Next Generation Shape Memory Prosthesis (NiTiBOND) for Stapedotomy: Short Term Results

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Abstract

Objectives:
To review hearing results and complications for the NiTiBOND next generation shape memory prosthesis and compare them with results for the current shape memory prosthesis (SMart).

Study Design:
Retrospective, multicenter chart review.

Methods:
Primary laser stapedotomy was performed using either a NiTiBOND or a SMart prosthesis. 92 ears in 79 patients were included in the study (67.4% female), 52 with the NiTiBOND prosthesis and 40 with the SMart prosthesis. Data collected included demographic variables, pre- and postoperative pure-tone air and bone conduction thresholds, speech discrimination scores, complications and the need for revision surgery. Pure-tone average (PTA) and PTA air-bone gap (ABG) pre- and postoperative were computed. 'Success' was defined as a postoperative ABG of ≤10dB.

Results:
There were no significant differences between groups in hearing results, including improvement in ABG, change in speech discrimination, change in air or bone PTA, or change in high-frequency bone PTA. Short-term (mean = 4.4 and 4.9 weeks, respectively) success rates for the NiTiBOND and SMart prostheses were 84.6% and 70.0%,respectively, with this difference closing at the most recent test (83.7% and 80.0%). No revision surgery took place in either group, and there were no differences in complications such as dizziness, tinnitus or taste disturbance, though the NITIBOND group tended to have a lower rate of transient or permanent vertigo.

Conclusions:
Compared with the SMart prosthesis, the NiTiBOND prosthesis is a safe prosthesis that achieves at least comparable hearing results and may offer some surgical advantages.

Introduction

Nitinol, a shape memory metal has been embraced by many otologists as an alternative to traditional stapes prostheses with similar or better outcomes. Nitinol prostheses virtually eliminate the potential for incus subluxation or fracture as opposed to a manual crimping. Recent publications have raised concern about the potential disadvantages of Nitinol. Unfortunately, the potential exists for laser or heat damage to the long process of the incus created in the process of crimping (closing) the currently available Nitinol prostheses. Concerns have also been raised about the potential for an allergic reaction to the nickel present within the Nitinol.

A new shape memory metal prosthesis has been introduced into the US market, which minimizes the potential for incus necrosis and nickel allergy. The NiTiBOND prosthesis has been introduced by Kurz Gmb and demonstrates a unique design to the shepherd's hook region of the prosthesis, which minimizes the nitinol contact to the incus by using a cloverleaf design with a ribbon as opposed to a wire. The upper portion of the prosthesis is made of nitinol while the lower portion is made of titanium. This design allows the laser closure of the prosthesis to occur further away from the incus, with a larger ribbon target for the laser reducing the potential for laser or heat injury to the long process of the incus. The sequential closure of the prosthesis is unique and allows a more customized crimp on the long process of the incus.

Our multicenter study examines the surgical hearing results obtained by two experienced stapes surgeons for the new NiTiBOND prosthesis compared to our own SMart prostheses results.

Methods and Materials

A retrospective review of the records of patients diagnosed with otosclerosis that have undergone stapedotomy surgery was undertaken after obtaining institutional review board approval. Fifty-two consecutive patients undergoing primary stapedotomy surgery using the NiTiBOND prosthesis and 40 consecutive patients undergoing transcanal stapedotomy with the SMart prosthesis were identified as meeting the inclusion criteria and are the subjects of this study. They were 67.4% female, with surgery performed on the left ear in 59.8%. Overall mean age at surgery was 51.2 yrs (SD 16.2). Patients in whom the SMart prosthesis was used were older on average than the NiTiBOND patients (56.3 yrs vs. 47.3 yrs, $p \leq .008$) and the length of follow-up and mean time to most recent audiometric test were longer for the SMart group.

Stapedotomy was performed via transcanal approach using a standard technique with a small fenestra created in the central third of the stapes footplate. NiTiBOND fixation to the long process of the incus was also performed with the laser according to the recommendations of the manufacturer. The stapedotomy surgery was unilateral in most instances (84.8%). The most common laser used was the CO2 laser (62%) with the KTP laser (18.5%) and the Diode laser (19.6%) used less frequently. Of the 92 patients, all had a first (one-month) audiological test and 83 had at least one more recent postoperative follow-up test. Test results for each interval are based on these numbers of subjects.

Results

Hearing

There were no significant differences in preoperative hearing between groups. The preoperative ABGs for both groups were approximately 26 dB. Postoperative hearing improved in both groups, with mean most recent PTAs for the NiTiBOND and the SMart groups at 36.8 and 34.2 dB, respectively and most recent ABGs of 6.3 dB and 5.8 dB, respectively. Most recent WRS was also similar in the two groups, and none of these hearing outcomes were significantly different between groups. The ABG at most recent follow-up test was less than or equal to 10 dB in 83.7% and 80.0% of the NiTiBOND and SMart prosthesis groups, respectively; not a statistically significant difference. ABG closure of less than or equal to 20 dB also did not differ between groups (95.3% and 97.5%, respectively). Improvement (>10 dB) in high-frequency bone conduction average (overclosure) was found in 10.4% of patients in the NiTiBOND group and 15% of the SMart group. A single NiTiBOND patient experienced profound postoperative sensorineural hearing loss, accounting for the 2.1% rate of worsening of the cochlear reserve.

Postoperative Complications

Transient vertigo was experienced by 15.7% of patients in the NiTiBOND group and 22.5% of the SMart group, with an additional two patients (5%) in the SMart group having a permanent sensation of vertigo. Transient taste disturbance occurred in 3.9% of the NiTiBOND group and 10% of the SMart group, with the same percentages experiencing permanent taste disturbance. None of the rates of complications were significantly different between prosthesis groups. No patient in either group has undergone revision surgery.

NiTiBOND prosthesis

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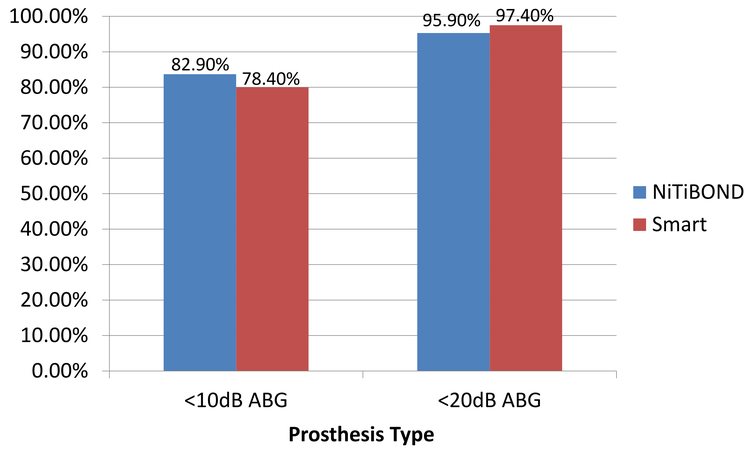

Percent of patients with most recent postoperative air bone gap (ABG) of ≤10dB and ≤20dB for both the NiTiBOND and SMart prosthesis groups.

Discussion

The incidence of prosthesis failure in patients who have undergone stapedotomy with the SMart has been reported to be as high as 11%. The most common finding was lateral displacement of the SMart prosthesis with loosening of the nitinol crimp and displacement out of the small fenestra. Ying et al. hypothesize that laser crimping of the nitinol prosthesis may result in damage to the mucoperiosteum in the long process of the incus, interfering with the delicate blood supply to the area.

The NiTiBOND prosthesis was designed to reduce the potential for incus necrosis and related problems. The cloverleaf design of the shepherd's hook allows sequential tightening of the prosthesis, providing more specificity related to the size and shape of the incus. The location of the three closure zones away from the incus coupled with the ribbon design of the shepherd's hook minimize the potential for laser char and mucoperiosteal damage during crimping. While none of the NiTiBOND patients in our study required revision surgery, the short-term follow-up of this study prevents any conclusions as to the efficacy of these design changes. Studies with longer follow-up will be needed to answer this important clinical question.

Hearing results in the present study are comparable to previous studies for both of the prostheses evaluated. Our success rate for an ABG ≤10 dB for patients in the SMart prosthesis group (80.0%) is similar to the results obtained by Fayad et al. (78.3%).[11] Our success rate for the NiTiBOND group (83.7%) is better than the results reported by Huber et al. (71%).[6] Our results do suggest that the NiTiBOND prosthesis hearing results are at least as good as the SMart prosthesis. We feel that tighter, sequential crimping of the NiTiBOND prosthesis may provide advantages .

Complications tended to be more frequent in the SMart prosthesis group in this study, although the differences failed to achieve statistical significance, perhaps because the prevalence of complications was relatively small in both groups. The SMart prosthesis group was a little older on average than the NiTiBOND group and that may help to explain some of the increased vertigo issues in this group of patients.

Conclusions

The next generation shape memory prosthesis (NiTiBOND) has been demonstrated to give hearing results at least as good as the most commonly used nitinol prosthesis (SMart) in stapes surgery. The NiTiBOND prosthesis is safe and has several potential advantages that will require longer follow-up to fully evaluate.