years). Twenty-eight pistons were implanted in the right ear and 32 in the left ear. No revision operations were included in this study. The surgical approach to the middle ear in all cases was transcanal and all operations were performed by the second author. The micro-pick technique described by Marquet [8] was used for the creation of a small fenestra in the stapes footplate. Patients were randomly selected and a Cawthorne Teflon piston with a shaft diameter of 0.3 mm was inserted in 34 cases and a Causse piston with a shaft diameter of 0.4 mm in 26 cases. During surgery the clinical grade of otosclerosis was estimated by the surgeon using the system described by Portmann and Guerrier [10]. All data from the operation were stored in a computer using Microsoft Excel 5.0 software. Systemic and oral antibiotic prophylaxis (with dagracycline) was given perioperatively in all cases. Conventional air/bone conduction and speech audiometry according to the ISO 1975 standard were performed before surgery and at 3–4 months after surgery in the same sound-isolated room.

For statistical analysis we used a repeated measures analysis of variance to test and estimate air-conduction (AC) and bone-conduction frequency-specific differences between the two prostheses with respect to changes in pre- and postoperative hearing.

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Fig. 1 **a** Pre- and postoperative mean air conduction (+ standard deviation) of 34 patients implanted with a 0.3-mm Teflon piston. **b** Pre- and postoperative mean air conduction (+ standard deviation) of 26 patients implanted with a 0.4-mm Teflon piston. ■ Pre-operative AC, ▨ Postoperative AC

Results

The average age of the 26 patients receiving the Causse 0.4-mm prosthesis (group 1) was 45 years. Average follow up was 122 weeks. The average age of the 34 patients implanted with the 0.3-mm Cawthorne prostheses (group 2) was 38 years. Average follow up in this group was 87 weeks. The grade of otosclerosis [10] found during surgery was similar in both groups (group 1: 2.41 ± 0.7 ; group 2: 2.46 ± 0.7). No patient in either group developed a postoperative infection, dead ear or other postoperative complaints such as persistent vertigo.

To evaluate audiological data, an Excel 5.0 spreadsheet program was used and demonstrated the preoperative air-bone gap in all cases. The conductive deficit was more

than 25 dB, and the hearing level was worse than 40 dB in both groups. The mean postoperative hearing level was about 25 dB for all frequencies (Fig. 1).

The model assumptions used for statistical analysis were checked by normal probability between and within patient residuals and by comparing frequency-specific standard deviations. *P*-values for effects with > 1 numerator degree of freedom were based on the Huynh-Feldt correction for non-sphericity. For all AC frequencies, *P*-values for higher-order orthogonal polynomials of the interactions were > 0.30, with the exception of the third order (0.055), giving no indication of a lack of linearity.

Postoperatively, an overclosure was found at 2000 Hz while an air-bone gap was ≤ 30 dB at the other frequencies. A sensorineural hearing loss (> 10%) did not occur, and there was no loss of speech discrimination.

Table 1 Gain in air conduction (dB HL ISO 1975) with 0.4-mm and 0.3-mm prostheses after stapedotomy with standard error of the mean

Prosthesis	AC frequency						
	125 Hz	250 Hz	500 Hz	1 kHz	2 kHz	4 kHz	8 kHz
0.4-mm piston	32.9 ± 2.5	37.6 ± 2.7	35.8 ± 2.5	33.3 ± 2.0	24.8 ± 1.7	15.5 ± 2.4	3.2 ± 2.5
0.3-mm piston	25.6 ± 2.9	26.4 ± 3.2	28.6 ± 2.9	28.0 ± 2.3	22.7 ± 2.0	16.1 ± 2.7	2.0 ± 2.9
Difference	7.3 ± 3.8	11.2 ± 4.2	7.2 ± 3.8	5.3 ± 3.1	2.1 ± 2.7	0.6 ± 3.6	1.2 ± 3.8

The changes in pure-tone hearing by AC according to the type of prosthesis used are shown in Table 1. Hearing improved in all ears except at 8 kHz. The decrease in hearing loss was greater for the 0.4-mm-diameter prosthesis between 125 Hz and 1 kHz ($P = 0.099$) but was not significant at 2 kHz, 4 kHz or 8 kHz ($P = 0.012$; linear interaction $P = 0.013$).

Discussion

The diameter of the stapes piston prostheses has been altered during the past decades. Initially the usual diameter of the stapes piston was 0.8 mm but was then reduced to 0.4 mm [2]. This diameter has since been further decreased to 0.3 mm. However, after 30 years of stapes surgery, Shea [12] claimed that his best hearing results were obtained with a 0.6-mm Teflon piston. This was disputed by Herzog [6] and Fish [3], who both reported best results after stapes surgery when utilizing a 0.4-mm-diameter piston. Fish [3] also compared hearing results obtained in 52 patients operated upon with either a 0.6-mm or a 0.4-mm stapedotomy and demonstrated no significant differences in results (but tested hearing only from 0.5 to 2.0 kHz). He still concluded that the 0.4-mm piston could be used successfully for stapes surgery.

Our present study of 60 randomly selected cases of otosclerosis showed that results of hearing between 125 Hz and 6 kHz were better when a 0.4-mm prosthesis was used following stapedotomy. The difference in postoperative Ac hearing when compared to a 0.3-mm prosthesis was more pronounced and statistically significant in the low frequencies up to 1 kHz.

In comparable previous studies, no significant difference was demonstrated when 0.4- and 0.6-mm prostheses were used after stapedectomy [3]. However, we demonstrated a difference in hearing results between pistons with different shaft diameters by measuring more frequencies (especially frequencies at 124 Hz and 250 Hz) than in the other studies. We believe that it is important to measure the greater range of frequencies for the evaluation of hearing results after stapes surgery. Tange and Dreschler [14] have shown that findings of high-frequency audiometry can predict the state of stapes fixation in patients with otosclerosis. Our study has also demonstrated the importance of the low frequencies in the analy-

sis of different types of stapes prostheses. Our experiences show that the 0.4-diameter all-Teflon piston has a better postsurgical hearing result in the low frequencies than the 0.3-mm all-Teflon piston.

However, we realize that the optimal prosthesis remains to be developed and that it is not possible to implant the same piston in all cases of otosclerosis. More comparative studies are needed to support the statements of this present study.

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