Long term audiometric outcomes following stapedectomy with the shape memory nitinol stapes prosthesis

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Introduction: Self-crimping pistons were introduced to remove the manual component of the crimping process during stapedectomy. Stable early and intermediate term hearing results equivalent to or better than those achieved using conventional prostheses have been demonstrated using a self-crimping shape memory nitinol prosthesis. The objective of this study was to assess long term hearing outcomes and their stability following stapedectomy using a self-crimping shape memory prosthesis. The results were compared to those of a group of patients who received a conventional, manually crimped prosthesis.

Methods: Retrospective case note review was performed of all patients who underwent stapedectomy for otosclerosis between July 2001 and November 2008. Patients were included if they had a minimum dataset of preoperative, early postoperative (≤ 2 years) and late postoperative (≥ 6 years) audiometry. Fifty six patients who received a SMart prosthesis (Olympus America Inc, Center Valley, PA, USA) are compared to 27 patients who received a conventional, manually crimped titanium prosthesis.

Results: Changes in audiometric parameters with time are shown in Tables 1 and 2. AC, BC and high tone BC all deteriorated. The small increase in ABG was not found to be statistically significant in either group (nitinol: $P = 0.93$; titanium: $P = 0.53$). There was a greater rate of deterioration in BC in the titanium than the nitinol group ($P = 0.037$). Ninety-six percent of patients with a nitinol prosthesis achieved an ABG ≤ 20 dB at early follow up and this was maintained (96%) in the long term, whereas the proportion of patients achieving this ABG in the titanium group fell from 92% at early follow up to 86% in the long term. The rate of revision surgery was 3% (1/29) in the titanium and 5% (3/60) in the nitinol group. The rate of revision surgery in the nitinol group after one year post surgery was negligible.

Discussion: In the titanium group there was a gradual, independent increase in each of the BC, high tone BC and ABG. In the nitinol group the deterioration in AC, BC and high tone BC are almost identical, suggesting that the deterioration in hearing over time is almost entirely a deterioration of the high frequency sensorineural hearing. The rate of deterioration in high tone BC was very similar in both groups over the course of long term follow up.

Conclusions: The excellent closure of the ABG achieved at early follow up remains remarkably stable up to 12 years. There is no evidence that circumferential firm fixation of the hook around the LPI has a detrimental effect in the long term and in fact the rate of revision surgery after one year post surgery is negligible.

Table 1: Early and late audiometric outcomes for titanium and nitinol groups

	Nitinol (n = 56)			Titanium (n = 27)		
	Mean	SD	Range	Mean	SD	Range
AC						
Preoperative	59.1	18.6	31.3 to 106.3	51.5	14.8	33.8 to 87.5
Early post op	34.2	13.8	11.3 to 78.8	29.0	12.2	11.3 to 58.8
Late post op	39.0	15.5	15.0 to 76.3	37.9	21.3	17.5 to 111.3
ABG						
Preoperative	29.5	9.6	13.8 to 56.3	30.1	11.8	10.0 to 51.3
Early post op	9.7	5.2	0 to 28.8	11.0	7.7	2.5 to 42.5
Late post op	9.8	6.1	1.3 to 27.5	12.6	11.1	1.3 to 45.0
ABG Closure						
Preoperative	NA	NA	NA	NA	NA	NA
Early post op	19.8	9.7	-2.5 to 43.8	19.2	12.4	-5.0 to 41.3
Late post op	19.8	10.2	-2.5 to 42.5	17.5	17.0	-33.8 to 41.3
Change in high tone BC level						
Preoperative	NA	NA	NA	NA	NA	NA
Early post op	4.2	6.8	-10.0 to 23.3	2.1	7.2	-8.33 to 18.3
Late post op	-0.3	9.3	-21.7 to 18.3	-3.8	10.6	-33.3 to 15.0
BC						
Preoperative	29.6	13.3	6.3 to 62.5	21.3	7.2	10.0 to 36.3
Early post op	24.5	13.5	6.3 to 66.3	18.0	8.8	5.0 to 40.0
Late post op	29.3	14.8	8.8 to 62.5	25.3	14.0	9.3 to 66.3
NA: Not applicable						
AC, ABG, BC (0.5,1,2,3 kHz); high tone BC level (1,2,4 kHz)						

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Table 2: Change in audiometric values over the course of long-term follow up (early follow-up against late follow-up)

	Nitinol group (n = 56)			Titanium group (n = 27)		
	Mean Δ	P*	95% CI	Mean Δ	P*	95% CI
AC	4.9	0.0001	(2.5, 7.2)	8.9	0.013	(2.0, 15.8)
BC	4.8	< 0.0001	(2.8, 6.8)	7.3	< 0.0001	(4.1, 10.4)
High tone BC	4.5	< 0.0001	(2.4, 6.5)	5.9	0.001	(2.5, 9.2)
ABG	0.1	0.93	(-1.4, 1.5)	1.7	0.53	(-3.7, 7.0)
CI: Confidence Interval						
Mean Δ : Refers to the mean of the difference between late follow-up and early follow-up						
*: P-values were derived from the paired t-tests						