#### ORIGINAL PAPER

# Revision stapes surgery for recurrent transmissional hearing loss after stapedectomy and stapedotomy for otosclerosis

# Chirurgia di revisione dopo stapedectomia e stapedotomia per otosclerosi

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#### Kev words

Otosclerosis • Stapedectomy • Stapedotomy • Revision surgery

#### Parole chiave

Otosclerosi • Stapedectomia • Stapedotomia • Chirurgia di revisione

## Summary

A total of 20 stapedotomy and 24 stapedectomy cases were retrospectively reviewed to establish the causes of failure, and to evaluate hearing results after revision surgery. Our series included 23 male and 21 female patients. Mean age at revision time was 42 years, and the mean interval from primary surgery and revision stapes surgery was 27 months. The retrospective review of our data, revealed that the most common cause for revision surgery was a displaced prosthesis (47.7%). After revision surgery, the mean post-operative air-bone gap was 14.78 dB. A mean post-operative air-bone gap within 10 dB occurred in 24 patients (54.5%), in 14 patients (31.5%) this was between 11 and 20 dB, in 5 patients (11.5%) between 21 and 30 dB, and in one patient (2.5%) > 30 dB. There were no "dead ears" in this series. Our results compare to other reported series, and confirm that after revision stape surgery, an air-bone gap closure within 10 dB is difficult to obtain. In the present series, the use of the total ossicular replacement prosthesis resulted in the poorest functional hearing results.

# Riassunto

È stata eseguita un'analisi retrospettiva su 20 interventi di revisione di stapedotomia e 24 di stapedectomia al fine di stabilire le cause del fallimento e di valutare i risultati funzionali ottenuti. Il gruppo comprende 23 pazienti di sesso maschile e 21 femminile. L'età media all'atto della revisione è stata di 42 anni e il periodo medio intercorso tra la chirurgia primaria e la chirurgia di revisione è stato di 27 mesi. L'analisi retrospettiva dei dati dimostra che la più comune causa di revisione è stata il dislocamento della protesi (47,7%). Dopo l'intervento di revisione, il valore medio dell'air-bone gap post-operatorio è stato di 14,78 dB. Il valore medio dell'air-bone gap post-operatorio entro i 10 db è stato ottenuto in 24 pazienti (54,5%), in 14 pazienti (31,5%) è stato compreso tra 11 e 20 dB, in 5 pazienti (11,5%) tra 21 e 30 dB, e in un paziente è stato superiore ai 30 dB. Nei nostri pazienti non si sono verificate perdite neurosensoriali gravi. I nostri risultati, confrontati con quelli ottenuti in altri studi, confermano la difficoltà nel raggiungimento di un air-bone gap post-operatorio entro 10 dB dopo chirurgia di revisione. Nel presente studio, l'uso del TORP è risultato gravato da risultati funzionali uditivi insoddisfacenti.

# Introduction

Since the stapes mobilization technique, proposed by Rosen<sup>1</sup>, and the fenestration of the oval window, proposed by Shea in 1958<sup>2</sup>, surgery for otosclerosis has undergone constant improvement aimed at standardizing a technique which was leading to a decrease in failures. There are no reliable indications to plan a large fenestra procedure or a small fenestra procedure, however, the surgeon's own experience, the anatomy and extent of the otosclerotic focus found

during surgery, can play a great decisional role in favour of one of the aforementioned procedures.

Functional results and incidence of failure, after large fenestra and small fenestra procedures, have often been compared, and there can be no doubt that both stapedectomy and stapedotomy procedures, even when performed with meticulous care, are burdened by an unpredictable failure rate which includes recurrent transmissional hearing loss <sup>3-15</sup>.

The most common cause of recurrent transmissional hearing loss, after stapes surgery, is prosthesis displacement or malfunction, while fibrous adhesion or oval window obliteration, due to otosclerosis, occur less frequently <sup>3 4 6 8-10 16-26</sup>.

This retrospective study was carried out on 1265 patients who underwent stapes surgery for otosclerosis performed by the same Senior surgeon, at the Department of Surgical Sciences and Organ Transplantations, Section of Otorhinolaryngology, University of Cagliari, Italy, from January 1986 to December 1998. Of these patients, 44 submitted to revision stapes surgery, for recurrent transmissional hearing loss, were studied.

Herein, the primary procedures, the causes of failure and the revision techniques are described. Long-term functional evaluation, according to the parameters recommended by the Committee on Hearing and Equilibrium <sup>27</sup>, are also reported.

## Material and methods

The present study was carried out on 44 surgical patients submitted to revision stapes surgery at the Department of Surgical Sciences and Organ Transplantations, Section of Otorhinolaryngology, University of Cagliari, Italy, between January 1986 and December 1998.

This series of 44 patients (23 male, 21 female) underwent surgical revision after stapedectomy or stapedotomy. Mean age at revision was 42 years (range 18-72). Of these patients, 10 were  $\leq$  30 years, 20 were 31-50 years old and 14 were > 50 years. A total of 43 patients underwent a single revision while 1 patient was submitted to a second revision.

Revision stapes surgery was performed in 20 patients after stapedotomy, in 19 patients after total stapedec-

tomy, and in 5 patients after partial stapedectomy, as primary treatment.

The indication for revision surgery was a reported recurrent hearing loss by the patient and a conductive hearing loss of at least 20 dB in the speech frequencies (500 to 2000 Hz), mean pre-operative airbone gap of 32.15 dB.

The mean interval between primary surgery and revision surgery was 27 months. In 73.9% of the patients, revision was performed within 3 years of primary surgery. Follow-up time, after revision surgery, ranged from 12 months to 11 years. Mean post-operative follow-up time was 35 months. Clinical history and intraoperative findings were examined to define causes of failure (Table I). Audiological evaluation has been performed according to the guidelines of the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology - Head and Neck Surgery 27, based on the assessment of the following parameters: postrevision air-bone gap, as the difference between mean air conduction threshold, and mean bone-conduction at frequences of 0.5-1-2 and 3 KHz (Table II); air-bone gap closure, as the difference between pre-revision airbone gap and post-revision air-bone gap at frequences of 0.5-1-2 and 3 KHz (Table III); modification after revision surgery of bone-conduction for high tones, as the difference between mean pre-operative bone-conduction and mean post-operative bone-conduction at frequencies of 1-2 and 4 KHz.

In addition, the post-revision air-conduction threshold has been evaluated at frequences of 0.5-1-2 and 3 KHz, and compared to the pre-revision value <sup>28</sup>.

Aim of the investigation was to establish the main causes for revision stapes surgery according to the initial technique and to make a functional post-revision evaluation.

Table I. Intra-operative findings.					
Finding	Primary stapedectomy (n = 24)	Primary stapedotomy (n = 20)	Total	%	
Dislocated prosthesis	12	9	21	47.7	
Incus long process erosion	7	1	8	18.2	
Incus long process fracture	2	1	3	6.8	
Incus long process disengaged prosthesis	1	4	5	11.35	
Total (proximal and distal) dislocation	2	3	5	11.35	
Fibrous adhesions	5	5	10	22.7	
Footplate hole obliteration	1	5	6	13.6	
Short prosthesis	3	0	3	6.8	
Reduced prosthesis sliding	1	1	2	4.6	
Incudomalleal joint fixation	2	0	2	4.6	
Total	24	20	44	100	

**Table II.** Mean, standard deviation and range of post-operative air-bone gap for all revisions and for stapedectomy and stapedotomy clusters.

	Mean post-operative		
	ABG	SD	Range
All revisions	14.78 dB	± 10.36 dB	0-41.25
Stapedectomy	16.12 dB	± 11.09 dB	0-41.25
Stapedotomy	12.44 dB	± 8.41 dB	0-23.75

**Table III.** Mean, standard deviation and range of air-bone gap closure (difference between pre- and post-operative ABG) for all revisions and for stapedectomy and stapedotomy clusters.

	Mean ABG closure	SD	Range	
All revisions	15.93 dB	± 11.95 dB	- 3.75-53.75	
Stapedectomy	14.93 dB	± 13.45 dB	- 4.5-53.75	
Stapedotomy	16.86 dB	± 10.75 dB	0-38.75	

#### TECHNIQUE OF REVISION SURGERY

The revision procedure was performed under local anaesthesia (Bupivacaine 0.5% with Epinephrine 1/200000) by an endoaural approach. The transmeatal incision was repeated under magnification using a Zeiss<sup>©</sup> (Zeiss, Göttingen, Germany) microscope with a 250 mm focusing lens. A total of 39 patients were submitted to incus stapedotomy revision when normal mobility and the continuity between incus and malleus were intra-operatively demonstrated. When necessary, a new prosthesis was introduced, fibrous adhesions resected by microscissors or CO. laser and a new hole in the neomembrane at the oval window performed with cold instruments. In cases of fibrous adhesions, a Sharplan 1030 carbon dioxide laser with an Acuspot 712 micromanipulator (Sharplan, Tel Aviv, Israel) set on the superpulse mode (2 watts, 0.1 sec. in a repeated single shot, 270 micron spot size) was used. A new piston-teflon prosthesis was inserted in 34 patients, in 5 patients a new trapeze platinum prosthesis was necessary.

Five patients originally submitted to primary stapedectomy, underwent malleostapedotomy with total ossicular replacement prosthesis (TORP) on account of subtotal erosion or fixation of the incus. This option was performed in the first 7 years of the series.

#### INTRA-OPERATIVE FINDINGS

The most common cause for revision surgery was displaced prosthesis in 21 out of the 44 patients (47.7%). In this group, the long process resorption or fracture was seen in 11 out of the 21 patients

(52.3%), and it was the most frequent cause of displacement. In 5 patients (11.35%), the prosthesis was displaced at the incus long process, in another 5 patients (11.35%) it was displaced both at the incus and oval window without any long process resorption or fracture. In 2 cases in this group, the patients reported having suffered head trauma.

Fibrous adhesions were considered the cause of failure in 10 out of 44 patients (22.7%).

In 6 patients (13.6%), 5 previously submitted to stapedotomy and one to posterior stapedectomy, footplate hole obliteration (partial obliteration in 2 cases and total obliteration in 4 cases) was observed during middle ear re-exploration.

In 3 patients (6.8%), the prosthesis was too short and, in another 2 cases (4.6%), it did not slide through the footplate hole without a clear hole re-obliteration. In the last 2 patients (4.6%), incudomalleal joint fixation was demonstrated.

The type of prostheses retrieved after primary surgery is reported in the Table IV. No statistically significant correlation was found (p = 0.86 and p = 1.12), at the Mann-Whitney test, between the two most frequent prostheses found at the time of revision surgery (platinum trapeze and wire Teflon piston), and the two main types of complications (displaced prosthesis for the long process resorption or fracture and fibrous adhesions, respectively).

## HEARING RESULTS

Follow-up time after revision surgery ranged from 12 months to 11 years. Mean post-operative follow-up was 35 months (SD  $\pm$  18 months).

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Table IV. Tv	Je ot	brostneses	reurieved	arter	primary	Surgery	/ ([] = 44).

	Platinum teflon piston	Platinum trapeze	Wire teflon piston
Stapedectomy	20	4	-
Stapedotomy	19	-	1

In this group of 44 patients, including revisions both after primary stapedectomy and stapedotomy, the mean post-operative air-bone gap was 14.78 dB (SD  $\pm$  10.36 dB) (Table II). A mean post-operative air-bone gap within 10 dB was found in 24 patients (54.5%), in 14 patients (31.5%), this was between 11 and 20 dB, in 5 patients (11.5%) between 21 and 30 dB while in one patient (2.5%), it was greater than 30 dB. In the same group, mean air-bone gap closure was 15.93 dB (SD  $\pm$  11.95 dB) (Table III). Variation of bone-conduction, for high tones (1, 2 and 4 KHz), was 1.05 dB (SD  $\pm$  10.25dB).

In the group of patients who underwent primary stapedectomy, mean post-operative air-bone gap was  $16.12 \text{ dB (SD} \pm 11.09 \text{ dB)}$  (Table II). A mean post-operative air-bone gap within 10 dB was found in 11 patients (45.7%), in 10 patients (41.6%) it was between 11 and 20 dB, in 2 patients (8.5%) between 21 and 30 dB and in one patient (4.2%) > 30 dB. Mean air-bone gap closure was  $14.93 \text{ dB (SD} \pm 13.45 \text{ dB)}$  (Table III). Variation of bone conduction for high tones was  $1.75 \text{ dB (SD} \pm 9.85 \text{ dB)}$ .

In the group of patients originally submitted to stapedotomy (20 cases), mean post-operative air-bone gap was 12.44 dB (SD  $\pm$  8.41 dB) (Table II). A mean post-operative air-bone gap within 10 dB occurred in 13 patients (65%), in 4 patients (20%) it was between 11 and 20 dB, in 3 patients (15%) between 21 and 30 dB. An air-bone gap > 30 dB did not occur in any of these patients. Mean air-bone gap closure was 16.86 dB (SD  $\pm$  10.75 dB) (Table III). Variation of bone conduction for high tones was 0.85 dB (SD  $\pm$  11.75 dB).

We also calculated the mean air conduction gain at 0.5, 1, 2 and 3 KHz, which was 18.56 dB (SD  $\pm 13.95 \text{ dB}$ ) in patients who underwent stapedectomy and 19.86 dB in patients who underwent stapedotomy (SD  $\pm 15.65 \text{ dB}$ ).

A significant sensorineural hearing loss occurred in 1 patient in the group that underwent stapedectomy revision.

# Discussion

Partial or total displacement of the prosthesis is considered the most frequent cause of delayed trasmis-

sional hearing loss after primary stapes surgery, the incidence ranging from 24.4% to 82% of revised cases 4 16-26 29 30. In our experience, displacement of the prosthesis was also found as the most frequent cause of failure (47.7%). It was mainly correlated with erosion (8 patients) or fracture (3 patients) of the incus long apophysis. Devascularization and erosion of the bone, above the lenticular process, may be due to the wear and tear movements of the prosthesis. Necrosis and erosion of the incudal long process probably occur also as the result of devascularization of the distal area where the prosthesis exerts a constant weight on the mucosa. Indeed, the blood supply to the bone of the long process of the incus that originates from the incudal artery, a branch of the anterior tympanic artery, prevalently enters from the mucosal network <sup>31</sup>. In our series, damage of the long process of the incus was more frequent in stapedectomy, as shown in 9 out of the 24 patients (37.5%). While of the 20 patients who underwent revision, after stapedotomy, only 2 cases of resorption/necrosis (10%) were found. This difference could hypothetically be attributed to the possibly higher movements of the hook of the prosthesis, after complete removal of the footplate, with secondary damage to the mucosa of the incus. Out of 10 patients, the prosthesis was unhooked from the incus long process in 5 cases, wherease in 5 cases the prosthesis was displaced both at the incus and the oval window. In 2 patients, displacement of the prosthesis was correlated with a traumatic event, as confirmed from anamnestic records.

The presence of fibrous adhesions (10 cases) was the second most common cause of revision surgery, in the present series (22.7%). The incidence of fibrosis has been reported to range from 2% to 37.5% of revised cases 3 4 8 16 20-23 26 32. The exact aetiopathogenesis of fibrosis, following stapes surgery, remains to be fully elucidated. Fibrosis may result from a postoperative inflammatory process or excessive mucosal damage during primary surgery 4. It can also occur as the result of a foreign-body reaction to materials that the prosthesis is made of. In some cases, this reaction can cause prosthesis dislocation or, more rarely, extrusion 21. Fibrous adhesion can involve the prosthesis, ossicles or may cover the oval window. In our series, fibrosis showed no particular relation with the stapedectomy or stapedotomy procedures, since

its incidence is equally distributed in the two groups of patients. On the basis of the primary intra-operative findings, we observed that excessive bleeding was frequently reported to occur in the primary procedure (7/10). This condition could negatively influence the exposure of the oval window, sometimes with excessive damage to the surrounding mucosa. In the remaining 3 cases, no causes were described and an excessive inflammatory foreign body reaction could not be excluded. In these cases, the use of the  $\mathrm{CO}_2$  laser, coupled with an Acuspot of 270 microns, appeared extremely useful to simply resect the fibrous adhesions without bleeding and with minimum manipulation of the endotympanic structures.

In 5 patients previously submitted to stapedotomy and 1 patient to posterior stapedectomy, total (4 cases) or partial (2 cases) obliteration of the footplate hole occurred. Obliteration was due to bony regrowth. Some Authors have reported this event, with an incidence ranging from 1.9% to 16% of cases <sup>4 17 19-26</sup>. In 2 patients (4.6%) who previously underwent stapedotomy and posterior stapedectomy, respectively, the prosthesis did not slide correctly through the footplate hole.

In all these patients, a new hole was reproduced, in the same area, by manual perforators or by drilling with a diamond burr 0.6 mm.

In 3 patients (6.8%) who previously underwent stapedectomy, the prosthesis was too short. This condition is usually accompanied by a lateralized oval neomembrane. In this situation, it has been suggested that to avoid a possible sensorineural hearing loss, the lateralized neomembrane should not be relocated in the vestibule, but that a hole should be made in the posterior third of the neomembrane  $^4$ . In our experience, we did not observe any sensorineural hearing loss and the problem was overcome by just relocating a new longer prosthesis, with a post-revision mean air-bone gap of 10 dB (SD  $\pm$  5.44 dB).

In the group including both stapedectomy and stapedotomy revisions (n = 44), the mean post-operative

air-bone gap was 14.78 dB. A mean post-operative air-bone gap within 10 dB occurred in 24 patients (54.5%), in 14 patients (31.5%) it was between 11 and 20 dB, in 5 patients (11.5%) between 21 and 30 dB and in one patient (2.5%), it was greater than 30 dB.

Functional results in the present series are comparable to those of others, in which the mean post-operative air-bone gap is approximately 10 dB in 39% to 80.4% of the revised series <sup>16-18</sup> <sup>20-23</sup> <sup>25</sup> <sup>26</sup>. However, revision surgery was less successful than primary surgery as shown by the functional results obtained in a previous study on 714 stapes primary procedures performed in our Department <sup>33</sup>. The mean post-operative air-bone gap, after 3 years, was within 10 dB in 86% of cases, between 11 and 20 dB in 10% of cases and between 21 and 30 dB in 4% of cases.

The most untoward functional results, in the present series, occurred in the group of patients with TORP. We found a statistically significant difference in the post-revision results, between the total ossicular replacement group and non (p 0.042). On the basis of data emerging from the present series, we are strongly of the opinion that the malleostapedotomy, proposed by Fisch et al. <sup>19</sup>, is a better alternative to the use of TORP, in this category of patients.

## **Conclusions**

Although primary stapes surgery provides excellent functional results, in a very large percentage of cases, transmissional hearing loss can persist or may recur in a small number of patients. In our experience, revision surgery after stapedectomy or stapedotomy allows good hearing results, but not as good as those achieved by primary surgery, while there is no statistically significant difference in functional results between the two groups. In the present series, the use of the TORP was related to the least effective functional hearing results.

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