ABSTRACTS

KURZ IMPLANTS, PRECISION INSTRUMENTS, VENTILATION TUBES

MIDDLE EAR SURGERY

SOFT CLIP

Experimental study on admissible forces at the incudomalleolar joint

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Hypothesis: The forces that cause rupture of the incudomalleolar joint during the fixation of stapedial prostheses can be determined by means of load-deflection measurements at the long process of the incus. As in other tissues, 3 ranges of forces can be defined: micro rupture, rupture, and short-term maximum.

Background: A crucial step in stapes surgery is the attachment of the stape-dial prosthesis to the long process of the incus. It is unknown which forces occur during the crimping process that increase the risk of damage to the incudomalleolar joint or incus luxation. The goal of this study was to assess the admissible range of forces at the long process of the incus that would be tolerable before damaging the structures and to compare them with the forces occurring during surgery.

Methods: Load-deflection curves in the lateral-medial and anterior-poste-rior direction were measured in 9 freshly frozen or fresh temporal bones. The force was measured with a load cell, and displacement was taken from the encoder information of the electrically driven translation stage on which the load cell was mounted. The long process of the incus was coupled to the load cell via a customized needle. We also monitored with video recordings for visual confirmation of findings.

Results: The rupture force at which the middle ear was found to be severe-ly injured was 894 (724-1018) mN in the anterior-posterior direction and 695 (574-771) mN in the lateral-medial direction. Micro-ruptures occurred at forces around 568 (469-686) mN in the anterior-posterior direction and in the lateral-medial direction at 406 (254-514) mN. Short-term maximum forces of 1,321 (1,051-1,533) mN were measured in the anterior-posterior direction and 939 (726-1,132) mN in the lateral-medial direction.

Conclusion: Rupture forces of the incudomalleolar joint could be defined with high accuracy. These results were used to calculate risks of incus lux-ation or subluxation during stapes surgery. Compared with the use of clip and SMA prostheses, the risk of damage from a crimping procedure is sig-nificantly higher.

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

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Objectives: 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 malleovestibulopexy, 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 necosis 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 TPlPi 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.

First Experience With a New Titanium Clip Stapes Prosthesis and a Comparison With the Earlier Model Used in Stapes Surgery

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Objectives/Hypothesis: The aim of the study was to gain the first clini-cal experience with a new titanium clip prosthesis in stapes surgery, and to compare this model with its predecessor. We placed particular emphasis on the practicability of fixing the prosthesis to the long process of the incus and on the postoperative improvement in hearing. Study Design: Retrospective chart review.

Methods: The study included 23 patients who had a CliP Piston à Wengen fitted and 21 patients with a Soft CliP Piston (both from Kurz Medizintechnik, Dusslingen, Germany). Air and bone conduction were tested preoperatively and 5 to 6 weeks after surgery in all patients, as well as after about 1 year in a subgroup.

Results: We found a mean air-bone gap of 8.5 +/- 5.2 dB in the frequencies 0.5, 1, 2, and 3 kHz for the patients with a CliP Piston à Wengen at follow-up audiometry after an average of 31 days, and of 6.4 +/- 3.7 dB for 11 patients after 412 days. The corresponding figures for patients with Soft CliP Pistons were 8.9 +/- 4.1 dB after 44 days, and 6.3 +/- 5.6 dB for 10 patients after 419 days. There were no statistically significant differences. All the prostheses were implanted without difficulty.

Conclusions: The two stapes prostheses studied gave good early audiometric results that showed no difference. After a short learning period, both could be pushed onto the long process of the incus with similar ease, although subjec-tively the new design of the Soft CliP seemed to adapt better to the different diameters of the process and took up less space in the middle ear.

Stapes surgery: First experiences with the new Soft-CliP® Piston

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Background: The first hearing results with a new stapes prsthesis with clip function (Soft-CliP® piston) are presented.

Patients and Methods: This new prosthesis was used in 15 patients (mean age 45.2 years; range 21-63 years) undergoing routine stapes surgery. Soft-CliP® piston prostheses with a shaft diameter of 0.4 mm and a length rang-ing from 4.25 mm to 5.5 mm were used. Postoperative audiological testing and measurement of the air-bone gap were performed after an average of 47.3 days and compared with the preoperative values.

Results: The median observed postoperative air-bone gap (ABG) was 8.33 dB ±4.16 dB. All patients had less than 20 dB ABG and in 53.3% of cases was less than 10 dB. The operating time showed a clear difference between the left (66.5 min ±37.79 min) and right ears (47.2 min ±11.08 min).

Discussion: This new prosthesis design greatly facilitates a very difficult step in stapes surgery, the prosthesis fixation to the incus. The first postop-erative hearing results are very promising but long-term results in a larger group of patients are still pending.

Development of a new CliP-Piston prosthesis for the Stapes

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275 inserted Clip-Pistons type " à Wengen" within three years revealed dif-ficulties in 14.5% of the cases. In those cases it was necessary to make ad-justments to the clip shape (plastic deformation) before insertion due to the individual dimension of the long incudal process. During 100 middle ear surgeries the cross sections of the long incudal processes where the clip is attached was measured. This resulted in data hitherto unknown. By virtue of a Finite Element Model (FEM) these data were used for optimizing the clip shape. Design criteria were a minimal variation of the contact force for different cross-sections and to minimize the force necessary to slide the clip over the incudal process. The new clip has a lower stiffness and can therefore be applied onto different incus diameters. The lower contact force reduces the risk of arrosion. Due to its optimized shape, the maximal stress in the clip is lowered preventing plastic deformation during the application procedure. The application force was decreased by up to 45% depending on the application points. This leads to easy and safe application reducing the risk of damaging the ossicular chain.