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**No more crimping in stapedotomy? A multicentre trial with the Nitinol stapes piston**

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Background: Manual piston malcrimping in stapedotomy is thought to be the major cause of the occurrence of the significant variations of postoperative air-bone gap closures (ABGC) and postoperative recurrences of conductive hearing loss. To bypass the drawbacks of manual crimping on stapedotomy outcomes, the self-crimping, shape memory alloy Nitinol stapes piston was utilised and its impact on hearing outcomes evaluated.

Study design: Prospective, multicentre study involving three tertiary care referral centres.

Methods: 60 patients with otosclerosis undergoing primary Laser-stapedotomy using the the Nitinol stapes piston were matched to reference patients from a conventional titanium piston database. The effects of the self-crimping Nitinol piston on the postoperative ABGC, the postoperative air-bone gap (ABG) variations and the postoperative hearing results were investigated 3, 6, 12 and 18 months postoperatively. These data were statistically compared with the results of the matched control patients in the titanium stapes piston database and the data of our pilot study.

Results: The mean postoperative ABG and the interindividual variations of the postoperative ABG were significantly smaller in the Nitinol group. The postoperative reliability of ABGC after 18 months of followup was similar in both groups. No infections or adverse reactions occurred during follow up. Conclusion: Our mid term results after 18 months of followup confirm the data of our pilot study. They show that the self-crimping shape memory alloy Nitinol stapes piston bypasses the drawbacks of manual malcrimping in stapedotomy, thus optimising the surgical procedure. This allows consistent air-bone-gap closure in patients with otosclerosis.