

Diagnostic Findings in Stapes Revision Surgery—A Retrospective of 26 Years

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Objective: The aim of the study is to obtain a detailed overview of the revision findings after stapes operations and to draw conclusions on a stapes prosthesis that can be recommended.

Study Design: Retrospective case series.

Setting: Tertiary otologic referral center.

Methods: Approximately 12,000 middle ear operations within a period of 26 years were evaluated. The findings of the revisions were classified into surgeon related, prosthesis related, and other causes.

Results: Three hundred forty three stapes revisions were done. Many different prostheses were found: the most common were Schuknecht prostheses and Teflon platinum, gold, and titanium pistons. Polyethylene strut, Teflon wire pistons, Shea (Teflon) pistons, and other techniques, such as columella or malleo vestibulopexy, were rarely found.

There are specific findings correlating to certain prostheses: Schuknecht prostheses were too short in 50% of the revisions (surgeon related), Teflon platinum caused necrosis or arrosion

of the long incudal process (prostheses related) in 69%, and gold caused reparative granuloma sometimes combined with necrosis of the incus in 70% (prostheses related). There was no specific diagnostic finding with titanium pistons, neither surgeon nor material related.

Conclusion: An analysis of revision findings over an extended observation period can enable middle ear surgeons to improve their surgical techniques and to select the best suited prosthesis. Self fabricated stapes prostheses (e.g., Schuknecht) do not conform to required quality standards and should not be used. GoPi, which is no longer available, and TPIPi showed prosthesis related diagnostic findings. The titanium prostheses used by the authors have proven to be excellently compatible and can therefore be recommended as safe stapes prostheses.

Key Words: Clip piston Gold piston Otosclerosis Schuknecht prosthesis Stapes prostheses Stapes revision surgery Teflon platinum piston Titanium piston.
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A wide variety of different prostheses has been used in stapes surgery for the past 50 years (1). After the replica (Teflon copy of a stapes) by Shea (2), materials such as polyethylene, polytetrafluoroethylene (Teflon), and metals (including steel, gold, titanium, and nitinol), have been used as well as autogenous materials (cartilage and bone).

Only in very few cases the sound transmission in the middle ear is inadequate or deteriorates over time. In such cases and in cases of postoperative complications, a revision operation is indicated. The diagnostic findings compiled during the operation may identify the cause of a function deficit.

The aim of this retrospective study was to analyze the causes that resulted in the revision operation based on the intraoperative diagnostic findings and to classify the

causes into surgeon-related, prosthesis-related, or unclear. The results will enable conclusions on a stapes prosthesis that can be recommended.

MATERIALS AND METHOD

Data were taken from a database of 12,000 middle ear operations performed primarily by the first author (G. S.) over the period of 1983 to 2008. We evaluated 1,713 primary stapes operations and 343 revisions. The analysis of the comprehensive data has been classified into the following:

- 1) Distribution of the prostheses used in primary surgery done by the first author (a.s., author surgery) (Table 1).
- 2) Symptoms in patients that resulted in the revision. In case of 2 symptoms, the main symptom was taken and allocated to the prosthesis (Table 2).
- 3) Intraoperative diagnostic findings compiled with the surgical microscope. First, the length of the prosthesis was evaluated: if it was too long, it caused vertigo when moving inward (prerequisite was local anesthesia); if it was too short, the medial end of the prosthesis was above the level of the oval niche. The movement was assessed with an in and out movement of the long incudal

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TABLE 1. Primary stapes operations

Period	Mobilisation of stapes	Schuknecht prosthesis	Teflon wire piston	Teflon platinum pi	Gold piston	Titanium		
						K piston	Clip àWengen	Soft CLIP piston
1983 2008	27							
1983 1984		10	3					
1983 1995				501				
1993 2000					482			
2000 2008						162		
2002 2006							344	
2005 2008								184
Total n				1,713				

process and/or the hammer with an appropriate instrument. Movement was either limited (e.g., footplate opening too narrow or scar tissue in the oval niche) or not possible at all (e.g., reobliteration or prosthesis standing on the edge of remnant parts of the footplate, slightly bending during medial movement). If the medial end of the prosthesis was outside the oval niche, it was assessed as dislocated. The fit of the prosthesis to the long incudal process was evaluated by palpation with an appropriate instrument (hook or needle) (e.g., loose contact because of inadequate crimping). Also evaluated was the surface of the long incudal process (arrosion or necrosis) and the surrounding tissue (scar tissue, granulation). The diagnostic findings were classified into surgeon related, prosthesis related, unclear, others, and no diagnostic findings (Table 3). The time intervals after which the revision was performed were recorded in years (Y).

The following findings were classified as surgeon related: prosthesis that is too short or too long, dislocated prosthesis that no longer contacts the oval niche, prosthesis with loose contact to the long incudal process (no arrosion), footplate opening that is too narrow or reobliteration of the footplate opening, scar tissue in the oval niche limiting the movement of the prosthesis, and fixation of malleus head and/or incus in the attic.

Prosthesis related findings were as follows: arrosion (circular bone resorption) and necrosis (complete bone resorption) of the long incudal process in the application area of the prosthesis, and granulation tissue.

Unclear causes were as follows: protrusion of the prosthesis; fistula (leakage in the region of the oval niche); and miscellaneous diagnostic findings, such as retraction process, perforation of the tympanic membrane, chorda related dysgeusia, and rupture of the round window membrane.

Classified as “no diagnostic finding” were revision cases in which the middle ear was normal with apparently well incorporated and mobile prosthesis and mobile malleus/incus.

Moreover, the diagnostic findings with various techniques (mobilization, columella, malleovestibulopexy, and crurotomy) were analyzed (Table 4).

Finally, the proportion of revisions and prostheses implanted by the first author (Table 1) during primary surgery and the percentage of findings during the revisions were analyzed. From these data, the authors attempt to answer the question which stapes prosthesis may be best suited.

The data of all operations are classified into preoperative, intraoperative, and postoperative diagnostic findings and saved in Microsoft Access by entering into customized forms. The database contains all relevant information, diagnostic findings, and special features of the outer auditory canal and middle ear operations that can be performed in a specialized otologic surgical ENT department. The data sets were initially evaluated with Microsoft Excel and then with KNIME (3), a data analysis program developed by the third author (M. R. B.).

The comparability of operations and diagnostic findings done by the first author over a period of 26 years is guaranteed by consistent quality standards.

The study was conducted in accordance with the ethical standards of the 1964 Declaration of Helsinki. The patients gave their informed consent to the evaluation of the anonymized data.

RESULTS

For a period of 26 years 1,713 primary stapes operations were done mainly by the first author. Types, materials, and figures are shown in Table 1. Twenty-seven times, only stapes mobilization was done.

TABLE 2. Main symptoms before revisions

	Hearing loss	Tinnitus	Loose wire syndrome	Vertigo	Fulfillness	Dysgeusia
Crurotomy	17					
Polyethylene strut	6					
Teflon Pi (Shea)	4	1				
Teflon wire piston	11			1		
Schuknecht prosthesis	54		10	2		
Teflon platinum piston	91	3	2	15		
Gold piston	45 ^a	25		7	12	1
Titanium K piston	9			1		
Clip àWengen pi	9		4 ^b	3		1
Soft Clip piston	1		1 ^b			

^aSensorineural hearing loss.

^b“Clattering/ringing.”

TABLE 3. Diagnostic findings in 26 years of stapes revision surgery

Surgeon related	Polyethylene strut		Teflon piston		Teflon wire piston		Schuknecht		Teflon platinum piston		Gold piston		Titanium K-piston		Clip aWengen		Soft clip piston	
	n	y	n	y	n	y	n	y	n	y	n	y	n	y	n	y	n	y
Prosthesis	1	31					37	2-25	6	1-8	8	0.5-2	2	0.1-1				
Too short			1	0.5			1	12	5	0.1-8								
Too long			1	3			4	4-24	3	1-20								
Displaced	4	20-23					1	8	7	0.5-5	2	1.5			3	0.2-0.4		
Loose contact							1	15	5	1-12					4	0.7-1		
Too narrow			1	15			3	4-13	2	1/4	2	0.5-2	3	0.5-1	1	1.8		
Reobliteration	1	30	1	30	3	2-14	2	3/21	6	3-15	1	1	2	1-3				
Scar tissue			1	4			3 ^a	7-17	2 ^a	0.5/2			1	2	5	1-2	1	2.5
Fixation			1	7			10	1-18	14	1-18					2	1.3-2		
Arrosion	1	10	2	9/15					48	2.5-20	9	1-9						
Incus	2	10/30	3	18-31							57	0.1-10						
Granulation																		
Protrusion									2	1/2	1	1						
Fistula									1	5	3 ^b	1-4	1	2.5	1	0.2		
Prosthesis																		
Oval niche																		
Other									2 ^b				1 ^c	4	5 ^c	0.2-1		
diagnostic finding																		
No diagnostic finding							1	25	2	0.5/7			1	2	2	0.5	3	0.5-1
Total n	6	5	12	62	83	105	11	24	4									

N indicates number; y, time interval primary surgery to revision (yr)

^a1 case: incus fixation by bone fragments

^b1 case: cholesteatoma pearl middle ear, perforation tympanic membrane, retraction pocket, chorda dysgeusia

^c1 case: fistula round window, 2 cases: perforation tympanic membrane, subluxation of the incus

TABLE 4. Diagnostic findings with various surgical techniques and prostheses

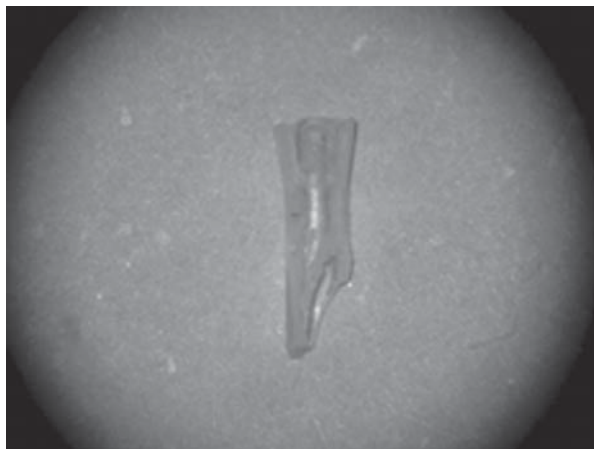
		n	Diagnostic findings
Mobilization		9	Refixation of stapes
Columella	Dentine	1	Displaced, macerated
	Bone	2 ^a	Medial migration
	Cartilage	2	Macerated
	Ceramic	1	Too thick
MVP		4	Protruded
Robinson wire		1	Displaced
Crurotomy		17	Stapedial crus atrophic

MVP indicates malleovestibulopexy.

^a1 × tibia span.

- 1) In the classification of the main symptoms (Table 2), hearing problems were the primary symptom for all types of prostheses, followed by tinnitus (21 × gold piston = GoPi) and vertigo (6 × GoPi, 10 × Teflon platinum-piston = TPIPi) and feeling of fullness and pressure in the ear (10 × GoPi). The hearing problems with the GoPi were combined in almost all cases with sensorineural hearing loss of high frequencies. The loose wire syndrome, in which the patient feels improved hearing after the Valsalva test, with 7 cases is most common of the Schuknecht Wire Prosthesis (SchP), followed by Titanium ClipàWengen Piston (ClipàW) (3 cases, combined with “clattering and ringing”) and 2 cases with Teflon platinum Piston (TPIPi). Chorda dysgeusia followed by a revision surgery was noted twice.
- 2) The major intraoperative diagnostic findings are classified by the various prostheses (Table 3). The fields with the most common diagnostic findings are marked bold: SchP, TPIPi, and GoPi. The time intervals in years (yr) after which the revision was performed can be read from this table for the individual prostheses.

Whereas Table 1 shows the distribution of the prostheses implanted by the first author in primary surgery

**FIG. 1.** Polyethylene strut.**FIG. 2.** Teflon piston (Shea).

(a-s), Table 3 shows the findings of revisions after primary surgery done also by other surgeons (o-s). The following prostheses were the most common: 105 TPIPi (45 × after a-s, 60 × after o-s), 83 GoPi (75 × after a-s, 8 × after o-s), and 58 SchP (after o-s). The following were found in smaller numbers: 11 Titanium K piston (TiKPi) (7 × after a-s, 2 × after o-s), 24 ClipàW and 4 Soft Clip titanium piston (SoftClip) (after a-s), 6 polyethylene strut prostheses (Poly), 5 Teflon Shea piston (SheaPi), and 12 Teflon wire piston (TWPi) (all after o-s).

Diagnostic findings after:

- Poly (Fig. 1), SheaPi (Fig. 2), and TWPi: these prostheses were found only rarely. The diagnostic findings are evenly distributed over the 4 cases with displaced Poly (after 20–23 yr) and do not show any significant finding. Among the findings of a TWPi with “reobliteration,” a rarity was noted: additionally to the TWPi on the long incudal process, another TWPi was found lying transverse in the attic on the incus body.

**FIG. 3.** Schuknecht prostheses.



FIG. 4. Teflon platinum piston.

- SchP (Fig. 3): in 50% of cases (29 cases), these prostheses were too short (surgeon-caused) (after 2–25 yr; average, 13 yr). Also, the SchP was displaced in 12.1% of cases (7 cases). Prosthesis-related incus arrosion was found in 15.5% of cases (9 cases). The other diagnostic findings were recorded only rarely.
- TPIPi (Fig. 4): the most common diagnostic result is incus necrosis (resulting from the prosthesis) with 45.7% of cases (48 cases) after 2.4 to 16 years

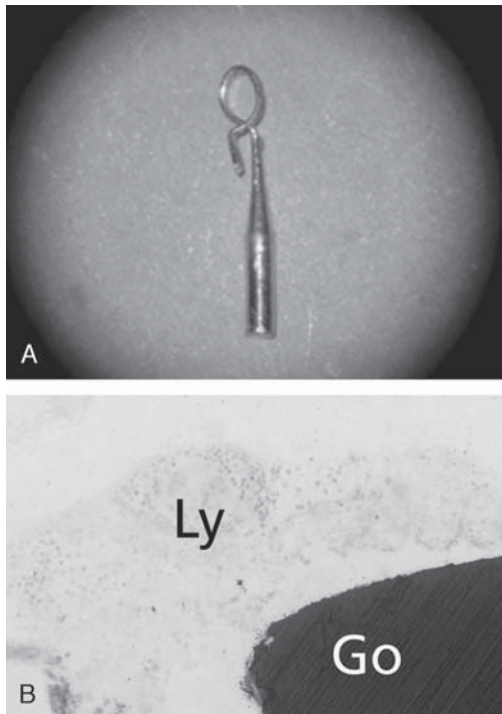


FIG. 5. A, Gold piston. B, Histology gold piston. Go indicates gold; Ly, lymphoid cells.

(average, 9.4 yr), followed by incus arrosion in 13.3% of cases. The remaining diagnostic findings were seen in less than 10%.

- GoPi (Fig. 5A): in 68.7% of cases (57 cases), granulation was found (Fig. 5B), followed by incus necrosis (caused by prosthesis) in 10.8% (9 cases) after 0.1 to 10.3 years (average, 4.6 yr), and 1.2 to 9.2 years (average, 5 yr). Surgeon-related cases (after a-s) were 9.6% (8 cases) with a GoPi that is too short (after 0.5–2 yr, average, 0.9 yr), which were routinely placed at a length of 4.25 mm over a period of approximately 1 year.
- TiKPi, ClipàW, and SoftClip (Fig. 6A) did not show any material-related diagnostic finding. Mainly surgeon-related causes were distributed evenly in small numbers and occurred after the short interval of 0.1 to 1.8 years. Table 2 shows 4 cases after implantation of a ClipàW with symptoms like “clattering/ringing.” Figure 6B shows an “improperly” shortened TiKPi causing reobliteration.

With all prostheses, the diagnostic findings “unclear causes” or “no findings” were seen only rarely. The fistula with TiKPi and ClipàW was caused by an oozer (mild form of the gusher phenomenon) (4). Two incus subluxations (“other diagnostic findings”) were caused by application of the ClipàW to an incudal process with a diameter that is too large.

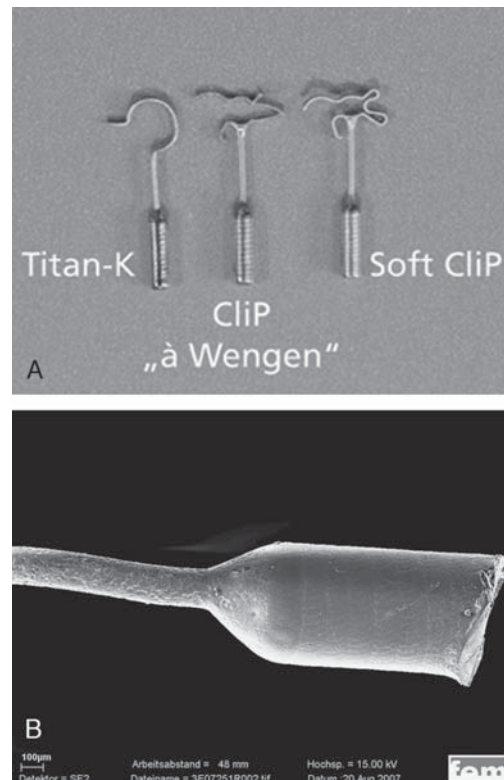


FIG. 6. A, Titanium pistons. B, Titanium K-piston, improperly shortened.

TABLE 5. Primary operations correlated to revisions

	Teflon platinum piston (n 501)			Gold piston (n 482)			Titanium K (n 162)			ClipàW (n 344)			Soft clip (n 184)				
	n rev	%	t(Y)	Ø(Y)	n rev	%	t(Y)	Ø(Y)	n rev	%	t(Y)	n rev	%	t(Y)	n rev	%	t(Y)
Surgeon related																	
Prosthesis	2	0.4	3/8		8	1.7	0.5-2	0.9	2	1.2	0.1/0.5	3	0.9	0.2-0.4			
Too short	4	0.8	0.1-8	2.5													
Too long	1	0.2	1.4														
Dislocated	1	0.2	1.4														
Loose contact	4	0.8	0.5-1.2	0.7	2	0.4	1.5		4	1.2	0.7-1	4	1.2	0.7-1			
Foot plate opening					1	0.2	2		1	0.3	1.8	1	0.3	1.8			
Too narrow									3	1.9	0.7-1						
Reobliteration					1	0.2			1	0.6	1						
Scar tissue																	
Fixation					1	0.2	1		2	0.6	1.3-2	5	1.5	1-2	1	0.5	2.5
Oval niche																	
Attic	4	0.8	10-13	11													
Incus	2.4	4.8	2.4-16	9.4	9	1.9	1-9	5									
Arrosion					40	8.3	0.1-10	4.6									
Necrosis					1	0.2	1										
Granulation	2	0.4	1/2														
Protrusion	1	0.2	5.4		3 ^a	0.6	1-4		1	0.6	2.5	1	0.3	0.2			
Fistula	2 ^b	0.4	2.2/16						1 ^c	0.6	4	2 ^a	1.2 ^d	1.5	0.2-1		
Other diagnostic finding									1	0.6	2	2	0.6	0.5	3	1.6	0.5-1
No diagnostic finding																	
Total n			45				65			9			24		4		

N indicates number of implanted prostheses (primary operation); n rev, number of revision cases; %: n rev / n; t(Y), time interval preoperation/revision in years (Y); Ø(Y), average value of time interval

^a 1 case: retraction pocket/perforation tympanic membrane/chorda dysgeusia

^b 1 case: cholesteatoma pearl middle ear/perforation tympanic membrane

^c Rupture of the round window

^d Incus subluxation

The prostheses and surgical techniques listed in Table 4 represent rare cases: the dentine total prosthesis (columella) was placed on a cartilage-perichondrium patch of the oval window (“neo” foot plate) because after previous tympanoplasty (o-s) malleus and incus had been removed despite a fixed stapes. After an initially good hearing result, the revision uncovered fragments (dissolution of dental substance in the middle ear). Remarkable is a bone columella (5,6) with a length of 5.5 mm. It was taken from the tibia, shaped to an extremely sharp point (Eastern Europe), and migrated medially deep into the inner ear where it caused vertigo, tinnitus, and poor hearing. The cartilage columella (7,8) was macerated; the ceramic prosthesis was too thick for the oval niche. The protrusions with malleovestibulopexy (MVP) occurred with TPIPi. The Robinson wire prosthesis (9) was found only once. It was displaced.

In the 17 cases, the crurotomy (10) (reuse of a stapes crus) indicates without exception an atrophy of the remaining crus, causing an insufficient sound transmission.

Table 5 shows that of all the prostheses used by the first author, the Teflon platinum pistons (n = 501), show incus necroses in 4.8%. The gold pistons (n = 482) show granulations in 8.3%. For these 2 types of prostheses, any other revision findings were seen in less than 2%. Altogether, the 3 types of titanium pistons show no significant cumulation of findings (below 1%).

DISCUSSION

Revision operations occur with varying frequency with all surgical procedures, even if they have become routine as is the case with the highly specialized stapes surgery. Factors that influence the frequency of revisions in stapes surgery are the prostheses themselves (e.g., material composition, shape, and surface morphology in interaction with the middle-ear structures or inner ear); the surgical technique (e.g., mobilization, crurotomy, stapedectomy, or stapedotomy); and the surgeon’s experience and a self-critical assessment in handling the prosthesis, instruments, and the surgical technique. There are of course unforeseeable and unpredictable circumstances that may result in revision: behavior of the patient and causes independent of surgery, such as ventilation disorders or eardrum perforations after a long time (Table 3: other diagnostic findings).

There are numerous publications on revision diagnostic findings after stapes operations but frequently without reference to or indication of the prosthesis (11–23). This may be because, particularly in the first 2 decades of stapes surgery, only a small number of prostheses types was developed and used. Several papers are presenting only a very small number of cases (24–27).

Characteristic findings were encountered with the most commonly used prostheses (SchP, TPIPi, and GoPi). In half of all cases, the SchP was too short. Incus necrosis and arrosion are “typical” delayed complications with the TPIPi after an average of 9.4 and 11.2 years. However, the first necrosis was documented after only 2.4 years. In more than two-thirds of revisions, the GoPi

showed a granulation reaction of the mucosa after the average of 4.6 years. Remarkably, severe mucosal reactions were noted within the first days and few weeks after the operation (a-s). The titanium prostheses (TiKPi, ClipàW, and SoftClip) had a significantly lower revision rate in the application period of 9 years, and no specific findings were seen.

However, it must be noted that the time of the revision is not identical to the initial appearance of the symptoms. Only in few cases of subjectively severe complaints such as vertigo or tinnitus, patients will present for an examination and treatment early. For example, this is the case with a prosthesis that is too long, resulting in vertigo (Table 3, column “too long”). In contrast, complaints, such as hearing deterioration, loose wire syndrome, and feeling of pressure in the ear (fulfillness), often are accepted for an extended period, particularly if there is a good hearing in the contralateral ear without any problems. If hearing on the contralateral side deteriorates after a number of years (aging process, disease process such as otosclerosis, or an acute event), the complaints with the operated ear, which were previously suppressed, become a reason for presenting to an ENT specialist. Also important is whether the patient or his ENT physician knows a specialized middle-ear surgeon with sufficient high-quality surgical experience who can assess the prognosis of a revision and is able to present it to the patient in an understandable and, for the patient, acceptable manner.

Therefore, complete information about the previous operation is useful for the overall assessment. Unfortunately, when evaluating the available surgical reports (after o-s), it was found that, in more than 60%, information about the mobility of the remaining chain (fixation in the attic) or the type of footplate opening (stapedectomy; partial stapedectomy, e.g., rear third or half or stapedotomy) was not available. In more than half of the surgical reports, the prosthesis was simply described as “piston” or “stapes prosthesis,” without any reference to the material, the length, or the diameter. This means that there was no adequate information for the assessment of the chances for a revision when counseling the patient. An implant card must be available with each middle-ear implant and handed out to the patient in all cases. Every middle-ear surgeon should be aware that after some time, the technique or prosthesis he has used may no longer be known or available for treatment in the future. Complete and detailed documentation regarding the prosthesis is absolutely essential also in case of future magnetic resonance imaging (MRI) examinations.

Table 3 shows all diagnostic findings, including the rare ones. It reflects the variety of stapes surgery over 26 years. The bold figures indicate the most common revision diagnoses.

Surgeon-Related Findings

A prosthesis that is too short results in bad hearing (air-bone gap). The SchP (2,28) was the most common prosthesis with this finding. The reason for this can be assumed to be the surgeon’s awareness that a prosthesis

that is too long may cause vertigo and inner ear damage. The high number of too short SchP leads to the demand that a customized prosthesis should not be implanted. Even with experienced surgeons, such prostheses do not conform to the currently required standardized quality for a middle-ear implant. Figure 3 shows an example of the various shapes of the wire loop, the knot and the length of removed SchP.

The GoPi with a length of 4.25 mm, implanted for 1 year, was too short. Revisions showed that because of static pressure change, for example, nose blowing (Valsalva maneuver), the GoPi was standing on the remnant part of the footplate (29,30).

The following revision diagnostic findings are not common; however, they also should be considered in detail to prevent future problems.

A prosthesis that is too long will cause vertigo, either immediately after the operation or later, particularly when swallowing, hiccupping, or by pressing the tragus onto the outer auditory canal. In 95% of cases, our experience is that a length of 4.5 mm is correct (1 TDPi after o-s had a length of 5.0 mm). However, measurement of the optimum prosthesis length would be desirable. The available instruments can only measure the distance between the long incudal process and the surface of the footplate before opening the inner ear. After opening, the thickness of the footplate or the recommended immersion depth (31,32) can only be estimated.

A dislocated prosthesis is generally caused by inadequate fixation to the long incudal process in combination with a prosthesis that is too short and scar adhesions. This diagnostic finding has primarily been noted with the Poly (33–35) (Fig. 1). This prosthesis was used in the beginning of stapes surgery and was placed between the lenticular process and the covering of the oval niche. The destruction of the long incudal process, which has been mentioned in literature (36), and mucosal reactions in the middle ear (2) were not found. For a period of more than 20 years since the previous operation, it can be assumed that these diagnostic findings have resulted in a revision at an earlier stage.

The loose prosthesis (without visible arrosion) indicates insufficient clamping at the long incudal process (37), which with the SchP, along with other causes, also can be attributed to the variation in the shape of the wire loop (Fig. 3). Figures 4 (TPIPi) (38) and 5A (GoPi) show a marked oval deformation of the prosthesis loops that were found and removed during the revision (in combination with incus necrosis). The ClipàW (Fig. 6A) has been developed for a standardized application of the prosthesis to the long incudal process (38,39). The 3 cases with a loose ClipàW resulted in “rattling and ringing” at volumes higher than 70 dB. The reason is an incus diameter that is too small for the clip width of 0.7 mm, resulting in a too low contact pressure (40).

For “footplate opening too narrow,” the prosthesis cannot move freely (e.g., after stapedotomy) in combination with a very thick foot plate (32). For 2 TiKPi (after a-s) with a narrow oval niche footplate opening,

only the crura were removed, and the stapes head remained in contact with the processus lenticularis of the incus. The stapedial tendon was preserved (41,42). This technique was used only for a short time because of an unacceptable air-bone gap.

The reobliteration was seen with a prosthesis which did not protrude sufficiently deep into the inner ear (31). The footplate opening was too small (stapedotomy) and was covered by a connective tissue patch (periosteum and perichondrium) or vein. It can be assumed that the tissue flap could not be placed deeply enough in the centrally opened foot plate. The inserted prosthesis was above the level of the footplate. The use of vein cover and the TPi (Shea) (Fig. 2) is not common in Germany; therefore, it is not evaluated and discussed here.

The scar tissue (fibrous adhesion) in the oval niche was fixing the prosthesis maybe because of too many and too large connective tissue pieces sleeving the prosthesis.

The attic fixation may be overlooked by the surgeon during the operation or may occur later. In 2 cases, the body of the incus was blocked by bone fragments. All bone fragments removed by curette (House curette), chisel, or drilling must therefore be carefully removed immediately, including those from the cavity of the House curette, after every use.

Prosthesis-Related Findings

Arrosion, often referred to as the “most common diagnostic finding” (43), is primarily encountered with the SchP and results from the possible fixation because of the knotted connective tissue (40).

Necrosis of the long incudal process has been found almost exclusively with the TPIPi (44). A hypothesis for that finding has been described in detail (40,45). Medial migration of the prosthesis into the inner ear is characteristic, caused by the spiral groove structure of the Teflon surface and the right-angle transition zone between the platinum band and the Teflon stem in combination with the shrinking connective tissue sleeve. Figure 4 shows a TPIPi removed in a case of necrosis with closed loop and connective tissue, which covers the transition zone “like a stocking.” In addition to an air-bone gap, vertigo can be explained as a symptom of vestibular reaction (Table 2). The toxic effect of platinum (cell poison) also may play a role for the necrosis (D. Plester, Oral Communication, 2008).

Granulation (“reparative granuloma”) (46,47) is encountered with the GoPi only. Figure 5A shows a GoPi with the laterally tilted, “tightened” loop, which has simultaneously strangled the long incudal process triggering a necrosis.

The GoPi, consisting of 99.9% pure gold (48), which was used for a period of approximately 5 years (Table 1) has not fulfilled initial hopes (45). The macroscopic glassy-reddish mucosa causes a feeling of fullness and pressure in the ear with tinnitus (“booming”) and sensorineural hearing loss (Table 2). The granuloma covered the entire GoPi, commonly also covering the long incudal process in the area of the gold band loop. If the mucosa

reached the long incudal process via the GoPi, bone resorption to the width of the covering pathologic mucosa was a regular finding. The histologic finding showed a lymphoid cell accumulation with unspecific inflammation reaction (Fig. 5B). A histologic examination of the long incudal process, which would have been desirable, could not be done because the incus was used for application of an alternative prosthesis. It is worth noting that 4 of the 8 GoPi that are too short (length, 4.25 mm) were displaced: they had no contact to the inner ear which was closed by connective tissue and did not show any granulation. This leads to the conjecture that direct contact between gold and the inner ear fluid (electrolyte solution) is necessary for development or retention of this alteration of the middle-ear mucosa. Based on this experience, the TiKPi has been developed (Fig. 6A) (49).

Granuloma formation, which is referred to in the literature (50,51), has not been detected with any prosthesis. This may be because this mucosa reaction, commonly combined with inner ear reaction extending to total hearing loss, only occurs in a short period after implant placement. Therefore, it is likely that the surgeon who has made the primary surgery performed the revision. Various causes have been suggested, such as foreign bodies like fibers or talcum powder. The cause of the lack of such isolated granulomas after a-s may be because, for a long period, a special lint-free wiping cloth (IVALON, Fabco) has been used exclusively for wiping the micro-instruments after every use, and powder-free gloves are worn. Moreover, the connective tissue used for sleeving the prosthesis and harvested from the endaural incision is being transported to the outside at all. It is cut into tiny little pieces directly in the area of the endaural incision and then placed in the middle ear around the prosthesis. Of course, coagulation forceps should not be used in the area where the connective tissue is harvested.

Causes of Unclear Origin

Protrusions and fistulas cannot be clearly attributed to the surgeon or the prosthesis. They represent a rarity and miscellaneous diagnostic findings. By applying a ClipàW, the incus subluxation because of an incudal process that is too thick and the ClipàW, which was found to be too loose (52) because of an incus process that is too thin (Table 2 “clattering/ringing”), lead to the development of the Soft-Clip (Fig. 6A). This clip shows a 46% lower application force in comparison with the ClipàW, resulting from the lower stiffness with a more constant contact force (40).

Miscellaneous Techniques and Prostheses

Mobilization with abortion of the stapes operation was always conducted if the stapes was mobilized during the operation by manipulation (e.g., dissecting the joint or cutting the stapedial tendon). A revision was required in only 5 cases because of renewed conductive hearing loss with implanting a prosthesis. In the other cases, it can be assumed that the fixation may have been a

malformation in the region of the ligamentum annulare and not “genuine” otosclerosis (Table 3).

Sensorineural hearing loss or vertigo was never encountered after extraction of the prostheses. This may be because a clearly visible opening to the inner ear in the connective tissue sleeve was always made beside the prosthesis before removal of the prosthesis. This prevented underpressure in the inner ear (corkscrew effect) during extraction of the prosthesis. Cutting and leaving the wire node in the oval niche, as described by many authors (21,43), was not required. The node was always above the level of the foot plate, and the knotted connective tissue had not formed any scar adhesions to the inner ear structures.

An Attempt to Find a Prosthesis to Recommend: Determining Success and Failure

Prerequisite to recommending a particular stapes prosthesis is to compare the total number of prostheses with their failures. Logically, this comparison can be done only for the prostheses used by the first author because the number of pistons implanted is known. Analogous to the revision findings in Table 3, Table 5 shows that incus necroses occurred in 4.8% of the Teflon platinum pistons, and granulations occurred in 8.3% of the gold pistons. Apart from very few exceptions, all other revision findings occurred in below 2%. In comparison, the 3 types of titanium pistons did not show a significant maximum of revision findings and a single prosthesis-related finding. Concerning the surgeon-related findings, the percentage of failures for titanium pistons is below 2%. It would be desirable if this relatively low number of failures could be further lowered by consequently adhering to the recommendations set forth in the conclusion.

CONCLUSION

The following applies for the surgical technique:

- Clean working conditions with powder-free gloves and lint-free cloth for wiping instruments and immediate removal of all bone fragments or bone meal are recommended.
- Checking the movement of malleus and incus eliminates the possibility of fixation in the attic and can help avoid revision surgery.
- In the case of stapes mobilization, the procedure should be aborted, and the stapes should remain in situ. The footplate opening, which is always made first, is closed again with tiny pieces of connective tissue. This also applies in the event of a gusher phenomenon or oozer because if the stapes superstructure is retained, this acts as a counter-structure for the sufficiently large pieces of connective tissue.
- In 95% of cases, the length of the prosthesis at 4.5 mm fits (measured from the bottom end of the piston to the start of the loop band).
- A prosthesis that is too long can be avoided if vertigo occurs after insertion of the 4.5 mm prosthesis with a

slight inward movement of the long incudal process (local anesthesia is a prerequisite). The piston must then be replaced with a prosthesis with a length of 4.25 mm. Caution: if acute vertigo occurs during the operation, the patient often will turn his head suddenly toward the surgeon. If the hand holding the instrument is securely supported by the patient's head, this will prevent sudden immersion of the prosthesis and of the instrument into the inner ear and the resulting damage.

- The prosthesis should be sleeved with connective tissue using very small pieces that do not reach the transition zone of the piston section to the metal band.
- When the prosthesis is placed, make sure it can move freely in the footplate opening. If the stapedotomy technique is used too rigidly, residual conductive hearing loss may result, particularly if the foot plate is thick. Removal of the rear third or half of the foot plate often has proven effective (partial platinectomy).

The following applies for the prosthesis selection:

- Surgeon-fabricated and customized prostheses (SchP) seem to not guarantee a constant quality.
- Prostheses with a round cross-section (e.g., wire) may become injured in the application site of the incus because of a higher contact pressure (contact force) of the small contact area in comparison with a band contact (53).
- TPIPi and the no longer available GoPi have a disproportionately high number of revisions from prosthesis-related causes (incus necrosis/granulation).
- TiKPi, ClipàW, and SoftClip, compared with all other prostheses found during revisions, have not produced any specific prosthesis-related findings over the evaluation period of up to 9 years.
- Middle-ear implants should be suitable for exposure to the highest possible Tesla values, ensuring that patients, after decades, can be exposed to MRI units with higher magnetic power than the current units with 1.5 to 3 Tesla. Such MRI units with higher field strength are already under development.

The frequency of revisions in stapes surgery can be minimized if the above recommendations for the surgical technique are observed. Detailed and complete documentation of the revision diagnostic findings and their critical evaluation will help with selection of prostheses. When writing the surgical report, it is important to record every single step of the operation and to describe the type of prosthesis (manufacturer, material, type, and dimensions). A simple way to give the implant card to the patient without delay is to complete the implant card immediately after the surgery.

This is particularly important with reference to future diagnostic radiologic examinations (CT and MRI) and also for medicolegal reasons.

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