ORIGINAL ARTICLE

The Influence of Crimping of Nitinol and Conventional Prostheses on Hearing Success for Otosclerosis Surgery

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Objective: The aim of this study was to compare hearing outcomes in otosclerosis surgeries with the Nitinol self-crimping piston versus conventional manual-crimping prostheses in an Asian population, who have a much lower prevalence of otosclerosis than Caucasians.

Materials and Methods: A total of 109 operations performed on 93 patients were included in the study. Thirty-four surgeries with Nitinol pistons and 75 surgeries with conventional prostheses were evaluated. All patients received pure-tone audiograms preoperatively and postoperatively.

Results: The mean age was 41.9 years old and the mean follow-up period was 18.0 months. In the Nitinol piston group, the postoperative air-bone gap (ABG) average (8.6 ± 8.5 dB) was significantly smaller than the preoperative ABG average (27.1 ± 7.6 dB, $p<0.001$). Similarly, the postoperative ABG average for conventional piston group was 12.5 ± 11.8 dB, which was also significantly smaller than preoperative ABG average (29.6 ± 9.1 dB, $p<0.001$). The Nitinol piston group showed comparable hearing outcomes (e.g., air and bone conduction thresholds and ABG average) with the conventional piston group (all $p>0.05$). Additionally, ABG closure within 20 dB was reached in 91.2% of patients for the Nitinol piston group, while in 84.0% for the conventional piston group ($p=0.383$).

Conclusion: This report is the first long-term comparative analysis of hearing results with Nitinol piston and conventional prostheses in an Asian population, and it verifies that Nitinol piston provides comparable long-term hearing outcomes with conventional prostheses. Importantly, Nitinol piston may offer an easier and more effective surgical choice for patients with otosclerosis.

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Introduction

Otosclerosis is a primary metabolic disease of the bony labyrinth that causes fixation of the ossicles.[1] Caucasians are the most affected race, with the prevalence of clinical otosclerosis 0.3-0.4% and about four times the prevalence compared to Asians.[2,3] Otosclerosis has become one of the most known and manageable causes of hearing loss. However, despite remarkable advances in surgical techniques[4-6] and great evolution of prostheses[7,8] to improve surgical outcome, the maneuver of crimping the prosthesis loop remains one of the most difficult and uncertain steps in stapes surgery.[9,10] This surgical challenge more significantly affects Asians than Caucasians because racial anatomic variations (e.g., smaller ear canal) cause difficulty in manipulation of the prosthesis and inaccurate crimping.

The recently developed Nitinol piston simplifies the crimping maneuver and minimizes the risk of inaccurate crimping by automatically fastening itself around the long process of the incus when the piston wire is heated to approximately 45°C.[11] Although its

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superiority over conventional prostheses is well documented in Western literature,[9,10,12,13] there is a relative lack of research comparing these two prostheses in Asian patients due to a much lower prevalence of otosclerosis. Hence, the influence of Nitinol piston on hearing success among Asians still remains unclear.

The aim of the study was to explore the long-term comparative results in Asian patients with otosclerosis treated with two different prostheses.

Materials and Methods

Patients

The medical records of 121 ears in 105 patients with otosclerosis after stapes surgery performed between 1996 and 2012 by the same senior surgeon (Dr. Shiao) at Taipei Veterans General Hospital, a tertiary referral center in Taiwan, were retrospectively reviewed. The diagnosis of otosclerosis was based on a clinical history of progressive hearing loss, normal otoscopic findings, and audiography showing conductive or mixed hearing loss. The absence of a stapes reflex and normal tympanometry were required. The cochlear capsule was evaluated by high-resolution computed tomography to verify the otosclerosis, while the clinical diagnosis was confirmed surgically and pathologically.

Ears with revision surgery (n=2), with insufficient audiometric data (n=8), or that were lost to follow-up (n=2) were excluded. The hospital's Institutional Review Board approved the study.

Surgical Procedure

Primary stapedotomy was performed in all of the patients under general anesthesia to avoid any slight movement from a patient at an important moment, causing postoperative serious complications, such as sensorineural hearing loss.[14,15] Before 2007, all of the ears were operated on using a conventional manual-crimping piston (Schuknecht stainless steel wire Teflon piston). In 2007, the new "heat-crimping" Nitinol piston (SMart™ Piston, Gyrus ENT, Bartlett, TN, USA) was introduced and since then, all of the ears were randomly assigned to either conventional manual crimping or heat crimping. Details of the surgical procedure were as previously reported.[16]

Audiometric Assessment

All of the patients underwent pre- and post-operative pure-tone audiograms following the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) guidelines.[17] Data on pre- and post-operative pure-tone average and air-bone gap (ABG) were compiled, and the mean thresholds were determined at 0.5, 1, 2, and 3 kHz. When the threshold at 3 kHz was not available, the average of the thresholds at 2 kHz and 4 kHz was estimated according to the new and revised reporting guidelines from the Committee on Hearing and Equilibrium.[17] The ABG was calculated using air conduction (AC) and bone conduction (BC) thresholds recorded on the same audiogram.

Outcome Measures and Statistical Methods

The Mann-Whitney U test was used for non-parametric data to compare both groups in terms of age, follow-up duration, and pre- and post-operative AC, BC, and ABG. Paired samples *t*-test was used to determine the significant differences between pre- and post-operative AC, BC, and ABG between the two groups, while Pearson's chi-square test or Fisher's exact test was used as appropriate, for categorical variables. All of the statistical analyses were performed using the SPSS, version 18.0 (SPSS, Inc., Chicago, IL, USA). Statistical significance was set at $p<0.05$.

Results

A total of 109 operations were performed on 93 patients (mean age, 41.9 years old; mean follow-up period, 18.0 months), including 45 (48%) with unilateral otosclerosis and 48 (52%) with bilateral otosclerosis. Among the 48 patients with bilateral otosclerosis, 16 (33%) underwent surgery on both ears. Of the 109 operated ears, 33 ears (30%) were in male patients and 76 (70%) were in females, while 42 ears (39%) were left ears and 67 (61%) were right ears.

Post-operatively, the means of AC and ABG were significantly better than those of AC and ABG (both $p<0.001$) (Table 1), but there was no significant deterioration of the mean BC ($p=0.128$). The percentages of ears with an ABG ≤10 dB and ≤20 dB after surgery were significantly higher than those before surgery (both $p<0.001$).

Table 1. Comparison of pre- and post-operative audiometric results in the study cohort (n=109)

Variable	Pre-OP	Post-OP	P-value
AC, dB (mean±SD)	56.0±13.5	40.3±16.4	<0.001
BC, dB (mean±SD)	27.5±10.7	28.5±11.9	0.128
ABG, dB (mean±SD)	28.8±8.8	11.3±11.1	<0.001
ABG ≤10 dB (%)	0%	54.1%	<0.001
ABG ≤20 dB (%)	0%	86.2%	<0.001

Pre-OP, pre-operative; Post-OP, post-operative;
AC, air conduction; BC, bone conduction;
ABG, air-bone gap; SD, standard deviation; dB, decibel

Table 2. Comparison of patient characteristics and audiometric results between the Nitinol and conventional piston groups

Variable	Nitinol piston (n=34)	Conventional piston (n=75)	P-value
Mean follow-up in months (SD)	16.4 (12.6)	18.6 (15.3)	0.869
Mean age in years (SD)	41.2 (11.6)	42.1 (12.2)	0.562
Bilaterality			0.686
Yes, n (%)	19 (55.9%)	45 (60.0%)	
No, n (%)	15 (44.1%)	30 (40.0%)	
Affected side			0.420
Right, n (%)	19 (55.9%)	48 (64.0%)	
Left, n (%)	15 (44.1%)	27 (36.0%)	
Tinnitus			0.656
Yes, n (%)	25 (73.5%)	52 (69.3%)	
No, n (%)	9 (26.5%)	23 (30.7%)	
Vertigo			0.053
Yes, n (%)	11 (32.4%)	12 (16.0%)	
No, n (%)	23 (67.6%)	63 (84.0%)	
Pre-OP hearing thresholds			
AC average (SD), dB	54.2 (11.3)	56.9 (14.3)	0.594
BC average (SD), dB	27.1 (9.7)	27.4 (11.2)	0.523
ABG average (SD), dB	27.1 (7.6)	29.6 (9.1)	0.238
AC ≤50dB (%)	13 (38.2%)	27 (36.0%)	0.823
BC ≤30dB (%)	25 (73.5%)	54 (72.0%)	0.868
ABG ≤30dB (%)	23 (67.6%)	43 (57.3%)	0.307
Post-OP hearing thresholds			
AC average (SD), dB	36.3 (12.7)	42.0 (17.6)	0.154
BC average (SD) , dB	27.3 (8.7)	29.0 (13.1)	0.956
ABG average (SD), dB	8.6 (8.5)	12.5 (11.8)	0.185
ABG ≤10 dB (%)	23 (67.6%)	36 (48.0%)	0.057
ABG ≤20 dB (%)	31 (91.2%)	63 (84.0%)	0.383

Pre-OP, pre-operative; Post-OP, post-operative;
AC, air conduction; BC, bone conduction; ABG, air-bone gap;
SD, standard deviation; dB, decibel

There were no significant differences between the Nitinol and conventional groups regarding demographic characteristics and pre-operative hearing status (all $p>0.05$) (Table 2). Both groups had significantly better mean post-operative AC and ABG (both $p<0.001$). There was no significant deterioration of mean BC after surgery in the Nitinol ($p=0.758$) and conventional ($p=0.068$) groups. The post-operative audiometric results (Table 2) indicated that the post-operative AC average, BC average, ABG average, and percentages of ears with an ABG ≤10 dB and ≤20 dB were comparable between the two groups (all $p>0.05$).

Discussion

Although an alternative approach to deal with hearing loss caused by otosclerosis has been developed,[18] stapes surgery is still the standardized technical procedure and the first treatment choice for otosclerosis.[15,19] Piston crimping during stapes surgery is a known important and difficult step because under- or asymmetrical-crimping may lead to insufficient sound transmission. Improper piston manipulation during crimping may also expose the middle and inner ears to mechanical trauma.[20] The shape-memory Nitinol piston, made of nickel and titanium alloy, has recently been developed to minimize the risk of inaccurate crimping by automatically changing to a previously "memorized" shape when heated to a temperature of 45°C.[11]

Although the self-crimping Nitinol piston simplifies the technical requirements of a surgical procedure, an area of concern is the post-operative hearing outcome. The superiority of the Nitinol piston over conventional prostheses as regards hearing outcomes is well documented in Western literature.[9,12,13] However, the direct applicability of these results on an Asian population with a much lower prevalence of otosclerosis remains unclear. There is also a relative paucity of literature on stapes prosthesis among Asians. The present report is the first long-term comparative analysis of hearing results with Nitinol piston and conventional prostheses in an Asian population, and it verifies that Nitinol piston provides comparable long-term hearing outcomes with conventional prostheses.

The new prosthesis is considered to offer a relatively good surgical option for the Asian population compared to Caucasians for two reasons. First, the relatively smaller ear canal size of Asians may cause difficulty in positioning and crimping of the prosthesis due to poorer surgical visualization, difficult spatial coordination, and restricted access. With the shape memory effect, the automatically fastening Nitinol piston can securely, uniformly, and precisely fashion itself around the long process of the incus, thereby minimizing the risk of under- or over-crimping.[9]

Second, otosclerosis has a racial predisposition, with much a lower prevalence among Asians that may result in the relative paucity of surgeons' experience with otosclerosis surgery, even in large medical centers. This may partly explain the relative lack of comparative research regarding surgical outcomes between Nitinol and conventional prostheses in Asian patients. Using the self-crimping Nitinol piston, the crimping maneuver is simplified and surgeons, especially those with less experience, may complete the stapes surgery without risk of inaccurate crimping.[11] In addition, the self-crimping piston offers the advantage of reduced operative time.[11,21]

Although the consistency and uniformity offered by a single surgeon/single center performing the otosclerosis surgeries is a great strength of our study because it reduces the influence of individual surgeons on surgical outcomes, some possible limitations should be discussed. First, although this report is the first long-term comparative analysis of hearing results with Nitinol piston and conventional prostheses in an Asian population, longer-term follow-up observations (i.e., 10 to 20 years or more) should be required to verify the influence of prosthesis crimping on hearing success after otosclerosis surgery in an Asian population.[4] Second, a limited number of patients was inevitable because of the low prevalence of otosclerosis in Asian populations (Asian to Caucasians ratio of 1:4).[3] Third, our results may not be directly applicable to other clinics because other surgeons may use different techniques or pistons. Furthermore, the limitations of this study also include the inherent bias associated with a retrospective review.

Conclusions

To date, this report is the first long-term comparative analysis of hearing results between the Nitinol piston

and conventional prostheses in an Asian population. The Nitinol piston provides comparable long-term hearing outcomes with conventional prostheses. However, the Nitinol piston can improve the simplicity of a surgical procedure and offer an easier and more effective treatment option for Asians. The present study provides supporting evidence for the use of the Nitinol piston in clinical practice and it may be recommended for otosclerosis surgery in Asians.

Disclosures

The authors have no financial relationships or conflicts of interest related to this work. This work was presented in part as an invited lecture at the First Asian Otology Meeting & the 3rd East Asian Symposium on Otology in Nagasaki, Japan, on June 2-3, 2012.

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