Stapedotomy: analysis of factors affecting functional prognosis

Original Article

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Abstract

Objectives: To evaluate the success rate of stapedotomy and investigate the influence of prognostic factors on hearing outcomes.
Materials and Methods: A retrospective study of 157 ears that underwent primary stapedotomy between 2001 and 2022. Patient- and procedure-related factors that influenced postoperative hearing thresholds were analyzed. The diameter of the Teflon prosthesis used (0,4 mm – 68 ears; 0,6 mm – 89 ears) and pre- and postoperative audiometric data were analyzed. Surgical success was defined as a postoperative air-bone gap (ABG) ≤ 10 dB HL.
Results: Surgical success was achieved in 64% of operated ears. Significant improvements in air conduction thresholds and ABG were observed, with an average hearing gain of 18,67 ± 10,8 dB HL. Comparison of the 0,6 mm- and 0,4 mm-groups, revealed no differences (p>0,05) regarding improvements in AC-PTA (21,11 vs. 18,71 dB), BC-PTA (2,40 vs. 0,29 dB) and ABG-PTA (118,71 vs. 18,62 dB). Surgical success was similar between the two types of prostheses, being slightly higher with the larger diameter prosthesis (66,3% vs. 61,8%). Multivariate analysis of prognostic factors identified preoperative ABG (p = 0,042) and patient age (p = 0,045) as independent predictors of less surgical success (95% CI). Variables such as gender, the presence of preoperative tinnitus or vertigo did not independently and significantly influence surgical success (p > 0,05).
Conclusions: Stapedotomy is a procedure with good functional outcomes. Prosthesis diameter does not influence surgical outcomes. Preoperative ABG > 30 dB HL and age < 50 years seem to be factors that influence surgical success. Gender, the presence of preoperative tinnitus or vertigo, do not appear to influence the success of the procedure.
Keywords: Otosclerosis; Stapedotomy; Stapes surgery; Prosthesis diameter; Functional success

Introduction

Otosclerosis is a primary osteodystrophy of the otic capsule, characterized by increased bone remodeling activity within remnants of the embryonic otic capsule. Multiple foci of bone remodeling at varying stages of activity may be present in the same ear. The location and extent of these lesions determine the possible symptoms, which are characterized by conductive or mixed hearing loss. In approximately 90% of the cases, the fissula ante fenestram is involved, resulting in stapes fixation and consequent conductive hearing loss.[1] Tinnitus and vertigo are also frequently reported symptoms.[2–5] Otosclerosis affects women twice as often as men and has a prevalence of 0.3–0.4% in the White population.[6] Stapedectomy, introduced by Shea in 1956, entails partial or total removal of the stapes footplate. However, this surgical approach has been progressively replaced by stapedotomy, in which a prosthesis is inserted through a small fenestra created in the stapes footplate.[7–9] Compared with stapedectomy, stapedotomy is associated with superior hearing outcomes, particularly at higher frequencies,[10] and a lower incidence of sensorineural hearing loss secondary to inner ear trauma.[6,7,10–13] In general, stapes surgery is considered a safe and effective procedure, with favorable hearing outcomes and low complication rates. Reported success rates in the literature range from 62% to 94%.[12–16] However, data on long-term hearing outcomes are limited, and it remains uncertain which patient subgroups would benefit the most from this procedure.[1] Although stapedotomy is widely recognized as the standard surgical treatment for otosclerosis, debate persists regarding the optimal prosthesis diameter, typically ranging from 0.4 to 0.6 mm.[8,9] Some studies have suggested that larger-diameter prostheses improve hearing outcomes,[16] whereas others have favored smaller-diameter prostheses due to the reduced risk of cochlear trauma.[13] This study aimed to evaluate the functional outcome of stapedotomy and to identify the potential predictors of surgical success.

Materials and methods

This retrospective study reviewed the medical records of patients who underwent primary stapedotomy between January 2001 and December 2022. A total of 119 patients were included, among whom 38 underwent bilateral surgery. For statistical purposes, each ear was analyzed independently. All patients were referred for exploratory tympanotomy based on a presumptive diagnosis of otosclerosis, characterized by progressive hearing loss and normal otoscopic findings. Audiological evaluation demonstrated conductive or mixed hearing loss and absence of stapedial reflexes. The exclusion criteria were previous stapedectomy or revision stapedotomy, lack of audiometric data, or follow-up period shorter than 12 months. The participants underwent primary stapedotomy via a transcanal approach under general anesthesia with orotracheal intubation. Stapes fixation and malleus and incus mobility were systematically assessed. Curettage of the posteroinferior wall of the external auditory canal was performed until the stapes, oval window, facial nerve, and pyramidal eminence were fully exposed. The incudostapedial joint was disarticulated, and the stapedial tendon and posterior crus were sectioned using micro scissors. The anterior crus was then carefully fractured, and the stapes superstructure removed. Subsequently, fenestration of the stapes footplate was performed using a manual microdrill. A Causse Teflon prosthesis was used in all ears, with the diameter (0.4 or 0.6 mm) chosen at the surgeon's discretion. A smaller prosthesis was preferred in cases with a prominent facial nerve or narrow oval window niche. Pure-tone audiometry was conducted preoperatively and repeated at 6 and 12 months postoperatively. Values obtained at 12 months were used for the analysis. The mean threshold level (MTL) for bone conduction (BC) and air conduction (AC) was calculated as the mean of the thresholds at 0.5, 1, 2, and 4 kHz. The air-bone gap (ABG) was calculated using the same frequencies. Hearing gain (HG) was defined as the difference between the pre- and postoperative ABG. The recommendations of the American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) Committee on Hearing and Equilibrium[17] were followed for evaluating the results and managing conductive hearing loss. Due to the unavailability of 3 kHz data, thresholds at 4 kHz were used instead.[12]

Demographic, clinical, surgical, and audiological data were collected. The evaluated parameters included age, sex, affected side, presence of tinnitus or vertigo, family history of otosclerosis, prosthesis diameter, and audiometric outcomes. Audiometric outcomes comprised pre- and postoperative AC, BC thresholds, ABG, and preoperative stapedius reflexes. Participants were divided into two groups according to prosthesis diameter: group A (0.4 mm) and group B (0.6 mm).

Surgical success was defined as a postoperative ABG 10 dB, in accordance with the AAO-HNS guidelines. However, as the literature often recommends a cutoff value of 20 dB for postoperative ABG, two analysis groups were created based on the postoperative ABG: ≤10 dB and ≤20 dB. Functional hearing was defined as postoperative MTL-AC ≤30 dB.

Categorical variables are described as absolute numbers and percentages, while audiometric data are expressed as means and standard deviations. Statistical analysis was performed using the IBM SPSS® software version 27.0. Categorical variables were compared using the chi-square test and results ware expressed with 95% confidence intervals. Pre- and postoperative auditory thresholds (MTL-AC, MTL-BC, and MTL-ABG) were compared using paired Student's t-tests. Independent t-tests were used to compare outcomes between groups. Significance level was set at 5% ($p < 0.05$). Multivariate logistic regression was used to evaluate the predictive value of the variables of age, sex, preoperative MTL-ABG, and presence of tinnitus or vertigo for surgical success (defined as postoperative MTL-ABG ≤ 10 dB).

Results

Descriptive analysis

This retrospective study included 157 patients, comprising 123 women (78%) and 34 men (22%). Most patients were aged ≤50 years (range 24–65 years), with a mean of 45.8 ± 8.6 years. Bilateral otosclerosis was diagnosed in 98 patients (62%), and among them, 38 underwent bilateral surgery. The descriptive characteristics and preoperative audiometric parameters of the patients are presented in Table 1 .

Audiological assessment

Preoperative audiometry

The mean preoperative MTL-AC and MTL-BC were 56.23 ±11.8 and 26.10 ±8.5 dB, respectively. The mean ABG was 30.13 ± 7.7 dB. Functional hearing (MTL-AC ≤30 dB) was present in only two patients (1.3%) before surgery. Pre- and postoperative audiometric results are shown in Table 2.

Table 1
Descriptive analysis of the study population (n = 157)

Sex	Male	34 (21,7%)
	Female	123 (78,3%)
Age	≤ 50 years	103 (65,6%)
	> 50 years	54 (34,4%)
Bilateral otosclerosis	Yes	98 (62,4%)
	No	59 (37,6%)
Side	Left	67 (42,7%)
	Right	90 (57,3%)
Family history	Yes	24 (15,3%)
	No	20 (12,7%)
	Unknown	113 (72,0%)
Preoperative tinnitus	Yes	67 (42,7%)
	No	90 (57,3%)
Preoperative vertigo	Yes	18 (11,5%)
	No	139 (88,5%)
Preoperative MTL-AC	≤ 30 dB	2 (1,3%)
	> 30 dB	155 (98,7%)

Abbreviation: MTL-AC, mean threshold level-air conduction

Table 2
Pre- and postoperative audiometric results

	Hearing threshold, mean (SD), dB			p*
	Preoperative	Postoperative	Hearing gain	
AC				
MTL	56,23 (11,8)	36,09 (15,1)	20,14 (13,5)	**<0,001**
Condução óssea				
BC	26,10 (8,5)	24,63 (12,9)	1,47 (9,6)	0,428
ABG				
MTL	30,13 (7,7)	11,46 (6,6)	18,67 (10,8)	**<0,001**

Abbreviations: SD, standard deviation; AC, air conduction; BC, bone conduction; ABG, air-bone gap; MTL, mean threshold level (0.5–4 kHz). Statistically significant values ($p < 0.05$) are in bold.

Postoperative audiometry

Postoperatively, the mean MTL-AC improved to 36.09 15.1 dB, representing a HG of 20.14 ± 13.5 dB ($p < 0.001$). Functional hearing was achieved in 88 patients (56.1%), indicating a statistically significant increase compared to the preoperative condition ($p < 0.001$, McNemar's test). Postoperative endpoints are described in Table 3. The postoperative MTL-BC was 24.63 ± 12.9 dB, indicating a non-significant improvement of 1.47 ± 9.6 dB ($p = 0.428$). The mean postoperative ABG was 11.46 ± 6.6 dB, corresponding to a mean HG of 18.67 dB ($p < 0.001$). Surgical success, defined as ABG ≤ 10 dB, was achieved in 101 ears (64.3%). A residual ABG gain of up to 20 dB was observed in 136 patients (86.6%), with 35 patients (22.3%) exhibiting a gain between 10–20 dB.

Prosthesis diameter

To evaluate the impact of the prosthesis diameter on surgical outcomes, patients were divided into two groups: 89 patients (57%) received a 0.6 mm prosthesis (group A), and 68 (43%) received a 0.4 mm prosthesis (group B). Hearing outcomes in both groups are described in Table 4.

Preoperative audiometry

There were no statistically significant differences between the two groups regarding the preoperative MTL-AC, MTL-BC, or ABG ($p > 0.05$), confirming group comparability (Table 4).

Postoperative audiometry

The postoperative HG, measured by the MTL-AC (Table 5), was similar between the groups (21.11 dB for group A vs. 18.71 dB for group B; $p > 0.05$) (Table 4). Functional hearing was achieved in 62% and 52% of the patients in groups A and B, respectively ($p > 0.05$) (Table 5). Improvement in MTL-BC amounted to 2.40 dB in group A and 0.29 dB in group B ($p > 0.05$). The postoperative mean ABG gain was comparable between the groups (18.71 dB in group A vs. 18.62 dB in group B), with no

Table 3
Postoperative endpoints

Postoperative endpoints	N (%)
Surgical success	
(ABG ≤10 dB)	101 (64,3%)
(ABG ≤20 dB)	136 (86,6%)
Functional hearing	
(MTL-AC ≤30 dB)	88 (56,1%)

Abbreviations: SD, standard deviation; AC, aid conduction; ABG, air-bone gap; MTL, mean threshold level (0.5–4 kHz).

Table 4
Pre- and postoperative audiometric results (frequency, kHz [SD])

	Group A (0,6 mm) N = 89	Group B (0,4 mm) N= 68	p
Preoperative, mean (SD)			
MTL-AC	57,01 (12,56)	55,23 (10,3)	0,532
MTL-BC	26,17 (9,2)	26,02 (8,2)	0,942
MTL-ABG	30,84 (8,7)	29,21 (7,3)	0,382
Postoperative, mean (SD)			
MTL-AC	35,90 (13,7)	36,32 (15,0)	0,703
MTL-BC	23,77 (12,3)	25,73 (12,3)	0,453
MTL-ABG	12,13 (5,9)	10,59 (7,9)	0,456

Abbreviations: SD, standard deviation; AC, aid conduction; BC, bone conduction; ABG, air-bone gap; MTL, mean threshold level (0.5–4 kHz).

Table 5
Postoperative hearing gain (frequency, kHz)

	Group A (0,6 mm) N = 89	Group B (0,4 mm) N= 68	p
MTL-AC	21,11	18,71	0,562
MTL-BC	2,40	0,29	0,539
MTL-ABG	18,71	18,62	0,789

Abbreviations: AC, air conduction; BC, bone conduction; ABG, air-bone gap; MTL, mean threshold level (0.5–4 kHz).

Table 6

	Group A (0,6 mm) N = 89	Group B (0,4 mm) N= 68
Endpoints, N (%)		
Surgical success	59 (66,3%)	42 (61,8%)
Functional hearing	55 (61,8%)	35 (51,5%)

Table 7
Predictors of surgical success (postoperative ABG ≤10 dB)

	Adjusted OR	95% CI	p*
Preoperative ABG	0,441	0,195-0,971	0,040
Age	0,765	0,568-0,987	0,043
Sex	0,483	0,139-1,684	0,249
Preoperative tinnitus	0,842	0,283-2,491	0,759
Preoperative vertigo	1,055	0,193-5,720	0,952

Abbreviations: ABG, air-bone gap; OR, odds ratio; CI, confidence interval. * Multivariate binary logistic regression, SPSS

significant difference ($p > 0.05$) (Table 4). Surgical success (ABG ≤ 10 dB) was achieved in 66.3% patients in group A and 61.8% patients in group B ($p > 0.05$) (Table 6).

Predictors of surgical success

Predictive factors for surgical success were identified using logistic regression with dichotomized postoperative MTL-ABG at 10 dB as the dependent variable (Table 7). A larger preoperative MTL-ABG was found to be a negative predictor of surgical success (ABG ≤10 dB) after adjusting for other potential predictors (odds ratio [OR]: 0.441, 95% confidence interval [CI]: 0.195–0.971, p = 0.040). Older age also emerged as an independent predictor of poor postoperative ABG outcomes (OR: 0.765, 95% CI: 0.568–0.987, p = 0.043). Sex and presence of vertigo or tinnitus were not identified as independent predictors of postoperative ABG ≤10 dB (p > 0.05).

Discussion

Although otosclerosis is a rare disease, it accounts for up to 10% of all cases of hearing loss and 18–22% of all cases of conductive hearing loss.[2,3,5] The diagnosis is based on the characteristic clinical and audiometric findings. The use of preoperative computed tomography (CT) is becoming increasingly common, particularly for medico-legal reasons. However, a normal CT scan does not rule out the diagnosis of otosclerosis, as imaging is primarily used to anticipate potential complications, determine the extent of disease, and assess prognosis.[18] Findings such as extensive otosclerotic foci, cochlear involvement, and round window obliteration are associated with poorer outcomes. Additionally, the presence of an enlarged vestibular aqueduct, facial canal dehiscence, or superior semicircular canal dehiscence may influence surgical planning.[18] The surgery of choice for correcting hearing loss due to otosclerosis is stapedotomy.[1] Several studies have demonstrated favorable postoperative outcomes and a low incidence of complications after stapedotomy; however, few studies have assessed the long-term effects and identified which subgroup of patients may benefit the most from this procedure.

This study focused on hearing outcomes post-stapedotomy to evaluate the impact of the prosthesis diameter and identify potential predictors of surgical success.

In our sample, 64.3% patients achieved surgical success. This rate falls at the lower end of the range reported by other studies, where ABG closure to within 10 dB ranged between 62% and 94%.[9,12,14,19] Notably, our results refer to functional outcomes at 12 months postoperatively, aligning with the long-term results in the literature, as early postoperative assessments tend to yield higher success rates. For instance, Vincent et al. reported a high success rate of 94.2% in a study of 1,838 patients undergoing stapedotomy with interposition of a venous graft between the fenestration and prosthesis piston, with a mean follow-up of 46.2 months. Conversely, Kisilevky et al. reported a success rate of 75.2% with a mean follow-up of 16.4 months, more closely aligning with our findings. Variations in the sample size, follow-up duration, surgical technique, and surgeon experience may contribute to these differences.[7,14] Furthermore, many studies adopted a success criterion of ABG ≤20 dB, which includes more than 90% of patients. In our study, this criterion was met in 86.6% of the cases, a slightly lower rate.[1,14]

Another relevant outcome is functional hearing (MTL-BC ≤30 dB), which is considered a clinical success metric from the patient's perspective. This rate was 56.1% in our study, slightly lower than the previously reported values of 61–78%.[1,19]

The choice of the prosthesis diameter remains controversial, with conflicting evidence in the literature. Some studies have reported no differences between prostheses of different diameters,[10,20,21] while others have demonstrated better hearing outcomes with larger-diameter pistons.[9,22–24] One of our aims was to examine the impact of the prosthesis diameter on hearing outcomes. Our findings showed comparable HG between groups A (0.6 mm) and B (0.4 mm), with MTL-ABG gain of 18.71 dB for group A and 18.62 dB for B (p = 0.789), and similar surgical success rates (66.3% vs. 61.8%; p = 0.454). Functional hearing outcomes were also similar between the groups (61.8% for group A and 51.5% for group B, p = 0.345).

These results are in line with those of previous studies, which found no significant differences in ABG closure <10 dB between the two prostheses.[10,20,21] A 2015 systematic review by Wegner et al. also found no evidence to support the superiority of larger-diameter prostheses in primary stapedotomy.[16] However, our findings suggest a slight trend toward better outcomes with the 0.6 mm prosthesis ($p > 0.05$), consistent with the findings of Khorsandi et al.[7]

Similarly, a meta-analysis by Laske et al. reported better outcomes with 0.6 mm prostheses, with higher MTL-AC and ABG values (difference of 4 dB) and a greater success rate (81.1% vs. 75.1%). Experimental studies using temporal bone models have also supported this trend, showing that larger-diameter prostheses produce greater round window vibration velocity for a given sound pressure, thus enhancing sound transmission.[16,25] The potential advantages of larger-diameter prostheses are often attributed to their sound transmission area being closer to that of the physiological stapes footplate (0.4 mm = 0.13 mm^2, 0.6 mm = 0.28 mm^2; footplate = 3.2 mm^2).[7] Conversely, smaller prostheses may reduce the risk of cochlear trauma or footplate fracture due to the smaller fenestration required.[11]

Regarding the potential predictors of surgical success, logistic regression analysis identified preoperative ABG as a negative predictor of surgical success, and it has been associated with lower ABG closure rates in multiple studies (Marchese et al., Bittermann et al., Koopmann et al., Kishimoto et al., Dhooge et al.).[9,14,26] Additionally, age appears to be a relevant predictor of functional success and should be considered in the selection of candidates for stapedotomy, with poorer outcomes observed in patients over 50 years of age, consistent with the findings of Marchese et al.[9]

Tinnitus was assessed based on the clinical records, and no data were available regarding the severity and characteristics of tinnitus. Preoperatively, tinnitus was documented in 43% cases, consistent with the rates in previous studies, ranging from 40% to 90%.[26] Additionally, preoperative vertigo was reported in approximately 12% cases, consistent with the rates in the literature.[26]

Both tinnitus and vertigo are subjective symptoms, which complicates their evaluation. To better understand their impact on postoperative outcomes, standardized and validated tools such as the Tinnitus Handicap Inventory and Dizziness Handicap Inventory should be administered in both the pre- and postoperative periods.

Our study has some limitations due to its retrospective design, including potential loss to follow-up and incomplete data because of missing documentation. Despite the large sample size, the power to analyze subgroups was limited. Moreover, surgeries were performed by different surgeons with varying levels of expertise. Other uncontrolled confounding factors, such as differences in the loop length and diameter (prosthesis anchoring to the incus), prosthesis brand, and fenestration size may have affected our results. Among the strengths of our study are the large sample size (157 cases) and long follow-up period (12 months), which exceeds that of many previous studies, mostly limited to six months. Additionally, hearing outcomes were assessed according to the AAO-HNS criteria, including high-frequency thresholds.

Finally, this study solely assessed postoperative hearing outcomes, with limited attention to patient satisfaction and quality of life. These parameters should be incorporated in future analyses of surgical success.

Conclusion

Stapedotomy is a surgical procedure that provides favorable functional outcomes. No significant differences were observed between the two prosthesis diameters evaluated (0.4 and 0.6 mm). Preoperative ABG and patient age were found to be negative predictors of surgical success. Conversely, sex and preoperative tinnitus or vertigo have no significant impact on the surgical outcomes.

Conflicts of interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

Data Confidentiality

The authors declare having followed the protocols used at their working center regarding patient data publication.

Protection of humans and animals

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and the 2013 Helsinki Declaration of The World Medical Association.

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Availability of scientific data

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