

耳硬化症鐙骨手術時發生鼓膜穿孔之預後

Outcomes After Tympanic Membrane Perforation During Primary Stapes Surgery for Otosclerosis

Alexander L. Luryi, MD ; Amy Schettino, MD; Elias M. Michaelides, MD; Seilesh Babu, MD ; Dennis I. Bojrab, MD ;
Christopher A. Schutt, MD

高雄長庚醫院 楊昭輝醫師

Commentary

耳硬化症病患的聽力常隨著疾病進展逐漸變差，需藉由助聽器輔助或手術治療恢復聽力。針對耳硬化症的鐙骨手術成效十分卓越，然而極少數仍有可能發生聽力下降或全聾的風險。在手術過程中，掀起鼓膜耳道皮瓣 (Tympanomeatal flap) 的動作可能會傷害到鼓膜而造成鼓膜穿孔，在顧慮到可能造成中耳腔感染的情況下，有些醫師會中止手術等待鼓膜癒合後再做鐙骨手術。然而，在近年來越來越精緻的中耳手術技術下，是否仍需有此項顧慮是這篇論作者想要釐清的重點。此研究的目的是評估鐙骨手術中發生鼓膜穿孔患者術後之聽力狀況與發生併發症的機會是否較高。

作者回溯性分析 2008 年 2 月至 2017 年 9 月間，Michigan Ear Institute 587 例 (652 耳) 因耳硬化症接受鐙骨手術的病患，其中有 10 耳 (1.5%) 在術中發生鼓膜穿孔 (intraoperative tympanic membrane perforation, ITMP)，642 耳沒有鼓膜穿孔 (No ITMP)。兩組患者間的年齡、性別、左右患病耳、麻醉方式以及 BMI 等分佈並無差異，兩組術前的氣導閾值 (AC threshold) 以及氣骨導差 (Air-bone gap) 也沒有統計差異。ITMP 組中有 9 例 (90%) 為小於 25% 鼓膜大小的小型穿孔，所有 ITMP 組均在手術中使用顳肌膜 (temporalis fascia) 做 underlay 修補。手術後的氣導閾值及骨氣導差進步的幅度，兩組之間均無明顯差別，術後發生感覺神經性聽力損失 (定義為術後的骨導閾值增加 15 分貝)，在 No ITMP 組為 7 個病人 (佔 1.1%)，ITMP 組中並未有術後感音性聽力損失，兩組並無統計學上的顯著差異。在術後併發症方面，發生術後味覺異常及耳部出血的比例，ITMP 發生的比例明顯較 No ITMP 組來的高 ($P < 0.05$)。

傳統鐙骨手術的觀念，認為鼓膜穿孔可能會有造成病患術後發生迷路炎及感覺神經性聽力損失的風險，因此若術中發現鼓膜穿孔建議終止手術，然而近代的鐙骨手術普遍認為手術仍可繼續進行。此篇文獻為第一篇針對此議題的研究，證實術中的鼓膜穿孔並不影響術後的聽力改善及併發症的發生，其結論並不令人意外。ITMP 組其術後發生味覺異常及耳部出血的比例較高，可能是因為將鼓膜翻破的醫師多是手術資歷比較資淺或是訓練中的住院醫師，也因此會有比較高的機會發生傷及鼓索神經和鼓膜耳道皮瓣造成味覺異常及耳部出血的情況，不過作者並沒有統計 ITMP 組執行醫師的手術經驗。另外，筆者比較有興趣的主題是原先已有鼓膜穿孔的耳硬化症患者，是否能在鐙骨手術時同時修補鼓膜，此篇研究並沒有列入分析，或許目前大多數的耳科醫師還是會將原有慢性中耳炎的鼓膜穿孔先修復後，再安排鐙骨手術之進行。

此篇分析單一中心一年半內施行的 652 耳鐙骨手術，比台灣的鐙骨手術數量多出許多，但發生術中鼓膜穿孔的僅有十例，因此此篇研究會因為 ITMP 組數目較少而影響其統計結果，且回溯型分析會產生許多資料收集時的偏差。不過這篇文章至少提供一些數據，讓手術資歷比較資淺的醫師在進行鐙骨手術時，若不慎造成鼓膜穿孔，不至於太過擔心術後的手術成效。

關鍵詞：耳硬化症，中耳，耳科學/耳神經學

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Alexander L. Luryi, MD ; Amy Schettino, MD; Elias M. Michaelides, MD; Seilesh Babu, MD ;
Dennis I. Bojrab, MD ; Christopher A. Schutt, MD

Objective/Hypothesis: Stapes surgery is occasionally complicated by an intraoperative tympanic membrane perforation (ITMP), traditionally indicating abortion of the procedure due to concerns for postoperative infection and sensorineural hearing loss (SNHL). This work examines outcomes and complications in completed primary stapes surgeries with and without ITMP.

Study Design: Retrospective review.

Methods: All patients diagnosed with otosclerosis between February 2008 and September 2017 at a tertiary otology referral center were reviewed retrospectively. Primary outcome measures were post-operative air-bone gap (ABG), air conduction and bone conduction pure tone averages, and post-operative complications.

Results: Review revealed 652 primary stapes operations meeting inclusion criteria, of which ITMP occurred in 10. There were no significant differences in pre-operative hearing metrics or demographic characteristics between ears with and without ITMP. There were also no significant differences in post-operative ABG (6.4 vs. 8.0 dB HL, $P = .43$) or change in ABG after surgery (-21.6 vs. -18.2 dB, $P = .34$) between these two groups. Patients with ITMP were more likely to complain of post-operative dysgeusia (30.0% vs. 5.3%, $P = .015$) but were no more likely to develop reparative granuloma, otitis media, or SNHL ($P > .05$).

Conclusions: The first review of ITMP and hearing outcomes after stapes surgery is presented. Our findings suggest that it is likely safe and appropriate to proceed with primary stapes surgery and concurrent tympanoplasty in the presence of a small ITMP with minimal risk of infection, SNHL, or worsened hearing outcomes.

Key Words: Otosclerosis, middle ear, otology/neurotology.

Level of Evidence: 4

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INTRODUCTION

Otosclerosis is a disease of abnormal bone remodeling that affects the otic capsule, manifesting as unilateral or bilateral progressive conductive hearing loss with rarer sensorineural or mixed hearing loss, vertigo, and tinnitus.^{1,2} It affects 3 to 4 of every thousand individuals, typically between the second and fifth decades of life, and affects twice as many females as males.^{3–5} Continued progression of hearing loss may be slowed through the use of sodium fluoride or bisphosphonates but restoration of

hearing relies on the use of amplification or surgical intervention.⁶

The surgical management of otosclerosis has evolved since its inception. After a period of infections, complications, and failures surrounding stapes surgery in the late 1800s, the antibiotic age allowed for renewed interest in otosclerosis surgery with progression from multi- and single-staged fenestration of the lateral semicircular canal to stapes mobilization, and eventually stapedectomy with placement of a tissue graft and prosthesis.⁷ Modern procedures disrupt the incudostapedial joint, displace the stapes suprastructure, and create a small opening in the footplate with a laser or drill to fit a piston prosthesis that connects to the incus. Variations remain in surgical technique, prostheses, laser use, and anesthetic modality between surgeons and institutions, creating debate surrounding optimal management.^{8–11}

A tympanic membrane perforation may inadvertently occur while a tympanomeatal flap is being raised to access the middle ear during stapes surgery. This has historically been an indication to abort the planned stapes surgery for fear of infection and subsequent hearing loss,¹² and these fears persist today in some practices despite the development of less invasive surgical techniques. The aim of this work was to evaluate the results of primary stapes surgery after intraoperative tympanic membrane perforation (ITMP), focusing on post-operative

From the Department of Neurotology (A.L.L., S.B., D.I.B., C.A.S.), Michigan Ear Institute, Farmington Hills, MI, U.S.A.; Department of Otolaryngology-Head and Neck Surgery (A.S.), University of Pennsylvania, Philadelphia, PA, U.S.A.; and the Department of Otorhinolaryngology-Head and Neck Surgery (E.M.M.), Rush University, Chicago, IL, U.S.A.

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Send correspondence to Alexander L. Luryi, MD, Department of Neurotology, Michigan Ear Institute, 30055 Northwestern Highway, Suite #101, Farmington Hills, MI 48334.

E-mail: alexander.luryi@gmail.com

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hearing outcomes and rates of post-operative complications.

MATERIALS AND METHODS

Study Population

Records of patients diagnosed with otosclerosis between February 2008 and September 2017 at a single tertiary otology referral institution were identified using International Classification of Diseases (ICD)-10 codes beginning with H80 and ICD-9 codes beginning with 387. Patients who did not have evidence of clinical otosclerosis, who had not undergone stapes surgery, who had undergone revision surgery, or who were missing necessary documentation were excluded. The medical documentation determined to be necessary for inclusion was: 1) A complete intake history, including history of present illness and past medical history; 2) A pre-operative audiogram, including bone and air conduction thresholds; 3) A surgical operative report; and 4) A post-operative audiogram, including bone and air conduction thresholds. This work was approved by the Internal Review Board of the Ascension Providence Hospital (Novi, MI).

Intervention

All patients were examined preoperatively under otomicroscopy, and audiograms were collected pre- and post-operatively. Pre-existing perforations, if present, were addressed prior to scheduling stapes surgery. All surgeries were primary stapedotomies and were performed under local anesthesia with sedation or general

anesthesia in the usual fashion. CO₂ lasers were used for lysis of the stapedial tendon and posterior stapes crus in most cases. ITMPs were repaired with fascia and medial grafting technique. Patients were not routinely admitted to the hospital overnight in cases of ITMP or otherwise.

Examined Variables and Statistical Analysis

Presence of ITMP was determined by the surgeon's operative report. When available, the size of the tympanic membrane was also recorded and divided into groups of "small" (<25% of the tympanic membrane) and "large" (≥25%). Pure-tone averages (PTAs) were calculated by averaging thresholds at 500, 1,000, 2,000, and 3,000 Hz for both air conduction (AC) and bone conduction (BC); in the majority of cases, a threshold at 4,000 Hz was used to interpolate the threshold at 3,000 Hz per the standards of the Hearing Committee of the American Academy of Otolaryngology-Head and Neck Surgery.¹³ The air-bone gap (ABG) was defined as the AC PTA minus the BC PTA. For assessment of post-operative hearing, the post-operative audiologic exam with the best (lowest) AC pure tone average was used, excluding exams performed after additional surgical intervention, if applicable. Post-operative sensorineural hearing loss (SNHL) was defined as a decrease in BC of at least 15 dB hearing level (HL). Non-hearing complications evaluated included otic hemorrhage (defined as bleeding from the ear, which did not resolve with conservative measures at home and required an emergency department or office visit to address), otitis media, soft tissue wound infections, vertigo, post-operative benign paroxysmal positional vertigo (BPPV) (within 1 month of surgery), third window symptoms (autophony or dizziness with loud noise or valsalva), dysgeusia and other taste disturbances, reparative granuloma, hearing distortion (rattling, buzzing, or vibration; "loose wire" symptoms), and the need for revision stapes surgery in that ear at any point.

Categorical variables were measured with frequency and column percentage and compared with Chi-squared

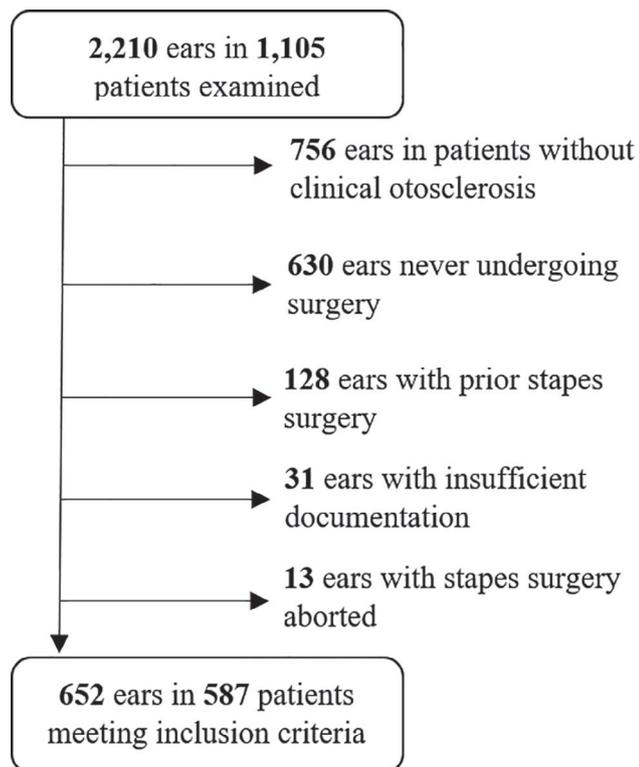


Fig. 1. Flowchart of records examined and excluded.

Characteristic	No ITMP n = 642	ITMP n = 10	P value
Gender			
Male	260 (40.5)	3 (30.0)	.50
Female	382 (59.5)	7 (70.0)	
Side affected			
Right	127 (19.8)	2 (20.0)	.97
Left	110 (17.1)	2 (20.0)	
Bilateral	405 (63.1)	6 (60.0)	
Anesthetic modality			
General	357 (55.6)	6 (60.0)	.78
Local with IV sedation	285 (44.4)	4 (40.0)	
Age (yr); mean (SD)	48.6 (12.3)	50.6 (11.2)	.62
BMI (kg/m ²); mean (SD)	27.7 (5.9)	29.8 (5.5)	.30

ITMP = intra-operative tympanic membrane perforation.

TABLE II.
Pre-operative and Post-operative Audiometric Characteristics of Patient Sample.

Hearing result dB, mean (95% CI)	No ITMPn = 642	ITMPn = 10	P value
Pre-operative AC PTA	53.7 (52.5–55.0)	56.1 (46.6–65.6)	.64
Pre-operative ABG	26.1 (25.4–26.9)	28.0 (22.7–33.3)	.54
Post-operative AC PTA	28.4 (27.1–29.6)	29.8 (22.1–37.5)	.78
Best post-operative ABG	8.0 (7.5–8.5)	6.4 (3.5–9.3)	.43
Change in ABG	–18.2 (–19.1 to –17.3)	–21.6 (–27.8 to –15.5)	.34

ABG = air-bone gap; AC = air conduction; CI = confidence interval; ITMP = intra-operative tympanic membrane perforation; PTA = pure tone average.

tests or Fisher's exact tests. Continuous variables were analyzed through mean and standard deviation and compared through Student's *t* tests. Two-tailed values of $P < .05$ indicated statistical significance. All statistical analysis was performed using SPSS Statistical Software for Windows (IBM, Armonk, NY).

RESULTS

Descriptive Statistics

Records of 2,210 ears in 1,105 patients were evaluated and 652 surgeries in 587 patients met inclusion criteria (Fig. 1). Thirteen procedures were aborted and were excluded from analysis, all due to an overhanging facial nerve or a stapes footplate, which was found to be mobile; no procedures were aborted due to ITMP. Median length of follow up was 398 days. Average age was 48.7 years and 59.7% of patients were female. ITMP occurred in 10 surgeries (1.5%). Nine ITMPs (90.0%) were small (<25% of the tympanic membrane) and the size of the remaining ITMP was not documented. All were repaired with fascia during surgery in an underlay technique. Pre- and intraoperative characteristics of patients who did and did not have ITMP are shown in Table I. ITMP was not associated with differences in gender, age,

pre-operative AC thresholds, pre-operative ABGs, or anesthetic modality employed.

Hearing outcomes for patients without and with ITMP are shown in Table II and Figures 2 and 3. Average ABG improved from 26.2 dB HL to 8.0 dB HL. There were no significant differences in pre-operative AC PTAs or ABGs, post-operative AC PTAs or ABGs, or changes in ABG through surgery between patients with and without ITMP. SNHL, defined as a drop in the BC PTA by 15 dB or greater, occurred in 7 patients (1.1%) without ITMP and 0 patients with ITMP ($P = .70$).

Non-hearing complications are shown in Table III. The most common post-operative complications encountered overall were dysgeusia (5.7%), third window symptoms, including autophony, or sound- or pressure-induced vertigo (4.9%), and dizziness (4.8%). The presence of ITMP was associated with an increased risk of dysgeusia (30.0% vs. 5.3%, $P = .015$) and aural hemorrhage (10.0% vs. 0.2%, $P = .030$) but was otherwise not associated with any complications. Overall, 6.7% of patients required revision stapes surgery due to persistent or recurrent hearing loss; this occurred in 44 patients (6.9%) of patients without ITMP and no patients with ITMP ($P = .34$).

DISCUSSION

Traditional teaching dictated that stapes surgery interrupted by a tympanic membrane perforation should

TABLE III.
Complications of Stapes Surgery in Patients With and Without Intraoperative Tympanic Membrane Perforation (ITMP)

Complication	No ITMP n = 642	ITMP n = 10	P value
Need for revision stapes surgery	44 (6.9%)	0	.34
Dysgeusia	34 (5.3%)	3 (30.0%)	.015
Third window symptoms	31 (4.8%)	1 (10.0%)	.42
Dizziness/vertigo (exc. BPPV)	30 (4.7%)	1 (10.0%)	.42
BPPV	23 (3.6%)	0	.53
Hearing distortion	15 (2.3%)	0	.60
Soft tissue infection	5 (0.8%)	0	.92
Otitis media	5 (0.8%)	0	.92
Reparative granuloma	5 (0.8%)	0	.92
Delayed TM perforation	3 (0.5%)	0	.94
Aural hemorrhage	1 (0.2%)	1 (10.0%)	.030
CSF leak	1 (0.2%)	0	.98
Facial weakness	0	0	1.00

BPPV = benign paroxysmal positional vertigo; CSF = cerebrospinal fluid; TM = tympanic membrane.

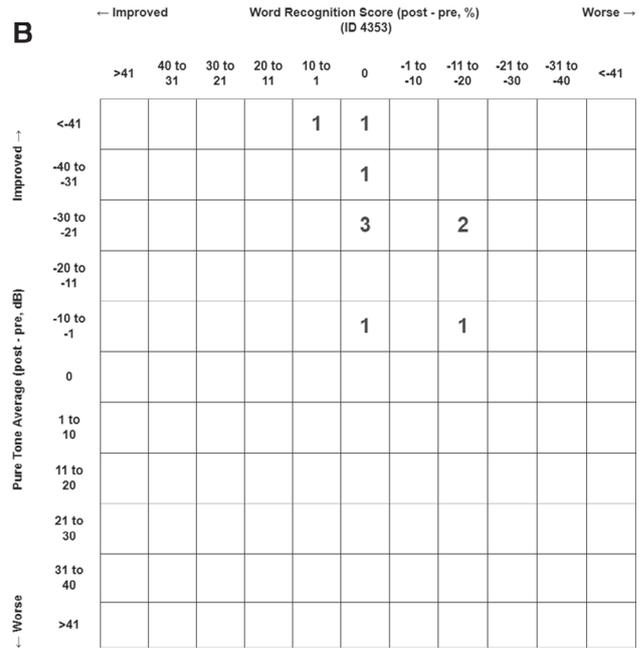
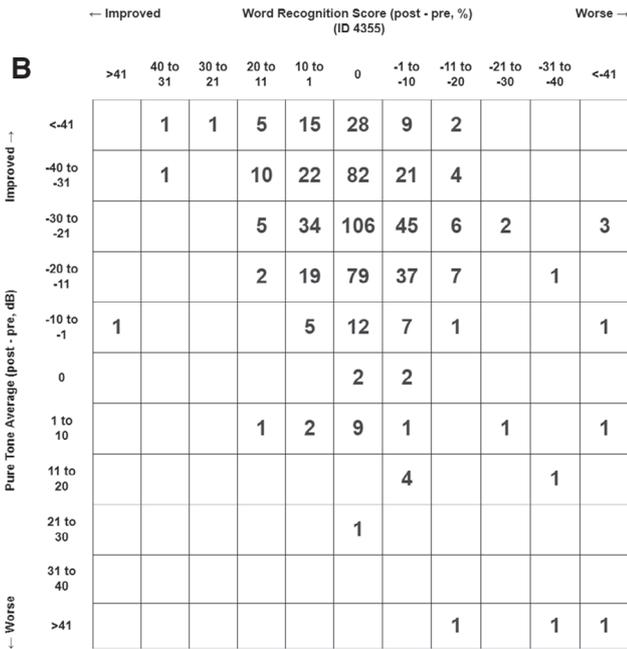
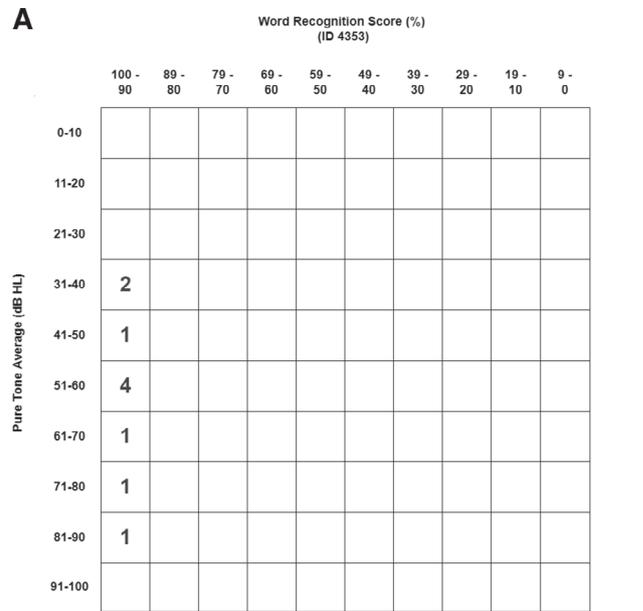
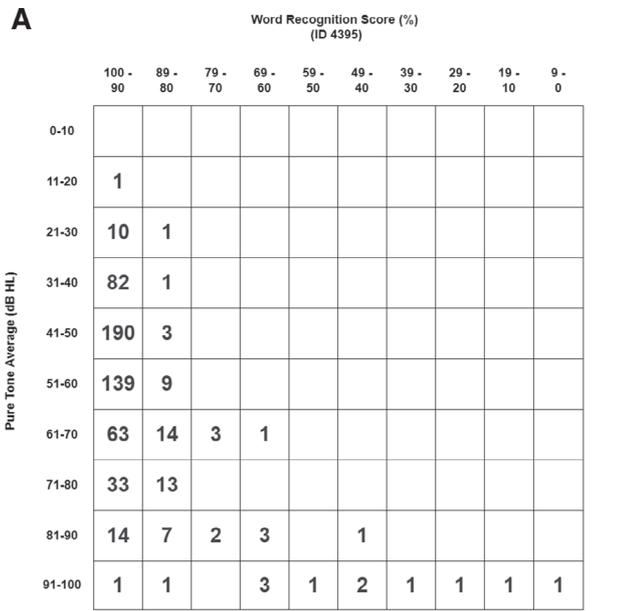


Fig. 2. Hearing outcome scattergram for undergoing stapes surgery WITHOUT ITMP; a) pre-operative and b) post-operative changes in pure tone averages and word recognition scores. Some patients are not included in this figure due to missing pre- or post-operative word recognition scores. ITMP = intraoperative tympanic membrane perforation.

Fig. 3. Hearing outcome scattergram for patients undergoing stapes surgery WITH ITMP; a) pre-operative and b) post-operative changes in pure tone averages and word recognition scores. ITMP = intraoperative tympanic membrane perforation.

be aborted to decrease the risk of labyrinthitis and SNHL in addition to adhesion formation and possible persistent conductive hearing loss.¹² While many otologists today tacitly acknowledge that this is not necessary for all perforations, some modern sources continue to maintain this practice as standard of care.¹⁴ Several reports have referenced the occurrence of this common intraoperative complication but its associated outcomes have not been formally evaluated in the literature.^{15,16}

In this study, we found that ITMP was not associated with any significant differences in post-operative hearing outcomes. Furthermore, there was no association between ITMP and SNHL, otitis media, or reparative granuloma. However, we did identify a statistically significant association between ITMP and both post-operative aural hemorrhage and complaints of dysgeusia. While aural hemorrhage only occurred in one of 10 surgeries with ITMP, dysgeusia occurred in 3 of 10 cases. One

possible explanation for this is the varying degree of trainee participation in these procedures. Studies of resident-performed stapes procedures reveal a combined rate of ITMP of approximately 5%, well above typical rates.^{16,17} It is conceivable that less experienced surgeons who are likely to cause tears in the tympanic membrane while elevating a tympanomeatal flap are also more likely to injure the chorda tympani, leading to dysgusia. Likewise, although aural hemorrhage only occurred in two patients in this study, a torn or irregularly cut tympanomeatal flap is more likely to bleed post-operatively and this may be correlated with surgeon experience.

Despite changing trends in the management of ITMP, consensus exists that a pre-existing tympanic membrane perforation should be repaired and allowed to heal prior to attempting stapes surgery.^{18,19} This is standard practice at our institution as well. As with management of ITMP, this recommendation is based on consensus rather than clinical evidence. However, these situations may not be directly comparable. The middle ear microbiome has been found to differ between patients with diseased and healthy middle ears. Patients with chronic otitis media have been found to have greater colonization of bacteroidetes and firmicutes, and less colonization of proteobacteria, than patients with healthy ears; however, patients with dry perforations had similar colonization patterns to healthy patients.²⁰ Furthermore, patients with pre-existing tympanic membrane perforations have a higher likelihood of persistent perforation, and therefore, infection than patients in which a small rent occurred intraoperatively, and this may increase the risk of labyrinthitis and SNHL. While no conclusions can be drawn about the safety of simultaneous tympanoplasty and stapes surgery in the setting of a dry perforation from the present work, this may be an interesting topic of future study.

One impediment to formal study of ITMP in stapes surgery is the relative rarity of this event in experienced hands. Most studies report an incidence of ITMP between 1% and 2%.^{21,22} As a result, collection of a sample sufficiently powerful to draw conclusions about rates of other complications, which are also rare, can be difficult. We present the largest series to date of tympanic membrane perforations sustained during stapes surgery, but this series remains underpowered to assess small differences in the risks of rare complications after ITMP, such as SNHL or reparative granuloma.

Although this analysis is the largest described series of ITMP during stapes surgery to date, several limitations must be considered. Due to the inadvertent nature of ITMP, this was a retrospective study by necessity, and therefore, is susceptible to all biases inherent to this study design, including missing data and insufficient follow up. Routine long-term follow up for patients with surgically corrected otosclerosis is not usually indicated, and while we assume patients with post-operative issues will return to our center for management, some patients with post-operative complications may have presented elsewhere and these complications were not captured. Our sample included patients of 11 neurotologic surgeons at various stages in their careers and with varying degrees of trainee involvement, and differences in career experience and trainee participation could not be

analyzed. Finally, a small proportion of cases were excluded due to inadequate documentation or follow up and the effects these exclusions had on our results are unknown.

CONCLUSION

An analysis of ITMP sustained during stapes surgery for otosclerosis is presented. ITMP repaired during stapes surgery is not associated with poorer hearing outcomes, infection, or SNHL, suggesting that this is likely a safe practice. Multi-institutional data would be helpful in ruling out small increases in risk of these complications associated with ITMP.

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