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Effect of CO_2 Laser Stapedotomy on Tinnitus in Patients with Otosclerosis and Predictive Role of Audiological Features

Morgane Saerens, Jean-Philippe Van Damme, Benoit Bihin, Guillaume Gersdorff and Pierre Garin*

Department of ENT, Hospital Erasme, Belgium

Abstract

Objective: To evaluate the effect of CO_2 laser stapedotomy and analyze the influence of audiometric factors on the evolution of tinnitus.

Study design: Retrospective case series.

Setting: Tertiary referral center.

Patients: 151 ears (139 patients, 17 years to 74 years) underwent Laser-assisted stapedotomy for otosclerosis between May 2009 and October 2018.

Intervention: CO_2 laser stapedotomy procedure for otosclerosis.

Results: The incidence of preoperative tinnitus in patients with otosclerosis in our cohort is 51.7%, with a complete disappearance in 61% of the cases. We haven't found any statistically significant results between the resolution of tinnitus after surgery and the hearing result pre and postoperatively (BC, AC, ABG, SRT, and WRS). On the other hand, we haven't found any audiometric predictive factors of the effects of surgery on tinnitus. We have seen a tendency to have more tinnitus regarding the number of laser shots, but the results aren't statistically significant.

Conclusion: Stapedotomy may also improve tinnitus in most of the patients with a diagnostic of otosclerosis. The tinnitus status does not appear to be related to the preoperative or postoperative audiometric results.

Keywords: Otosclerosis; Stapedotomy; Tinnitus, Laser; Stapes surgery

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Correspondence:
Morgane Saerens, Department of ENT, Hospital Erasme, Route de Lennik 808, 1070 Brussels, Belgium, Tel: 0032472701284; E-mail: saerensmorgane@gmail.com

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Introduction

Otosclerosis is hereditary temporal bone osteodystrophy, characterized by an increase in bone remodeling activity in the Otic capsule. From this inflammatory reaction, it results in reduced mobility or fixation of the stapes footplate with consecutive progressive conductive hearing loss with/without additional sensorineural component [1-3]. The involvement usually starts around the oval window, in the fissula ante fenestram and spreads to the annular ligament, the anterior crura of stapes, and the footplate. Anterior progression of the disease toward cochlea may cause Sensory-Neural Hearing Loss (SNHL) [4].

Three different cornerstones of treatment are available for clinicians: A "wait-and-see" strategy, prescription of hearing aids, and surgery. Primary stapes surgery performed for otosclerosis is a well-established procedure with good postoperative outcome sand low risk of complications [5]. Stapes surgery is put forward to resolve the progressive conductive or mixed hearing loss [2,6-8].

Stapedotomy is considered as the surgical modality of choice by surpassing the fixation of the footplate. The beneficial effect of stapedotomy on hearing and the relatively low incidence of permanent complications have been confirmed in many studies. There are varied surgical techniques, instruments, and materials that can be used to perform this procedure [9].

Subjective tinnitus is an abnormal sound sensation perceived by a patient but having no real external acoustic stimulus as its source. Chronic tinnitus is a common feature of clinical otosclerosis. Stapes surgery for otosclerosis has been shown to affect tinnitus greatly. This symptom can be dependent on audiometric features. Multiple studies have identified potential prognostic factors,

but the results are conflicting.

The incidence of tinnitus in patients with otosclerosis ranges from 56% to 92% according to the literature [2,10-14]. This symptom often represents a major concern for the patient as it is shown in the study over 157 patients of Skarżyński et al. [11] talking about the prevalence and severity of tinnitus in otosclerosis. For 23.4% of patients, tinnitus was a problem equal to or greater than hearing loss.

The pathophysiology behind the tinnitus has not been clearly explained, despite scientific research.

Conductive hearing loss produced by stapes blockage results in hearing deprivation and, consequently, loss of the masking effect of hearing. Thus, progressive conductive hearing loss allows the tinnitus to reach increasingly perceptible levels. This hypothesis could explain the link between the ABG and tinnitus symptoms, as well as the considerable improvements seen after surgery and their potential relationship with post-operative ABG size [15].

It is also widely maintained that tinnitus in otosclerosis is produced by labyrinth lesions. Otosclerotic focuses on the cochlea causing biochemical changes in the inner-ear fluids can be another etiology of tinnitus in otosclerosis [4]. A decrease in cochlear input because of hair cell loss, with consequent loss of inhibition in the central auditory pathway, can also explain tinnitus associated with sensorineural hearing loss. A mechanical wave alteration due to the stapes blockage can also affect the inner ear pressure distribution. The change of the pressure homeostasis could modify hair cells electromotility causing tinnitus [15,16]. The "exchange hypothesis" of tinnitus formation in otosclerosis assumes that the newly formed bone tissue, because of its rich vascularization, leads to pulsatile tinnitus [17].

The considerable improvement observed after surgery indicate that tinnitus is not usually caused by labyrinth lesions, that generally originates from mechanical dysfunction in the middle or inner ear, and is associated with more reversible central auditory pathway hyperactivity [15].

The tinnitus improvement with stapes surgery ranges from 69.4% to 91% according to the literature [4,12,14,16-19]. Thus, we can conclude that stapes surgery is effective for the treatment of tinnitus.

This retrospective study aimed to evaluate the evolution of tinnitus after stapedotomy in a consecutive series of 151 operations performed by the same surgeon with the same technique and to determine whether audiometric features influence the outcome of tinnitus.

Materials and Methods

Study design

A retrospective review of patients who underwent stapedotomy for otosclerosis with stapes fixation in our tertiary medical center.

Patients

A total of 151 procedures performed between May 2008 and October 2018 at the Department of Otorhinolaryngology of Godinne University Hospital were included in this study. The patients were operated on by the same surgeon with the same technique under general anesthesia. All patients included had adequate data for analysis.

The inclusion criteria were: 1) primary stapedotomy, 2) diagnosis of otosclerosis excluding other causes of stapes fixation, 3) CO_2 laser stapedotomy 4) reconstruction with a Fisch-type piston prosthesis (®Medtronic Xomed, Jacksonville, Florida, USA) 5) preoperative and postoperative audiograms performed at our institution 6) diagnosis of conductive or mixed hearing loss. Patients with revision stapes surgery were excluded.

Surgical procedure

All cases were performed using a transcanal approach under general anesthesia.

The stapedotomy was performed with the CO_2 laser. The laser was set to continuous wave mode (23 Watts) at a working distance of 275 mm. A laser beam with a 0.6 mm diameter was used for a 0 mm, 4 mm diameter prosthesis for the calibrated platinotomy. A piston length of 4.75 mm was chosen in a clear majority of cases (96.7%). We used a Fisch-type piston combining a Teflon shaft with a platinum hook in all cases.

All ears underwent a small fenestra stapedotomy, however, in two cases, leading to a hemiplatinectomy. A total platinectomy hasn't been seen in this series.

No cases of facial paralysis, dead ear, or chronic vertigo ears were encountered in this study. Revision surgery was necessary for 12 patients due to, most of the time, late hearing impairment (11/12).

Outcome measure

The audiometric evaluation includes the preoperative and postoperative Air-Bone Gap (ABG), Air-Conduction thresholds (AC), Bone-Conduction thresholds (BC), Speech Reception Threshold (SRT), and Word Recognition Score of 100% (WRS). Only AC and BC results that were obtained at the same time postoperatively were used for calculation of ABG as recommended by the Committee on Hearing and Equilibrium of the AAO-HNS [19].

Audiometry for pure tones and speech was performed following the ISO 8253-1 and 8253-3 standards, respectively. The Pure-Tone Average (PTA) was calculated from thresholds at frequencies of 0.5, 1, 2, and 4 kHz in both AC and BC. We hadn't used the 3,000 Hz because this frequency is not measured constantly in Europe. We have extracted the audiometric data from the first year after the surgery.

Speech audiometry was performed systematically for the preoperative and postoperative assessment. The Speech Reception Threshold (SRT) and the word recognition score of 100% (WRS) were assessed using the French Fournier's disyllabic words list.

Data about the presence or absence of tinnitus after six months postoperatively were extracted from results medical chart reports. Patients with tinnitus haven't been assessed with particular questionnaires. No information on the severity or characteristics of the tinnitus is reported.

Statistical analysis

Statistical analysis was performed using the R software (The R Foundation for Statistical Computing, Austria, Vienna, 2020, version 3.6.0).

To ensure that the "lost to follow-up" group did not bias study results, a mixed linear regression model has been used to calculate the evolution of the average with the time, considering the initial score of each patient. The corrected averages are similar to the gross average, which is following the hypothesis that the initial characteristic of the

Table 1: Proportion of patients presenting preoperative and postoperative tinnitus (N).

	Absence of tinnitus after six months postoperatively	Presence of tinnitus after six months postoperatively
Absence of tinnitus preoperatively	46	8
Presence of tinnitus preoperatively	41	26

Table 2: Postoperative tinnitus and audiometry.

	Groups based on the median	N	Tinnitus	No tinnitus	proportion	Missing	P-value
Preoperative							
ABG	Low	81	52	16	0.2353	13	0.278
	high (>28.75)	70	40	19	0.322	11	
AC	Low	76	46	18	0.2812	12	0.749
	high (>51.25)	75	46	17	0.2698	12	
BC	Low	82	50	17	0.2537	15	0.68
	high (>22.5)	69	42	18	0.3	9	
Postoperative							
ABG	Low	64	44	13	0.2281	7	0.336
	high (>11.25)	51	31	17	0.3542	3	
AC	Low	64	43	15	0.2586	6	0.844
	high (>30)	55	35	15	0.3	5	
BC	Low	62	40	17	0.2982	5	0.569
	high (>18.75)	53	35	13	0.2708	5	

Table 3: Percentage of patients with postoperative tinnitus depending on the postoperative ABG at mid-term follow-up.

ABG	Absence of tinnitus	Presence of tinnitus	Patients without this data	P-value
(0.10)	70.59	17.65	11.765	0.15
(10.20)	58.62	34.48	6.897	
(20.60)	80	20	0	

patients not followed are similar to those followed up.

Predictive factors of tinnitus were analyzed using logistic regression to calculate the p-value.

Results

The number of patients presenting preoperative and postoperative tinnitus is described in Table 1.

The incidence of preoperative tinnitus in patients with otosclerosis in our cohort is 51.7%, which is lower than in the literature described above.

After more than six months postoperatively, 41 patients (61%) had a complete disappearance of their tinnitus.

The association of tinnitus with various audiometric predictors is considered in our study.

Neither the importance of the AC level nor the postoperative ABG closure seems to change the incidence of tinnitus after stapes surgery (Table 2 and 3).

About the postoperative BC change, we haven't found a statistic difference in the two groups of patients either (with or without tinnitus postoperatively) (Table 2).

The presence of tinnitus postoperatively does not seem to be associated with worse postoperative results on the speech audiometry, data being similar in the two groups of patients (Table 4).

Regarding the presence of preoperative tinnitus, we haven't found any link with the preoperative audiometric parameters and the presence of tinnitus before surgery. The audiometric data are similar in both groups with a maximum difference of 3dB, as you can see in Table 5.

Table 4: SRT and WRS in patients with and without tinnitus postoperatively.

		Mean (SD)
SRT	No postoperative tinnitus	27.3 dB (11.51)
	Postoperative tinnitus	28.2 dB (7.40)
WRS	No postoperative tinnitus	43.5 dB (12.90)
	Postoperative tinnitus	44.5 dB (10.86)

No statistical difference was found between the number of laser shots for the stapedotomy and the presence of tinnitus postoperatively. However, we see that the number of patients with tinnitus tends to rise with the number of laser shots (Table 6 and Figure 1).

Over 54 patients who don't have reported tinnitus preoperatively, 8 of them (12%) have developed tinnitus remaining at six months postoperatively in our cohort. *De novo* tinnitus doesn't seem to be related to the occurrence of a SNHL. Only one patient with de novo tinnitus had a loss of 10dB or more at 4000 Hz (Table 7).

In the group of patients with persistent tinnitus postoperatively, one patient over 22 had an SNHL. This complication hasn't been reported in the other groups. The presence of postoperative tinnitus doesn't seem to be linked to the occurrence of a SNHL, specifically at 4000 Hz (Table 7). However, this analysis can't be significant due to

Table 5: Description of preoperative audiometric data in patients with and without tinnitus preoperatively.

	ABG	CO 0.5 kHz	CO 1 kHz	CO 2kHz	CO 4 kHz	CA 0.5 kHz	CA 1 kHz	CA 2 kHz	CA 4 kHz
No tinnitus	28dB	22dB	22dB	34dB	19dB	58dB	55dB	46dB	50dB
Tinnitus	30dB	18dB	21dB	32dB	22dB	58dB	55dB	49dB	53dB

Table 6: Incidence of tinnitus postoperatively according to the number of laser shots.

Number of laser shot	Number of patients without tinnitus	Number of patients with tinnitus	Missing	Proportion of patients with tinnitus	P-value
0-1	10	0	1	0	0.16
2	15	5	5	0.25	
3-4	55	24	15	0.30	
5-10	10	6	3	0.38	

Table 7: Description of the presence of tinnitus and SNHL at mid-term postoperative follow-up (N).

	Absence of preoperative tinnitus		Presence of preoperative tinnitus	
	Absence of postoperative tinnitus	Presence of postoperative tinnitus	Absence of postoperative tinnitus	Presence of postoperative tinnitus
No SNHL at 4000Hz	33	6	30	20
SNHL at 4000Hz	6 (15.3%)	1 (14.3%)	2 (6.25%)	2 (9.1%)
No SNHL at 2000Hz	39	7	32	20
SNHL at 2000Hz	0	0	0	2
No SNHL at 1000Hz	37	7	32	21
SNHL at 1000Hz	2	0	0	1
No SNHL at 500Hz	39	7	32	22
SNHL at 500Hz	0	0	0	0
No SNHL (4 frequencies)	39	7	32	21
SNHL (4 frequencies)	0	0	0	1

Table 8: Description of the progression of the BC between the T0 (preoperatively) and T1 (postoperative follow-up) (T0 -T1) and the presence of tinnitus.

	Absence of preoperative tinnitus		Presence of preoperative tinnitus	
	Absence of postoperative tinnitus	Presence of postoperative tinnitus	Absence of postoperative tinnitus	Presence of postoperative tinnitus
BC 500Hz	-5.0dB (SD:8.1)	-3.6dB (SD:6.9)	-4.53dB (SD:8.36)	-5.0dB (SD:10.0)
BC 1000Hz	-3.7dB (SD:9.4)	-8.6dB (SD:7.5)	-5.78dB (SD:7.2)	-3.86dB (SD:9.38)
BC 2000Hz	-8.3dB (SD:8.8)	-10.7dB (SD:12.1)	-6.72dB (SD:8.39)	-5.0dB (SD:10.91)
BC 4000Hz	+3.1dB (SD:9.1)	-2.1dB (SD:8.1)	-0.31dB (SD:8.51)	-0.68dB (SD:9.42)
BC (4frequencies)	-3.5dB (SD:5.4)	-6.2dB (SD:5.7)	-4.34dB (SD:5.61)	-3.64dB (SD:6.60)

the small number of patients in each subgroup.

In Table 8, we see that the presence of postoperative tinnitus doesn't seem to be related to a poorer evolution of the BC. Patients with tinnitus have an improvement of the BC at all frequencies, and differences with those without tinnitus range from 0.37dB to 4.9dB.

Discussion

The primary indication for stapes surgery is to improve hearing. As a positive side effect, it can also alleviate tinnitus in most otosclerotic patients. The pathophysiology behind the tinnitus has not been clearly explained. One hypothesis is that conductive hearing loss produced by stapes blockage results in hearing deprivation and, consequently, loss of the masking effect of hearing, allowing the tinnitus to reach increasingly perceptible levels. That can explain the high rate of tinnitus recovery after stapes surgery ranging from 52.5% to 73% (Table 9).

After more than six months postoperatively, 41 patients (61%) had a complete disappearance of their tinnitus, which is following the literature (Table 9).

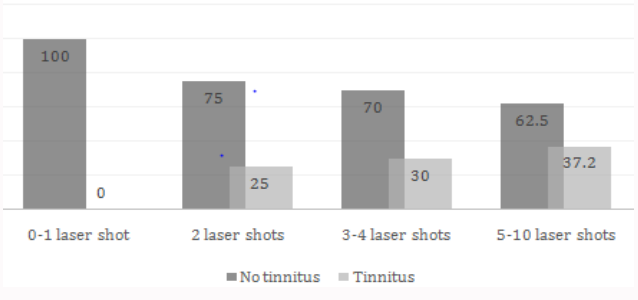

Figure 1: Percentage of patients with tinnitus postoperatively depending on the number of laser shots.

The association of tinnitus with various audiometric predictors is considered in our study. The review of the literature is conflicting.

Table 9: Studies documenting the course of tinnitus after stapes surgery (percentages).

Authors	N	Persistence of tinnitus postoperatively	Complete resolution of tinnitus postoperatively	Comments
Gersdorff et al. [18]	50	36%	64%	improved in 16% of cases, unchanged in 14%, and worsened in 6%
Sobrinho et al. [14]	48	36.70%	63.30%	Significant improvement in 20.45%, slight improvement in 6.81%, no change in 9,09%, No worsening of tinnitus
Sparano et al. [19]	40	47.50%	52.50%	Improvement in 85%, no change in 12.5%, worsened in 2.5%
Dhooge et al. [2]	147	40.20%	59.80%	
Szymanski et al. [16]	149	27%	73%	Improvement in 17% and unchanged in 10% of cases. No worsening
Ayache et al. [12]	67	44.10%	55.90%	Decreased in 32.4% of cases, unchanged in 8.8%, and increased in 2.9% of cases
Del Bo et al. [13]	200	30%	70%	
Our results	67	39%	61%	

One way in which stapes surgery can influence tinnitus in otosclerosis patients is by changing the conductive part of the equation. The potential improvement of the BC postoperatively due to the Carhart effect could also be a positive factor in the evolution of tinnitus postoperatively.

In the study of Sobrinho et al. [14] small postoperative ABG correlated with remission or reduction of tinnitus in the 39.58% of patients with Severe Disabling Tinnitus (SDT) (7 or higher level on the visual analog scale) but not when all tinnitus cases are combined. A larger preoperative ABG correlated with a larger reduction of tinnitus after successful surgery. A lower preoperative BC level correlated with more intense tinnitus before surgery and greater reduction postoperatively. Larger preoperative ABG predicts total remission of tinnitus postoperatively in both SDT and less intense cases [14].

Gersdorff et al. [18] have reported a study of over fifty patients with otosclerosis and tinnitus. Their experience has shown that an unfavorable postoperative course of tinnitus did not appear to be linked to the postoperative audiometric result (ABG) [18].

Sparano et al. [18] have also demonstrated that both decrease and relief of tinnitus were statistically associated with an improved postoperative ABG [18].

Szymanski et al. [16] haven't found any association with preoperative audiometric (AC, BC, ABG) or patient data and a favorable outcome of the tinnitus after surgery. Patients who had poor hearing outcomes (ABG closure) reported the abolition of their tinnitus, suggesting that this was due to the improvement in the fluid mechanics of the cochlea resulting from stapedectomy. They conclude that the outcome of stapedotomy concerning tinnitus improvement cannot be predicted preoperatively [16].

Another study led by Ayache about characteristics and postoperative course of tinnitus in otosclerosis hasn't found any correlation between the course of the tinnitus and the degree of preoperative hearing loss (ABG) and the preoperative BC thresholds at high frequencies (1 to 2 and 4 kHz) [12].

In our study, the presence of tinnitus postoperatively doesn't appear to be linked to the postoperative audiometric results (ABG, BC, AC) as in the study of Gersdorff et al. and Szymanski et al. [16] On the other hand, no preoperative audiometric data seems to be associated with a favorable outcome in terms of tinnitus improvement as described by Ayache et al. [12] and Szymanski et al. [16].

The analysis of 1014 cases made by Gristwood and Venables has shown that tinnitus has an association with mean preoperative BC level, mean preoperative AC level and mean preoperative ABG. Paradoxically, the probability of finding a patient with tinnitus falls as the BC mean level rises (less tinnitus when the BC is worse), and the probability of tinnitus is also seen to fall with rising AC levels (less tinnitus when the AC is worse). The results of the ABG is difficult to interpret, as the proportion of tinnitus cases initially rises with the ABG level, but then falls again in the group of patients with the largest ABG [10].

In another study, based on 157 patients led by Skarżyński, there was no statistical correlation between the preoperative tinnitus severity and audiometric results [11].

Regarding the presence of preoperative tinnitus, what about the hypothesis of the loss of the masking effect of hearing, not covering the tinnitus, we haven't found any link with the preoperative audiometric parameters and the presence of tinnitus before surgery, which is following the study of Skarżyński et al. [11].

Another interesting association can be found between the number of laser shots for the stapedotomy and the presence of tinnitus postoperatively. The CO_2 laser light is characterized by its absorption in water, diminishing penetration but generating heat and noise, which can potentially harm inner ear function.

Postoperative tinnitus tends to be more frequent in the group of patients who have received a higher number of laser shots for the stapedotomy suggesting long-lasting inner ear damage, but these data aren't statistically significant. Thus, we need to evaluate these data with a more significant cohort of patients.

Concerning the surgical technique, the surgeon has decided to maintain the laser at low power to avoid potential complications such as SNHL. Resulting in this choice, the number of laser shots can be higher than one. Obviously, it is highly recommended to wait between shots to avoid the side effects of the laser.

Few studies describe the incidence of new tinnitus after the surgery. In the literature, the incidence of *de novo* tinnitus after stapes surgery ranges from 0% to 7% [2,12,13].

Over 54 patients who don't have reported tinnitus preoperatively, 8 of them (12%) have developed tinnitus remaining at six months postoperatively in our cohort. The analyses over the presence of SNHL or BC evolution ant de novo tinnitus haven't been significant due to the small number of patients in each subgroup.

The limitations of this study include those inherent to retrospective reviews, such as lack of controls. Some records obtained from medical charts may be incomplete or lost with time, leading to missing data. Despite the large studied population size, our current study is limited by sample size to make firm statements about subgroups. Moreover, it remains challenging to draw firm conclusions from these results as patient reporting, and medical chart reports on tinnitus are subjective parameters. To objectively assess the impact of stapedotomy on tinnitus, standardized and validated questionnaires, providing a score for comparison, should be incorporated in the pre- and post-operative patient assessment.

Conclusion

Tinnitus is frequently associated with otosclerosis, and the postoperative improvement of this symptom is highly significant. It must be explained in the preoperative consultation as tinnitus can be an equal or greater concern for the patients than hearing loss.

Stapes surgery is also effective in the treatment of tinnitus with a complete resolution of this symptom after six months postoperatively in 61% of patients.

We haven't found any association between preoperative and postoperative tinnitus and the data of the audiometry as it was expected regarding the literature and the potential etiology of the tinnitus in this disease.

There is a tendency to have more tinnitus regarding the number of laser shots, but the results aren't statistically significant.

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