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Prognostic factors influencing postoperative air-bone gap in stapes surgery / Albera, Andrea; Parandero, Fiorella; Andriani, Roberto; Albera, Roberto; Riva, Giuseppe; Canale, Andrea. - In: ACTA OTORHINOLARYNGOLOGICA ITALICA. - ISSN 1827-675X. - 42:4(2022), pp. 380-387. [10.14639/0392-100x-n0612]

*Availability:*

This version is available at: 11583/2982258 since: 2023-09-18T11:53:34Z

*Publisher:*

PACINI EDITORE

*Published*

DOI:10.14639/0392-100x-n0612

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OTOLOGY

# Prognostic factors influencing postoperative air-bone gap in stapes surgery

## Fattori prognostici del miglioramento del gap tra via aerea e via ossea nella chirurgia della staffa

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### SUMMARY

**Objective.** Otosclerosis is an osteodystrophic disease of the otic capsule, determining conductive or mixed hearing loss, which can be successfully treated with stapedotomy. The aim of the present multicentric retrospective study was to identify prognostic factors related to better auditory outcomes in stapes surgery.

**Methods.** 581 patients affected by otosclerosis were submitted to stapedotomy under local anaesthesia in two different hospitals. Both Teflon and titanium prostheses were adopted.

**Results.** A statistically significant decrease of postoperative air-conduction thresholds and air-bone gap (ABG) values was seen, whereas the mean bone-conduction threshold did not differ from the preoperative condition. Among the various parameters investigated, the prosthetic material, duration of surgery and intraoperative detection of unexpected anatomical anomalies of the middle ear were found to be related to lower postoperative ABG values.

**Conclusions.** All the previously mentioned parameters played a significant role in determining the postoperative auditory outcomes and can therefore be considered prognostic factors for the success of the stapedotomy.

**KEY WORDS:** stapedotomy, conductive hearing loss, prognostic factors, otosclerosis, air-bone gap

### RIASSUNTO

**Obiettivo.** L'otosclerosi è un processo osteodistrofico che interessa la capsula otica e determina un'ipoacusia trasmissiva o mista che può essere trattata chirurgicamente mediante un intervento di stapedotomia. Lo scopo del presente studio retrospettivo multicentrico è l'identificazione di eventuali fattori prognostici correlati a migliori risultati uditivi nella chirurgia della staffa.

**Metodi.** 581 pazienti affetti da otosclerosi sono stati sottoposti a stapedotomia in anestesia locale in due diversi ospedali. Sono state adottate protesi sia in teflon sia in titanio.

**Risultati.** I nostri dati hanno dimostrato, nel postoperatorio, una diminuzione statisticamente significativa dei valori di soglia per via aerea e del gap tra via aerea e via ossea (ABG), mentre i valori medi della soglia per via ossea risultano sovrapponibili alla condizione preoperatoria. Tra i vari parametri studiati, il materiale della protesi, la durata dell'intervento chirurgico e il rilevamento intraoperatorio di anomalie anatomiche dell'orecchio medio sono risultati correlati a inferiori valori di ABG postoperatorio.

**Conclusioni.** Tutti i parametri precedentemente citati svolgono dunque un ruolo significativo nel modificare gli esiti uditivi postoperatori e possono quindi essere considerati fattori predittivi per il successo della stapedotomia.

**PAROLE CHIAVE:** stapedotomia, ipoacusia trasmissiva, fattori prognostici, otosclerosi, air-bone gap

### Introduction

Otosclerosis is a localised disorder of bone metabolism within the human otic capsule leading to fixation of the stapes footplate by spongiotic foci located anteriorly to the oval window, thus the region of the fissula ante fenestram<sup>1,2</sup>.

Received: January 26, 2022

Accepted: April 19, 2022

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**How to cite this article:** Albera A, Parandero F, Andriani R, et al. Prognostic factors influencing postoperative air-bone gap in stapes surgery. *Acta Otorhinolaryngol Ital* 2022;42:380-387. <https://doi.org/10.14639/0392-100X-N0612>

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This osteodystrophic phenomenon is one of the most common causes of progressive conductive and mixed hearing loss in young adults, particularly between the third and fifth decades; however, otosclerosis can also frequently be associated with sensorineural deafness due to progressive involvement of the endosteal portion of the cochlea<sup>3</sup>.

Stapes surgery, a minimally invasive procedure usually performed under local anaesthesia, is considered the gold standard procedure to restore the mechanical sound transmission through the middle ear<sup>4</sup>; nevertheless, a hearing aid can always be considered a valid alternative for patients who are not eligible for surgery<sup>5</sup>.

Several surgical techniques have been described in the literature, among which the most frequently applied are a conventional procedure, in which the stapes suprastructure (SSS) is removed before placement of a prosthesis<sup>4</sup>, and reverse stapedotomy, originally proposed by Fisch and in which, for safety, an early perforation of the footplate followed by insertion of the piston is performed before removal of the SSS<sup>6</sup>. Although many authors agree on the lesser intraoperative risk of complications, i.e. floating footplate, with the reversal of steps, their results are very discordant with respect to postoperative hearing outcomes and the same consideration can be asserted regarding both the material and diameter of the prosthesis<sup>7,8</sup>. On the contrary, despite the justifiable preferences of the surgeon, knowledge of all surgical techniques and experience with different instruments and prostheses is universally considered essential in the training background of an otolaryngologist, in order to be able to improvise in the case of unforeseen circumstances.

Stapedotomy provides excellent results in terms of air-bone gap (ABG) closure in the vast majority of cases; however, in the literature, about 10% of patients do not achieve fully satisfactory hearing restoration following surgery, with persistent mild to moderate conductive hearing loss<sup>9,10</sup>.

A highly successful functional outcome of stapes surgery is commonly referred to postoperative ABG values lower than 10 dB, while the achievement of an ABG closure between 10 and 20 dB, despite still being well accepted by patients, is considered as a partial success of surgery<sup>11,12</sup>.

The aim of the present multicentric retrospective study was to define whether there are factors that can influence, and therefore predict, one-year postoperative auditory improvement (in terms of ABG) after stapedotomy performed under local anaesthesia.

## Materials and methods

The present retrospective study was conducted on 581 patients suffering from otosclerosis and submitted to stape-

dotomy under local anaesthesia in two different centres, AOU Città della Salute e della Scienza of Turin (481 cases, 82.8%) and Fatebenefratelli Hospital of Milan (100 cases, 17.2%).

Diagnosis of otosclerosis was based on normal otoscopic findings, progressive conductive hearing loss worse at lower tones with air conduction (AC) pure-tone average (PTA)  $\geq$  30 dB in the range 0.5 to 4 kHz, a minimum 15-dB preoperative ABG level and normal tympanogram (type A) with absence of cochleostapedial reflexes<sup>5</sup>.

Exclusion criteria of the present study were patients undergoing revision surgery, fluctuating hearing loss with vertigo, tympanic membrane perforation, intraoperative finding of congenital ossicular chain malformation, epitympanic fixation or erosion of the incus and superior or posterior semicircular canal dehiscence.

A preoperative imaging evaluation was not performed on any patient in the diagnosis or surgical planning for otosclerosis.

Each patient was routinely subjected to pure tone audiometry, by testing all common frequencies up to 8 kHz, before surgery and at each postoperative control, scheduled at one month, six months and one year after surgery. However, all postoperative hearing thresholds mentioned herein refer only to PTA values and average ABG (mean hearing threshold at 0.5-1-2-4 kHz) assessed at one year after stapedotomy as to include sufficiently consolidated auditory results.

All surgical procedures were performed under local anaesthesia by the same senior surgeons in the two hospitals.

The detailed description of the surgery, which was always performed in the same way for all patients, is provided in a specific section as supplementary material. The only variables that have been applied to the surgical procedure, depending on the surgeon's preference, were the stapes approach and type of prostheses. In some patients, the conventional steps of stapedotomy (posterior crurotomy, fracture of the anterior crus and subsequent removal of the SSS) were performed before placement of the prosthesis. In contrast, reverse stapedotomy was carried out in all other patients. As for the prosthesis, depending on their habits, the surgeons used either a fluoroplastic (Teflon) piston with a 0.3- or 0.4- mm shaft diameter, or a titanium soft clip piston with a 0.4 mm shaft diameter. All prostheses considered in the study had a length of 4.5 mm.

Overnight hospitalisation depended on the intraoperative or early postoperative onset of vertigo, nausea and vomiting, or transient facial nerve palsy due to local anaesthesia, which all recovered before discharge; other variables that contraindicated same-day discharge and affecting the need for hospitalisation were the absence of a family member or

caregiver to arrange comfortable home transport and great distance between the patient's home and hospital. Furthermore, same-day discharge after stapedotomy was implemented in Turin only for a few years whereas, previously, the internal clinical protocol required at least an overnight hospital stay in any case after surgery.

Among the parameters taken into account to define which factors can affect ABG closure, we considered both gender and age of patients, unilateral or bilateral disease, type of hospitalisation (same-day surgery or day hospital with overnight stay), duration of surgery, diameter of the external auditory canal (EAC), preoperative ABG, surgical approach to the stapes and characteristics of the prosthesis. Finally, both the intraoperative detection of anatomical middle ear abnormalities (narrow oval window niche, very thick posterior crus, obliterative footplate, bulging intratympanic facial nerve) and the onset of intraoperative surgical complications (extreme footplate mobilisation or its fracture, transient vertigo, excessive bleeding) were also included among the variables taken into account for the study. The diameter of the EAC was indirectly reported according to the diameter of the otologic speculum used to perform the surgical procedure and the duration of the surgery was recorded in minutes from the first incision of the posterior tympanomeatal flap to the Merocel packing of the EAC.

#### Statistical analysis

Statistical analysis was performed using SPSS 24.0 statistical software for Microsoft Windows (SPSS, Inc., Chicago, IL). Descriptive statistics for both continuous variables (means and standard deviations) and categorical variables (frequencies) were assessed. Variables were compared by means of parametric tests due to their normally distribution, in particular the independent-samples and paired-samples t-test. Pearson correlation was used to explore the relationship between continuous variables. Two-sided exact tests were used and p values < 0.05 were considered significant for all tests.

## Results

Among the 581 patients submitted to stapedotomy whose characteristics met the study inclusion criteria, 372 patients were female (64%) and 209 patients were male (36%) with a mean age of  $49.3 \pm 11$  years (range 18-79). Otosclerosis was unilateral in 160 patients (27.5%) and bilateral in 421 patients (72.5%). Stapedotomy was performed in 303 cases on the right side (52.2%) and in 278 cases on the left side (47.8%).

An independent-samples T-test reported no significant dif-

ference between patients submitted to stapedotomy in Turin and Milan with regards to preoperative and postoperative AC PTA, BC PTA and ABG values ( $p > 0.05$ ).

Mean preoperative and 1-year postoperative AC PTA, BC PTA and ABG values are reported in Table I. In accordance with the expectations of the intervention, our data demonstrated a statistically significant decrease of mean AC PTA thresholds ( $p < 0.001$ ) and stable BC PTA thresholds ( $p > 0.05$ ) after stapedotomy at paired-samples t-test. Furthermore, we highlighted a significant postoperative decrease of ABG values ( $p < 0.001$ ), with a mean value of 10.8 dB.

At the end of the surgery, 29.3% of patients were monitored for only a few hours before discharge, whereas 70.7% of patients were hospitalised for the night and were discharged the following morning; no patient needed prolonged hospitalisation for more than a day.

With regards to the diameter of the EAC highlighted intraoperatively, 35.7% and 30.5% of the surgeries were performed with a 6.5 mm and 6 mm diameter speculum, respectively. The other diameters observed were 7 mm (15.5%), 5.5 mm (12.8%), 5 mm (3.2%) and 7.5 mm (2.3%).

The independent-samples T-test performed among the 581 patients included in the study showed no significant postoperative ABG differences between males and females, right and left ear, unilateral and bilateral otosclerosis, same-day discharge and overnight hospitalisation (Tab. II). With regards to the surgical technique, conventional stapedotomy was correctly performed in 54.8% of patients and the reversal of steps was preferred in the remaining 45.2% of patients. Although slightly better auditory outcomes were highlighted when the platinotomy was performed as the first step in the reverse stapedotomy procedure, there was finally no significant difference between the two approaches in terms of ABG closure ( $p = 0.140$ , Tab. III).

Concerning the stapedial prosthesis tightened to the long process of the incus, the surgeons preferred to apply a 4-mm diameter piston ( $n = 439$ , 75.6%); moreover, a prosthesis in fluoroplastic material was used in most surgeries ( $n = 480$ , 82.6%).

While we obtained significantly lower postoperative ABG

**Table I.** Preoperative and one-year postoperative auditory results of 581 patients submitted to stapedotomy. The reported PTA values are average thresholds at 0.5, 1, 2 and 4 kHz.

	Preoperative	Postoperative	P-value
AC PTA	$56.7 \pm 14$ (30-86)	$38.7 \pm 17$ (6-120)	< 0.001*
BC PTA	$27.6 \pm 11$ (9-70)	$27.9 \pm 14$ (2-120)	> 0.05
ABG	$29.2 \pm 9$ (15-58)	$10.8 \pm 10$ (0-53)	< 0.001*

All reported values are expressed in dB HL. Ranges are in brackets. AC: air conduction; BC: bone conduction; ABG: air-bone gap; \* statistically significant.

**Table II.** Average postoperative ABG values according to gender, side of the disease, unilateral or bilateral nature of the disease and type of hospitalisation after stapedotomy.

		Post-Op ABG	P-value
Gender	Male	11.6 ± 9.8 dB	0.166
	Female	10.4 ± 10.2 dB	
Side	Right	10.8 ± 10.2 dB	0.879
	Left	10.9 ± 10.1 dB	
Bilateral disease	No	11.9 ± 10.8 dB	0.096
	Yes	10.1 ± 9.8 dB	
Hospitalisation	Same-day surgery	10.6 ± 10.7 dB	0.670
	Overnight stay	11.0 ± 9.9 dB	

**Table III.** Mean postoperative ABG values according to the characteristics of the prosthesis (both material and diameter) and type of surgical approach to the stapes.

		Post-Op ABG	P-value
Prosthetic material	Fluoroplastic (Teflon)	10.3 ± 10.1 dB	0.046*
	Titanium	12.1 ± 7.2 dB	
Diameter of prosthesis	0.3 mm	12.1 ± 8.1 dB	0.096
	0.4 mm	10.3 ± 10.1 dB	
Surgical approach	Conventional stapedotomy	11.2 ± 10.7 dB	0.140
	Reverse stapedotomy	9.8 ± 10.4 dB	

\*statistically significant.

scores when fitting a wider piston than the 3mm diameter prosthesis ( $p = 0.042$ ), there was no significant difference in postoperative ABG values between Teflon or titanium prostheses ( $p = 0.056$ ).

Pearson's correlation coefficient did not show any significant correlation between postoperative ABG values and patients age ( $p = 0.093$ ), EAC diameter ( $p = 0.100$ ) and the same preoperative ABG values ( $p = 0.066$ ).

Unfortunately, it was possible to retrospectively trace the intraoperative data relating to the finding of middle ear

anatomical anomalies or to the onset of complications only in the 480 patients who underwent stapedotomy in Turin (Tab. IV).

Based on our data, the detection of unexpected anatomical anomalies during surgery was found in 22.3% of patients and was reported to significantly affect postoperative hearing with higher ABG closure values ( $p = 0.006$ ); in particular, the niche of the oval window particularly narrow was the anatomical anomaly that most negatively affected the postoperative hearing outcome ( $p = 0.002$ ). On the contrary, the occurrence of mild intraoperative complications, which were reported in 13.5% of patients, did not play a significant role in modifying postoperative ABG values ( $p = 0.179$ ).

Finally, the average duration of the stapedotomy was  $27.6 \pm 8$  min and, in particular, 38.8% of interventions lasted  $\leq 20$  minutes, 43.7% of the interventions lasted between 21 and 30 minutes and only 17.5% of interventions lasted more than 30 minutes.

Pearson's correlation coefficient reported a significant positive correlation between the length of surgery and postoperative ABG values ( $p = 0.002$ ;  $r = .139$ ) and a negative correlation between length of surgery and the EAC diameter ( $r = -0.232$ ;  $p < 0.001$ ). Furthermore, the mean duration of the stapedotomy was significantly longer when the reverse technique was carried out ( $p = 0.034$ ), when a wider diameter of the piston was applied ( $p < 0.001$ ), in case of detection of anatomical anomalies ( $p < 0.001$ ) and in case of onset of intraoperative surgical complications ( $p = 0.014$ ).

## Discussion

The present study aimed to retrospectively review a large cohort of patients undergoing stapedotomy in order to assess whether certain parameters could predict the extent of hearing improvement after primary surgery.

We set up a multicentre study by bringing together the surgical series of two senior surgeons coming from the same

**Table IV.** Mean postoperative ABG values according to the intraoperative finding of middle ear anatomical anomalies or surgical complications.

		Post-Op ABG	P-value
Middle ear anatomical anomalies (n = 480)	None (77.7%)	9.8 ± 10.6 dB	0.006*
	Narrow oval window niche (16.3%)	13.1 ± 10.0 dB	
	Obliterative footplate (2.9%)		
	Very thick posterior crus (2.1%)		
	Bulging intratympanic facial nerve (1%)		
Intraoperative complications (n = 480)	None (86.5%)	10.8 ± 10.5 dB	0.179
	Footplate fracture or excessive footplate mobilisation (7.9%)	9.1 ± 10.8 dB	
	Excessive bleeding (3.3%)		
	Transient acute vertigo (2.3%)		

\*statistically significant.

surgical school and working in two reference hospitals for otosurgery: since no significant differences were found in surgical habits and on average preoperative and postoperative hearing thresholds between groups (Turin and Milan), all interventions were considered similar and therefore studied together.

High surgical success rates were achieved in our series. The mean one-year postoperative ABG value on 581 patients was 10.8 dB, with an ABG closure  $\leq 10$  dB obtained in 62.3% of cases and therefore in line with the results reported in literature, varying between 54% at 86% after stapedotomy, both microscopic and endoscopic assisted<sup>11-14</sup>. Concerning diagnosis of otosclerosis, according to the results of a recent systematic review by Wegner et al.<sup>15</sup>, the choice of both centres was to never perform a preoperative high-resolution computed tomography (HRCT) as it was considered unnecessary to confirm diagnosis and the surgical indication of those patients with clinical and audiometric findings strongly suggestive of otosclerosis. A radiological evaluation was performed only in subjects with suspected further abnormalities of the middle ear and who were therefore excluded from the study.

All surgical procedures were correctly performed under local anesthesia, thus reducing the potential serious complications of general anaesthesia with endotracheal intubation<sup>16</sup> also allowing the patient to be discharged a few hours later in the absence of symptoms. With careful selection of patients and adequate preoperative explanation of the surgical steps, we have been performing stapedotomy under local anaesthesia for about 10 years with high patient compliance and satisfaction on the part of the operator thanks to shorter surgical times and the possibility to test for subjective hearing improvement before concluding the surgical procedure. Only in a few cases (32 patients, 5.5%) was it necessary to add mild conscious sedation with fentanyl 1  $\mu\text{g}/\text{kg}$  and propofol in a target-controlled infusion (TCI) due to sudden uncontrolled movements or discomforts like anxiety, dizziness, or excessive pain<sup>17</sup>. The safety and efficacy of mild propofol anesthesia in middle ear surgery was also reported by Thota et al., who reported shorter recovery times, less nausea and vomiting in the immediate postoperative and improved patient satisfaction<sup>18</sup>.

In our case series 70.7% of patients were hospitalised and discharged the next morning, although this result is certainly influenced by the previous clinical protocol of the two hospitals which required an overnight stay after almost any type of otologic surgery. The possibility of carrying out same-day discharge after stapedotomy was fully introduced only a few years ago and the data of this study confirm that outpatient execution of this intervention allows to reduce the occupancy rate of beds in the ward without influencing

ABG closure. Very few authors have previously presented their results on same-day stapedotomy and only Ralli et al., although evaluating only 24 patients, recently confirmed that the precision of this technique allows experienced surgeons to safely discharge patients a few hours after surgery under local anaesthesia<sup>19</sup>.

In agreement with data in literature, we observed that otosclerosis occurs about twice as frequently in women compared to men (64 and 36%, respectively)<sup>20,21</sup> and in most cases affects both ears (72.5%, consistent with 75.6% mean value reported from Hueb et al.<sup>22</sup>); nevertheless, neither gender nor unilateral or bilateral disease affected postoperative auditory outcomes. Similarly, age of patients at time of surgery, although the older age is often considered a negative prognostic factor due to increased cochlea frailty<sup>10</sup>, did not significantly affect postoperative ABG values after stapedotomy.

Among the parameters that were analysed in the present study, there was also the diameter of the EAC, which has never been evaluated in relation to the postoperative hearing outcome of the stapedotomy so far. This diameter, whose most frequently encountered intraoperative values were 6 and 6.5 mm based on the ear speculum, has not been shown to play a predictive role in postoperative ABG closure, although a narrow EAC is undeniably recognised as a parameter of difficulty as it limits the mobility and visibility of the surgeon.

Concerning the surgical approach to the stapes, all surgeries were performed by means of a microdrill, which is considered safe and can even be used in patients with a small preoperative ABG without increasing the risk of sensorineural hearing loss due to inner ear damage<sup>23</sup>. Although reverse stapedotomy was proposed by Fisch in 1980 to prevent excessive mobilisation of the platform or fractures during crurotomy and, theoretically, achieve better hearing outcomes<sup>6,7</sup>, we found no significant differences in postoperative ABG between conventional and the reverse stapedotomy.

Similar outcomes were reported in a recent review of the literature, namely comparable audiological results between techniques despite confirming better results in terms of footplate and incus-associated complications with the reversal of surgical steps thanks to an increase in the stability of the ossicular system<sup>8</sup>. Although the choice of which technique to use is therefore always up to the surgeon and our data support this statement, it is important to emphasise that the intraoperative detection of middle ear anomalies such as a narrow oval window niche or a very thick posterior crus, in the case of SSS still intact, can limit the way to space between facial nerve and SSS, and thus hinder the reverse stapedotomy.

In our subseries of 480 patients for whom it was possible to obtain sufficient surgical data, the intraoperative identification of middle ear anomalies, which was highlighted in 22.3% of subjects, was demonstrated to significantly worsen postoperative ABG values. In particular, the very narrow oval window niche, whose incidence according to literature ranges from 2.6% to 31%<sup>12,24</sup> and which was detected in 16.3% of our patients, was correlated with an ABG closure even higher than 4 dB compared to normal subjects. On this topic, Vincent confirmed our results by having analysed more than 3000 stapedotomies, reporting that a successful outcome may be expected although with evident effect of middle ear abnormalities on the success rate of this surgery<sup>24</sup>.

The duration of surgery is another intraoperative parameter that has been correlated with postoperative auditory outcomes: our results showed that the shorter the operative time, the better the final result in terms of ABG closure as very good outcomes (ABG lower than 10 dB) were obtained in interventions that lasted less than 20 minutes. The operative time, as expected, was found to be significantly longer in case of intraoperative findings of anatomical anomalies of the middle ear or in case of minor surgical complications. However, stapedotomy can be also technically challenging due to anatomic variations in size, shape, or irregularity of the EAC and, in fact, in our series, the surgical time was significantly increased parallel to the reduction of the EAC diameter. Although the final auditory result did not ultimately change in relation to the latter parameter, surgical delay described is likely to be related to the surgeon's need to perform a larger atticotomy to get a correct view of the SSS.

Since the development of stapes surgery in 1956, a large number of prostheses have been used and both size and material have always been the focus of research for improvement. Looking in the literature, the piston diameter varies from 0.3 mm up to 0.8 mm<sup>25</sup>. Experimental studies based on mathematical and anatomical models have shown a trend towards better auditory outcomes of stapedotomy in case of larger diameter prostheses<sup>26,27</sup>, since it is reasonable that an extremely narrow piston will not transmit enough sound energy into the vestibule due to smaller volume displacement. In contrast, a recent systematic review by Wegner et al. concluded that there is insufficient evidence to support the superiority of a larger-diameter piston compared to a smaller-diameter one for primary stapedotomy<sup>28</sup> and, indeed, our results also did not show significantly different postoperative ABG values between 0.3 mm and 0.4 mm diameter prostheses. Furthermore, although Faramarzi et al. reported, in a recent randomised clinical trial, similar short-term auditory results in the use of prostheses of different

materials<sup>29</sup>, our data showed significantly better hearing outcomes with fluoroplastic pistons compared to titanium ones, with a mean postoperative ABG value lower by 2 dB when using those in Teflon. We are convinced that a piston in fluoroplastic material, once sufficient experience in insertion has been achieved, guarantees good results by virtue of intrinsic characteristics such as excellent chemical, biological and electrical inertness, high thermal stability and an elastic memory which avoids excessive crimping of the Teflon loop around the long process of the incus. Similar conclusions were also reported by Durko et al., who consider this material as the best option for stapedotomy<sup>30</sup>. The occurrence of mild intraoperative surgical complications has been reported in 13.5% of surgeries and among them, the most frequent were an excessive footplate mobilisation or a footplate fracture (8%); however, the piston was correctly placed in all patients and we never had to use gelfoam or fat as sealing to prevent perilymph leakage. Another frequent intraoperative complication in our series was significant bleeding, which at times made the placement of the prosthesis very challenging and which Demir reported was significantly lower in cases of incisions with cautery compared to cold instruments, with no difference in postoperative pain and in wound healing<sup>31</sup>. Finally, the last quite infrequent complication highlighted among our patients was the onset of transient acute vertigo, which is reported in the literature in up to 77% of cases<sup>31</sup>, likely due to excessive injections of local anaesthetic in the EAC prior to tympanomeatal flap elevation and sometimes due to perilymphatic displacement during the positioning of the piston. Despite these unpleasant occurrences, the onset of intraoperative surgical complications did not play a significant role in modifying the postoperative hearing outcome. However, the strengths of this case series were the focus on a large sample (almost 600 patients) with medium-term audiological follow-up (at least 1 year) and the completion of all surgeries by only two highly experienced surgeons, thus making unlikely that interpersonal differences in surgical approach or expertise had an influence on hearing outcomes.

## Conclusions

In conclusion, the present multi-centre retrospective study, including 581 patients undergoing primary stapedotomy for otosclerosis, confirms the safety and efficacy of this intervention performed under local anaesthesia, with excellent auditory results in terms of postoperative blood gas analysis. Furthermore, the study suggests some predictors of failure of the stapedotomy (postoperative ABG > 10 dB) such as the material of the prosthesis, the length of surgery and intraoperative detection of anatomical abnormalities

such as a narrow oval window niche. Therefore, our findings can encourage the development of increasingly effective surgical approaches and provide the surgeon with very useful preoperative or intraoperative information on the likelihood of stapedotomy success.

### *Conflict of interest statement*

The authors declare no conflict of interest.

### *Funding*

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

### *Author contributions*

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by FP, RA1, GR, RAn and AC. AA wrote the first draft of the manuscript and other authors provided critical revision.

### *Ethical consideration*

Written informed consent to be inserted in our database was obtained by each patient and the protocol study, carried out according to the 1964 Helsinki Declaration and its later amendments or comparable ethical standards, was approved by the Institutional Review Board of the University of Turin (protocol n. 0058243, May 2021).

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## Supplementary material

### *Detailed description of the surgical steps of the stapedotomy*

All surgical procedures were always performed by the same senior surgeon in the two clinical centres respectively and every patient was submitted to stapedotomy under local anaesthesia.

In particular, a combination of adrenaline (1 in 15.000) and mepivacaine (3%) as the local anaesthetic agent was used, injected anteriorly at the 3 o'clock position, inferiorly at the 6 o'clock position and posteriorly at the 9 o'clock position of the external meatus. The approach to the middle ear was performed by means of a posterior tympanomeatal flap and, if necessary, a small atticotomy was carried out by means of a curette in order to expose the oval window region.

Then, according to the surgeon's preference, the stapes approach was performed in two different ways. In some patients, the conventional surgical steps of stapedotomy were

performed before placement of the prosthesis: disarticulation of the incudostapedial joint (ISJ), posterior crurotomy, fracture of the anterior crus towards the promontory and subsequent removal of the stapes suprastructure (SSS). In contrast, the reverse stapedotomy originally proposed by Ugo Fisch was carried out in all other patients, with an early and safer perforation of the footplate followed by insertion of the piston before disarticulation of the ISJ and removal of the SSS.

Similarly to the surgical approach, even as regards the prosthesis were used two different types depending on the surgeon's preference and habit: a fluoroplastic piston (Teflon) with a 0.3- or 0.4 mm shaft diameter, and a titanium soft clip piston with a 0.4 mm shaft's diameter. All prostheses considered in the study had a 4.5 mm length.

The malleus neck was always probed at the end of the procedure to rule out any ossicular chain fixation. Finally, the tympanomeatal flap was repositioned and a ciprofloxacin 0.3%/dexamethasone 0.1% soaked Merocel was placed in the external acoustic meatus.