



Comparison of superelastic nitinol stapes prostheses and platin teflon stapes prostheses

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Abstract

Introduction Stapes plasty is an established procedure to improve hearing in case of otosclerosis. By reinforcing the prostheses, an optimization of the prosthesis could be achieved. The aim of the study was to evaluate the audiological results of the Nitinol Superelastic stapes prosthesis compared with a Platin–Teflon prosthesis.

Material and methods In a retrospective setting, the audiological results of nine patients who have been implanted with a Nitinol Alloy Superelastic stapes prosthesis were compared with the results of ten patients, which have been implanted with a Platinum–Teflon piston prosthesis. All operations were performed by the same experienced ear surgeon.

Results The Nitinol-group presented an average of postoperative air–bone-gap over all frequencies (0.5–6 kHz) of all patients of 15.1 dB. In the Platin–Teflon group, the average of postoperative air–bone-gap was 14.9 dB. Moreover, the post surgery delta–bone-conduction pre- to post surgery showed no differences (0.5–6 kHz). There were no surgical complications in both groups.

Conclusion Based on the patient collective, stapes plasty using a Nitinol Superelastic stapes prosthesis is a sufficient method for improving the hearing conduction.

Design Retrospective case series.

Setting University Department.

Keywords Stapes prosthesis · Otosclerosis · Nitinol · Stapes surgery · Air bone gap

Introduction

Otosclerosis is one of the most common causes of acquired hearing loss in the population [1]. For therapy, stapes plasty deals as an established therapy option for restoring the conductive hearing loss. After surgery, the patients can achieve a good postoperative hearing. Since the beginning of modern surgical procedures, the methods of stapes plasty have been continually improved. Surgery can basically be performed quickly with good or very good chances of success and in most cases without high risk [2]. A postoperative deafness of the operated ear or a partial loss of inner ear functions occur in less than 5% of the cases [3]. If both ears are affected, the worse ear should be operated first [4].

There are a lot of different stapes prostheses on the market. Moreover current stapes prostheses were also constantly further developed. Differences in shape as well as in material, length, diameter and weight are seen nowadays. All these modifications aim to simplify the surgical technique and improve audiological outcomes. One of these developments is the Superelastic Nitinol prosthesis.

Nitinol is an alloy of titanium and nickel that can exhibit superelastic metal properties. By its use it is possible to fix a prosthesis to the incus without manual effort by placing the prosthetic loop over the incus. As a result, the prosthesis loop surrounds the incus in its a predefined shape. This eliminates the need for manual crimping, which simplifies and standardizes surgical procedures and thus reduces the risks of sensorineural hearing loss during or after surgery [5].

The question arises as weather this prosthesis leads to the same audiological results, in particular air–bone gap (ABG) results in comparison to the standard platinum band prosthesis that needs to be crimped. Moreover the aim was to reveal, if this prosthesis causes inner

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ear damages shown by bone conduction and whether this threshold drops, and lastly, if this prosthesis is a feasible option in terms of complications during surgery.

Materials and methods

The study was approved by the representative human institutional review board. In a retrospective setting, the audiological results of nine patients who have been implanted with a Nitinol Alloy Superelastic stapes prosthesis (Audio Technologies, Gossolengo, Italy, distributed by Spiggle & Theis, Overath, Germany) (Figs. 1, 2) were analyzed (study group).

This group consisted of five male and four female patients. The mean age of the patients was 53 years (range 38–67 years). Five stapedotomies were performed on the right ear, four on the left ear. The prostheses had the dimensions standard hook wire ϕ 0.2 mm, columella ϕ 0.4 mm and total length 0.7 mm shortenable. The average of preoperative ABG of all patients over all frequencies was 30.7 dB. In each surgery, the prosthesis was placed on the long process of the incus and in the perforation of the fixed footplate. With very little force, the prosthesis eyelet was slid over the long incus process. Due to the superelastic properties of Nitinol, the prosthesis was thereby sufficiently fixed, no further mechanical crimping was needed. In the oval window, the prosthesis stem was checked for correct position and mobility followed by overlaying with venous blood to seal the oval window. All surgeries were performed between May and November 2017.

The patients in the control group have been implanted with a Platinum-PTFE Piston prosthesis (Audio Technologies, Gossolengo, Italy, distributed by Spiggle & Theis, Overath, Germany). This group consisted of ten patients, six male and four female patients. The mean age of the patients was 41 years (range 19–58 years). The prostheses had the dimensions columella ϕ 0.4 mm and total length 7.0 mm shortenable. In the control-group, the average of preoperative ABG of all patients over all frequencies was 27.7 dB.

The patients underwent the same procedure as the study group. As using a Platin-PTFE stapes prosthesis, the loop had to be crimped to close the eyelet around the incus. The surgeries were performed between 2013 and 2016.

All operations were performed under general anesthesia by the same experienced ear surgeon (first author).

Postoperative measurements of the air–bone gap (ABG) were performed at a median of 43 days after surgery (min: 29, max: 150) and compared with the preoperative values.

For statistical analysis, the student t-test was used. A $p < 0.05$ was considered statistically significant.

Fig. 1 Superelastic Nitinol stapes prosthesis (with kind permission by “Spiggle und Theis Company”, Overath, Germany)



Results

Over all frequencies (0.5–6 kHz), the Nitinol-group presented an average of postoperative ABG of 15.1 dB (min. 0 dB, max. 40 dB). Split up in frequencies, the median ABG at 500 Hz was 15 dB, at 1 kHz 15 dB, at 2 kHz 5 dB, at 4 kHz 15 dB and 6 kHz 15 dB.



Fig. 2 Intraoperative view of a Superelastic Nitinol stapes prosthesis

Table 1 Median air–bone-gap post surgery of the superelastic Nitinol Stapes prostheses and the Platin–Teflon prostheses in dB

Frequency	0.5 kHz	1 kHz	2 kHz	4 kHz	6 kHz
Superelastic Nitinol stapes prosthesis	15	15	5	15	15
Platin–Teflon prosthesis	17.5	12.5	10	20	17.5

In the Platin–Teflon group, the average of postoperative ABG over all frequencies of all patients was 14.9 dB (min. 0 dB, max. 40 dB). Split up in frequencies, the median ABG at 500 Hz was 17.5 dB, at 1 kHz 12.5 dB, at 2 kHz 10 dB, at 4 kHz 20 dB and at 6 kHz 17.5 dB (Table 1, Fig. 3).

Moreover, the post surgery Delta-Bone-conduction pre- to post surgery showed no differences. Over all frequencies, the Delta BC pre-post surgery was in the NitAP-group 0 dB and in the Platin–Teflon group dB 1.4 dB (Table 1, Fig. 4, 5). All these differences were not significant ($p > 0.05$).

There were no surgical complications in both groups. No patient reported an unsatisfactory hearing result. No patient suffered from deafness. There was no facial palsy or permanent dysgeusia in any patient.

Discussion

Stapes plasty is a common procedure to treat patients with otosclerosis [1–8]. For sound transmission it is essential that the prostheses are properly fixed [7]. This is a crucial factor for the hearing results [9]. Insufficient or no crimping can lead to a loss of sound transmission up to 28 dB. A close coupling of at least two opposite points can lead to good results [10].

Therefore, crimping a stapes prosthesis is considered as the most delicate maneuver in ear surgery [1, 2]. Further, growing mucosa in the prosthesis–incus-interface has only a minimal effect to the sound transmission and cannot compensate any insufficient prosthesis fixation [9]. In addition, crimping of the stapes prosthesis can lead to a too tight attachment or can result in injury to the incus or the inner ear [3].

For this reason, Nitinol stapes prostheses have been developed. Nitinol is an alloy of titanium and nickel that can exhibit superelastic metal properties. At state-of-the-art, Nitinol consist of 55% nickel and 45% titanium. The aim of development was to create a corrosion-free metal with almost no magnetic properties. In Nitinol development, two essential properties were found: a mechanical shape memory, also called superelasticity, and a possible thermal memory. The elasticity of implants means that even after extreme deformation, the material automatically returns to its original shape. The thermal memory implies that the material moves back into its predetermined shape during the production process by application of heat and remains stable in it [11].

Fig. 3 Air–bone-gap post-surgery of the Superelastic Nitinol (Nit) and the Platin–Teflon (Plat-T) stapes prostheses. There are no significant differences between the two groups

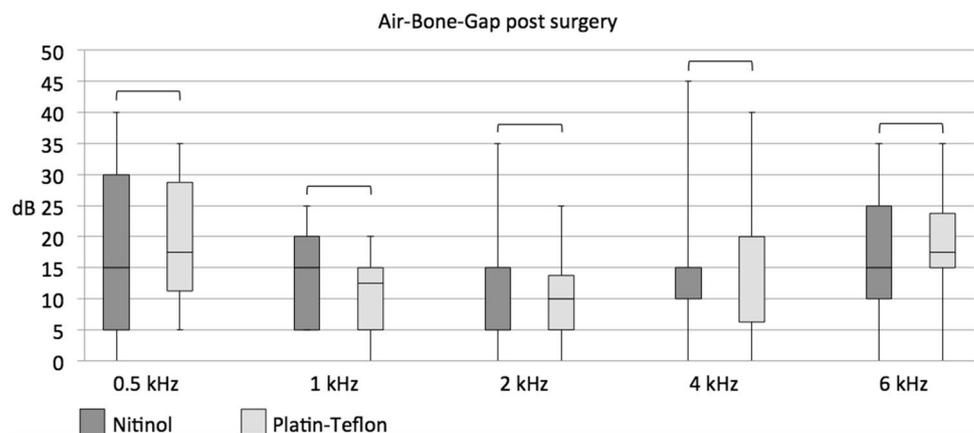


Fig. 4 Delta of the bone conduction (pre–post surgery) of the Superelastic Nitinol stapes prosthesis

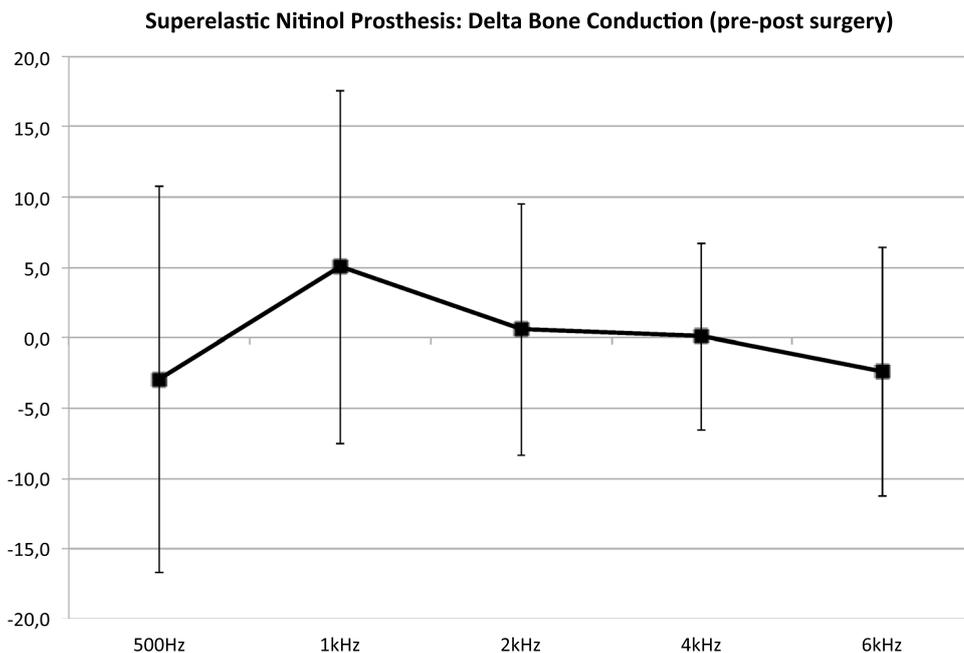
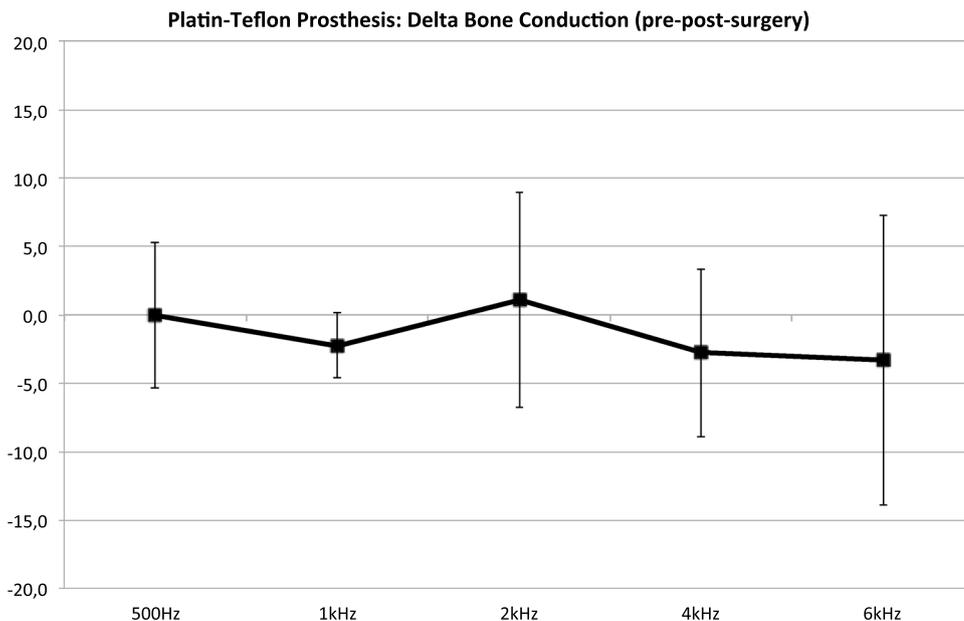


Fig. 5 Delta of the bone conduction (pre–post surgery) of the Platin–Teflon stapes prosthesis



These two characteristics resulted in two kinds of Nitinol stapes prostheses: one superelastic type, which is a preshaped and closes automatically, and one type where heat is needed to close the loop, for example electrocautery, lasers or warm water [6] so called shape memory prostheses. In addition Nitinol is also very resistant and light [4, 5, 12]

Under microscopic view it is often difficult to determine whether the prosthesis is tight enough or not. Moreover, if it is too tightly clamped, the consequence could be a necrosis of the incus. The Nitinol prostheses can help with this issue. Due to the shape memory, the diameter of the loop

is defined, thus—despite to any different diameters of the incus—the force should be in a non-extreme extend [13].

For our investigation, we analyzed the Superelastic Nitinol prostheses. We found, that these prostheses result in equivalent audiological results compared to Platin–Teflon prostheses. No significant differences could be detected. Our results are in line with other studies using superelastic Nitinol prostheses reporting to be a feasible option with no significant postoperative change of the bone conduction, an improved air bone gap and a good handling. However, these data present no control group [5, 12] or a control group with heat-crimping Nitinol prostheses [4].

In clinical context, the placement of the superelastic loop over the incus could be more difficult than crimping prostheses, therefore a light risk in using Nitinol prostheses cannot be ruled out.

But also using shape memory Nitinol prostheses are known to provide good results. They lead to a tight fixation and to improved functional results [7]. The improvement in ABG closure is in the range of 3 dB pure-tone average and more pronounced at higher frequencies [7]. Our results using the Superelastic prostheses are in line with these results. Comparing short term results for NiTiBOND® (heat activated Nitinol) with SMart Pistons® (heat activated nitinol) three months after implantation, the NiTiBOND® stapes prosthesis revealed as a safety and reliability prosthesis, with postoperative air–bone gap means of 8.1 for the NiTiBOND® and 9.9 for the SMart® Piston [14]. Comparisons of heat-activated nitinol stapes prosthesis and platinum wire prostheses showed a mean postoperative ABG of 8 dB for the Nitinol prostheses and 7 dB for the Platinum prostheses, confirming that this material is suitable for stapes surgery [15]. Although, the heat activated crimping prostheses show complications as well, namely a lateral displacement of the prostheses out of the vestibule and/or incus [16], Nitinol prostheses can never be overcrimped [6]. However, in systematic database analysis, superiority of Nitinol heat-crimping prosthesis could not be demonstrated in this matter [17].

But for stapes surgeries, also many other different prostheses using different techniques are on the market. For example soft clip couplers where the prosthesis has to be slit on the incus are reported to provide good audiological results in stapes surgery [2].

Nitinol is unproblematic in MRI-investigations. Studies with 1.5 Tesla showed, that nitinol pistons do not move during the scan [6].

Nitinol has been proven to be a safe material for surgeries. It is generally characterized by good corrosion properties. Moreover, the majority of biocompatibility studies suggest that these alloys have low cytotoxicity and low genotoxicity. The release of Ni ions is negligible with concentrations below the normal human daily intake, there is no elevation of nickel content in the incus [18, 19]. However, localized erosion of the incudal bone was found with this material nevertheless [18].

Taken together, these characteristics of Nitinol make the prostheses suitable for stapes surgery [6]. Our results provide a part for the evidence of safety for the Superelastic stapes prostheses. As this prosthesis needs not to be crimped intraoperative, it represents a practicable alternative to conventional prosthesis. However, the final functional gain depends on many different intraoperative and postoperative factors.

Compliance with ethical standards

Conflict of interest MT received travel support to conferences by “Spigle und Theis Company”.

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