

ABSTRACTS

KURZ IMPLANTS, PRECISION INSTRUMENTS, VENTILATION TUBES

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MIDDLE EAR INTELLIGENCE

TTP-VARIAC SYSTEM	5
TTP-VARIO SYSTEM	6
TTP-TUEBINGEN TYPE PROSTHESIS	6
DUESSELDORF TYPE PROSTHESIS	7
MNP MALLEUS NOTCH PROSTHESIS	9
OMEGA CONNECTOR	9
MRP MALLEUS REPLACEMENT PROSTHESIS	10
CLIP PARTIAL FLEXIBAL	10
CLIP PARTIAL PROSTHESIS DRESDEN TYPE	11
ANGULAR CLIP PROSTHESIS	12
REGENSBURG TYPE TOTAL PROSTHESIS	13
NITIFLEX	13
MATRIX	13
K-PISTON	14
SOFT CLIP	14
CLIP PISTON À WENGEN	16
CLIP PISTON MVP	17
NITIBOND	18
STAPES PROSTHESES	19
KURZ PRECISE CARTILAGE KNIFE	20
CARTILAGE PUNCH	21
TENSION	22
TOTAL AND PARTIAL RECONSTRUCTION	23
TITANIUM AND OTHER MATERIALS	24
MRI	27
COUPLING OSSICULOPLASTY	27
VENTILATION TUBES	28

ABSTRACTS

KURZ IMPLANTS, PRECISION INSTRUMENTS, VENTILATION TUBES

MIDDLE EAR SURGERY

TTP-VARIAC SYSTEM

Middle Ear Reconstruction Using the Titanium Kurz Variac Partial Ossicular Replacement Prosthesis

Meulemans J., Wuyts F. L., Forton G. E. J.

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Importance: Satisfactory functional results following ossicular chain reconstruction mainly depend on a stable connection between the tympanic membrane and the stapes, which is in turn dependent on the type of prosthesis used. Knowledge about the safety and functional outcome of the commercially available middle ear prostheses is therefore of great importance.

Objective: To evaluate the efficacy and safety of the Kurz TTP-Variac System partial ossicular replacement prosthesis (PORP) in ossiculoplasty.

Design, Setting and Participants: Retrospective review of all ossiculoplasties performed by 1 surgeon at a secondary referral center from August 2006 through July 2012. Participants were patients with cholesteatoma, chronic otitis media, or ossicular chain disruption in the absence of inflammatory disease who underwent ossicular reconstruction.

Exposure: Ossiculoplasty using a Kurz TTP-Variac System PORP.

Main Outcome and Measures: Mean preoperative and postoperative air-bone gaps (ABGs) and improvements in ABG were analyzed for each frequency by means of a 4-frequency pure-tone average. Successful postoperative hearing was defined as postoperative ABG smaller than 20 dB.

Results: Eighty-nine ears in 83 patients aged 7 to 85 years were included. Transmeatal tympanoplasty was performed in 17 ears (19%). Seven ears (8%) underwent tympanoplasty with canal wall-down mastoidectomy, and 65 ears (73%) underwent canal wall-up (combined approach) tympanoplasty with mastoidectomy. The study population comprised 61 primary tympanoplasties (69%) and 28 revision cases (31%). Mean follow-up was 13 months. Overall, the ABG significantly improved from a mean (SD; range) of 26.19 (11.53; 3.75-51.25) dB to 15.58 (9.80; 0-48.75) dB ($P < .01$ for all frequencies). Mean ABG improvement was 10.62 dB. Successful postoperative hearing was obtained in 65 ears (73%). Revision surgery, especially in ears with ossicular chain disruption without inflammatory disease, was associated with poorer functional outcome, whereas preservation of the malleus was associated with a better functional outcome ($P < .05$). There were few complications (1 prosthesis extrusion, 2 prosthesis dislocations, 2 reperforations, 3 cases of residual cholesteatoma, and 3 of light sensorineural hearing loss).

Conclusion and Relevance: The titanium Kurz TTP-Variac System PORP is an effective prosthesis to reconstruct the ossicular chain. Complications are rare, illustrating the safety of the prosthesis.

Long-term hearing result using Kurz titanium ossicular implants

Hess-Erga J., Møller P., Vassbotn F. S.

Published: European Archives of Oto-Rhino-Laryngology, May 2013 DOI: 10.1007/s00405-012-2218-x

Titanium implants in middle ear surgery were introduced in the late 90s and are now frequently used in middle ear surgery. However, long-term studies of patient outcome are few and have only been published in subgroups of patients. We report the long-term effect of titanium middle ear implants for ossicular reconstruction in chronic ear disease investigated in a Norwegian tertiary otological referral centre. Retrospective chart reviews were performed for procedures involving 76 titanium implants between 2000 and 2007. All patients who underwent surgery using the Kurz Vario titanium implant were included in the study. Audiological parameters using four frequencies, 0.5, 1, 2, and 3 kHz, according to AAO-HNS guidelines, was assessed pre and postoperatively. Otosurgical procedures, complications, revisions, and extrusion rates were analyzed. The study had no drop-outs. The partial ossicular replacement prosthesis (PORP) was used in 44 procedures and the total ossicular replacement prosthesis (TORP) in 32 procedures, respectively. Mean follow-up was 5.2 years (62 months). The ossiculoplasties were performed as staging procedures or in combination with other chronic ear surgery. The same surgeon performed all the procedures. A postoperative air-bone gap of ≤ 20 dB was obtained in 74 % of the patients, 82 % for the Bell (PORP) prosthesis, and 63 % for the Arial (TORP) prosthesis. The extrusion rate was 5 %.

We conclude that titanium ossicular implants give stable and excellent long-term hearing results.

Variable length titanium prostheses for type III tympanoplasty. Intraoperative length adjustment and fixation of the cartilage overlay

Zenner H.-P., Zimmermann R., Steinhardt U., Maassen M. M.

Published: HNO 01 Apr 2006, 54(4):298-302 (German) DOI: 10.1007/s00106-006-1391-x

Introduction: For type III tympanoplasty by partial ossicular replacement prosthesis (PORP) or total ossicular replacement prosthesis (TORP), the length of the prosthesis must match the individual intraoperative anatomical and physiological characteristics.

Materials and Methods: Databanks were used to determine the necessary sizer length of the sizer disc. The measurement template for the size of the cartilage to overlay the prosthesis headplate was derived from the headplates of the Tuebinger titanium prostheses (TTP®) and the Dresdener titanium prostheses. Finally all functions were integrated into a synthetic plate.

Results: The result was a simple and reasonably priced disposable multi-functional instrument (Tuebinger sizer disc TSD) which allowed an exact measurement for every prosthesis in TORP and PORP. For the TTP®-Variac, the TSD enabled the simple intraoperative production of prostheses with the length desired by the surgeon. For PORP the TSD enabled an adaptation of the diameter of the prosthesis foot for TTP®, TTP®-Vario and TTP®-Variac and provided a template for the size determination of the cartilage overlay of the titanium prosthesis head. The sizers and the resulting prostheses were used for initial tympanoplastic operations. Audiometric investigations carried out 6 weeks postoperatively gave results corresponding to those previously obtained in a study with TTP® and TTP®-Vario using the old instrumentation.

Conclusions: The new instrumentation leads to an improvement of the intraoperative practicability and a simplification. The audiological results remain the same.

Ossiculoplasty with KURZ titanium prosthesis

Nguyen D.-Q., Morel N., Dumas G., Troussier J., Lavieille J.-P., Schmerber S.

Published: Ann Otolaryngol Chir Cervicofac. 2005 Sep;122(4):187-93. (French)

Objectives: Report the functional and anatomic results of ossicular reconstruction by titanium prosthesis.

Materials and Methods: Retrospective chart reviews were performed for 111 patients who had undergone titanium ossicular implants between November 1998 and 2002 (61 PORP, 50 TORP). The anatomical and audiometric data were analyzed on average at 3 and 20 months.

Results: At 20 months, the improvement of air-bone-gap mean was 12.7 dB with better results at low frequencies. The global success rate was 66% (PORP 77%, TORP 52%). It decreased significantly in the open techniques. Extrusion rate was low (2/111) and the labyrinthization rate was 3.6%. Twenty patients required a surgical revision (18%). In 9 patients, the prosthesis was too short. At long-term follow-up, the gains were stable in 60 patients, improved in 32 patients and worsened in 19 patients.

Conclusion: The success rate is higher in the group of the PORP with the closed technique. The stability of the TORP in open technique still remains problematic. In all cases, the risk of extrusion requires a large cartilage graft recovering the plate of the prosthesis. The high rate of luxation (9/111 prosthesis too short) has led us to increase slightly the length of the prosthesis (+1.22 mm mean).

TTP-VARIO SYSTEM

Synchronous ossiculoplasty with titanium prosthesis during canal wall down surgery for advanced cholesteatoma: anatomical and hearing outcomes

Iseri M., Ustundag E., Ulubil S. A., Ozturk M., Bircan O.

Published: The Journal of Laryngology & Otology (2012), 126, 131–135. DOI: 10.1017/S0022215111002520

Objective: To analyse patients with cholesteatoma undergoing canal wall down mastoidectomy together with ossicular reconstruction with a titanium prosthesis, in order to identify factors associated with hearing outcomes.

Study Design: Retrospective review of 97 cases undergoing single-stage surgical management.

Methods: All patients underwent canal wall down mastoidectomy. Kurz titanium ossicular prostheses were used for ossicular chain reconstruction. Pre-operative and post-operative air conduction and bone conduction hearing thresholds were obtained at 500, 1000, 2000 and 3000 Hz.

Results: The mean pure tone average improved from 46.02 ± 14.54 dB pre-operatively to 29.32 ± 14.64 dB postoperatively, for both total and partial ossicular replacement prosthesis groups combined. The mean air-bone gap improved from 30.38 ± 11.12 dB pre-operatively to 15.62 ± 9.65 dB post-operatively, for both groups combined.

Conclusion: Reconstruction with a titanium prosthesis offers good functional results when performed during canal wall down surgery for advanced cholesteatoma as a single-stage procedure.

Preliminary ossiculoplasty results using the Kurz® titanium middle ear implants

Heylbroeck Ph., De Vel E., Dhooge I.

Published: 24th Politzer Meeting 31 August – 4 September 2003, Amsterdam, the Netherlands: Selected Abstracts

Titanium has been an accepted prosthetic material for decades in craniofacial and orthopaedic surgery. The last decennium, studies were published reporting the results of titanium prostheses used for ossiculoplasty. The new, lightweight titanium prostheses are designed to maximize visualization of the capitulum and footplate region. Mechanically they are characterized by a high degree of rigidity and low weight. Acoustically they have low sound damping, low acoustic impedance, and a second resonance that might increase to broadband frequency transmission. These characteristics suggest the possibility of improved signal transfer in the main speech frequencies at around 2 kHz. A prospective clinical study was started to evaluate the efficacy of the variable (= adjustable length) Tübingen titanium prosthesis (TTP-Vario). Twenty patients were evaluated. A canal wall up procedure was performed in 3 cases, a canal wall down procedure in 17 cases. A postoperative air bone gap of < 20 dB was obtained in 60% of bell prosthesis patients and < 25dB in all bell prosthesis patients. The pure-tone average air-bone gap for the aural prosthesis was < 20 dB in 43%, < 25 dB in 64% and < 30 dB in 85% at 1 month. The results were stable or improved for later time intervals. To date there have been no extrusion. The surgeon finds the prosthesis easy to handle and the open head of the prosthesis facilitates correct placement on the capitulum of the stapes or on the footplate. From a surgical point of view, the Kurz titanium prosthesis is an excellent middle ear prosthesis due to the design and the possibility of individual adjustment. The hearing results are good. Further studies are needed to confirm long-term efficacy.

TTP-TUEBINGEN TYPE PROSTHESIS

Ossiculoplasty With Titanium Prosthesis

Martins J., Silva H., Cortal V. F., Amorim H., Carvalho C. F.

Published: Acta Otorrinolaringológica Española. Accepted 27 February 2011 DOI: 10.1016/j.otoeng.2011.02.004

Objectives: The goal of this study was to make a review of the patients who underwent Ossicular chain reconstruction with titanium prosthesis during an 8-year period in our Department.

Methods: A retrospective study was made on the ossiculoplasty cases over a period of eight years in a Public Hospital District. The information was extracted by clinical process consultation. Between 1999 and 2008, 124 ossiculoplasties using Kurz® titanium prosthesis for chronic otitis media were performed (78 partial ossicular chain reconstructions and 46 total Ossicular chain reconstructions). The single stage, staged and revision ossicular chain reconstruction were included in the analysis. All patients had a minimum of 6-month postoperative follow-up (mean 3 years and 4 months). Comparisons of preoperative and postoperative pure tone averages were performed. Air-bone gap and implant extrusion rates were measured. The success of the reconstruction was defined as a postoperative air-bone gap (ABG) of 20 dB or better.

Results: Successful ossiculoplasty was obtained in 73.1% of partial ossicular chain reconstructions and 30.4% of total ossicular chain reconstructions ($P < 05$). The postoperative pure-tone average air-bone gaps was 16 dB in partial reconstructions and 26.7 dB in total reconstructions ($P < 05$). There were five cases of prosthesis extrusion.

Conclusions: The majority of the ossiculoplasties improved the hearing status satisfactorily. There was no difference in hearing results in one-stage and two-stage partial ossicular chain reconstruction, but there were better hearing results in the cases of two-stage total Ossicular chain reconstruction.

Hearing results with the titanium ossicular replacement prostheses

Schmerber S., Troussier J., Dumas G., Lavieille J.-P., Nguyen D. Q.

Published: Eur Arch Otorhinolaryngol (2006) 263: 347-354.
DOI: 10.1007/s00405-005-1002-6

The purpose was to study the hearing results in patients receiving a Kurz titanium Bell partial ossicular replacement prosthesis (PORP) or an Aerial total ossicular replacement prosthesis (TORP). The study was a retrospective chart review in a tertiary otologic referral center. A computerized otologic database was used to identify 111 patients implanted with either a PORP or TORP prosthesis. Audiograms were reviewed and air-bone gaps were calculated for each patient. The improvement of the average air-bone gap (ABG) was 10.2 and 12.7 dB at 3 and 20 months after ossiculoplasty, respectively. Sixty-six percent of patients (73/111) had a postoperative air-bone gap of 20 dB or less. The ABG for the titanium PORP prosthesis was 14.3 \pm 9.7 dB, compared with 25.2 \pm 13.7 dB for the TORP prosthesis ($P < 0.05$). The ABG to within 20 dB or less was obtained in the PORP group in 77% of the cases, versus 52% of the cases in the TORP group ($P < 0.05$). Two extrusions of the prostheses were observed at 17 and 20 months after surgery (1.8%). Revision procedures for functional failure were carried out in 20 patients (18%). The rate of sensorineural hearing loss was 3.6%. The major factors influencing good audiometric results were the surgical procedure preserving the external auditory canal and the presence of the stapes. The best hearing results were achieved when a PORP was used in an intact canal wall (ICW) procedure, and the worst hearing results were achieved when a TORP was used in a canal wall down (CWD) procedure. The titanium Kurz prosthesis has been an effective implant at our institution for ossicular reconstruction.

Acoustomechanical properties of open TTP® titanium middle ear prostheses

Zenner H.P., Freitag H.-G., Linti C., Steinhardt U., Rodriguez J. J., Preyer S., Mauz P.-S., Sürth M., Plank H., Baumann I., Lehner R., Eiber A.

Published: Hearing Research. 2004 Jun;192(1-2):36-46.
DOI: 10.1016/j.heares.2004.02.004

Objective: The purpose of the study was to identify acoustomechanical properties of various biostable and biocompatible materials to create a middle ear prosthesis with the following properties: (i) improved handling including a good view of the head of the stapes or footplate and adjustable length, (ii) improved acoustical characteristics that are adequate for ossiculoplastic. The identified material should serve to build CE and FDA approved prostheses for clinical use in patients.

Methods: Test models made of Teflon, polyetheretherketone, polyethyleneterephthalate, polysulfone, gold, Al₂O₃ ceramics, carbon and titanium were investigated for their potential to fulfill the requirements. Acoustical properties were investigated by laser Doppler velocimetry (LDV) in mechanical middle ear models (MMM). Measured data were fed in to a recently created computer model of the middle ear (multibody systems approach, MBS). Using computer-aided design (CAD) measured and computed data allowed creation and fine precision of titanium prostheses (Tubingen Titanium Prostheses, TTP). Their handling was tested in temporal bones. Acoustomechanical properties were investigated using the MBS and mechanical middle ear models.

Main Outcome Measures: Input impedance, mass, stiffness, and geometry of test models and prostheses were determined. Furthermore, their influence on the intraprosthesis transfer functions and on coupling to either tympanic membrane or stapes was investigated.

Results: Final results were FDA- and CE-approved filigreed titanium prostheses with an open head that fulfilled the four requirements detailed above. The prostheses (TTP) were developed in defined lengths of between 1.75 and 3.5 mm (partial) and 3.0 and 6.5 mm (total) as well as in adjustable lengths (TTP-Vario).

Conclusions: The results suggest acoustomechanical advantages of TTPs because they combine a significantly low mass with high stiffness. In contrast to closed prostheses, the open head and filigreed design allow an excellent view of the prosthesis foot during coupling to the head or footplate of stapes, contributing to an improved intraoperative reliability of prosthesis coupling.

Open Tuebingen Titanium Prostheses for Ossiculoplasty: A Prospective Clinical Trial

Zenner H. P., Stegmaier A., Lehner R., Baumann I., Zimmermann R.

Published: Otology & Neurotology 2001, 22:582-589

Objective: The overall purpose of the study was the evaluation of the efficacy of Tuebingen titanium prostheses (TTPs) for ossiculoplasty.

Study Design: A two-part clinical study of 216 patients undergoing ossiculoplasty was performed. The first part was a prospective study using TTPs ($n = 114$). The second part involved study of historical control patients ($n = 102$) with gold and ceramic prostheses. **Interventions:** All patients underwent ossiculoplasty.

Main Outcome Measures: Measures included median air conduction thresholds and air-bone gaps.

Results: All patients were per-protocol patients. When the air-bone gap "gold standard" (i.e., ≤ 10 dB) was investigated in the main speech spectrum, partial TTPs reached this level at 2 kHz in 44% ($n = 22$) and at 3 kHz in 38% ($n = 19$). Gold and ceramics revealed significantly lower values. Similar results were obtained for total prostheses. Differences for TTPs and ceramics were statistically significant (Mann-Whitney U test, $\alpha = 5\%$).

Conclusion: The use of TTPs for ossiculoplasty is an efficient treatment method.

DUESSELDORF TYPE PROSTHESIS

Ossiculoplasty with titanium prostheses

Romer M., Vorburger M., Huber A.

Published: MEMRO 2006, 4th International Symposium on Middle Ear Mechanics in Research and Otology: Selected Abstracts

Objective: To determine the hearing results and the complication rate one year after ossiculoplasty with the Kurz titanium system.

Material and Methods: A retrospective chart review of 82 procedures in 77 patients. Included in the study were 36 Aerial-TORP and 46 Bell-PORP between October 2001 and October 2004. The air and bone conduction thresholds as well as the complication rate were evaluated.

Results: The mean preoperative air bone gap (ABG) was 32.9 (± 13.4) dB. 16 (± 7.2) months postoperatively the average ABG was 17.6 (± 11.8) dB. The extrusion rate was 3/82 (3.7%). In one case (1.2%) the prosthesis perforated the stapes footplate and was dislocated into the vestibule without significant sensorineural hearing loss. The tympanic membrane reperforation rate and the cholesteatoma recurrence rate was 3/82 (3.7%) and 1/82 (1.2%) respectively.

Conclusion: The Kurz titanium prosthesis system provides hearing success comparable with current ossiculoplasty studies and low complication rate.

Results with Titanium Ossicular Reconstruction Prostheses

Gardner E. K., Jackson C. G., Kaylie D. M.

Published: Laryngoscope 2004 Jan;114(1): 65-70.
DOI: 10.1097/00005537-200401000-00011

Objectives/Hypothesis: Despite the enthusiasm of recent short-term reviews, no center in the United States has published results meeting American Academy of Otolaryngology-Head and Neck Surgery guidelines with titanium-based prostheses. The purpose of the study was threefold. The first purpose was to review results with a titanium prosthesis system in cases meeting American Academy of Otolaryngology-Head and Neck Surgery

reporting guidelines. The second was to compare these results with previously published results using non-titanium-based prostheses. The third was to examine the authors' results for any evidence of a "learning curve."

Study Design: Retrospective chart review was performed for the period from February 2000 to August 2001 and for the period from July 2002 to February 2003.

Methods: Of 313 cases, 130 consecutive cases were identified in the first period and 65 in the second time period. One hundred two patients had adequate follow-up for published guidelines. All cases were performed by the senior author (c.g.j.). Comparison data were obtained from a previous publication involving the senior author.

Results: Successful rehabilitation (≤ 20 dB pure-tone average air-bone gap) of conductive hearing loss was obtained in 70% of partial ossicular chain reconstructions and 44% of total ossicular chain reconstructions when titanium prostheses were used. Comparison data revealed successful rehabilitation in 48% and 21% of non-titanium-based partial and total reconstructions, respectively. Postoperative pure-tone average air-bone gaps were not significantly different when compared with results in the period from July 2002 to February 2003.

Conclusion: Newer titanium-based ossicular reconstruction devices represent an improvement over previously used non-titanium-based prostheses. The authors think that this improvement is realized rapidly because no learning curve existed in their data.

Preliminary Ossiculoplasty Results using the Kurz Titanium Prostheses

Krueger W. W., Feghali J. G., Shelton C., Green J. D., Beatty C.W., Wilson D. F., Thedinger B. S., Barrs D. M., McElveen J. T.

Published: *Otology & Neurotology* 23: 836-839 (2002)
DOI: 10.1097/00129492-200211000-00004

Objective: Limitations in biocompatibility and hearing improvement with ossicular chain reconstruction prostheses are addressed with new, light-weight titanium prostheses designed to maximize visualization of the capitulum and footplate regions. The effectiveness of these new prostheses is being tested in a prospective multicenter study.

Study Design: Prospective case series. **Setting:** Multicenter (8 sites), primarily tertiary private practice or academic otologic clinics.

Patients: A convenience sample of 31 patients undergoing ossiculoplasty, with 16 partial ossicular chain reconstructions using the Bell prosthesis and 15 total reconstructions using the Aerial prosthesis.

Intervention: Ossiculoplasty using new Kurz titanium prostheses. Cartilage was interposed between the tympanic membrane and the prosthesis.

Main Outcome Measures: Air-bone gap for pure tone average and 3,000 and 4,000 Hz, assessed preoperatively and 3 months, 6 months, and 12 months postoperatively; percent of patients obtaining an air-bone gap of ≤ 20 dB; high-frequency average (1,000, 2,000, and 4,000 Hz) to evaluate sensorineural hearing loss; and extrusion rate.

Results: A postoperative air-bone gap of ≤ 20 dB was obtained in 81% of Bell prosthesis patients and 67% of Aerial prosthesis patients at 3 months. The results were stable to improved for later time intervals. High-frequency gaps were similar to the pure tone average gap. To date, there have been no instances of extrusion, and all the surgeons found the prostheses easy to use and thought that the design characteristics facilitated accurate placement.

Conclusions: Initial evaluation of the Kurz titanium prostheses produced low extrusion rates (none to date) with excellent hearing results, including good high-frequency conduction. Good visualization and accurate placement were easy to achieve. Further studies are needed to confirm long-term efficacy.

Reconstruction of the ossicular chain with titanium implants. Results of a multicenter study

Begall K., Zimmermann H.

Published: *Laryngo-Rhino-Otol* 2000, 79 (3):139-145. (German)
DOI: 10.1055/s-2000-298

Background: For decades, oto-surgeons have been trying to find suitable alloplastic materials for replacing ossicles in the case of morphological and functional disorders in the middle ear. The focus of attention has been on tissue tolerance and functionality.

Patients: A retrospective analysis of the implantation of titanium prostheses is presented (Type "Duesseldorf", Heinz Kurz GmbH, Dusslingen, Germany) in 528 patients operated in 14 ENT hospitals. The hospitals involved are ENT hospitals with different fields of specialization presenting a representative cross-section of surgical ENT treatment. Evaluated were healing results, hearing gain and surgical handling of the implants.

Results: Despite pathological middle ear conditions, the tissue-implant healing rate was very high. In 4.4% of the patients the implants were rejected. In the case of partial ossicular reconstruction, an average hearing gain between 10 and 20 dB was achieved. Total reconstruction of the ossicular chain showed even better audiological results (15 to 20 dB on average).

Conclusion: Due to the good morphological and functional results achieved, titanium implants have proven their worth for middle ear micro-surgery. Their advantages are their light weight and delicate structure, facilitating very good micro-surgical handling. It is advisable to place a thin layer of cartilage between the prosthesis headplate and the tympanic membrane. In this manner, the number of material extrusions can be safely reduced, however, extrusions cannot completely be avoided.

Replacement of ear ossicles with titanium prostheses

Stupp C. H., Stupp H. F., Grün D.

Published: *Laryngorhinootologie*. 1996 Jun;75(6):335-7. (German)
DOI: 10.1055/s-2007-997590

Background: Titanium has been a well established implant material for many years. New material processing techniques now permit the manufacture of small implants for ossicular chain reconstruction.

Methods: Between November 1994 and September 1995, 100 titanium middle ear implants (55 PORP, 45 TORP) were used for reconstruction of the ossicular chain. A range of five different sizes for partial and total prostheses suits all implantation needs. The shape of the implants can be altered by bending. Time consuming intraoperative shaping and trimming is avoided.

Results: At a follow-up time of three months (33 patients) and six months (17 patients), no adverse reactions or extrusions occurred. Biologic fixation between the foot of the partial prosthesis and the head of the stapes was found eight months after implantation. A hearing result of 0-20 dB residual air-bone gap was achieved in 79%.

Conclusion: Titanium middle ear implants show good bio-compatibility and are readily integrated into the ossicular chain. Although delicate in shape, they offer excellent mechanical properties in respect to sound conduction and implantation. Initial results show Titanium to be a perfect implant material for middle ear prostheses, although long-term results are not yet available.

Three years experience with titanium implants in the middle ear

Stupp C. H., Dalchow C., Grün D., Stupp H. F., Wustrow J.

Published: *Laryngorhinootologie* 1999 Jun;78(6):299-303. (German)
DOI: 10.1055/s-2007-996875

Background: In continuation of our previously published report on initial experience with titanium implants in the middle ear [13], we now present

the results of routine use over a three year period.

Methods: From November 1994 to November 1997, 661 titanium implants (Dusseldorf model) were implanted in the authors' clinics (355 PORP, 306 TORP). There was no preselection of patients. Five hundred eighty-two follow up examinations were performed with a medium follow up time of 11.6 months.

Results: The good initial results of the previous study with respect to biocompatibility and functional hearing results were confirmed in the long term follow-up. The average air-bone gap was calculated over the frequencies 0.5, 1, 2, and 4 kHz. Closure to within 20 dB was achieved in 72% of cases. The air-bone gap tended to decrease with increasing time of implantation. Adverse reaction to the prostheses did not occur. Extrusion occurred in one case of complete middle ear atelectasis with resorption of the interposed cartilage. Insufficient improvement of hearing was attributable to a short implant in 12 cases (1.8%). In three cases (0.5%) insufficient stability of the PORP was attributable to eroded stapes suprastructure, and in three others (0.5%) a dislocation was responsible for a poor hearing result. Middle ear fibrosis with impairment of sound transmission was seen in 3 patients (0.5%).

Conclusion: The superior acoustic properties of the delicate yet rigid low-weight titanium implants combined with excellent biocompatibility lead to a good hearing result if a meticulous surgical technique is employed. The easy handling makes it a pleasure to work with these prostheses.

MNP MALLEUS NOTCH PROSTHESIS

An Optimal Partial Ossicular Prosthesis Should Connect Both to the Tympanic Membrane and Malleus: A Temporal Bone Study Using Laser Doppler Vibrometry

Niklasson A., Gladiné K., Rönnblom A., von Unge M., Dirckx, J., Tano K.

Published: Otolology & Neurotology: 03/2018 - vol 39 - Issue 3 - p 333-339
DOI: 10.1097/MAO.0000000000001699

Objective: To compare stapes vibrations in different partial ossicular replacement prosthesis (PORP) applications.

Methods: Stapedial vibrations were measured on fresh frozen human temporal bones with laser Doppler vibrometry. Eight different types of common ossiculoplasty methods were compared regarding recovery of stapes vibrations in relation with the normal ossicular chain. The PORPs were divided into three groups: 1) PORPs with the lateral contact only with the tympanic membrane, 2) PORPs with lateral contact only to the malleus handle, and 3) PORPs with lateral contact with both the malleus handle and the tympanic membrane.

Results: The PORPs with lateral contact only to the malleus handle performed better than the PORPs with lateral contact to the tympanic membrane only at 2 kHz, but the best recovery was found in the group with contact both to the malleus handle and the tympanic membrane.

Conclusion: The best sound transmission might be achieved by placing a PORP in contact with both the tympanic membrane and the handle of the malleus.

Titanium prosthesis with malleus notch: a study of its "user-friendliness"

Yung M.

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DOI: 10.1017/S0022215107005944

"User-friendliness" is an important factor in the choice of ossicular prosthesis. The current titanium prostheses have a flat, open head plate and are

designed to sit under the tympanic membrane. Previously, the author had designed titanium prostheses with a malleus notch extension at the head plate. The present study aimed to assess whether these customised prostheses were user-friendly, compared with conventional prostheses. Fourteen surgeons were recruited to examine the user-friendliness of several ossicular prostheses. They performed ossiculoplasties on temporal bones and rated the user-friendliness of the malleus notch prosthesis against that of some of the more popular conventional ossicular prostheses. For malleus-stapes assembly, eight out of 13 surgeons preferred the malleus notch prosthesis to the Dusseldorf and Goldenberg designs. For malleus-footplate assembly, six out of 10 surgeons preferred the malleus notch prosthesis to the Dusseldorf and Richards designs. Most of the surgeons stated that the reconstruction was more stable using the malleus notch prosthesis.

OMEGA CONNECTOR

Results of chain reconstruction with missing stapes superstructure using a jointed coupling module (Omega connector) with titanium total prostheses

Fischer M.

Published: German Society for Oto-, Rhino-, Laryngology, Head and Neck Surgery. 86th Annual Meeting of the German Society for Oto-, Rhino-, Laryngology, Head and Neck Surgery e.V. Berlin, May 13-16, 2015. Dusseldorf: German Medical Science GMS Publishing House; 2015. March 26, 2015. Poster Abstract (German) DOI: 10.3205/15hnod336

Introduction: The Omega connector, a jointed coupling module for chain reconstruction with missing stapes superstructure, has been available for some years. The literature contains only two studies reporting the results of the implantation with 14 and 17 patients.

Methods: Retrospective evaluation of audiological results with 56 consecutive operations conducted by the author using the Omega connector. The Omega connector has always been placed where it could be securely positioned on the footplate when used with chain reconstruction in the presence of a defect of the stapes superstructure.

Results: 56 operations using the Omega connector have been registered since 2009. The data of preoperative and postoperative audiograms for 48 patients were available for analysis. They covered mostly male patients (68%) and left ears (62%). The preoperative conductive hearing loss (air-bone-gap, average of distances between air and bone conduction threshold at 500 Hz, 1kHz, 2 kHz and 3 kHz) was on average (SD) 35.36 dB (13.24), after the operation the residual conductive hearing loss was on average 24.54 dB (8.67). 41.67% of patients reach the „criterion for success“ of a residual conductive hearing loss of a maximum of 20 dB. The postoperative results were analyzed with reference to different influence factors.

Conclusions: The Omega connector in combination with titanium total prostheses shows promising results, even in the absence of stapes superstructure. Ventilation malfunctions are often the cause of lack of success. A two-stage procedure should be considered in the case of CWD operations with cholesteatoma.

Ossiculoplasty with Total Ossicular Replacement Prosthesis and Omega connector: Early Clinical Results and Functional Measurements

Mantei T., Chatzimichalis M., Sim J. H., Schrepfer T., Vorburger M., Huber A. M.

Published: Otolology & Neurotology 09/2011: 32(7):1102-7
DOI: 10.1097/MAO.0b013e3182267e3b

Objective: Among other difficulties, achieving a stable position of a total ossicular replacement prosthesis (TORP) is demanding because of a limited view on the TORP-footplate interface and individual angles between the footplate and tympanic membrane. The Kurz Omega Connector aims at a simplified insertion of the TORP. The performance of total ossicular

reconstruction using the Omega Connector was evaluated.

Study Design: Prospective cohort study and experimental measurements with a fresh human temporal bone. **Setting:** Tertiary referral center.

Patients: Seventeen consecutive patients receiving total ossicular reconstruction were included. Historical control group composed of 36 patients. **Interventions:** Total ossicular reconstruction using the Omega Connector.

Main outcome Measures: (a) Handling of the TORP and Omega Connector intraoperatively, (b) functional short-term results compared with a historical control group, (c) sound transmission properties with 3 different connective positions between the TORP and the Omega Connector.

Results: Placing the Omega Connector on the footplate and coupling the Omega Connector to the TORP was straightforward in 65% of cases. A stable final position of the TORP was obtained in 88% of cases. Mean (SD) preoperative and postoperative air-bone gaps were 36.00 (11.05) and 25.29 (12.25) dB and were almost identical with those in the historical control group ($p = 0.9$). In the experimental measurements, functional outcomes with "partial connection" showed almost the same results as those with "full connection."

Conclusions: The Omega Connector provides easy handling of the TORP. The short-term functional results were comparable to those achieved previously without the Omega Connector. The temporal bone measurement supports tolerance in connective position between the TORP and the Omega Connector.

The Ω Connector - A Module for Jointed Coupling of Titanium Total Prostheses in the Middle Ear

Schmid G., Steinhardt U., Heckmann W.

Published: Laryngo-Rhino-Otologie 2009, vol. 88, no (12), pp. 782-788
DOI: 10.1055/s-0029-1231047

Background: Hearing improvement after reconstruction of a defect ossicular chain depends on material, design and - crucially - coupling of the prosthesis. Coupling a total ossicular replacement prosthesis to the stapes footplate can be problematic and lead to prosthesis instability. In order to solve this problem, the Ω Connector was developed, a module allowing the middle ear surgeon to couple a titanium total prosthesis to the stapes footplate in a flexible, angle-variable manner.

Material and Method: The Ω Connector is made of pure titanium and consists of three components: head, neck and base plate. The head allows a jointed coupling to the stem of a titanium total prosthesis. Positioned between the remnants of the stapes crura, the base plate proves for a stable connection with the stapes footplate.

Results: The Ω Connector was implanted during 14 revision surgeries. In 10 of these surgeries a total ossicular replacement prosthesis was removed which was implanted at an earlier date and which was fixed and no longer functioning. In all 14 cases it was possible intraoperatively to position the Ω Connector correctly and to couple it to a titanium total prosthesis. The postoperative hearing gain was between 10 to 25 dB, with an average of 18 dB.

Conclusion: For the first time, the Ω Connector offers to the surgeon the option to couple a titanium total prosthesis via a micro ball joint. Hearing results achieved so far are satisfying. The results confirm the advantages of the Ω Connector during implantation of a titanium total prosthesis. For a final evaluation, long-term studies have yet to be made.

MRP MALLEUS REPLACEMENT PROSTHESIS

Ossiculoplasty in Missing Malleus and Stapes Patients: Experimental and Preliminary Clinical Results With a New Malleus Replacement Prosthesis With the Otology-Neurotology Database

Vincent R., Bittermann A. J. N., Wenzel G. Oates J., Sperling N., Lenarz T., Grolman W.

Published: Otol Neurotol. 2013; 34 (1): 83-90
DOI: 10.1097/MAO.0b013e318277a2bd

Objectives: To present the preliminary results of new malleus replacement prosthesis combined with a total ossicular prosthesis in middle ear reconstruction in patients missing the malleus and stapes.

Study Design: Prospective experimental and nonrandomized clinical study. **Setting:** Tertiary referral center.

Methods: An original titanium malleus replacement prosthesis (MRP) was designed to be inserted into the external auditory canal and to replace a missing malleus for various middle ear pathologies. The MRP was tested experimentally and clinically. The vibratory properties of the new prosthesis were measured using laser Doppler vibrometry. Ninety patients with missing malleus and stapes, undergoing 92 ossicular reconstructions were enrolled in this study from September 1994 to March 2012. Comparative analyses were made between a group of 34 cases of ossicular reconstructions with total prosthesis (TORP) positioned from the tympanic membrane to the stapes footplate (TM-to-footplate assembly) and a group of 58 cases of ossicular reconstructions with TORP positioned from a newly designed malleus replacement prosthesis (MRP) to the stapes footplate (MRP-to-footplate assembly). Preoperative and postoperative audiometric evaluation using conventional audiometry, that is, air-bone gap (ABG), bone-conduction thresholds (BC), and air-conduction thresholds (AC) were assessed.

Results: Experimentally, the vibratory properties of the MRP are promising and remain very good even when the MRP is cemented into the bony canal wall mimicking its complete osseous-integration, if this were to occur. This finding supports the short-term clinical results as in the TM-to-footplate group; the 3-month postoperative mean ABG was 23.3 dB compared with 12.5 dB in the MRP-to-footplate group (difference, 10.8; 95% confidence interval, 4.0 - 17.6); 37.0% of patients from the TM-to-footplate group had a postoperative ABG of 10 dB or less, and 48.1% of patients had a postoperative ABG of 20 dB or less, as compared with 58.1% and 79.1%, respectively, in the MRP-to-footplate group. The average gain in AC was 11.0 dB in the TM-to-footplate group as compared with 21.3 dB in the MRP-to-footplate group (difference, -10.3; 95% confidence interval, -18.2 to -2.4).

Conclusion: The results of this study indicate that superior postoperative hearing thresholds could be achieved using a MRP-to-footplate assembly, compared with a TM-to-footplate assembly in patients with an absent malleus undergoing ossiculoplasty. The postoperative AC thresholds, after 3 months and 1 year, are significantly lower in patients treated with the MRP-to-footplate assembly.

CLIP PARTIAL FLEXIBAL

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

Wolferts G., Schicke D., Delank K.W.

Published: 86th Annual Meeting of the German Society for Oto-, Rhino-, Laryngology, Head and Neck Surgery. Berlin, May 13-16, 2015. Düsseldorf: German Medical Science GMS Publishing House; 2015. Doc15hnod526, March 26, 2015. Poster Abstract (German). DOI: 10.3205/15hnod526

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

Birk S., Brase C., Hornung J.

Published: Otol Neurotol 2014; 35(7) :1248-1250
DOI: 10.1097/MAO.0000000000000383

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

Beutner D., Luers J. C., Bornitz M., Zahnert T., Hüttenbrink K.-B.

Published: Otol Neurotol. 2011; 32 (4) : 646-9
DOI: 10.1097/MAO.0b013e318213867a

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.

CLIP PARTIAL PROSTHESIS DRESDEN TYPE

Short and Long-Term Outcomes of Titanium Clip Ossiculoplasty

Kahue Ch. N., O'Connell B. P., Dedmon M. M., Haynes D. S., Rivas A.

Published: Otol Neurotol 2018; 39(6): e453-e460
DOI: 10.1097/MAO.0000000000001795

Objective: To report short (~4 mo) and long-term (>12 mo) audiometric outcomes following ossiculoplasty using a titanium clip partial ossicular reconstruction prosthesis.

Methods: Case series at a single tertiary referral center reviewing 130 pediatric and adult patients with conductive hearing loss (CHL) secondary to chronic otitis media (n = 121, 93%) or traumatic ossicular disruption (n = 9, 7%) who underwent partial ossiculoplasty from January 2005 to December 2015 with the CliP prosthesis.

Results: At both short and long-term follow-up, postoperative air-bone gap (ABG) was significantly improved (18 dB HL, IQ range 13–26, $p < 0.0001$ and 18 dB HL, IQ range 13–29, $p = 0.0002$, respectively) when compared with preoperative values (29 dB HL, IQ range 19–37). No significant change in ABG was noted when comparing short and long-term intervals (18 versus 18 dB HL, $p = 0.44$). Fifty seven percent of cases (51/89) achieved a long-term ABG less than or equal to 20 dB at the time of their last follow-up. The extrusion and displacement rates were 1.5% (2/130), and 0.8% (1/130), respectively. There were no cases of iatrogenic sensorineural hearing loss.

Conclusions: Partial ossiculoplasty with the titanium CliP produces good hearing outcomes with a favorable safety profile. At long-term follow-up (minimum of 12 mo), median ABG was 18 dB and remained stable when compared with short-term follow-up. The majority of patients had successful long-term results, with 57% of patients achieving an ABG is less than or equal to 20 dB. Low rates of extrusion (1.5%) and prosthesis displacement off the stapes (0.8%) support the long-term stability of the CliP prosthesis in the middle ear.

Coupling problems in middle ear reconstruction

Zahnert T.

Published: MEMRO 2006, 4th International Symposium on Middle Ear Mechanics in Research and Otolaryngology: Selected Abstracts.

The normal and reconstructed middle ear can be considered as a mechanical vibrating system. After the implementation of tympanoplasty as a standardized surgical technique various reconstruction techniques and implants were suggested for the reconstruction of the tympanic membrane and the ossicular chain. Laser-Doppler-vibrometry and model calculations have given new insight into the vibration modes of the normal and reconstructed middle ear during the recent years. Nowadays it can be concluded, that not only material properties of implants but also coupling factors have an important influence on good hearing results. We investigated coupling factors between tympanic membrane and the surrounding bone, between the tympanic membrane and middle ear implants and between the prosthesis and the ossicular chain using model calculations and temporal bone experiments. The quality of the tympanic membrane, which can be considered as the "motor of the middle ear", has the most important impact on the sound transfer to the inner ear. Ventilation and mucosa problems can damp the tympanic membrane vibrations as well as the reconstruction techniques or the mechanical properties of transplants. The coupling of the tympanic membrane to either the surrounding bone or the cartilage transplants has an influence on the stiffness. The contact of the tympanic membrane to the malleus handle is of importance in order to allow good sound conduction to middle ear prostheses in the high frequency range. Furthermore the contact of prostheses to the stapes head or the footplate may influence hearing results. In our investigations the angle of prostheses towards the tympanic membrane and the stiffness of coupling plays an important role. Concerning the angle it is of importance to distinguish between the x and y - direction. An absolutely stiff contact between malleus and stapes can reduce the sound transfer and increase the risk of prosthesis dislocation or even damage of the annular ligament. Even nowadays modern middle ear reconstructions can only simulate the simple function of a columella. In future it may be important to invent middle ear implants which will be able to fulfil both required middle ear functions - the sound transfer and the compensation of atmospheric pressure changes. It can be assumed that hearing results may improve due to an unstressed coupling of middle ear prostheses by taking the above mentioned techniques and findings into consideration.

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

Wolferts G., Schicke D., Delank K.W.

Published: 86th Annual Meeting of the German Society for Oto-, Rhino-, Laryngology, Head and Neck Surgery. Berlin, May 13-16, 2015. Düsseldorf: German Medical Science GMS Publishing House; 2015. Doc15h-nod526, March 26, 2015. Poster Abstract (German)
DOI: 10.3205/15hnod526

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.

Titanium Clip Prosthesis

Hüttenbrink K.-B., Zahnert T., Wüstenberg E.G., Hofmann G.

Published: Otolaryngology & Neurotology 25:436-42 (2004)

Objective: Prostheses for the reconstruction of a defective ossicular chain should be stable and firmly anchored to the ossicular remnants. This will prevent a defective connection from causing diminished sound transmission efficiency and will keep the prosthesis from tilting or even losing contact, which would result in a sound transmission block. Through temporal bone experimentation, we have consequently developed a very lightweight titanium prosthesis, which is fastened onto the stapes head with a clip mechanism.

Methods: When temporal bone experiments using laser Doppler vibrometry confirmed that the prosthesis functioned well acoustically and when luxation experiments proved that it could be safely used without the risk of stapes dislocation, the prosthesis was used in a clinical application within an observational study. The University of Dresden Otorhinolaryngological Hospital as well as seven surgeons from five other hospitals participated in the study.

Results: The results of 133 operations showed that, in over 90% of the cases, the prosthesis could be implemented without problems and with good mechanical stability. The first acoustical results obtained during the first year from 49 patients showed a sound transmission improvement range from 12 dB to 14 dB.

Conclusion: With the clip prosthesis, it seems possible to further improve defective middle ear function, which would allow the patient to regain social hearing after middle ear reconstruction. The reliability of the fastening is an innovation. Revision operations showed a stable prosthesis-stapes complex in the middle of a recurring cholesteatoma and the prosthesis could always be easily pulled from the stapedia suprastructure.

ANGULAR CLIP PROSTHESIS

Titanium Angular Clip: A New Prosthesis for Reconstruction of the Long Process of the Incus

Hüttenbrink K.-B., Luers J.C., Beutner D.

Published: Otolaryngology & Neurotology 30(8):1186-1190, December 2009
DOI: 10.1097/MAO.0b013e3181b287f2

Objective: To describe a new titanium angular clip prosthesis for bridging the incudostapedial joint in the event of an isolated lesion of the distal end of the long process of the incus.

Study Design: Clinical retrospective study.

Methods: We retrospectively reviewed the course of 22 patients with isolated defects of the long process of the incus where the ossicular chain was reconstructed by a titanium angular clip prosthesis.

Results: The placement of the prosthesis was successful in all patients, and no complication was encountered during its installation. At the first follow-up visit after 3 weeks, the mean air-bone gap (ABG) was reduced by around 10 dB from a mean of 26 dB preoperatively to 16 dB postoperatively. The mean postoperative hearing result of patients with a Type A tympanogram (7-dB ABG) was consistently better than for patients with a Type B or a Type C tympanogram (19-dB ABG in both).

Conclusion: Despite the limited number of patients, this preliminary study demonstrates the effectiveness of the angular clip prosthesis in reconstructing the ossicular chain. In cases of a normal aeration of the tympanic cavity, this reliable reconstruction of the biological chain offers a near-to-normal hearing restoration.

REGENSBURG TYPE TOTAL PROSTHESIS

A Micro-Computed Tomographic Study: Determination of the Angle Between the Tympanic Membrane and Stapes Footplate in a Total Ossicular Reconstruction Prosthesis Reconstruction

Herkenhoff S., Fischer B., Gleich O., Strutz J., Kwok P.

Published: Otol Neurotol. 2011 Jun;32(4):610-5.
DOI: 10.1097/MAO.0b013e318213af4d

Objectives: To examine the anatomical relationship of the angles between tympanic membrane and stapes footplate and the variation of these angles among different temporal bones in order to characterize the optimal shape of total ossicular reconstruction prostheses (TORPs).

Methods: Ten specimens of human temporal bones were prepared for examination with microcomputed tomography. Five of the 10 temporal bones were implanted with 3 types of TORPs before subjecting them to micro-computed tomography. The angles between tympanic membrane and stapes footplate were determined. The contact of the TORPs to these structures was assessed.

Results: The angle between the stapes footplate and the tympanic membrane was, on average, 25.9 degrees in a plane along the transverse axis of the stapes footplate and 24.6 degrees in a plane along the longitudinal axis of the stapes footplate. Consideration of these angles in TORPs resulted in an optimal contact with the tympanic membrane and stapes footplate, especially for these with a large foot.

Conclusion: TORPs should be adjusted in shape before insertion into the middle ear. Further developments should consider prostheses with preadjusted angles or appliances for the exact modification of the prostheses during surgery.

NITIFLEX

Initial experience with the NiTiFLEX® Stapes Prosthesis

Zirkler J., Rahne T., Plontke S.

Published: 86th Annual Meeting of the German Society for Oto-, Rhino-, Laryngology, Head and Neck Surgery. Berlin, May 13-16, 2015. Poster Abstract (German) DOI: 10.3205/15hnod534

Introduction: The attachment to the long process of the incus is the most important part of stapes surgery. We report here on our initial experience with the new NiTiFLEX Stapes Prosthesis, a development of the Soft Clip® Stapes Prosthesis (Kurz). The clip is now made of nitinol, a nickel-titanium alloy. The contact pressure on the long process of the incus has been further reduced and the attachment to the long process of the incus should be simplified.

Method: A stapedioplasty was done in 11 patients (6f, 5m) (a revision operation). The average age of the patients was 45 years. The footplate was perforated by a CO2 laser (scanning mode).

Results: The NiTiFLEX Stapes Prosthesis could be placed in all patients without complications. There was no significant change in bone conduction after the operation. The sound conduction gap could be satisfactorily reduced in all patients. (4PTA 0.5-4 preoperative on average 23.6, postoperative 6.3 dB). We considered the handling of the prosthesis to be very good.

Conclusion: When considering the limited experience, the NiTiFLEX Stapes Prosthesis is a promising development of the (Soft) Clip technique. The audiological results of the small series of cases are very satisfactory and comparable with other prostheses. However, long-term results with a greater number of cases are still necessary.

Initial experience with the NiTiFLEX® Stapes Prosthesis at the ENT Hospital Erlangen

Brase C., Pohmer S., Stockmayer N., Iro H., Hornung J.

Published: 86th Annual Meeting of the German Society for Oto- Rhino- Laryngology, Head and Neck Surgery. Berlin, May 13-16, 2015. (German) DOI: 10.3205/15hnod316

Introduction: One of the most important steps in stapes surgery is fixing the stapes prosthesis to the long process of the incus. In recent times great efforts have been made to simplify this step with “self-fixing” prostheses. This paper reports on our initial experience with the Kurz NiTiFLEX Stapes Prosthesis.

Material and Methods: A total of 16 NiTiFLEX prostheses was implanted between 8/2014 and 11/2014. All operations were performed under full anesthesia. The preoperative air-bone gap at 0.5, 1, 2 and 4 kHz was compared with the postoperative air-bone gap after an average of one month and after about 3 months.

Results: During the operation it was shown that the prosthesis was not well attached to all processes of the incus. In three cases the prosthesis could not be fixed during the operation due to the thickness of the process of the incus and had to be removed. The audiological results for the patients in whom the prosthesis could be fixed were comparable with those of other self-fixing prostheses.

Conclusion: The NiTiFLEX Stapes Prosthesis can be fixed without difficulties to normally shaped processes of the incus and yields good postoperative audiological results. As a development of the well-known SoftClip prosthesis with superelastic material, the NiTiFLEX prosthesis should be suitable for a wide range of processes of the incus. However, due to the relatively small prostheses eyelet, it cannot be used for every anatomical variation of the long process of the incus.

MATRIX

Initial experiences with the Matrix Type Stapes Prosthesis

Rösch S., Moser G., Töth M., Rasp G.

Published: Austrian Annual Meeting of ENT, 2015. Poster Abstract (German) DOI:10.1097/MAO.0b013e3182a43619

Introduction and Question: A new prosthesis joined the wide range of prostheses available for stapedioplasty about two years ago, the Kurz Matrix Type. This report describes our initial experience with this prosthesis with the postoperative audiology results and the handling during the operation.

Method: Retrospective data analysis using the ENTstatistics Digital database.

Results: A total of 22 patients received the Kurz Matrix Type Stapes Prostheses on one side (n=22) during a primary stapes operation from September 2014 to May 2015. A test of the 0.5, 1.0, 2.0 and 4.0 kHz frequencies showed an average improvement of the air-bone gap of approximately 15 dB. The postoperative follow-up for all patients was less than 12 months.

Discussion/Conclusion: The initial analysis of the experience with the Matrix Type Stapes Prosthesis at our hospital appears to lead to good results in improving hearing. In particular, the handling of the prosthesis during the operation is satisfactory for the surgeon. The new design of the loop with a wider and perforated surface and the spiral shape seems to improve the crimping procedure in particular and the subsequent seating of the prosthesis on

the long process of the incus. Now comparative studies with other types of prostheses and a longer follow-up are required to assess the long-term results.

K-PISTON

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

Schimanski G., Schimanski E., Berthold M.R.

Published: *Otology & Neurotology*: April 2011 - 32(3): 373-383.
DOI: 10.1097/MAO.0b013e3182096da1

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 necrosis 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 TPIPi 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.

Stapes Prosthesis Attachment: The effect of Crimping on Sound Transfer in Otosclerosis Surgery

Huber A. M., Ma F., Felix H., Linder T.

Published: *Laryngoscope* 2003 May;113(5):853-8. Poster Abstract (German)
DOI: 10.1097/00005537-200305000-00015

Objectives/Hypothesis: Although in stapes surgery successful hearing improvement may be achieved in the majority of patients, unsatisfactory closure of the air-bone gap can be recorded. One of many reasons for unexpected failures of stapes surgery may be the insufficient crimping of a stapes prosthesis onto the incus. The objectives of the study were to assess the amount of sound transmission loss in response to the quality of prosthesis crimping and to identify a required loop attachment pattern to obtain good sound transmission results.

Study Design: Experimental.

Methods: A temporal bone model was developed to measure the sound transmission properties between incus and prosthesis on 17 fresh human temporal bones. The attachment of a titanium stapes piston was assessed without crimping, followed by loose crimping and tight fixation to the incus, using scanning laser Doppler interferometry, endoscopic photography, micro grinding technique, and scanning electron microscopy. An algo-

rithm had to be developed to simulate acoustical stimulation using electro-mechanical stimulation.

Results: Optimal tight crimping of the stapes piston revealed consistent good sound transfer function ranging from 0 to 7 dB loss, and loss remained, on average, at 2 dB. The mean transmission losses for conditions of loose crimping and no crimping were surprisingly small (within 10 dB). However, these unusual crimping conditions allowed a wide range of losses up to 28 dB. A close coupling at least at two opposite points was obligatory to obtain consistently good results.

Conclusions: Perfect hearing reconstruction necessitates ideal crimping of a prosthesis to obtain consistently good results. However, the final functional gain depends on many different intraoperative and postoperative factors.

Retrospective analysis of early postoperative hearing results obtained after stapedotomy with implantation of a new titanium stapes prosthesis

Zuur C. L., de Bruijn A. J. G., Lindeboom R., Tange R. A.

Published: *Otology & Neurotology* 24:863-867 (2003)

Objective: To evaluate the early postoperative hearing results of a new titanium stapes prosthesis (K-Piston) implanted in patients with otosclerosis.

Study Design: A retrospective analysis of preoperative and early postoperative hearing thresholds. **Setting:** One tertiary referral and teaching hospital. **Patients:** Eighteen men and 40 women, mean age 47 years, with otosclerosis. **Intervention:** Primary stapedotomy.

Main Outcome Measure: Main outcome measures were the mean gains in bone-conduction and air-conduction pure-tone thresholds, and pure-tone averages for different frequency combinations. Success and failure of the individual cases were presented using Amsterdam Hearing Evaluation Plots.

Results: The overall postoperative air-bone gap for the frequency combination 0.5-1-2-4 kHz was 8.4 (standard deviation: 5.2) dB. In 79% of the patients the postoperative air-bone gap was less than 10 dB. Air-conduction improved even in higher frequencies, while the Carhart effect was not seen in most cases. In three patients a deterioration of bone-conduction was observed ranging from 11 to 16 dB sound pressure level (SPL), and in four patients the gain in air-conduction was insufficient (3-29 dB SPL) to close the preoperative air-bone gap to within 20 dB.

Conclusion: The new low-weight, full-titanium stapes prosthesis with its slight rough surface and its good mechanical stability and biocompatibility can safely and successfully restore the function of the middle ear when implanted in patients with otosclerosis.

SOFT CLIP

Experimental study on admissible forces at the incudomalleolar joint

Lauxmann M., Heckeler C., Beutner D., Lüers J. C., Huettenbrink K.-B., Chatzimichalis M., Huber A., Eiber A.

Published: *Otol Neurotol*. 2012 Aug;33(6):1077-84
DOI: 10.1097/MAO.0b013e318259b34b

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 stapedial 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-posterior 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 severely 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 luxation or subluxation during stapes surgery. Compared with the use of clip and SMA prostheses, the risk of damage from a crimping procedure is significantly higher.

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

Schimanski G., Schimanski E., Berthold M. R.

Published: *Otology & Neurology*; April 2011 - Volume 32(3): 373-383
DOI: 10.1097/MAO.0b013e3182096da1

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 necrosis 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 TPIPi 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

Hornung J. A., Brase C., Bozzato A., Zenk J., Iro H.

Published: *Laryngoscope*, 2009 Dec; 119(12): 2421-7
DOI: 10.1002/lary.20641

Objectives/Hypothesis: The aim of the study was to gain the first clinical 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 subjectively 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

Brase C., Zenk J., Wurm J., Schick B., Iro H., Hornung J.

Published: *HNO* 2009;57(509-513). (German)
DOI: 10.1007/s00106-009-1899-y

Background: The first hearing results with a new stapes prosthesis 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 ranging 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 postoperative 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

Schimanski G., Steinhardt U., Eiber A.

Published: Proceedings of the 4th International Symposium. Zurich, Switzerland, 27 - 30 July 2006. *Middle Ear Mechanics in Research and Otology*; pp. 237-245. DOI: 10.1142/9789812708694_0032

275 inserted Clip-Pistons type "à Wengen" within three years revealed difficulties in 14.5% of the cases. In those cases it was necessary to make adjustments 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.

CLIP PISTON À WENGEN

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 malleovestibuloplasty, 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 necrosis 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 TPiPi 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.

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Objectives/Hypothesis: The aim of the study was to gain the first clinical 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 subjectively 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.

CO2 laser-assisted stapedotomy combined with à Wengen titanium clip stapes prosthesis: superior short-term results

Forton G. E. J., Wuyts J., Floris L., Delsupehe K. G., Verfaillie J., Loncke R.

Published: Otolaryngology & Neurotology: December 2009; 30(8):1071-8
DOI: 10.1097/MAO.0b013e3181a52ab4

Objectives: To report on the short-term results of CO2-laser assisted stapedotomy combined with the à Wengen titanium clip stapes prosthesis. A comparison with published series using other prostheses and/or different stapedotomy techniques is made.

Study Design: Retrospective case series.

Patients: Patients with a history and audiologic data matching stapes fixation and computed tomographic imaging excluding other anomalies such as malleus fixation, dehiscence superior semicircular canal, and large vestibular aqueduct that may mimic stapes fixation-like hearing loss.

Intervention: All patients underwent CO2 laser-assisted stapedotomy (Lumenis Co. Israel CO2 laser, Acuspot 712, SurgiTouch 870 scanner) and subsequent reconstruction by means of the àWengen titanium clip stapes prosthesis by Heinz Kurz Medizintechnik GmbH (Germany).

Outcome Measures: Comparison and statistical analysis of preoperative and postoperative audiologic data.

Results: Sixty-two stapedotomies were performed (61 patients) using the CO2 laser and àWengen titanium clip stapes prosthesis. The mean postoperative air-bone gap 3 months postoperatively was 5.1 ± 0.5 dB (standard deviation [SD], 4.1 dB; 0.5, 1, 2, 4 kHz). Air-bone gap closure less than or equal to 10 dB was achieved in 54 cases (87%). Air-bone gap closure less than 20 dB was achieved in all cases. The average gain was 27.8 ± 1.5 dB (SD, 12 dB; 0.5, 1, 2, 4 kHz). The average bone-conduction threshold shift or "overclosure" on 2,000 Hz was 13.6 ± 1.3 dB (SD, 10 dB). There was no postoperative perceptible hearing loss exceeding 15 dB on any measured frequency. The Amsterdam Hearing Evaluation Plots have also been used to evaluate our data. These data were statistically analyzed and compare favorably to other published series.

Conclusion: The authors conclude that the combination of CO2 laser-assisted stapedotomy and the àWengen titanium clip stapes prosthesis is a combination likely to yield superior results in experienced hands.

Development of a new CliP-Piston prosthesis for the Stapes. Middle Ear Mechanics in Research and Otolaryngology

Schimanski G., Steinhardt U., Eiber A.

Published: Proceedings of the 4th International Symposium. Zurich, Switzerland, 27 - 30 July 2006. Middle Ear Mechanics in Research and Otology: pp. 237-245.
DOI: 10.1142/9789812708694_0032

275 inserted Clip-Pistons type "à Wengen" within three years revealed difficulties in 14.5% of the cases. In those cases it was necessary to make adjustments 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.

First Experience with a New Stapes Clip Piston in Stapedotomy

Grolman W., Tange R. A.

Published: Otology & Neurotology: 2005 July;26(4):595-8
DOI: 10.1097/01.mao.0000178132.89353.54

Objective: Hearing results after 23 implantations of a newly designed titanium-clip stapes piston prosthesis (the à Wengen Clip Piston prosthesis) in patients with otosclerosis were evaluated. This is a new type of stapes piston was designed to avoid the crimping onto the incus in stapedotomy. This one clip fits all designs and enables solid fixation by clicking the prosthesis onto the long process of the incus without crimping.

Study Design: A retrospective pilot study was carried out by microcomputer of the preoperative and postoperative audiological results of patients in whom the titanium-clip stapes piston prosthesis was implanted.

Setting: Ear, nose and throat department of Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands.

Patients: 23 patients underwent a stapedotomy for hearing improvement suffering from otosclerosis. Implantations of a newly designed titanium-clip stapes piston prosthesis (the à Wengen Clip Piston prosthesis) in patients with otosclerosis were evaluated.

Intervention(s): The stapedotomy was performed with the à Wengen Clip Piston prosthesis.

Main outcome measure(s): Pre and postoperative audiograms were used to evaluate the hearing gain improvement with the new stapes piston. Especially we looked at the airborne gap closure and the sensorineural hearing after the surgical procedure and compared these with the ones before surgery.

Results: The hearing results showed a closure of the pure-tone average air-bone gap to within 10 dB in 56.6% of cases (10 of 23 implantations) and to within 20 dB in 100% (23 of 23 implantations). A residual air-bone gap of greater than 20 dB was seen in the present pilot study. Postoperative overclosure of bone-conduction thresholds was discovered only for the frequency of 2 kHz. Sensorineural hearing loss greater than 10% did not occur, and there was no decline in the speech discrimination.

Conclusions: The use of a newly designed titanium-clip stapes piston prosthesis with a diameter of 0.4 mm gives good results in cases of stapedotomy for otosclerosis. The titanium-clip design is a new development in the evolution of stapes piston prostheses. Surgical introduction, placement, and fixation are not always easy, depending on the anatomy of the middle ear and the thickness of the fixation area on the long process of the incus.

No more crimping: the new clip piston à Wengen.
Visiting Professor at HNO-University Hospital Basel, Switzerland à Wengen D.

Published: 24th Politzer Meeting 31 August – 4 September 2003, Amsterdam, the Netherlands: Selected Abstracts

Objective: Crimping of the stapes prosthesis might result in injury to the incus. Attachment is often not tight. Facilitated fixation of a stapes prosthesis could improve surgery and provide more stable results.

Method: After development of a unique titanium clip over a seven year period (Kurz AG, Dusslingen Germany) and reception of a CE-mark, the first implantation was performed in September 2000. Full FDA approval was received in June 2002. Up to May 2003 more than 2400 Clip Piston àWengen have been purchased in several countries around the world.

Results: Only 60% of the circumference of the incus is touched by the clip permitting adequate mucosal blood supply to the lenticular process. Application of the prosthesis is quick and stable. There is no need for crimping anymore. The clip holds precisely in the main axis of movement of the long process of the incus.

Conclusion: This new stapes prosthesis facilitates surgery and reduces OR-time. There is no need for crimping anymore. Acoustic coupling is ideal due to the spring action of the self-retaining clip. Most surgeons have switched entirely to this prosthesis. Long-term results will be needed to prove the reduction of incus necrosis. In the nearly three year period of observation since the first implantation there was no loosening of the clip.

CLIP PISTON MVP

A New Self-Fixing and Articulated Malleus Grip Stapedectomy Prosthesis

Häusler R., Steinhardt U.

Published: Adv Otorhinolaryngol, (2007) Vol 65, 197-201
DOI: 10.1159/000098807

A new prosthesis for malleus-grip stapedectomy is presented: the Clip® Piston MVP according to Häusler. The titanium piston is equipped with a self-fixing clip mechanism for automatic fixation of the prosthesis on the proximal malleus handle as well as a ball and socket articulation allowing easy introduction of the piston at an optimal angle into the oval window as well as adjustment of the insertion depth. A first series of malleus-grip stapedectomies performed with the Clip® Piston MVP shows a hearing gain of 20 to 50 dB and a residual air-bone gap of ≥ 20 dB in all cases. In one patient, revision surgery was necessary because of piston ejection from the oval window. It appears that with the new Clip® Piston MVP the previously difficult surgery of malleus-grip stapedectomy has become straight forward and technically simpler.

Initial Experience with Titanium MVP Clip Prosthesis

Singh P. P.

Published: MEMRO 2006, 4th International Symposium on Middle Ear Mechanics in Research and Otology: Selected Abstracts

Introduction: After introduction of stapes surgery malleovestibulopexy (MVP) was the natural extension of this procedure. Although the hearing results of stapes surgery were usually excellent, the hearing results of MVP were quite variable. This probably resulted from poor understanding of middle ear mechanics and usage of the same prosthesis as used for stapes surgery. Modification of prosthesis design and technique has resulted in improved hearing outcomes after this procedure.

Purpose: To evaluate the hearing outcomes of malleovestibulopexy using titanium MVP clip prosthesis which has recently been introduced.

Material and Methods: Six patients undergoing exploratory tympanotomy for congenital conductive hearing loss or failed stapes surgery and requiring malleovestibulopexy are included in this study. Extended tympanomeatal flap was employed for exposure of middle ear and upper malleus handle. The prosthesis was introduced and the clip was slipped on malleus handle. Minor adjustments were required to attain the perpendicularity of the shaft and shaft insertion in the vestibule. Drilling of handle with diamond burr was required in half the cases to better adapt the clip on malleus handle.

Results: The mean of air-bone gap averaged over speech frequencies was within 20 dB in all six cases and within 10 dB in four cases. No deterioration of bone conduction threshold was observed.

Conclusions: The hearing results of malleovestibulopexy using newly introduced titanium MVP clip prosthesis have been encouraging and almost equal results of stapes surgery. The improved results seem to be consequent to the unique design of the prosthesis which factors in two key variables of this procedure viz anchorage of prosthesis on malleus handle and perpendicularity of the prosthesis shaft in relation to stapes footplate.

Laser doppler vibrometry data of the Clip piston MVP

Arnold A., Stieger CH., Häusler R.

Published: MEMRO 2006, 4th International Symposium on Middle Ear Mechanics in Research and Otolaryngology: Selected Abstracts

Background: A new malleus handle prosthesis for malleo-vestibulopexy and revision stapedotomy has been developed at our department and successfully used during the last five years. The piston prosthesis bears the CliP®-mechanism to facilitate attachment to the malleus handle and length and position can easily be adjusted intraoperatively with a movable hinge.

Objective: The study was devised to determine if the special developed hinge of the CliP Piston MVP causes a loss of sound transfer from the malleus grip to the vestibulum.

Methods: A middle ear model was set up, consisting of a vibrator normally used in an active implantable hearing device with a metal arm in shape and dimension of an actual malleus handle, where the CliP Piston MVP was attached with the hinge bend to an angle of about 120°. The piston end of the prosthesis dipped in a hole of a plastic container filled with water simulating a piston hole in the footplate. The excitation level corresponded to more than 110 dB SPL for frequencies between 100 Hz – 10000 Hz. With a laser doppler vibrometer the movements were picked up at different spots in the area of the clip, the hinge and the piston.

Results: The overall characteristics of the transferfunction was practically identical (difference < 3dB). Additionally biphasic resonance peaks (5-10 dB) were observed around 1000 Hz.

Discussion: Our results show very stable transfer properties over the frequency band. The noticed resonance peaks of 5-10 dB are very probably below significance level in clinical pure tone audiometry. This is in accordance with our experience from clinical practice.

Conclusion: The CliP Piston MVP provides good transfer characteristics from the malleus handle to the vestibulum.

NITIBOND

Next generation shape memory prosthesis (NiTiBOND) for stapedotomy: Short-term results

Green J.D. Jr, McElveen J.T. Jr.

Published: Laryngoscope. 2017 Apr;127(4):915-920.
DOI: 10.1002/lary.26114

Objectives/Hypothesis: To review hearing results and complications for the NiTiBOND next generation shape memory prosthesis and compare them with results for the current shape memory prosthesis (SMart). **Study Design:** Retrospective, multicenter chart review.

Methods: Primary laser stapedotomy was performed using either a NiTiBOND or a SMart prosthesis. Ninety-two ears in 79 patients were included in the study (67.4% female), 52 with the NiTiBOND prosthesis and 40 with the SMart prosthesis. Data collected included demographic variables, pre- and postoperative pure-tone air and bone conduction thresholds, speech discrimination scores, complications, and the need for revision surgery. Pure-tone average (PTA) and PTA air-bone gap (ABG) pre- and postoperative were computed. Success was defined as a postoperative ABG of ≤10 dB.

Results: There were no significant differences between groups in hearing results, including improvement in ABG, change in speech discrimination, change in air or bone PTA, or change in high-frequency bone PTA. Short-term (mean = 4.4 and 4.9 weeks, respectively) success rates for the NiTiBOND and SMart prostheses were 84.6% and 70.0%, respectively, with this difference closing at the most recent test (83.7% and 80.0%, respectively). No revision surgery took place in either group, and there were no differences in complications such as dizziness, tinnitus, or taste disturbance, though the NiTiBOND group tended to have a lower rate of transient or permanent vertigo.

Conclusions: Compared with the SMart prosthesis, the NiTiBOND prosthesis is a safe prosthesis that achieves at least comparable hearing results and may offer some surgical advantages.

How to Avoid a Learning Curve in Stapedotomy: A Standardized Surgical Technique

Kwok P., Gleich O., Dalles K, Mayr E., Jacob P., Strutz J.

Published: Otolaryngology & Neurotology 2017 Aug;38(7):931-937.
DOI: 10.1097/MAO.0000000000001475

Objective: To evaluate, whether a learning curve for beginners in stapedotomy can be avoided by using a prosthesis with thermal memory-shape attachment in combination with a standardized laser-assisted surgical technique.

Study Design: Retrospective case review. **Setting:** Tertiary referral center. **Patients:** Fifty-eight ears were operated by three experienced surgeons and compared with a group of 12 cases operated by a beginner in stapedotomy. **Intervention:** Stapedotomy. **Main Outcome Measures:** Difference of pure-tone audiometry thresholds measured before and after surgery.

Results: The average postoperative gain for air conduction in the frequencies below 2kHz was 20 to 25dB and decreased for the higher frequencies. Using the Mann-Whitney-U test for comparing mean gain between experienced and inexperienced surgeons showed no significant difference ($p=0.281$ at 4kHz and $p>0.7$ for the other frequencies). A Spearman rank correlation of the postoperative gain for air- and bone-conduction thresholds was obtained at each test frequency for the first 12 patients consecutively treated with a thermal memory-shape attachment prosthesis by two experienced and one inexperienced surgeon. This analysis does not support the hypothesis of a "learning effect" that should be associated with an improved outcome for successively treated patients.

Conclusion: It is possible to avoid a learning curve in stapes surgery by applying a thermal memory-shape prosthesis in a standardized laser-assisted surgical procedure.

Early functional results using the NiTiBOND® prosthesis in stapes surgery

Canu G., Lauretani F., Russo F. Y., Ferrary E., Lamas G., Sterkers O., De Seta D., Bernardeschi D.

Published: Acta Otolaryngol. 2016 Nov 4:1-6
DOI 10.1080/00016489.2016.1247499

Conclusion: The NiTiBOND® prosthesis allows early results to be obtained similar to those with a manually crimped prosthesis fitted by experienced surgeons, thus reducing the learning curve in this critical step of the procedure.

Objective: To analyze the 1-month results using the nitinol NiTiBOND® prosthesis in primary otosclerosis surgery and to compare the results with those obtained with fully fluoroplastic or fully titanium pistons.

Materials and Methods: Fifty consecutive cases operated on with the NiTiBOND® prosthesis (nitinol group) were compared with 50 cases operated on with a fully fluoroplastic piston (fluoroplastic group), and with 131 cases operated on with a fully titanium piston (first titanium group), and also with 50 cases operated on with the same titanium piston just before using the NiTiBOND® piston (last titanium group). Pure-tone and speech audiometry was performed 1 month after surgery for the nitinol group. Comparison was made between the early hearing results of the four groups.

Results: The mean air-bone gap closure for the nitinol group was 16 ± 1.0 dB (mean \pm SEM, $n=50$); an air-bone gap of <15 dB and <10 dB was obtained in 100% and 84% of cases, respectively. These hearing results were similar to the last titanium group and significantly better than those observed in the fluoroplastic and first titanium groups.

Promising Clinical Results of an Innovative Self-Crimping Stapes Prosthesis in Otosclerosis Surgery

Schrötzlmair F., Suchan F., Kisser U., Hempel J.-M., Sroka R., Müller J.

Published: *Otology & Neurotology*; December 2013 - Volume 34 - Issue 9 - p 1571–1575. DOI: 10.1097/MAO.0b013e3182a5d12d

Objectives: This clinical study was performed to retrospectively analyze the hearing improvement of patients with otosclerosis who underwent stapesplasty with a novel nitinol prosthesis in comparison with the use of already established prostheses (titanium and clip prostheses) and to evaluate the suitability of the nitinol prosthesis for ear surgeons with limited experience in otosclerosis surgery.

Study Design: Retrospective data analysis. **Setting:** Tertiary referral center.

Patients: Sixty patients who underwent otosclerosis surgery between July 1, 2010, and June 30, 2012, in the ENT department of the University of Munich. Two patients were operated on both sides. For four patients, the stapesplasty was a revision surgery.

Interventions: Sixty-two procedures of otosclerosis surgery were performed by 6 ear surgeons, one of whom with profound experience in stapesplasty.

Main Outcome Measures: 1) Postoperative air-bone gap, determined for all surgeons together as well as itemized for the experienced and the nonexperienced stapes surgeons; 2) closure of the air-bone gap in 10 dB bins; and 3) change of high-tone bone-conduction level.

Results: Pure-tone audiometry documented less postoperative air-bone gap and a higher percentage of air-bone gap closure when using the nitinol prosthesis, especially in comparison with the clip prosthesis. Also, nonexperienced stapes surgeons received better audiometric results when using the novel nitinol prosthesis.

Conclusions: Clinical evaluation suggests the novel nitinol prosthesis to be a promising tool in otosclerosis surgery for experienced stapes surgeons as well as for ear surgeons with limited experience in stapes surgery.

Mid-Term Results After a Newly Designed Nitinol Stapes Prosthesis Use in 46 Patients

Röösli C., Huber A. M.

Published: *Otology & Neurotology* 2013 Sep; 34(7)
DOI: 10.1097/MAO.0b013e318299a973

Objective: Analysis of 12-month midterm clinical and audiometric data of patients with otosclerosis who underwent stapedotomy using a newly designed prosthesis made of nitinol, a shape memory alloy.

Patients: Fifty-five ears of 50 consecutive patients who underwent stapedotomy between March 2010 and July 2011 were included. They met the inclusion criteria of primary procedures, a clinical follow-up and absence of nickel allergy.

Intervention: Stapedotomy and insertion of a newly designed stapes prosthesis.

Main Outcome Measures: Preoperative and postoperative (3 and 12 mo) air and bone conduction thresholds were recorded. Pure tone average and air bone gap (difference of air and bone conduction thresholds) were calculated for 500, 1,000, 2,000, and 3,000 Hz. The occurrence of complications was assessed.

Results: Air conduction thresholds, pure tone average, and airborne gap improved significantly 3 and 12 months postoperatively. Bone conduction threshold improved significantly at 2,000 Hz 3 months postoperatively and at 1,000 and 2,000 Hz 12 months postoperatively. A PTA of less than 20 dB was achieved in 96% of ears. No sensorineural hearing loss or other prosthesis-related adverse effects were observed.

Conclusion: Postoperative hearing results are comparable to the results obtained with other self-crimping prostheses. No complications or failures related to the prosthesis occurred. A longer followup is necessary to prove long-term stability of hearing results and safety of the new prosthesis.

Clinical Evaluation of the NiTiBOND Stapes Prosthesis, an Optimized Shape Memory Alloy Design

Huber A. M., Schrepfer T., Eiber A.

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DOI: 10.1097/MAO.0b013e31823e28cb

Objective: To prospectively analyze short-term (3 mo) results in patients with otosclerosis who underwent stapedotomy with the newly designed NiTiBOND prosthesis and compare them with patients that underwent Smart piston stapedotomy. We aimed to assess “noninferiority” for the new prosthesis.

Study Design: Prospective controlled trial. **Setting:** Tertiary referral center.

Patients: Thirty-eight patients were included in the NiTiBOND group (41 ears), and 74 patients were included in the Smart Piston group (75 ears).

Intervention(s): Stapedotomy.

Main Outcome Measure(s): Pure-tone audiometry 3 months after surgery, intraoperative prosthesis handling as assessed using a questionnaire, and complications were analyzed.

Results: Pure-tone audiometry showed postoperative air-bone gap means (standard deviation) of 8.1 (8.3) and 9.9 (5.4) dB; air-bone gap closure within 10 dB was achieved in 71% and 72% and within 20 dB in 93% and 96% for the NiTiBOND and the Smart piston prosthesis, respectively. Noninferiority was shown at all frequencies and in the pure-tone average. The NiTiBOND prosthesis provides excellent intraoperative handling, and no adverse reactions were reported.

Conclusion: Preliminary short-term results suggest safety and reliability for the new NiTiBOND stapes prosthesis.

STAPES PROSTHESES

Does the diameter of the stapes prosthesis really matter? A prospective clinical study

Bernardeschi D., De Seta D., Canu G., Russo F.Y., Ferrary E., Lahlou G., Sterkers O.

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DOI: 10.1002/lary.27021. Epub 2017 Nov 24.

Objectives/Hypothesis: To evaluate the influence of the diameter of stapes prosthesis on functional outcomes in stapes surgery. **Study Design:** Prospective cohort study.

Methods: Fifty consecutive small fenestra stapedotomies performed using a 0.4-mm-diameter prosthesis were compared with 50 consecutive small fenestra stapedotomies carried out using a 0.6-mm-diameter piston. Audiological assessment following the recommendations of the Committee on Hearing and Equilibrium was performed 1 month after surgery. Postoperative complications between the two groups were noted.

Results: There were no statistically significant differences in demographic data between the two groups, and no differences in preoperative bone-conduction (BC) or air-conduction (AC) hearing thresholds for all frequencies (analysis of variance [ANOVA] and χ^2 tests). No differences were found in the mean preoperative BC and AC pure-tone average and air-bone gap (ABG). In the postoperative evaluation, a statistically significant difference was found for the mean AC gain (20 ± 8.7 vs. 24 ± 11.5 , $P = .042$, ANOVA) as well as for the postoperative AC threshold at 0.125 and 0.25 kHz and the postoperative BC threshold at 0.25 kHz ($P < .01$, ANOVA). A postoperative ABG ≤ 10 dB was obtained in 90% and 94% of patients in the 0.4-mm- and 0.6-mm-diameter piston groups, respectively (difference not significant, χ^2 test). No postoperative dead ear and/or sensorineural hearing loss was noted in either group.

Conclusions: The 0.6-mm piston allowed a statistically significant higher AC gain compared with the 0.4-mm diameter piston. A larger diameter piston may be preferable if there are no anatomical or technical reasons that would favor a smaller prosthesis.

KURZ PRECISE CARTILAGE KNIFE

Cartilage Plate Tympanoplasty

Beutner D., Huettenbrink K.-B., Stumpf R., Beleites T., Zahnert T., Luers J.-C., Helmstaedter V.

Published: Otolaryngology & Neurotology, 2009
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Objectives: The purpose of this work was to report our modified cartilage plate tympanoplasty technique ("tulip leaves") and to analyze its clinical outcome in primary and recurrent cases of chronic otitis media with and without cholesteatoma.

Study Design: Clinical retrospective study.

Methods: Patients being operated on with this technique at the University Department of Otorhinolaryngology, Dresden, Germany, between 1993 and 2001 were invited for survey, otomicroscopy, and pure-tone audiometry in 2003. Patients' charts were used to draw necessary conclusions.

Results: A total of 39 patients who were treated with this technique after canal wall down tympanomastoidectomy and cavity obliteration were included in this long-term analysis after a median follow-up of 6 years. Seventeen patients (44%) experienced chronic otitis media with cholesteatoma, whereas 22 (56%) of them had a diagnosis of chronic otitis media without cholesteatoma. At the time of examination, all patients displayed a closed tympanic membrane. However, retractions were observed in 19 patients (48%). One patient required (3%) revision surgery for recurrent cholesteatoma due to prosthesis extrusion during the study period.

Conclusion: On the basis of this study, we recommend the tuliplike arrangement of thin but large auricular cartilage slices for the reconstruction of tympanic membrane defects in high-risk ears. This combination proved its high stability and long-lasting vitality in our long-term study. These characteristics are crucial for permanent disease removal and for reducing the risk of recurrent pathologic abnormality.

Type III tympanoplasty applying the palisade cartilage technique: a study of 61 cases

Neumann A., Schultz-Coulon H.-J., Jahnke K.

Published: Otol Neurotol. 2003 Jan;24(1):33-7.

Objective: To determine the morphologic and hearing results of the combined application of the palisade cartilage technique and titanium ossicular replacement prostheses in Type III tympanoplasty.

Study Design: Retrospective review of 61 tympanoplasties. **Setting:** Tertiary referral center. **Patients:** 59 patients (39 women and 20 men, mean age 36 years, range 7-81 years) consecutively operated on because of cholesteatoma, adhesive otitis, chronic otitis media, subtotal tympanic membrane defects, and tympanofibrosis requiring tympanoplasty with ossiculoplasty.

Interventions: Tympanoplasty Type III, with application of the palisade cartilage technique and total or partial titanium ossicular replacement prosthesis.

Main Outcome Measures: Otoscopic findings and hearing results using a four-frequency pure tone average air-bone gap.

Results: A recurrent defect was seen in 1 ear (1.6%). The graft take rate was 100%. There were no extrusions of prostheses. Preoperatively, a pure tone average air-bone gap of 0 to 10 dB was seen in 1 ear, 11 to 30 dB in 30, and 31 to 50 dB in another 30 ears. Postoperatively, the corresponding numbers were 11, 41, and 9 ears, respectively. Hearing results were better in the total ossicular replacement prosthesis group.

Conclusion: The palisade cartilage technique is suitable to manage difficult pathologic conditions in middle ear surgery. It was demonstrated that the palisade cartilage technique can be combined safely with titanium ossicular replacement prostheses. Regarding postoperative hearing results, the negative preselection of pathologic conditions must be considered.

Acoustic properties of different cartilage reconstruction techniques of the tympanic membrane

Mürbe D., Zahnert T., Bornitz M., Hüttenbrink K.-B.

Published: Laryngoscope 2002 Oct; 112(10):1769-76.
DOI: 10.1097/00005537-200210000-00012

Objectives/Hypothesis: The use of cartilage in reconstruction of the tympanic membrane has been established especially in cases such as tubal dysfunction and adhesive processes. Cartilage offers the advantage of higher mechanical stability compared with membranous transplants but may alter the acoustic transfer characteristics of the graft. Apart from material properties, it can be assumed that, also, the microsurgical reconstruction technique might influence the sound transmission properties of the reconstructed tympanic membrane. The purpose of the study was to investigate the acoustic transfer characteristics of different cartilage transplants being typically used in different reconstruction techniques of the tympanic membrane.

Methods: Cartilage plates of different thicknesses (1.0, 0.7, 0.5, and 0.3 mm), cartilage palisades, and cartilage island transplants of varying size were investigated by means of an ear canal-tympanic membrane model. In contrast to former single-point measurements, sound-induced vibrational amplitudes of the entire transplant were measured by scanning laser Doppler vibrometry (measuring points, $n = 133$) (PSV-200, Polytec, Waldbronn, Germany). Frequency response functions (displacement vs. sound pressure) of all measured points were determined in the frequency range of 200 Hz to 4 kHz for the different transplants.

Results: Cutting thick cartilage transplants into thin plates or palisades decreased the first resonance frequency and increased its amplitude, reflecting improved sound transmission properties of the transplant. From an acoustical point of view, the 0.5-mm cartilage plate seems preferable compared with the palisade technique. Cartilage island techniques showed vibration characteristics superior to plate or palisade techniques.

Conclusions: Apart from material characteristics, the sound transmission

properties of the reconstructed tympanic membrane are strongly influenced by the reconstruction technique. The choice of the surgical technique should consider requirements based on mechanical stability and acoustic transfer characteristics of the transplant.

Experimental investigations of the use of cartilage in tympanic membrane reconstruction

Zahnert T., Hüttenbrink K.-B., Mürbe D., Bornitz M.

Published: Am J Otol. 2000 May;21(3):322-8.
DOI: 10.1016/S0196-0709(00)80039-3

Background: Temporalis fascia, perichondrium, and cartilage are commonly used for reconstruction of the tympanic membrane in middle ear surgery. Cartilage grafts offer the advantage of higher mechanical stability, particularly in cases of chronic tubal dysfunction, adhesive processes, or total defects of the tympanic membrane, in contrast to fascia and perichondrium, which presumably offer better acoustic quality.

Hypothesis: The purpose of this study was to determine the acoustic transfer characteristics of cartilage of varying thickness and its mechanical deformation when exposed to fluctuations in atmospheric pressure.

Method: Ten pairs of cartilage specimens from the cavum conchae and the tragus were obtained from fresh human cadavers. Young's modulus was determined by mechanical tension tests and statistically evaluated using the t test. The acoustic transfer characteristics of an additional 10 specimens were measured by a laser Doppler Interferometer after stimulation with white noise in an external auditory canal-tympanic membrane model. Mechanical stability was determined by measuring displacement of the cartilage using static pressure loads of ≤ 4 kPa.

Results: Young's modulus determinations for conchal and tragal cartilage were 3.4 N/mm² and 2.8 N/mm², respectively, but the difference was not significant. Acoustic testing showed a 5-dB higher vibration amplitude in the midfrequency range for conchal compared with tragal cartilage, but the difference was not significant. Reducing cartilage thickness led to an improvement of its acoustic transfer qualities, with a thickness ≤ 500 microm resulting in an acceptable acoustic transfer loss compared with the tympanic membrane.

Conclusion: Both conchal and tragal cartilage are useful for reconstruction of the tympanic membrane from the perspective of their acoustic properties. The acoustic transfer loss of cartilage can be reduced by decreasing its thickness. A thickness of 500 microm is regarded as a good compromise between sufficient mechanical stability and low acoustic transfer loss.

CARTILAGE PUNCH

Long-term Follow-up Study of the Sandwich Cartilage Shoe Technique in Cases of Insecure Stapes Footplate

Lüers J. C., Schwarz D., Anagiotos A., Gostian A.-O., Beutner D., Hüttenbrink K.-B.

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DOI: 10.1097/MAO.0000000000001093

Objective: Analysis of the audiometric results after repair of a defective footplate with the sandwich cartilage shoe technique in a follow-up study.

Study Design: Retrospective analysis of audiometric data. **Setting:** Hospital.

Patients: The cohort consisted of 12 patients, who underwent ossicular reconstruction after sandwich cartilage shoe technique in a case of insecure stapes footplate. The mean age was 42.7 years with an equal sex distribution. In every patient, cholesteatoma was the reason for surgery with 75% being revision cases.

Intervention: Sandwich cartilage shoe technique in case of insecure stapes

footplate at the department of otorhinolaryngology, head and neck surgery at the University of Cologne over an 8-year period (2007–2015).

Main Outcome Measure: The use of the “sandwich cartilage shoe technique” in case of a broken or unstable footplate allows a safe occlusion of the open vestibule.

Results: The statistical analysis revealed a significant improvement of the pure-tone average ($p = 0.011$) and airborne gap (ABG) ($p = 0.016$) after total ossicular replacement prosthesis (TORP) implantation. The hearing was stable at 9 months of follow up.

Conclusion: The sandwich cartilage shoe technique offers a safe and effective option as a two-stage procedure in treating patients with fractures of the stapes footplate in case of chronic otitis media. In view of the possible risk of deafness going along with a destruction of an inner ear window, our results can be considered substantial as all our patients will at least be able to regain “social hearing” as they all either achieved a hearing threshold is less than 30 dB or can be sufficiently supplied with a conventional hearing aid.

Footplate Reconstruction: Preliminary Results

Rusiecka M., Bernal-Sprekelsen M.

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DOI: 10.1097/MAO.0000000000000467

Introduction: A partially or fully absent or largely perforated footplate is a challenging condition that may be encountered during middle ear surgery, especially in patients with a history of chronic ear problems or with previous tympanoplasties.

Materials and Methods: Retrospective study on a limited number of cases undergoing revision tympanoplasty in which a new footplate was created from the cartilage, and the ossicular chain was reconstructed with a titanium prosthesis in 1 stage. Minimum follow-up was 24 months. Outcome measurements included the preoperative and postoperative bone conduction to assess the function of the inner ear, and the preoperative and postoperative threshold levels of air and bone conduction in 4 frequencies to assess the possible hearing improvement.

Results: Six patients could be included. The audiologic results showed the average air conduction gain of 11 dB. We did not observe any significant deterioration in the bone conduction which, in some cases, even improved (average change of +3 dB). The symptoms related to a perilymphatic fistula were resolved. The technique described herein has proven to be safe and reliable.

Conclusion: Reconstruction of the footplate with autologous cartilage and simultaneous type III tympanoplasty seems to be a promising solution for those rare but challenging cases in which the footplate is partially or fully absent.

The Sandwich Cartilage Shoe Technique for Ossicular Reconstruction in a Case of an Unsecure Stapes Footplate

Bremke M., Huettenbrink K.-B., Beutner D.

Published: Laryngoscope, 2011 Sep;121(9):1950-2.
DOI: 10.1002/lary.21919

This article describes a new surgical method for total ossicular reconstruction in case of a broken stapes footplate. We developed the technique of the “cartilage shoe sandwich”, which consist of two surgical steps. First, the closure of the oval window is achieved by a cartilage shoe without a central perforation. During this surgical intervention, the prearrangement of a secure placement of a total ossicular replacement prosthesis is provided by a second cartilage with a central hole that is plugged with silicone. In a staged procedure, the silicone plug is removed and the ossicular reconstruction can be performed. The audiological results of the first patients show a stable inner ear function with an air-conduction gain of 9 dB. The technique described herein has proved to be safe and reliable in total ossicular reconstruction in the event of an unsecure stapes footplate.

Cartilage 'shoe': a new technique for stabilisation of titanium total ossicular replacement prosthesis at centre of stapes footplate

Beutner D., Luers J. C., Hüttenbrink K.-B.

Published: J Laryngol Otol. 2008 Jul; 122(7):682-6.
DOI: 10.1017/S0022215108002545

Objective: After tympanoplasty using a total ossicular replacement prosthesis, many unsatisfactory hearing results are due to dislocation of the prosthesis.

Material and Methods: We developed a cartilage guide for stabilising the total ossicular replacement prosthesis in the oval window niche. An oval-shaped piece of cartilage measuring 2.5 x 3.5 mm with a central hole was precisely punched out of a thin cartilage plate. The cartilage was placed in the oval niche, and its hole centred the prosthesis on the stapes footplate.

Results: Hearing results in 52 patients confirmed acoustically the effectiveness of this method of total ossicular replacement prosthesis stabilisation on the stapes footplate. Subsequent 'second-look' surgery revealed stable ingrowth of the cartilage 'shoe' into the oval niche.

Conclusion: Such a cartilage shoe might address one of the causes of unsatisfactory hearing following ossicular chain reconstruction with a total ossicular replacement prosthesis.

The Cartilage Guide: A solution for Anchoring a Columella-Prosthesis on Footplate

Hüttenbrink K.-B., Zahnert Th., Beutner D., Hofmann G.

Published: Laryngorhinootologie 2004; 83: 450-456.
DOI: 10.1055/s-2004-814447

Background: A torp (columella-prosthesis) is the typical ossicular reconstruction in cases of a destroyed stapedia arch. Yet, many unsatisfactory hearing results are due to the lack of a stable, reliable anchoring of the base of the prosthesis on the footplate. Some solutions have been postulated, amongst them the perforation of the footplate with a tiny spike at the lower end of the prosthesis, which, however, many otosurgeons regard as too dangerous for the inner ear. Specially designed silicone sheets cannot guarantee a permanent guide of the columella.

Methods: From our good experience with cartilage in different reconstruction procedures, we therefore developed a cartilage guide for the oval window niche. An oval 2,5 x 3,5 mm cartilage with a central hole is cut out of a thin (0,2 - 0,3 mm) cartilage plate with a help of a cartilage punch, which we had designed in collaboration with Heinz Kurz manufacture. The cartilage is placed into the oval niche and its hole guides the prosthesis onto the centre of the footplate.

Results: Temporal bone experiments demonstrated a reliable sound transport through this guide. Revision surgery revealed a stable ingrowth of the cartilage plate into the oval niche, its perforation securely guiding the prosthesis similar to a piston on to the footplate. The first short time hearing results (max. 1 year) in 22 patients confirmed the acoustic quality of this stabilisation of a columella on the footplate as compared to a matched control group.

Conclusion: The stabilization of the columella with a cartilage-guide might solve one of the many problems with unsatisfactory hearing results after the reconstruction of a completely destroyed ossicular chain.

TENSION

Impact of Prosthesis Length on Tympanic Membrane's and Annular Ligament's Stiffness and the Resulting Middle Ear Sound Transmission

Neudert M., Bornitz M., Lasurashvili N., Schmidt U., Beleites Th., Zahnert Th.

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Hypothesis: Prosthesis' length creates tension in ossicular reconstructions, which directly effects the middle ear sound transmission. **Background:** Relatively long prostheses are often used to stabilize the middle ear reconstruction to prevent dislocation. Thereby, tension on the flexible components such as the tympanic membrane (TM) and the annular ligament (AL) is increased. Only little is known on the amount of displacement-related stiffening of the TM and AL, as well as the consecutive reduction in middle ear transfer function (METF).

Methods: An expandable total ossicular replacement prosthesis was tensionfree inserted in nine cadaveric temporal bones between the malleus handle and the stapes footplate. Upon heat activation the prosthesis was lengthened, thus inducing tension on the reconstruction. The METF was assessed before and after elongation. TM's and AL's stiffness were determined by measuring their force-displacement characteristics.

Results: Upon activation the prostheses were elongated between 50 and 200 µm. A frequency-dependent METF reduction was measured with a decrease of 5 to 25dB below 1.0kHz. At frequencies >2.0kHz the reduction was less prominent or the METF showed even an improvement of up to 10dB. TM's stiffness remained constant during the elongation-induced displacement, whereas the AL's stiffness increased. The METF reduction below 1.0kHz correlated with the increasing AL's stiffness.

Conclusion: Tension has a significant impact on the METF after middle ear reconstruction. As little tension as possible should be used to enable best sound transmission. Stabilization of prosthesis should be achieved with dislocation devices to ensure secure coupling to the ossicular remnants without creating additional tension.

Optimum tension for partial ossicular replacement prosthesis reconstruction in the human middle ear

Morris D.P., Bance M., van Wijhe R.G., Kieffe M., Smith R.

Published: Laryngoscope. 2004 Feb;114(2):305-8.
DOI: 10.1097/00005537-200402000-00024

Objective: Hearing results from ossiculoplasty are unpredictable. There are many potentially modifiable parameters. One parameter that has not been adequately investigated in the past is the effect of tension on the mechanical functioning of the prosthesis. Our goal was to investigate this parameter further, with the hypothesis that the mechanical functioning of partial ossicular replacement prostheses (PORP) from the stapes head to the eardrum will be affected by the tension that they are placed under.

Methods: Fresh temporal bones were used to reconstruct a missing incus defect with a PORP-type prosthesis. Three different lengths of PORP were used, and the stapes vibrations were measured with a laser Doppler vibrometer using a calibrated standard sound in the ear canal. Eight temporal bones were used.

Results: Tension had a very significant effect on stapes vibration. In general, loose prostheses resulted in the best overall vibration transmission. The effects were most marked at the lower frequencies. There was a slight advantage to tight prostheses in the higher frequencies, but much less than the decrement in lower frequencies with tight prostheses.

Conclusion: In ossicular reconstruction, best stapes vibration results in our model are achieved by shorter prostheses, which result in lower tension.

Comparison of the mechanical performance of ossiculoplasty using a prosthetic malleus-to-stapes head with a tympanic membrane-to-stapes head assembly in a human cadaveric middle ear model

Bance M., Morris D.P. Vanwijhe R.G., Kieffe M., Funnell W.R.

Published: Otol Neurotol. 2004 Nov;25(6):903-9.

Hypothesis: Ossiculoplasty using prosthetic reconstruction with a malleus assembly to the stapes head will result in better transmission of vibrations from the eardrum to the stapes footplate than reconstruction with a tympanic membrane assembly to the stapes head. Both types of reconstruction will be affected by tension of the prosthesis.

Background: Theories (and some clinical studies) that the shape of the normal tympanic membrane is important suggest that prosthetic reconstruction to the malleus performs better than reconstruction to the tympanic membrane. This has not been previously tested by directly measuring vibration responses in the human ear. Our previous work suggests that tympanic membrane assembly to the stapes head type prostheses performed best under low tension. This had not been previously tested for malleus assembly to the stapes head type prostheses.

Methods: Hydroxyapatite prostheses were used to reconstruct a missing incus defect in a fresh cadaveric human ear model. Two types of prostheses were used, one from the stapes head to the malleus (malleus assembly to the stapes head), the other from the stapes head to the tympanic membrane (tympanic membrane assembly to the stapes head). Stapes footplate center responses were measured using a laser Doppler vibrometer in response to calibrated acoustic frequency sweeps.

Results: Tension had a very significant effect on both types of prostheses in the lower frequencies. Loose tension was best overall. The malleus assembly to the stapes head type prostheses consistently performed better than the tympanic membrane assembly to the stapes head type prostheses when stratified for tension.

Conclusion: Tension has a significant effect on prosthesis function. Malleus assembly to the stapes head type prostheses generally result in better transmission of vibrations to the stapes footplate than tympanic membrane assembly to the stapes head type prostheses.

TOTAL AND PARTIAL RECONSTRUCTION

Function, Applicability, and Properties of a Novel Flexible Total Ossicular Replacement Prosthesis With a Silicone Coated Ball and Socket Joint

Stoppe T., Bornitz M., Lasurashvili N., Sauer K., Zahnert T., Zaoui K., Beleites T.

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DOI: 10.1097/MAO.0000000000001797

Hypothesis: A total ossicular replacement prosthesis (TORP) with a silicone coated ball and socket joint (BSJ) is able to compensate pressure changes and therefore provide better sound transmission compared with rigid prostheses.

Background: Dislocation and extrusion are known complications after TORP reconstruction, leading to revisions and recurrent hearing loss. Poor aeration of the middle ear, scar tension, and static pressure variations in conjunction with rigid prosthesis design causes high tension at the implant coupling points.

Methods: A novel TORP prototype with a silicone coated BSJ has been developed. Experimental measurements were performed on nine fresh cadaveric human temporal bones of which five were used for a comparison between rigid TORP and flexible TORP tympanoplasty. The middle ear transfer function was measured at ambient pressure and at 2.5 kPa, both positive and negative pressure, applied in the ear canal.

Results: The flexible TORP design yields a better transmission of sound after implantation and at negative pressure inside the tympanic cavity,

compared with rigid TORP. In average, it provides an equivalent sound transfer like the intact middle ear. At positive pressure, the flexible TORP performs slightly worse. Both performed worse than the intact middle ear, which is related to an uplifting of the prostheses.

Conclusion: The findings may be considered preliminary as this experimental study was limited to just one of the many different possible situations of tympanoplasty and it involved a small sample size. Nevertheless, the results with the flexible TORP were promising and could encourage further investigations on such prostheses.

Comparison of the functional results of partial and total prostheses with chronic otitis media

Dombrowski T., Minovi A., Dazert S.

Published: 86th Annual Meeting of the German Society for Oto- Rhino- Laryngology, Head and Neck Surgery e.V. Berlin, May 13-16, 2015. Meeting Abstract (German). DOI: 10.3205/15hnod328

Surgical treatment of chronic otitis media often requires not only reliable reconstruction of the tympanic membrane but also restoration of the ossicle chain for sound transmission. The combination of autologous cartilage with a partial (PORP) or total prosthesis (TORP) of titanium is one of the most common surgical methods. The objective of the study was a differential comparison of both types of prosthesis with reference to the functional results. We evaluated the results of 199 patients who were operated on in our hospital for chronic epitympanic or mesotympanic otitis media from 2006 to 2013 in a retrospective, exploratory data analysis.

The TORP group experienced significantly poorer preoperative and postoperative conductive hearing loss (CHL) but higher average postoperative reduction of the CHL. The best hearing improvement for the PORP group was at 0.5kHz (7.93dB average reduction of CHL), and the worst at 4kHz (4.06dB). After TORP implantation there was an average reduction of the CHL at frequencies between 8.37dB (3kHz) and 10.53dB (4kHz).

The functional result of the PORP showed no connection to the postoperative observation period. At TORP implantation the CHL improved, significantly in some cases, after more than 6 months. A regular and significant hearing improvement can be achieved with both prostheses. In the low-frequency range the PORP achieved a significant hearing improvement, while the TORP appeared to have advantages above 25dB particularly with revision operations and preoperative CHL. The hearing result with PORP prostheses with increased follow-up time showed no change, while after TORP implantation hearing results were improved in all frequencies after more than 6 months.

Cartilage Palisades in Type 3 Tympanoplasty: Functional and Hearing Results

Vashishth A., Mathur N. N., Verma D.

Published: Indian J Otolaryngol 09/2014, Volume 66, Issue 3, pp 309 - 313.
DOI: 10.1007/s12070-014-0717-3

To evaluate the functional and hearing outcomes using full thickness broad cartilage palisades for tympanic membrane reconstruction in type 3 tympanoplasty with titanium prostheses. The retrospective study performed at a tertiary referral institute included 30 patients with posterior mesotympanic retraction pockets or tympanic membrane perforations requiring tympanic membrane and type 3 ossicular reconstruction. Patients with disease extending beyond the aditus requiring canal wall down mastoidectomy were excluded. Disease removal from posterior mesotympanic and epitympanic recesses was confirmed using angled endoscopy and ossicular reconstruction was performed using titanium partial or total ossicular replacement prostheses. Tympanic membrane reconstruction was done, with or without attic reconstruction, using full thickness broad cartilage palisades harvested from the tragus with perichondrium attached laterally. Patients were assessed at 24 and 48 weeks for graft status and any evidence of implant extrusion. Hearing evaluation was done using subjective assessment and pure tone audiometry. In total, 27 out of 30 patients had intact and completely healed

grafts at 48 weeks postoperatively (a success rate of 90 %) showing full union and epithelialization of palisades, and with three patients displaying small defects. The mean pure tone air bone gap pre- and postoperatively was 32.4 and 8.8 dB, respectively, with most patients reporting satisfactory postoperative hearing. No evidence of implant extrusion was found in the 48-week period. Tympanic membrane reconstruction using full thickness palisades of tragal cartilage provides good functional and hearing outcomes in type 3 tympanoplasty with titanium prostheses.

A micro-computed tomographic study: determination of the angle between the tympanic membrane and stapes footplate in a total ossicular reconstruction prosthesis reconstruction

Herkenhoff S., Fischer B., Gleich O., Strutz J., Kwok P.

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DOI: 10.1097/MAO.0b013e318213af4d

Objectives: To examine the anatomical relationship of the angles between tympanic membrane and stapes footplate and the variation of these angles among different temporal bones in order to characterize the optimal shape of total ossicular reconstruction prostheses (TORPs).

Methods: Ten specimens of human temporal bones were prepared for examination with micro-computed tomography. Five of the 10 temporal bones were implanted with 3 types of TORPs before subjecting them to micro-computed tomography. The angles between tympanic membrane and stapes footplate were determined. The contact of the TORPs to these structures was assessed.

Results: The angle between the stapes footplate and the tympanic membrane was, on average, 25.9 degrees in a plane along the transverse axis of the stapes footplate and 24.6 degrees in a plane along the longitudinal axis of the stapes footplate. Consideration of these angles in TORPs resulted in an optimal contact with the tympanic membrane and stapes footplate, especially for prostheses with a large foot.

Conclusion: TORPs should be adjusted in shape before insertion into the middle ear. Further developments should consider prostheses with preadjusted angles or appliances for the exact modification of the prostheses during surgery.

Germany Tympanoplasty today - an analysis of 11000 cases of reconstructive middle ear surgery - the Würzburg experience

Müller J., Schön F., Brill S., Helms J., Hagen R.

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Nowadays middle ear surgery is not only done to treat mastoiditis and to prevent its complications, which are highly dangerous. Middle ear surgery is also done to restore the hearing. Ojala summed up the situation in the seventies when he stated that „hearing after tympanoplasty usually does not improve (and in some cases even deteriorates)“. Since Wullstein (Würzburg) described the basic principles of tympanoplasty in the early 50ties, many other otologists made additional contributions to our current knowledge of tympanoplasty. The aims of tympanoplasty have been and still are:

- the elimination of the pathological changes
- to create stable conditions and easy access for postoperative care
- to reconstruct the sound conduction mechanism.

Numerous grafting materials have been recommended for the closure of tympanic membrane perforations. This paper evaluates three different grafting materials for the reconstruction of the tympanic membrane:

- Perichondrium
- Cartilage
- Perichondrium-Cartilage Composite Graft

The study is based on a computerized documentation system called „Würzburger Ohrbogen“. This system includes now more than 11000 patient's records. The database comprises information on surgical details (324 items)

and patients follow up. All patients included in the study had a minimum follow up of 6 months.

The aim of the study was to analyse the audiological results of different grafting materials, which were combined with ossicular chain reconstruction. In general, the audiological results achieved in ears which needed a tympanoplasty type I or III showed postoperatively for 80 % of the patients an improved hearing compared to preoperatively. The best hearing results were achieved in those ears in which primary tympanoplasty type I was performed without ossicular chain reconstruction (type I tympanoplasty). The grafting materials we used (perichondrium, cartilage palisades, perichondrium-cartilage composite graft (PCCG)) showed 6 months postoperative a similar air bone gap. The audiograms were measured for the frequencies from 0.5 kHz to 8 kHz. Hearing results were best at 2 kHz. As expected, those patients who required type III TORP tympanoplasty enjoyed less hearing recovery than those who required a type I tympanoplasty or a PORP.

Perichondrium and the cartilage techniques led to similar results. It should not be unmentioned that reoperations occurred. The perforation closure rate in type III tympanoplasties was 92.3%, the total reoperation rate was 7.7 %. Based on temporal bone studies using a laser doppler vibrometer also the influence and the audiological quality of different middle ear prostheses is discussed. The results of the temporal bone study as well as the initial clinical findings using a new light titanium (n=396) prostheses are discussed. Not surprisingly the combination of different graft materials and different prostheses led to similar clinical results except in type III TORP tympanoplasty. In these type of tympanoplasty with a reconstruction of the ossicular chain between stapes footplate and reconstructed eardrum significant better results were obtained when using cartilage. Based on our data we can conclude that tympanoplasty nowadays is able to improve the hearing.

TITANIUM AND OTHER MATERIALS

Biocompatibility of nitinol stapes prosthesis

Roosli C., Schmid P., Huber A.M.

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DOI: 10.1097/MAO.0b013e318201622e.

Objective: Use of the SMart piston, a nitinol-based, self-crimping prosthesis in stapes surgery may allow improved functional results because of better sound transmission properties at the incus-prosthesis interface because of the elimination of manual crimping. Possible disadvantages include thermal damage or strangulation of the incus and its mucoperiosteum or nickel intolerance. The goal of this study was to morphologically assess the fixation of this prosthesis to the incus, investigate the reaction of the middle ear mucosa to the prosthesis, identify alterations to the incudal bone, and detect deposits of nickel in the tissue around the prosthesis.

Study Design: Prospective consecutive case analysis. **Setting:** Tertiary referral center. **Patients:** Four patients with an unfavorable functional result after primary SMart-piston stapedotomy. **Intervention:** Revision malleostapedotomy with explantation of the incus and prosthesis for further analysis.

Main Outcome Measures: Analysis of intraoperative findings and post-operative examination of the explants using light- and scanning-electron microscopy, energy dispersive x-ray analysis, and atom absorption spectrometry.

Results: The intraoperative, macroscopic, and scanning electron microscopic investigation showed tight circular fixation of the prostheses, whereas a gap between the prosthesis and the lateral incus was found in 1 case. All prostheses were overgrown by mucosa. Superficial localized erosion of the incudal bone was found in 2 cases. There was no elevation in nickel content in the removed tissue samples.

Conclusion: The lateral gap between prosthesis and incus did not affect fixation of the prosthesis, neither did covering by a mucosal layer. Bone erosion was most likely caused by laser in one and by the prosthesis in another

explant. No signs of increased nickel deposits could be found on energy dispersive x-ray analysis or atom absorption spectrometry. We conclude that a nitinol stapes prosthesis is safe for treatment of stapedial fixation.

Titanium versus autograft ossiculoplasty

Fong J. C., Michael P., Raut V.

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Conclusion: In this comparative series, hearing results were superior with titanium compared with autograft ossiculoplasty in the absence of a stapes superstructure. However, in the presence of a stapes superstructure, titanium ossiculoplasties gave superior results to autografts only when comparing an air-bone gap of < 10 dB.

Objective: To compare the hearing outcomes of autograft versus titanium ossiculoplasty at 1 year.

Methods: Two consecutive groups of patients with chronic suppurative otitis media with and without cholesteatoma suitable for ossiculoplasty, either primarily or as a staged procedure, were recruited for the study. A total of 52 consecutive patients who underwent an autograft ossiculoplasty were compared with 51 consecutive patients who underwent a titanium ossiculoplasty. Hearing results were statistically compared at 1 year between the two groups using the four frequency average (FFA) of 0.5/1/2/4 kHz and the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) four frequency average of 0.5/1/2/3 kHz. The results were analysed statistically.

Results: A statistically significant number of titanium TORP ossiculoplasties achieved an air-bone gap closure to within < 20 dB compared with the autograft equivalent group (p = 0.039 FFA; p = 0.016 AAO-HNS). The number of titanium PORP ossiculoplasties achieving an air-bone gap closure to within < 10 dB compared with the autograft equivalent group was also statistically significant (p = 0.006 FFA; p = 0.002 AAO-HNS).

Titanium versus Nontitanium Prostheses in Ossiculoplasty

Coffey Ch., S., Lee F.-S., Lambert P. R.

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DOI: 10.1097/MLG.0b013e31817bd807

Objectives/Hypothesis: To compare the hearing outcomes and complications observed using either titanium or nontitanium prostheses in a 7-year consecutive series of ossiculoplasties performed by a single surgeon.

Study Design: Retrospective.

Methods: A database of ossicular reconstruction surgeries was reviewed for preoperative and postoperative audiometric data including air and bone conduction thresholds at four frequencies and speech reception thresholds. Outcomes were evaluated at time points less than and greater than 6 months postoperatively. Baseline demographic and surgical characteristics and postoperative complications were also noted.

Results: A total of 105 cases had sufficient audiometric data available for analysis, including 80 performed with titanium and 25 with nontitanium implants. Follow-up ranged from 1.2 to 74.2 months, with a mean of 14.9 months. Mean air-bone gap at initial follow-up was 21.7 dB in the nontitanium group and 15.4 dB in the titanium group; this difference was significant (P = .01). Postoperative air-bone gap of less than 20 dB at initial follow-up was achieved in 50.0% of nontitanium cases and 77.1% of titanium cases (P = .012). This difference in "success" rates persisted at longer follow-up but did not achieve statistical significance. Mean speech reception thresholds at <6 months was 29.7 dB in the nontitanium group and 22.6 dB in the titanium group (P = .049). Extrusion was observed with two nontitanium prostheses (8.0%) and three titanium prostheses (3.8%) (P > .05).

Conclusions: Titanium ossicular prostheses provide hearing outcomes su-

prior to those of nontitanium prostheses when evaluated within 6 months after ossiculoplasty.

Surgical-handling properties of the titanium prosthesis in ossiculoplasty

Maassen M. M., Löwenheim H., Pfister M., Herberhold S., Jorge J. R., Baumann I., Nüsser A., Zimmermann R., Brosch S., Zenner H.-P.

Published: Ear Nose Throat J. 2005 Mar;84(3):142-4, 147-9.

Despite the wide variety of ossiculoplasty techniques that are available, success rates are limited. Current use indicates that surgeons prefer ceramic, autograft bone, and plastic pore prostheses. During the past decade, titanium prostheses have been used with great promise. Although their use is not widespread, satisfaction rates are high. An earlier study of ossiculoplasty showed that titanium prostheses were effective in reducing conductive hearing loss. To date, the surgical-handling attributes of titanium middle ear prostheses have not been assessed. We report the results of our survey of 32 otologic surgeons who used the open Tubingen titanium prosthesis for primary and revision ossiculoplasty during tympanoplasty in 400 patients at 12 academic and nonacademic otolaryngology clinics, most of them in Germany. Because the audiometric efficacy of titanium prostheses has been previously reported, our primary outcomes measures included ease of use with respect to the amount of time required to prepare the implants for placement and the surgeons' overall impression of the intraoperative handling characteristics of the implants, taking into consideration factors such as positioning, length adjustment, visibility, and the stability of the coupling. Surgeons also compared the properties of the titanium implant with those of gold, ceramic, and autograft implants that they had used in the past. Based on the results of 383 of the 400 ossiculoplasties, our survey revealed that the titanium implant was significantly superior to the others in all measured respects.

Ossicular Reconstruction with Titanium Prosthesis

Martin A. D., Harner S. G.

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Objectives: To evaluate the results when using titanium total ossicular replacement prosthesis (TORP) or partial ossicular replacement prosthesis (PORP) in chronic ear disease.

Study Design: Retrospective chart review was performed.

Methods: Sixty-eight ossicular procedures using a titanium TORP (n = 30) or PORP (n = 38) were performed at a tertiary referral center between December 1999 and June 2002. The ossiculoplasty was performed either alone or in combination with other chronic ear surgery. Cartilage grafts were used universally. Nineteen percent were primary operations, and 6% were planned second stages. The majority were revision procedures. Follow-up ranged from 3 months to 2.5 years.

Results: The prosthesis is easy to insert, well tolerated, and has a low extrusion rate. Average air-bone gap (ABG) improvement was 13 dB with closure of the ABG to within 20 dB in 57% of cases. Hearing results were better for primary versus revision cases for PORPs versus TORPs and for intact canal wall (ICW) procedures versus canal wall-down (CWD) procedures.

Conclusion: Titanium is a satisfactory material for use in ossicular reconstruction because of its ease of insertion, tissue tolerance, and low rate of extrusion. Caution is advised when selecting candidates for this procedure during revision surgery, especially if the canal wall and stapes superstructure are absent.

119. Anatomical and functional results of titanium prostheses in middle ear ossiculoplasty

Gerard J.M., Blaivie C., Decat M., Garin P., Gersdorff M.

Published: 24th Politzer Society Meeting 31 August – 4 September 2003, Amsterdam, the Netherlands: Selected Abstracts

In the majority of chronic middle ear disease, there is an ossicular chain defect. Various types of prostheses are used for ossiculoplasties. The most common are autogenous or allogeneous bone or cartilage, plastipore, hydroxyapatite, bioactive glass and many other prostheses. Since a few years different metals were also available, like gold and titanium. Between November 1997 and January 2003, 77 patients were operated for chronic ear disease. Two types of titanium ossicular prostheses were used for ossiculoplasties (40 Spiggel and Theis® and 37 Kurz®). We performed interpositions of the tragal or allograft cartilage. The mean age was 41 years old and the average follow-up was 31 months for the Spiggel and Theis® and 5 months for the Kurz®. We used 43 total ossicular prostheses (TORP) and 34 partial (PORP). One patient had a prosthesis extrusion after a postoperative infection. All others had stable anatomical results. The pure tone average air-bone gap (PTA-ABG) was calculated on 500,1000, 2000 and 4000 Hz in preoperative and at the last postoperative consultation. For the TORPs, the PTA-ABG \leq 20 db was found in 55% of the cases for the Spiggel and Theis® and 63% for the Kurz®. For the PORPs it was 54% for the Spiggel and Theis® and 71 for the Kurz®.

Titanium ossicular prostheses offer advantages compared to other prostheses having a very easy and simple surgical manipulation, excellent anatomical stability and good functional results. The Kurz® prostheses procured us better functional results because of the sizer prostheses set which permits a better evaluation of the height and the right position of the prosthesis.

Early Results With Titanium Ossicular Implants

Ho S. Y., Battista R. A., Wiet R. J.

Published: Otolaryngology & Neurotology, March 2003; 24(2): 149 - 152

Objective: To report the efficacy of titanium middle ear prosthesis for ossicular reconstruction. **Study Design:** Retrospective chart reviews were performed for 25 patients who had undergone titanium ossicular implants between January 1, 1999, and June 1, 2001. **Setting:** Tertiary otology referral center. **Patients:** All patients had a minimum of 6 months of postoperative follow-up and no evidence of recurrent otologic disease. **Intervention:** All patients had undergone ossiculoplasty using titanium middle ear implants.

Main Outcome Measures: Comparisons of preoperative and postoperative pure tone averages were performed. Air-bone gap closures and implant extrusion rates were measured.

Results: Overall mean pure tone averages improved 22.2 dB with air-bone gap improvement at 20.9 dB. Fifty-six percent of patients achieved air-bone gap less than 20 dB postoperatively. The overall extrusion rate was 4%. However, with the placement of cartilage graft interposed between the prosthesis and the tympanic membrane, no extrusion was observed.

Conclusion: Titanium implants provide comparable hearing improvement compared with other materials. The extrusion rate seems quite low if cartilage interposition graft is inserted. Its ease of handling, biocompatible properties, and sound conducting properties improve its efficacy as an ossicular implant.

Reconstruction of the entire ossicular conduction mechanism

Battaglia A., McGrew B. M., Jackson C. G.

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Objectives/Hypothesis: Stapes fixation combined with fixation, absence, or malformation of the malleus-incus complex requires an uncommon surgical reconstruction and offers a unique combination of challenges and hazards. This situation may occur in the presence of severe tympanosclerosis, otosclerosis, congenital ossicular malformations, and revision surgery for either stapedectomy or chronic ear disease. In previous reports, this procedure has been grouped with total ossicular reconstruction without much distinction. However, the challenges unique to this problem deserve special consider-

ation. The present report offers a treatment plan for a group of patients requiring reconstruction of the entire ossicular conduction mechanism including removal of the stapes footplate. **Study Design:** Retrospective review.

Methods: Three thousand three hundred fifty (3350) charts of patients requiring total ossicular replacement prostheses (TORPs) were reviewed. Of this group of patients, only 21 of 3350 patients from 1977 to 1999 required TORP placement and removal of the stapes footplate. The patients were followed for an average period of 50 months.

Results: Hearing results indicated an overall improvement in the air-bone gap of 10 dB, with 52% achieving an air-bone gap of less than 20 dB. Of the 21 cases, 5 revision surgeries were performed. Three were performed because of a displaced TORP (14.2%), and 2 were performed because of extruded TORPs (9.5%).

Conclusions: Reconstruction of the entire ossicular conduction mechanism including removal of the stapes footplate can be successfully achieved with improvement of the air-bone gap of less than 20 dB. Hearing results and extrusion rates are comparable to reported results of TORP placement on a mobile footplate. Successful stapedectomy and simultaneous ossicular chain reconstruction can be performed as a single or staged procedure. Special attention is paid to avoid intrusion of the prosthesis into the vestibule.

Revision Ossicular Reconstruction with the Titanium Kurz Prosthesis

Downs B. W., Pearson J. M., Zdanski C. J., Buchman C. A., Pillsbury H. C.

Published: Laryngoscope 112: August 2002
DOI: 10.1097/00005537-200208000-00002

Objectives/Hypothesis: One European multicenter study has reported favorable outcomes after ossicular reconstruction with the titanium Kurz prosthesis. At the time of this study, however, no study has analyzed its outcomes when used for reconstruction after prior failure with another implant (revision reconstruction). The study reports our experience with the titanium Kurz prosthesis for revision ossicular reconstruction. **Study Design:** A retrospective review was made of all revision ossicular reconstructions at our institution from October 1998 to September 2001.

Methods: Seventeen cases were reviewed. Patients were divided into two groups: patients who underwent revision ossicular reconstruction with the Kurz prosthesis and patients who underwent revision ossicular reconstruction with another prosthesis (the "other" group). Audiograms were reviewed and air-bone gaps were calculated for each patient.

Results: The average postoperative air-bone gap after Kurz revision was 15.6 dB, a statistically significant improvement over the average postoperative air-bone gap from the "other" revision group ($P = .022$).

Conclusions: The titanium Kurz prosthesis has been an effective implant at our institution for revision ossicular reconstruction. Future research should focus on a prospective, randomized trial comparing the Kurz prosthesis with other prostheses currently in use.

Titanium as a material for ossicular replacement – basic aspects and clinical application

Schwager K.

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DOI: 10.1055/s-2002-25037

Background: The use of titanium as a biomaterial in ossicular chain reconstruction is increasing. The situation for integration of biomaterials is more difficult in the semiopen implantation site middle ear than in other parts of the body. Important for integration is the contact of the biomaterial's surface toward proteins. Studies of the integration in living tissue still have to be performed in animal experiments. Morphological examinations of explanted prostheses after clinical use complete the picture of an ossicular replacement material.

Methods: Preclinical studies were performed to compare the adsorption behaviour of titanium, stainless steel and aluminum oxide toward radioactive marked albumin and native collagen type I. An animal model in the rabbit was performed to study the integration of titanium in the middle ear morphologically. Middle ear prostheses removed during revision surgery were studied as well.

Results: Titanium showed an adsorption amount of 360 microgram/cm², stainless steel of 230 microgram/cm² and aluminum oxide of 500 microgram/cm² out of an albumin solution of 400 mg/ml. Comparing desorption the mean loss was 16 % for titanium, 21 % for stainless steel and 23 % for aluminium oxide. Reassembled collagen fibrils could be detected after adsorption in collagen type I solution by means of scanning electron microscopy. Morphological studies in animal experiments showed regular healing after implantation. Explanted prostheses from humans did not show any cellular signs of repulsion.

Conclusion: The results of preclinical studies and clinical use demonstrate titanium as a useful material for ossicular reconstruction in middle ear surgery.

Titanium as an ossicular replacement material: results after 336 days of implantation in a rabbit

Schwager K.

Published: Am J Otol. 1998 Sep; 19(5):569-73

Objective: Titanium in other parts of the body, well known for its biocompatibility, was examined in an animal model for its use as an ossicular replacement material.

Study Design: The biocompatibility of titanium was studied in the middle ear of rabbits using light and scanning electron microscopy. Titanium pins were placed as middle ear prostheses or as free implants and were examined after 28, 84, 168, and 336 days.

Results: After 28 days, the prostheses were covered by regular mucosa. The free implants took up to 336 days to be totally epithelialized. There were no inflammatory cells observed on the surface of the material nor were unusual amounts of fibrous tissue seen. In addition, the titanium material exhibited an affinity toward bone.

Conclusions: The results of this animal experiment indicate that titanium is a useful material for ossicular replacement prostheses.

MRI

Behavior of metal implants used in ENT surgery in 7 Tesla magnetic resonance imaging

Thelen A., Bauknecht H. C., Asbach P., Schrom T.

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DOI: 10.1007/s00405-006-0082-2

Magnetic resonance imaging (MRI) has become increasingly important as an imaging technique in cross-sectional imaging of head and neck diseases. To investigate whether MRI examinations can be performed without risk in patients with metal implants even at higher field strengths, we examined different materials in 7 Tesla MRI. Implants near sensory organs like the middle ear or eye are of particular interest here. Using the 7 Tesla research MRI for small animals, we tested implants made of various metals like titanium, gold, gold/platinum, platinum/iridium, gold-plated silver, PTFE and stainless steel for heating, translocation and rotation according to a standardized protocol. A fiber optic temperature probe measured the heating of the implant before, during and after MRI scanning. None of the implants showed significant heating. The gold-plated stainless steel ventilation tube was the only implant to markedly change its position already in the Petri dish. Of the remaining implants, a trachea support ring, a nose dilatator and

the wire from the ventilation tubes moved during vibration of the Petri dish. With exception of two implants, all implants changed positions in the water bath. In the swim test, the gold implants showed the least movement of all the implants. In this study, the properties of the non-ferromagnetic implant materials differed in the 7 Tesla MRI. Stainless steel ventilation tubes, the trachea support ring and the nose dilatator were not suited for the 7 Tesla MRI system, because they changed their position during MRI. In the case of ventilation tubes with a steel wire, the wire should be removed before MRI to prevent injury to the external auditory canal. There was a tendency for the pure gold implants to move less in the 7 Tesla MRI than all other tested materials. General statements cannot be made about the MRI suitability of different implants. Every implant should be individually examined to confirm its definitive MRI compatibility. Particularly, middle ear implants warrant special attention here due to their closeness to the oval window.

Safety evaluation of titanium middle ear prostheses at 3.0 tesla

Martin A. D., Driscoll C. L., Wood C. P., Felmlee J. P.

Published: Otolaryngol Head Neck Surg 2005 Apr;132(4):537-42.

Objective: To assess the magnetic resonance imaging (MRI) safety of titanium middle ear prostheses at 3.0 tesla (T).

Study Design and Setting: Titanium middle ear prostheses from 3 commercial vendors were examined for magnetic field interactions at 3 T. Initially, ex vivo studies were performed to test for rotational motion and forward displacement (translational motion) of the prostheses in a static magnetic field. If movement was observed during this screening study, then the prosthesis was tested to determine the translational or rotational force acting upon the prosthesis. In addition to testing for prosthesis displacement, temperature changes of the prostheses were measured to assess for radiofrequency heating during imaging.

Results: Twenty-one of the 24 titanium prostheses tested revealed no movement when tested in the 3 T static magnetic field. Three prostheses revealed minimal movement during the screening study. A translational force test (string test) was performed upon these 3 prostheses, and the measured angle of displacement was used to determine the force. This calculated force acting upon each prosthesis was essentially zero. Therefore, we conclude that the magnetic field interaction is negligible. A positive control with a ferromagnetic stainless steel prosthesis demonstrated obvious displacement during the screening study, as well as deflection of the prosthesis by 90 degrees in the translational force test. Last, heating of the titanium prostheses did not occur in the 7 models tested.

Conclusions: Middle ear prostheses made from titanium are safe, neither deflecting nor heating during magnetic resonance examinations conducted at 3 T.

COUPLING OSSICULOPLASTY

Coupling problems in middle ear reconstruction

Zahnert T.

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The normal and reconstructed middle ear can be considered as a mechanical vibrating system. After the implementation of tympanoplasty as a standardized surgical technique various reconstruction techniques and implants were suggested for the reconstruction of the tympanic membrane and the ossicular chain. Laser-Doppler-vibrometry and model calculations have given new insight into the vibration modes of the normal and reconstructed middle ear during the recent years. Nowadays it can be concluded, that not only material properties of implants but also coupling factors have an important influence on good hearing results. We investigated coupling factors between tympanic membrane and the surrounding bone, between the

tympanic membrane and middle ear implants and between the prosthesis and the ossicular chain using model calculations and temporal bone experiments.

The quality of the tympanic membrane, which can be considered as the “motor of the middle ear”, has the most important impact on the sound transfer to the inner ear. Ventilation and mucosa problems can damp the tympanic membrane vibrations as well as the reconstruction techniques or the mechanical properties of transplants. The coupling of the tympanic membrane to either the surrounding bone or the cartilage transplants has an influence on the stiffness. The contact of the tympanic membrane to the malleus handle is of importance in order to allow good sound conduction to middle ear prostheses in the high frequency range.

Furthermore the contact of prostheses to the stapes head or the footplate may influence hearing results. In our investigations the angle of prostheses towards the tympanic membrane and the stiffness of coupling plays an important role. Concerning the angle it is of importance to distinguish between the x and y – direction. An absolutely stiff contact between malleus and stapes can reduce the sound transfer and increase the risk of prosthesis dislocation or even damage of the annular ligament. Even nowadays modern middle ear reconstructions can only simulate the simple function of a columella. In future it may be important to invent middle ear implants which will be able to fulfill both required middle ear functions – the sound transfer and the compensation of atmospheric pressure changes. It can be assumed that hearing results may improve due to an unstressed coupling of middle ear prostheses by taking the above mentioned techniques and findings into consideration.

VENTILATION TUBES

Infection frequency and type of bacteria after tympanostomy tube drainage in childhood: gilded-silver tubes versus silicone tubes

Schmäl F., Nieschalk M., Delank K.W., Stoll W.

Published: HNO 1999 Feb; 47 (2):107-111.

Otorrhea is the most common complication after tympanostomy tube insertions. In Germany there are currently two commonly used types of tympanostomy tubes: silicon tubes (ST) and gilded silver tubes (GT). Previously published in vitro studies by Tajima uncovered a positive correlation between the silicon concentration in culture fluid and the rate of growth of *Staphylococcus aureus*. Our study retrospectively evaluates the types of bacteria and rates of otorrhea after ST and GT insertions. The present study was undertaken to determine which of these tubes had a higher incidence of otorrhea and then whether silicon tubes stimulated the growth of certain types of bacteria, such as *Staphylococcus aureus*. In all, 186 ST and 59 GT were placed in 245 ears of 144 children. Both ST and GT were separated into three groups: first insertion of a tympanostomy tube, second implantation and insertion of a tympanostomy tube in an infected ear in the course of a mastoidectomy. No differences between ST and GT in causing otorrhea were found in the three groups. Nevertheless, ST in comparison to GT was associated with a higher incidence of infections with *Pseudomonas aeruginosa*. In contrast, a higher incidence of *Staphylococcus aureus* related to ST could not be proved. Twenty percent of the ears with mastoiditis were found to have *Pseudomonas aeruginosa*, but none of these ears implanted with a GT developed postoperative otorrhea. Our findings show that GT should be used when a ventilation tube is used during a mastoidectomy. Further, it is tenable to implant only GT because postoperative otorrhea in many cases is caused by insufficient water protection and water is frequently polluted with *Pseudomonas aeruginosa*.

Heinz Kurz GmbH
Tuebinger Strasse 3 | 72144 Dusslingen | Germany
Phone: +49 (0)7072/9179-0 | Fax: +49 (0)7072/9179-79
E-Mail: info@kurzmed.com | www.kurzmed.com

KURZ Medical, Inc.
5126 South Royal Atlanta Drive | Tucker, GA 30084 | USA
Toll Free Order #: 866.449.8020 | Phone: 770.349.6330
Fax: 770.934.3384 | E-Mail: info@kurzmed.com
www.kurzmed.com

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