

## ORIGINAL RESEARCH

# Endoscopic malleostapedotomy versus incudostapedotomy for stapes fixation with or without lateral chain fixation: A comparative outcomes study

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**Abstract**

**Objectives:** This study aims to evaluate and compare the surgical outcomes of endoscopic malleostapedotomy (EMS) and endoscopic incudostapedotomy (EIS).

**Methods:** A retrospective analysis was conducted on 36 consecutive ears in 33 patients who underwent stapes surgery using either EMS (EMS group) or EIS (EIS group). Operational practicability across surgical steps, postoperative hearing, operation time, switch of approach, and complications were compared between the two groups.

**Results:** The EMS and EIS groups comprised seven (19.4%) and 29 ears (80.6%), respectively. The EMS group exhibited a greater proportion of moderate practicability in anchoring site exposure (42.9%, three of seven) and in securing the prosthesis (100%, seven of seven) in comparison to the EIS group, which had 0% (0 out of 29) and 41.4% (12 out of 29), respectively. Postoperative hearing improvements were equivalent between the groups, with EMS achieving a mean air-bone gap improvement of 28.8 dB and EIS of 23.2 dB. The ABG closure rates within 10 dB and 20 dB for the EMS group were 28.6% and 100%, respectively, and not significantly different from the EIS group ( $p = .103$ ). However, the average surgical duration for EMS was extended by 77.4 min. The rate of complications was comparable between the groups (EMS 14.3%, EIS 10.3%,  $p = 1.000$ ).

**Conclusion:** The findings indicate that while EMS requires a longer operation time because of decreased practicability in specific surgical steps, it provides comparable outcomes to EIS, underscoring the potential of endoscopic techniques to establish malleostapedotomy as a surgical option as it is with traditional incudostapedotomy.

**Level of Evidence:** 4.

**KEYWORDS**

congenital middle ear anomaly, endoscopic stapes surgery, incudostapedotomy, malleostapedotomy, otosclerosis

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## 1 | INTRODUCTION

Stapes surgery serves as an effective treatment for conductive or mixed hearing loss resulting from stapes footplate fixation, commonly observed in conditions like otosclerosis or congenital stapes ankylosis.<sup>1,2</sup> The surgical procedure restores movement of the ossicular chain and subsequent sound transmission to the inner ear by connecting the malleus or incus to the stapes footplate with a prosthesis, after stapedotomy. In cases where the stapes is fixed without any other ossicular abnormality, the standard approach is incudostapedotomy. This involves affixing the prosthesis between the incus and the stapes footplate. However, if there is concurrent lateral chain fixation or if the long process of the incus is abnormal, the prosthesis cannot be secured to the incus. These unfavorable situations require the implementation of malleostapedotomy, which anchors the prosthesis to the malleus.<sup>3,4</sup>

The trends in stapes surgery have witnessed significant advancements, particularly with the adoption of the endoscopic approach. Endoscopic stapes surgery has garnered attention due to its less invasive nature and the potential for comparable audiological outcomes to traditional microscopic techniques. Multiple studies have examined the surgical outcomes of endoscopic stapes surgery, analyzing factors such as surgical field visualization, operation time, the learning curve for surgeons, and patient outcomes.<sup>5-7</sup> However, current research on endoscopic stapes surgery is limited to traditional incudostapedotomy despite the fact that malleostapedotomy can be performed entirely using an endoscope alone, as demonstrated by Iannella et al. in six revision stapes surgery cases.<sup>8</sup> To date, this is the only clinical study on endoscopic malleostapedotomy (EMS). Moreover, no studies have compared the surgical outcomes of EMS and endoscopic incudostapedotomy (EIS).

Therefore, the objective of this study was to analyze the surgical outcomes of EMS and compare them with those of EIS.

## 2 | MATERIALS AND METHODS

### 2.1 | Subjects

The Institutional Review Board and Hospital Research Ethics Committee of Chungnam National University Hospital (Daejeon, Korea) approved this study. A retrospective analysis was performed on 36 consecutive ears from 33 patients who exhibited conductive hearing loss resulting from stapes fixation (either otosclerosis or congenital stapes ankylosis) with or without lateral chain fixation. The patients underwent stapes surgery via an ear endoscope between March 2016, marking the commencement of endoscopic stapes surgery at our institution, and June 2023. Preoperative assessment included pure-tone audiometry and high-resolution computed tomography (CT) scans of the temporal bone for all patients. Otosclerosis was diagnosed with the clinical presentation of progressive conductive hearing loss, a normal tympanic membrane, and the identification of otospongiotic foci around the cochlea including the fissula ante fenestram on

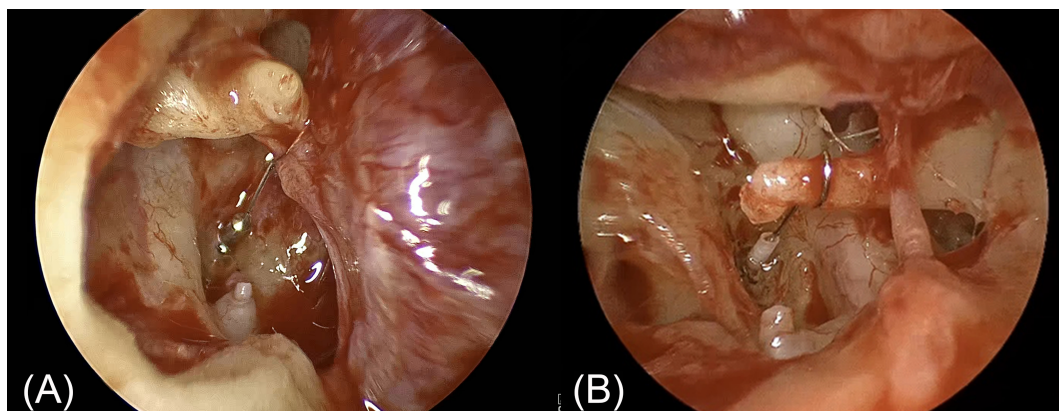
CT. Congenital stapes ankylosis was defined by non-progressive conductive hearing loss and normal tympanic membrane and CT findings. We excluded patients with less than 6 months of follow-up, those who underwent stapes surgery using conventional microscopic methods, and cases where conductive hearing loss was associated with external ear or other craniofacial anomalies. Patients were categorized into two groups for analysis: those who underwent EMS (EMS group) and those who underwent EIS (EIS group).

### 2.2 | Surgical procedure

All surgeries were performed under general anesthesia using a transcanal approach with 0- and 30-degree rigid endoscopes with 3 mm outer diameter and 14 cm length (Karl Storz, Germany). The tympanomeatal flap was raised to access the middle ear. A segment of the posterior superior canal wall was removed to expose the oval window niche. A comprehensive assessment of ossicular morphology and mobility was conducted. EMS was opted for in cases with abnormalities of the incus and/or fixation of the lateral chain. For revision stapes surgeries, any eroded incus or displaced prosthesis was removed. In instances of a dysplastic incus or fixed lateral ossicular chain, the malleus head and incus were removed after detaching the incudomalleolar joint. The tympanic membrane was separated from the malleus handle, just below the lateral process, to reveal the prosthesis anchoring site. Using a malleable rod, the distance from the malleus handle to the stapes footplate was measured. The stapes prosthesis (Lesinski platinum/fluoroplastic piston or a McGee-modified loop piston, Medtronic Xomed, FL, USA) was trimmed and bent to size. A fenestra was created on the stapes footplate using a CO<sub>2</sub> laser or microperforator following stapes superstructure removal. In cases with a preexisting footplate fenestra, fibrous tissue was removed, and the opening was enlarged as required. The prosthesis was placed in the fenestra and crimped to the malleus handle (Figure 1A). Soft tissue was used to seal the fenestra, and a piece of cartilage was placed to reinforce the prosthesis loop, preventing its exposure. The tympanomeatal flap was repositioned to conclude the procedure. EIS was performed in cases with isolated stapes immobilization. Unlike EMS, the stapes prosthesis was positioned between the long process of the incus and the stapes footplate fenestra without incus removal or tympanic membrane detachment from the malleus in EIS (Figure 1B).

### 2.3 | Operational practicability of endoscopic procedures

The practicability of endoscopic techniques during EMS and EIS was appraised across six key surgical steps based on intraoperative documentation and video recordings. The steps included (1) visualizing and evaluating stapes abnormalities; (2) visualizing and evaluating lateral ossicular chain abnormalities; (3) revealing the anchoring site (malleus handle for EMS, incus long process for EIS); (4) measuring from the anchoring site to the stapes footplate; (5) creating a fenestra on the



**FIGURE 1** An intraoperative image of endoscopic malleostapedotomy (A) and incudostapedotomy (B).

stapes footplate; and (6) securing the prosthesis between the anchoring site and stapes footplate. The practicability of each step was rated on a three-tier scale, reflecting the complexity and effort required: low (infeasible); moderate (feasible with difficulty); and high (feasible with ease). Two authors, in consultation, evaluated the rate of practicability.

## 2.4 | Clinical parameters and hearing evaluation

Patient demographics, clinical characteristics, etiology, operation duration, hearing outcomes, and complications, including dizziness, chorda tympani injury, and sensorineural hearing loss, were evaluated. Hearing function was tested using pure-tone audiometry. Pure-tone averages for air conduction (AC) and bone conduction (BC) were calculated using frequencies of 500, 1000, 2000, and 3000 Hz as recommended by the American Academy of Otolaryngology Committee on Hearing and Equilibrium.<sup>9</sup> Per these the guidelines, the preoperative average air-bone gap (ABG) is calculated as the difference between the preoperative average AC and BC threshold. Similarly, the postoperative average ABG is the difference between the postoperative average AC and BC threshold. The improvement in ABG is determined by calculating the difference between the average preoperative and postoperative ABGs.<sup>9</sup>

## 2.5 | Statistical analysis

Given the relative rarity of indications for malleostapedotomy compared to incudostapedotomy, we determined the sample size using a two-sided binomial test, aimed at achieving adequate study power. The success rates for ABG closure within 10 dB for EMS and EIS were derived from existing literature, setting the null proportion (P0) at 33.3%<sup>8</sup> and the alternative proportion (P1) at 88.2%.<sup>10</sup> The ratio of subjects in the EMS to EIS groups was established at 1:4, with type I and type II errors preset at 0.05 and 0.20, respectively. Consequently, the minimum required sample sizes for the EMS and EIS groups were

calculated as six and 24, respectively. Sample size calculations were performed using PASS version 13 software (NCSS Inc., Kaysville, UT).

For comparative analysis, Fisher's exact test was used to assess differences in sex, side of the operated ear, etiology, operational practicability for each surgical step, and postoperative ABG closure within 10 and 20 dB between the two groups. Mann-Whitney *U* test was utilized to compare variables such as age, operation duration, preoperative and postoperative pure-tone average thresholds, preoperative and postoperative ABGs, and ABG improvement. All statistical analyses were conducted using SPSS version 24 software (SPSS, Inc, an IBM Company, Chicago, Illinois).  $p < .05$  was considered statistically significant.

## 3 | RESULTS

### 3.1 | Demographic and clinical characteristics

Seven (19.4%) and 26 ears (80.6%) were included in the EMS and EIS groups, respectively. The mean patient ages were 35.6 years (standard deviation [SD] 20.8) for the EMS group and 37.6 years (SD 16.7) for the EIS group. Congenital stapes ankylosis was the primary etiology in both groups. Preoperatively, the mean BC and AC thresholds were similar between the groups. The preoperative mean ABG was higher in the EMS group compared to the EIS group because all except for one case with incus necrosis in the EMS group had stapes fixation combined with lateral chain fixation (Table 1).

### 3.2 | Operational practicability of endoscopic procedures

All steps of the EMS and EIS procedures were performed exclusively with an endoscope. Of these, the steps involving the exposure of the anchoring site and the securing of the prosthesis were noted for their complexity and were rated as having moderate practicability. In the EMS group, a higher proportion of patients—75.0% (three of seven)

	Total (n = 36)	EMS group (n = 7)	EIS group (n = 29)
Mean age (range), y	37.2 (17.3)	35.6 (20.8)	37.6 (16.7)
Sex (%)			
Male	17 (47.2)	4 (57.1)	13 (44.8)
Female	19 (52.8)	3 (42.9)	16 (55.2)
Operated ear (%)			
Right	18 (50)	3 (42.9)	15 (51.7)
Left	18 (50)	4 (57.1)	14 (48.3)
Etiology			
Congenital stapes ankylosis	22 (61.1)	4 (57.1)	18 (62.1)
Otosclerosis	14 (38.9)	3 (42.9)	11 (37.9)
Preop BC, mean (SD), dB	23.9 (10.1)	19.3 (6.5)	25.0 (10.6)
Preop AC, mean (SD), dB	56.3 (11.8)	58.8 (8.4)	55.7 (12.6)
Preop ABG, mean (SD), dB	32.4 (8.5)	39.5 (3.9)	30.7 (8.4)

**TABLE 1** Demographics and clinical features of patients.

Abbreviations: ABG, air bone gap; AC, air conduction; BC, bone conduction.

**TABLE 2** Comparison of operational practicability between the EMS and EIS groups.

Surgical step	EMS group			EIS group			p-Value
	Low	Moderate	High	Low	Moderate	High	
Visualizing and evaluating stapes abnormalities, No. (%)			7 (100)			29 (100)	1.000
Visualizing and evaluating lateral ossicular chain abnormalities, No. (%)			7 (100)			29 (100)	1.000
Revealing the anchoring site, No. (%)		3 (42.9)	4 (57.1)			29 (100)	.005
Measuring from the anchoring site to the stapes footplate, No. (%)			7 (100)			29 (100)	1.000
Creating a fenestra on the stapes footplate No. (%)			7 (100)			29 (100)	1.000
Securing the prosthesis between the anchoring site and stapes footplate, No. (%)		7 (100)	0 (0)		12 (41.4)	17 (58.6)	.008

Note: Low, moderate, and high indicate infeasible, feasible with difficulty, feasible with ease, respectively.

Abbreviations: EMS, endoscopic malleostapedotomy; EIS, endoscopic incudostapedotomy.

for the anchoring site exposure and 100% (seven of seven) for the prosthesis securing—were rated with moderate practicability compared to 0% (0 out of 29) and 41.4% (12 out of 29), respectively, in the EIS group. These differences were statistically significant ( $p = .005$  and  $p = .008$ , respectively) (Table 2).

### 3.3 | Hearing outcomes and complications

Postoperative BC thresholds averaged 15.5 dB (SD 5.1) in the EMS group and 18.4 dB (SD 12.5) in the EIS group, with no significant difference between the groups ( $p = .984$ ). The mean postoperative AC thresholds were 26.3 dB (SD 9.1) for the EMS group and 26.0 dB (SD 12.8) for the EIS group, with no significant difference ( $p = .534$ ). The mean postoperative ABG was 10.7 dB (SD 5.0) in the EMS group and 7.5 dB (SD 5.7) in the EIS group, with no significant between-group difference ( $p = .186$ ). Improvement in ABG was noted in all patients. In the EMS group, 28.6% of cases achieved an ABG closure

within 10 dB. In the EIS group, this outcome was observed in 65.5% of the patients, and the difference in closure rates was not significant ( $p = .103$ ). When comparing operating times, the mean duration was significantly longer for the EMS group at 201.4 min (SD 32.0) than for the EIS group at 124.0 min (SD 36.7) ( $p < .001$ ). Chorda tympani injury was the most common complication in both groups, with no significant difference in the incidence of complications ( $p = 1.000$ ) (Table 3).

## 4 | DISCUSSION

Over the past several decades, the application of endoscopes in middle ear surgery has expanded significantly, leading to numerous studies on endoscopic stapes surgery. Additionally, a recent systematic review and meta-analysis demonstrated that endoscopic stapes surgery is safe and offers superior visibility and a reduced incidence of postoperative dysgeusia compared to the conventional microscopic

**TABLE 3** Comparison of postoperative hearing results, operation time, and complication between the EIS and EMS groups.

	EMS group	EIS group	p-Value
Post op BC, mean (SD), dB	15.5 (5.1)	18.4 (12.5)	.984
Post op AC, mean (SD), dB	26.3 (9.1)	26.0 (12.8)	.534
Post op ABG, mean (SD), dB	10.7 (5.0)	7.5 (5.7)	.186
ABG improvement, mean (SD), dB	28.8 (6.9)	23.2 (9.0)	.105
ABG closure			.103
ABG within 10 dB, No. (%)	2 (28.6)	19 (65.5)	
ABG within 20 dB, No. (%)	7 (100)	29 (100)	
Operation time, mean (SD), min	201.4 (32.0)	124.0 (36.7)	< .001 <sup>a</sup>
Complication, No. (%)	1 (14.3)	3 (10.3)	1.000
Dizziness	0 (0)	1 (3.4)	
CTN injury	1 (14.3)	2 (6.9)	
SNHL	0 (0)	0 (0)	

Abbreviations: ABG, air bone gap; AC, air conduction; BC, bone conduction; CTN, chorda tympani nerve; SNHL, sensorineural hearing loss.

<sup>a</sup>p < .05 between the two groups for a given parameter.

approach.<sup>11</sup> Despite these advantages, the adaptation of endoscopes in malleostapedotomy has not been as rapid as in incudostapedotomy. Therefore, we evaluated the surgical outcomes of EMS and compared them to those of EIS to ascertain if EMS can yield comparable results. All malleostapedotomy procedures were successfully performed using an endoscopic technique exclusively, without the need for conversion to an open approach, as in EIS. Postoperative hearing results were highly satisfactory, with all patients achieving a postoperative ABG of  $\leq 20$  dB. Apart from a single case of chorda tympani nerve injury, no specific complications were noted, echoing the outcomes associated with EIS.

Malleostapedotomy involves two key surgical steps. First, the tympanic membrane is dissected from the malleus handle, revealing the site for prosthesis anchoring, which is located 1–2 mm distal to the lateral process of the malleus. Subsequently, the stapes prosthesis is secured between the malleus handle and the stapes footplate.<sup>3</sup> We noted that these steps require considerable effort during EMS, resulting in extended operation times. These procedures are technically demanding, even when conducted bimanually under microscopic guidance. However, innovations like self-crimping and shape-memory nitinol prostheses have been developed to overcome these challenges.<sup>12,13</sup> Iannella et al., who employed a super elastic self-crimping prosthesis, reported ease in performing this step.<sup>8</sup> However, in South Korea, where our study was conducted, the unavailability of such advanced prostheses necessitated the use of traditional tools and one-handed crimping. Therefore, the nature and type of the prosthesis influencing the crimping technique are vital factors in determining the feasibility of endoscopic stapes surgery.

The outcomes of malleostapedotomy have seen significant improvements over the decades, akin to incudostapedotomy. In a major study from the 1980s, only 67% of patients achieved a postoperative ABG of  $\leq 20$  dB, with 8% experiencing sensorineural hearing loss post-surgery.<sup>14</sup> However, with refined surgical techniques, later studies have reported better outcomes,<sup>3,15–17</sup> with recent studies showing over 90% success rates without specific complications. These

advancements are attributed to the development of customized prostheses and a deeper understanding of ossicular anatomy.<sup>18–21</sup> Our results align with these recent studies, including that by Iannella et al., who reported the feasibility of EMS,<sup>8</sup> with all but one patient in their study showing a postoperative ABG within 20 dB.

The initial EMS research by Iannella et al. focused on patients with residual conductive hearing loss following stapes surgery for otosclerosis. Conversely, more than half of the patients in our EMS group had class II congenital middle ear anomalies, as per the Teunissen-Cremers classification, which indicates stapes ankylosis along with other ossicular malformations.<sup>22</sup> Our results demonstrated a postoperative ABG of 20 dB or less in all patients of this subgroup, slightly surpassing those from previous studies on microscopic malleostapedotomy for the same anomalies.<sup>23,24</sup> The previously mentioned endoscopic benefits contributed to these outcomes. Comparatively, our cohorts with otosclerosis showed similar hearing results, although the statistical power was limited by the small sample size. Thus, further research with larger cohorts is necessary to determine if surgical outcomes for EMS vary between congenital anomalies and otosclerosis as indications for malleostapedotomy.

To the best of our knowledge, this is the first study comparing EMS with traditional EIS and describing EMS for congenital middle ear anomalies. Nevertheless, our study is limited by its small sample size. In line with most studies on stapes surgery, we defined successful postoperative hearing as achieving an ABG within 10 dB. Both the EMS and EIS groups exhibited success rates below their respective null points, and the differences in success rates were not statistically significant. However, it is important to note that the differences in success rates were smaller than the disparities between the set null points. This observation suggests that a larger sample size may be necessary to achieve adequate statistical power. Another limitation is the relatively short follow-up period; while 6 months may suffice to evaluate early complications and hearing recovery, it may not be enough to assess late complications such as prosthesis extrusion. Finally, surgical outcomes can be influenced by the surgeon's



experience, and there is a learning curve associated with endoscopic stapes surgery, as with the microscopic technique.<sup>25</sup> Therefore, to minimize inter-surgeon variability, we included only surgeries performed by a single surgeon (the corresponding author) with over a decade of experience in stapes surgery. However, to validate our findings, a multicenter study involving multiple surgeons nationwide would be necessary.

## 5 | CONCLUSIONS

This study indicates that EMS and EIS demonstrate comparable surgical outcomes. Consequently, the endoscopic approach shows promise as a well-established surgical alternative for microscopic malleostapedotomy, similar to its established role in traditional incudostapedotomy. Thus, the findings of this study contribute to broadening the application of endoscopic ear surgery in stapes procedures.

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### CONFLICT OF INTEREST STATEMENT

The authors declare that they have no competing interests.

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