Functional results using Superelastic nitinol stapedial prostheses in patients with otosclerosis

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Abstract: This article presents the results of a comparative evaluation of surgical treatment of patients suffering from conductive and mixed hearing loss in various clinical forms of otosclerosis using nitinol stapedial and titanium prostheses. In the department of surgical treatment of diseases of the ear and the base of the skull of the NMICO from 2017 to 2024, the functional results of stapedoplasty using titanium and nitinol prostheses were compared in the near (up to 3 months) and long-term (more than 6 months) postoperative period. The comparison groups included 50 patients who were divided into two equal in all major indicators groups that differ only in the type of prosthesis used (SE NiTiNOL/PTFE and Ti/PTFE). In the postoperative period (the average follow-up period was 3 years), the values of the bone-air interval in operated patients were evaluated; clinical and experimental comparison of computed tomography data obtained during the installation of titanium and nitinol prostheses was also carried out. Functional results were assessed in the immediate (1–3 months) and long-term (6 months–3 years) periods after surgery. The average postoperative CVI was 12.29 dB (SD ± 5 dB) in patients in the group with nitinol prostheses and 11.93 dB (SD ± 5 dB) in titanium. 88% and 80% of patients in both groups had an "excellent" or "good" result in hearing improvement. The cadaveric material was used to compare the CT data obtained during the installation of stapedial prostheses: in 4 cases, when installing a nitinol prosthesis, there were no artifacts, which made it possible to visualize the prosthesis attachment ring; in the other 4 cases with a titanium prosthesis, this was not possible to detect. The installation of a nitinol prosthesis has a number of advantages: it does not require additional fixation of its head on the long crura of the incus in the form of a "compression", which minimizes the risks of trauma of the inner ear structures and, accordingly, the development of sensorineural hearing loss in the postoperative period, as well as the use of NiTiNOL prostheses reduces the likelihood of developing aseptic necrosis of the long crura of the incus due to the properties of the metal and a decrease in its thickness. Analyzing the data of computed tomograms of patients after stapedoplasty, only in the group with installed nitinol prostheses, it was possible to visualize the position of the prosthesis on the long crura of the incus and her integrity, and prostheses position in the vestibule.

Keywords: otosclerosis, stapedial prostheses, stapedoplasty, treatment results

Introduction

Otosclerosis is a primary focal disease of the enchondral layer of the bone capsule of the labyrinth, affecting only humans. It is clinically manifested as progressive hearing loss of a conductive, mixed or sensorineural nature [1, 2]. The ethiology of otosclerosis remains not fully studied. To date, a variety of reasons leading to the disease development are assumed: genetical, immunological, viral theory, otosclerosis as a result of hormone disruption. The most frequent localization of the remodeled otosclerotic bone is in front of the fenestra vestibule niche, the round window niche, as well as the apical and medial walls of the cochlea [1, 4, 5]. Other lesions are located in the following decreasing order: behind the fenestra vestibule niche, the posterior wall of the internal auditory canal, its

anterior wall, around the cochlea aqueduct, around the semicircular ducts and directly in the footplate of the stirrup [5]. The diagnosis of otosclerosis is based on the patient's complaints: hearing loss, tinnitus, dizziness. Also, proceeding from the data of the disease anamnesis and the vita anamnesis. A physical examination is necessary: an intact tympanic membrane with clear anatomic landmarks. Subjective and objective methods of hearing examination are also needed (whisper and spoken speech testing hearing, tuning fork research, audiometry and impedance analyses) and imagine study data (computed tomography – CT of temporal bones) [6, 7]. It should be noted that recently increasing attention is paid to the study of CT data of temporal bones in patients with otosclerosis including in our Center. According to their results, it is possible to identify the localization of lesions and their prevalence. Based on these data, surgical approach and operation prognosis are determined. Also, according to these data, a differential diagnosis of otosclerosis with isolated middle ear abnormalities can be performed: abnormal development of the malleus and/or incus bones with a motion footplate of the stapes, various abnormalities of the middle ear in the presence of a motionless footplate of the stirrup, anomalies of the middle ear in the absence of the footplate of the stirrup, as well as with serousus otitis media, posttraumatic ossicular chain rupture, tympanosclerosis [8, 9].

As known, the piston stapedoplasty technique is characterized by complications: avascular necrosis of the long stem of the incus, dislocation and even extrusion of the prosthesis, which occur in 10-13%, according to various authors [10-12], as well as the formation of perilymphatic labyrinth fistulas, leading to sensorineural hearing loss.

As before, currently in otosurgery, the result of stapedoplasty is evaluated according to tonal threshold audiometry in the near (up to 3 months) and long-term (more than 6 months) postoperative period in the form of a reduction in bone-air interval. However, it is not possible to assess the cause of the unaccetptable result of stapedoplasty only as a matter of record of the tonal threshold audiometry in all cases. Therefore, in recent years, great importance has been paid to the imaging methods of the stirrup prosthesis. CT of the temporal bones allows to determine the displacement of the prosthesis, either the absence of contact between the stirrup foot plate and the proximal end of the piston, or the separation of the piston loop from the long stem of the incus, complete dislocation of the piston, too short piston, the presence of fibrous tissue filling the niche of the fenestra vestibule, simple necrosis of the long stem of the incus, periossicular and/or periprosthetic fibrosis, the proliferation of an otospongious site of damage filling the oval fossa and blocking the movement of the prosthesis in the postoperative period [13]. F. Warren et al. (2008) believe that it is also necessary to take into account what material the prosthesis is made of when evaluating a stirrup prosthesis using CT [14].

For the piston technique of stapedoplasty, different types of prostheses are available and used, which differ in the connection technology on the long stem of the incus, shape, width, stem length, piston length, and the material from which they are made. According to the technique of conjunction with the long stem of the incus, prostheses can be divided into cogging, thermally activated and clipping [15]. According to the composition, stapedial prostheses can consist of both titanium, which has proven itself well for its biocompatibility and its mechanical properties [16, 17], and superelastic nitinol used in recent years. In the latter version, the head of the prosthesis is made of nitinol. The axis and the piston part, which exposed into the inner ear, are made of Teflon. Nitinol is a nickel-titanium alloy (55% nickel, 45% titanium), which, depending on the method used, with various mechanical properties during heat treatment: a metal spring made of nitinol completely returns to its original shape even in the case of severe deformations [18]. One of the main advantages of nitinol prostheses is its soft and reliable fixation without the need to compress the prosthesis ring. On the one hand, this is due to the properties of the nitinol material, on the other hand, to a thickness loss of the material, which reduces the likelihood of complications in the postoperative period. Also, due to the properties of nitinol, the possibility of dislocation of the in-

cus during manipulations with the prosthesis and its installation is minimized [15, 19, 20].

We performed a comparative evaluation of the obtained results of surgical treatment in groups of patients using prostheses made of nitinol (SE NiTiNOL/PTFE) - group 1 and titanium (Ti/PTFE) – group 2. The needed length of the prosthesis was determined by the distance measuring (with a special instrument) between the prop (the lower surface of the long stem of incus) and the tympanic surface of the stirrup footplate in the vestibule (which was about 3.5-3.7 mm) with the addition of an immersion depth of the prosthesis in the vestibule, approximately eaqual to the thickness of the footplate (about 0.5–0.8 mm depending on the degree of its lesion by the otosclerotic process). By simple arithmetic operations, it was obtained that the desired length of the prosthesis was on average 4.0-4.5 mm. The prosthesis was inserted into the surgical field using a vacuum aspirator, the distal end of the prosthesis was put on a long stem of the incus, the proximal end was installed in the formed perforation of the stirrup footplate. Additional manipulations were not required to fix the distal part of the prosthesis on the long stem of the incus. The audiological result of the operation was evaluated at frequencies of 0.5, 1, 2 and 4 kHz. Bone-air gap was estimated as the difference between bone and air conduction at the revelant frequencies.

Despite the positive functional (audiological) outcomes obtained in both groups, it should be considered that the installation of a titanium prosthesis requires additional fixation of its head on the long stem of incus by “compression”. This is liable to cause additional traumatization of the inner ear structures, which in turn can increase the percentage of sensorineural hearing loss in the postoperative period, unlike installation of a superelastic self-compressing nitinol prosthesis.

The aim of the study was to perform a comparative evaluation of the results of the use of nitinol and titanium prostheses in patients with otosclerosis during stapedoplasty in the near and long–term postoperative period of CT data of patients at the pre- and postoperative stages (follow-up period was 1-3 years), as well as the results of comparing CT data of titanium and nitinol prostheses by experiment.

Materials and methods

The study included 50 patients aged 17 to 61 years with a diagnosis of otosclerosis, operated in the management of «Ear and Skull base pathology Department» of National Medical Research Center of Otorhinolaryngology of the Federal Medical-Biological Agency from 2017 to 2020. The analyses of tonal threshold audiometry data in the near and long-term postoperative periods were performed. General clinical otorhinolaryngological examination, tonal threshold audiometry, impedance metry, CT of the temporal bones with an interval of no more than 0.6 mm were performed at the preoperative period. Thus, 44 (88%) patients underwent surgery under local anesthesia and 6 (12%) under endotracheal anesthesia. In all cases an endaural incision was used for tympanotomy, followed by the use of a perforator and hooks for perforating the foot plate under the control of a microscope (Pentero Zeiss). All 50 primary surgeries using the piston stapedoplasty technique in patients with fenestral and fenestral-cochlear types of otosclerosis were performed sequentially by one surgeon, as a result of which it turned out that 25 patients had a titanium prostheses with Teflon and 25 others – a nitinol prostheses.

Postoperative supervision included an evaluation of functional results and fixation of possible complications. During the audiological examination at the preoperative and postoperative stages, the difference in bone and air conduction was estimated and recorded at the level of 500, 1000, 2000 and 4000 Hz. A conductive form of hearing loss (fenestral type of otosclerosis) was detected in 20 (40%) patients at the preoperative stage and mixed hearing loss (fenestral–cochlear type) in 30 (60%) patients according to the tonal threshold audiometry data. The average thresholds of bone conduction at the preoperative stage were 30.05 dB and the average thresholds of air conduction were 58.15 according to the tonal threshold audiometry data. The average bone-air interval on preoperative audiograms of patients was 27.65 dB.

The average period of postoperative supervision was up to 3 years (but not less than 12 months, and in some patients - up to 5 years). Repeated audiological examinations were

performed at 1-3, 6, 12-38 months after surgery, depending on the patient's turnout. All patients underwent surgery on the second ear with a difference of 6 months to 2 years after the first surgical intervention. After that, they underwent a repeated hospital routine examination, including a CT scan of the temporal bones. As the result, it was possible to assess the position of the prosthesis piston in the area of the foot plate, its location on the long stem of the incus.

Results

Functional results were evaluated in the near (1-3 months) and long-term (6 months – 3 years) periods after the operative treatment. To evaluate the functional results, the arithmetic mean of the thresholds of air and bone sound conduction tonal threshold audiometry for frequencies was calculated 0,5–1–2–4 kHz and the bone-air interval value. The result of stapedoplasty was regarded as "excellent" if the average value of the postoperative bone-air interval did not exceed 10 dB, "good" – 10-15 dB, "satisfactory" – up to 20 dB, "unsatisfactory" – more than 20 dB, assuming that the postoperative thresholds of bone conduction remained constant or in some patients improved by some frequencies (for example, 2 kHz); Table 1.

Type of protesis	«Excellent»	«Good»	«satisfactory»	«unsatisfactory»
SE NiTiNOL(n=25)	13 (52%)	9 (36%)	3 (12%)	0 (0%)
Ti/PTFE(n=25)	12(48%)	8 (32%)	4(16%)	1 (4%)*
Total=50	25 (50%)	17 (34%)	7 (14%)	1 (2%)*

Table 1. Functional results of the operation in the long term (> 6 months)

Patient No1: A Ti/PTFE prosthesis is installed during stapedoplasty.

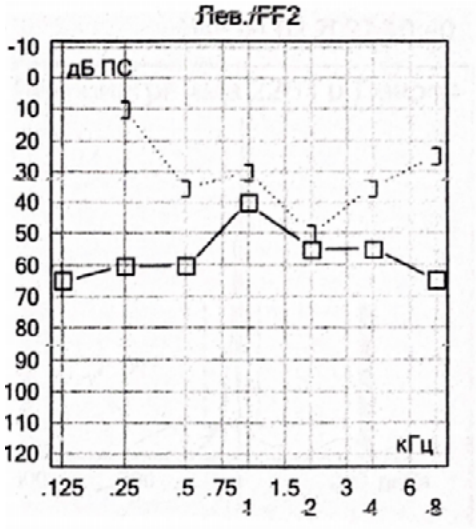

Fig. 1 Preoperative pure tone threshold audiometry

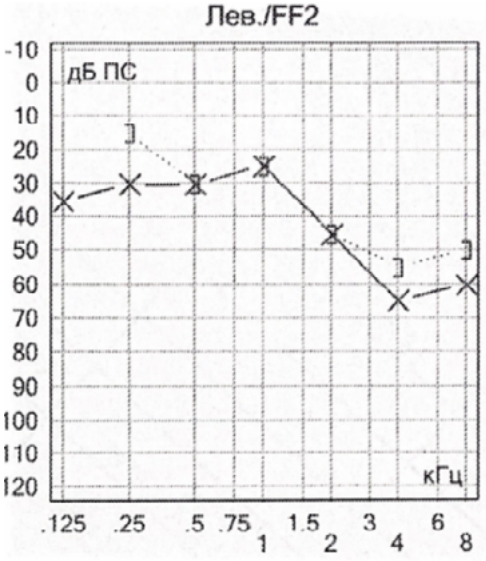

Fig. 2 pure tone threshold audiometry after surgery.

A percentage of 88 and 80 of patients in both groups had an "excellent" or "good" hearing improvement result as shown in Table 1. None of the patients had complete hearing loss. In one case, there was no improvement in hearing due to aseptic necrosis of the long stem of incus. The average postoperative bone-air interval was 12.29 dB (standard deviation ± 5 dB) in patients in the group with nitinol prostheses and 11.93 dB (standard deviation ± 5 dB) in titanium ones.

The preoperative and postoperative bone conduction thresholds in all patients were at the same level in both the titanium and nitinol prostheses group, while the air conduction thresholds decreased (improved) in both groups.

As examples, we present the data of tonal threshold audiometry of patients before and after surgery with the installation of a titanium or nitinol prosthesis (Fig. 1-4).

Patient No2, who has a SE NiTiNOL prosthesis installed.

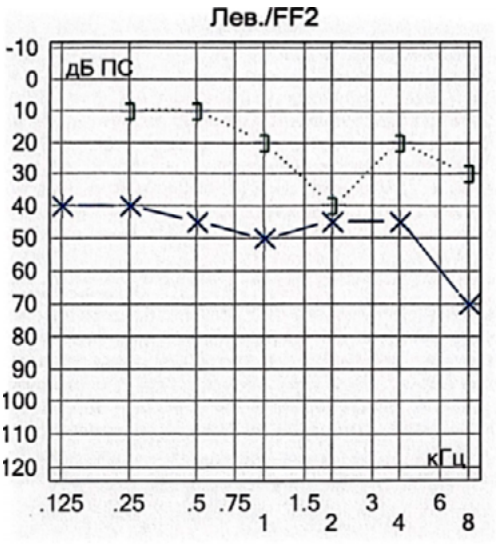

Fig. 3 Preoperative pure tone threshold audiometry

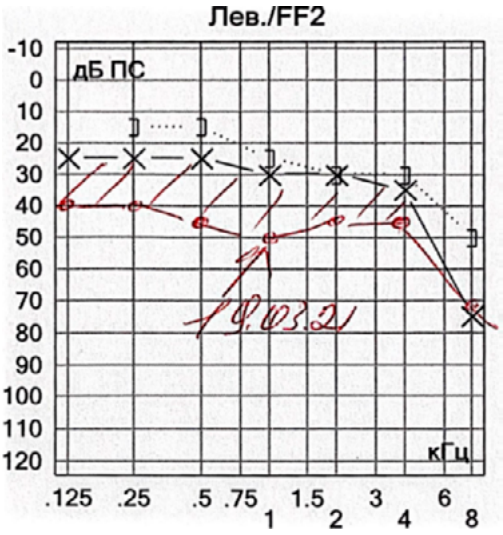

Fig. 4 pure tone threshold audiometry after surgery

The installed stapedial prosthesis was visible at the CT scan of the temporal bones after surgical treatment with a difference of 1-3 years. The CT data of patients with titanium and nitinol prostheses were compared. It was possible to assess its position on the long stem of the incus, in the area of the vestibule, the entirety of the long stem of the incus (which indicated the absence of its aseptic necrosis) due to the absence of artefacts only in the group with installed nitinol prostheses (Fig. 5, 6).

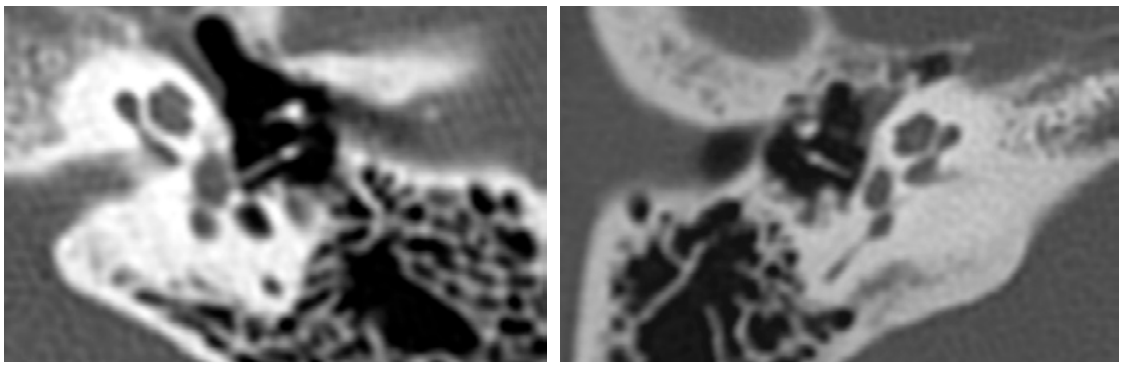

Fig. 5 CT scan of the temporal bones in a patient with installed SENiTiNOL

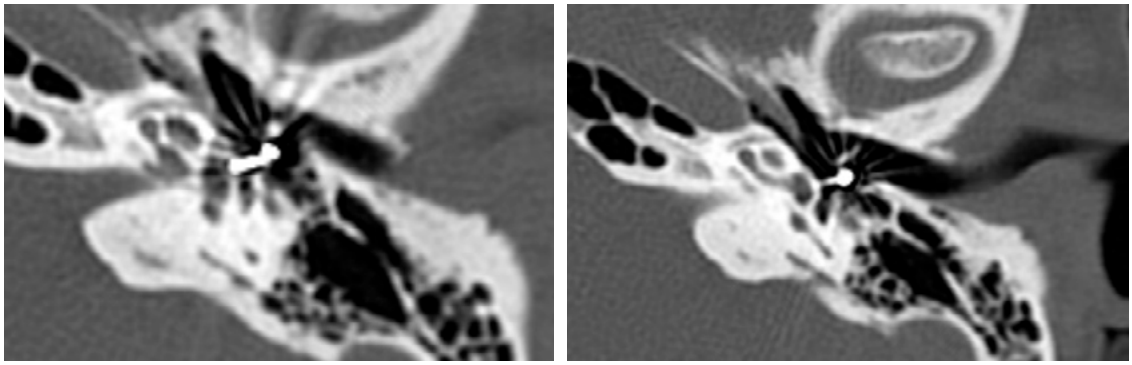

Fig. 6 CT scan of the temporal bones in a patient with installed Ti/PTFE

In addition, the CT data obtained during the installation of titanium and nitinol prostheses were compared experimentally on 8 cadaverous bones (4 in each of the two studies). The possibility of visualizing the attachment area of the prosthesis ring has also been determined. As a result, it turned out that in 4 cases with the installation of a nitinol prosthesis there were no artefacts, which made it possible to visualize the ring of the prosthesis attachment. In the other 4 cases with a titanium prosthesis, it was not possible to identify this (Fig. 7).

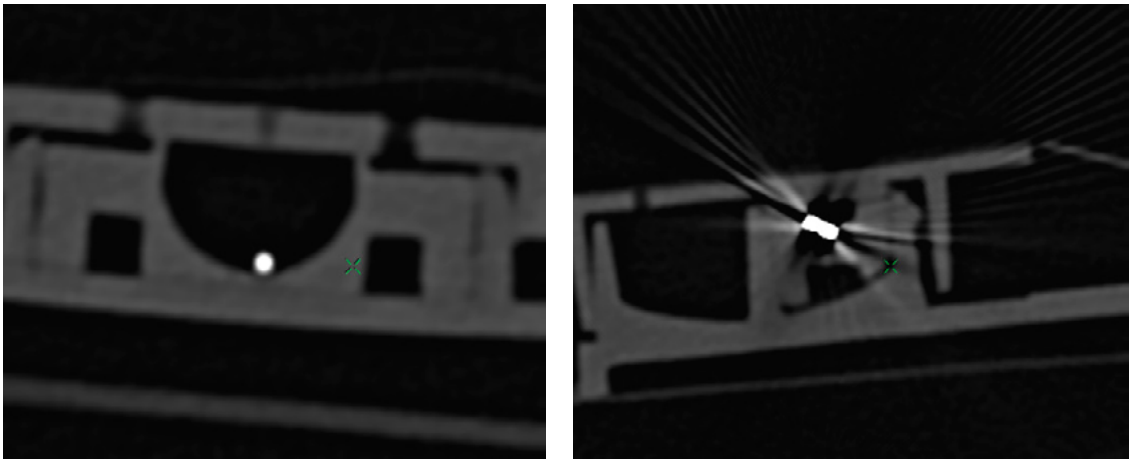

Fig. 7 CT scan showing visualization of the prosthesis attachment ring

Conclusions

A comparison analysis of the results of the piston stapedoplasty technique showed that in the postoperative period in patients of both groups using both titanium and nitinol prostheses, in 80 and 88% of cases positive ("excellent" and "good") functional outcomes were noted by way of a reduction in bone-air interval to 10 and/or 15 dB. The practical information is consequence of the fact that the installation of a nitinol prosthesis does not require adjunctive fixation of its head on the long stem of the incus in the form of "compression": there is no risk of traumatization of the inner ear structures and thus the development of sensorineural hearing loss in the postoperative period. Also, the use of SE NiTiNOL prostheses reduces the likelihood of aseptic necrosis of the long stem of the incus due to the properties of the metal and a decrease its thickness.

CT of the temporal bones is one of the necessary and obligatory methods of examining patients with otosclerosis at the preoperative stage to determine the localization and prevalence of locus, as well as differential exclusion with other ear diseases. It was possible

to visualize the position of the prosthesis on the long stem of the incus, in the area of the vestibule, its length, the entirety of the long stem of the incus in the first group with SE NiTiNOL due to the absence of artefacts analyzing the data of computed tomograms of patients after stapedoplasty. CT imaging of a stapedial prosthesis in the postoperative period is especially important when obtaining unsatisfactory functional outcomes of surgery and/or the development of postoperative complications in order to determine further patient surveillance and the need for revision tympanotomy or repeated stapedoplasty surgery.

Disclosure of interest.

The authors declare that they have no competing interests.

Authors' contribution.

The authors declare the compliance of their authorship according to the international ICMJE criteria. All authors made a substantial contribution to the conception of the work, acquisition, analysis, interpretation of data for the work, drafting and revising the work, final approval of the version to be published and agree to be accountable for all aspects of the work.

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