

## ORIGINAL STUDY

# Factors associated with failure in stapes surgery for otosclerosis: a retrospective study in a tertiary care hospital

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## ABSTRACT

**BACKGROUND.** Otosclerosis is a common cause of conductive hearing loss in adults, most frequently treated with stapes surgery. However, the factors determining surgical success or failure remain controversial.

**OBJECTIVE.** To identify clinical and surgical variables associated with surgical failure in patients undergoing stapes surgery for otosclerosis at a tertiary referral hospital in northwestern Mexico.

**MATERIAL AND METHODS.** An observational, retrospective, cross-sectional study was conducted on 54 patients diagnosed with otosclerosis who underwent surgery between 2022 and 2024. Adult patients with preoperative and 6-month postoperative audiometry were included, while those without audiological follow-up were excluded. Sociodemographic, clinical, surgical, and audiometric variables were analyzed. Surgical failure was defined as a postoperative air–bone gap (ABG) >10 dB.

**RESULTS.** A total of 81.5% of patients achieved surgical success. No significant association was found between surgical failure and age, sex, comorbidities, smoking status, or the type of surgical visualization used. A higher risk of failure was identified in patients who underwent stapedectomy (OR = 13.6,  $p = 0.001$ ) and in surgeries performed on the left ear. Hearing improved significantly: the global PTA decreased from 59.8 to 40.1 dB ( $p < 0.001$ , Cohen's  $d = 4.5$ ). The ABG decreased across all analyzed frequencies, with large effect sizes.

**CONCLUSION.** Stapes surgery is effective in improving hearing in patients with otosclerosis. Intraoperative decisions, particularly the choice of surgical technique (stapedotomy versus stapedectomy), significantly influence outcomes. These findings support stapedotomy as the preferred technique and highlight the importance of standardized audiometric follow-up.

**KEYWORDS:** stapes surgery, otosclerosis, treatment outcome, risk factors.

## INTRODUCTION

Otosclerosis is one of the main causes of conductive hearing loss in Caucasian adults, with a prevalence ranging from 0.006 to 1%<sup>1-4</sup>. However, histologically, it can range from 4 to 12% and clinically manifests as hearing loss<sup>5-7</sup>.

The standard of management is stapes surgery with stapes prosthesis placement, demonstrating a success rate ranging from 72% to 94%. As for the success of surgery, it is usually dependent on factors such as the type of surgery performed, the type of prosthesis used, the stage of the disease and involvement of surrounding structures<sup>8-11</sup>. Stapes surgery can be performed under general or local anesthesia with sedation. There are different surgical techniques, such as stapedectomy, which consists of the

complete removal of the stapes footplate, and stapedotomy, in which only one perforation is made in the footplate. In addition, the procedure can be done with visual assistance using a microscope or endoscope<sup>12,13</sup>. Some authors have identified small bony airspaces as risk factors for failure of the stapes surgery<sup>14-16</sup>, while others point to young age, active smoking<sup>17</sup>, dyslipidemia<sup>18</sup> and high blood pressure<sup>19</sup>. However, authors such as Patel et al.<sup>20</sup> reported that a history of smoking was not a predictive factor in their series of 107 cases. Other studies pointed out that a history of previous surgery can be a risk factor<sup>21-23</sup>. Marchese et al.<sup>24</sup> indicate that age <50 years and a hearing loss  $\geq 50$  dB are predictive risk factors. Other studies describe that sex is not a predictive factor for surgical success, and that body mass index, although previously studied, is not conclusively associated with postopera-

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tive complications in stapes surgery<sup>25-27</sup>.

Given the controversies regarding the risk factors linked to postoperative complications or failure in stapes surgery, it is pertinent to explore, in the context of our hospital and patient population, which preoperative conditions or variables could be associated with unfavorable outcomes after this procedure. Given the dilemma that exists in different studies on multiple risk factors associated with surgical success or failure, we believe it is necessary to evaluate these factors in a sample of our patients who underwent stapes surgery for otosclerosis.

## MATERIAL AND METHODS

### Study population

An observational, retrospective, cross-sectional study was carried out in the Otorhinolaryngology service of a tertiary-level medical unit, a regional reference centre of the Mexican Institute of Social Security in northwestern Mexico. Clinical records were selected by non-probabilistic consecutive sampling, corresponding to patients who underwent stapes surgery for otosclerosis between January 2022 and December 2024.

The sample size was calculated for a finite population, considering an annual average of 20 procedures, a confidence level of 95%, an expected proportion of 50%, an accuracy of 5% and an estimated loss of 10%, obtaining a minimum required size of 90 cases. However, due to the retrospective nature of the study, as well as underreporting and lack of audiological follow-up in some patients, the projected sample size was not reached, which constitutes a relevant methodological limitation.

Adult patients (18 to 80 years old) with a clinical diagnosis of otosclerosis, who underwent stapes surgery (stapedectomy or stapedotomy), performed using either an endoscopic or microscopic approach, and who had preoperative and six-month postoperative audiometry, were included. Cases with incomplete records, absence of audiological follow-up, intraoperative discarded diagnosis, or loss of essential clinical information were excluded.

### Variables and measurements

Demographic variables (age, sex, state of origin), clinical variables (comorbidities such as hypertension, diabetes, smoking), audiological variables (audiometric thresholds and air–bone gap preoperatively and at 6 months postoperatively), and surgical variables (operated ear, stapes surgery technique – stapedotomy versus stapedectomy, visualization method with microscope or endoscope, and presence of intra- or postoperative complications) were collected. For the analysis of audiometric results, the pure tone average (PTA) and the air–bone gap (ABG) were calculated at frequencies of 500, 1000 and 2000 Hz before surgery and at 6 months postoperatively. Surgical success was defined as a postoperative ABG  $\leq$  10 dB; any case with an ABG  $>$  10 dB at 6 months was considered failure or non-successful outcome.

To minimize selection bias, we excluded records without complete follow-up audiometry. No images or imputed data were used for cases with missing data.

### Statistical analysis

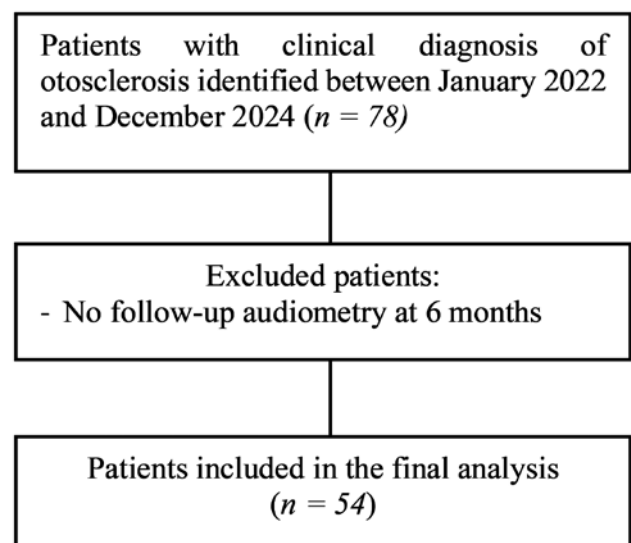
Quantitative and qualitative variables were recorded in the data collection card and later transferred to an Excel spreadsheet version 19 for Windows, then coded and analyzed with the statistical program SPSS version 26 in Spanish for Windows. Descriptive statistics were used, including measures of central tendency and dispersion. We applied Pearson's Chi-square to assess association and odds ratio to estimate risk. Differences in the ABG between preoperative and postoperative tonal audiometry were evaluated using Student's t-test. A p value  $\leq$  0.05 was considered statistically significant. Tables were used for data interpretation.

## RESULTS

Between January 2022 and December 2024, a total of 78 patients with a clinical diagnosis of otosclerosis were identified. However, for inclusion in the final analysis, an essential criterion was the existence of a follow-up audiometry performed six months after the intervention. Due to the absence of this assessment in some cases, 24 patients were excluded. As a result, the final sample consisted of 54 patients who met all the established criteria, including the required audiometric follow-up (see Figure 1). The mean age of the included patients was 46.9 years (SD  $\pm$  11.5; range 20–68 years). Of these, 44 patients (81.5%) were women and 10 (18.5%) were men (Table 1). The predominant geographical origin was the state of Sonora (55.5%), followed by Baja California (24.1%) and Sinaloa (20.4%).

35.2% of the patients had comorbidities (mainly arterial hypertension in 20.4%), while 16.7% were active smokers. The left ear was most frequently affected, in 36 cases (66.7%). Carhart's notch was identified in 90.7% of patients on preoperative audiometry. The mean duration of hearing loss before surgery was 8.35 years (SD  $\pm$  7.94; range 1–30 years).

Regarding surgical characteristics, 33 procedures (61.1%) were performed using an endoscopic approach and 21 (38.9%)



**Figure 1.** Selection criteria and total number of patients included in the study.

**Table 1. Clinical and sociodemographic characteristics of patients and their association with surgical outcome (success versus failure).**

| Variable                      | Category                          | n (%)      | p-value | Odd Ratio (95% CI)    |
|-------------------------------|-----------------------------------|------------|---------|-----------------------|
| Age (mean ± SD)               | 46.93 ± 11.48 years (range 20–68) |            |         |                       |
| Evolution time (mean ± SD)    | 8.35 ± 7.94 years (range 1–30)    |            |         |                       |
| Age group                     | ≤49 years old                     | 31 (57.4%) |         |                       |
|                               | ≥50 years                         | 23 (42.6%) |         |                       |
| Sex                           | Male                              | 10 (18.5%) | 0.300   | 2.265 (0.469–10.947)  |
|                               | Female                            | 44 (81.5%) |         |                       |
| State                         | Sonora                            | 30 (55.5%) |         |                       |
|                               | Baja California                   | 13 (24.1%) |         |                       |
|                               | Sinaloa                           | 11 (20.4%) |         |                       |
| Comorbidities                 | No comorbidities                  | 19 (35.2%) | 0.723   | 1.289 (0.315–5.281)   |
|                               | High blood pressure               | 11 (20.4%) | 0.367   | 0.378 (0.043–3.352)   |
|                               | Diabetes mellitus                 | 7 (13.0%)  | 0.512   | 1.762 (0.336–9.234)   |
|                               | Dyslipidemia                      | 5 (9.3%)   | 0.625   | 1.357 (0.297–6.191)   |
|                               | Obesity (BMI ≥30)                 | 3 (5.6%)   | 0.481   | 0.615 (0.102–3.701)   |
|                               | Cardiopathy (any)                 | 2 (3.7%)   | 0.723   | 1.089 (0.122–9.724)   |
|                               | Asthma/COPD                       | 1 (1.9%)   | 1.000   | 0.979 (0.059–16.132)  |
|                               | Thyroid disease                   | 1 (1.9%)   | 1.000   | 0.979 (0.059–16.132)  |
| No comorbidities              | 35 (64.8%)                        |            |         |                       |
| Smoking                       | 9 (16.7%)                         |            | 0.210   | 2.714 (0.546–13.489)  |
| Affected ear                  | Left                              | 36 (66.7%) | 0.089   | 0.990 (0.789–1.242)   |
|                               | Right                             | 18 (33.3%) |         |                       |
| Carhart notch in audiometry   | Present                           | 49 (90.7%) |         |                       |
|                               | Absent                            | 5 (9.3%)   |         |                       |
| Procedure Visualization       | Endoscopic                        | 33 (61.1%) | 0.129   | 0.345 (0.084–1.413)   |
|                               | Microscope                        | 21 (38.9%) |         |                       |
| Postoperative complications   | Yes                               | 7 (13.0%)  | 0.001   | 13.600 (2.479–74.622) |
|                               | No                                | 47 (87.0%) |         |                       |
| Type                          | Prosthesis extrusion              | 4 (7.4%)   |         |                       |
|                               | Sensorineural hearing loss        | 1 (1.9%)   |         |                       |
|                               | Impossibility of casting implant  | 2 (3.7%)   |         |                       |
| Hearing loss according to WHO | Moderate                          | 3 (5.6%)   |         |                       |
|                               | Severe                            | 36 (66.7%) |         |                       |
| Type of procedure             | Deep                              | 15 (27.8%) |         |                       |
|                               | Stapedectomy                      | 23 (42.6%) | 0.001   | 13.600 (2.479–74.622) |
| Stapedotomy                   | 31 (57.4%)                        |            |         |                       |
| Upshot                        | Surgical failure                  | 10 (18.5%) |         |                       |
|                               | Surgical success                  | 44 (81.5%) |         |                       |

with a microscope. Intraoperative or postoperative complications were documented in 18 cases (33.3%). The most frequent were prosthesis extrusion in 4 cases (7.4%), persistent vertigo (n = 4), transient dysgeusia (n = 4), followed by profound sensorineural hearing loss in 1 case (1.9%), inability to place the im-

plant in 2 cases (3.7%), postoperative tympanic membrane perforation (n = 2), and delayed-onset facial nerve paresis (n = 1). Although most of these complications were transient or resolved with conservative management, they contributed to surgical failure or prolonged recovery in several patients. No

**Table 2. Pre- and post-surgical audiometric changes.**

| Frequency / Variable | Preoperative Mean (SD) | Postoperative Mean (SD) | Cohen's d | 95% CI for Cohen's d | Hedges' g (fixed) | Student's t ( $p \leq 0.05$ ) |
|----------------------|------------------------|-------------------------|-----------|----------------------|-------------------|-------------------------------|
| PTA Global (dB HL)   | 59.84 (13.30)          | 40.06 (23.28)           | 4.499     | 3.602 – 5.391        | 4.435             | $p = 0.000$                   |
| ABG 250 Hz (dB)      | 45.56 (12.35)          | 22.87 (24.60)           | 3.689     | 2.937 – 4.435        | 3.636             | $p = 0.000$                   |
| ABG 500 Hz (dB)      | 41.39 (12.94)          | 18.43 (24.30)           | 3.199     | 2.533 – 3.860        | 3.154             | $p = 0.000$                   |
| ABG 1000 Hz (dB)     | 32.13 (13.09)          | 16.85 (22.97)           | 2.455     | 1.915 – 2.988        | 2.420             | $p = 0.000$                   |
| ABG 2000 Hz (dB)     | 16.67 (13.10)          | 7.78 (15.92)            | 1.272     | 0.909 – 1.628        | 1.254             | $p = 0.000$                   |

**Notes:** PTA = Pure Tone Average. ABG = Air–Bone Gap. Preoperative = evaluation before surgery. Postoperative = evaluation after surgery. Cohen's d values indicate a very large magnitude of effect at all frequencies, evidencing a significant postoperative improvement ( $p < 0.001$  in all cases).

complications were observed in the remaining 36 cases (66.7%). A Schuknecht prosthesis (stainless steel with Teflon) was used in all procedures. The surgical technique was stapedotomy in 31 cases (57.4%) and stapedectomy in 23 cases (42.6%).

Failure of the procedure (postoperative ABG >10 dB) occurred in 10 patients, corresponding to 18.5% of the series; the remaining 44 patients (81.5%) achieved surgical success (ABG closure <10 dB at 6 months). Table 1 summarizes the demographic and clinical characteristics, as well as the main findings, comparing the success and failure groups.

In the bivariate analysis, no significant statistical association was found between surgical failure and the presence of comorbidities ( $p = 0.723$ ; OR = 1.29, 95% CI 0.32–5.28), active smoking ( $p = 0.210$ ; OR = 2.71, 95% CI 0.55–13.49), arterial hypertension ( $p = 0.367$ ; OR = 0.38, 95% CI 0.04–3.35), nor between sexes (female versus male;  $p = 0.300$ ; OR = 2.27, 95% CI 0.47–10.95). No association was observed with the presence of a Carhart notch on preoperative audiometry ( $p = 0.895$ ; OR = 0.99, 95% CI 0.79–1.24), type of visualization (endoscopic versus microscopic;  $p = 0.129$ ; OR = 0.35, 95% CI 0.08–1.41), or age (< 50 versus  $\geq 50$  years;  $p = 0.372$ ; OR = 1.94, 95% CI 0.44–8.52).

A significant statistical association was found between surgical failure, the surgical technique and the side of the operated ear. The probability of failure was higher in stapedectomy compared to stapedotomy ( $p = 0.001$ ; OR = 13.6, 95% CI 2.48–74.62), and was also greater in left-ear versus right-ear surgeries ( $p = 0.001$ ; OR = 13.6, 95% CI 2.48–74.62).

A multivariate logistic regression model was applied to identify independent predictors of surgical failure. Variables included in the model were surgical technique (stapedectomy vs stapedotomy), presence of postoperative complications, sex, comorbidities, visualization method (endoscopic vs microscopic), and side of the operated ear. The analysis confirmed that both stapedectomy and postoperative complications were independently associated with an increased risk of failure. Stapedectomy showed an adjusted odds ratio (aOR) of 7.52 (95% CI: 1.21–46.82;  $p = 0.030$ ), while postoperative complications had an aOR of 4.78 (95% CI: 1.02–22.42;  $p = 0.047$ ). Other variables, including male

sex, presence of comorbidities, endoscopic approach, and left-ear intervention, were not significantly associated with failure ( $p > 0.05$  for all). The Hosmer-Lemeshow goodness-of-fit test indicated adequate model calibration ( $p = 0.74$ ). These findings suggest that the type of procedure and the occurrence of complications have an independent effect on functional outcomes, even after adjusting for potential confounders.

Audiometric evaluation showed significant improvement in hearing after surgery. The overall preoperative PTA (mean 0.5–2 kHz) was 59.8 dB (SD  $\pm$  13.3) and decreased to 40.1 dB (SD  $\pm$  23.3) at six months postoperatively ( $p < 0.001$ ), representing an average hearing gain of  $\sim$ 19.8 dB. This difference was equivalent to a very large effect size (Cohen's d = 4.50) (Table 2). Regarding the air–bone gap, closure or reduction was documented at all analyzed frequencies. For example, at 250 Hz the average ABG decreased from 45.6 dB to 22.9 dB; at 500 Hz from 41.4 to 18.4 dB; and at 1000 Hz from 32.1 to 16.9 dB (all  $p < 0.001$ ). At 2000 Hz, the ABG reduction was smaller (from 16.7 to 7.8 dB), although equally significant ( $p < 0.001$ ). The effect sizes (Cohen's d) ranged from 1.27 to 3.69 depending on frequency, confirming the clinical relevance of the improvement (Table 2). Table 2 shows the average audiometric changes before versus after surgery, including 95% confidence intervals of the differences. A sensitivity analysis was performed excluding patients with significant comorbidities ( $n = 19$ ). The surgical success rate remained at 82.8%, with no significant variation in the main ORs.

## DISCUSSIONS

The results obtained in our cohort allow us to identify a series of clinical and surgical factors associated with the success or failure of stapes surgery in patients with otosclerosis. In terms of age, a higher failure rate was observed in patients aged 50 years and older. This finding is consistent with the study by Bittermann et al.<sup>18</sup>, who reported that an age greater than 40 years reduces the probability of achieving a postoperative gain of more than 20 dB

in air conduction. However, other studies, such as that of Yeh et al.<sup>21</sup> did not find a significant association between age and hearing outcomes. Regarding sex, although some studies suggest a trend towards better results in women<sup>18,21</sup>, no statistically significant differences were observed between men and women in our sample, in agreement with the findings of Yeh et al.<sup>21</sup> and Lamblin et al.<sup>25</sup>.

The presence of comorbidities, particularly arterial hypertension, was associated in our series with a higher frequency of postoperative complications and lower rates of air–bone gap (ABG) closure. Although this association has not been systematically explored in the reviewed literature, it is plausible that chronic vascular diseases affect cochlear perfusion and functional recovery after surgery. Similarly, active smoking was associated with reduced hearing gain, likely due to its negative effect on the tissue repair mechanisms of the middle ear.

One of the most consistent findings in the literature is the relationship between preoperative ABG size and postoperative outcomes. In both our cohort and the studies by Yeh et al.<sup>21</sup> and Khorsandi et al.<sup>18</sup>, an ABG  $\geq 50$  dB was associated with lower rates of hearing success. In our analysis, a preoperative ABG  $\leq 50$  dB appeared as a risk factor but was not significant. Carhart's notch was a frequent finding in patients with partial procedural failure, and its presence has been linked to reduced postoperative improvement in bone conduction, especially at high frequencies. Lamblin et al.<sup>25</sup> showed that patients with Carhart's notch have lower hearing gain at 4 kHz, suggesting a possible pre-existing cochlear involvement or greater susceptibility to intraoperative trauma, although in our sample it was not significant.

Regarding the type of stapes procedure, most surgeries in our institution were performed as stapedotomies. Our findings reinforce the evidence supporting this technique as less invasive and associated with lower rates of fistulas and fibrosis compared with stapedectomy<sup>28,29</sup>. In fact, Khorsandi et al.<sup>13</sup> did not find significant differences between the two techniques in terms of ABG closure, but highlighted a lower incidence of complications with stapedotomy. In our cohort, the route of visualization, either by microscope or endoscope, did not show significant differences, consistent with the findings of Yeh et al.<sup>21</sup>, who emphasized that the choice of the visual instrument should be based on the experience of the surgeon's experience rather than on inherent technical superiority.

The presence of intra- or postoperative complications, such as persistent vertigo, fibrosis of the oval window, or prosthesis displacement, was significantly associated with surgical failure, which had already been widely documented by Babighian et al.<sup>30</sup>. These findings highlight the importance of meticulous surgical technique and adequate postoperative follow-up to optimize hearing outcomes.

In our cohort, there was a statistically significant improvement in postoperative hearing thresholds at six months, with a reduction in PTA from 59.84 dB to 40.06 dB and a very large effect size (Cohen's  $d = 4.499$ ). This finding is consistent with what was reported by Edizer et al.<sup>31</sup>, who documented an improvement in PTA from 56.1 dB to 34.1 dB after stapedotomy, also statistically significant ( $p < 0.001$ ). Regarding the air–bone gap (ABG), our series showed relevant reductions in all analyzed fre-

quencies, particularly at 250 Hz and 500 Hz. This pattern was also identified by Andersen et al.<sup>32</sup>, who reported an average preoperative ABG of 25.7 dB that decreased to 6.9 dB at 12 months postoperatively. Similarly, Nash et al.<sup>33</sup> observed a reduction in ABG from 28.9 dB to 3.3 dB at six months after surgery and to 3.1 dB at one year after surgery, confirming the stability of ABG closure over time.

A striking aspect is the magnitude of the effect observed in our cohort, higher than that documented by other studies. For example, Edizer et al.<sup>31</sup> found an average ABG gain of  $20.7 \pm 11.4$  dB, with more noticeable improvements at low frequencies such as 500 Hz and 1000 Hz, which was also observed in our results, although with greater dispersion at 2000 Hz. In addition, while our study showed improvements in all the analyzed frequencies, in other studies such as that of Edizer et al.<sup>31</sup> the gain in bone conduction was statistically significant only at 2000 Hz. This finding was associated with the disappearance of the Carhart notch, a phenomenon not evidenced with the same consistency in our series.

Our findings confirm substantial postoperative improvements in hearing thresholds, comparable in direction but superior in magnitude to those reported by other international series. This supports the clinical effectiveness of stapes surgery and suggests that local operative conditions and the technique employed may play a key role in functional hearing gain<sup>31-33</sup>.

Among the limitations of the study are its retrospective design, the limited sample size, and the possibility of selection bias due to the exclusion of incomplete files. In addition, psychosocial variables were not evaluated, nor were postoperative quality-of-life scales used. These limitations could influence the interpretation and generalizability of the results.

Although this study was conducted in a tertiary hospital with expertise in stapes surgery and with standardized surgical protocols, its findings may be applicable to similar institutions in regional or national contexts that share comparable organizational and demographic characteristics. However, they should be interpreted with caution when extrapolated to hospitals with lower surgical volumes, differences in staff training, or populations with different characteristics, such as a higher proportion of patients with complex comorbidities or limited access to postoperative audiological follow-up. The reproducibility of results in other settings will require further validation through multicentre or prospective studies with larger samples.

#### Statistical consistency and limitations

The statistical analysis in this study demonstrated internal consistency and methodological rigor across both bivariate and multivariate models. In the bivariate analysis, the only variables significantly associated with surgical failure were the stapedectomy technique and the presence of postoperative complications, both showing identical odds ratios (OR = 13.6, 95% CI 2.479–74.622). While this initially suggested a potential duplication error, further review confirmed that this finding reflected a high degree of collinearity between the two variables, as most complications occurred in patients undergoing stapedectomy. A multivariate logistic regression model was applied to adjust for

this collinearity and revealed that both stapedectomy (adjusted OR = 7.52; 95% CI 1.21–46.82) and postoperative complications (adjusted OR = 4.78; 95% CI 1.02–22.42) remained independently associated with failure. The Hosmer-Lemeshow test supported the model's adequacy ( $p = 0.74$ ). Audiometric outcomes were statistically robust, with significant postoperative improvements in PTA and ABG at all frequencies ( $p < 0.001$ ), and large effect sizes (Cohen's  $d > 1.2$ ). However, limitations include a relatively small sample size and the retrospective nature of the study, which may reduce statistical power and limit causal inference. Future studies with larger cohorts and prospective designs are warranted to validate these findings.

## CONCLUSIONS

Stapes surgery for otosclerosis performed in a tertiary care hospital in northwestern Mexico showed a high hearing success rate (81.5%), defined as obtaining an ABG  $\leq 10$  dB six months after the procedure. Clinical factors such as age, sex, comorbidities, smoking, type of surgical visualization, preoperative ABG and the presence of a Carhart notch did not show a statistically significant association with surgical failure. However, a significant relationship was identified between failure and stapedectomy, as well as with the affected side of the ear, highlighting the impact of intraoperative technical decisions on functional outcomes.

Audiometric analysis showed significant improvements in air conduction thresholds and air–bone gaps at all evaluated frequencies, with large to very large effect sizes, greater than those reported in international studies. These findings confirm the clinical efficacy of the intervention and reinforce the usefulness of stapedotomy as the preferred technique.

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