

Original Investigation

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

Functional Results

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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 OUTCOMES 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).

CONCLUSIONS 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.

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In ossicular chain reconstruction, maximal rehabilitation of conductive hearing loss is the ultimate goal. Success mainly depends on the total eradication of disease, good aeration of the middle ear, and a stable connection between the tympanic membrane and the stapes, which in turn is highly dependent on the characteristics of the prosthesis used.¹ Ideally, the ossicular reconstruction prosthesis should be safe, biocompatible, easy to handle, capable of efficient sound transmission, and have a low extrusion rate.² Over the years, a variety of materials, including gold, ceramic, polyethylene, and hydroxyapatite prostheses, have been used. Because of its excellent biocompatibility, light weight, and tensile strength, titanium was introduced as a new material for ossiculoplasty in 1993. Since then, titanium prostheses have been used for ossicular reconstruction, in the form of either a partial ossicular replacement prosthesis (PORP) or a total ossicular replacement prosthesis (TORP). In 1999, Stupp and colleagues³ were the first to report a satisfactory functional outcome after titanium ossiculoplasty. Since then, several authors using different titanium prostheses (eg, Open Tübingen, Spiggle & Theis, Kurz) have reported good hearing results with a postoperative air-bone gap (ABG) lower than 20 dB in 43.8% to 89% of cases and extrusion rates of 5.2% or lower, illustrating the superior biocompatibility of these prostheses.⁴⁻¹⁰ However, many studies fail to report long-term follow-up and include results of both total and partial prostheses in the same study. In this series, only the Kurz TTP-Variac System PORP (Kurz GmbH) was used. The aim of the present study was to examine the ability of the Kurz TTP-Variac System PORP to restore ossicular continuity resulting in functional improvement, as well as to assess the safety of said prosthesis. Functional gain, postoperative ABG, improvement in ABG, and rate of successful postoperative hearing in the overall study population and in several subgroups (absent vs present malleus, wet vs dry preoperative condition of the ear, primary vs revision procedures, canal wall-down [CWD] vs canal wall-up [CWU] procedures, and chronic otitis media with cholesteatoma vs chronic otitis media without cholesteatoma vs ossicular chain disruption without presence of inflammatory disease) were calculated and compared. The rate of complications (prosthesis extrusion, prosthesis dislocation, recurrent perforation of the tympanic membrane, sensorineural hearing loss [SNHL], and recurrence of cholesteatoma) was determined.

Methods

Participants

In total, 90 patients (35 women and 55 men) ranging in age from 7 to 85 years underwent ossicular reconstruction using a Kurz TTP-Variac System PORP (Kurz GmbH) between August 2006 and July 2012. Of these 90 patients, 9 needed a revision tympanoplasty with redone ossicular reconstruction, bringing the total number of operated ears during the study period to 99. In total, 10 operations (in 9 patients) were excluded from the study, causing 7 participants to be excluded altogether: 7 patients were lost to follow-up (follow-up time <20 days), 1 of whom was ultimately included in the study for the revision

operation only. One patient was mentally disabled, resulting in unreliable audiometric data and exclusion. Two patients underwent a revision operation too recently to have sufficient follow-up time after the second operation; thus, they were only included for their first operation. Therefore, of the 9 revision tympanoplasties, only 7 were included in this study. Accordingly, this study comprises 89 ears in 83 patients (31 women and 52 men). During the same period, a total of 947 middle ear procedures were performed by one of us (G.E.J.F.), so the study sample represents 9.4% of all cases. Several variables (age, sex, date of surgery, length of follow-up, CWD or CWU mastoidectomy, primary or revision surgery, underlying disease, preoperative status of the middle ear [wet vs dry] and removal or preservation of the malleus) and complications (prosthesis extrusion, prosthesis dislocation, recurrent perforation of the tympanic membrane, sensorineural hearing loss [SNHL], and recurrence of cholesteatoma) were registered in an Access file (Microsoft) and later exported to an Excel spreadsheet (Microsoft). Statistical analysis was carried out by means of SPSS Statistics Professional (IBM). Institutional review board approval was not required because of the retrospective nature of this study and the fact that no personal details of the patients are mentioned.

Surgical Technique

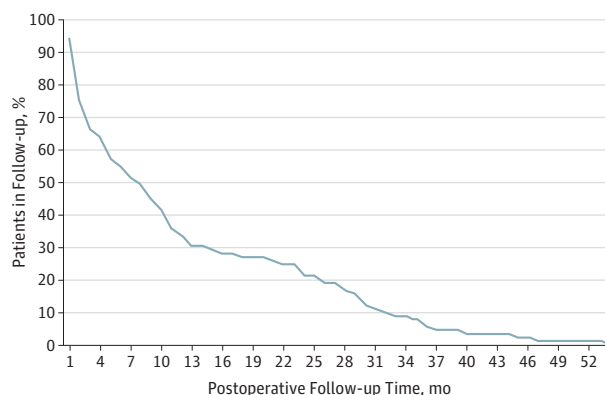
All patients were operated on by one of us (G.E.J.F.) at the Department of Otorhinolaryngology and Head and Neck Surgery of Heilig Hart General Hospital (Roeselare, Belgium). In cases of chronic otitis media with or without cholesteatoma, an attic-mastoidectomy was performed, whenever possible using the CWU technique. Canal wall-down mastoidectomy was reserved for extensive or recurrent cholesteatoma. In cases of an isolated ossicular chain disruption in the absence of inflammatory disease, the tympanoplasty and ossiculoplasty were generally performed via the transmeatal approach. In all patients, including those with cholesteatoma, ossicular reconstruction was achieved in a 1-stage procedure using the titanium Kurz TTP-Variac System PORP (Kurz GmbH). The prosthesis consists of a slit bell, a narrow shaft, and a headplate that is open, thus allowing the surgeon to see through the headplate, which facilitates placement of the prosthesis onto the capitulum of the stapes.⁵ Using the dummy sizers attached to the multifunctional disk to measure the optimal distance between the capitulum of the stapes and the tympanic membrane, the prosthesis length can be determined quickly and precisely. The length of the prosthesis is then fixed at the required point using a special micropliers. Prior to placement of the prosthesis on the intact stapes, which was mobile on palpation in all cases, the eardrum is repaired or reinforced using a conchal cartilage graft. In most cases, including those involving transmeatal approaches, full-thickness conchal cartilage is used to close the tympanic membrane perforation and to cover the prosthesis head on the condition that the cartilage thickness does not exceed 0.5 mm. When the conchal cartilage strip is of exceptional thickness, a thinner 0.3-mm piece is cut using a calibrated cartilage cutter (Kurz). Also, when the cartilage graft as a whole does not suffice to close the perforation, the cartilage is divided into 2 0.3-mm grafts, also using the Kurz cartilage cutter.

Thus, direct contact between the eardrum and the titanium prosthesis is always avoided in order to prevent extrusion. Whenever an intact, healthy malleus is present, an attempt is made to place the cartilage graft between the tympanic membrane and the malleus handle and to position the prosthesis so that it rests against the malleus handle while also touching the cartilage graft. The prosthesis head is adjusted to the position of the drum.

Audiometry and Statistics

All patients underwent a preoperative hearing test that determined pure-tone thresholds in the frequency range from 250 to 4000 Hz by air and bone conduction (Madsen Orbiter II). The postoperative follow-up examination included micro-otoscopy and pure-tone audiometry. All patients were tested again multiple times after the operation, most commonly after 2 weeks, 6 weeks, and 3 months, again by air and bone conduction. After this initial follow-up period, hearing tests were usually performed every 6 months. These tests were performed by qualified audiologists at our department. The audiological data used for our calculations and reported in this article are the preoperative hearing thresholds and the most recent postoperative hearing thresholds. Data were stored in an Access 2010 database (Microsoft) and later exported to an Excel 2010 spreadsheet (Microsoft). We calculated the preoperative and postoperative ABGs at 250, 500, 1000, 2000, and 4000 Hz. A mean preoperative and postoperative ABG using the calculated values for 500, 1000, 2000, and 4000 Hz (pure-tone average [PTA] ABG) was also defined.¹¹ Finally, PTAs for air conduction were calculated. In contrast to the guidelines of the Committee on Hearing and Equilibrium from the American Academy of Otolaryngology-Head and Neck Surgery, 3000 Hz was not used in our calculations, according to European custom. A postoperative ABG of 20 dB or less was considered a successful outcome. Postoperative hearing gain (improvement in air conduction threshold) and improvement of the ABG (difference between preoperative and postoperative ABG) were also calculated for all frequencies. An SNHL was defined as a high-frequency pure-tone bone conduction average (measured at 1, 2, and 4 kHz) that was more than 10 dB worse than the preoperative value. Statistical analysis was performed by F.L.W. using Microsoft Excel 2010 (Microsoft) and SPSS statistics software, version 20 (IBM). For descriptive analysis, mean, SD, and minimum and maximum values were calculated. All audiological values are presented using a box-and-whisker plot.¹² Normality of the data was verified with the Kolmogorov-Smirnov test. Analysis of variance (ANOVA) was used to compare the functional results between the groups with underlying chronic otitis media with and without cholesteatoma and isolated ossicular chain disruption. The χ^2 test was used to compare percentages of hearing results between the different subgroups. The *t* test for independent samples was used to detect differences in functional results between cases with preserved vs removed malleus, as well as for revision vs primary surgery. Mann-Whitney *U* tests were used to compare functional results between the dry ear and wet ear groups and between the CWU and CWD groups, given the small number in 1 of

Figure 1. Relationship Between Proportion of Patients in Follow-up and Time After the Operation

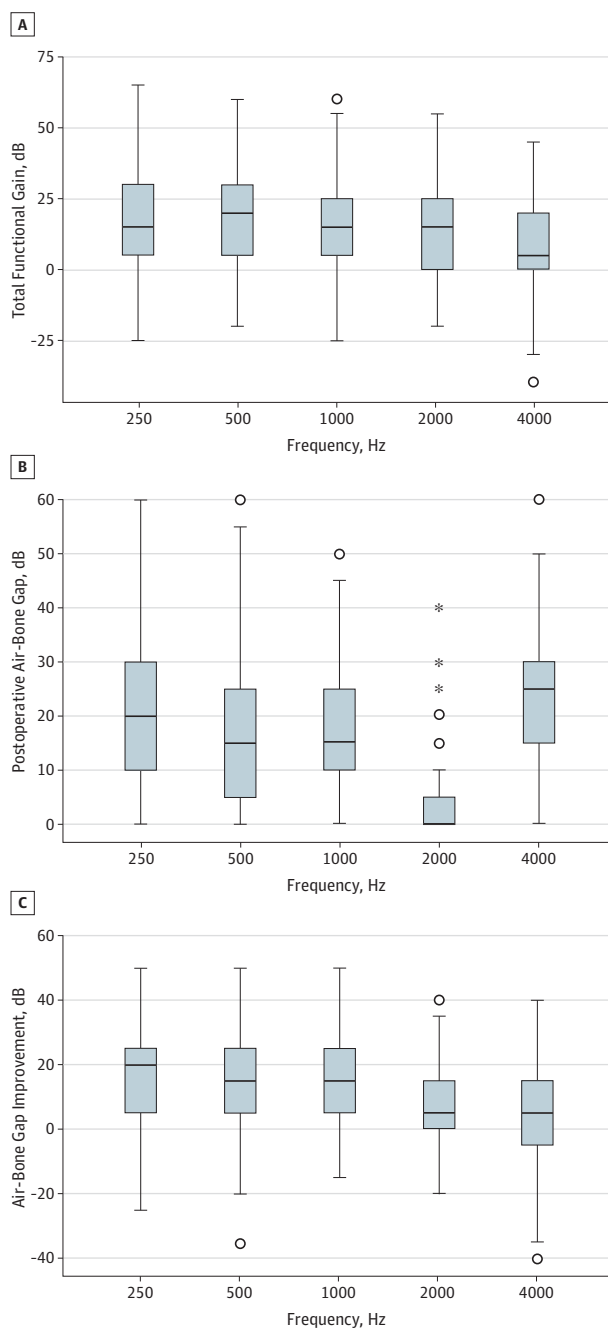


the groups in each of these comparisons. The interaction between 2 independent variables was examined by means of a 2-way ANOVA statistical analysis.

Results

In total, 89 ears in 83 patients (52 men and 31 women) were included in the study. Postoperative follow-up time is illustrated in Figure 1. Mean (range) clinical and audiological follow-up was 13 months (3 to 232 weeks). The follow-up time was at least 6 months in 50 cases (56%) and at least 12 months in 31 cases (35%). Underlying disease was chronic otitis media with cholesteatoma in 51 ears (57%), chronic otitis media without cholesteatoma (including patients with tympanosclerosis [*n* = 3] and labyrinthine fistula [*n* = 1]) in 21 ears (24%), and ossicular chain disruption without presence of inflammatory disease in 17 cases (19%) (including revision surgery for a dislocated previously placed Kurz TTP-Variac System prosthesis [*n* = 2] or remodeled incus [*n* = 3], absence of the incus and malleus after radical mastoidectomy in the past [*n* = 1], and straightforward ossicular chain disruption, mainly caused by a ruptured incudostapedial joint or a fractured incus [*n* = 11]). Transmeatal tympanoplasty without mastoidectomy was performed in 17 ears (19%). Seven ears (8%) underwent tympanoplasty with CWD mastoidectomy, whereas the remaining 65 ears (73%) underwent tympanoplasty with CWU mastoidectomy. The study sample comprised 61 primary tympanoplasties (69%) and 28 revision cases (31%). Only 7 of the revision cases had been operated on previously in our center by one of us (G.E.J.F.). None of those 7 revisions were planned second-stage procedures; they were required because of PORP extrusion (*n* = 1), PORP dislocation (*n* = 2, of which in 1 case dislocation was combined with reperforation of the tympanic membrane), isolated reperforation of the drum (*n* = 1), and recurrent cholesteatoma (*n* = 3). The other 21 revision cases had been operated on for the first time in another hospital and are a mixture of revision surgery for residual cholesteatoma or chronic otitis media and failed or absent ossicular chain reconstruction.

Figure 2. Box-and-Whisker Plots of Postoperative Audiological Results



A, Total functional gain; B, postoperative air bone gap; C, air-bone gap improvement. All test results are shown for 250, 500, 1000, 2000, and 4000 Hz. The horizontal line inside each box indicates the median; the top and bottom borders of the box mark the 75th and 25th percentiles, respectively. The whiskers above and below the box mark the 90th and 10th percentiles, respectively. The circles beyond the whiskers indicate outliers beyond the 90th or 10th percentiles. The asterisks indicate extreme, solitary outliers.

Complications and Postoperative Evolution

Extrusion of the PORP was observed in only 1 case (1%), whereas dislocation of the Variac prosthesis occurred in 2 cases (2%; dislocation combined with reperforation of the tympanic membrane in 1 case). Closure of the tympanic mem-

brane was achieved in 87 cases (98%). Reperforation of the tympanic membrane occurred in only 2 cases (2%). Residual cholesteatoma was discovered in 5 ears (6%), 2 of which had first been operated on elsewhere. Consequently, a second surgical procedure was necessary in 9 ears (prosthesis dislocation in 2 cases, prosthesis extrusion in 1 case, recurrence of cholesteatoma in 5 cases, and reperforation of the tympanic membrane in 2 cases [combined with prosthesis dislocation in 1 case]). Seven of these 9 revision procedures were included in the study. The rate of SNHL was 3% (3 cases), with a mean (range) SNHL of 13.89 (16.67-11.67) dB.

Overall Functional Results

Figure 2A depicts the functional gain (air conduction) for each frequency in the frequency domain between 250 and 4000 Hz. In the total group (N = 89), the mean air conduction PTA improved from a preoperative value of 51.22 dB to a postoperative value of 37.70 dB, yielding a mean (SD) PTA functional gain (preoperative PTA minus postoperative PTA) of 13.52 (15.48) dB. Figure 2B illustrates the postoperative ABG for each frequency. The mean PTA ABG improved by 10.62 (95% CI, 8.07-13.17) dB, starting from a preoperative mean (SD; range) of 26.19 (11.53; 3.75-51.25) dB and increasing to a postoperative mean (SD; range) of 15.58 (9.80; 0-48.75) dB. This improvement was statistically significant for all frequencies (2-tailed $P < .01$, paired t test). Figure 2C illustrates the improvement of the PTA ABG for the different frequencies. Closure of the ABG was worst at 4 kHz. Successful postoperative hearing results (defined as a postoperative ABG of ≤ 20 dB) were obtained in 65 of 89 cases (73%). The postoperative PTA ABG was between 11 and 20 dB in 29 cases (33%) and 10 dB or less in 36 cases (40%). In Table 1, the functional results for the overall group and different subgroups are summarized. In the group with long follow-up (≥ 12 months, $n = 31$), functional results proved to be stable over time: the mean PTA ABG after 6 months was not significantly different from the mean PTA ABG measured at the most recent presentation (paired samples t test, $P = .52$). Intermittent changes of the ABG, however, were observed because of banal conditions (eg, otitis externa, acute otitis media, or otitis media with effusion), as was a slight decrease of the SNHL due to progressive presbycusis.

Primary Surgery vs Revision Surgery

The mean (SD) postoperative PTA ABG in primary surgery cases ($n = 61$) was 12.62 (7.05; 0-30.00) dB, starting from a mean preoperative PTA ABG of 22.99 dB. In revision cases ($n = 28$), the mean (SD; range) postoperative PTA ABG was 21.79 (11.76; 3.75-48.75) dB, starting from a mean preoperative PTA ABG of 32.77 dB. Mean improvements in PTA ABG were 10.37 and 10.98 dB, respectively. The difference in mean postoperative PTA ABG was statistically significant (2-tailed $P < .01$, independent samples t test, after equality of variances was proved using Levene's test for equality of variances). Successful hearing results were obtained in 51 of 61 primary cases (84%) and in 14 of 28 revision cases (50%), which is a statistically significant difference ($P < .01$, Pearson χ^2).

Table 1. Functional Results in Overall Group and Different Subgroups

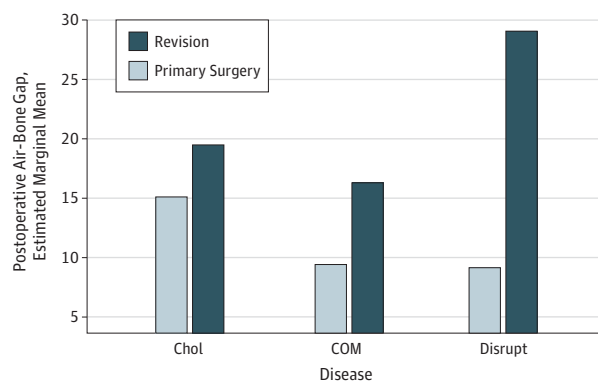
Group	Ears, No.	Postoperative ABG, dB		Success Rate, ^a No. (%)	Improvement in ABG, Mean, dB
		Mean (SD)	Median		
Overall	89	15.58 (9.80)	13.75	65 (73)	10.62
CWU + malleus absent	17	19.26 (11.66)	16.25	9 (53)	7.65
CWU + malleus present	56	13.37 (8.84)	11.87	45 (80)	11.74
Primary procedure	61	12.62 (7.05)	11.25	51 (84)	10.37
Revision procedure	28	21.79 (11.76)	20.63	14 (50)	10.98
Cholesteatoma	51	16.50 (8.99)	15.00	36 (71)	7.92
COM	21	11.31 (6.26)	10.00	19 (90)	13.75
Chain disruption	17	17.87 (13.99)	15.00	10 (59)	15.07
CWU	83	14.86 (9.57)	12.50	63 (76)	10.75
CWD	6	22.71 (9.45)	22.50	2 (33)	8.54
Wet ear	6	19.79 (11.28)	19.38	3 (50)	14.17
Dry ear	83	15.11 (9.87)	12.50	62 (75)	10.38

Abbreviations: ABG, air-bone gap; COM, chronic otitis media; CWD, canal wall down; CWU, canal wall up.
^a Success was defined as achievement of an ABG \leq 20 dB.

Underlying Disease

The overall group was divided into 3 subgroups, depending on the underlying disease (chronic otitis media with cholesteatoma, chronic otitis media without cholesteatoma, and ossicular chain disruption in absence of inflammatory disease), and functional results were compared. In the group with underlying chronic otitis media with cholesteatoma (51 ears [57%]), mean (SD; range) postoperative PTA ABG was 16.50 (8.99; 3.75-48.75) dB, starting from a mean preoperative PTA ABG of 24.41 dB. The mean PTA ABG improvement was 7.92 dB. Successful hearing results were obtained in 36 ears (71%). Postoperative PTA ABG was 10 dB or less in 16 ears (29%). The group with chronic otitis media without cholesteatoma (21 ears [24%]) improved from a mean preoperative PTA ABG of 25.06 dB to a mean (SD; range) postoperative PTA ABG of 11.31 (6.26; 0-22.50) dB. Mean PTA ABG improvement was 13.75 dB. In 19 ears (90%), successful hearing was achieved. Postoperative PTA ABG was 10 dB or less in 12 ears (57%). Finally, in the group with an ossicular chain disruption in the absence of inflammatory disease (17 ears [19%]), the PTA ABG improved by a mean 15.07 dB, from a preoperative mean of 32.94 dB to a postoperative mean (SD; range) of 17.87 (13.99; 0-48.75) dB. Successful postoperative hearing was achieved in 10 ears (59%). In 8 ears (47%), the postoperative ABG was 10 dB or less. Although the group with chronic otitis media without cholesteatoma tended to yield better results than the 2 other subgroups, these differences in mean postoperative PTA ABG were not statistically significant (ANOVA test, $P = .08$). The rates of successful hearing in the different subgroups demonstrated no statistically significant differences (Pearson χ^2 , $P = .08$). However, when both the underlying disease and revision vs primary surgery parameters are taken into account, a statistical analysis using a 2-way ANOVA test not only demonstrates a significant effect of primary surgery vs revision surgery ($P < .001$) but also reveals a significant interaction effect ($P = .008$) between the revision surgery parameter and the underlying disease parameter. In general, the PTA ABG was significantly higher for the revision group than for the primary surgery group. In addition, this effect of revision or primary surgery differed significantly depending on the underlying disease. The mean (SD)

Figure 3. Estimated Marginal Means of Postoperative Air-Bone Gap With Underlying Disease and Revision vs Primary Surgery as 2 Independent Variables



Estimated marginal means of the postoperative air-bone gap were calculated by 2-way analysis of variance with underlying disease and revision vs primary surgery as 2 independent variables. The combination of revision surgery and underlying ossicular chain disruption shows a significant negative interaction. Chol indicates cholesteatoma; COM, chronic otitis media; Disrupt, ossicular chain disruption in the absence of inflammatory disease.

ABG closure for the group with an ossicular chain disruption was significantly worse (30.36 [11.63] dB) than for the other disease processes. This subgroup included revision surgery for a dislocated previously placed Kurz TTP-Variac System prosthesis ($n = 2$) or remodeled incus ($n = 3$) and absence of the incus and malleus after radical mastoidectomy in the past ($n = 1$). The findings of the 2-way ANOVA test are depicted in Figure 3.

Canal Wall-Up vs Canal Wall-Down Procedures

In our series, only 6 CWD procedures were performed (7%), all in the cholesteatoma group. Of these 6 ears, only 1 was a primary surgery case whereas the 5 others were revision cases. The association between the CWD mastoidectomy parameter and the revision surgery parameter proved statistically significant (Fisher exact test, $P < .05$). The postoperative functional results for the 6 CWD procedures revealed a mean (SD);

range) PTA ABG of 22.71 (9.45; 10.00-40.00) dB. Successful postoperative hearing was obtained in only 2 ears (33%). In contrast to these rather poor results, the mean (SD; range) postoperative PTA ABG in the CWU group (n = 83 [93%]) was 14.86 (9.57; 0-48.75) dB and the postoperative success rate was 76% (63 ears). The difference in mean postoperative PTA ABG between the 2 groups was statistically significant (Mann-Whitney *U* test, $P < .05$).

Wet vs Dry Preoperative Status of the Ear

Before the operation was started, the status of the middle ear was assessed as being “wet” or “dry” on the basis of the presence or absence, respectively, of purulent discharge. In 6 ears (7%; cholesteatoma in 5 cases and chronic otitis media without cholesteatoma in 1 case), purulent discharge was observed. In this wet group, the mean (SD; range) postoperative PTA ABG was 19.79 (11.28; 8.75-40.00) dB and the mean PTA ABG improvement was 14.17 dB. The success rate was 50% (3 ears). In the dry ear group (n = 83 [93%]), the mean (SD; range) postoperative PTA ABG was 15.11 (9.87; 0-48.75) dB, whereas the mean PTA ABG improvement was 10.38 dB. The success rate was 75% (62 ears). Although the functional outcome in the dry ear group tended to be better than in the wet ear group, these differences were not statistically significant (Mann-Whitney *U* test, $P > .10$ for all frequencies; χ^2 test, $P > .10$).

Preservation of the Malleus vs Removal of the Malleus

Whenever an intact malleus was present and disease spreading anterior to the malleus did not necessitate removal of the head of the malleus, the cartilage graft was placed between the tympanic membrane and the dissected malleus handle. The prosthesis was positioned adjacent to the malleus and, whenever possible, touching the malleus handle. Among the few CWD procedures (n = 6), the malleus was removed in 5 cases, thus rendering analysis of the impact of malleus preservation on hearing outcome in the CWD group impossible. However, in the CWU procedures (n = 83), malleus preservation was achieved in 56 cases (67%). In 17 cases, the malleus had to be removed because of erosion or disease spreading anterior to the malleus (20%). Information about malleus preservation was not available in 10 cases (12%). The postoperative functional results in the CWU group with removed malleus revealed a mean (SD) postoperative PTA ABG of 19.26 (11.66) dB and a mean PTA ABG improvement of 7.65 dB. Successful postoperative hearing was obtained in 9 patients (53%). In the CWU group with preserved malleus, the mean (SD) postoperative PTA ABG was 13.37 (8.84) dB and the mean PTA ABG improvement was 11.74 dB. The postoperative success rate was 80% (45 ears). The mean postoperative PTA ABG in the group with preserved malleus was statistically significantly smaller than in the group with removed malleus (2-tailed $P < .05$, independent samples *t* test). The PTA ABG improvement and postoperative success rates were higher in the group with preserved malleus, but these differences were not statistically significant (independent samples *t* test, $P = .08$, and χ^2 test, $P = .05$, respectively).

Discussion

In this study, we attempted to investigate and evaluate the efficacy of titanium PORPs, in particular the Kurz TTP-Variac System, in middle ear reconstruction. Although a variety of studies concerning this topic have already been published, comparison of the results in the literature is problematic because of the lack of a universally accepted protocol for reporting results after ossicular reconstruction.¹³ Moreover, several studies include results of both partial (PORP) and total (TORP) ossicular reconstruction without making a distinction between these 2 subgroups.^{8,10,14-17} Other studies are multicentric, lacking surgical uniformity.⁸ Finally, in some publications, different types of titanium PORPs were used.^{8,15} Direct comparison between published series is further thwarted because all required parameters for statistical analysis are rarely reported.^{2,4,8,10,17,18} In Table 2, our postoperative results are compared with other published results. The type of prosthesis used is indicated in the table. To our knowledge, our series of 89 patients is the largest single-center study in which the Kurz TTP-Variac System PORP is used by the same surgeon for reconstruction of the ossicular chain. We observed a mean postoperative PTA ABG of 15.58 dB, a mean PTA ABG improvement of 10.62 dB, and a success rate of 73%. Mean follow-up time was 13 months, and results proved to be stable during the follow-up. As shown in Figure 2B, the postoperative ABG on 4 kHz tended to be more pronounced compared with lower frequencies, a finding that is also observed by Schmerber et al¹⁷ and that can be attributed to prosthesis design. In a study on the effect of prosthesis design on vibration of the reconstructed ossicular chain, Kelly et al¹⁹ suggest that a prosthesis should be as light as possible and sufficiently rigid for improved high-frequency transmission. Compared with other materials such as gold or ceramics, titanium is lighter and stiffer, yielding superior results on high frequencies.⁴ With respect to earlier published results, summarized in Table 2, direct comparison of our own mean postoperative PTA ABG was only possible with 4 studies^{5,14-16} because the required parameters for statistical comparison (eg, standard deviations) were lacking in the other series. Only the mean postoperative PTA ABG reported by Vassbotn et al¹⁴ proved to be significantly lower than ours and amounted to 9 dB (independent *t* test, $P < .01$). Regarding the PTA ABG improvement in the different studies, the results communicated by Vassbotn et al,¹⁴ Krueger et al,⁵ and Ho et al¹⁶ proved to be significantly higher than ours and amounted to 19.0, 19.4, and 20.6 dB, respectively (independent *t* test, $P < .01$). A comparison of the postoperative success rates of the studies mentioned in Table 2 reveals that only the study by Quaranta et al,¹⁰ which exclusively included cholesteatoma cases, showed a statistically significant lower success rate (χ^2 test, $P < .01$). In all other studies, no significant differences in rates of postoperative successful hearing were observed (χ^2 test, $P = .16$).^{4,5,8,14,16-18} With the results of Quaranta et al¹⁰ excluded, the global success rate amounted to 75% (study success cross-tabulation).^{4,5,8,14,16-18} However, a closer look at the aforementioned studies reveals some weaknesses. In the article by Vassbotn et al,¹⁴ the study

Table 2. Comparison of Postoperative Results as Reported in Various Series

Variable	Present Work	Vassbotn et al, ¹⁴ 2007	Krueger et al, ⁵ 2002	Schmerber et al, ¹⁷ 2006	Quaranta et al, ¹⁰ 2011	Dalchow, ⁸ 2001	Zenner et al, ⁴ 2001	Ho et al, ¹⁶ 2003	Vincent et al, ¹⁸ 2011	De Vos et al, ¹⁵ 2006	Gelfand and Chang, ² 2011
Prosthesis used	Kurz PORP Variac	Kurz PORP Vario	Kurz PORP Vario	Kurz PORP Vario	Micron Ti off-centered PORP	Fixed-length Kurz (513 patients) and adjustable Spiggle & Theis (134 patients) PORP	Tübingen Ti prosthesis (TTP), PORP	PORP, NOS	Flex/HA PORP (Medtronic-Xomed)	Spiggle & Theis (30 patients) and KURZ PORP (35 patients)	Ti PORP, NOS
Patients, No.	89	38	16	61	19	647	51	14	288	65	Unk
Follow-up	13 mo (mean)	NA	3 mo (16/16), 6 mo (9/16), and 12 mo (4/16)	>10 mo	24 mo (mean)	6-72 mo	12-24 mo	NA	43.6 mo	11.8 mo	8-12 wk
ABG, mean, dB											
Preop	26.19	28	>30 (in 56% of cases) and >40 (in 31% of cases)	NA	23.9	>30 (in 49% of patients) <20 (in 22% of patients)	NA	38.7	24.6	32.7	28.3
Postop	15.58	9	14.1 (3 mo)	14.3 (3 mo)	24.1	14	NA	18.1	13.1	18.1	18.8
Gain	10.62	19	19.4	NA	-0.2	15	NA	20.6	11.5	14.6	9.5
PTA, mean, dB											
Preop	51.22	47	NA	NA	NA	NA	NA	68.3	50.7	NA	NA
Postop	37.70	27	NA	NA	NA	NA	NA	46.6	41.1	NA	NA
Gain	13.53	20	NA	NA	NA	NA	NA	21.7	9.8	NA	NA
Final ABG range, %, dB											
≤10	40	53	31.3 (3 mo)	NA	0	43	44 at 2 kHz and 38 at 3 kHz	14	54.3	NA	NA
>10-20	33	36	50.0 (3 mo)	NA	43.8	33	NA	50	16.4	NA	NA
>20	73	89	81.3 (3 mo)	77 (3 mo)	43.8	76	70 at 2 kHz and 66 at 3 kHz	64	70.4	NA	NA

Abbreviations: ABG, air-bone gap; NA, not applicable; NOS, not otherwise specified; PORP, partial ossicular replacement prosthesis; postop, postoperative; preop, preoperative; Ti, titanium; unk, unknown.

population consists of 38 PORP and 35 TORP procedures. Mean follow-up time, underlying disease, proportion of revision cases, and complication rate are known only for the total (PORP + TORP) group and not for the PORP group in particular, which makes comparison with our group, which included a substantial proportion of cholesteatoma and revision cases, difficult. The results of the study by Krueger et al⁵ also have to be interpreted carefully because of the small population (16 ears) and the limited follow-up time (up to 12 months in only 4 of 16 ears). In the series by De Vos et al¹⁵ and Dalchow,⁸ several types of prostheses were used, decreasing the surgical uniformity. The results reported by Ho et al¹⁶ have to be interpreted with caution because of the small population (N = 14), the unknown follow-up time, and the use of a PORP that is not further specified. When the aforementioned results are taken into account, our mean ABG improvement is modest compared with those of other studies, whereas our success rates approximate the best results described in the literature. This can be explained by the relatively low preoperative ABGs in our groups with underlying chronic otitis media with and with-

out cholesteatoma (24.41 and 25.06 dB, respectively). This illustrates our policy of performing surgery at an early stage before complete destruction of the ossicular chain has occurred (especially destruction of the stapes superstructure).

Regarding complications, our study confirms the low extrusion rate of titanium prostheses earlier mentioned in the literature. We observed only 1 prosthesis extrusion (1%) due to middle ear atelectasis. Dalchow⁸ reported a comparable extrusion rate⁸ but did not mention whether it concerns a partial or total prosthesis extrusion. Displacement of the prosthesis was observed in 2 cases (2.2%) in our study, compared with 4.9% reported by Schmerber et al,¹⁷ 4.3% by De Vos et al,¹⁵ and 3.5% by Quaranta et al.¹⁰ The rate of SNHL in our series was 3%, compared with 3.6% reported by Schmerber et al,¹⁷ 6.3% by Krueger et al,⁵ 8.5% by Quaranta et al,¹⁰ 0.3% by Vincent et al,¹⁸ and 2.7% by Vassbotn et al.¹⁴ However, comparison of the rate of SNHL needs to be interpreted carefully because variable definitions of SNHL are used and the calculation of SNHL rate is most often based on the total group, including PORP and TORP cases. Sensorineural hearing loss also includes the physiological de-

terioration of presbycusis. In our series, only 2 patients (2%) developed a postoperative perforation of the reconstructed tympanic membrane, compared with 3% reported by De Vos et al¹⁵ and 1.3% reported by Vincent et al.¹⁸ Residual cholesteatoma was observed in 5 cases in our series (6% of the total population, or 10% of the cholesteatoma population), compared with 1.4% (2.8% of cholesteatoma cases) reported by De Vos et al¹⁵ and 1.7% reported by Quaranta et al.¹⁰

In our series, we demonstrated a similar mean PTA ABG improvement in the primary and revision surgery groups. However, because revision cases presented with a substantially more pronounced mean preoperative PTA ABG, the mean postoperative PTA ABG was significantly lower in the primary surgery group compared with the revision surgery group. In this way, middle ear reconstruction seemed to close the preoperative ABG in a relatively constant way, leading to a significantly higher postoperative success rate in the primary surgery group. Because our series contains a substantial proportion of revision cases (31%), this probably negatively influenced our overall functional results. In the study by Schmerber et al,¹⁷ the ears that had undergone previous tympanoplasty performed elsewhere or in childhood had poorer postoperative auditory results: success rates were 59% in the revision group vs 74% in the primary surgery group. In contrast, revision surgery did not show a statistically significant adverse effect on the postoperative PTA ABG in the series of De Vos et al.¹⁵

A closer look at the underlying disease reveals no statistically significant differences—either in mean postoperative PTA ABG or in postoperative success rate—among the different subgroups. This finding is supported by Vassbotn et al,¹⁴ who observed no significant differences in functional outcome between the cholesteatoma and noncholesteatoma groups. However, Schmerber et al¹⁷ reported a similar mean PTA ABG improvement but a lower success rate in the cholesteatoma group vs the noncholesteatoma group (61% vs 79%; $P < .05$). Gelfand and Chang² also demonstrated a negative effect of cholesteatoma on functional outcome (multivariate regression, $P < .01$).

However, when both the underlying disease and the revision vs primary surgery parameter are taken into account, our statistical analysis reveals a significant interaction of these 2 independent variables. Moreover, the mean postoperative PTA ABG in the revision surgery-ossicular chain disruption group was significantly worse compared with the other combined subgroups. Interestingly, in a comparison of only the cholesteatoma group vs the chronic otitis media without cholesteatoma group, no significant differences in outcome were observed between either the cholesteatoma and chronic otitis media groups or between the revision and primary surgery cases. Thus, it is reasonable to think that the significantly worse results of the combined revision surgery-chain disruption group negatively affect the functional results in the overall revision surgery group in which all 3 underlying diseases are included. We suggest that worse results in this subgroup might be due to scarring, tympanosclerosis, and the fact that ears that have to be revised because of problems with the first reconstruction are “difficult ears” (selection bias) in which a stable connection between the tympanic membrane and stapes is difficult to achieve. The combined revision surgery-underlying

chain disruption without inflammatory disease subgroup also contains second-look operations solely performed to restore the ossicular chain but otherwise in the absence of residual inflammatory disease or residual cholesteatoma. We believe that these data favor our policy of performing single-stage middle ear surgery with immediate reconstruction of the ossicular chain rather than performing a mastoidectomy to eradicate middle ear disease, followed by a second-look operation with reconstruction of the ossicular chain 1 year later (classic 2-stage surgery). In cases of cholesteatoma surgery, however, a meticulous postoperative follow-up strategy using computed tomography and magnetic resonance imaging (including non-echo-planar diffusion-weighted imaging) has to be carried out to ensure early discovery of residual cholesteatoma.²⁰⁻²⁴ When these imaging techniques suggest recurrent disease and/or that the postoperative ABG is starting to increase after an initial stable period, a second-look operation is performed.

In the literature, conflicting views about the effect of CWU vs CWD mastoidectomy have existed for decades.^{2,14,15,17} Canal wall-down mastoidectomy was found to have no negative impact on functional results by Gelfand and Chang,² Vassbotn et al,¹⁴ and De Vos et al.¹⁵ However, Schmerber et al¹⁷ observed a significantly worse success rate in the CWD group compared with the CWU group (33% vs 72%). In our series, we report success rates similar to those reported by Schmerber et al¹⁷ (33% in the CWD group vs 76% in the CWU group). The postoperative PTA ABG in the CWD group was significantly higher compared with that in the CWU group (22.71 vs 14.86 dB; $P < .05$). However, these findings need to be interpreted with caution because of the small CWD population in the present study.

In our series, the preoperative status of the ear (wet vs dry) did not negatively affect postoperative functional results. This is consistent with findings by Claes et al,²⁵ who did not find any influence of the preoperatively wet or dry condition of the ear on functional results in allograft tympanoplasties.

Finally, we observed a significantly smaller postoperative ABG in the CWU group with preserved malleus compared with the CWU group with removed malleus. Improvement in ABG and postoperative success rate also showed a tendency to be more favorable in the group with preserved malleus, but this was not statistically significant. These results are supported by earlier research by De Vos et al,¹⁵ who identified availability of the malleus handle, status of the middle ear mucosa, and status of the stapes footplate as significant predictors for hearing results in ossiculoplasty.

Conclusion

In our series of 89 ears, we have demonstrated that the titanium Kurz TTP-Variac System PORP is an effective prosthesis for reconstructing the ossicular chain, yielding satisfactory and stable functional results, irrespective of the initial disease or preoperative presence of otorrhea. Revision surgery, especially in combination with underlying ossicular chain disruption without inflammatory disease, was associated with poorer functional outcome, whereas preservation of the malleus was associated with a better functional outcome.

Complications such as prosthesis extrusion, recurrent tympanic membrane perforation, prosthesis dislocation, SNHL, and residual cholesteatoma are rare, stressing not only the efficacy but also the safety of the prosthesis used. Additional studies addressing the functional outcome and safety of this prosthesis in the long term are needed in the future.

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Study concept and design: Meulemans, Forton.

Acquisition of data: Meulemans, Forton.

Analysis and interpretation of data: All authors.

Drafting of the manuscript: Meulemans.

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