# **ORIGINAL ARTICLE**

# The Outcomes and the Affecting Factors of Stapes Surgery for Otosclerosis

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**Objective:** The primary objective of the present study was to estimate the success rate of stapes surgery for otosclerosis. The secondary objective was to find the factors affecting the outcomes.

Material and Methods: This study was a retrospective study that included the ears of otosclerosis patients who underwent stapes surgery between January 2015 and December 2021. The successful outcome was the postoperative air-bone gap of 10 dB or less without sensorineural hearing loss.

**Results:** One hundred fifty-five ears were included in the present study. The short-term success rate was 87 out of 155 (56.1%). After follow-up, eleven (7.1%) operated ears underwent revision surgery, and the long-term success rate was 72 out of 96 (75.0%). From multivariate analysis, A-ABG of 35 dB or less and BMI of 25 kg/m<sup>2</sup> or less had adjusted OR 4.6 (95% CI 2.0 to 10.2), p<0.01 and 2.4 (95% CI 1.1 to 5.0), p=0.02, respectively.

**Conclusion:** The success rates of stapes surgery were 56.1% in the short-term and 75.0% in the long-term post-operation. Factors influencing the outcome included preoperative air-bone gap and body mass index. It is recommended that a prospective study be conducted to address the limitations of the present study.

Keywords: Otosclerosis; Stapes surgery; Stapedectomy; Stapes; Conductive hearing loss

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Otosclerosis is a disease of the otic capsule. It is caused by the bone spongification process, or otospongiosis<sup>(1)</sup>. The endochondral bone remodeling process, composed of resorption and deposition of bone, results in sclerotic bone formation. Otosclerosis is a genetic disease inherited in autosomal dominant pattern with variable penetrance between 25% and  $40\%^{(2-5)}$ . The clinical prevalence in Europe was about 0.3% to 0.4%, which was more significant in females than males at a ratio of 2:1. The age of onset is usually in the third decade of life. Although it is the common cause of progressive conductive hearing loss in adults, the hearing loss can be conductive, sensorineural, or mixed. The bilateral involvement is about 75%. The primary objective of treatment is to improve hearing

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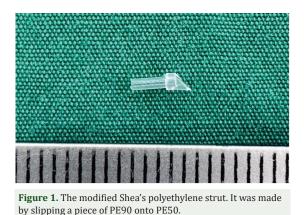
Department of Otorhinolaryngology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand. Phone: +66-2-4198040, Fax +66-2-4198044 Email: phoupong.pho@mahidol.ac.th

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Prakairungthong S, Atipas S, Thongyai K, Limviriyakul S, Suvarnsit K, Phousamran P. The Outcomes and the Affecting Factors of Stapes Surgery for Otosclerosis. J Med Assoc Thai 2025;108:384-92. DOI: 10.35755/jmedassocthai.2025.5.384-392-02702 levels and the patient's quality of life. Although there are a few treatment modalities, such as medication and hearing aids, the treatment of choice still involves stapes surgery.

The first stapedectomy was introduced with a Teflon stapes replica prosthesis in 1956<sup>(6)</sup>. Stapes surgery has developed in various aspects, including surgical techniques and prostheses. Several factors influence the surgical outcomes. The surgery can be categorized into two main types, stapedotomy, which is the creation of a small opening within the central footplate, and stapedectomy, which is the total or partial removal of the stapes footplate. The characteristics of the prostheses also impact the outcomes, such as material, design, size, and crimping process. Other factors may also affect the outcomes, such as age<sup>(7-9)</sup>, gender<sup>(7,10)</sup>, degree of preoperative hearing loss<sup>(7,10)</sup>, and history of otologic procedure<sup>(9)</sup>.

Siriraj Hospital is a university hospital in Thailand that offers tertiary care with experienced otologists. This institute primarily performs stapedectomy for otosclerosis. The most used prosthesis is a modified Shea's polyethylene (PE) strut adapted from Dr. Frederick R Guilford in 1968<sup>(11)</sup>. It was made by slipping a piece of PE90 onto PE50 (Figure 1). The success rates of the operation were 78.65% at one



month and 90.24% at six months post-operation, respectively<sup>(12)</sup>. Due to its cost-effectiveness, this institute has adopted stapedectomy with the modified Shea's PE strut as the preferred standard technique.

The success rate for stapes surgery varied among the institutes due to many factors. There are a few studies about stapes surgery in Thailand, but no research has been conducted about the factors influencing surgical outcomes.

Hence, the present study aimed to estimate the success rate of stapes surgery in patients with otosclerosis in this tertiary care hospital. The secondary objective was to find the factors affecting the outcomes.

# **Materials and Methods**

# Study design and population

A retrospective chart review of the electronic database was conducted. Inclusion criteria included patients diagnosed with otosclerosis who underwent primary stapes surgery at Siriraj Hospital between January 2015 and December 2021. The exclusion criteria were ears with revision stapes surgery or insufficient information. Demographic data such as age, gender, weight, height, body mass index (BMI), and underlying disease were collected.

Certified audiologists performed the pre- and post-operative audiometry. Air conduction thresholds (ACTs) were measured at frequencies of 0.25, 0.5, 1, 2, 3, 4, and 8 kHz, while bone conduction thresholds (BCTs) were recorded at 0.5, 1, 2, 3, and 4 kHz. Additionally, the speech reception threshold (SRT) and word recognition score (WRS) were documented. The SRT is the lowest intensity level (dB) at which a person can correctly repeat 50% of the presented spondee words. The WRS, also known as the speech discrimination score (SDS), measures the percentage of phonetically balanced monosyllabic words correctly identified by the listener at a suprathreshold level, which is usually above the SRT 35 dB.

The operation details including date, type, operative time, laterality, surgeon, type of prosthesis, and intraoperative complications were collected. The ears operated on were followed for at least one-year post-operation before the data analysis.

## Sample size calculation

From the previous study<sup>(12)</sup>, the success rate at one-month post-operation was about 79%. The sample size was calculated by estimating an infinite population proportion formula. The study included a sample size of 155 subjects, with a type I error rate of 0.05 and a margin of error of 0.064.

### Surgical procedure

The surgical procedures were performed in the operating room under general or local anesthesia. The surgeon was an otologist or fellow under supervision. All the operations were microscope-assisted. Stapes surgery was performed via a transcanal approach. After the injection of 1% xylocaine with adrenaline, the endomeatal incision was performed. The tympanomeatal flap was elevated to enter the middle ear cavity. Scutum was curetted for good exposure. The chorda tympani nerve was retracted inferiorly and preserved as a priority. The middle ear was explored. The ossicular chain mobility was tested to confirm the stapes footplate fixation. The primary objective of surgery was stapedectomy, either total or partial with the conventional tailor-made PE prosthesis. A measuring rod measured the distance between the lenticular process of the incus and the footplate. The control hole on the fixed footplate was created to observe the perilymphatic fistula. The prosthesis was made by slipping PE90 onto PE50. The distance was equal to the length of PE50. Either the tragal perichondrium graft or the vein graft was harvested. The stapedial muscle was cut, and the stapes suprastructure was removed. The entire footplate was removed in one piece when possible. After placing the prepared graft to cover the oval window, the prosthesis was placed in interposition below the lenticular process and hooked with the beveled end of PE90. The end of PE50 touched the graft beneath. The end of PE50 was trimmed and beveled in case of a narrow footplate. The round window reflex was checked to confirm the intact ossicular chain function. Some patients underwent stapedotomy with fluoroplastic piston prostheses. The procedure started in the same way. The prosthesis

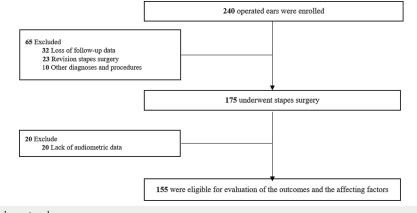


Figure 2. The study protocol.

was trimmed after measuring the distance between the lenticular process of the incus and the footplate. The stapes suprastructure was fractured. The perforator was then used to create a fenestra on the footplate. After inserting a piston into the fenestrated hole, the hook was hung with the long process of incus. The tympanomeatal flap was repositioned. Finally, the external ear canal was packed with a piece of rayon and a chain of cotton balls.

## **Outcomes and measurement**

According to the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)<sup>(13)</sup>, the air-conduction pure tone average (air-PTA) or bone-conduction PTA (bone-PTA) (dB) was calculated from ACT or BCT (dB) at 0.5, 1, 2, and 3 kHz. If the audiogram did not perform at 3 kHz, the mean of the threshold at 2 and 4 kHz was used instead. The gain (dB) means the difference between pre- and post-operative audiograms at the individual frequency or the average threshold. The air-bone gap (ABG) (dB) was calculated from the difference between ACT and BCT at the same frequency. The mean of ABG at 0.5, 1, 2, 3 kHz was called the average ABG (A-ABG) (dB).

The PTA was categorized according to the degree of hearing loss based on the World Health Organization (WHO)'s Grades of hearing impairment<sup>(14)</sup>.

Success is defined when the postoperative A-ABG is 10 dB or less without a bone-PTA increase of more than 10 dB. Overclosure was defined as the gain in bone-PTA of 10 dB or more. The hearing results of the operation were presented in the form of the Amsterdam Hearing Evaluation Plots (AHEPs)<sup>(15)</sup>. The short-term outcomes were defined as those occurring within four to twelve weeks post-operation, while the long-term outcomes were characterized as those occurring within 12 to 24 months post-operation.

For successful outcomes, factors influencing the results were if the p-value was less than 0.2 in the univariate analysis. Subsequently, a multivariate analysis was conducted.

The surgical outcomes were presented as mean  $\pm$  standard deviation (SD) and prevalence (%).

The factors affecting the outcomes were reported as adjusted odds ratio (OR) and 95% confidence interval (CI).

# Statistical analysis

Descriptive statistics were utilized for demographic data. The paired t-test compared preoperative and postoperative continuous variables, while the McNemar test handled categorical variables. Group post-operation comparisons used the t-test and non-parametric statistics for means, and categorical data like prevalence and odds ratios were analyzed with chi-square or Fisher's exact tests. Following univariate analysis, multivariate logistic regression analysis was conducted, incorporating factors from univariate analysis with a p-value of less than 0.2. A p-value of less than 0.05 was considered statistically significant. Statistical analysis was performed using IBM SPSS Statistics for MAC, version 29.0 (IBM Corp., Armonk, NY, USA).

# Ethical consideration

The present research was approved by the Institute's Ethical Committee (COA no. Si738/2022).

# Results

# Patient characteristics and demographic data

Referring to Figure 2, 240 operated ears were

enrolled in the present study. Sixty-five ears were excluded, and 20 ears lacked audiometric data for the relevant period. The characteristics and demographic data are presented in Table 1. The present study included 155 operated ears from 138 patients, with a mean age of 47.9±10.12 years. Approximately 70% of the participants were female, and around 40% had underlying diseases. The most common underlying conditions were hypertension at 22.6% and dyslipidemia at 16.8%. Bilateral involvement and history of previous stapes surgery on the other side were observed in 80.0% and 25.8% of cases, respectively. The air-PTA and A-ABG measurements were 60.8±11.33 dB and 31.5±9.68 dB, respectively. Most patients experienced severe at 47.1% and 45.8% experienced moderate hearing loss.

The majority of the operations were stapedectomy, at 81.3%, utilizing the modified Shea's PE strut in 74.2% as the standard procedure at the present study institute. In some instances, due to a narrowing footplate or surgeon preference, stapedotomy with fluoroplastic piston prosthesis was performed on patients. The operation time was  $81.9\pm37.38$  minutes. General anesthesia was the most used anesthetic technique at 91.0%. The side of the operation was relatively equal between the left and right.

#### The outcomes

#### The success rates:

At four to twelve weeks post-operation, 106 ears (68.4%), exhibited the postoperative A-ABG of less than 10 dB. There were 22 ears (14.2%) where the postoperative bone PTA increased by more than 10 dB. The success rate was 87 out of 155 (56.1%), with an overclosure rate of 13 out of 155 (8.4%).

Stapedectomy had a higher success rate than stapedotomy at 58.7% versus 44.8%, however, the difference was not statistically significant (OR 1.8, 95% CI 0.8 to 4.0, p=0.17). The success rate of the operation performed by staff was higher than that of fellows at 59.0% versus 45.5%, but this difference was also not significant (OR 1.7, 95% CI 0.8 to 3.7, p=0.16).

The success rate at 12 to 24 months postoperation was calculated. Eleven ears (7.1%) required revision stapes surgery within one year due to failed results and complications. Forty-eight ears lacked audiometric data for the relevant periods, so 96 ears were included in the analysis. The long-term success rate was 72 out of 96 (75.0%).

The audiometric outcomes:

As shown in Figure 3, the ACT improved

#### Table 1. Patient characteristics and demographic data

Characteristics	Results
Number of operated ears	155
Age; mean±SD (years)	$47.9 \pm 10.12$
Sex; n (%)	
Male	46 (29.7)
Female	109 (70.3)
Smoking status; n (%)	
Non-smoker	140 (90.3)
Ex-smoker	6 (3.9)
Smoker	7 (4.5)
Underlying disease; n (%)	63 (40.6)
Diabetes mellitus	13 (8.4)
Hypertension	35 (22.6)
Dyslipidemia	26 (16.8)
Allergic rhinitis/chronic rhinosinusitis	6 (3.9)
Neoplasm	7 (4.5)
Others	22 (14.2)
Surgeon; n (%)	
Staff	122 (78.7)
Fellow (under supervision)	33 (21.3)
Prosthesis; n (%)	
Tailor-made prosthesis (PE90/50)	115 (74.2)
Fluoroplastic piston	38 (24.5)
Others	2 (1.3)

SD=standard deviation; PE=polyethylene

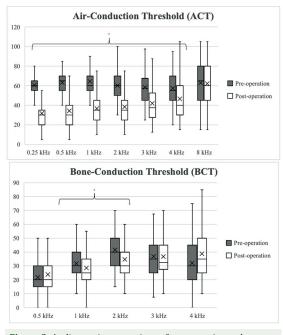


Figure 3. Audiometric comparison of preoperative and postoperative air-conduction threshold (ACT) (dB) and bone-conduction threshold (BCT) (dB).

\* p<0.05 was considered statistically significant

#### Table 2. The audiometric outcome

Outcomes	Pre-operation	Post-operation	Gain	p-value
Number of the operated ears	1	55		
Audiometric data; mean $\pm$ SD				
Air-PTA (dB)	$60.8 \pm 11.33$	38.1±17.11	$22.8 \pm 14.89$	< 0.01*
Bone-PTA (dB)	$29.3 \pm 10.48$	$30.3 \pm 14.80$	$-1.0\pm13.03$	0.33
A-ABG (dB)	$31.5 \pm 9.68$	7.7±9.24	$23.8 \pm 11.83$	< 0.01*
SRT (dB)	$60.3 \pm 11.65$	36.2±16.35	24.1±16.66	< 0.01*
WRS (%)	$96.5 \pm 10.54$	95.9±14.68	$0.6 \pm 14.3$	0.58
Severity; n (%)				
Normal	0 (0.0)	32 (20.6)		
Mild	1 (0.6)	69 (44.5)		
Moderate	71 (45.8)	40 (25.8)		
Severe	73 (47.1)	10 (6.5)		
Profound	10 (6.5)	4 (2.6)		
Disability; n (%)	154 (99.4)	54 (34.8)		< 0.01*

PTA=pure tone average; A-ABG=average air-bone gap; SRT=speech reception threshold; WRS=word recognition score; SD=standard deviation

 $^{*}$  p<0.05 was considered statistically significant

at nearly all frequencies except 8 kHz. The BCT decreased at 1 and 2 kHz but increased at 4 kHz. Table 2 shows the improvement of air-PTA, A-ABG, and SRT, while WRS and bone-PTA did not change significantly. The severity of hearing loss distribution was notably rearranged. Hearing outcomes were also evaluated using AHEPs (Figure 4).

The factors associated with the short-term outcomes:

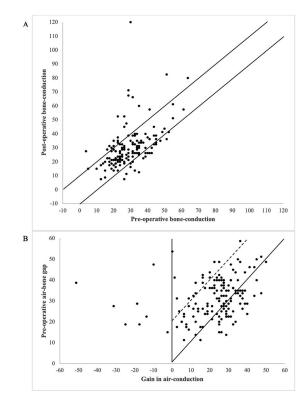
The factors that could influence the outcomes are listed in Table 3. The mean ages of the success and non-success groups were  $47.1\pm9.86$  years and  $49.1\pm10.41$  years, respectively. The preoperative air-PTA and preoperative A-ABG were analyzed using ROC analysis, determining the most reliable cut-off points to be 65 dB and 35 dB, respectively.

The multivariate analysis was performed. According to Table 4, the factors associated with successful outcomes were A-ABG of 35 dB or less (adjusted OR 4.6, 95% CI 2.0 to 10.2, p<0.01), and BMI of less than 25 kg/m<sup>2</sup> (adjusted OR 2.4, 95% CI 1.1 to 5.0, p=0.02).

# Discussion

Otosclerosis is caused by the fixation of the stapes footplate due to otospongiosis<sup>(1)</sup>. The preferred treatment is stapes surgery with prosthesis replacement.

The successful outcome was defined as the closure of the ABG to 10 dB or less. The outcomes were evaluated at four to twelve weeks and 12 to 24 months post-operation. The short-term success



**Figure 4.** Audiometric short-term results of 155 operated ears visualized with the AHEPs. (A) Preoperative and postoperative BCT (dB) plotted for individual ears. (B) Postoperative gain in ACT (dB) plotted against preoperative A-ABG for individual ears.

rate was 56.1%, and the long-term success rate was 75.0%. The revision rate within one-year post-operation was 7.1%.

#### Table 3. Factors affecting the outcomes

Non-success	Success	OR (95% CI)	p-value
68	87		
46 (67.6)	63 (72.4)	1.3 (0.7 to 2.5)	0.52
34 (50.0)	61 (70.1)	2.4 (1.2 to 4.5)	0.01*
54 (79.4)	70 (80.5)	1.1 (0.5 to 2.4)	0.87
16 (23.5)	24 (27.6)	1.2 (0.6 to 2.6)	0.57
42 (61.8)	66 (75.9)	1.9 (1.0 to 3.9)	0.06
29 (42.6)	48 (55.2)	0.6 (0.3 to 1.1)	0.12
52 (76.5)	74 (85.1)	1.8 (0.8 to 4.0)	0.17
61 (89.7)	80 (92.0)	1.3 (0.4 to 3.9)	0.63
47 (69.1)	68 (78.2)	1.6 (0.8 to 3.3)	0.20
40 (58.8)	70 (80.5)	2.9 (1.4 to 5.9)	< 0.01*
32 (47.1)	70 (80.5)	4.6 (2.3 to 9.4)	< 0.01*
	68         46 (67.6)         34 (50.0)         54 (79.4)         16 (23.5)         42 (61.8)         29 (42.6)         52 (76.5)         61 (89.7)         47 (69.1)         40 (58.8)	68         87           46 (67.6)         63 (72.4)           34 (50.0)         61 (70.1)           54 (79.4)         70 (80.5)           16 (23.5)         24 (27.6)           42 (61.8)         66 (75.9)           29 (42.6)         48 (55.2)           52 (76.5)         74 (85.1)           61 (89.7)         80 (92.0)           47 (69.1)         68 (78.2)           40 (58.8)         70 (80.5)	68         87           46 (67.6)         63 (72.4)         1.3 (0.7 to 2.5)           34 (50.0)         61 (70.1)         2.4 (1.2 to 4.5)           54 (79.4)         70 (80.5)         1.1 (0.5 to 2.4)           16 (23.5)         24 (27.6)         1.2 (0.6 to 2.6)           42 (61.8)         66 (75.9)         1.9 (1.0 to 3.9)           29 (42.6)         48 (55.2)         0.6 (0.3 to 1.1)           52 (76.5)         74 (85.1)         1.8 (0.8 to 4.0)           61 (89.7)         80 (92.0)         1.3 (0.4 to 3.9)           47 (69.1)         68 (78.2)         1.6 (0.8 to 3.3)           40 (58.8)         70 (80.5)         2.9 (1.4 to 5.9)

BMI=body mass index; PE=polyethylene; PTA=pure tone average; A-ABG=average air-bone gap; OR=odds ratio; CI=confidence interval \* p<0.05 was considered statistically significant

 Table 4. Multivariate analysis of the factors associated with successful outcomes

Factors	Adjusted OR (95% CI)	p-value
Air PTA ≤65 dB	2.0 (0.9 to 4.6)	0.09
A-ABG ≤35 dB	4.6 (2.0 to 10.2)	< 0.01*
Right side	0.6 (0.3 to 1.2)	0.58
$BMI < 25 \text{ kg/m}^2$	2.4 (1.1 to 5.0)	0.02*
Operation time <90 minutes	1.7 (0.8 to 3.9)	0.17
Stapedectomy	2.3 (0.9 to 5.8)	0.09

PTA=pure tone average; A-ABG=average air-bone gap; BMI=body mass index; OR=odds ratio; CI=confidence interval

\* p<0.05 was considered statistically significant

From the previous studies<sup>(8,16-22)</sup>, the success rate was 45.2% to 95.6%. The success rates were lower when compared to the previous study by the same institute<sup>(12)</sup>. The results from the two studies were not comparable because the present study used stricter criteria for success.

Table 5 presents a comparative analysis between the present study and the others. The success rate varied among the institutions due to multiple factors. Most of the studies involved stapedotomy as the surgical procedure for stapes. The fluoroplastic piston prosthesis was predominantly utilized. The timing for evaluation differed across studies, and the A-ABG was computed from various frequencies. The success rate changed over time<sup>(21)</sup>. The long-term outcome is a more reliable guide to counseling a patient. The stapedectomy with the traditional tailor-made prosthesis was the most used operation in the present study. In addition, the surgeons consisted of highly experienced otologists, young staff, and fellows. So, there were variations in the surgeon's experience. After the operation, ACT improved across most frequencies. The air-PTA decreased by  $22.8\pm14.89$  dB, and the A-ABG decreased by  $23.8\pm11.83$  dB. These findings correlated with the previous studies<sup>(16,17,23,24)</sup> that reported the mean gain of the air-PTA about 21.4 to 29.2 dB and A-ABG about 16.9 to 22.9 dB.

Although the BCT improved significantly at 1 and 2 kHz, the bone PTA did not change significantly. The BCT at 2 kHz decreased by about 7 dB. One study<sup>(25)</sup> reported the gain of the BCT at 2 kHz about 4 to 12 dB. It could be from the disappearance of Carhart's phenomenon due to impedance mismatch between the middle and inner ear because of fixation of the stapes<sup>(26)</sup>.

The prevalence of hearing impairment significantly decreased post-operation. Under the regulations of the Ministry of Social Development and Human Security of Thailand, individuals with an air-PTA of 40 dB or higher qualify as hearing-disabled. The prevalence of hearing disability declined from 99.4% to 34.8% in the short-term period following the operation. This suggests that the surgical intervention may potentially reduce the prevalence of hearing disability in Thailand by 64.6%. These results may differ between countries due to varying criteria for disability.

Univariate analysis identified several factors with a p-value of less than 0.2 that might affect outcomes as air PTA of 65 dB or less, A-ABG of 35 dB or less, right side, BMI of less than 25 kg/m<sup>2</sup>, operation time of less than 90 minutes, and stapedectomy procedure. Multivariate analysis confirmed that some of these factors still influenced the outcomes. Table 5. Success rate comparison with the previous studies

Study	Operation	n	Timing	Success rate (%)	Criteria of success
Vincent et al. <sup>(16)</sup> , USA, 2006	Stapedotomy	2,527	3 to 11 months 12 to 18 months	95.5 95.6	A-ABG (0.5, 1, 2, 4 kHz) ≤10 dB
Dhooge et al. <sup>(17)</sup> , Beigium, 2017	Stapedotomy	230 181	1 month ≥1 year	77.4 70.7	A-ABG (0.5, 1, 2, 3 kHz) ≤10 dB
Yeh et al. <sup>(18)</sup> , Taiwan, 2019	Stapedotomy	181	3 months	53.0	A-ABG (0.5, 1, 2, 3 kHz) $\leq 10 \text{ dB}$
Deniz et al. <sup>(19)</sup> , Turkey, 2019	Stapedotomy	245	6 months	75.1	A-ABG (0.5, 1, 2, 4 kHz) ≤10 dB
Xie et al. <sup>(20)</sup> , China, 2019	Stapedotomy	58	$\geq$ 3 months	71.4	A-ABG (0.5, 1, 2, 4 kHz) $\leq 10 \text{ dB}$
Peñaranda et al. <sup>(8)</sup> , Columbia, 2020	Stapedotomy	486	<6 months	67.4	A-ABG (0.5, 1, 2, 3 kHz) $\leq 10 \text{ dB}$
Saerens et al. <sup>(21)</sup> , Belgium, 2021	Stapedotomy	151	1 to 12 months >1 year	45.2 47.8	A-ABG (0.5, 1, 2, 4 kHz) ≤10 dB
Albera et al. <sup>(22)</sup> , Italy, 2022	Stapedotomy	581	1 year	62.3	A-ABG (0.5, 1, 2, 4 kHz) $\leq 10 \text{ dB}$
This study, Thailand, 2023	Mostly stapedectomy	155 107	4 to 12 weeks 12 to 24 months	56.1 75.0	A-ABG (0.5, 1, 2, 3 kHz) ≤10 dB

A-ABG=average air-bone gap

A preoperative A-ABG of 35 dB or less was associated with successful outcomes. Several studies have indicated this correlation. The smaller preoperative ABG had a better audiometric result at 0.25 kHz and 4 kHz<sup>(8)</sup>. Two studies<sup>(17,19)</sup> found that the large preoperative A-ABG was associated with an unsuccessful outcome. The most reliable cut-off point of preoperative A-ABG from receiver operating characteristic (ROC) analysis was 34.5 dB, with a sensitivity of 66% and specificity of 83%<sup>(19)</sup>. The severity of the disease could explain these findings. The patients with severe round window involvement had a higher pre- and postoperative A-ABG<sup>(27)</sup>. Based on the findings, physicians are advised to consider stapes surgery during the initial stages of the disease. On the contrary, a study<sup>(7)</sup> did not agree with this association due to no difference in success rate between the patients with preoperative A-ABG 30 dB or less and more than 30 dB.

The stapes surgery requires surgical precision. So, patient factors, such as a large shoulder, a short neck, and a narrow ear canal, might cause trouble for surgical access. Furthermore, the difficulty upon awakening from surgery might lead to prosthesis displacement<sup>(28)</sup>. However, patients with a BMI of 25 kg/m<sup>2</sup> or less had a better result in the present study. The previous study showed no significant differences in postoperative A-ABG across the BMI categories<sup>(29)</sup>.

The initial hearing threshold could affect the outcome<sup>(7,8,10,19)</sup>. The patients with preoperative air PTA of 55 dB or less had a higher prevalence of successful outcomes<sup>(7)</sup>. However, this study showed that patients with the preoperative air-PTA of 65 dB or less did not have significantly better prognosis.

The right ear could be more complicated because the patient's ipsilateral shoulder abutted the dominant operating hand for right-handed surgeons. Some studies<sup>(7,8,22)</sup>, including the present study, did not find an association between the side and the outcome.

Stapedotomy was superior to stapedectomy in hearing outcomes, especially in high frequencies<sup>(30-36)</sup>. Furthermore, the incidence of postoperative sensorineural hearing loss was lower in stapedotomy<sup>(33,34,37-41)</sup>. The present study found that stapedectomy had a slightly higher success rate than stapedotomy due to surgeon familiarity and case difficulty.

Surgeons' experience influences stapes surgery outcomes. A study revealed that those with six years or less of experience often had unsuccessful results<sup>(42)</sup>. At the present study medical institute, fellows performed surgeries under staff supervision, which could intervene at any moment. Consequently, the study found no difference in success rates between staff and fellows.

The literature review identified factors influencing surgical outcomes. Prostheses' characteristics, including material, design, size, and incus crimping process, impacted the results. In general, the fluoroplastic piston seems to be the most employed prosthesis<sup>(43)</sup>. The meta-analysis showed that 0.6-mm-diameter piston prostheses, compared to 0.4-mm-diameter, were correlated with better outcomes in postoperative hearing thresholds, improvement in the ABG, and success rate<sup>(44)</sup>. The patients aged 50 years or less had a higher success rate than those aged more than 50 years old<sup>(7)</sup>. However, one study found that, with increasing age, there was an improved postoperative ABG and an increased chance of

surgical success<sup>(9)</sup>. The ABG closure was better in female patients. The younger age was associated with better postoperative results<sup>(10)</sup>. The univariate analysis conducted in the present study revealed no significant differences in age, gender, procedure type, or prosthesis type between the success and unsuccess groups.

# Limitation

The present study had limitations. Firstly, data from electronic medical records were sometimes lost or incomplete. Secondly, sample sizes were insufficient due to restricted elective operations and lost follow-ups during the COVID-19 pandemic. Thirdly, there was a variation in surgeons and audiologists involved. A prospective study addressing these issues is necessary.

# Conclusion

The success rates of stapes surgery were 56.1% in the short-term and 75.0% in the long-term postoperation. Factors influencing the outcome included preoperative ABG and BMI. It is recommended that a prospective study be conducted to overcome the limitations of the present study.

# What is already known about this topic?

Several studies have reported the success rate and factors influencing stapes surgery for otosclerosis. However, there is a lack of information regarding the presented institute and the factors that impact the outcomes.

## What does this study add?

The success rates of stapes surgery in the presented institute were 56.1% and 75.0% at short-term and long-term post-operation. The factors affecting the outcome were preoperative ABG and BMI.

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# **Conflicts of interest**

The authors declare no conflict of interest.

# References

- Siebenmann F. Totaler knöcherner verschluss beider labyrinthfenster und labyrinthitis serosa infolge progressiver spongiosierung. Verh Dtsch Otol Ges 1912;21:267.
- Thys M, Van Camp G. Genetics of otosclerosis. Otol Neurotol 2009;30:1021-32.
- Babcock TA, Liu XZ. Otosclerosis: From genetics to molecular biology. Otolaryngol Clin North Am 2018;51:305-18.
- Altmann F, Glasgold A, Macduff JP. The incidence of otosclerosis as related to race and sex. Ann Otol Rhinol Laryngol 1967;76:377-92.
- Tato JM, Tato JM Jr. Otosclerosis and races. Ann Otol Rhinol Laryngol 1967;76:1018-25.
- Shea JJ Jr. Fenestration of the oval window. Ann Otol Rhinol Laryngol 1958;67:932-51.
- Chen PH, Lin KN, Lin HY, Yu RB, Liu PY, Shih WT, et al. Factors associated with hearing outcomes after stapedotomy in Taiwanese patients with clinical otosclerosis. Ear Nose Throat J 2024;103:NP76-84.
- Peñaranda D, Moreno S, Montes F, Garcia JM, Rico Z, Peñaranda A. Fifteen-year follow-up of stapedotomy patients: Audiological outcomes and associated factors in a middle income country. Audiol Neurootol 2021;26:53-60.
- Patel S, Benyo S, Saadi R, Liaw J, King TS, Isildak H. Predictive patient factors for poor outcomes following stapedotomy for otosclerosis. Otol Neurotol 2022;43:619-24.
- Shah V, Ganapathy H. Factors affecting the outcome of stapes surgery. Indian J Otolaryngol Head Neck Surg 2018;70:256-61.
- Draper WL, Herndon JW. A new prosthesis for stapes surgery. Laryngoscope 1972;82:864-7.
- Thongyai K, Prakairungthong S, Chongvisal S, Limviriyakul S, Srisomboon P, Suvarnsit K. Hearing gain with tailor-made polyethylene strut in total stapedectomy. Siriraj Med J 2017;69:18-23
- Monsell EM. New and revised reporting guidelines from the Committee on Hearing and Equilibrium. American Academy of Otolaryngology-Head and Neck Surgery Foundation, Inc. Otolaryngol Head Neck Surg 1995;113:176-8.
- Olusanya BO, Davis AC, Hoffman HJ. Hearing loss grades and the international classification of functioning, disability and health. Bull World Health Organ 2019;97:725-8.
- de Bruijn AJ, Tange RA, Dreschler WA. Efficacy of evaluation of audiometric results after stapes surgery in otosclerosis. II. A method for reporting results from individual cases. Otolaryngol Head Neck Surg

2001;124:84-9.

- Vincent R, Sperling NM, Oates J, Jindal M. Surgical findings and long-term hearing results in 3,050 stapedotomies for primary otosclerosis: a prospective study with the otology-neurotology database. Otol Neurotol 2006;27(8 Suppl 2):S25-47.
- Dhooge I, Desmedt S, Maly T, Loose D, Van Hoecke H. Long-term hearing results of stapedotomy: analysis of factors affecting outcome. Eur Arch Otorhinolaryngol 2018;275:1111-9.
- Yeh CF, Wang MC, Chu CH, Shiao AS. Predictors of hearing outcomes after stapes surgery in otosclerosis. Acta Otolaryngol 2019;139:1058-62.
- Deniz B, Ihsan K, Ismail G, Rauf Oguzhan K, Muge O. Analysis of factors affecting postoperative functional outcome in patients with otosclerosis. Auris Nasus Larynx 2020;47:203-8.
- Xie J, Zhang LJ, Zeng N, Liu Y, Gong SS. The clinical characteristics of otosclerosis and benefit from stapedotomy: our experience of 48 patients (58 ears). Acta Otolaryngol 2019;139:843-8.
- Saerens M, Van Damme JP, Bihin B, Garin P. Hearing results in 151 primary stapedotomies for otosclerosis: The effects of using different audiologic parameters and criteria on success rates. Otol Neurotol 2021;42:e1436-43.
- Albera A, Parandero F, Andriani R, Albera R, Riva G, Canale A. Prognostic factors influencing postoperative air-bone gap in stapes surgery. Acta Otorhinolaryngol Ital 2022;42:380-7.
- 23. Nash R, Patel B, Lavy J. Changes to hearing levels over the first year after stapes surgery: An analysis of 139 patients. Otol Neurotol 2018;39:829-33.
- Dziendziel B, Skarzynski H, Gos E, Skarzynski PH. Changes in hearing threshold and tinnitus severity after stapes surgery: Which is more important to the patient's quality of life? ORL J Otorhinolaryngol Relat Spec 2019;81:224-33.
- Awengen DF. Change of bone conduction thresholds by total footplate stapedectomy in relation to age. Am J Otolaryngol 1993;14:105-10.
- Carhart R. Clinical application of bone conduction audiometry. Arch Otolaryngol (1925) 1950;51:798-808.
- Mansour S, Nicolas K, Ahmad HH. Round window otosclerosis: radiologic classification and clinical correlations. Otol Neurotol 2011;32:384-92.
- Muelleman T, Shew M, Muelleman RJ, Villwock M, Sykes K, Staecker H, et al. Obesity does not increase operative time in otologic surgery: An analysis of 5125 cases. Otol Neurotol 2018;39:e103-7.
- 29. Gadkaree SK, Weitzman RE, Yu PK, Miller AL, Ren Y, Corrales CE. The role of body mass index on hearing outcomes after stapes surgery. Otol Neurotol

2020;41:21-4.

- House HP, Hansen MR, Al Dakhail AA, House JW. Stapedectomy versus stapedotomy: comparison of results with long-term follow-up. Laryngoscope 2002;112:2046-50.
- Fisch U. Stapedotomy versus stapedectomy. Am J Otol 1982;4:112-7.
- Colletti V, Fiorino FG. Stapedotomy with stapedius tendon preservation: technique and long-term results. Otolaryngol Head Neck Surg 1994;111:181-8.
- Somers T, Govaerts P, Marquet T, Offeciers E. Statistical analysis of otosclerosis surgery performed by Jean Marquet. Ann Otol Rhinol Laryngol 1994;103:945-51.
- Bailey HA Jr, Pappas JJ, Graham SS. Small fenestra stapedectomy. A preliminary report. Laryngoscope 1981;91:1308-21.
- McGee TM. Comparison of small fenestra and total stapedectomy. Ann Otol Rhinol Laryngol 1981;90:633-6.
- Moon CN Jr, Hahn MJ. Partial vs. total footplate removal in stapedectomy: a comparative study. Laryngoscope 1984;94:912-5.
- Persson P, Harder H, Magnuson B. Hearing results in otosclerosis surgery after partial stapedectomy, total stapedectomy and stapedotomy. Acta Otolaryngol 1997;117:94-9.
- Kos MI, Montandon PB, Guyot JP. Short- and longterm results of stapedotomy and stapedectomy with a teflon-wire piston prosthesis. Ann Otol Rhinol Laryngol 2001;110:907-11.
- Sedwick JD, Louden CL, Shelton C. Stapedectomy vs stapedotomy. Do you really need a laser? Arch Otolaryngol Head Neck Surg 1997;123:177-80.
- 40. Cremers CW, Beusen JM, Huygen PL. Hearing gain after stapedotomy, partial platinectomy, or total stapedectomy for otosclerosis. Ann Otol Rhinol Laryngol 1991;100:959-61.
- 41. Quaranta N, Besozzi G, Fallacara RA, Quaranta A. Air and bone conduction change after stapedotomy and partial stapedectomy for otosclerosis. Otolaryngol Head Neck Surg 2005;133:116-20.
- 42. Brkic FF, Erovic BM, Onoprienko A, Janik S, Riss D, Lill C, et al. Impact of surgeons' experience and the single-shot perioperative antibiotic prophylaxis on outcome in stapedotomy. PLoS One 2021;16:e0247451.
- Brar T, Passey JC, Agarwal AK. Comparison of hearing outcome using a Nitinol versus Teflon prosthesis in stapedotomy. Acta Otolaryngol 2012;132:1151-4.
- 44. Laske RD, Röösli C, Chatzimichalis MV, Sim JH, Huber AM. The influence of prosthesis diameter in stapes surgery: a meta-analysis and systematic review of the literature. Otol Neurotol 2011;32:520-8.