Surgical-handling properties of the titanium prosthesis in ossiculoplasty

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Abstract

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 Tübingen 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 audiomeric 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.

Introduction

Reports indicate that reconstruction of the ossicular chain is necessary in 40 to 90% of all tympanoplasty procedures. Closure of the air-bone gap to less than 20 dB occurs in 40 to 70% of patients who have an intact stapes and in 20 to 55% of those whose stapes suprastructure is missing. A wide variety of ossiculoplasty techniques and materials have been developed since Wullstein introduced passive implantable prostheses in 1952. The most commonly used reconstruction materials are autografts, homografts, and synthetic prostheses made of plastic pore, gold, ceramic and, most recently, titanium. Despite the variety of prosthesis materials, only limited information is available on surgeons’ preferences for each. In clinical practice, surgeons base their choice of material on the surgical-handling characteristics of the different prostheses, as well as on audiometric performance data. With respect to surgical-handling attributes, the ideal prosthesis would be easy to use, biocompatible, and versatile enough to allow for adaptation in individual cases. A good prosthesis should also remain in place and stable over the long term.

In addition to the type of material used, the design of a prosthesis also influences its surgical-handling properties, the most important of which pertain to visual control, positioning, and coupling. The latest step in the effort to achieve the ideal prosthesis was the development of the open titanium prosthesis. Its audiomeric performance was previously shown to be at least equal to that of the other materials used for ossicular reconstruction. To date, no data have been published on the intraoperative ergonomic properties of titanium prostheses. This lack of information led us to conduct a study of surgeons’ opinions regarding their use of the titanium prosthesis. We also asked surgeons to compare their experience with the titanium implant with their previous experience in using gold, ceramic, and autograft implants.

Subjects, materials, and methods

Surgeons. Our study was based on questionnaire responses provided by 32 otologic surgeons who used the open Tübingen titanium prosthesis for primary and revi-
sion ossiculoplasty during tympanoplasty in 400 patients at 12 academic and nonacademic otolaryngology clinics, most of them in Germany. These surgeons performed both partial ossicular replacement prosthesis (PORP) and total ossicular replacement prosthesis (TORP) procedures.

To be eligible to participate in the survey, surgeons were required to have had experience in placing titanium, gold, ceramic, and autograft ossicular implants. No restrictions were placed on individual surgical techniques used to reconstruct the tympanic membrane. All procedures had been performed between Jan. 15, 1998, and Dec. 23, 1999.

Patients. The selection of patients whose cases were included in this study was based on several criteria. Patients were required to be 18 years of age or older and of sound mind. They had to have had a lesion on at least part of the incus and/or a missing stapes superstructure. The presence or absence of the malleus handle was not taken into consideration.

Each patient received only one implant during the study. To guard against systematic selection bias, we studied the cases of consecutively presenting patients who met the eligibility criteria.

Questionnaire. The participating surgeons were asked to complete the questionnaire as soon as possible after each operation. The three main sections of the survey concerned the patient’s clinical status, the preparation of the ossicular implant, and the handling of the implant during the operation.

Clinical status. These questions concerned the patient’s history of surgery on the affected ear and the condition of the ear with respect to otorrhea, inflammation, etc.

Preparation. Surgeons were asked about (1) the type of operation (partial or total), (2) the amount of time required to prepare the titanium implant for placement, (3) the type of implant material (gold, ceramic, or autograft) they used before the titanium implant became available, (4) their opinion of the efficacy of the alternatives, and (5) their estimation, based on their experience, as to how much preparation would have been required to use an alternative implant.

Intraoperative handling. Most of this part of the questionnaire asked physicians to rate various aspects of placing titanium and alternative implants on a scale of 1 (favorable rating) to 7 (unfavorable). These ratings concerned issues such as the surgeons’ ability to secure placement immediately without the need to modify the implant’s length and the time required to modify the implant if the initial attempt at placement failed. Surgeons were also asked to rate their overall impression of the intraoperative handling characteristics of all the types of implants, taking into consideration factors such as positioning, length adjustment, the degree of visibility of the stapes head (with the PORP) or footplate (with the TORP), and the stability of the coupling.

Prostheses. The particular titanium prosthesis used in this study was the open Tübingen titanium prosthesis (Heinz Kurz GmbH Medizintechnik; Dusslingen, Germany). This implant has been approved for use by the United States Food and Drug Administration and by the Communauté Européenne. Two types of Tübingen titanium implants are available. The generally shorter implants used for the PORP procedures ranged in length from 1.75 to 4.75 mm; the length of those used for the TORP procedures ranged from 2.5 to 6.0 mm.

Statistical analysis. Questionnaire responses were analyzed with the aid of the SPSS 8.0 statistical package. For pairwise comparisons of ratings for titanium, gold, ceramic, and autograft implants, we used the Mann-Whitney U test ($\alpha = 5\%$). Probability ($p$) values of less than 0.05 were considered to be statistically significant. Distribution of scores was calculated on box and whisker plots. Differences between PORP and TORP results were explored with contingency tables and evaluated according to the Pearson chi-square test.

Protocol safeguards. This investigation was performed in accordance with the principles established at the 18th World Medical Assembly of 1964 (Declaration of Helsinki) and subsequent amendments adopted in Tokyo (1975) and Venice (1983). The investigation was approved by the independent, interdisciplinary, registered Ethics Committee made up of members of the medical faculty at the University of Tübingen. Informed consent was obtained from all participants.

Results

Patients. The 400 patients who underwent surgery included 230 men and 166 women (the sex of 4 patients was not recorded). Enough data were missing from 17 questionnaires to disqualify them from the statistical analysis. Of the remaining 383 operations, 216 (56.4%) were revision procedures and 167 (43.6%) were primary procedures.

Preoperatively, the middle ear was dry in 196 patients (51.2%), while 184 patients (48.0%) had acute exacerbations of chronic otitis media; information on the clinical status of 3 patients was not recorded. The tympanic membrane was intact in 115 patients (30.0%); 78 patients (20.4%) had a small defect, 121 (31.6%) had a midsize defect, 50 (13.1%) had a subtotal defect, and 18 (4.7%) had a total defect. Information on 1 patient was missing.

Type of operation. Of the 383 patients, 256 (66.8%) received a PORP and 127 (33.2%) received a TORP.

Length of implant. Surgeons generally preferred the 2.0-, 2.25-, and 2.5-mm titanium PORP and the 4.0-mm TORP (figure 1).

Choice of alternatives. If a titanium prosthesis had not been available, surgeons would have used a gold prosthesis in 248 cases (64.7%), the head of the malleus in 58 cases (15.1%), ceramic in 45 cases (11.7%), the incus in 29 cases (7.6%), and an unspecified material in 3 cases (0.8%).

Preparation of the prosthesis. Of 387 operations for
which preparation data were available, the Tübingen titanium prosthesis was taken directly from the package and used without the need for modification prior to implantation in 365 cases (94.3%). Most of the modifications in the remaining 22 cases involved simply bending the device to change the angle between the shaft and the open platform. By contrast, the 174 questionnaires that included information on the preparation of ceramic prostheses indicated that modification would have been necessary in 129 cases (74.1%) and unnecessary in only 45 (25.9%).

On 136 questionnaires, surgeons provided information on the length of time it has taken them to reshape a nonmetal (ceramic or autograft) implant before placement in similar situations. The length of time in these cases ranged from 2 minutes up to 30 minutes in a single unrepresentative case (median: 5). Half of these modifications took between 3 and 10 minutes. The amount of time required to modify a metal (titanium or gold) prosthesis when necessary was significantly ($p < 0.001$) shorter.

**Intraoperative handling.** Evaluation of the handling characteristics of the prosthesis inside the middle ear was based on the surgeons’ overall impression of factors such as positioning, length adjustment, visibility, and the stability of the coupling.

**Positioning.** The titanium prosthesis was placed into position with the tip of a vacuum or with a Fisch-McGee wire-crimping forceps. Surgeons correctly chose the proper position of the titanium implant on the first attempt significantly more often than they estimated they had with the gold ($p = 0.005$), ceramic ($p < 0.001$), and the autograft ($p < 0.001$) implants (figure 2).

**Length adjustment.** In 362 of the 383 cases (94.5%), length adjustment to achieve the proper tension was not necessary, as the surgeon intuitively chose the correct implant length on the first attempt.

**Visibility.** Surgeons reported good visibility when positioning the titanium prosthesis in the capitulum of the stapes during partial ossiculoplasty (figure 3, A) and when positioning it on the footplate in the oval window niche during total ossiculoplasty (figure 3, B). In both cases, they judged that the titanium prosthesis was significantly better than the gold ($p = 0.003$), ceramic ($p < 0.001$), and autograft ($p < 0.001$) implants.

**Stability of the coupling.** Coupling properties were assessed in terms of stability in the eardrum and stapes. In 182 cases (47.5%), the malleus (or what remained of it) was still in situ, and the surgeon was able to interpose the prosthesis between the malleus and the stapes capitulum or the footplate. Surgeons indicated that the stability of the titanium coupling to the eardrum (figure 4, A) and to the stapes head or footplate (figure 4, B) was significantly better than the stability of the gold, ceramic, or autograft implants ($p < 0.001$).

**Overall assessment.** Overall, the surgeons rated the ease of handling the titanium implant in the middle ear significantly higher than that of the gold, ceramic, and ossicular prostheses ($p < 0.001$) (figure 5).

**Discussion**

Despite the introduction of new designs for middle ear prostheses during the past 40 years, no single device has emerged as the uniformly accepted standard. For this and other reasons, ossiculoplasty remains an unreliable procedure. Nevertheless, we believe that a comparison of the different types of prostheses and their particular intraoperative handling characteristics might lead to further improvement in prosthesis design and perhaps in the results of ossiculoplasty itself. This belief provided the impetus for our study.

We focused our attention on the intraoperative handling characteristics of the titanium prosthesis as assessed prospectively by surgeons during the immediate postoperative period. We compared these findings with the surgeons’ retrospective assessments (based on their experience) of gold, ceramic, and autograft implants.

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**Figure 1.** Graphs show the percentages of cases for which surgeons selected various lengths of titanium implants for PORP (A) and TORP (B) procedures.
Because a study of the audiometric benefits of titanium prostheses was recently reported by Zenner et al., we did not investigate this particular parameter.

In 2001, Goldenberg and Emmet published the results of their survey of members of the American Otological Society and the American Neurotology Society regarding their use of middle ear implants. They found that although only 12% of respondents performed such surgery, their satisfaction with titanium implants was extraordinary (satisfaction rate: 100%). This approval may be attributable in part to the excellent intraoperative handling characteristics demonstrated in our study.

Because metal prostheses are available in a wide variety of lengths (unlike nonmetal prostheses), significantly less time was required to prepare them for implantation. Our finding that surgeons preferred the 2.0-, 2.25-, and 2.5-mm titanium prostheses for PORP and the 4.0-mm device for TORP is consistent with the results of a study by Stupp et al., who conducted a retrospective multicenter study of the nearly closed Düsseldorf titanium prosthesis (Kurz) in 661 patients.

The weight of the different prostheses varies. Ceramic units are the heaviest, ranging from 29.8 to 35.7 mg. Gold implants weigh between 28.0 and 40.2 mg, and titanium devices are the lightest, weighing between 4.1 and 10.1 mg. The greater weight of the ceramic and gold prostheses may have a more unfavorable effect on their acoustic properties. The titanium prostheses weigh approximately the same amount as do stapes ossicles. The more a prosthesis weighs, the more difficult it is to manipulate intraoperatively and the more likely it is to tilt during and after placement. The lighter a prosthesis is, the better it adheres to blood, which makes handling easier. Less weight also facilitates fine readjustments during positioning.

The process of adjusting the length of a prosthesis to achieve the appropriate amount of tension and establish proper conduction is primarily a function of a surgeon’s experience and judgment. Only 6% of the surgeons surveyed by Goldenberg and Emmet indicated that they used a sizer to determine the length of a prosthesis before implantation. Some prostheses are designed so that surgeons have the option of clearly seeing both contact points simultaneously. Good visibility may contribute to good coupling.

The specific design of a prosthesis has an effect on the surgeon’s ability to see the surgical field during positioning. Design features that improve visibility include a slim axis, a small foot, and an open head. The latter is a particular design attribute of the Tübingen implant but...
not other titanium prostheses. The open head allows for a nearly unobstructed view of the stapes footplate during positioning. Visibility can also be improved by reshaping a prosthesis.

The fact that the surgeons in our study indicated that the coupling characteristics and stability of the titanium implant in the eardrum and stapes were superior to that of the others may also be attributable to design features that allow for simultaneous visualization of both contact points during both PORP and TORP procedures. The structure of ceramic and autograft implants, on the other hand, can block the surgeon’s vision of the coupling site and thereby have a negative impact on the reliability of the coupling process. Visibility with gold implants is better than that with ceramic and autograft implants, but it is not as good as visibility with titanium prostheses.

In conclusion, our survey showed that the intraoperative handling characteristics of the Tübingen titanium prosthesis are superior to those of the gold, ceramic, and autograft implants; the surgeons’ preference for them is not simply attributable to their familiarity with this type of implant. If future long-term studies confirm this degree of satisfaction with titanium and if acoustic outcomes remain favorable, titanium may become a preferred material for performing both total and partial ossiculoplasties. Finally, considering that bone autografts require so much operating-room time to prepare, the choice of ready-to-use titanium implants may prove to be no less cost-effective.

Acknowledgments

The authors thank the following participants for contributing data to the study group: J. Arndt (Karlsruhe), M. Bloching (Halle), F. Bootz (Bonn), H.E. Eckel (Klagenfurt), W. Enzmann (Berlin), M. Gjuric (Zagreb), C. Herberhold (Bonn), S. Keiner (Bonn), A. Koitschev (Tübingen), K. Küttner (Suhl), A. Mai (Stade), H.S. Maune (Kiel), O. Michel (Leipzig), A. Mir-Salim (Halle), J. Naujoks (Stade), A. Neumann (Neuss), H.J. Neumann (Halle), J. Oeken (Halle), W.P. Pedal (Oldenburg), P.K. Plinkert (Heidelberg), R. Poser (Stade), S. Preyer (Tübingen), S. Redel (Oldenburg), H.J. Schultz-Coulon (Neuss), R. Steinert (Oldenburg), N. Terjung (Oldenburg), A. Weber (Leipzig), and S. Wollschläger (Oldenburg). In addition, we thank the DATINF Co. of Tübingen (www.datinf.com) for providing support with statistical analysis and Mr. G. Felsheim for performing the audit.

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