# ABSTRACTS

## KURZ IMPLANTS, PRECISION INSTRUMENTS, VENTILATION TUBES

## MIDDLE EAR SURGERY

### NITIBOND

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

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

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**Objectives/Hypothetis:** 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 demograph-ic 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 discrimina-tion, 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.**

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**Objective:** To evaluate, whether a learning curve for beginners in stapedoto-my can be avoided by using a prosthesis with thermal memory-shape attach-ment 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 2 kHz was 20 to 25 dB 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 4 kHz 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.**

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**Conclusion:** The NiTiBOND® prosthesis allows early results to be obtained similar to those with a manually crimped prosthesis fitted by experienced sur-geons, 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 ± 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.**

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**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 per-formed by 6 ear surgeons, one of whom with profound experience in sta-pesplasty.

**Main Outcome Measures:** 1) Postoperative air-bone gap, determined for all surgeons together as well as itemized for the experienced and the nonex-perienced 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 pros-thesis, especially in comparison with the clip prosthesis. Also, nonexperi-enced 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.**

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**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 stapetotomy 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 airbone 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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**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.