



## Original article

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## STAPEDOTOMY WITH IMPLANTATION OF THE FISCH-TYPE 0,4 MM TITANIUM STAPES PROSTHESIS, A GOOD ALTERNATIVE IN STAPES SURGERY

## SUMMARY

The aim of this short-term result study was to present our experience with the Fisch-type 0,4 mm titanium prosthesis we use in stapes surgery.

We retrospectively analyzed the postoperative hearing results obtained in 162 stapes operations with implantation of the Fisch-type 0.4 mm titanium piston. We compared them with the hearing results obtained with two types of prostheses we used before we introduced the titanium piston (49 stapes operation with implantation of the Causse-type Teflon pistons with a diameter of 0.6 mm and 45 stapes operations with implantation of the Fisch-type Teflon and stainless steel pistons with a diameter of 0,4 mm). In the majority of patients, a stapedotomy technique was performed. Only in 14 cases, the stapes footplate was removed. Pure-tone audiometry with appropriate masking was performed approximately six weeks postoperatively. The average postoperative ABG was calculated as the postoperative air PTA minus the postoperative bone PTA.

Although the functional results of the three different types of stapes prosthesis did not vary significantly, the Fisch-type 0.4 mm titanium piston gave a somewhat better result in closing the ABG in the "within 10 dB" range. This may be due to a better fixation of the prosthesis to the long process of the incus.

The good characteristics of the titanium piston made it our first choice in stapes surgery, gradually replacing the other two types of stapes prostheses.

**Key words:** prosthesis, titanium piston, stapes surgery

## INTRODUCTION

From the polyethylene strut designed by Shea in 1957, stapes prostheses have undergone a lot of modifications (1). The biomaterials used for composing the stapes prostheses have also evolved. The stapelial pistons are currently composed of a variety of materials like Teflon (fluoroplastic), stainless steel, platinum, gold, and more recently titanium and nitinol, an alloy from titanium and nickel which has the property of shape memory (1,2). Several studies have been published, comparing the results of the different stapes prostheses used in stapes surgery. The different

materials and diameters of the pistons were analyzed and compared (3-6).

In 2004, at the ENT Department of the University of Medicine and Pharmacy Timișoara, we introduced the Fisch-type titanium stapes piston with a diameter of 0.4 mm (Stryker Leibinger, Freiburg, Germany), which gradually replaced the other two types of stapelial pistons, currently in use at that time: the Fisch-type Teflon and stainless steel piston with a diameter of 0.4 mm (Xomed, Jacksonville, Florida, USA) and the Causse-type Teflon piston with a diameter of 0.6 mm (Richards-Smith and Nephew, Memphis, USA).

The purpose of this study was to retrospectively analyze the cases operated with implantation of the Fisch titanium 0.4 mm piston, and to compare the results obtained with the results of the other two types of pistons we used before.

#### MATERIAL AND METHODS

Between January 2004 and December 2008, a total of 162 stapes operations with implantation of the Fisch-type titanium stapes piston with a diameter of 0.4 mm (Figure 1) were performed in our department.



Figure 1. The Fisch-type titanium piston

In the period between 2001 and 2005, 49 Causse-type Teflon pistons with a diameter of 0.6 mm (Figure 2) and 45 Fisch-type Teflon and stainless steel pistons with a diameter of 0.4 mm (Figure 3) were inserted.

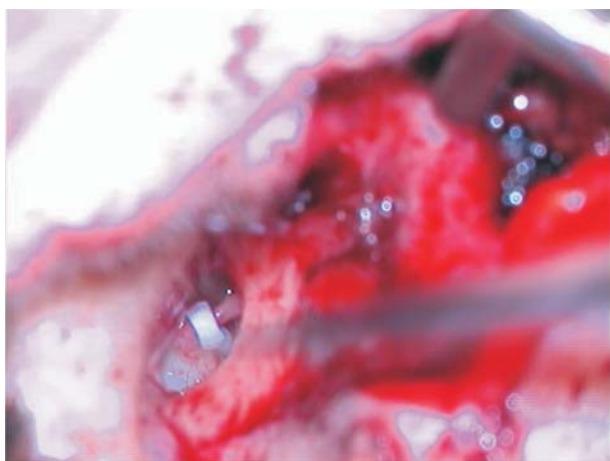


Figure 2. The Causse-type Teflon piston

In the majority of patients, stapedotomy technique was performed (3,7,8). In 14 cases, the stape footplate was removed, but only when required by the trend of the operation (eg. dislocated footplate, facial nerve dehiscence). The stapedotomy opening was performed with a 0.8 mm diamond burr,

when the 0.6 mm Causse-type piston was inserted, and with a set of 0.4 mm and 0.6 mm Fisch manual perforators as the titanium and the Teflon stainless steel 0.4 mm pistons were inserted.



Figure 3. The Fisch-type Teflon and stainless steel piston

After measuring the distance between the footplate and the lateral surface of the incus, we trimmed the length of the titanium prosthesis using a specially designed cutting block (Fisch type). The Teflon stainless steel piston could be trimmed with a scalpel, whereas the Causse type Teflon pistons were of various pre-fixed sizes. The Fisch type titanium and Teflon stainless steel pistons were crimped over the incus with a Mc Gee forceps. This step was done before removing the stapes superstructure (3,8). The 0,6 mm Teflon Causse-type piston was placed over the incus by using two hooks, after removing the stapes superstructure, and did not necessitate crimping (8). In all cases of stapedotomy and stapedectomy, the piston was placed into the opening and the oval window niche was sealed with connective tissue pledges. We also placed the connective tissue over the piston-incus connection.

#### RESULTS

Each patient who underwent stapes surgery was audiologically tested. Pure-tone audiometry with appropriate masking was performed preoperatively and approximately six weeks (mean value) post-operatively. Pure tone average values (PTA) were calculated using the 4-tone averages at frequencies of 0.5, 1, 2 and 3 kHz. The average preoperative air-bone gap (ABG) was calculated as the preoperative air PTA minus the preoperative bone PTA. We also calculated a mean value of the preoperative ABG for every group of patients in which one type of the three stapes prostheses was used (4). The otosclerotic lesions found during surgery were classified according to Portman as type 1: normal aspect (ankylosis of the annular ligament); type 2: focus involves the anterior

quarter of the footplate; type 3: focus involves more than the anterior half of the footplate; type 4: focus involves the entire footplate; and type 5: complete obliteration of the footplate (5). We considered the patients' age, preoperative hearing and oval window pathology as the patients' characteristics most likely to influence the functional outcome of a stapes operation (5). The distribution of the mean preoperative ABG, of the oval window pathology and of the patients' age at surgery versus the type of prosthesis used is presented in Table 1.

considered as an unsuccessful operation (4). The results of the three different types of stapedial pistons were measured by analyzing the obtained average postoperative ABG and are presented in Table 2.

Three cases of postoperative sensorineural hearing loss of over 20 dB (0.5-3 kHz) occurred, one with the Fisch-type titanium piston, one with the Cause-type Teflon piston and one with the Fisch-type Teflon and stainless steel piston. However, the occurrence of these three cases seemed unrelated with the type of the stapedial piston used. Only four of the patients with postoperative ABG higher than

*Table 1. Distribution of the mean preoperative ABG, oval window pathology and the patients' age at surgery versus type of stapes prosthesis.*

	Fisch-type Titanium piston		Fisch-type Teflon and Stainless steel piston		Cause-type Teflon piston	
Average age at surgery	45.2 years		44.7 years		46.3 years	
Mean preoperative ABG	30.4 dB		33.3 dB		31.4 dB	
Oval window pathology	n	%	n	%	n	%
Type 1	19	12%	4	9%	5	10%
Type 2	75	46%	21	47%	22	45%
Type 3	55	34%	15	33%	18	37%
Type 4	8	5%	3	7%	3	6%
Type 5	5	3%	2	4%	1	2%

The data presented show a homogeneous distribution of these factors between the three groups of patients operated with different stapedial pistons.

The average postoperative ABG was calculated as the postoperative air PTA minus the postoperative bone PTA, as in the 1995 guidelines set by the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) (10). The obtained results were recorded in 10 dB groups: 0-10, 11-20, 20+ dB. Functional success of the operation was defined as an average postoperative air-bone gap within the 0-10 dB group. In addition, an average postoperative ABG reported between 11 and 20 dB was considered as a fairly decent functional result (moderate functional result). A remaining postoperative ABG of more than 20 dB was

20 dB elected revision surgery. The findings during the second surgery were: one case of short prosthesis (Fisch titanium piston), one case of loose prosthesis with minimal erosion of the short process of the incus (Fisch Teflon and stainless steel piston) and two cases of displacement of the piston associated with incus necrosis (one Fisch Teflon and stainless steel piston and one Cause Teflon piston).

## DISCUSSION

In the last decade, the titanium prostheses have been used more and more frequently in the reconstruction of the ossicular chain. Its very good biocompatibility, due to the formation of a superficial layer of TiO<sub>2</sub>, with a very low rate of

*Table 2. Average postoperative air-bone gap versus type of prosthesis*

Average Postoperative ABG (dB)	Fisch-type Titanium piston		Fisch-type Teflon and Stainless steel piston		Cause-type Teflon piston	
	n	%	n	%	n	%
0-10	105	65%	27	59%	31	63%
11-20	41	25%	13	30%	12	25%
20+	16	10%	5	11%	6	12%

solvability, its high ratio of resistance/weight and its practical lack of toxicity make titanium very eligible for implantation (9).

In our case, the hearing results obtained with the Fisch titanium stapes prosthesis did not vary significantly from those obtained when using the two other types of stapes prostheses. Still, the Fisch-type titanium piston gives a somewhat better result in the 0-10 dB range of the postoperative ABG in 65% of the cases (63% - Causse Teflon piston and 59% - Fisch Teflon and stainless steel piston). This may be due to a better fixation of the prosthesis to the incus. In our opinion, the flat band-shaped loop and the rigidity of the material permit a good crimping and a stable connection with the long process of the incus. On the other hand, the Fisch Teflon and stainless steel piston gives the poorest result, with a postoperative ABG in the 0-10 dB range obtained in 59% of the patients. This may be due to the stainless steel loop, which seemed to us too rigid, making the crimping over the incus more difficult. Placing the Causse Teflon piston over the long process of the incus, by using two hooks, seems also more complicated to us. The thicker 0.6 mm Causse piston makes it necessary to remove the stapes suprastructure before placing the prosthesis, making the long process of the incus less stable. These, however, are subjective opinions and can differ in case of other surgeons.

Alexander M. Huber et al. emphasize the importance of an optimal prosthesis fixation to the incus for obtaining good hearing results. They compare the functional results of stapedotomy performed using a Nitinol prosthesis with a control group in which conventional stapes prostheses (platinum Teflon prostheses and titanium prostheses) were used. Nitinol is an alloy from titanium and nickel that has the property of shape memory. By heating this metal, its shape transforms into a predefined form. Although the ABG closure within 20 dB was quite similar, the closure of the ABG within 10 dB was much in favor of the Nitinol prosthesis, with a significant difference. The authors also assessed intraoperatively the quality of prosthesis-incus fixation by using a LDI scanning system, finding a significant better fixation of the Nitinol prosthesis. They concluded that a tight contact of the prosthesis with the long process of the incus leads to better functional results mostly in closing the ABG within the 10 dB range (2).

C. L. Zuur et al. in a retrospective analysis of early postoperative hearing results after stapedotomy with implantation of a titanium stapes prosthesis (K piston) obtained a postoperative ABG less than 10 dB in 79% and of less than 20 dB in 97% of the

patients. The authors attribute the good performance of the prosthesis to the rough surface of the titanium band shaped loop which enhances a stable grip between incus and piston, while the slight rough surface at the shaft end induces the formation of a stable membrane in the stapedotomy opening with good energy transfer (11).

Rinze A. Tange et al. compared two different full metal stapes prostheses used in surgery for otosclerosis, the gold piston and the titanium piston. The lighter titanium piston gave a higher ABG closure within 10 dB, whereas the heavier gold piston had a higher overclosure rate. The authors explain the better ABG closure with the titanium piston, by being less malleable than gold and permitting more tighter fixation onto the incus. The higher overclosure rate with the gold piston must have its explanation by the four times higher weight of this piston. The overall hearing results obtained with both this full metal stapes pistons were however comparably equal, with an ABG closure under 20 dB of 91% for gold and 94% for titanium (5).

Concerning the different diameters of the pistons, it did not occur to us that the larger 0,6 mm diameter of the Causse-type Teflon piston significantly influenced the functional result of the operation.

Fisch compared the postoperative results of the 0.6 mm and 0.4 mm diameter wire Teflon pistons he used with the stapedotomy technique. The 0.4 mm piston yielded poorer results three weeks postoperatively, but there was no significant difference in the results of both the 0.6 mm and 0.4 mm pistons at three-month and one-year follow-up. This suggested that the thinner 0.4 mm piston needed more time to be successful, but the results for both diameters of the pistons were ultimately the same (3).

The Fisch-type titanium piston seemed to us easy to handle and to trim. The specially designed cutting block (Figure 2) and holding forceps enable accurate handling and trimming of the prosthesis.

## CONCLUSION

Although the functional results of the three different types of stapes prostheses did not vary significantly, the Fisch-type 0.4 mm titanium piston gave a somewhat better result in closing the ABG in the "within 10 dB" range. This may be due to a better fixation of the prosthesis to the long process of the incus.

All this characteristics of the titanium piston made it our first choice in stapes surgery, gradually replacing the other two types of stapes prostheses.

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## STAPEDOTOMIJA SA UGRADNJOM FIŠOVE 0,4 MM TITANIJUMSKE PROTEZE STAPESA KAO DOBRA ALTERNATIVA U HIRURGIJI STAPESA

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## SAŽETAK

**Cilj ove kratke studije bio je da se prikažu naša iskustva sa Fišovom 0,4 mm titanijumskom protezom koju koristimo u hirurgiji stapesa.**

**Retrospektivno smo analizirali rezultate postoperativnog sluha koje smo dobili u 162 operacije stapesa sa ugradnjom Fišove 0,4 mm titanijumske proteze. Ove rezultate smo uporedili sa rezultatima sluha koje smo dobili sa protezama koje su korišćene pre uvođenja titanijumskih proteza (49 operacija stapesa sa ugradnjom Causa teflonske proteze prečnika 0,6 mm i 45 operacija stapesa sa ugradnjom Fišove teflonske proteze i proteze od nerđajućeg čelika prečnika 0,4 mm). Kod većine pacijenata urađena je tehnika stapedotomije. Samo u 14 slučajeva uklonjena je osnova stapesa. Tonska audiometrija sa odgovarajućim maskiranjem urađena je otprilike šest nedelja postoperativno. Prosečan postoperativni koštano vazdušni razmak izračunat je kao postoperativni prosečni tonski audiogram dobijen putem vazduha, minus postoperativni prosečni tonski audiogram dobijen putem kosti.**

**Premda se funkcionalni rezultati upotrebom tri različita tipa proteza stapesa nisu značajno razlikovali, Fišova 0,4 mm titanijumska proteza dala je nešto bolje rezultate u zatvaranju koštano vazdušnog razmaka u opsegu "u okviru 10 dB". Ovo može biti rezultat bolje fiksacije proteze za duži krak inkusa.**

**Dobre karakteristike titanijumske proteze su je učinile našim prvim izborom u hirurgiji stapesa, čime je ona postepeno zamenila druga dva tipa proteza stapesa.**

***Ključne reči:* proteza, titanijumska proteza, hirurgija stapesa**