Self-Crimping Superelastic Nitinol Prosthesis and Malleostapedotomy: A Temporal Bone Study

Giuseppe Magliulo

*Otolaryngology -- Head and Neck Surgery* 2013 148: 272 originally published online 4 December 2012

DOI: 10.1177/0194599812469503

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What is This?
Self-Crimping Superelastic Nitinol Prosthesis and Malleostapedotomy: A Temporal Bone Study

Giuseppe Magliulo, MD

No sponsorships or competing interests have been disclosed for this article.

Abstract

Objective. The aim of this study was to compare the results of application of 2 types of superelastic nitinol prostheses.

Study Design. Temporal bones study with planned data collection.

Setting. Tertiary referral center.

Subjects and Methods. Malleostapedotomy was performed in 15 human temporal bones implanting 3 different prostheses: manually crimping polytetrafluoroethylene (MC-PTFE) piston, nitinol self-crimping polytetrafluoroethylene (SC-PTFE) piston, and a modified nitinol self-crimping polytetrafluoroethylene (mSC-PTFE) piston. The first 2 have a diameter of 0.4 mm and length of 7 mm, whereas the mSC-PTFE piston has a diameter of 0.4 mm but a length of 7.75 mm. We evaluated various parameters of prosthesis attachment—that is, the time for implantation of SC and mSC nitinol loop pistons and the MC platinum loop piston, the quality of attachment of the prostheses to the malleus, their positions with respect to the center of the stapes footplate, and the protrusion of the piston into the vestibule.

Results. The mSC-PTFE superelastic nitinol prosthesis showed a statistically significant difference in mean operation time (mSC vs SC, \( P < .0001 \); SC vs MC, \( P < .0001 \); mSC vs MC, \( P < .0001 \)). The protrusion of the piston into the vestibule was highly reproducible in all 3 prostheses.

Conclusion. Because of its greater length, the mSC-PTFE allows for management of the most varied anatomical conditions. At the same time, its self-crimping nature prevents the risk of distortion of the prosthesis by the crimping process and reduces the operation time in combination with standardized bending of the prosthesis shaft.

Keywords

malleostapedotomy, superelastic nitinol, temporal bone, revision otosclerosis surgery

Malleostapedotomy (MS) was popularized by Fisch as an alternative to traditional incus stapedotomy in revised otosclerosis surgery and tympanosclerosis. Fisch et al recommended 2 essential surgical steps to obtain successful and reproducible outcomes: (1) the systematic exposure and removal of the calcified anterior malleus process and ligament and (2) the compensation of a 12- to 15-degree angle between the malleus handle and the center of the footplate together with the 2- to 4-degree adaptation of the prosthesis loop to facilitate its crimping onto the malleus hand. The latter procedures are the most time-consuming and technically demanding steps in malleostapedotomy surgery, and they are strictly linked to the type of prosthesis (material and form of the loop and shaft).

In a temporal bone study, Kwok et al compared 3 different prostheses (Gyrus nitinol piston [GNP]; Storz titanium stapes piston [STSP]; Kurz malleovestibulopexy piston [MVP]). They found that the STSP, even if manually crimped, gave the best results in terms of loop attachment to the malleus position with the center of the footplate depth in the oval window. Although the self-crimp property of the GNP ensured the easiest and fastest fixation to the malleus, its loop provided only 3 contact points with the malleus handle. This risks posterior rotation that may result in contact of the prosthesis with the anterior edge of the footplate hole and has a negative impact on the chances of hearing improvement.

Another critical point was depicted by Gluth et al. They encountered some temporal bones with the distance between the malleostapedotomy crimp site and stapedotomy site exceeding 7.0 mm where a 7.75-mm piston would have been required. They observed that some commercially produced malleostapedotomy pistons are less than the 7.75-mm length. Thus, they suggested that surgeons should start with a longer piston (like the Fisch titanium piston length of 8.5 mm) and then trim down to the actual measured length.

A new type of nitinol was recently introduced for stapes surgery: the superelastic nitinol with a self-crimping property. It allows creation of a polytetrafluoroethylene

Corresponding Author:
Giuseppe Magliulo, MD, “Organi di Senso” Department, University “La Sapienza,” Rome, Italy

Email: giuseppemagliulood@yahoocom
piston prosthesis with a band-shaped loop that requires no crimping, heat, or laser to close the prosthesis onto the long process of the incus (self-crimping polytetrafluoroethylene [SC-PTFE]). We used this prosthesis to perform malleostapedotomy with encouraging results.\textsuperscript{11} In an effort to incorporate the recommendations of Kwok et al\textsuperscript{4} and Gluth et al,\textsuperscript{8} we asked the manufacturer (AudioTechnologies, Gossolengo, Italy) to produce a trimmable MS prosthesis with a length of 7.75 mm and with a 13-degree bent shaft and a 3-degree bent superelastic nitinol loop. These values represent the mean of the angle between the malleus handle and the center of the footplate, allowing a time-sparing step during the adaptation of the prosthesis to the individual anatomical variants.

The aim of this study was to compare the results of application of these 2 types of superelastic nitinol prostheses in 15 temporal bones. The operation time, attachment, position, and the depth in the vestibule of these prostheses were examined to determine the optimal connection between the malleus handle and the vestibule.

Materials and Methods

Malleostapedotomy was performed in 15 human temporal bones using the procedure described by Fisch et al.\textsuperscript{2} Three different prostheses were implanted: a trimmable manually crimping polytetrafluoroethylene (MC-PTFE) piston, a trimmable SC-PTFE piston, and our modified trimmable self-crimping nitinol polytetrafluoroethylene (mSC-PTFE) piston (manufactured by AudioTechnologies). The first 2 have a diameter of 0.4 mm and length of 7 mm, whereas the SC-PTFE piston has a diameter of 0.4 mm but a length of 7.75 mm. (Figure 1). The MC-PTFE and SC-PTFE\textsuperscript{2} connecting pieces were bent to adapt the prosthesis to the angle between the malleus handle and footplate and promontory, respectively. The mSC-PTFE piston was devised to consider these angles, and it was previously bent by the manufacturer. It needed only a small adjustment. The shape of the loop is oval and flat, and all 3 different prostheses have a 4-mm diameter.

All of the prostheses were then trimmed after calculating their length with a measuring rod and placed perpendicular to the stapes footplate, imagining a horizontal line that crosses the malleus laterally and distally to the lateral malleus process. Another 0.5 mm was added in consideration of the protrusion of the piston in the vestibule.

A specific micro-forceps was used to insert the SC-PTFE and mSC-PTFE piston prostheses. The micro-forceps had 2 grooves that facilitated the opening of the superelastic nitinol hook when it was pressed onto the malleus handle as close as possible to the lateral malleus process and the opening of the footplate. These prostheses self-attached without any other surgical manipulation due to the superelastic properties of this type of nitinol.

The piston prosthesis was classically assembled with a manual crimper in the site of the malleus described previously. In each temporal bone, we subsequently implanted the 3 prostheses tested after the removal of those previously inserted.

We evaluated various parameters of prosthesis attachment: the time for implantation of SC and mSC nitinol loop pistons and MC platinum loop piston, the quality of attachment of the prostheses to the malleus, their positions with respect to the center of the stapes footplate, and the protrusion of the piston into the vestibule.

In all temporal bones, other surgical steps (mastoidectomy, posterior tympanotomy, and opening of the vestibule by removing the lateral semicircular canal) were performed to measure the insertion depth of the piston in the vestibule and the distance between the malleus and footplate using a millimeter rule with a 2-point needle caliper.

The significance of the calculated parameters was statistically analyzed using analysis of variance (ANOVA). When the ANOVA \( P \) value was <.05, Bonferroni’s \( t \) test was used to do pairwise group comparisons.

The institutional review board of Sapienza University approved the study.

Results

In the temporal bones, the band-shaped wire loop of the 3 prostheses formed all-around contact with the malleus handle, and the quality of their attachment was adequate with no apparent differences. No particular differences were seen in the position of the pistons. In all temporal bones, they were perpendicularly centered to the footplate. The mean ± SD operation time for the insertion of the SC-PTFE

Figure 1. The 0.4-mm modified nitinol self-crimping polytetrafluoroethylene trimmable prosthesis with a length of 7.75 mm, a 13-degree bent shaft, and a 3-degree bent superelastic nitinol loop.
superelastic nitinol prosthesis was 11.3 ± 1.7 minutes compared with 18.1 ± 2.7 minutes for the MC-PTFE platinum prosthesis and 8.9 ± 1.9 minutes for the mSC-PTFE superelastic nitinol prosthesis, showing statistically significant differences among them (mSC vs SC, \( P < .0001 \); SC vs MC, \( P < .0001 \); mSC vs MC, \( P < .0001 \)). The data regarding insertion of the 2 malleostapedotomy prostheses are listed in Table 1. The protrusion of the piston into the vestibule was highly reproducible in all 3 prostheses with no statistical difference (\( P = .0607 \)) (Figures 2 and 3). This allowed for adjusting the prostheses according to the specific anatomical situation encountered.

Only 2 temporal bones did not confirm this trend. Both showed a >7-mm distance between the malleostapedotomy grip site and the stapes footplate stapedotomy site. This precluded protrusion of the SC-PTFE and MC-PTFE pistons into the vestibule because their length did not exceed 7 mm. In these anatomical variants, the mSC-PTFE piston prototype prosthesis (length 7.75 mm) offered a good solution.

The other parameters (distance of tip of lateral process to loop) showed only minimal differences with no statistical significance (\( P = .5327 \)).

**Discussion**

Fisch et al\(^2\) identified the fundamental surgical steps for successful malleostapedotomy. The technical critical points are preservation of the integrity of the tendon of the malleus muscle and of the chorda tympani to improve stability of the prosthesis during closure of the loop and removal of the anterior tympanomalleolar process and ligament in all cases. This latter point is controversial because other surgeons think that is reasonable to do so in cases where malleus fixation is suspected, but it should not be required in cases where incus necrosis is encountered without suspected malleus fixation.

However, other factors essential for the reproducibility of this surgical procedure are the size and shape of the

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**Table 1. Summary of Statistics of Different Parameters Measured in 15 Temporal Bones with 3 Different Prostheses**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Median</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distance of malleus to footplate, mm</td>
<td>6.25</td>
<td>6.28</td>
<td>0.44</td>
</tr>
<tr>
<td>Depth of piston in vestibule, mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MC</td>
<td>0.30</td>
<td>0.31</td>
<td>0.33</td>
</tr>
<tr>
<td>SC</td>
<td>0.50</td>
<td>0.49</td>
<td>0.06</td>
</tr>
<tr>
<td>mSC</td>
<td>0.50</td>
<td>0.46</td>
<td>0.26</td>
</tr>
<tr>
<td>Distance of tip of lateral process to loop, mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MC</td>
<td>1.50</td>
<td>1.46</td>
<td>0.16</td>
</tr>
<tr>
<td>SC</td>
<td>1.50</td>
<td>1.45</td>
<td>0.16</td>
</tr>
<tr>
<td>mSC</td>
<td>1.40</td>
<td>1.43</td>
<td>0.15</td>
</tr>
</tbody>
</table>

Abbreviations: MC, manually crimping prosthesis; mSC, modified bent self-crimping prosthesis; SC, self-crimping prosthesis.
malleostapedotomy prosthesis. The anatomy of the malleus handle and its relationship with the footplate are not perpendicular, and a 12- to 15-degree angle forces the surgeon to intentionally bend the shaft of the prosthesis to compensate for this angle. This adjustment prevents anterior or posterior displacement of the prosthesis and unpredictable protrusion into the vestibule. Another manual adjustment affects the loop for a 2- to 4-degree angle, improving the connection with the malleus handle at the lateral process to compensate for the angle between the malleus handle and the promontory. The ideal shape of the loop should be oval and have a 1.2-mm diameter and 1.8-mm length, as suggested by Kwok et al.4 In some commercially available prostheses, this is accomplished by enlarging the loop by passing it over a dilating instrument. These dimensions allow an all-around connection of the loop with the malleus handle at the level of the lateral process, stabilizing the prosthesis in a firm position to maintain a perpendicular orientation of the prosthesis on the center of the footplate.

Although Kwok et al found the STSP to be superior in terms of reproducibility of both the position of the piston with respect to the malleus handle and the footplate and the penetration depth into the vestibule, the ideal MS prosthesis that allows management of the individual anatomical variants is not yet fully available. Successful results are often linked to the ability of the surgeon to prepare an adequate prosthesis shape. This step may be significantly time-consuming.

Moreover, Gluth et al reported that in 10% of the temporal bones examined, the distance between the MS grip site and the stapes footplate was 7.0 mm, rendering 0.5-mm penetration into the vestibule impossible even if we do not consider the need to bend the prosthesis, a maneuver that induces an unavoidable reduction of the length of the prosthesis. They found that the minimal upper-limit requirement for the total length of the prosthesis must be at least 7.75 mm. At the same time, they advocated extension of its total crimped length to account for other potentially longer anatomical conditions and other factors involved in the need for more length (bending of the prosthesis, the effect of loop crimping, unintended distortion of the prosthesis by the crimping process, and the thickness of the footplate) as made by the STSP manufacturer (8.5 mm). They proposed a specific technique of MS piston measurement, once the prosthesis is properly shaped and placed with its barrel on the footplate. They measured the distance between the lateral edge of the malleus handle at the intended crimp site and the lateral apex of the loop and, subtracting this from the adequate depth into the vestibule, trimmed the piston to the desired length with consideration of the loop size changes induced by the crimping process. This is another maneuver best left to the individual ability and sensibility of the surgeon.

Our investigation was specifically designed to evaluate the possibility of standardizing the 2 steps of malleostapedotomy (prosthesis bending and the crimping process), taking into account the suggestions of Kwok et al and Gluth et al. In our temporal bones, we tested 2 commercially available prostheses, one manually crimping (MC-PTFE) and the other self-crimping (SC-PTFE), with a new superelastic type of nitinol. Furthermore, we evaluated a prototype (mSC-PTFE) with a superelastic nitinol loop and length of 7.75 mm. These prostheses were similar in terms of ensuring an all-around contact zone with the malleus. Attachment was easier and faster with the SC-PTFE and mSC-PTFE because of the self-crimping nature of the superelastic nitinol. Their operation times differed significantly from that of MC-PTFE.

Similar to the study by Kwok et al,4 we calculated other parameters after manual adjustments of the 2 analyzed prostheses. Again, no significant differences were noted between MC-PTFE and SC-PTFE with regard to the penetration depth into the vestibule and the footplate position with the exception of 2 temporal bones in which the prostheses failed to penetrate into the vestibule. In these bones, the greater length of the mSC-PTFE provided an optimal vestibule penetration of the barrel of no less than 0.4 mm. Note that in 4 bones, the MC-PTFE prosthesis was minimally distorted by the crimping process, with no effect in 2 cases and less than the expected depth of the prosthesis in the remaining cases. As predicted, no distortion was seen when SC-PTFE and mSC-PTFE were used, indicating a better quality of the crimp stability of the 2 nitinol prostheses vs the manually crimped piston.

The findings of this study, with its limitation due to the small series analyzed, confirmed the suggestions of Gluth et al in terms of the need for a longer prosthesis when malleostapedotomy is planned.

On the other hand, the superelastic nitinol, with its malleability and more elastic property than the traditional nitinol, seemed to have an interesting impact on the stability of the connection of the loop with the malleus, as well as sparing operation time of the manual crimping process.

Further standardization of the technique favoring the reduction of the time-consuming step of prosthesis bending has been provided by the mSC-PTFE. The standard 13-degree shaft required only minimal adjustment. It would be advisable to have the mSC-PTFE or other similar prostheses in the operating room, each with a single-shaft angle degree of 12 to 15 degrees to manage the different angles between the malleus handle and stapes footplate. This would increase sparing time.

Analogously, although the diameter of the loop of the prostheses employed was compatible with those of all of our malleus handles, it would be desirable to have a full range of malleus handle diameters, as proposed by Reineke et al and Hornung et al.

**Conclusion**

The self-crimping nature of the SC-PTFE and mSC-PTFE facilitates and improves the quality of attachment to the malleus handle and prevents the risk of distortion of the prosthesis by crimping. At the same time, it reduces the operation time in combination with standardized bending of the prosthesis shaft of the mSC-PTFE. The MC-PTFE, SC-PTFE, and mSC-PTFE had performances similar to those of other
commercial prostheses in terms of the quality of attachment to the malleus, position, and depth in the oval window. Because of its greater length, mSC-PTFE allows for management of the most varied anatomical conditions.

**Author Contributions**

Giuseppe Magliulo, substantial contributions to conception and design, acquisition of data, and analysis and interpretation of data; drafting the article and revising it critically for important intellectual content; and final approval of the version to be published.

**Disclosures**

**Competing interests:** None.

**Sponsorships:** None.

**Funding source:** None.

**References**