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#### **Main Article**

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# Improvement of hearing results by bone cement fixation in endoscopic stapedotomy

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#### Abstract

**Objective.** This study aimed to compare the hearing results of two different stapedotomy techniques used in the clinic at different time points.

**Methods.** An endoscopic surgery group (group 1; n = 37) were compared retrospectively with a microscopic surgery group (group 2; n = 57). A small fenestra and Teflon piston technique were used in all patients. Bone cement was used for fixation between the prosthesis and incus in the endoscopic group only. Bone conduction threshold and air–bone gap were used as the comparison parameters.

**Results.** The pre-operative air-bone gap was 31.26 dB in group 1 and 32.51 dB in group 2. The post-operative air-bone gap was 8.93 dB in group 1 and 14.28 dB in group 2. There was a significant difference between the groups in post-operative air-bone gaps. There was no significant difference between the groups in post-operative bone conduction thresholds. **Conclusion.** The endoscopic technique using bone cement fixation was better for closing the air-bone gap.

#### Introduction

One of the main causes of conductive hearing loss is otosclerosis. The clinical prevalence is 0.3–0.4 per cent; in addition, otosclerosis was found in 3.4 per cent of cadaveric temporal bones histologically. Stapedotomy is a well-known treatment option for otosclerosis. This operation primarily aims to improve the conductive hearing loss, while preserving the bone conduction threshold.

Traditionally, stapedotomy is conducted under a microscopic view, with a trainee watching through a side ocular (a co-observation tube that enables a second person to see the surgical field). The image quality and angle are generally different for the surgeon and trainee because of the binocular setting of the microscope. Endoscopic middle-ear surgery was introduced into our daily practice a few decades ago.<sup>2</sup> In this technique, the surgeon and trainee view the same image. There is no difference in image quality, angle or dimension.

Different trainees and surgeons (experienced or inexperienced) perform stapes surgery in our clinic. The trainees change every year, while the surgeons become more experienced. Before 2013, everyone at the clinic used microscopes, but after a short transition period in 2013, we adopted endoscopic visualisation for stapes surgery. We now also include a fixation material in our surgical technique. This study aimed to compare the hearing results of two different time periods, in which different visualisation techniques and bone cement fixation or no fixation were used in stapedotomy.

#### Materials and methods

We analysed the hearing results of stapedotomies performed for otosclerosis between 2010 and 2015. Three surgeons and three trainees conducted the stapedotomies. The surgeons were permanent, but the trainees changed every year. Only one of the surgeons was specialised in otology. Every trainee performed a stapedotomy operation during the last year of the five-year curriculum, after gaining experience on standard otological operations.

Patients who had undergone stapedotomy with stable results at follow up (at least one year post-operatively) were included in this retrospective study. Those undergoing revision operations were not included. All patients had signed an informed consent form regarding the procedure. The study protocol was approved by the university committee on human research.

Group 1 (37 patients) was operated on under an endoscopic view and group 2 (57 patients) was operated on under a microscopic view. We used a Zeiss S8 operation microscope with a side ocular (co-observation tube) (Carl Zeiss, Oberkochen, Germany), and a Karl Storz (Tuttlingen, Germany) high-definition endoscopic system, with a 4-mm diameter, 18-cm length, 0-degree endoscope. The same surgical technique was used for all patients, but some received additional fixation (see below).

# Surgical technique

The operations were performed under general anaesthesia. The ear canal was injected with lidocaine 1 per cent with 1:100 000 adrenaline. The tympanomeatal flap was elevated using a Rosen incision. The mobility of ossicles were controlled. After confirmation of stapes fixation, the scutum was removed by curettes until the oval window was fully visualised. If needed, the chorda tympani nerve was mobilised. The stapedial tendon was then cut, the incudostapedial joint was separated and the stapes crura were removed. The distance between the stapes footplate and incus was measured using a measuring rod. A small fenestra was opened on the stapes footplate by manual perforators, and a Teflon prosthesis was placed gently. We used a 0.4-mm diameter Teflon piston prosthesis in all patients. We did not use any sealing material on the footplate around the prosthesis. Bone cement (Ketac Cem Easy Mix; 3M ESPE, Starnberg, Germany) was used for fixation between the prosthesis and incus in the endoscopic group only (Figure 1).

# **Audiograms**

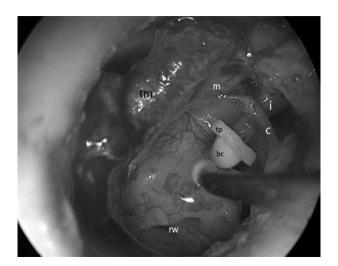
Standard pure tone audiograms were performed before, and at 3 and 12 months after the operation. The mean air and bone conduction thresholds at 0.5, 1, 2 and 3 kHz were calculated. Pure tone averages and air–bone gaps were compared in accordance with the American Academy of Otolaryngology – Head and Neck Surgery guidelines.<sup>3</sup> Success rate was classified into four groups according to the post-operative air–bone gap (0–10 dB, 10–15 dB, 15–20 dB and more than 20 dB). Post-operative bone conduction levels were also classified into groups (decreases of 0–5 dB, 5–10 dB and more than 10 dB).

### Statistical analysis

Parametric variables were compared using *t*-tests, and non-parametric variables were compared with the Mann–Whitney U test. The PASW\* (SPSS, version 18) program was used for statistical analysis.

# **Results**

Group 1 (endoscopic group) had 37 patients and group 2 (microscopic group) had 57 patients. Group 1 had 25 females



**Fig. 1.** Bone cement fixation technique in endoscopic stapedotomy. tm = tympanomeatal flap; m = malleus; i = incus; tp = Teflon piston; c = chorda tympani; bc = bone cement; rw = round window

TABLE I. PRE- AND POST-OPERATIVE AIR-BONE GAPS AND BONE CONDUCTION THRESHOLDS

Parameter	Group (mean ± SD)		р
	1 (endoscopic)	2 (microscopic)	
Pre-op ABG	31.26 ± 7.88	32.51 ± 8.88	>0.05
Post-op ABG	8.93 ± 8.03	14.28 ± 10.66	<0.05
Pre-op bone conduction	23.07 ± 7.6	25.29 ± 12.17	>0.05
Post-op bone conduction	21.18 ± 9.01	26.43 ± 16.73	>0.05

SD = standard deviation; pre-op = pre-operative; ABG = air-bone gap; post-op = post-operative

TABLE II. SUCCESS RATE ACCORDING TO POST-OPERATIVE AIR-BONE GAP

Post-op ABG	Group ( <i>n</i> (%))	Group (n (%))		
	1 (endoscopic)	2 (microscopic)		
<10 dB	29 (78.3)	26 (45.6)		
<15 dB	32 (86.4)	40 (70.2)		
15-20 dB	2 (5)	6 (10.5)		
>20 dB	3 (8)	11 (19.2)		

There was a significant difference between groups 1 and 2 in post-operative (post-op) airbone gap (ABG) closure (p < 0.01).

**TABLE III.** SUCCESS RATE ACCORDING TO POST-OPERATIVE BONE CONDUCTION THRESHOLD

Post-op bone conduction threshold	Group (n (%))		
	1 (endoscopic)	2 (microscopic)	
Improvement	23 (62.2)	33 (57.8)	
Decline of 0-5 dB	11 (29.7)	10 (17.5)	
Decline of 5–10 dB	0 (0)	7 (12.2)	
Decline of >10 dB	3 (8)	7 (12.2)	

There was no difference between groups 1 and 2 in post-operative (post-op) bone conduction threshold ( p > 0.05).

and 12 males (average age, 42.2 years), and group 2 had 35 females and 22 males (average age, 43.8 years).

The pre-operative air–bone gap was 31.3 dB in group 1 and 32.5 dB in group 2 (p > 0.05). The post-operative air–bone gap was 8.9 dB in group 1 and 14.3 dB in group 2 (p < 0.05) (Table I). The between-group differences in post-operative air–bone gap closures classified as less than 10 dB or less than 15 dB indicated that the endoscopic approach was better than the microscopic approach (p < 0.01) (Table II). When we compared the post-operative bone conduction thresholds, there was no significant difference between the techniques (p > 0.05) (Table III).

The number of operations conducted by trainees (group 1 = 5, group 2 = 6) was not sufficient for a meaningful comparison of results between experienced and inexperienced individuals; however, the numbers were equally distributed between groups, so the general results are not affected.

### **Discussion**

Stapedotomy is a delicate operation; it requires continuous attention and detailed knowledge. The ENT residents usually

carry out this operation in our clinic at the end of their training. They assist their mentor during operations in the earlier years of residency. After a long watch-and-learn period, the trainees conduct stapedotomies by themselves, under the observation of an experienced surgeon.

- Stapedotomy can be performed either under endoscopic or microscopic vision
- In this study, bone cement fixation was used in the endoscopic technique only
- The endoscopic technique was better at closing the air-bone gap
- Both techniques were equal in preserving the bone conduction hearing level
- The better results of endoscopic stapedotomy were probably due to bone cement
- There are insufficient data to conclude about the effect of visualisation

Until 2013, we used a microscope for this procedure, but after 2013 we started to use endoscopes. This change in practice improved the transfer of knowledge for the residents and the other surgeons who were not specialised in otology. We observed that the operating theatre staff were more focused when endoscopic ear surgery was in progress, compared with microscopic surgery. Iannella *et al.* compared endoscopic and microscopic stapedotomy by questioning the residents on middle-ear anatomy, the surgical steps employed and their personal opinions. The authors reported that endoscopic identification was better, especially around the stapes.<sup>4</sup>

In a recent review, an air-bone gap closure of less than 10 dB varied between 59 and 96 per cent according to the technique and surgeons.<sup>5</sup> The articles in the review mostly represented the results of experienced surgeons. Our endoscopic stapedotomy result (78.3 per cent) was above the average, even though we had surgeons of different experience levels. However, the microscopic stapedotomy result (45.6 per cent) was below the rate reported in the literature. If we take an air-bone gap closure of less than 15 dB as the success criterion, then the success rate was 86.4 per cent for endoscopic surgery and 70.2 per cent for microscopic surgery. Surmelioglu et al. reported no difference between the hearing results of endoscopic and microscopic stapedotomy operations, but they did not classify patients according to an airbone gap closure of less than 10 dB.6 Kojima et al. reported similar results for endoscopic surgery (86.7 per cent) with a less than 10 dB criterion; they reported a lower success rate for microscopic surgery (78 per cent).

In a meta-analysis, Laske *et al.* found that an air-bone gap closure of less than 10 dB was more likely for 0.6 mm pistons than for 0.4 mm pistons.<sup>8</sup> They reported an average success rate of 81.1 per cent for the 0.6 mm piston and 75.1 per cent for the 0.4 mm piston. We used a 0.4 mm Teflon piston, with a 78.3 per cent success rate for endoscopic stapedotomy. The 0.6 mm pistons had a wider and more rigid connection with the incus. The bone cement may compensate for this factor.

Many different ossiculoplasty and stapes surgery techniques using bone cement have been reported. It is common to use bone cement in the case of incus long process erosion in stapes

surgery. Rompaey *et al.* also used bone cement in stapedotomy for overcoming crimping problems. They found that using bone cement overcame the crimping problem, but the results were not as good as those of a historical control group of patients who had not had this problem. We have not encountered any problems associated with the use of bone cement during surgery or follow up. Our results were better in the bone cement group also.

We believe that endoscopic surgery is better for trainees, because everyone in the operating theatre is focused on the monitor, as when watching an exciting football match. The trainees follow every move of the surgeon carefully. However, the number of operations conducted by trainees (group 1=5, group 2=6) was not sufficient for a meaningful comparison of experienced and inexperienced individuals. The numbers were equally distributed between groups, so the general results would not have been affected.

Using animal models for endoscopic stapedotomy is another good alternative for training. Cordero *et al.* proposed ovine for this model.<sup>11</sup>

In our setting, the endoscopic technique was better at closing the air-bone gap. Both the endoscopic and microscopic techniques were equal in preserving the bone conduction hearing level. The better results of endoscopic stapedotomy might be due to improved visualisation of the surgical field or the use of bone cement for fixation.

Competing interests. None declared.

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