Superiority of Nitinol Piston Over Conventional Prostheses in Stapes Surgery: First Comparative Results in the Chinese Population in Taiwan

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Background: A growing number of studies conducted on stapes surgery have suggested that firm and adequate attachment of the prosthesis onto the long process of the incus plays a key role in surgical success. For this reason, a new prosthesis made of Nitinol characterized by “self-crimping” has been developed. Although better postoperative outcomes achieved with a Nitinol piston have been previously confirmed, the superiority of the Nitinol piston over the conventional manual-crimping prostheses remains controversial. The aim of this study was to determine the advantages of the Nitinol piston with regard to hearing improvement.

Methods: We retrospectively compared postoperative hearing in otosclerosis surgeries with the Nitinol piston versus the manual-crimping prostheses. Sixteen surgeries with Nitinol pistons (carried out between April 2007 and August 2009) and 21 surgeries with conventional prostheses (carried out between January 2004 and January 2009) were evaluated. All patients received pure-tone audiograms preoperatively and postoperatively.

Results: In the Nitinol piston group, the air-bone gap (ABG) average (7.92 ± 6.75 dBHL) was significantly smaller postoperatively than preoperatively (26.79 ± 8.33 dBHL, p < 0.001). Similarly, the ABG average for the conventional piston group (13.09 ± 6.99 dBHL) was significantly smaller postoperatively than preoperatively (26.19 ± 6.76 dBHL, p < 0.001). Although both groups demonstrated an improvement in average ABG postoperatively, the Nitinol piston group showed a greater improvement than the conventional piston group (p = 0.018). Additionally, ABG closure within 10 dB was attained in significantly more patients (75%) in the Nitinol piston group compared with the conventional piston group (33.3%, p = 0.012).

Conclusion: The Nitinol piston has a distinct advantage over conventional prostheses, providing an easier, safer and more effective treatment option in otosclerosis surgery. To our knowledge, this is the first comparative analysis of hearing results of the Nitinol piston with conventional prostheses in the Chinese population in Taiwan. In this population, there is a much lower prevalence of otosclerosis, leading to a lack of surgical experience in otosclerosis surgery, even at large medical centers. This may explain, in part, the relative lack of studies conducted on stapes prostheses in Asian patients. Therefore, our preliminary research may provide a reference for future investigations on stapes surgery in Asian patients with otosclerosis based on ethnic differences. [J Chin Med Assoc 2010;73(5):241–247]

Key Words: nitinol piston, otosclerosis, stapes prosthesis, stapes surgery

Introduction

Since Shea first described stapedectomy for otosclerosis in 1956,1 remarkable advances have been made in stapes surgery to improve surgical outcome. Despite a great evolution of surgical techniques and prostheses, the process of manual crimping remains one of the most challenging and uncertain steps in stapes surgery. Surgical limitations lie not only in individual anatomic variations (e.g. incus deformity and ear canal size) causing difficulty in positioning and manipulation of a prosthesis, but also in inaccurate crimping...
(e.g. over-, under- or asymmetrical crimping), which may result in improper attachment of the prosthesis onto the incus, leading to subsequent surgical failure or complications, especially for less-experienced surgeons. Current studies conducted on stapes surgery have suggested that firm and adequate attachment of the piston onto the long process of the incus is the key to effective sound energy transmission and constant hearing restoration.6,16

In the past 50 years, a continuing search for an easier, safer and more effective way to crimp the prosthesis to the incus have led to great innovations in prostheses design. The prosthesis has evolved from Teflon memory effect prostheses, Shepherd’s crook prostheses and titanium-gold clip prostheses to the most recently developed Nitinol piston prosthesis.7

Nitinol, an acronym for “Nickel Titanium Naval Ordnance Laboratory”, is a nickel-titanium alloy (approximately 50% nickel and 50% titanium by weight) with a shape memory effect, first discovered by William Buehler and Frederick Wang at the Naval Ordnance Laboratory in 1962.8 The shape memory effect, a distinguishing characteristic of Nitinol, allows the alloy to change its shape to a shape previously “memorized” when heated. Nitinol, which has excellent biocompatibility and elasticity, is the most widely used shape memory alloy, having such extensive biomedical applications as orthodontic wires, orthopedic implants, stents, and catheters.6,9–12

Recently, a new piston prosthesis made of Nitinol and characterized by “self-crimping” has been developed. The newly developed piston has a fluoroplastic shaft and Nitinol wire loop. With the shape memory effect, the Nitinol piston can securely, uniformly and precisely fashion itself around the incus, thus resulting in improved surgical outcomes as shown by several studies.6,13–15 The reason it is called “self-crimping” is because the Nitinol wire loop automatically fastens itself around the long process of the incus by application of a heat source (e.g. bipolar or laser forceps) to a temperature of 45°C. The shape-memory Nitinol piston simplifies the crimping maneuver and minimizes the risk of under- or over-crimping.6,16

In the past few years, the Nitinol piston has aroused the interest of otologists for clinical application for otosclerosis. Several studies have focused on the comparison between pre- and postoperative hearing results.13,15,17 However, there are relatively few studies with regard to differences in surgical outcomes between the Nitinol piston and conventional prostheses,14,18–22 and some of them have suggested that there is no statistically significant difference of hearing results between the 2 groups.14,18,19 Consequently, the superiority of the Nitinol piston over conventional prostheses remains a controversial issue.

The prevalence of clinical otosclerosis in Asian populations is much lower than that in Caucasian people.23,24 Therefore, surgeons’ experience in otosclerosis surgery is quite limited, even at large medical centers in Asia. This may explain, in part, the relative paucity of studies conducted on stapes prosthesis in Asian patients. To our knowledge, a comparison of hearing results of the Nitinol piston with conventional prostheses has not been described in Asian populations, and we present the first report in a Chinese population in Taiwan.

Methods

Subjects

We retrospectively reviewed the medical records of 91 ears in 78 patients (13 patients had bilateral stapedotomies) with a surgically and pathologically confirmed diagnosis of otosclerosis at the Department of Otorhinolaryngology–Head and Neck Surgery of Taipei Veterans General Hospital, from 1996 to 2009. Differing surgeons’ individual influence on surgical outcome, such as surgical experience, especially in terms of crimping, was reduced by having all the operations completed by Dr A.S. Shiao. Patients who had revision surgery, whose audiometric data were insufficient or who were lost to follow-up were not included in this evaluation. To omit the influence of the learning curve on the surgical results, 47 surgeries between 1996 and 2003 were excluded. Sixteen surgeries with Nitinol pistons (carried out between April 2007 and August 2009) and 21 surgeries with conventional prostheses (carried out between January 2004 and January 2009) were evaluated (Figure 1).

Generally, the length of the prostheses, either Nitinol or conventional, ranged from 4.0 to 4.5 mm, and the diameter from 0.4 to 0.6 mm.

Methods

All patients received pure-tone audiograms preoperatively and postoperatively. The American Academy of Otolaryngology–Head and Neck Surgery guidelines were followed.25 We compiled data on the pre- and postoperative pure-tone average and air-bone gap (ABG). The mean thresholds of the above-mentioned data were determined at 0.5, 1, 2, and 3 kHz. When the threshold at 3 kHz was not available, the average of 2 kHz and 4 kHz was estimated according to the new and revised reporting guidelines from the Committee on Hearing and Equilibrium.26
The ABG was calculated using air conduction (AC) and bone conduction (BC) thresholds recorded on the same audiogram. Although the Committee recommends reporting the mean and standard deviation of the postoperative ABG as the hearing results, a postoperative ABG less than 10 dB is currently considered to be a measure of an optimal result of stapes surgery. In our study, we used postoperative ABGs less than 10 dB as a comparative parameter of Nitinol and conventional pistons. The study was approved by the Taipei Veterans General Hospital Institutional Review Board.

**Statistical analysis**

The Mann-Whitney U test was used for nonparametric statistics for comparing interval level data such as age, follow-up duration, preoperative AC and BC, preoperative and postoperative ABGs, and changes in ABG. A paired samples t test was used to determine significant difference between pre- and postoperative ABGs. Pearson’s χ² test was performed for categoric variables to compare the percentage of patients who demonstrated postoperative ABG closure within 10 dB. All statistical comparisons and descriptive statistics were conducted using the SPSS software package (SPSS Inc., Chicago, IL, USA). Differences were considered statistically significant if p was ≤ 0.05 (2-tailed).

**Results**

The patient characteristics of the Nitinol piston and conventional piston groups are shown in Table 1. There were 14 patients in the Nitinol piston group and 20 in the conventional piston group. The mean age of the patients at the time of surgery in the Nitinol piston group was 42.81 ± 12.58 years, and in the conventional piston group was 45.57 ± 9.76 years; there was no significant difference in age between the 2 groups (Table 1). The mean duration of follow-up was 12.76 ± 1.38 weeks in the Nitinol piston group and 14.02 ± 3.81 weeks in the conventional piston group, with no significant difference between groups. Mean preoperative AC was 56.01 ± 12.44 dBHL for the Nitinol piston group and 56.87 ± 10.55 dBHL for the conventional piston group (p=0.902), while mean preoperative BC was 29.21 ± 11.12 dBHL for the Nitinol piston group and 30.68 ± 9.95 dBHL for the conventional piston group (p=0.580). Mean preoperative ABG
was 26.79 ± 8.33 dBHL for the Nitinol piston group and 26.19 ± 6.76 dBHL for the conventional piston group \((p=0.927)\). The 2 groups were easily comparable because there were no significant differences in age, duration of follow-up, preoperative hearing levels, and preoperative ABG.

In the Nitinol piston group, postoperative ABG average \(7.92 ± 6.75\) dBHL was significantly smaller than that preoperatively \(26.79 ± 8.33\) dBHL, \(p=0.018\); Table 2). Postoperative ABG for the conventional piston group was \(13.09 ± 6.99\) dBHL was also significantly smaller than that preoperatively \(26.19 ± 6.76\) dBHL, \(p<0.001\). ABG had a mean decrease of \(14.53 ± 11.11\) dB and \(9.04 ± 9.98\) dB for the Nitinol and conventional groups, respectively. Although the difference in mean ABG change was not statistically significant \((p=0.152)\), the Nitinol piston group showed greater improvement in mean ABG than did the conventional piston group postoperatively \((p=0.018)\). Additionally, ABG closure within \(10\) dB was attained in significantly more patients in the Nitinol piston group \((75\%)\) compared with the conventional piston group \((33.3\%, p=0.012)\).

**Table 1.** Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>Nitinol piston</th>
<th>Conventional piston</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>42.81 ± 12.58</td>
<td>45.57 ± 9.76</td>
<td>0.529</td>
</tr>
<tr>
<td>Range</td>
<td>27–63</td>
<td>24–58</td>
<td></td>
</tr>
<tr>
<td>Duration of follow-up (wk), mean ± SD</td>
<td>12.76 ± 1.38</td>
<td>14.02 ± 3.81</td>
<td>0.080</td>
</tr>
<tr>
<td>Sex ((n))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>11</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>14</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Ear ((n))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>8</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>8</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>21</td>
<td></td>
</tr>
</tbody>
</table>

\(\text{SD}=\text{standard deviation.}\)

**Table 2.** Audiometric results*

<table>
<thead>
<tr>
<th></th>
<th>Nitinol piston</th>
<th>Conventional piston</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air-bone gap (dBHL)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>26.79 ± 8.33</td>
<td>26.19 ± 6.76</td>
<td>0.927</td>
</tr>
<tr>
<td>Postoperative</td>
<td>7.92 ± 6.75</td>
<td>13.09 ± 6.99</td>
<td>0.018</td>
</tr>
<tr>
<td>Air-bone gap change</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.53 ± 11.11</td>
<td>9.04 ± 9.98</td>
<td>0.152</td>
<td></td>
</tr>
<tr>
<td>Air-bone gap &lt;10 dBHL</td>
<td></td>
<td></td>
<td>0.012</td>
</tr>
</tbody>
</table>

*Data presented as mean ± standard deviation or %.

Discussion

Since the first prosthesis made of Teflon was introduced in otosclerosis surgery in 1956,\(^1\) a continuing evolution of prostheses has led to significant progress in microsurgery techniques. The most recently designed prosthesis is the Nitinol piston, which has been developed to eliminate the limitations of manual crimping in stapes surgery. Although several studies have suggested that a better hearing result would be achieved postoperatively in stapes surgery with a Nitinol piston, it remains controversial whether the self-fashioning Nitinol piston could be a viable alternative to the conventional manual crimping prosthesis.

Most studies that have conducted a comparison of postoperative mean ABGs showed that the Nitinol piston has no advantage over the conventional piston prosthesis,\(^14,18,19\) while the opposite conclusion was made by Tenney et al.\(^22\) In addition, Rajan et al reported no significant differences in hearing results between the Nitinol piston and conventional piston prosthesis in their preliminary trial,\(^18\) but a significant difference was discovered in their expanded follow-up research.\(^27,28\) Taking into consideration the fact that an increasing number of studies have put emphasis on postoperative ABG closure within \(10\) dBHL as a measure of surgical success, some studies have compared the Nitinol piston and conventional piston prosthesis by measuring the percentage of ears with postoperative ABG less than \(10\) dBHL; however, there remain no consistent conclusions.\(^19–21\)

In our study, both groups achieved significantly improved outcomes postoperatively compared to preoperatively. In particular, postoperative hearing results obtained from stapes surgery with the Nitinol piston were found to be significantly superior to those obtained with the conventional piston, regardless of which measure of surgical success was used, i.e. ABG or ABG closure. Recent publications are presented in Table 3 to compare our results with those of other studies.\(^14,18–22\) Our results are consistent with those of the most recently published studies,\(^20–22\) and may help resolve the controversy regarding the effectiveness of the Nitinol piston in stapes surgery.

Based on a comprehensive review of the literature and our research, we discuss a possible explanation for
better outcomes obtained with the Nitinol piston. First, the 2-point contact between the piston loop and the straight alligator forceps in the manual crimping process may not lead to a circumferential firm attachment of the loop onto the long process of the incus. Compared with the manual crimping piston, the self-crimping Nitinol piston can be uniformly crimped to the long process of the incus without a gap. A stable and seamless connection between the incus and piston loop would enhance efficiency of the prosthesis in the transfer of acoustical energy from the ossicles onto the piston. A human temporal bone study that measured the sound transmission loss between the incus and prosthesis revealed that a loose crimping status allowed an unpredictably wide range of sound transmission loss up to 28 dB, while tight crimping only caused an average transmission loss of 3 dB, which is similar to that found in the incudostapedial joint.4 Furthermore, with respect to the long-term effects of inappropriate crimping, either over- or under-crimping may result in a lack of initial hearing improvement. If a prosthesis is crimped loosely, the vibration between the incus long process and prosthesis loop may lead to a notching of the long process, causing subsequent incus erosion.4,29 Moreover, over-aggressive crimping of the piston loop may cause pressure damage to the incus long process, inducing potential bone resorption.16 Both a notching effect and direct pressure on the incus long process may result in further loosening of the wire loop and subsequent prosthesis displacement.4,29 Furthermore, the Nitinol piston itself, not only the loop, may be responsible for prosthesis failure. Of more concern, manual malcrimping may cause damage to the incus long process to such an extent that a long-process fracture might develop.19 On the other hand, the Nitinol piston crimps itself neither loosely nor excessively, and its optimal crimping is attributable to the shape memory effect. In conclusion, accurate crimping of the prosthesis loop plays a key role in stapes surgery success.3,6,30

To date, only a few recent efforts have continued to address the practical use of the Nitinol piston in stapes surgery. There has also been little research on the clinical application of the Nitinol piston in Asian patients with otosclerosis, in whom there is a much lower prevalence than in Caucasians. To the best of our knowledge, we have carried out the first comparative analysis of outcome differences between Nitinol and conventional pistons in Chinese patients in Taiwan. Based on the favorable results in Chinese patients, our study may provide a reference for future research on stapes surgery in Asian populations, in which there is a much lower prevalence than in Caucasians. To the best of our knowledge, we have carried out the first comparative analysis of outcome differences between Nitinol and conventional pistons in Asian patients with otosclerosis.

Table 3. Comparison of hearing results from different studies

<table>
<thead>
<tr>
<th>Authors</th>
<th>Nitinol pistons (n)</th>
<th>Conventional pistons (n)</th>
<th>Nitinol piston ABG (dBHL ± SD)</th>
<th>Conventional piston ABG (dBHL ± SD)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harris &amp; Gong (2007)19</td>
<td>26</td>
<td>28</td>
<td>5.42 ± 9.54</td>
<td>5.98 ± 5.47</td>
<td>0.350</td>
</tr>
<tr>
<td>Brown &amp; Gantz (2007)14</td>
<td>40</td>
<td>39</td>
<td>8 ± 6</td>
<td>7 ± 6</td>
<td>0.230</td>
</tr>
<tr>
<td>Tenney et al (2008)20</td>
<td>47</td>
<td>47</td>
<td>7.127</td>
<td>11.69</td>
<td>0.024</td>
</tr>
<tr>
<td>Kuo et al (2010) [this study]</td>
<td>16</td>
<td>21</td>
<td>7.92 ± 6.75</td>
<td>13.09 ± 6.99</td>
<td>0.018</td>
</tr>
</tbody>
</table>

*Four-tone average ABGs were calculated from 0.5, 1, 2, and 4 kHz. ABG = air-bone gap; SD = standard deviation.
resulting in a paucity of surgeons’ experience in otosclerosis surgery, even at large medical centers. In addition, body size seems to play a crucial factor in the middle ear volume difference between Chinese and Caucasian populations. The ethnic variation in middle ear anatomy may directly affect prosthesis sizing and selection. Incorrect sizing of prosthesis length is frequently associated with inadequate crimping. Smaller ear canal size in Chinese populations may also cause difficulty in positioning and crimping of prostheses. Inaccurate crimping, as mentioned above, may have a significant impact on surgical success.\(^\text{29,31,32}\) Using the self-crimping Nitinol piston, surgeons, especially those who are less experienced, can complete the stapes surgery without the risk of inaccurate crimping.

The major concern about application of a Nitinol prosthesis is the biocompatibility, which is determined by 2 important factors: foreign body reaction and metal corrosion. A foreign body reaction invoked by implanted material results in fibrous encapsulation surrounding the implant. A histomorphometric study conducted on the bone reaction of rat tibiae to Nitinol implants compared with titanium or other titanium alloy materials revealed no significant differences among the tissue reactions, but Nitinol implants showed significantly lower percentages of bone contact and bone contact area than those of other materials that were compared.\(^\text{35}\) Metal corrosion, another determined component of biocompatibility, causes degradation of the implanted material in the tissue. Corrosion is an issue worth further study, not only because it can result in prosthesis failure, but also because it can induce metal ion release from the implant, causing possible adverse effects. In Nitinol, which has a high nickel percentage, prevention of nickel release is crucial because nickel ions can cause toxicity to the exposed tissue and invoke a severe allergic reaction. It has been reported that approximately 16–23% of the population are allergic to nickel.\(^\text{34,35}\) Additionally, an \textit{in vitro} model used to study nickel carcinogenesis demonstrated that nickel is a highly carcinogenic material.\(^\text{35}\) For the reasons mentioned above, it is important to have proper implant passivation for forming a protective layer of titanium oxide on the surface of Nitinol prostheses. With regard to the biocompatibility of Nitinol, it has been shown that with the outermost protective titanium oxide layer, Nitinol has a high corrosion resistance similar to that of pure titanium, leading to negligible release of nickel ions with concentrations below the normal human daily intake.\(^\text{36}\)

A technical problem encountered during our experiments was the texture characteristic of Nitinol. The soft-textured Nitinol tends to cause distortion of the piston shaft, leading to shortening of the Nitinol piston and subsequently results in an inadequate length for connection between the incus long process and stapes footplate. Further research on prostheses design is required to improve such limitations.

Despite our encouraging results to confirm significantly better hearing using the Nitinol piston compared with the conventional piston, the study was limited by small patient numbers and collection of only short-term hearing results. Further research is required on the potential benefits of application of the Nitinol piston in stapes surgery for otosclerosis.

In conclusion, we verified that the Nitinol shape-memory prosthesis has a distinct advantage over conventional prostheses, providing an easier, safer and more effective treatment option in otosclerosis surgery. In addition, we have carried out the first comparison of hearing results using the Nitinol piston with conventional prostheses in a Chinese population in Taiwan in which there is a much lower prevalence of otosclerosis. Surgeons’ experience in otosclerosis surgery is limited, even at large medical centers. This may explain, in part, the relative lack of research conducted on stapes prosthesis in Asian patients. Therefore, our preliminary study may provide a reference for future stapes surgeries in Asian patients with otosclerosis based on ethnic differences.

References


