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Main Article

Role of stapes surgery in improving hearing loss caused by otosclerosis

M R Marchese, G Paludetti, E De Corso, F Cianfrone

Abstract

The aim of our study was to evaluate the functional results of stapes surgery and to compare the effectiveness of small fenestra stapedotomy with that of total stapedectomy in improving hearing in patients affected by otosclerosis.

Three hundred and fifty-seven consecutive ears, in 265 patients affected by otosclerosis, underwent surgery. All cases underwent either primary small fenestra stapedotomy (group A, 196/357, 54.91 per cent) or stapedectomy (group B, 161/357, 45.09 per cent). After surgery, 256/357 (71.71 per cent) cases showed a 0–20 dB gap. There were no significant differences in hearing results between the two groups at either early or late post-operative assessment. The mean post-operative pure tone average and air–bone gap results were slightly greater for group B than for group A, at both early and late post-operative assessments, but these differences were not statistically significant. Therefore, in group A, the mean pure tone average at 4 kHz significantly improved, from 56.60 to 47.66 dB at early post-operative assessment and to 52.98 dB at late post-operative assessment.

Our study suggests that the technique of microtomy of the oval window is able to improve hearing results especially at high frequencies.

Key words: Otologic Surgical Procedures; Stapes Surgery; Otosclerosis; Outcome Assessment

Introduction

Since the introduction of stapes surgery more than 40 years ago,[1] surgery for the correction of hearing loss caused by otosclerosis has quickly evolved, especially in recent years.[2] From the design and material used for the prosthesis, to the introduction of microdrills and lasers, new innovations have enabled progressive improvement in hearing results and reduction in complications (especially inner-ear damage).

In spite of the variety of procedures used, the main objectives of otosclerosis surgery are the removal of disease and the restoration of good hearing function, along with minimising the risk of irreversible complications. Currently, there are many different stapedectomy methods available. The choice of which technique is still a point of discussion in the international literature.

An exhaustive review of literature on otosclerosis surgery revealed fluctuating trends in its treatment–from total extraction of the footplate (so-called stapedectomy) to a small perforation in the footplate centre (stapedotomy, widely performed in recent years).

Creation of a hole in the centre of the footplate, just large enough for insertion of a piston, is less likely to induce iatrogenic inner-ear lesions than removal of the whole footplate, and it results in a more effective acoustic mechanical transmission.[3,4]

Furthermore, technological advances (including use of lasers to create the stapedotomy) hold the hope of causing less damage to the inner ear.[5]

Neverthless, the choice of technique should depend on the experience and comfort level of the surgeon.[6] Indeed, the experience of the surgeon may be more important than technical or technological innovations in determining the success of stapes surgery.[7]

The aim of our retrospective study was to evaluate functional results after stapes surgery and to compare the effectiveness of small fenestra stapedotomy with that of total stapedectomy in improving hearing in patients with conductive hearing loss due to otosclerosis.

Methods

From January 1996 to January 2004, 410 consecutive ears in 265 patients affected by otosclerosis were operated upon in the department of otorhinolaryngology of the Sacred Heart Catholic University,

From the Institute of Otorhinolaryngology, Policlinico 'A Gemelli', Università Cattolica del Sacro Cuore, Rome, Italy.
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Rome. Of these 410 ears, 357 cases (in 228 of the 265 patients) with complete clinical, surgical and functional data were enrolled for this retrospective study.

A total of 236/357 procedures (66.90 per cent) were performed on women and 118/357 (33.10 per cent) on men. Patients' age at surgery ranged from 20 to 71 years, with an average of 42.48 years.

The diagnosis of otosclerosis was based on a clinical history of progressive hearing loss, normal otoscopic findings, an audiogram showing a mean conductive hearing loss >20 dB in the range of 0.5 to 3–4 kHz, and the absence of the cochleo-stapedial reflexes. For patients in whom both ears met inclusion criteria, each ear was treated separately for analytical purposes.

All cases underwent primary stapedectomy or small fenestra stapedotomy. Ears were divided into two groups, group A and group B; these included 196/357 (45.09 per cent) cases undergoing stapedotomy and 161/357 (54.91 per cent) undergoing stapedectomy, respectively. Between 1996 and 1999, the majority of patients underwent stapedectomy. Subsequently, the main surgical procedure was the small fenestra technique (Figure 1).

Demographic data are summarised in Table I. There were no significant differences between the two groups with regard to sex, side or age.

Audiograms were obtained a minimum of 48 hours pre-operatively. Functional results were recorded for the first time within six days after surgery. The long-term results given here are based on the latest available audiogram, obtained after a mean of 26 months (minimum 12 months, maximum 36 months).

Audiological evaluation was carried out using the tonal audiometric test, according to the guidelines of the committee on hearing and equilibrium of the American Academy of Otolaryngology-Head and Neck Surgery.[8] The pure tone average (PTA) was calculated as the mean of 0.5, 1, 2 and 3 kHz thresholds. In cases in which the 3 kHz threshold was not obtained, PTA thresholds were calculated from 0.5, 1, 2 and 4 kHz. The air–bone gap (ABG) was calculated from the air and bone conduction thresholds determined in each study. Post-operative hearing gain was calculated from the pre-operative ABG and the follow-up examination. A high

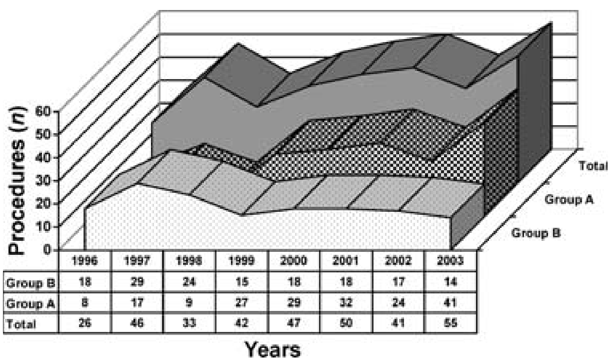

FIG. 1

Annual incidence of stapedotomy (group A) and stapedectomy (group B).

TABLE I

DEMOGRAPHIC DATA

	Total ears*		Group A ears†		Group B ears‡	
	n	%	*n*	%	*n*	%
Sex						
Women	239	66.90	126	64.30	113	70.20
Men	118	33.10	70	35.70	48	29.80
Side						
Right	172	48.17	91	46.40	81	50.30
Left	185	51.83	105	53.60	80	49.70
Case type						
Bilateral	258	72.20	137	69.90	121	75.10
Unilateral	99	27.80	59	30.10	40	24.90
Age (years)	40.34 ± 10.32		41.24 ± 10.45		42.48 ± 11.60	

*$n = 357$; †$n = 196$ (54.91%); ‡$n = 161$ (45.09%)

frequency PTA of 1, 2 and 4 kHz was calculated from the pre- and post-operative bone conduction thresholds in order to evaluate sensorineural hearing loss.

Statistical analysis of the results was performed with the Student *t*-test and chi-square tests. Significance was set at $p < 0.05$.

Surgical technique

Surgery was generally performed under local anaesthesia with adequate pre-operative sedation (339/357, 94.95 per cent). In a few cases (18/357, 5.05 per cent), general anaesthesia was used at the patient's request.

The standard approach was transcanal via an ear speculum. A posterior tympanomeatal flap was elevated, the chorda tympani was cut only in 29/357 cases (8.12 per cent), and the crural arch fractured and removed. The footplate was perforated with either a hand drill (312/357, 87.40 per cent), a motor-driven drill in cases of thick bone (15/357, 4.20 per cent) or an erbium:yttrium aluminium garnet laser (30/357, 8.40 per cent) in cases of floating footplates. The aim was to perform a narrow perforation (about 0.6 mm). Accidentally, in cases of fracture or a floating footplate, posterior half fenestration (123/161, 76.39 per cent), anterior platinectomy (11/161, 6.84 per cent) and subtotal stapedectomy (27/161, 16.77 per cent) were performed. All footplates were reconstructed with a Schuknecht Teflon wire piston. A 0.6 mm diameter piston was used in group B and in 156/196 (79.60 per cent) cases in group A, and a 0.4 mm width prosthesis was used in the remaining 40/196 (20.40 per cent) cases in group A. After stapedectomy, the oval window was sealed with blood coagula or Gelfoam. Finally, the tympanomeatal flap was replaced.

All stapedotomies were performed by one otologist and all stapedectomies by another, experienced otologist.

Results

The pre-operative air conduction PTA obtained for the 357 cases was 57.16 dB. After surgery, the early

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air conduction PTA was 43.13 dB ($p < 0.05$) and the late air conduction PTA reached 42.74 dB ($p < 0.05$) (Table II).

The mean pre-operative ABG was 30.04 dB. This fell to 16.19 dB within six days of operation and to 15.36 dB after one year (i.e. improvements of 13.85 and 14.68 dB, respectively) (Table II).

The bone conduction threshold was unchanged or improved in 319/357 (89.36 per cent) cases. However, a deterioration of more than 10 dB was observed in 10/357 (2.80 per cent).

Figure 2 shows cases' pre- and post-operative ABGs, divided into categories of 0–20, 21–40 and >40 dB. Before surgery, we observed ABGs of 0–20 dB in 34/357 (9.53 per cent) cases, of 21–40 dB in 288/357 (80.67 per cent) and of >40 dB in 35/357 (9.8 per cent). After surgery, we observed an ABG of 0–20 dB in 256/357 (71.71 per cent) cases, of 21–40 dB in 100/357 (28.01 per cent) and of >40 dB in 1/357 (0.28 per cent).

The PTA and ABG results for groups A and B are shown in Table III. There were no significant differences in the early and late post-operative PTA results between the two groups. The mean PTA and ABG results from both the early and late post-operative assessments were slightly greater for group B than group A, but these differences were not statistically significant.

The hearing gain recorded after surgery, at both the early and late assessments, did not indicate a statistically significant difference between groups A and B. Therefore, both groups showed a slight change in ABG during the interval between the early and post-operative assessments. This indicates that both procedures provided satisfactory long-term results and that these results can be considered stable from the immediate post-operative period.

Hearing results were also compared for each frequency. In group A, the mean value of the averaged pure tone threshold at 4 kHz significantly improved from 56.60 dB pre-operatively to 47.66 dB at early post-operative assessment and 52.98 dB at late post-operative assessment. However, in group B, subjects' hearing at 4 kHz changed from 55.18 dB pre-operatively to 54.12 dB at early post-operative assessment and 59.30 dB at late post-operative assessment ($p > 0.05$). After stapedotomy (i.e. group A), early post-operative assessment showed a significant ABG decrease, from 24.44 to 12.68 dB, a gain of 11.76 dB. For the same group, late post-operative assessment showed an ABG of 15.84 dB, a positive gain of 8.6 dB ($p < 0.05$). Finally, for group A, both early and late post-operative PTA and ABG

TABLE II

FUNCTIONAL RESULTS FOR ALL CASES*

Time	AC-PTA			ABG		
	dB	SD	*p*	dB	SD	*p*
Pre-op	57.16	12.22		30.04	7.97	
T1	43.13	15.31	<0.05[†]	16.19	7.63	<0.05**
T2	42.74	13.25	<0.05[‡]	15.36	7.29	<0.05[§]

*$n = 357$. [†]Pre-operative (pre-op) air conduction pure tone average (AC-PTA) *vs* early post-operative AC-PTA. [‡]Pre-operative AC-PTA *vs* late post-operative AC-PTA. **Pre-operative air–bone gap (ABG) *vs* early post-operative ABG. [§]Pre-operative ABG *vs* late post-operative ABG. SD = standard deviation; T1 = early post-operative (within 6 days); T2 = late post-operative (after a mean of 26 months)

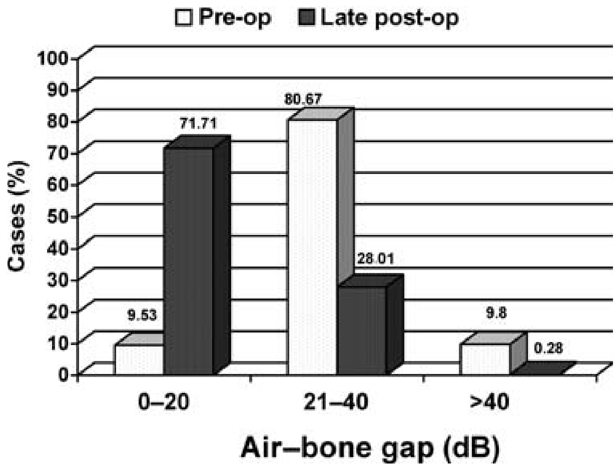

FIG. 2

Pre-operative (pre-op) and late post-operative (late post-op) air–bone gaps.

TABLE III

FUNCTIONAL RESULTS FOR GROUPS A* AND B[†]

	Group A (mean ± SD)	Group B (mean ± SD)	*p*
AC-PTA (dB HL)			
Pre-op	56.33 ± 11.56	57.80 ± 12.72	NS
T1	42.15 ± 15.98	43.87 ± 14.82	NS
T2	41.97 ± 13.52	43.28 ± 13.16	NS
ABG (dB HL)			
Pre-op	30.79 ± 8.64	29.47 ± 7.41	NS
T1	14.73 ± 7.05	15.79 ± 7.48	NS
T2	15.75 ± 8.29	16.52 ± 7.11	NS
Gain (dB HL)			
Pre-op – T1	16.42	14.59	NS
Pre-op – T2	15.04	12.95	NS
AC-PTA at 4 kHz (dB HL)			
Pre-op	56.60	55.18	NS
T1	47.66	54.12	<0.05
T2	52.98	59.30	<0.05
ABG at 4 KHz (dB HL)			
Pre-op	22.15	24.44	NS
T1	12.68	21.04	<0.05
T2	15.84	23.04	<0.05
ΔBC (dB HL)			
Pre-op – T1	3.52 ± 5.67	3.81 ± 6.32	NS
Pre-op – T2	3.83 ± 4.39	3.46 ± 5.76	NS
ΔBC (% of ears)			
Unchanged	93.36	90.68	NS
Worsened >10 dB	3.64	5.32	NS

*$n = 196/357$; [†]$n = 161/357$. SD = standard deviation; AC-PTA = air conduction pure tone average; pre-op = pre-operative; T1 = first post-operative assessment (within 6 days); T2 = last post-operative assessment (after mean of 26 months); ABG = air–bone gap; gain = post-operative hearing gain (calculated from pre- and post-operative ABG results); ΔBC = change in bone conduction; NS = not significant ($p > 0.05$)

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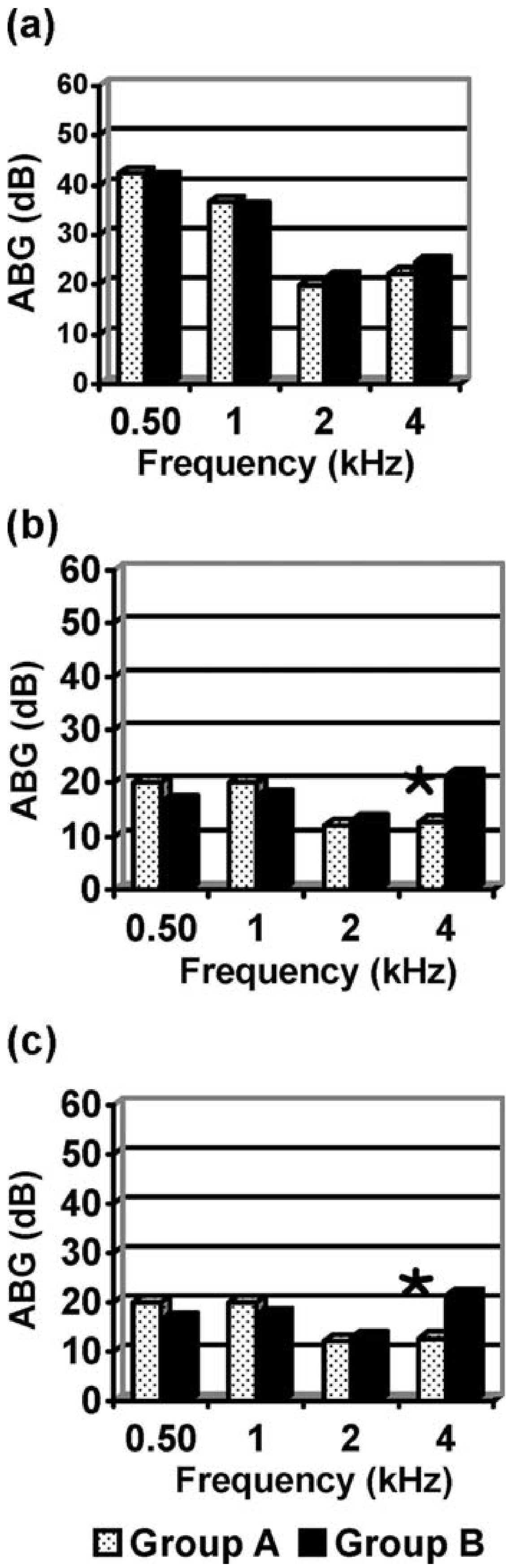

FIG. 3

(a) Pre-operative air–bone gap (ABG) at 0.5, 1, 2 and 4 kHz. (b) Early post-operative ABG at 0.5, 1, 2 and 4 kHz. (c) Late post-operative ABG at 0.5, 1, 2 and 4 kHz. *$p < 0.05$.

results at 4 kHz were lower ($p < 0.05$) compared with group B results (Table III and Figure 3).

Before surgery, an ABG of 0–20 dB was recorded in 22/196 (11.22 per cent) of group A cases and in 12/161 (7.46 per cent) of group B cases (Figure 4). Furthermore, a pre-operative ABG of 21–40 dB was seen in 157/196 (80.11 per cent) of group A cases and in 127/161 (78.88 per cent) of group B cases. After surgery, an ABG of 0–20 dB was recorded in 140/196 (71.42 per cent) of group A cases (stapedotomy) and in 118/161 (73.3 per cent) of group B cases (stapedectomy) (Figure 5). Thus, the incidence of patients with a 0–20 dB ABG increased significantly ($p < 0.05$) in each group, comparing pre- to post-operative results. However, there was not a statistically significant difference between the two groups in this respect ($p > 0.05$).

The percentage of patients with either unchanged or improved sensorineural hearing was 93.36 per cent (183/196) in group A and 90.68 per cent (146/161) in group B ($p > 0.05$). The incidence of patients with a >10 dB worsening of sensorineural hearing was slightly greater in group B than group A (5.32 *vs* 3.64 per cent, respectively) (Table III).

Discussion

Since the introduction of stapes surgery more than 40 years ago, many studies have demonstrated its success in improving hearing in patients affected by otosclerosis.

However, there is currently animated discussion about the details of surgery. The controversy over which technique – stapedectomy or small fenestra stapedotomy – is safer and more effective in the treatment of hearing loss due to otosclerosis centres around three issues: effectiveness in improving hearing, complication rate and stability of long-term hearing improvement.

In our study, we evaluated the surgical and functional results of otosclerosis surgery, comparing data for ears undergoing stapedectomy (large fenestra) and stapedotomy (small fenestra). The

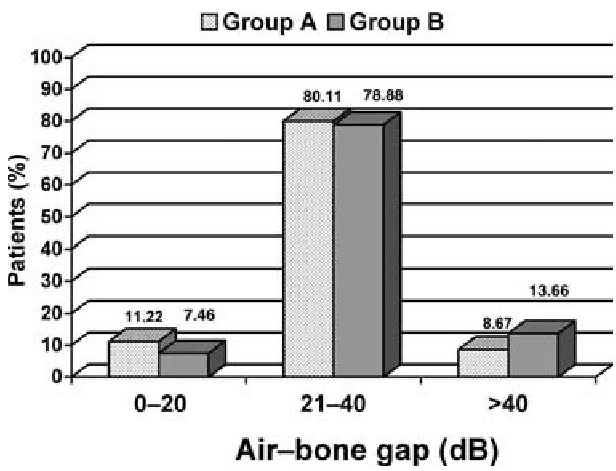

FIG. 4

Pre-operative air–bone gaps in groups A (stapedotomy) and B (stapedectomy).

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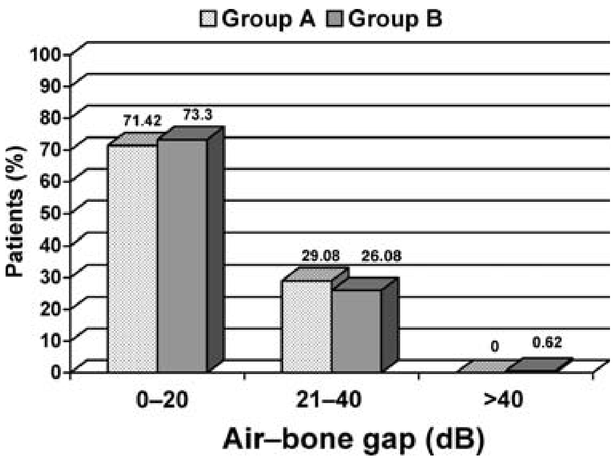

FIG. 5

Late post-operative air–bone gaps in groups A (stapedotomy) and B (stapedectomy).

audiological assessments were performed pre-operatively, soon after surgery and one or more years after surgery, according to the American Academy of Otolaryngology-Head and Neck Surgery guidelines.[8]

These results should be cautiously compared with those of other studies, because of the methodological differences in analysis.

In all cases, the air conduction PTA and ABG results, from both early and late post-operative assessments, showed significant improvement compared with pre-operative values. Moreover, the late post-operative air conduction PTA and ABG results were respectively only 0.39 and 0.83 dB less than the early post-operative results ($p > 0.05$). These data suggest the long-term stability of our post-surgical hearing results. A hearing gain with a residual ABG of <20 dB was achieved in 71.71 per cent of cases. This success rate is somewhat lower than that reported by authors who calculated the post-operative ABG by subtracting the pre-operative bone conduction threshold from the post-operative air conduction threshold.[9–13] However, this latter approach fails to take into account the Carhart effect, leading to an overestimation of ABG closure.[14] Our results should be compared with (and are similar to) those reported by authors using the same evaluation criteria.[15]

In spite of the various results published in the literature, the chief role of surgery in the treatment of otosclerosis is unanimously accepted. Our study confirmed the previously published finding that stapes surgery is successful in improving hearing loss caused by otosclerosis.

However, there are many different methods used to perform stapedectomy, and the choice of technique is still a matter of discussion in the international literature.

In recent years, stapedotomy has become popular and is increasingly replacing stapedectomy.[16–20] Several reports have examined the functional results of the two procedures, with contrasting findings. Some authors found no significant difference between the two techniques.[18,21] Others, however, concluded that stapedotomy was more effective in closing the air–bone gap, especially at higher frequencies.[17,22,23]

In our experience, the mean thresholds and the short- and long-term post-operative hearing results were better in the stapedotomy group than in the stapedectomy group, but this difference was not statistically significant. Similar data were obtained by House *et al.*[6] However, they described better results for ABG at 4 KHz in stapedotomy cases but found no difference for PTA. In our series, post-operative results for both PTA and ABG at 4 KHz were statistically significantly improved in the stapedotomy group compared with the stapedectomy group.

Moreover, the mean post-operative bone conduction threshold was improved by as much as 3 dB in both groups. These improvements in bone conduction thresholds for both the small and the large fenestra approaches seemed to be stable over time. They may be attributed to the elimination of the mechanical effects of otosclerosis on bone conduction, known as Carhart's effect. Another series found even greater improvements in bone conduction.[24] Therefore, our results are similar to those reported by authors using the same evaluation criteria.[25]

The prevalence of significant sensorineural hearing loss (>10 dB) was less in group A, but the difference between the two groups was not statistically significant.

- **The aim of this retrospective study was to evaluate functional results after stapes surgery and to compare the effectiveness of small fenestra stapedotomy with total stapedectomy in improving conductive hearing loss due to otosclerosis**
- **Three hundred and fifty-seven consecutive otosclerotic ears underwent surgery. All cases underwent primary small fenestra stapedotomy or total stapedectomy**
- **Results suggest that the technique of microtomy of the oval window is able to improve hearing, especially in the high frequency region**

The results obtained following early and late post-operative evaluation of small fenestra and large fenestra procedures compare favourably. There appears to be no deleterious effects of either procedure on cochlear reserve.

This retrospective study supports the opinion of authors[18,26,27] who advocate small fenestra stapes surgery in order to improve hearing results, particularly in the high frequency region.

Nowadays the technical evolution of stapes surgery continues employing the less traumatic and more conservative technique of laser surgery.[28] The goal remains the same: greater functional improvements with fewer complications.

Finally, given the effectiveness and long-term stability of both stapedectomy and stapedotomy, the decision of which technique to perform should depend on the experience and comfort level of the surgeon.

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Address for correspondence:
Dr Maria Raffaella Marchese,
Institute of Otorhinolaryngology,
Policilinico Universitario 'A Gemelli',
Università Cattolica del Sacro Cuore,
Largo Gemelli n 8,
00168 Rome,
Italy.

Fax: +39 6 3051194
E-mail: raffaellamarchese@yahoo.it

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