ORIGINAL ARTICLE

Implantation of 3 Different Types of Stapes Prostheses: A Retrospective Study

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OBJECTIVE: In this short-term result study, we present our experience with the various surgical techniques and prostheses that we use in stapes surgery.

MATERIALS AND METHODS: We retrospectively analyzed the subjects' postoperative hearing results after stapes surgery involving the implantation of 1 of 3 different types of stapedial pistons. We studied the outcomes of a total of 154 stapes operations: one hundred forty-three stapedotomies (performed with a diamond microdrill and Fisch-type manual perforators) and 11 stapedectomies. In 49 patients, a Causse-type Teflon piston with a diameter of 0.6 mm was inserted; in 45 patients, we used a Fisch-type Teflon and stainless steel piston with a diameter of 0.4 mm; and recently, in 60 patients, we used a Fisch-type titanium piston with a diameter of 0.4 mm. Pure-tone audiometry with appropriate masking was performed approximately 6 weeks postoperatively. The average postoperative air-bone gap was calculated as the postoperative air PTA minus the postoperative bone PTA.

RESULTS: Although the Fisch-type Teflon and stainless steel 0.4-mm piston provided a somewhat poorer result in the zero-to-10 dB range than did the other prostheses, that difference was not significant, and the results in the zero-to-20 dB range were comparable among the 3 types of prosthesis.

CONCLUSION: The material and shape of the prosthesis do not greatly influence the results of stapes surgery. The experience and manual skill of the surgeon remain very important factors in providing a successful outcome. The choice of stapes prosthesis depends primarily on the preference of the surgeon.

During the last several decades, stapes surgery has undergone various modifications. The main surgical techniques used today for the treatment of otosclerosis are total stapedectomy, partial posterior stapedectomy, and stapedotomy^[1,2]. The biomaterials used in stapes prostheses have also evolved. The stapedial piston is currently composed of a variety of materials such as Teflon (a fluoroplastic material), stainless steel, platinum, gold, and, more recently, titanium^[2,3]. Several studies comparing the results of the various procedures used in stapes surgery have been published, and the materials and diameters of the pistons used have been analyzed and compared^[3-6].

Over the last 5 years in the Ear, Nose, and Throat Department at Victor Babeş University of Medicine and Pharmacy in Timişoara, Romania, 3 different types of pistons have been used in stapes surgery: the Fisch-type Teflon and stainless steel piston with a diameter of 0.4 mm (Xomed, Jacksonville, Fla, USA), the Causse-type Teflon piston with a diameter of 0.6 mm (Richards-Smith and Nephew, Memphis, Tenn, USA), and the Fisch-type titanium stapes piston with a diameter of 0.4 mm (Stryker Leibinger, Freiburg, Germany).

The purpose of this study was to retrospectively analyze the cases performed during the period specified and to present our experience with the various surgical techniques and prostheses that we use in stapes surgery.

MATERIALS AND METHODS

Between January 2001 and January 2006, 154 stapes operations (46 men and 108 women) were performed in our department. At 143 patients, a stapedotomy technique was performed in which a diamond microdrill and Fisch-type manual perforators were used. In 11 patients, the stapes footplate was removed, but only when required by the interoperative course (eg, a dislocated footplate, facial dehiscence). In 49 patients (32%), a Causse-type Teflon piston (Figure 1) with a diameter of 0.6 mm was inserted, in 45 patients (29%) we used a Fisch-type Teflon and stainless steel piston (Figure 2) with a diameter of 0.4 mm, and recently in 60

patients (39%) we used a Fisch-type titanium piston (Figure 3) with a diameter of 0.4 mm. The stapedotomy incisions were made with a 0.7-mm diamond burr when the 0.6-mm Causse-type piston was inserted and with a



Figure 1: Causse-type Teflon piston



Figure 2: Fisch-type Teflon and stainless steel piston



Figure 3: Fisch-type titanium piston

set of 0.4-mm and 0.6-mm Fisch manual perforators when the Teflon stainless steel and titanium 0.4-mm piston was inserted. In 5 ears, we encountered an obliterative otosclerosis that necessitated the drilling open of the oval-window niche.

After we had measured the distance between the footplate and the lateral surface of the incus, the Teflon stainless steel piston was trimmed with a scalpel blade, and the titanium prosthesis was trimmed with a cutting block. The Causse-type Teflon pistons were of various prefixed sizes. The Fisch-type Teflon stainless steel and titanium pistons were crimped over the incus with a McGee forceps, a step performed before the stapes superstructure was removed^[2,3]. We used 2 hooks to place the 0.6-mm Teflon Causse-type piston over the incus after we had removed the stapes superstructure, and crimping was unnecessary^[2]. In all patients who underwent stapedotomy or stapedectomy, the piston was placed into the opening and the oval-window niche was sealed with connective tissue pledgets.

RESULTS

Each patient on whom stapes surgery was performed also underwent an audiologic evaluation. Pure-tone audiometry with appropriate masking was performed preoperatively and approximately 6 weeks (mean value) postoperatively. The 4-tone averages at frequencies of 0, 5, 1, 2, and 3 kHz were used to calculate the pure-tone average values (PTA). The average preoperative air-bone gap (ABG) was calculated by subtracting the preoperative bone PTA from the preoperative air PTA. We also calculated the mean value of the preoperative ABG for every group of patients in which 1 of the 3 types of stapes prosthesis had been used. The otosclerotic lesions found during surgery were classified according to Portman^[2] as type 1, normal aspect (ankylosis of the annular ligament); type 2, focus involving the anterior quarter of the footplate; type 3, focus involving more than the anterior half of the footplate; type 4, focus involving the entire footplate; and type 5, complete obliteration of the footplate^[5]. We considered each patient's age, preoperative hearing level, and oval-window pathology as the characteristics most likely to influence the functional outcome of stapes surgery^[5]. The distribution of the mean preoperative ABG, the oval-window pathology, and the patient's age at surgery versus the type of prosthesis used are presented in Table 1. The data show a homogeneous distribution of those factors among the 3 groups of patients categorized by stapedial piston type.

The average postoperative ABG was calculated as the postoperative air PTA minus the postoperative bone PTA, according to the 1995 guidelines of the American Academy of Otolaryngology-Head and Neck Surgery^[7]. The results were recorded in groups of 10-dB

Table 1: Characteristics of the study subjects and type of prosthesis used in stapes surgery

	Causse-Ty	/pe	Fisch-Type Teflon		Fisch-Type	
	Teflon Piston		and Stainless Steel		Titanium Piston	
			Piston			
Average age at surgery (y)	46.3		44.7		47.1	
Mean preoperative air-bone gap (dB)	31.4		33.3		29.8	
Oval-window pathology	n	Percent	n	Percent	n	Percent
Type 1 otosclerotic lesion	5	10	4	9	7	12
Type 2 otosclerotic lesion	22	45	21	47	27	45
Type 3 otosclerotic lesion	18	37	15	33	20	33
Type 4 otosclerotic lesion	3	6	3	7	4	7
Type 5 otosclerotic lesion	1	2	2	4	2	3

increments: zero to 10, 11 to 20, and higher than 20 dB. The functional success of the operation was defined as an average postoperative air-bone gap within the zero-to-10 dB group. An average postoperative ABG between 11 and 20 dB was considered a moderately functional result. A remaining postoperative ABG of more than 20 dB was considered an unsuccessful operation. The results of the 3 different types of stapedial pistons were measured by analyzing the average postoperative ABG obtained (Table 2). There was no significant difference in the hearing results obtained according to the type of stapes prosthesis used. In our opinion, the larger 0.6-mm diameter of the Causse-type Teflon piston did not influence the outcome of the operation.

Two cases of postoperative sensorineural hearing loss of over 20 dB (range, 0.5-3 kHz) occurred, 1 in a patient with the Causse-type Teflon piston and 1 in a patient with the Fisch-type Teflon and stainless steel piston. However that result was entirely unrelated to the type of the stapedial piston used.

DISCUSSION

Various stapes prostheses of different materials, forms, and diameters have been used in stapes surgery, and there is no consensus regarding the stapes prosthesis of choice^[3-6]. In our department, the Causse-type Teflon 0.6-mm piston and the Fisch-type Teflon and stainless steel 0.4-mm piston have been used in stapes surgery. At the beginning of 2004, however, we introduced the Fisch-type titanium 0.4-mm piston, which has gradually replaced the other 2 types.

In the literature, few comparative studies of different stapes prosthesis can be found. Fisch^[3]

compared the postoperative results of the 0.6-mm and 0.4-mm diameter wire Teflon pistons used with the stapedotomy technique. The 0.4-mm piston yielded poorer results 3 weeks postoperatively, but there was no significant difference in the results of the 0.6-mm and the 0.4-mm pistons 3 months after surgery and at the 1-year follow-up examination. This suggests that the thinner 0.4-mm piston needed more time to be successful, but the results for any pistons were ultimately the same^[3].

De Bruijn and colleagues compared the full Teflon piston and the full gold piston and noted that the heavier gold piston gives more gain in the low- and mid-frequency ranges, but the lighter Teflon piston gives more gain in the high-frequency range, although that difference was not significant^[6].

Tange and colleagues compared 2 full-metal stapes prostheses (the gold piston and the titanium piston) used in surgery for otosclerosis. Use of the lighter titanium piston^[5] resulted in a higher ABG closure within 10 dB, and the heavier gold piston had a higher overclosure rate. The authors explained that the better ABG closure provided by the titanium piston occurred because titanium is less malleable than gold and permits a tighter fixation onto the incus. The higher overclosure rate with the gold piston results from its weight, which is 4 times greater than the titanium type^[5]. The overall hearing results obtained with both full-metal stapes pistons were comparable (ABG closure under 20 dB: gold, 91%; titanium, 94%)^[5].

In our study, in which the 3 different types of stapes prosthesis mentioned previously were compared, the Fisch-type Teflon and stainless steel piston was associated with a somewhat poorer result than the

Table 2: Average postoperative air-bone gap and type of prosthesis used in stapes surgery

Average Postoperative Air-	Causse-Type Teflon Piston		Fisch-Type Teflon and Stainless Steel Piston		Fisch-Type Titanium Piston	
Bone Gap (dB)						
	n	Percent	n	Percent	n	Percent
0 - 10	31	63	27	59	37	62
11 - 20	12	25	13	30	17	28
20 +	6	12	5	11	6	10

Causse-type Teflon piston and Fisch-type titanium piston, with a postoperative ABG in the zero-to-10 dB range in 59% of the patients (Causse-type Teflon piston, 63%; Fisch-type titanium piston, 62%). However, that difference was not significant, and the results in the zero-to-20 dB range (88% Causse-type Teflon piston, 89% Fisch-type Teflon and stainless steel piston, and 90% Fisch-type titanium piston) were comparable. We found the stainless steel loop of the piston to be slightly too rigid, and that rigidity made the crimping over the incus more difficult. Using 2 hooks to place the Caussetype Teflon piston over the long process of the incus seemed unnecessarily complicated to us. We suggest that the thicker 0.6-mm Causse piston makes the removal of the stapes superstructure necessary before the prosthesis is placed, which renders the long process of the incus less stable. These are, however, our subjective opinions, and those of other surgeons may differ.

The titanium piston seems easy to handle and to trim. The specially designed cutting block and holding forceps enable accurate handling and trimming of the prosthesis. The flat band-shaped loop and the rigidity of the material facilitate good crimping and create a stable connection with the long process of the incus. For economic reasons, we prefer to trim a single prosthesis rather than to store various prostheses of prefixed size.

In a retrospective analysis of early postoperative hearing results after stapedotomy with the implantation of a titanium stapes prosthesis (K piston), Zuur and colleagues obtained a postoperative ABG of less than 10 dB in 79% of their subjects and less than 20 dB in 97%. The authors attributed the good performance of the prosthesis to the rough surface of the titanium bandshaped loop, which enhances a stable grip between the incus and the piston, while the slight rough surface at the shaft end induces the formation of a stable membrane with good energy transfer in the stapedotomy opening^[8]. These characteristics of the titanium prosthesis and its biocompatibility and mechanical stability render it a good alternative for use in stapes surgery. Several years ago, these features

compelled us to use the titanium prosthesis in our practice, and its use has gradually replaced that of the other 2 prostheses.

The functional results obtained with the 3 different types of stapes prostheses were comparable. In our opinion, the material and the shape of the prosthesis do not influence the results of the operation in a key way. The expertise and manual skill of the surgeon remain very important factors in providing a successful outcome after stapes surgery. The choice of the stapes prosthesis used depends primarily on the preference of the surgeon.

REFERENCES

- Naumann HH, Wilmes E. Operations for stapedial ankylosis. In: Naumann HH, Helms J, Herberhold C, Jahresdorfer RA, Kastenbauer ER, Panje WR, et al, editors. Head and neck surgery. Vol 2. Stuttgart, New York: Georg Thieme; 1996. p. 238-44.
- Tos M. Surgical solutions for conductive hearing loss. Stuttgart, New York: Georg Thieme; 2000. p. 86-99, 113-115, 122-129.
- 3. Fisch U, May J, editors. Tympanoplasty, mastoidectomy, and stapes surgery. Stuttgart, New York: Georg Thieme; 1994. p. 265-7.
- 4. Huttenbrink KB. Biomechanics of stapesplasty: a review. Otol Neurotol 2003; 24:548-57; discussion 557-9.
- Tange RA, Grolman W, Dreschler WA. Gold and titanium in the oval window: a comparison of two metal stapes prostheses. Otol Neurotol 2004; 25:102-5.
- de Bruijn AJ, Tange RA, Dreschler WA. Comparison of stapes prostheses: a retrospective analysis of individual audiometric results obtained after stapedotomy by implantation of a gold and a teflon piston. Am J Otol 1999; 20:573-80.
- 7. Black B. Reporting results in ossiculoplasty. Otol Neurotol 2003; 24:534-42.
- 8. Zuur CL, de Bruijn AJ, Lindeboom R, Tange RA. Retrospective analysis of early postoperative hearing results obtained after stapedotomy with implantation of a new titanium stapes prosthesis. Otol Neurotol 2003; 24:863-7.