

ABSTRACTS

KURZ IMPLANTS, PRECISION INSTRUMENTS, VENTILATION TUBES

MIDDLE EAR SURGERY

CLIP PARTIAL FLEXI BAL

Long-term hearing results and patient satisfaction after tympanoplasty with Titanium-Clip Prostheses

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Introduction: Titanium-Clip® Prostheses (Dresden or FlexiBal® type, Kurz) have been in use for reconstruction of the ossicle chain for several years. So far only a few studies of the long-term audiological and otological results have been published. The quality of life of patients has not been analyzed.

Methods: From 2003-2013 140 patients received a tympanoplasty with implantation of a Titanium-Clip® Prosthesis in this hospital. We conducted a retrospective, monocentric study with prospective follow-up of up to eleven years after the initial procedure. Otological microscope findings and audiological measurement data were evaluated for the analysis. The quality of life was evaluated based on the Glasgow Benefit Inventory. The objective of the study was to find information on the long-term hearing results (air-bone gap before and after operation), the seating of the prosthesis, the rate of revision operations, protrusions and extrusions, and patient satisfaction.

Results: 30 patients were recruited and the average follow-up was 64 months. The validated analysis of quality of life showed an improvement; protrusions or extrusions were documented in isolated cases. The sound transmission component - measured over frequencies 0.5-4 kHz - was reduced pantonally from an average of 21 dB to 10.2 dB.

Conclusion: This study demonstrates that the results remain stable over the long term and in contrast to other methods of chain reconstruction the sound conduction component is reliably reduced. This was also the first time that a validated measurement procedure could be used to show that the subjective quality of life of patients is positively affected over the long term. Reconstruction of the ossicle chain with titanium Clip® Prostheses is now an established procedure.

Experience With the Use of a Partial Ossicular Replacement Prosthesis With a Ball-and-Socket Joint Between the Plate and the Shaft

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Background: In the further development of alloplastic prostheses for use in middle ear surgery, the Dresden and Cologne University Hospitals, working together with a company, introduced a new partial ossicular replacement prosthesis in 2011. The ball-and-socket joint between the prosthesis and the shaft mimics the natural articulations between the malleus and incus and between the incus and stapes, allowing reaction to movements of the tympanic membrane graft, particularly during the healing process.

Study Design: Retrospective evaluation

Methods: To reconstruct sound conduction as part of a type III tympanoplasty, partial ossicular replacement prosthesis with a ball-and-socket joint between the plate and the shaft was implanted in 60 patients, with other standard partial ossicular replacement prosthesis implanted in 40 patients and 64 patients. Pure-tone audiometry was carried out, on average, 19 and 213 days after surgery. Results of the partial ossicular replacement prosthesis with a ball-and-socket joint between the plate and the shaft were compared with those of the standard prostheses.

Results: Early measurements showed a mean improvement of 3.3 dB in the air-bone gap (ABG) with the partial ossicular replacement prosthesis with a ball-and-socket joint between the plate and the shaft, giving similar results than the standard implants (6.6 and 6.0 dB, respectively), but the differences were not statistically significant. Later measurements showed a statistically significant improvement in the mean ABG, 11.5 dB, compared with 4.4 dB for one of the standard partial ossicular replacement prosthesis and a tendency of better results to 6.9 dB of the other standard prosthesis.

Conclusions: In our patients, we achieved similarly good audiometric results to those already published for the partial ossicular replacement prosthesis with a ball-and-socket joint between the plate and the shaft. Intraoperative fixation posed no problems, and the postoperative complication rate was low.

Titanium Clip Ball Joint: A Partial Ossicular Reconstruction Prosthesis

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Objective: To describe a new titanium clip prosthesis for partial ossicular reconstruction with a micro ball joint in the headplate for compensation of tympanic membrane displacements.

Patients: Laboratory experiments followed by 18 consecutive patients. Interventions: A micro ball joint was implemented into a headplate of titanium middle ear prosthesis. First, the new prosthesis was tested in the laboratory in temporal bone experiments. Second, the new prosthesis was clinically installed in 18 patients.

Outcome Measures: Results of laser Doppler vibrometry and force measurements in the laboratory experiments, analysis of a questionnaire, and preoperative and postoperative pure tone audiometry.

Results: The frictional resistance in the joint was measured to be 12 mN that should allow for adequate mobility under physiologic conditions. The effective sound transmission of the prosthesis was demonstrated by laser Doppler vibrometry. Intraoperatively, the installation of the prosthesis was always straightforward with headplate prosthesis shaft angles between 60 and 90 degrees. Postoperatively, pure tone audiometry revealed satisfying hearing results with a remaining average air-bone gap of 18.2 dB over the frequencies 500, 1,000, 2,000, and 3,000 Hz. No signs of prosthesis dislocation were discovered within the follow-up period of approximately 6 months.

Conclusion: The experimental data show that the new modified prosthesis headplate fulfills the requirements necessary for sound transmission. The joint allows the plate to follow movements of the tympanic membrane. This characteristic in conjunction with the proven clip design ensure for optimal prosthesis placement and effectiveness.