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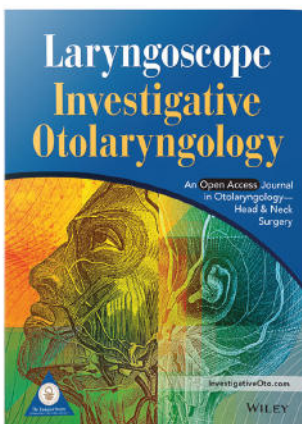


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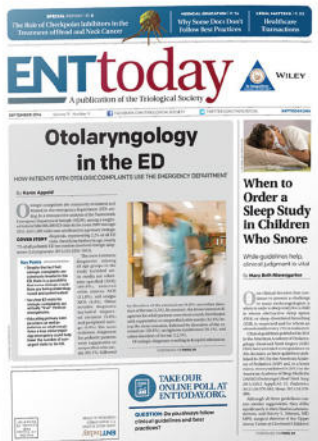


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ORIGINAL RESEARCH

Does stapedotomy improve high frequency conductive hearing?

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Abstract

Objectives: Stapedotomy is performed to address conductive hearing deficits. While hearing thresholds reliably improve at low frequencies (LF), conductive outcomes at high frequencies (HF) are less reliable and have not been well described. Herein, we evaluate post-operative HF air-bone gap (ABG) changes and measure HF air conduction (AC) thresholds changes as a function of frequency.

Methods: Retrospective review of patients who underwent primary stapedotomy with incus wire piston prosthesis between January 2016 and May 2020. Pre- and postoperative audiograms were evaluated. LF ABG was calculated as the mean ABG of thresholds at 250, 500, and 1000 Hz. HF ABG was calculated at 4 kHz.

Results: Forty-six cases met criteria. Mean age at surgery was 54.0 ± 11.7 years. The LF mean preoperative ABG was 36.9 ± 11.0 dB and postoperatively this significantly reduced to 9.35 ± 6.76 dB, ($P < .001$). The HF mean preoperative ABG was 31.1 ± 14.4 dB and postoperatively, this also significantly reduced to 14.5 ± 12.3 dB, ($P < .001$). The magnitude of LF ABG closure was over 1.5 times the magnitude of HF ABG closure ($P < .001$). The gain in AC decreased with increasing frequency ($P < .001$).

Conclusion: Hearing improvement following stapedotomy is greater at low than high frequencies. Postoperative air bone gaps persist at 4 kHz. Further biomechanical and histopathologic work is necessary to localize postoperative high frequency conductive hearing deficits and improve stapedotomy hearing outcomes.

Level of Evidence: 4, retrospective study.

KEYWORDS

conductive hearing loss, hearing loss, high-frequency hearing loss, otosclerosis, stapedotomy

1 | INTRODUCTION

Otosclerosis is a source of conductive hearing loss in the adult population.¹ The pathophysiology involves abnormal bone remodeling of the

stapes, resulting in a progressive fixation of the stapedial footplate.^{2,3} More than 80% of patients with otosclerosis experience progressive bilateral conductive hearing loss.⁴ The management of otosclerosis with concomitant conductive hearing loss includes stapedotomy,

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which reestablishes a mobile ossicular chain, with the goal of stable, long-term improvements in hearing.⁵

Pure tone audiometry (PTA) is routinely used to assess hearing during pre- and postoperative clinical evaluations. A 2018 review by Cheng et al, demonstrated the short and long-term durability of hearing improvements following stapedotomy using PTA data from several published series.⁶ However, the traditional pure-tone average (PTA₄) recommended by the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS),^{7,8} may not sufficiently communicate changes in high-frequency (HF) conductive hearing.^{9,10} HF bone conduction thresholds following stapes surgery have not been robustly studied and reported outcomes are variable.^{5,11-13}

Prior studies suggest the benefit from stapes surgery on HF air conduction (AC) thresholds declines with increasing stimulus frequency.¹⁴⁻¹⁷ Several retrospective studies of stapedotomy demonstrate significant HF AC deficits following surgery.^{6,18,19} Persistent or new HF hearing deficits have traditionally been thought to be sensorineural in etiology¹⁷; however, limitations in bone conduction testing at frequencies above 4 kHz make it challenging to differentiate between sensorineural and conductive pathology.

It remains unknown if elevated high frequency AC thresholds are due to persistent conductive deficits or represent a persistent or new sensorineural loss. We hypothesize that HF air bone gaps (ABG) persist following stapedotomy. Herein, we performed a retrospective analysis of hearing outcomes in patients who underwent stapedotomy to evaluate postoperative HF conductive hearing outcomes and measure HF AC thresholds changes as a function of frequency.

2 | MATERIALS AND METHODS

2.1 | Subjects

A consecutive series of patients who underwent stapedotomy at a single tertiary care center between January 2016 and May 2020 were reviewed. Inclusion criteria were: Patients that underwent primary stapedotomy using incus wire piston prosthesis with available pre- and postoperative audiograms. Exclusion criteria included: Patients undergoing revision procedures, history of ossiculoplasty, and concomitant middle ear pathology. Institutional review board approval was obtained from the Human Subjects Committee: Approval #H00020062.

2.2 | Surgical technique

All stapedotomies were performed by the same surgeon at a single tertiary care Otolaryngology department with patients under general anesthesia. The small fenestra technique was employed.²⁰ After the elevation of a tympanomeatal flap and visualization of the pyramidal process, stapedial tendon and tympanic facial nerve, ossicular mobility was assessed. Either a CO₂ or potassium-titanyl-phosphate (KTP) laser was used to sever the incudostapedial joint, tendon, and posterior

crus of the stapes superstructure. Following down-fracture of the stapes superstructure, the laser was used to create an aperture in the footplate; if the stapes footplate was deemed too thick, a drill-out with a microdrill (0.6-0.8 mm) was performed. The aperture was widened, and an appropriate length (4.25-5.5 mm) and diameter (0.5 vs 0.6 mm) Nitinol stapes prosthesis (Grace Medical, Memphis, Tennessee) was positioned onto the incus and placed into the oval window fenestration. After thermal crimping of the prosthesis, a blood patch was applied at the oval window.

2.3 | Audiometric evaluation

Pre- and postoperative standard pure-tone air and bone conduction thresholds were extracted from the audiometry exams performed closest to the date of surgery. The pure-tone thresholds for both air and bone conduction at 250, 500, 1000, 2000, 3000, and 4000 Hz were recorded. AC readings at 6000 and 8000 Hz were also recorded. The ABGs were defined as the difference between the pure tone thresholds for air and bone conduction. The AAO-HNS/PTA₄ ABG was defined as the mean ABG at 500, 1000, 2000, and 3000 Hz (in cases where 3000 Hz was unavailable, the average of the 2000 Hz and 4000 Hz thresholds was used).⁸ The low-frequency (LF) ABG was defined as the mean ABG at 250, 500, and 1000 Hz. The HF ABG was defined as the ABG at 4000 Hz.

Per AAO-HNS recommendations, hearing results were depicted in a scattergram formation demonstrating the relationship between the average ABG pure-tone threshold to the word recognition (WRS).⁸ Patients without word discrimination scores (due to non-testable primary language) were excluded from this portion of the analysis. The impact of demographic factors (age and gender) and surgical factors (laser type and footplate drill out) on both HF and LF ABG closure were also studied.

2.4 | Secondary analysis of Pauli 2019

To assess the generalizability of our findings, we performed a secondary analysis of audiometric outcomes reported from a large database review (n = 732) of stapes surgery outcomes.²¹ We evaluated the change in air bone gap at low and high frequencies with the methods described above. Low frequency was redefined as 500, 1000 and 2000 Hz as the 250 Hz thresholds were not available for analysis. 4 kHz was considered high frequency.

2.5 | Statistical analysis

The mean ± SD (SD) is reported for all ABGs as well as the Δ ABGs (calculated from pre- and postop audiograms). Student's t test (two-tailed, paired) was used to compare measurements between low- and high-frequency ABG for each analysis. Univariate linear regression analysis was used to assess changes in AC thresholds between pre-

and post-operative audiograms as a function of frequency. Multivariate linear regression analysis was used to assess the impact of the demographic, surgical, and clinical factors described above on HF ABG closure. Between-group analyses to evaluate the specific impact of surgical and prosthesis factors were completed using Student's *t* test (independent, equal variance). Significance was set at $P < .05$ for all statistical tests. All statistical tests were performed using GraphPad Prism version 9.0.0 for Mac OS X, GraphPad Software, San Diego, California, www.graphpad.com.

3 | RESULTS

3.1 | Demographics

Sixty-two stapedotomies were identified during the study period. Of these surgeries, 16 were excluded: 12 for being revision procedures, 3 for missing either pre- or postoperative audiograms, and 1 for coincident superior semicircular canal dehiscence. Each of the remaining 46 cases met inclusion criteria (Table 1).

Two cases were procedures completed on the contralateral ear of the same patient, for a total of 44 unique patients of which 22 (50.0%) were female. Age of the patients ranged from 31 to 82 years old, with a mean age of 54 years. The reason for surgery was due to otosclerosis in 44 cases (95.7%) and trauma in 2 cases (4.3%). The 2 cases identified as prior traumas included a subluxation of the incudostapedial joint with promontory/stapes fixation in one and fracture of the stapes superstructure with footplate fixation in the other.

The KTP laser was used in 28 (60.9%) and the CO₂ laser was used in 18 (39.1%) cases. Fifteen patients (33.3%) required additional footplate fenestration with either a 0.6 or 0.8 mm diamond bur. The most

frequently used prosthesis was the nitinol wire with a length of 4.25 mm (58.7%) and diameter of 0.6 mm (87.0%). The time between surgery and post-operative audiogram was 2.6 ± 2.2 months (mean \pm SD).

3.2 | Standard air-bone gaps

The pre- and postoperative ABGs were compared for all the cases. When reported according to AAO-HNS guidelines, the preoperative PTA-ABG was 28.9 ± 10.4 dB and postoperatively this improved to 6.47 ± 5.45 dB ($P < .001$).⁸ The magnitude of ABG closure was 22.5 ± 13.1 dB. Forty-three patients (93.5%) experienced an improvement in their ABG per AAO-HNS standards and 3 patients (6.5%) experienced a deterioration of their ABG.

3.3 | Low vs high frequency air-bone gaps

The preoperative mean LF ABG (36.9 ± 11.0 dB) was larger than the mean HF ABG (31.1 ± 14.4 dB, $P = .0316$). Postoperatively, the mean LF ABG (9.35 ± 6.76 dB) was significantly smaller than the mean HF ABG (14.5 ± 12.3 dB, $P = .0163$). While both the mean LF and HF ABGs were significantly improved by 27.6 ± 12.3 dB and 16.6 ± 19.0 dB respectively ($P < .0001$) (Figure 1); the proportion of ABG closure in the low frequencies was about 1.7 times the closure observed in the high frequencies ($P < .001$) (Figure 2). Forty-five patients (98%) experienced an improvement in LF ABG while only 1 patient (2%) experienced no change. In comparison, 39 patients (85%) experienced an improvement in the HF ABG while 5 patients (11%) had a deterioration, and 2 patients (4%) experienced no change.

3.4 | High frequency air conduction

Bone conduction thresholds are not routinely measured above 4 kHz, which limits assessment of ABG at 6 and 8 kHz. As such, post-operative changes in AC thresholds are used to determine effects of surgery on high frequency hearing. In our cohort, AC thresholds at 6 kHz improved from 72.0 ± 23.2 dB preoperatively to 57.7 ± 25.4 dB post-op ($P = .006$) (Figure 3). At 8 kHz, preoperative hearing was 65.2 ± 24.8 dB, and post-operatively it changed to 61.3 ± 24.9 dB, which was not significant ($P = .451$). A simple linear regression model demonstrated that the magnitude of change in AC (Y) decreases as the frequency (X) increases and this was modeled with ($Y = -0.003853X + 34.76$ [$r^2 = 0.951$], $P < .001$).

3.5 | Word recognition scores

A scattergram for pre- and post-treatment WRS in the 40 patients with available data is shown in Figure 4. Preoperative WRS was 90.0

TABLE 1 Patient demographics

Characteristic	Value (n = ears)
Age, y	
Mean	54.0
Range	31-82
Sex, No. (%)	
Male	23 (50.0%)
Female	23 (50.0%)
Sidedness, No. (%)	
Right	25 (54.3%)
Left	21 (45.7%)
Clinical history, No. (%)	
Otosclerosis	44 (95.7%)
Trauma	2 (4.3%)
Duration of hearing loss, No. (%)	
< 1 year	2 (4.3%)
1-5 years	9 (19.6%)
>5 years	35 (76.1%)

FIGURE 1 Pre and postoperative ABG changes (mean and 95% CI). ABG, air-bone gap, AAO-HNS = PTA₄

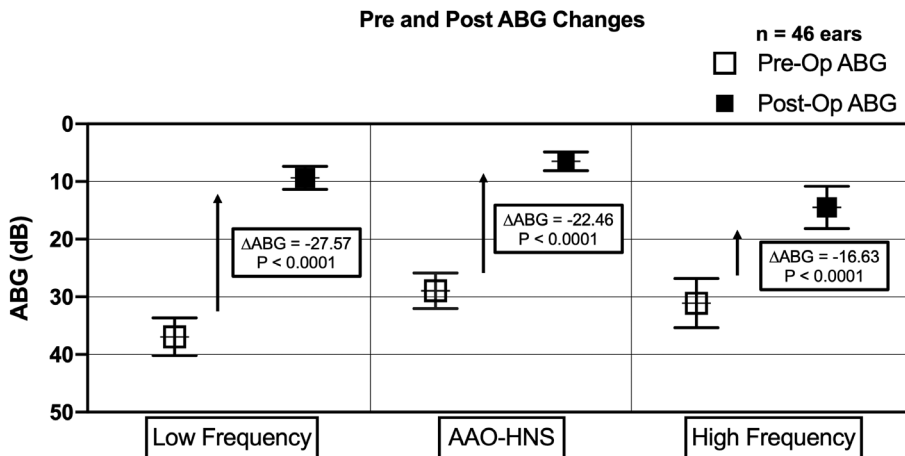


FIGURE 2 Change in ABG by frequency (mean and 95% CI). ABG, air-bone gap; LF, low-frequency; HF, high-frequency

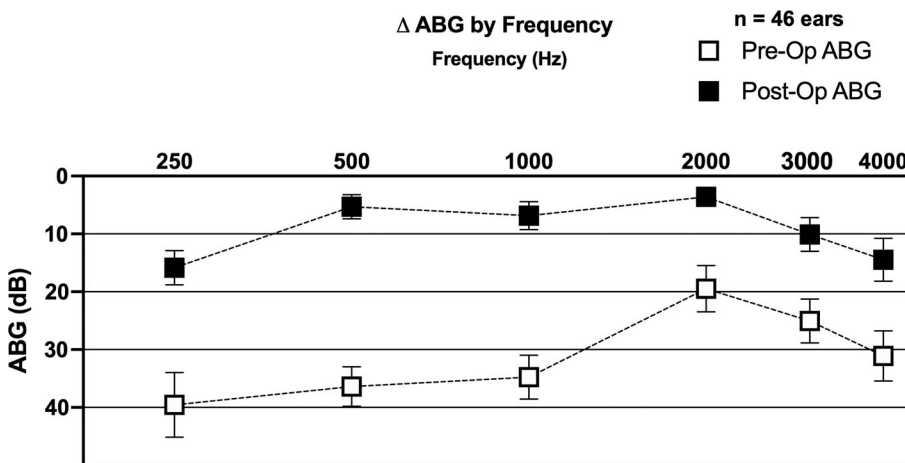
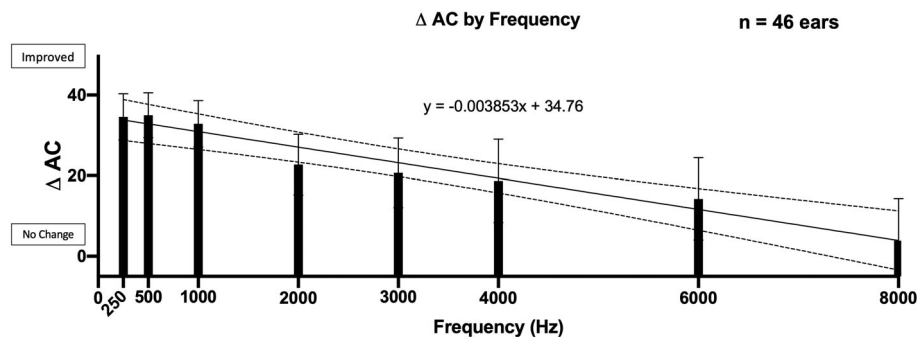


FIGURE 3 Change in AC threshold by frequency (mean and 95% CI). AC, air conduction



± 16.0% and postoperative WRS was 89.4 ± 17.0%. WRS did not differ significantly following surgery ($P = .860$).

3.6 | Surgical factors affecting outcome

Multivariate analysis was performed to evaluate the effects of various demographic, surgical, and clinical factors on both the HF and LF ABG (Table 2). Of all the factors assessed (age, gender, laser type, footplate status, prosthesis length & diameter), none were associated with either increased or decreased HF ABG closure. Increased age was

associated with worse LF ABG closure ($\beta = -0.334$, 95% CI: -0.650 to -0.0190 , $P = .0383$). None of the other assessed factors demonstrated an association with LF ABG closure.

Univariate analysis by laser type with multiple paired t-tests demonstrated that the KTP laser resulted in a greater magnitude of HF ABG closure than the CO₂ laser (20.4 ± 11.0 dB and 10.8 ± 16.3 dB respectively, $P = .0384$). There was no significant association between laser type and magnitude of LF ABG closure ($P = .966$). Footplate drill out did not have an effect on either HF or LF ABG closure ($P > .3$) (Table 3). Neither prosthesis length nor diameter appeared to have a significant impact on either LF or HF ABG closure on univariate analysis (Table 4).

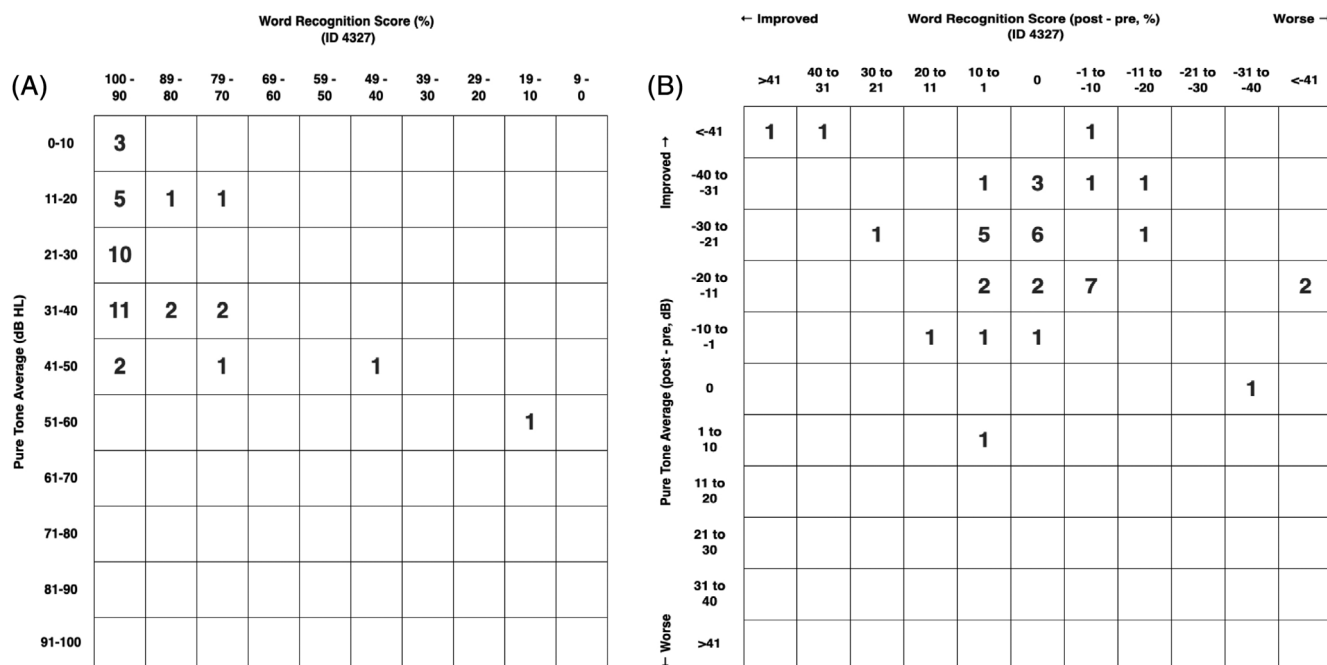


FIGURE 4 Pre and postoperative WRS scattergrams per AAO-HNS standards

TABLE 2 Multivariate linear regression results

Total ears n = 46 Variables	All multivariable testing was performed with least squares regression. A more positive β coefficient, is associated with greater gain (improvement)					
	HF ABG gain			LF ABG gain		
	β	95% CI	p	β	95% CI	p
Age	-0.0497	-0.560 to 0.461	.845	-0.335	-0.654 to -0.0168	.0396*
Female ^a	-5.11	-17.4 to 7.17	.405	-1.04	-8.71 to 6.63	.786
KTP laser ^b	10.1	-2.48 to 22.7	.112	-0.163	-8.01 to 7.68	.967
Footplate drillout ^c	2.45	-10.4 to 15.3	.702	2.18	-5.83 to 10.2	.586
Prosthesis length ^d	-9.73	-38.0 to 18.5	.490	-13.2	-30.8 to 4.4	.138
Prosthesis Diameter ^e	4.57	-12.9 to 22.0	.599	2.91	-7.96 to 13.8	.591

Abbreviations: HF, high-frequency; LF, low-frequency; Ref, reference level.

*Denotes statistical significance.

^aRef: Male.

^bRef: CO₂.

^cRef: Footplate preserved.

^dProsthesis length ranges [4.25, 4.50, 4.75, 5.50].

^eRef: 0.6 mm prosthesis diameter.

3.7 | Results of Pauli 2019 analysis

Review of the published outcomes from Pauli 2019 found that the preoperative mean LF ABG (29.3 ± 10.1 dB) was slightly lower than the mean HF ABG (32.0 ± 16.0 dB, $P < .001$). Postoperatively, the mean LF ABG (8.00 ± 10.5 dB) was significantly smaller than the mean HF ABG (16.0 ± 15.3 dB, $P < .001$). While both the mean LF and HF ABGs were significantly improved by 21.6 ± 0.79 dB and 16.0 ± 0.77 dB respectively ($P < .001$); the proportion of ABG closure in the low frequencies was about 1.4 times the closure observed in the high frequencies ($P < .001$).

4 | DISCUSSION

We report that stapedotomy results in greater closure of the LF ABG than the HF ABG. While we found significant improvements in hearing as defined by the AAO-HNS guidelines,⁸ with ABG closure rates (0-10 dB) of 83%; our frequency-based ABG analysis demonstrates that a greater degree of ABG closure (0-10 dB) occurs in the low frequencies (72%) than at 4 kHz (46%). In addition, we demonstrated a linear decrease in AC gain with increasing frequency until 8 kHz, where there was no significant difference between the pre- and post-operative thresholds.

TABLE 3 Univariate (multiple paired t tests) analysis by laser/footplate status

Total Ears n = 46	Laser type		Footplate status	
	KTP Laser N = 28	CO ₂ Laser N = 18	Preserved N = 31	Drill-out N = 15
HF ABG				
Pre-Op ABG	33 ± 13	28 ± 15	32 ± 14	30 ± 15
Post-Op ABG	13 ± 8.0	17 ± 17	16 ± 14	11 ± 8.6
Δ ABG (SEM)	20 ± 16*	11 ± 23*	16 ± 20	18 ± 18
LF ABG				
Pre-Op ABG	37 ± 10	37 ± 12	37 ± 10	37 ± 13
Post-Op ABG	9.1 ± 7.4	9.7 ± 5.8	10 ± 7.1	7.4 ± 5.7
Δ ABG (SEM)	28 ± 13	28 ± 14	27 ± 13	29 ± 14
PTA ₄ -AAO				
Pre-Op ABG	30 ± 8.7	28 ± 13	29 ± 10	29 ± 11
Post-Op ABG	6.6 ± 5.5	6.3 ± 5.5	7.2 ± 6.1	4.9 ± 3.4
Δ ABG (SEM)	23 ± 10	22 ± 14	22 ± 12	24 ± 12

*Denotes statistical significance.

TABLE 4 Univariate (multiple paired t tests) analysis by Prosthesis length/diameter

Total Ears n = 46	Prosthesis length		Prosthesis diameter	
	4.25 mm N = 27	4.5 mm N = 17 ^a	0.6 mm N = 40	0.5 mm N = 6
HF ABG				
Pre-Op ABG	31 ± 16	28 ± 15	31 ± 15	33 ± 13
Post-Op ABG	16 ± 15	17 ± 17	15 ± 13	14 ± 7.4
Δ ABG (SEM)	15 ± 22	21 ± 13	17 ± 20	19 ± 15
LF ABG				
Pre-Op ABG	38 ± 10	36 ± 12	37 ± 12	36 ± 5
Post-Op ABG	9.8 ± 7.4	8.3 ± 5.9	10 ± 6.9	7.7 ± 5.4
Δ ABG (SEM)	29 ± 13	28 ± 14	27 ± 13	29 ± 7
PTA ₄ -AAO				
Pre-Op ABG	30 ± 11	30 ± 9.2	29 ± 11	29 ± 9.3
Post-Op ABG	7.3 ± 6.2	5.1 ± 4.3	6.7 ± 5.6	4.8 ± 2.2
Δ ABG (SEM)	23 ± 12	25 ± 10	22 ± 12	24 ± 10

^aTwo cases requiring prosthesis length of 4.75 and 5.5 mm were not included.

Our findings support our hypothesis that gains in hearing following stapedotomy are frequency-dependent, favoring low and mid frequencies. Our secondary analysis of the results from over 700 patients published by Pauli 2019 shows a more complete closure of the ABG at low frequencies than high frequencies with similar magnitudes to our data set. Our prior work on high-frequency conductive hearing following middle ear surgery^{9,10} suggests that across middle ear surgical procedures, post-operative high frequency ABGs persist and may be under-reported using current PTA₄ standards.⁸

Other studies have examined extended high-frequency AC thresholds (10-20 kHz) in relation to stapes surgery. Mair and Laukli demonstrated that significant AC threshold loss occurs in extended high frequencies following stapes surgery, but found such losses less likely following stapedotomy as compared to stapedectomy.¹⁴ Tange and Dreschler utilized high-frequency

audiometry to support this idea and also suggest that preoperative HF AC thresholds may predict the degree of stapes fixation.¹⁵ More recently, some studies have demonstrated a decrease in the benefit of stapedotomy in the higher frequencies^{18,22}; however, these findings are limited by reporting of AC without mention of bone conduction thresholds.

The location of the frequency-specific differences in hearing thresholds following stapes surgery is not clear. Some otologists believe that excessive drilling, ossicular manipulation and the use of certain lasers may result in sensorineural losses.²³⁻²⁵ Others have demonstrated that high-frequency sensorineural hearing loss initially seen following stapes surgery may improve with time.¹⁷ Pauli et al did evaluate for the effects of laser type and use of a microdrill on high frequency hearing outcomes. Interestingly, they did not find any significant difference in high frequency hearing results by surgical

method.²¹ While our multivariate analysis did not identify surgical factors that were associated with differences in high frequency ABG hearing outcome, our findings are limited by our small sample size.

Herein, we report retrospective data from our own clinical practice as well as a large-scale database of stapedotomy outcomes that affirms the idea that a portion of high frequency deficits following stapes surgery are conductive in nature. Prior work in cadaveric temporal bones supports the idea that the altered biomechanics of the middle ear following piston reconstruction may lead to reduced perilymph stimulation and a persistent conductive deficit.^{26,27} While additional biomechanics work suggest that the use of larger-diameter pistons is associated with better conductive hearing outcomes,²⁸ a large scale systematic review of clinical data suggests that the piston diameter is not reliably associated with increased ABG closure overall and our own findings suggest that it does not differentially impact the low or high frequency ABG.²⁹ Importantly, the degree to which threshold elevation at 6 and 8 kHz, or even beyond is due to a conductive component is unclear. Further studies using high frequency bone conduction transducers are warranted. Better delineation of conductive and sensorineural contributions to high frequency deficits following surgery would clarify the role that surgical factors, prosthesis design and fenestration type play in the correction of conductive loss.

High-frequency hearing deficits will lead to difficulties with speech discrimination in noise and impair sound localization.³⁰⁻³³ Previous work by Chadwell and Greenberg demonstrated a significant decrease in the speech intelligibility in noise for 10 post-stapedotomy patients.³⁴ Further testing of hearing in noise for post stapedotomy patients, will help determine the degree to which persistent high-frequency ABGs contribute to real world hearing impairment. Routine measurement and reporting of hearing thresholds in surgical patients provide the opportunity to identify factors associated with superior outcomes and adjust clinical and surgical practice to replicate these results. In addition, measuring high-frequency ABGs more consistently will present an opportunity for otologists to assess if differences in procedural technique or prosthesis dimensions impact high-frequency hearing outcomes.

The limitations of our study include the retrospective nature and small sample size of our study population. Additionally, there is some variability with respect to when post-operative audiograms were performed which may introduce some heterogeneity in the interpretation of our results. Finally, we did not attempt to categorize each case by the grade of otosclerosis or the degree of surgical complexity which limits both the internal and external validity of our analysis.¹⁵ However, despite these logistical limitations at our own institution, when we employed our method of comparing the high and low frequency ABGs to the large set of stapedotomy outcomes produced by Pauli et al, we found a greater degree of ABG closure in the lower frequencies when compared to the high frequencies. We believe that post-operative high frequency ABGs are prevalent but often not reported in the literature or in practice. Additionally, we have shown that the AAO-HNS PTA₄ system may mask high frequency ABGs and obscure persistent high frequency hearing deficits post-operatively.

In summary, when reported using conventional means, our audiometric outcomes following stapedotomy appear consistent with large published series. Differences in the high- and low- frequency ABG

reduction reported by our group, suggest that the current techniques improve low-frequency conductive hearing to a greater degree than high-frequency hearing. We suggest future work focus on identifying potential surgical or prosthesis factors that may influence high frequency hearing outcomes. In addition, future development of testing protocols for high frequency bone conduction transducers would be useful for quantifying ABG above 4 kHz. Finally, the cause of persistent high-frequency hearing deficits is not clear. Future otopathologic work is necessary to evaluate the hair cells in the basal turn of the cochlea in temporal bone donors who underwent stapedotomy in life. Correlating these findings with available audiometric data will afford us a clearer view of the impacts of stapes surgery on high frequency hearing and lead to surgical strategies that improve conductive losses at all affected frequencies.

5 | CONCLUSION

In a series of patients undergoing stapedotomy, post-operative hearing gains decrease with increasing frequency. Current audiometric reporting standards are biased towards detecting lower frequency gains, and do not sufficiently capture higher frequencies. Efforts should be made to include high-frequency hearing evaluation to more comprehensively assess patients' full spectrum of hearing following middle ear surgery.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

Prithwijit Roychowdhury involved in study design, acquisition of data, data analysis, and manuscript preparation. Marc D. Polanik involved in study design and acquisition of data. Judith S. Kempfle involved in study design and acquisition of data. Melissa Castillo-Bustamante involved in study design and acquisition of data. Cheryl Fikucki involved in acquisition of data. Michael J. Wang involved in manuscript preparation. Elliott D. Kozin involved in study design and manuscript preparation. Aaron K. Remenschneider involved in study design, acquisition of data, data analysis, and manuscript preparation.

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