

## ORIGINAL ARTICLE

### Usefulness of Hydroxyapatite Bone Cement to Overcome Crimping Problems in Primary Stapedotomy.

Vincent Van Rompaey, Andrzej Zarowski, Jean-Philippe Vercruysse, Thomas Somers, Erwin Offeciers

University Department of Otorhinolaryngology and Head & Neck Surgery, Skull Base Team, Sint Augustinus Hospital, Wilrijk, Antwerp (VRV, ZA, VJP, ST, OE)

**Objective:** To report hearing outcome in primary stapedotomy cases where crimping is difficult and hydroxyapatite (HA) bone cement is used to fix the prosthesis around the long process of the incus.

**Study design:** Nonrandomised, retrospective cohort study.

**Setting:** One tertiary-referral otologic center.

**Materials and Methods:** Twenty-three primary cases of surgically treated otosclerosis where an unsatisfactory crimp was obtained and HA bone cement was used to secure the prosthesis. Air-bone gap (ABG), bone-conduction (BC) and air-conduction thresholds were evaluated preoperatively, at 1-3 months and last follow-up available. Pure-tone averages were calculated according to the guidelines of the Committee on Hearing and Equilibrium for evaluating conductive hearing loss.

**Results:** Nine male patients and 14 female patients were included. Age varied from 39 years to 79 years (median 53 years). Median short-term follow-up was 2.5 months. Median intermediate-term follow-up was 12 months (at last follow-up available). At short-term and intermediate-term, the respective median postoperative ABG was 11.9 dB and 10.6 dB in the study group. No adverse reactions or unsuspected BC deteriorations were seen.

**Conclusion:** In surgically treated otosclerosis patients where unsatisfactory prosthesis crimping is experienced, the additional fixation of the piston using HA bone cement can provide a clinically significant hearing improvement by avoiding a loose-piston syndrome. However, it does not provide a similar improvement when compared to patients where the crimping act is performed without difficulties.

**Key words:** Otosclerosis, Stapes surgery, Hydroxyapatite cement, Conductive hearing loss.

Submitted : 23 March 2011

Accepted : 18 April 2011

## Introduction

The technique of stapedotomy as a minimally invasive highly successful surgical intervention to improve hearing in patients with otosclerosis is well established. <sup>[1,2]</sup> Some of the literature on stapes surgery is currently focussing on the correlation between tight crimping and hearing outcome. <sup>[3,4]</sup> One example is the shape memory heat-crimping prosthesis made of a nickel and titanium alloy (Nitinol). <sup>[5,6]</sup> Another way to improve crimping was proposed by Goebel and Jacob in 2005 <sup>[7]</sup>, and suggested the use of hydroxyapatite (HA) bone cement in primary cases where prosthesis crimping was difficult or not optimal.

Our objective is to report the hearing outcome of using Mimix HA bone cement (Biomet Microfixation, Dordrecht, the Netherlands) to fix the prosthesis in primary stapedotomy cases where no satisfactory crimp was obtained.

## Materials and Methods

### Inclusion criteria

Patients with otosclerosis who underwent primary stapes surgery were included. During surgery, there needed to be an unsatisfactory crimp, i.e. a prosthesis which was not tightly fixed to the long process of the incus. All of these patients were operated because of

### Corresponding address:

Erwin Offeciers, MD, PhD  
University Department of Otorhinolaryngology and Head & Neck Surgery Sint Augustinus Hospital  
Oosterveldlaan 24, 2610 Wilrijk (Antwerp)  
Phone: +32 3 443 36 04 • Fax: +32 3 443 36 11  
E-mail: erwin.offeciers@gza.be

Copyright 2005 © The Mediterranean Society of Otolaryngology and Audiology

suspected otosclerosis, defined as a history of progressive unilateral or bilateral hearing loss, no history of trauma or chronic middle ear infection, a normal-appearing tympanic membrane, an ipsilateral negative Rinne tuning fork test, ipsilateral or bilateral conductive or mixed hearing loss on pure-tone audiometry with a significant air-bone gap (ABG), normal type A tympanogram and absent stapedial muscle's tendon reflexes.

#### *Exclusion criteria*

Revision cases e.g. due to partial or complete lysis of the long process of the incus were excluded, as well as patients with congenital fixation or stapes superstructure abnormalities (e.g. monopodal stapes or fracture).

#### *Surgical technique*

All procedures were performed under general anaesthesia via a transcanal approach using a Richard's orthostatic ear speculum. Local infiltration in the lateral part of the external auditory canal with xylocaine and epinephrine 1%. A Rosen incision is performed while producing an anteriorly-based tympanomeatal flap. The fibrous annulus is raised out of the bony sulcus at the notch of Rivinus. The middle ear is exposed until visualisation of the round window niche, incudostapedial joint, pyramidal eminence, horizontal segment of the facial nerve and stapes footplate is completed. The chorda tympani is preserved and displaced if necessary, while reducing the scutum with a curette. Malleus and incus are palpated for mobility. Stapes mobility is tested and fixation is confirmed. The incudostapedial joint is interrupted and the stapedial muscle's tendon is divided with microscissors or CO<sub>2</sub>-laser. The posterior crus of the stapes is removed using the CO<sub>2</sub>-laser or microdrill. Afterwards, the stapes is rotated along the axis of the anterior crus to minimize trauma to footplate. The distance between long process of the incus and stapes footplate is measured. Removal of the stapes superstructure. A calibrated small-hole fenestration is made (also known as stapedotomy or platinotomy) by using CO<sub>2</sub>-laser or microdrill. One surgeon breaks the anterior crus after having performed the stapedotomy. Positioning of the prosthesis in the fenestration hole and manual crimping of the 0.4-mm or 0.6-mm Teflon prosthesis around the long process of the incus. If unsatisfactory

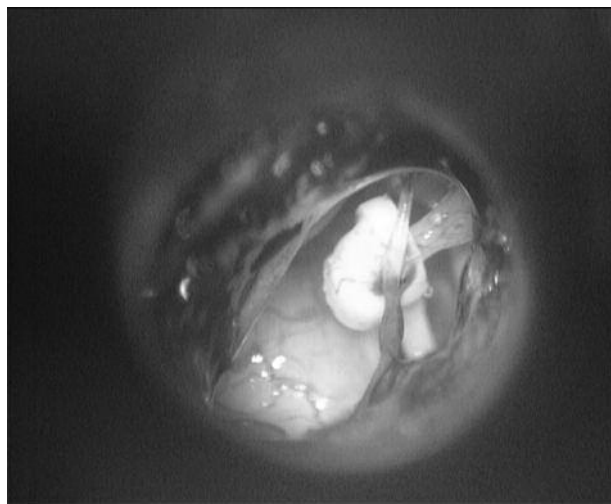
crimp was obtained, HA bone cement was applied. Fibrous strands and mucosa around the long process of the incus have to be removed prior to using the cement in order to have a bloodless, dry bony surface on which the cement adheres well. The HA bone cement paste is produced by reaction of the powder component (a HA based mixture of tetracalcium phosphate) with the liquid component (a dilute citric acid). Both components are mixed in equal amounts for 30-45 seconds until a homogenous mixture is formed. If a dough-like consistency has been achieved, the cement is transferred to the site of surgery with a Rosen needle or microhook. It is gently applied to the dry bone of the long process of the incus along the prosthesis attachment. Once the cement is well in place, one should not disturb the repair for <sup>[5-7]</sup> minutes to allow the paste to harden. If the cement is dissolved with blood, it is better to remove all the cement and do the application over again in dry circumstances. With a micropick one evaluates the hardness of the cement and once it has lost its sheen and acquired a ceramic hardness, one may test the effect of the reconstruction by delicate pressure on the malleus and observe the simultaneous movement of the prosthesis or round window membrane. <sup>[7]</sup> Repositioning of the chorda tympani and the tympanomeatal flap. Two synthetic sponges soaked in an antibiotic ointment are used to stabilize the flap. These sponges are removed 2 days after surgery.

#### *Patient characteristics and study design*

The procedures were performed by two surgeons (the two senior authors) in a tertiary-referral otologic and neurotologic center from March 2007 until February 2010. Data were gathered retrospectively on 23 consecutive patients. All patients had a fixed stapes. In 19 cases the CO<sub>2</sub>-laser was used to create the fenestration, the microdrill was used in 4 cases. <sup>[8]</sup>

In two (not included) cases where Mimix™ was used we observed a monopodal stapes. These two cases were classified as a congenital fixation and thus excluded. In one included case where HA bone cement was used, a revision procedure was performed 3 years afterwards due to lateralisation of the piston after trauma. The piece of HA bone cement was incorporated and vascularised by the incus (Figure 1). However, the prosthesis was luxated out of the platinotomy. The surgeon again used HA bone cement

to fix the prosthesis. The latest revision procedure was not included in order to avoid dependent cases in analysis. Another case was excluded because fracture of the stapes superstructure was observed during surgery, combined with fixation of the footplate. Hearing outcome of these four cases is reported separately.



**Figure 1.** Photograph taken during revision surgery of a patient with a lateralized piston after trauma. Transmeatal view in a left ear, chorda tympani lateral to a Teflon piston attached to the incus. The HA cement can be seen lateral and caudal to the Teflon piston at the end of the long process of the incus. Interestingly, the HA cement was vascularised and was still fixating the prosthesis adequately after it moved out of the stapedotomy due to trauma.

Historical controls were operated on in the period 1997 – 2003. This group includes patients where 0.4-mm and 0.6-mm Teflon prostheses are used. It consists of 301 consecutive patients reported earlier. Age varied from 7 years to 83 years (median 45 years). Overall hearing outcome in this series was similar to the results in previously reported Ear Audit data (short-term ABG closure rate within 10 dB of 73.5% and within 20 dB of 97.3%).<sup>[9]</sup>

#### *Outcome measures*

The preoperative audiometry was obtained no within 1 month before the surgery. Hearing outcome data were retrieved retrospectively at a fixed interval of 1-3 months (short-term) and 12 months (intermediate-term). Pre- and postoperative pure-tone averages (PTA) were calculated of 500 Hz, 1.000 Hz, 2.000 Hz and 3.000 Hz, as required by the guidelines on

conductive hearing loss by the Committee on Hearing and Equilibrium of the AAO-HNS.<sup>[10]</sup> Postoperative ABG was calculated as postoperative air conduction minus postoperative bone conduction. ABG closures within 10 dB and 20 dB are reported, as well as median postoperative ABG.

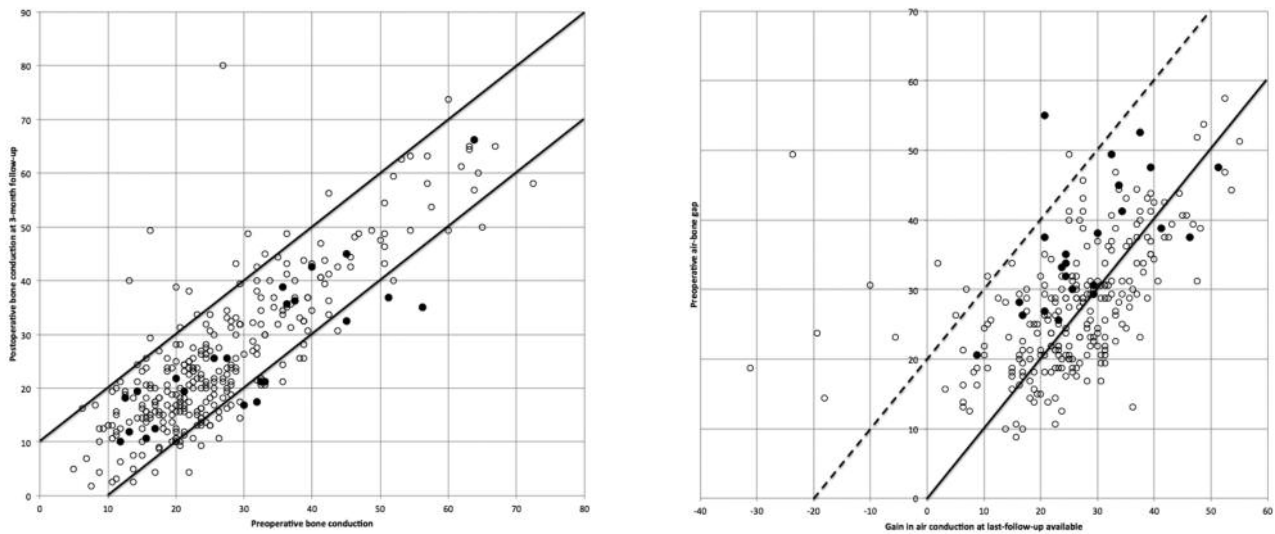
#### *Statistics*

A P value of 0.05 or less was considered as statistically significant. The Kolmogorov-Smirnov test was used to test for normal distribution, the Mann-Whitney U test was used to compare continuous variables in 2 non-parametric groups, the Pearson Chi-square test was used to compare stochastic variables in 2 non-parametric groups.

#### **Results**

Male-female ratio is approximately 2:5, including 9 male patients and 14 female patients. Age varied from 39 years to 79 years (median 53 years). Median short-term follow-up was 2.5 months. Median intermediate-term follow-up was 12 months (at last follow-up available). Hearing outcome is displayed in the Amsterdam Hearing Evaluation Plots (AHEP) in figure 2.<sup>[11, 12]</sup> Summarized hearing outcome of the study population (group A) and a group of historical controls with prospective inclusion (group B) is displayed in Table 1. Cases in group B were operated in a period when Mimix™ was not available to us and serve as our standard for comparison. Except for the additional use of HA cement, the surgical technique was identical. A 0.4-mm Teflon piston was used in 12 cases, while a 0.6-mm Teflon piston was used in the other 11 cases.

Age was distributed normally in both groups (Kolmogorov-Smirnov test). When comparing the results of group A and B, no statistically significant difference (SSD) was seen in preoperative BC and ABG (Mann-Whitney U test). When comparing the results of both surgeons, no SSD was seen in preoperative hearing and short-term and intermediate-term hearing outcome, which is to be expected as both surgeons use a similar surgical technique (Mann-Whitney U test). When comparing the results of group A and B, no SSD was present concerning short-term and intermediate-term AC gain and ABG closure to within 10 and 20 dB (Mann-Whitney U test, Pearson Chi-square test). In Table 2 we compare hearing



**Figure 2.** Audiometric results of stapes procedures visualized with the AHEPs. Empty circles are the 301 historical controls, circles with black filling are the 23 study patients. **A**, Preoperative BC plotted against postoperative BC at 3-month follow-up for each ear that underwent surgery. The 2 diagonal lines enclose the area within BC that did not change for more than 10 dB. **B**, Intermediate-term postoperative gain in AC plotted against the preoperative ABG for each ear that underwent surgery. The solid diagonal line indicates total closure of the gap between preoperative AC and preoperative BC. Every point below this line is defined as overclosure. An unsuccessful operation result with regard to AC is defined as a negative change in AC or a change in AC that was not enough to close the gap between postoperative AC and preoperative BC to 20 dB or less. This is indicated by the dotted diagonal line

**Table 1.** Preoperative, short-term and intermediate-term postoperative hearing outcome of the currently reported Mimix™ series and the historical control group.

dB	Mimix™	Historical controls
N	23	301
Median preoperative BC (range)	31.9 (11.9 – 63.8)	23.8 (14.4 – 72.5)
Median preoperative AC (range)	63.1 (36.3 – 118.8)	51.3 (25 – 107.5)
Median preoperative ABG (range)	35 (20.6 – 55)	26.3 (5 – 57.5)
Median postoperative BC 3mo (range)	21.8 (10 – 66.3)	21.9 (24.4 – 80)
Median postoperative AC 3mo (range)	34.4 (20 – 98.1)	27.5 (0 – 111.3)
Median postoperative ABG 3mo (range)	11.9 (3.1 – 31.9)	5.6 (-39.4 – 50)
ABG closure within 20 dB 3mo	91.3%	96.7%
ABG closure within 10 dB 3mo	43.5%	77.4%
BC increase over 15 dB 3 mo	0%	2.0%
Median postoperative BC LFU (range)	22.5 (10 – 67.5)	20 (1.9 – 80)
Median postoperative AC LFU (range)	33.1 (18.1 – 96.3)	25.6 (8.8 – 110)
Median postoperative ABG LFU (range)	10.6 (3.8 – 34.4)	4.4 (-18.8 – 38.8)
ABG closure within 20 dB LFU	91.3%	97.1%
ABG closure within 10 dB LFU	52.2%	82.7%

**PTA**, pure-tone average; **dB**, decibel; **BC**, bone conduction; **AC**, air conduction; **ABG**, air-bone gap; **3mo**, 3-month follow-up; **LFU**, last follow-up available.

**Table 2.** Short-term and intermediate-term postoperative hearing outcome of the currently reported Mimix™ series and the historical control group. A comparison between 0.4-mm and 0.6-mm is made.

	Mimix™		Historical controls	
Piston size	0.4	0.6	0.4	0.6
N	12	11	86	215
ABG closure within 20 dB 3mo	83.3%	100%	96.5%	96.7%
ABG closure within 10 dB 3mo	25%	63.6%	69.8%	80.5%
ABG closure within 20 dB LFU	83.3%	100%	93.3%	76.7%
ABG closure within 10 dB LFU	41.7%	63.6%	98.4%	84.7%

**PTA**, pure-tone average; **dB**, decibel; **BC**, bone conduction; **AC**, air conduction; **ABG**, air-bone gap; **3mo**, 3-month follow-up; **LFU**, last follow-up available.

outcome of the 0.4-mm versus the 0.6-mm piston. When comparing the results of the 0.4-mm and 0.6-mm pistons in group A and B there is a SSD present in short-term postoperative ABG (Mann-Whitney U test P value 0.035). This difference disappears in group A (Mann Whitney U test P value 0.218) and persists in group B (Mann Whitney U test P value 0.002) at intermediate-term.

If we take a closer look at the two cases in group A where an ABG closure within 20 dB could not be achieved at last follow-up available, we notice that in both cases a 0.4-mm piston was used. We observed one case with preoperative AC PTA of 94.4 dB where the ABG was closed to within 20 dB at 3-month follow-up (ABG PTA 16.3 dB), but the ABG increased to 25.7 dB at 12 months. In the other case, we observed a preoperative BC PTA of 63.8 dB and AC PTA of 118.8 dB (only at 500 Hz measurable threshold of 115 dB, others not measurable at 120 dB). The short-term postoperative BC PTA increased to 68.8 dB while the postoperative AC PTA improved to 98.3 dB (hearing gain of 20.5 dB). One year after the procedure the AC PTA has improved to 91.3 dB. Since the patient has a similar hearing loss on the contralateral side, and hearing aids are not providing a satisfying functional benefit, cochlear implantation has been suggested. If these two outliers would be excluded, short-term and intermediate-term ABG would not differ significantly between the 0.4-mm and 0.6-mm piston groups (Mann-Whitney U test P value 0.303 and 0.218 respectively).

The two excluded cases with a monopodal stapes had a preoperative ABG of 28.8 dB and 36.3 dB, and a

respective short-term ABG PTA of 16.3 dB and 12.5 dB. The revision case after lateralisation of the piston had a preoperative ABG of 46.3 dB and a short-term ABG PTA of 17.5 dB. The stapes fracture case had a preoperative ABG of 63.8 dB and a short-term ABG PTA of 25 dB.

We did not yet observe incus necrosis in this population up to the latest control. No adverse reactions or unsuspected BC increases were seen. No revision surgeries were performed on these patients because of ABG increase of unknown etiology.

## Discussion

The current report further elaborates the suggestion of Goebel and Jacob <sup>[7]</sup> that HA bone cement can be used in the difficult primary stapedotomy. They reported on hearing outcome of one patient who had a preoperative ABG of 14 dB, which improved to a postoperative ABG of 9 dB. <sup>[7]</sup> The rationale for using HA bone cement is to allow single-unit movement of the incus-prosthesis interface. Our study provides the first consecutive series of 23 difficult primary stapedotomies, which were assisted by HA bone cement to improve prosthesis crimping around the long process of the incus.

The ABG closure rate to within 10 dB was definitely worse than the historical control group. However, if the two outliers reported in the results section are excluded, a 100% ABG closure to within 20 dB is obtained. If we compare hearing outcome between the 0.4-mm and 0.6-mm piston in the HA bone cement group, there is a statistically significant difference between the two groups in short-term ABG closure



within 20 dB and 10 dB favouring the 0.6-mm piston group. A few possible explanations can be considered. Because preoperative hearing was similar in both groups, the difference could be related to an intraoperative variable acting as a contaminating factor. First, the 0.4-mm piston is used in situations where the anatomical condition is less advantageous for placing a 0.6-mm piston, i.e. overhanging facial nerve, narrow oval window, etc. The other explanation is based on the physical properties of the prosthesis-vestibulum interface. Since the acoustic effect of stapedotomy is proportional to the volume displacement generated by the piston, the 0.4-mm prosthesis requires a larger movement amplitude and therefore is more prone to limitation by minimal residual fixation of the ossicular chain.<sup>[14]</sup> We have to acknowledge that a 0.4-mm piston was used in the two outliers reported in the results section. These two cases are responsible for the statistically significant difference and might act as confounders.

A similar study has been conducted earlier by Tysome and Harcourt using glass-ionomeric cement to avoid loose wire attachment in a non-selected population of surgically treated otosclerosis patients.<sup>[13]</sup> They reported an ABG closure within 10 dB of 77% and within 20 dB of 92% using a PTA of 0.5, 1, 2 and 4 kHz. This PTA is not recommended by the Committee guidelines on evaluation of conductive hearing loss<sup>[10]</sup>, and unfortunately not comparable to our report.

One revision case has shown that the HA bone cement is firmly attached and vascularised to the incus and prosthesis even after more than 3 years, while withstanding trauma resulting in lateralisation of the prosthesis. Interestingly, the HA cement was vascularised and was still fixating the prosthesis adequately after it moved out of the stapedotomy due to trauma.

There are definite limitations to this study, predominantly because of possible selection bias (niche population of cases with a slender long process). Other limitations of this study include the relatively small sample size of 23 patients in a period of about 3 years, which is explained by the inclusion of a subgroup with difficult crimping. The distribution of 0.4-mm versus 0.6-mm in the HA bone cement group (n=12 versus n=11 respectively) also differed from the control population (n=86 versus n=215 respectively),

which might underestimate our overall outcome in ABG closure. In this report, we have studied short-term and intermediate-term hearing outcome, but long-term hearing results are still to be studied and reported. However, it can be quite difficult to achieve a sound study design. Direct comparison or randomisation is difficult because these prostheses were difficult to crimp successfully in the first place.

There are several options for further study. One option can be to analyze all primary procedures and compare the overall hearing outcome between the current period, including this cohort, and a historic consecutive sample from a period where HA bone cement was not yet used. Due to sample size issues this is not a relevant solution, as reported before.<sup>[15]</sup> The most correct option seems to be randomisation between the use of HA cement, a Nitinol or aWengen clip piston. However, crimping problems caused by a slender long process of the incus and the choice of the best solution to the problem, remain a challenging issue.

The authors believe that using Mimix™ is feasible in cases where crimping is difficult and the prosthesis is not firmly attached to the incus, since there are few alternatives and a loose-piston syndrome should definitely be avoided. It provides a satisfactory hearing outcome with 100% ABG closure within 20 dB in the difficult cases where a 0.6-mm piston was used.

## **Conclusion**

In surgically treated otosclerosis patients where troublesome prosthesis crimping is experienced, the additional fixation of the piston using HA bone cement can provide a clinically significant hearing gain in the technically challenging cases to avoid a loose-wire syndrome. However, it does not provide a similar hearing outcome when compared to patients where the crimping act is performed without difficulties.

## **References**

1. Marquet J. Le syndrome de surdité due à une déficience de la prothese stapédienne. Soc Fr ORL CR Sci Congr. 1965; 86:151-160.
2. Shea JJ, Jr. The teflon piston operation for otosclerosis. Laryngoscope. 1963; 73:508-509.
3. Huber AM, Veraguth D, Schmid S, Roth T, Eiber A. Tight stapes prosthesis fixation leads to better functional results in otosclerosis surgery. Otol Neurotol. 2008; 29:893-899.

4. Huber AM, Ma F, Felix H, Linder T. Stapes prosthesis attachment: the effect of crimping on sound transfer in otosclerosis surgery. *Laryngoscope*. 2003; 113:853-858.
5. Rajan GP, Atlas MD, Subramaniam K, Eikelboom RH. Eliminating the limitations of manual crimping in stapes surgery? A preliminary trial with the shape memory Nitinol stapes piston. *Laryngoscope*. 2005; 115:366-369.
6. Fayad JN, Semaan MT, Meier JC, House JW. Hearing Results Using the SMart Piston Prosthesis. *Otol Neurotol*. 2009; 30:1122-1127.
7. Goebel JA, Jacob A. Use of Mimix hydroxyapatite bone cement for difficult ossicular reconstruction. *Otolaryngol Head Neck Surg*. 2005; 132:727-734.
8. Somers T, Vercruysse JP, Zarowski A, Verstreken M, Offeciers E. Stapedotomy with microdrill or carbon dioxide laser: influence on inner ear function. *Ann Otol Rhinol Laryngol*. 2006; 115:880-885; discussion 886.
9. Van Rompaey V, Yung M, Claes J, et al. Prospective Effectiveness of Stapes Surgery for Otosclerosis in a Multicenter Audit Setting: Feasibility of the Common Otology Database as a Benchmark Database. *Otol Neurotol*. 2009; 30:1101-1110.
10. Foundation AAoO-HaNS. Committee on Hearing and Equilibrium guidelines for the evaluation of results of treatment of conductive hearing loss. *Otolaryngol Head Neck Surg*. 1995; 113:186-187.
11. de Bruijn AJ, Tange RA, Dreschler WA. Efficacy of evaluation of audiometric results after stapes surgery in otosclerosis. II. A method for reporting results from individual cases. *Otolaryngol Head Neck Surg*. 2001; 124:84-89.
12. de Bruijn AJ, Tange RA, Dreschler WA. Efficacy of evaluation of audiometric results after stapes surgery in otosclerosis. I. The effects of using different audiologic parameters and criteria on success rates. *Otolaryngol Head Neck Surg*. 2001; 124:76-83.
13. Tysome JR, Harcourt J. How we do it: ionomeric cement to attach the stapes prosthesis to the long process of the incus. *Clin Otolaryngol*. 2005; 30:458-460.
14. Huttenbrink KB. Biomechanics of stapesplasty: a review. *Otol Neurotol*. 2003; 24:548-557; discussion 557-549.
15. Van Rompaey V, Van de Heyning P, Yung M. Response to "Riechelmann H, Tholen M, Keck T, Rettinger G. Perioperative glucocorticoid treatment does not influence early post-laser stapedotomy hearing thresholds. *Am j otol* 2000;21:809-812". *Otol Neurotol*. 2010; 31:177-178.