Hearing Results After Stapedotomy With a Nitinol Piston Prosthesis

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Objective: To compare the hearing results in patients with otosclerosis who underwent a stapedotomy with either a platinum wire prosthesis or a commercially available, heat-activated nitinol stapes piston prosthesis.

Design: Retrospective medical chart review.

Setting: Academic tertiary care medical center.

Patients: Seventy-nine consecutive patients diagnosed as having otosclerosis who underwent primary stapedotomy (33 men and 46 women) were included in this study (41 ears per group).

Intervention: Stapedotomy.

Main Outcome Measures: The operative records of the senior surgeon (B.J.G.) were retrospectively reviewed, and hearing results were obtained. The hearing results of the patients who received a platinum wire prosthesis were compared with those who received a nitinol prosthesis.

Results: Results for the platinum wire prosthesis group revealed a postoperative mean (SD) air-bone gap (ABG) of 7 (6) dB, a mean (SD) ABG closure of 21 (12) dB, and a postoperative mean (SD) speech reception threshold of 25 (16) dB. Results for the nitinol prosthesis group revealed a postoperative ABG of 8 (6) dB, an ABG closure of 25 (10) dB, and a postoperative speech reception threshold of 25 (12) dB.

Conclusions: These data show that the nitinol prosthesis is equivalent to the platinum wire prosthesis in closing the ABG in patients with otosclerosis. Comparable efficacy combined with the ease and safety of heat-activated crimping supports the continued use of this prosthesis for stapes surgery.

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In 1956, John Shea ushered in the modern era of stapes surgery for otosclerosis with the development of the stapedectomy technique.1 The use of the piston prosthesis soon followed with the development of the small-fenestra stapedotomy technique in the early 1970s.1 In 1978, the small-fenestra technique was further refined to incorporate the use of a laser to make the fenestra.2 Over time, there were many modifications in the material and architecture of stapes prostheses. The piston-style prosthesis, however, remains the dominant device in use today.

One persistent disadvantage of the piston-style prosthesis has been the relative difficulty of crimping the prosthesis on the long process of the incus. This step is critical in successful stapes surgery, as tight crimping has been postulated to cause direct trauma to the long process of the incus and/or avascular necrosis. Loose crimping can potentially lead to abrasion, erosion, and potential resorption or necrosis of the long process.

A recent review of cases of stapedectomy revision reported that as many as 81% to 87% of revision cases demonstrated a displaced or malfunctioning prosthesis.3 A number of authors have suggested that a malfunctioning prosthesis is a direct result of malcrimping of the prosthesis.3 It has also been demonstrated that the quality of crimping is critical for the predictability of hearing results after surgery.6 Numerous authors have suggested that the increase in revision procedures is the result of relative inexperience in the performance of this maneuver.7 This inexperience, in turn, is due to an increasing paucity of candidates for surgery, with a resultant decrease in cases for residents in training and surgeons in practice.8 A recent study that examined the competence of novice and experienced surgeons in performing stapedectomy revealed substantial differences in their respective skill sets,9 thus supporting this contention.

These factors have all contributed to the ongoing search for an easier way to crimp the prosthesis to the incus. One potential method is to use shape memory metal alloys that obviate the need for manual crimping. Shape memory alloys, eg, nitinol, have the ability to conform to a preset shape af-
ter application of heat. Nitinol, which is made of nickel and titanium, has well-documented biocompatibility in numerous applications in other specialties. A prosthesis that uses this alloy for the wire loop portion of a piston prosthesis (SIM Piston Prosthesis; Gyrus ENT LLC, Bartlett, Tennessee) was recently developed based on the design of Knox and Reitan. This wire, in turn, is attached to a fluoroplastic base. The prosthesis is provided in an open conformation, but in its closed position, it is designed to circumferentially firmly crimp around the long process of the incus. After the loop of the prosthesis is appropriately positioned over the long process of the incus, a transition between these 2 states is induced by the application of a heat source (mini-bipolar or laser) to a temperature of 45°C. Therefore, no physical crimping is necessary for this process.

In the present study, we retrospectively evaluated the performance of the nitinol prosthesis in comparison to a platinum wire piston prosthesis (Smith & Nephew Richards Inc, Memphis, Tennessee) (our previous prosthesis of choice) with specific regard to the postoperative airbone gap (ABG). Our hypothesis was that there was no difference between the 2 prostheses with respect to the postoperative ABG and speech reception threshold (SRT), thus supporting the routine use of the more technically effortless nitinol prosthesis in stapes surgery.

PATIENT CRITERIA

After institutional review board approval, the operative records of the senior surgeon (B.J.G.) were reviewed, and the hearing results were obtained for all patients who underwent stapedotomy for otosclerosis (1997-2004). For surgical consideration, the patients were required to have a normal-appearing tympanic membrane, normal middle ear aeration, and an ABG that resulted in a negative Rinne test result at 512 kHz (bone conduction greater than air conduction). Patients who received a platinum wire prosthesis (1997-2001) were then compared with patients who received a nitinol prosthesis (2001-2004) regarding preoperative and postoperative ABG, ABG closure, and postoperative ABG and speech reception threshold (SRT). Revision surgical procedures were excluded for the purpose of this study, as were patients who underwent stapedotomies for other reasons (eg, congenital fixation, tympanosclerosis, and trauma).

SURGICAL TECHNIQUE

All surgical procedures were performed with the patient under monitored sedation with local blockage of the ear with 1% lidocaine and 1:20,000 U of epinephrine. A tympanomeatal flap was incised and raised medially, with care being taken to provide at least a 4-mm length of flap. The posterior tympanic bone was then curetted to permit full visualization of the oval window. Afterward, the stapes was inspected and palpated to confirm the diagnosis of otosclerosis. The lateral ossicular chain was also palpated to verify its mobility. The argon laser with a Gherini-Causse probe (set at 1 W, 0.1-second duration) was then used to remove a portion of the posterior crus to allow visualization of the footplate. Next, a rosette was created in the footplate to allow placement of a 0.6-mm piston. The distance between the oval window and the long process of the incus was measured, and an appropriate-sized prosthesis was selected. The nitinol prosthesis was then placed and crimped with the laser, while the platinum wire prosthesis was placed and manually crimped. Finally, the incudostapedial joint was separated and the stapedial tendon was vaporized. This procedure (initially described by Fisch12) was used because it allows placement of the prosthesis and stabilization of the incus while the crura are in place. The prosthesis position was again evaluated for tightness and mobility. If the position was satisfactory, the oval window was sealed by a blood patch that was acquired by scratching of the promontory. The tympanomeatal flap was then returned to its native position, and hearing was tested by whispered spondae.

Treatment with antibiotic-steroid combination drops was initiated the following day. The patients continued to use the drops until their first return visit, which was scheduled for 4 weeks later. Audiograms were obtained 1 month after surgery if there was no evidence of effusion and if the ABG was reversed. They were then obtained in all patients at 3 months and at 1 year after surgery; however, a number of patients either underwent audiography at their local otolaryngologist (and the audiograms were therefore unavailable to us) or did not return for subsequent testing. Thereafter, follow-up audiometric testing was scheduled at yearly intervals unless problems necessitated earlier testing.

Table 1. Patient Characteristics

<table>
<thead>
<tr>
<th>Sex</th>
<th>Platinum Wire Prosthesis</th>
<th>Nitinol Prosthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>17</td>
<td>16</td>
</tr>
<tr>
<td>Female</td>
<td>22</td>
<td>24</td>
</tr>
<tr>
<td>Follow-up (range), mo</td>
<td>20 (1-79)</td>
<td>9 (1-36)</td>
</tr>
</tbody>
</table>

PATIENT CHARACTERISTICS

A total of 79 patients (33 men and 46 women) were included in our study (41 ears per group). The mean age at the time of surgery in the platinum wire prosthesis group was 46 years (age range, 27-73 years). The mean age at the time of surgery in the nitinol prosthesis group was 45 years (age range, 28-74 years). The average follow-up period for the platinum wire prosthesis group was 20 months (range, 1-79 months). The average follow-up period for the nitinol prosthesis group was 9 months (range, 1-36 months). These data are summarized in Table 1.

HEARING RESULTS

Four-tone average ABGs (500, 1000, 2000, and 4000 kHz) were computed from the preoperative and the latest available postoperative audiograms in both groups. The ABG closure was computed by subtracting the postoperative ABG from the preoperative ABG. The preoperative and postoperative SRT results were similarly computed from the preoperative audiograms and the latest available postoperative audiograms for each patient. The mean (SD) and the range of values for each of the groups are shown in Table 2. Recommendations from the Committee on Hearing and Equilibrium were followed for reporting hear-
ing results. Individual hearing results for each patient are demonstrated in dot-plot graphs comparing preoperative and postoperative ABGs and SRTs for both the platinum wire (Figure 1) and the nitinol (Figure 2) prosthesis groups.

DATA COMPARISON

Paired 2-tailed t tests were used to compare the individual variables. A 2-tailed test was used because the nitinol prosthesis could theoretically have either enhanced or worsened hearing results in comparison to the platinum wire prosthesis. A significant difference was defined as $P < .05$. A significant difference was noted in the preoperative ABG between groups ($P < .007$), but there was no significant difference in the postoperative ABG ($P < .23$) or ABG closure ($P < .09$). There were no differences in the preoperative ($P < .17$) or postoperative ($P < .91$) SRT.

Table 2. Audiometric Results and Statistical Comparison

<table>
<thead>
<tr>
<th>Variable</th>
<th>Platinum Wire Prosthesis</th>
<th>Nitinol Prosthesis</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative ABG</td>
<td>27 (10) [6 to 46]</td>
<td>34 (9) [8 to 47]</td>
<td>.007</td>
</tr>
<tr>
<td>Postoperative ABG</td>
<td>7 (6) [0 to 20]</td>
<td>8 (6) [0 to 32]</td>
<td>.23</td>
</tr>
<tr>
<td>ABG closure</td>
<td>21 (12) [-3 to 46]</td>
<td>25 (10) [9 to 48]</td>
<td>.09</td>
</tr>
<tr>
<td>Preoperative SRT</td>
<td>47 (13) [25 to 75]</td>
<td>51 (11) [25 to 80]</td>
<td>.17</td>
</tr>
<tr>
<td>Postoperative SRT</td>
<td>25 (16) [5 to 100]</td>
<td>25 (12) [5 to 65]</td>
<td>.91</td>
</tr>
</tbody>
</table>

Abbreviations: ABG, air-bone gap; SRT, speech reception threshold. $a$Values are expressed as mean (SD) [range] in decibels.

In this study, we sought to compare the performance of the nitinol piston prosthesis and the platinum wire piston prosthesis with respect to their ability to close the ABG in patients with otosclerosis. Our results demonstrate that the postoperative ABG with the nitinol prosthesis is comparable to the postoperative ABG with the platinum wire prosthesis (Table 2). Our findings are in agreement with those of a previous small series in which a nitinol piston prosthesis was compared with a titanium piston prosthesis as well as those of an upcoming larger series (Jeffrey Harris, MD, PhD, unpublished observations, 2007). These data demonstrated a
greater but nonsignificant reduction \( (P < .09) \) in ABG after surgery in the nitinol prosthesis group (Table 2). The reduction is likely attributable to greater preoperative ABGs in the nitinol prosthesis group (Table 2). The SRT, both before and after surgery, was also comparable between the 2 groups (Table 2).

One potential criticism of this study is the limited follow-up of some of our patients in the nitinol prosthesis group (average, 9 months). The purpose of our study was to provide only an initial evaluation of hearing results in patients who received the nitinol prosthesis. Our data, however, are presented with the caution that they are early results.

One exciting prospect of the nitinol prosthesis is the potential for limiting the increasing number of revision procedures being performed. As has been documented by many authors to date, revision stapes surgery is technically more difficult, has inferior audiometric results, and has a higher rate of complications.\(^5,15,17\) Many practicing neurotologists and otologists have shown that prosthetic malpositioning and incus abnormalities (neurotologists and otologists have shown that pros- thesis malpositioning and incus abnormalities (necrosis or subluxation) are common causes of persistent prosthesis malpositioning and incus abnormalities (necrosis or subluxation) are common causes of persistent prosthesis malpositioning and incus abnormalities (necrosis or subluxation).\(^3\) As discussed earlier, the nitinol prosthesis eliminates the need for manual crimping, thus eliminating the possibility of manual crimping. Long-term follow-up will ultimately determine if the firm circumferential pressure provided by the nitinol prosthesis reduces the incidence of these complications. It is interesting to note, however, that no episodes of incus necrosis or prosthesis slippage have occurred in our series of primary stapedotomies to date.

Numerous concerns have been raised about the potential risk of ferromagnetic middle ear implants in the context of ever more powerful magnetic resonance imaging (MRI) magnets. These concerns have been most recently addressed by testing for stapes prosthesis displacement in implanted guinea pigs subjected to 1.5- and 3.0-T fields. None of the multiple materials implanted demonstrated displacement from the oval window.\(^3\) Indeed, application of a 4.7-T field to animals implanted with ferromagnetic (400 series) stainless steel implants failed to demonstrate prosthesis mobilization.\(^18\) The nitinol component of the nitinol prosthesis contains 55% nickel and 45% titanium by weight, and its magnetic properties are most consistent with nonmagnetic (300 series) stainless steel.\(^18\) A theoretic concern could exist for nitinol prosthesis displacement during MRI. Therefore, the nitinol prosthesis was specifically tested for displacement during a typical series of MRI sequences (1.5 T) and was found to have no shift in either its position or its conformation. Also, the movement of the plate it was resting on had no effect on its orientation with respect to the magnetic field created by the MRI.\(^11\) To our knowledge, we have had no complications regarding prosthesis displacement due to MRI, and discussion with other groups that use the nitinol prosthesis failed to reveal any episodes of displacement. Because of the uncertainty at higher magnetic fields, however, it is prudent to warn patients who receive this prosthesis about undergoing MRI at stronger fields than 1.5 T until further studies support it.

One final concern regarding this prosthesis is the potential for an allergic response to the nickel component in nitinol in the middle ear. Approximately 17% of the population reacts to patch testing of nickel sulfate.\(^19\) Despite this concern, nitinol enjoys widespread use in other specialties, with implantation in the trachea, bronchus, biliary tract, gastrointestinal tract, and urinary system as well as the cerebral, coronary, and peripheral vasculature.\(^20\) Although thousands of patients have been implanted with nitinol in its varied applications, we have found only 1 report in the literature reporting an allergic reaction to nitinol in a patient who received an intracardiac patent foramen ovale–occluding device.\(^22\) There were no complications attributable to an allergic response to the nickel component of the nitinol prosthesis in our series, despite the high incidence of nickel sensitivity in the population. In light of these observations and results, the threat of allergic response to the nickel component of nitinol exists but appears to be an exceedingly uncommon occurrence.

In conclusion, the nitinol piston prosthesis represents the latest advancement in stapes prosthesis design in that it incorporates heat-sensitive crimping to preclude the technically difficult step of manual crimping. It is at least as effective as a standard prosthesis in closing the ABG in patients with otosclerosis. Long-term analyses of the performance of this prosthesis will ultimately demonstrate if the reproducible, firm crimp of the nitinol prosthesis results in fewer revision procedures in comparison to standard prostheses.


