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Retrospective analysis of the results of implanting Nitinol pistons with heat-crimping piston loops in stapes surgery

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Abstract The study presented here evaluates the hearing results after the implantation of a new nickel–titanium (Nitinol) prosthesis in stapes surgery; on heating, this prosthesis crimps itself around the long process of the incus. In addition, we compare the outcome with results published in the literature. The medical records of all patients who underwent surgery for otosclerosis with implantation of a Nitinol piston during the period 2004–2006 were evaluated retrospectively. 83 patients (58 women and 25 men), with a provisional diagnosis of otosclerosis that was confirmed during surgery in all but one of the cases, were treated by primary stapes surgery (85 ears). We were able to include 53 patients (55 ears) who had audiograms with air and bone conduction preoperatively and both 2–6 weeks and about 1 year after surgery. We found a mean air–bone gap (ABG) for the frequencies 0.5, 1, 2 and 4 kHz (ABG4000) of 10.4 ± 5.5 dB after a mean postoperative follow-up period of 24.5 ± 16 days, and of 7.4 ± 3.7 dB after 462 ± 119 days. For the frequencies 0.5, 1, 2 and 3 kHz (ABG3000), the results were 9.1 ± 4.8 and 6.4 ± 3.9 dB. The differences in preoperative versus postoperative air–bone gap, referred to as ABGC, after 25 and 462 days, respectively, were 19.4 ± 8.9 and 22.3 ± 8.8 dB for AGB4000, and 19.5 ± 8.8 and 22.2 ± 8.9 for ABG3000. Very good results were achieved with a new nickel–titanium prosthesis that crimps itself around the long process of the incus, thus facilitating stapes surgery and at the same time stabilizing the high quality of the results. However, no long-term results after 10 years or more, which would allow a final judgment, are yet available.

Keywords Otosclerosis · Nitinol · Shape memory · Stapes surgery · Crimping

J. A. Hornung (✉) · C. Brase · A. Bozzato · J. Zenk · H. Iro
Department of Otorhinolaryngology,
Head and Neck Surgery, University of Erlangen-Nuremberg,
FAU Medical School, Waldstr. 1, 91054 Erlangen, Germany
e-mail: joachim.hornung@uk-erlangen.de

B. Schick
Department of Otorhinolaryngology,
Saarland University, Homburg, Germany

Introduction

For many years, stapes surgery (stapedectomy/stapedotomy) has played a substantial role in microsurgical ear operations in cases of otosclerosis, achieving good to very good hearing results on a regular basis. Despite continual development of surgical techniques and prostheses, however, there still remain difficult and critical steps in the procedure that may substantially influence an operation's outcome.

One of these steps is securing the stapes prosthesis to the long process of the incus. Malattached pistons do transmit sound, but cause substantial interindividual variation in the resulting hearing gain as well as unsatisfactory long-term results.

Moreover, there is also a chance of malattached prostheses causing incus necrosis due to vibrations [1–3].

Recently, the SMart™ stapes prosthesis from Gyrus ACMI-ENT, Bartlett, TN, USA has become widely available in Germany. The characteristic of this fluoroplastic piston prosthesis is its Nitinol wire bracket, a nickel–titanium alloy coated with titanium oxide. The outstanding property of this alloy is its shape memory, i.e. when

subjected to heat over 45°C, phase alteration in the alloy causes the material to take a predetermined shape, imprinted during the manufacturing process [4–6]. This outstanding property enables the Nitinol wire to wrap itself around the long process of the incus without manual manipulation.

Subjecting the material to heat may be accomplished using fine bipolar forceps with 2–5 W power, a CO_2 laser with 1–3 W power in continuous wave mode or a special battery-powered heat applicator (Gyrus ACMI-ENT, Bartlett, TN, USA).

Preliminary conclusions have been published about the positive results achieved with this prosthesis, albeit in a small number of patients [7–9]. Since this prosthesis was introduced to Germany in 2004, it has been the "prosthesis of choice" in stapes surgery in our department.

The aim of this study was to collect and evaluate data from patients who had this prosthesis implanted, in order to report on the short- and medium-term results.

Materials and methods

Patients

All patients with a provisional diagnosis of otosclerosis who underwent surgery, and had a Nitinol stapes prosthesis implanted (SMart™ Piston, Gyrus ENT, Bartlett, TN, USA), between 1 January 2004 and 31 December 2006 were included in this study. Patients who had revision surgery were not included in this evaluation.

During this period, 85 ears (83 patients: 58 women and 25 men) were operated on. Postoperative auditory follow-up investigations were performed on 55 of these 85 ears (53 patients: 39 women, 14 men; mean age 46.2 years; range 12–73 years) in the short term (1–12 weeks; mean 24.5 days; range 6–85 days) as well as after an intermediate period (after at least 10 months; mean 462 days; range 299–793 days).

Data from the 30 patients who did not attend follow-up in our department after 10 months were comparable to the remaining 53 patients, in particular with respect to the original hearing loss and improvement at the first follow-up visit. In terms of age and sex, or in the hearing results obtained pre- and postoperatively, there were no significant differences in the characteristics of this group from the 53 patients for whom complete follow-up data were available.

Before surgery, all these patients underwent audiological as well as clinical examinations. In all cases but one, a 12-year-old girl suffering from congenital stapes fixation, the clinical diagnosis of stapes fixation was confirmed at operation.

Surgical technique

One of the authors performed the operation using an endaural approach in the following sequence:

1. endaural auxiliary incision
2. elevation of a tympanomeatal flap
3. confirmation of stapes footplate fixation by ossicular chain palpation
4. resection of the scutum using curette or diamond drill
5. determination of appropriate piston length by precise measurement

6a. severing the staple tendon employing CO_2 laser (Type 40C, Lumenis Co., Tel Aviv, Israel, with micromanipulator AcuSpot™ 712)
7a. division of incudostapedial joint with small hook
8a. division of posterior stapes crus employing CO_2 laser
9a. fracture of the anterior stapes crus by tilting towards the promontory and removal of the stapes superstructure
10a. fenestration to the stapes footplate using CO_2 laser
11a. adjusting the Nitinol piston
12a. securing the hook-wire using bipolar forceps with 2–5 W power or using a CO_2 laser with 1–3 W power.

If the CO_2 laser was not available, the following procedure was carried out instead:

6b. severing the stapes tendon with small scissors
7b. manual fenestration to the footplate
8b. placing the prosthesis
9b. securing the hook-wire (refer to 11a)
10b. division of the incudostapedial joint with small hook
11b. division of the posterior stapes crus with small hook
12b. fracture of the anterior stapes crus by tilting towards the promontory and removal of the stapes superstructure

13. sealing the stapedotomy site with soft tissue
14. repositioning of the tympanomeatal flap.

Suspected footplate fixation, due probably to otosclerosis (52 patients) or to congenital stapes fixation (1 patient), was confirmed during surgery in all of the 53 patients. 43 (78.2%) of the operations were performed under general anaesthesia, whereas 12 procedures (21.8%) were done using local anaesthetic together with mild sedation. The operation was carried out in the right ear in 29.1% of the cases ($n = 16$); the left ear was operated on in 39 cases (70.1%). 30 procedures were carried out using CO_2 laser and 25 procedures without laser. In 44 cases, the CO_2 laser was used to activate the self-crimping process; in 11 cases heat activation was performed with bipolar forceps. All the prostheses implanted were 0.4 mm in diameter. Most of the ears (40) required a 4.5-mm-long piston; a 4.25 mm prosthesis was implanted in 8 ears and a 4.75 mm prosthesis

was placed in 6 ears. One exceptional case required a 5.25 mm prosthesis.

Hearing assessment

All the patients had preoperative and postoperative pure tone audiograms taken, at the same time measuring the hearing results for bone and air conduction. The analysis included only those patients for whom audiograms were available both within the period of 1 week to 3 months postoperatively and after at least 10 months. This applied to 53 of the 83 patients (55 of the 85 ears) who underwent surgery. According to the guidelines of the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology, Head and Neck Surgery, 1994, the outcome of an operation was rated according to the difference between preoperative air and bone conduction values and the corresponding postoperative values, resulting in the "air–bone gap". The frequencies 0.5, 1, 2 and 3 kHz (ABG3000) were used to determine the mean ABG [10]. In order to compare the results with those of other teams, the frequencies 0.5, 1, 2 and 4 kHz were added for calculating the ABG4000.

Results

Results of preoperative hearing analysis

For all the ears included in the study for the frequencies 1, 2 and 4 kHz, the mean preoperative bone conduction was 25.5 ± 12.9 dB (range 8.3–60).

The mean preoperative ABG was 29.8 ± 8.7 dB (range 12.5–46.3) for the frequency combination of 0.5, 1, 2 and 4 kHz, and 28.6 ± 8.5 dB (range 10.0–45) for 0.5, 1, 2 and 3 kHz.

Results of postoperative hearing analysis

Short term

For the period of 24.5 ± 16 days (range 6–85 days), the mean ABG3000 was 9.1 ± 4.8 dB (range 0–21.3). For the frequency combination 0.5, 1, 2 and 4 kHz, the value was 10.4 ± 5.5 dB (range 1.3–25). The differences between preoperative and postoperative ABG3000 and ABG4000 were 19.5 ± 8.8 dB (range –1.3 to 38.8) and 19.4 ± 9.0 (range 1.3–40), respectively. The mean difference between preoperative and postoperative bone conduction threshold (overclosure) for the frequencies 1, 2 and 4 kHz was 4.4 ± 6.7 dB (range –13.3 to 18.3). In 34 ears (61.8%), the ABG3000 was below 10.0 dB; in 98.1% of the cases (n = 54 ears), the ABG3000 was below 20 dB.

Intermediate period

After an average of 462 ± 119 days (range 299–793), the ABG3000 was 6.4 ± 3.9 dB (range 0–22.5) and the ABG4000 7.4 ± 3.7 dB (range 1.3–20.0). The differences between preoperative and postoperative ABG3000 and ABG4000 were 22.2 ± 8.9 (range 2.5–43.8) and 22.4 ± 8.9 dB (range 6.3–41.3), respectively. The difference between preoperative and postoperative bone conduction threshold (overclosure) for the frequencies 1, 2 and 4 kHz was 1.7 ± 5.7 dB (range –11.7 to 25). In 87.3% of the cases (n = 48 ears), the ABG3000 was below 10 dB; in 98.1% below 20 dB.

All prostheses but two were attached to the long process of the incus without aid, simply utilizing the self-crimping mechanism. A subjective assessment of prosthesis attachment was carried out by the surgeon responsible and, without exception, was rated as "very good". In two cases where the Nitinol piston would not fit, the long process of the incus was exceptionally thin and long. After a certain learning curve, attachment of the prosthesis was carried out successfully very quickly and reliably. The power chosen in the beginning for the bipolar forceps, as well as for the CO_2 laser, was largely reduced to lower values so as not to damage the process of the incus by heat. According to our evaluation and experience, power of 2–3 W for the bipolar forceps and 1–1.5 W for the CO_2 laser in cw-mode is sufficient to achieve satisfactory fixation of the prosthesis. Of the 83 patients who underwent surgery, one patient suffered postoperative complete sensorineural hearing loss on day 3 after surgery; despite immediate intervention and removal of the prosthesis, this turned out to be irreversible. In association with the vertigo that resolved postoperatively only slowly in this patient, the finding during the subsequent intervention of a prosthesis that was probably too long leads us to assume that this was the cause of irritation of the inner ear and resultant deafness.

Discussion

In general, stapes surgery aims to eliminate or greatly reduce sound transmitting components causing conductive hearing loss due to stapes fixation. This has proved successful in a large number of operations, either via stapedotomy or stapedectomy [11]. Since the procedure was introduced by Shea [12], many different stapes prostheses have been developed and introduced, but without discovering the ideal one. Almost any kind of prosthesis has to be attached to the long process of the incus. Even McGee [3] found this attachment to be problematic, as well as posing a substantial risk of causing irreversible or variable hearing loss after stapes surgery. More specific insight into the mechanisms

leading to very unsatisfactory results was gained in revision stapes surgery [3, 13, 14]. This revealed that the cause of malfunction most frequently lay in piston loosening or repositioning, followed by necrosis of the process of the incus, undiscovered fixation of the incus or malleus, strands of connective tissue and scar tissue, as well as recurring or progressive obliteration of the oval niche caused by otosclerosis.

Further investigation into the mechanics of the middle ear, including the use of laser Doppler interferometry, revealed that a stable connection between incus and piston is essential for satisfactory postoperative hearing [1, 2, 15]. On the other hand, sound may sometimes be transmitted very well, even with the prosthesis malcrimped or not secured at all; however, there may be great variability of the remaining ABG as well as very inconsistent hearing results. The results of these studies, as well as the findings from revision operations, call for making efforts towards good and stable attachment of the stapes prosthesis to the long process of the incus [1–3, 15, 16].

The self-crimping mechanism of the Nitinol shape memory prosthesis was developed in order to overcome the above-mentioned limitations of manual crimping. The mechanism of securing the prosthesis to the long process of the incus is reliable, reproducible and predictable. In most cases, the loop hugs the long process of the incus in an excellent and circumferential way. Provisional results from other teams (Table 1) reveal that the mechanism for securing the prosthesis works and that excellent results, such as improving the ABG and reducing interindividual variations in hearing capacity, can be achieved with simple intraoperative handling [7–9, 17–20]. Our own results and experience in using this prosthesis correlate with the outcomes cited so far (also see Table 1). In this respect, our results are very good, even at the very early stage of 25 days after surgery. Our ABG values of 6.4 ± 3.9 dB, determined after about 16 months (mean), equal the results of the other teams. Regarding our own results, however, it is remarkable that the standard deviation is as low as 3.9 dB, although the results originate from four surgeons. This suggests that by implanting the Nitinol piston a surgeon's individual influence, especially in the case of crimping, is greatly reduced, and standardization of the procedure as well as of the outcome can thus be achieved.

On the other hand, this firm connection of the prosthesis can also cause bone resorption or necrosis of the long process of the incus. In histological examinations of the temporal bone as early as 1979, Gibbin [21] demonstrated that there was progressive damage to the incus process when a prosthesis was directly attached. Possible reasons for this which have been discussed include a disturbance of perfusion through the mucosa of the long process of the incus, pressure phenomena due to the prosthetic loop, and foreign body reactions with subsequent inflammation of the bone [21–23]. As the Nitinol piston wire is finally looped around the long process of the incus in the same way as a manually crimped stapes prosthesis, it is to be expected that bone resorption or necrosis, leading to hearing loss and revision operations, may also occur in the long term, for the reasons just mentioned.

Naturally, the follow-up period here is too short to be able to pass final judgement about this relatively new prosthesis. This circumstance certainly requires further evaluation of the hearing results after 5 or 10 and more years. Regardless of the fact that no conclusions about the long-term stability of the achieved hearing improvement due to the Nitinol prosthesis can be drawn yet, the current short- and medium-term results are certainly encouraging and demonstrate the reliability and effectiveness of the "self-crimping mechanism".

Table 1 Results from different surgical teams using the Nitinol piston in stapes surgery, presented according to length of the control period (column 6)

Consultant	Number of ears	ABG3000 (dB HL ± SD)	ABG4000 (dB HL ± SD)	ABG less than 10 dB (%)	Control period (days)	Overclosure (dB ± SD)	ABG improvement (dB ± SD)
Own results (2008)	55	9.1 ± 4.8	10.4 ± 5.5	62	25	4.4 ± 6.7	19.5 ± 8.8
Rajan [9]	9	6.5 ± 2.9			90		
Sorom [20]	63	5.7 ± 4.3		88	135	4.2 ± 7.7	21.5 ± 11.2
Rajan [19]	90	5.5 ± 4.8		88	180		
Brown [17]	41		8 ± 6		270		25 ± 10
Harris [18]	26	5.4 ± 5.4	7.1 ± 8.1		84–1,080		
Rajan [19]	90	5.3 ± 4.6			540		
Sorom [20]	29	6.3 ± 5.0		79	681	4.7 ± 10.2	22.3 ± 10.7
Own results (2008)	55	6.4 ± 3.9	7.4 ± 3.7	87	462	1.7 ± 5.7	22.2 ± 8.9

ABG air–bone gap; *ABG3000* air–bone gap for the frequencies 0.5, 1, 2 and 3 kHz; *ABG4000* air–bone gap for the frequencies 0.5, 1, 2 and 4 kHz; *SD* standard deviation

After a short phase of getting used to implanting this prosthesis, the surgeons rated it as very good. However, among the more than 100 prostheses implanted at our clinic, we experienced two cases in which the piston could not be satisfactorily crimped to the long process of the incus. In both cases, the long incus process was exceptionally thin, so that on subjecting the wire loop to heat it was not possible to achieve the necessary stabilization.

The determination of the loop's diameter was based on the mean value from incus processes of 50 corpses, which were obtained when developing the prostheses [24]. It poses no problem should the incus process be distinctly larger than the average size, as the loop can simply be bent open manually before securing the prosthesis, so as to crimp itself tightly to the incus process when heated. A completely different situation arises if the incus process is too thin: even after adequate induction of the crimping procedure a small gap may still remain, leaving the prosthesis attachment too loose. In order to solve this problem, the manufacturers should offer a variant of the prosthesis in which the Nitinol wire is imprinted during the manufacturing process to form a loop with a smaller diameter than the regular model. This would provide an "emergency prosthesis" for use when the process of the incus is thin. To our knowledge, no such variant has yet been manufactured. In both cases, we used a standard platinum band fluoroplastic prosthesis that had to be bent completely round the incus process to achieve adequate fixation.

From the beginning we have mainly used bipolar forceps for activating the crimping mechanism. In the course of time, we reduced the power applied from 10 W at first to a sufficient 2–3 W now. In the process, we tried to achieve almost contactless heat transmission in the immediate vicinity of the loop by heating and vaporizing a drop of water lingering between the forceps' branches. This was increasingly successful with practice.

Heating the loop with CO_2 laser, we also reduced the power from 5 to 1–1.5 W in continuous mode. As the laser spot diameter exceeds the diameter of the loop's wire, we had to be very careful in positioning the laser power, so as to avoid mucosal damage on the long process of the incus. On the other hand, the laser allows for very accurately targeted heating of the loop. For better protection of the mucosa, which if damaged may cause bone resorption, at least in the animal model [25], very small gelatin sponge pellets (Gelita-Spon®, Gelita Medical BV, Amsterdam, The Netherlands), dipped in water, were placed on either side of the loop. This effectively protects the mucosa by absorbing surplus laser energy or laser energy reflected by the loop. In this respect, we should once again like to explicitly state that this metal alloy changes shape within a fraction of a second even at only 45°C. It is not necessary to exceed this temperature to induce the crimping procedure, and higher temperatures should be avoided.

Almost 5 years have now passed since the first application of the Nitinol piston; a period in which we have not had to carry out any revision operations because of bone resorption.

One question regarding the application of the Nitinol piston is that of biocompatibility and, in particular, allergic reactions to nickel. The studies still do not provide a complete answer to this question. The Nitinol alloy's nickel content exceeds 50%. Due to oxidation processes, a titanium oxide layer forms on the surface of this alloy, giving biocompatibility characteristics similar to titanium. This physicochemical process is responsible for Nitinol emitting less nickel than high-grade steel alloys used for medicinal purposes. An even more stable surface can be achieved by additional surface upgrading [5, 26]. Although Nitinol has been in use as a material in middle ear surgery for only a few years, it has been used for much longer in endovascular stents for vascular surgery and in self-expanding stents for trachea and oesophagus, and has demonstrated good biocompatibility in numerous experiments [5, 26, 27]. The studies on hand [7–9, 17–20, 28] do not mention any problems with the prosthesis's biocompatibility. In particular, no evidence of cytotoxic, allergenic or genotoxic activity has been found for Nitinol [29]. We have not found any interference in wound healing processes or hypersensitivity reactions that could have been attributed to the Nitinol material used.

One further frequently posed question is that of the MRI compatibility of the material from which the prosthesis is made. In this respect, Martin [30] demonstrated that the SMart™ piston was safe up to 3.0 T.

To compare our results and those of other surgical teams using the SMart™ stapes prosthesis with the results obtained using other prostheses, recent publications are presented in Table 2 [31–37] and divided into two groups. Results in the first group [31–34, 36, 37] were achieved with prostheses that had to be crimped manually around the long process of the incus using the appropriate tool. With the exception of one surgical group [31], the results achieved were in the same range as those with the SMart™ stapes prosthesis. The main advantages of these prostheses are that they are mostly cheaper than the SMart™ stapes prosthesis and can be used irrespective of the thickness of the process of the incus. Using these models, it is not necessary to have an "emergency prosthesis" in reserve. On the other hand, in our opinion, the experience and know-how of the surgeon have a greater role in the hearing results that can be achieved. The second part of Table 2 shows the results of prostheses which, like the SMart™ stapes prosthesis, do not have to be crimped manually; this means that the experience and know-how of the surgeon are less

Table 2 Results from different teams using various prostheses in stapes surgery

Consultant	Number of ears	ABG3000 (dB HL ± SD)	ABG4000 (dB HL ± SD)	ABG less than 10 dB (%)	Control period	ABG improvement (dB ± SD)	Type of prosthesis	Price (euro)
Prostheses that have to be crimped								
Velegrakis [37]	42		7.0	83.3	1.5–5 years		Velegrakis Piston[a]	129
Casale [31]	30		14.08 ± 4.6	26.6	18 months		Fluoroplastic Platinum[a]	59
Casale [31]	30		13.33	26.6	18 months		Titanium[b]	102
Tange [36]	53		7.6 (0.5–2 kHz)		95.1 weeks	20.2	K-Piston Titanium[c]	72
Tange [36]	53		11.6 (0.5–2 kHz)		95.1 weeks	20.2	Gold Piston[c]	o.n.m.
Quaranta [34]	72 (stapedotomy only)	6.0		84.7	More than 6 months		All Teflon[d]	
Mangham [33]	38		4.5 ± 6.7	87	1 year		Schuhknecht Teflon stainless steel[e]	41
Mangham [33]	25		4.8 ± 3.0	96	1 year		De La Cruz Teflon–platinum[e]	75
Mangham [33]	151		5.0 ± 4.8	93	1 year		Mangham Teflon–platinum double fold[e]	
"Non-crimping" prostheses								
Lippy [32]	47	2.6	4.2	100		27.8	Robinson titanium[e]	
Lippy [32]	47	2.65	3.8	95.7			Robinson stainless steel[e]	64
Mangham [33]	17		4.4 ± 6.3	76	1 year		Robinson Teflon[e]	
Tange [35]	63		11.6	71		25.7	CliP-piston àWengen[c]	102
Mangham [33]	31		7.7 ± 6.4	84	1 year		CliP-piston àWengen[c]	102

ABG air–bone gap; *ABG3000* air–bone gap for the frequencies 0.5, 1, 2 and 3 kHz; *ABG4000* air–bone gap for the frequencies 0.5, 1, 2 and 4 kHz; *SD* standard deviation; *o.n.m.* offered no more; *price (euro)* price of prosthesis in Germany in euro without tax

[a] Smith & Nephew Richards Inc., Memphis, TN, USA

[b] Leibinger, Freiburg, Germany

[c] Kurz GmbH, Dusslingen, Germany

[d] Manufacturer not mentioned

[e] Gyrus ACMI, Bartlett, TN, USA

noticeable. These audiological results, too, show no difference from those obtained with the Nitinol prostheses. In the case of the bucket prostheses, a wire bracket is placed over the long process of the incus and with the àWengen prosthesis this clip is slid onto the process and "clicked" into position. Both these prostheses should result in less trauma to the mucosa of the long process of the incus, thereby reducing the risk of tissue necrosis [38]. On the other hand, the clip prosthesis has similar problems to the SMart™ stapes prosthesis regarding the different diameters of the process and the associated difficulties in fixation. It may also happen that the clip prosthesis, which costs in Germany about two-thirds of the SMart™ piston (Price of a SMart™ piston in Germany in euro without tax: 167.00), cannot be adequately fixed [39].

Of course, the SMart™ piston is the most expensive of the above-mentioned prostheses, but considering the results listed in Table 1, which were achieved by different surgeons probably with different surgical experience, the good outcomes are all close by. That means in our opinion, the individual influence of the surgeon is reduced and a standardization of a critical step in stapes surgery can be achieved.

Conclusion

The analysis of the outcomes we achieved with the heat-induced, self-crimping Nitinol stapes prosthesis shows excellent short- and medium-term hearing results. The mechanism triggering stable attachment of the loop around the long process of the incus provides a substantial simplification in stapes surgery, while simultaneously delivering positively stable and reproducible hearing results. The limitations of manual crimping can be improved with this prosthesis while at the same time standardizing stapes surgery in general. On the other hand, there is still some uncertainty as to how often bone resorption and necrosis of the long process of the incus, resulting in hearing loss and necessitating revision operations, also occur with this prosthesis. We will have to wait for the long-term results after 10 years or more for this information.

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