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A Multi-Center Study of Ossiculoplasty Hearing Outcomes and a Grading Scale of Ear Environment Risk

Michael B. Gluth, MD; Ryan T. Judd, MD; Richard K. Gurgel, MD; John L. Dornhoffer, MD; Walter Kutz, MD; Matthew L. Carlson, MD; Jafri Kuthubutheen, MBBS, PhD; Ryan D. Anderson, MD; Daniel E. Killeen, MD; Jason H. Barnes, MD; Wanda L. Fussell, MD; Chaithanya Jeganathan, MD

Objective: To determine which ear environment risk factors impact ossiculoplasty hearing outcomes and to generate a statistically-valid grading system for ossiculoplasty outcome reporting.

Study Type: Retrospective case series.

Methods: A multi-institutional database was generated from cases performed between 2011 and 2019. Preoperative and postoperative hearing thresholds were recorded alongside potential ear environment risk factors. Multiple variable linear regression statistical analyses of risk factors were applied to determine independent association with postoperative pure tone average air-bone gap (PTA-ABG). Significant factors were used to generate a statistically-weighted grading scale of Ear Environment Risk (EER).

Results: 1679 cases had a mean follow-up time of 33.6 months (SD 36.3) and a mean postoperative PTA-ABG of 21.2 (SD 12.8). Multiple revision status ($p < 0.001$), presence of canal wall down mastoidectomy cavity ($p = 0.020$), absent malleus ($p < 0.001$), absent stapes superstructure ($p = 0.016$), frequent otorrhea ($p = 0.008$), pediatric age ($p < 0.001$), and blunted/lateralized tympanic membrane ($p = 0.003$) were independently correlated with PTA-ABG. These factors were incorporated into an EER Scoring System with four distinct risk groups wherein each risk group was significantly correlated with PTA-ABG, and this grading system was better correlated with PTA-ABG (Kendall's $\tau = 0.193$) than other existing published grading scales.

Conclusion: Grading environment risk according to a novel EER scoring system generates meaningful risk groupings that correlate with ossiculoplasty postoperative PTA-ABG, and this holds potential to frame reporting of hearing outcomes for future ossiculoplasty research.

Key Words: conductive hearing loss, ear surgery, middle ear, ossicular chain, ossiculoplasty.

Level of Evidence: 3

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INTRODUCTION

The modern concept of ossiculoplasty, including the use of synthetic materials, is roughly as old as the concept of tympanoplasty itself. Indeed, alongside the classic descriptions of tympanoplasty by Wullstein and Zöllner of the 1950s,[1,2] one will also discover the first report of a synthetic ossicular replacement prosthesis by Wullstein in 1952 wherein a vinyl-acrylic strut was placed between a mobile stapes footplate and a grafted tympanic membrane.[3] A few years later, Hall and Rytzner reported use of an incus autograft for ossiculoplasty in 1959.[4]

Early attempts at ossiculoplasty using various synthetic materials such as solid plastics and metals were plagued by undesired consequences such as foreign body reaction, demineralization of adjacent native ossicles, resorption, and extrusion,[5–10] and this prompted a

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From the Section of Otolaryngology-Head and Neck Surgery, University of Chicago (M.B.G.), Chicago, Illinois, U.S.A.; Department of Otolaryngology-Head and Neck Surgery (R.T.J.), The Ohio State University, Columbus, Ohio, U.S.A.; Pritzker School of Medicine, University of Chicago (R.T.J.), Chicago, Illinois, U.S.A.; Department of Otolaryngology-Head and Neck Surgery (R.K.G., R.D.A.), University of Utah, Salt Lake City, Utah, U.S.A.; University of Utah School of Medicine (R.K.G., R.D.A.), Salt Lake City, Utah, U.S.A.; Department of Otolaryngology-Head and Neck Surgery (J.L.D.), University of Arkansas for Medical Sciences, Little Rock, Arkansas, U.S.A.; Department of Otolaryngology-Head and Neck Surgery (W.K., D.E.K.), UT Southwestern Medical Center, Dallas, Texas, U.S.A.; Department of Otorhinolaryngology-Head and Neck Surgery (M.L.C., J.H.B., W.L.F.), Mayo Clinic, Rochester, Minnesota, U.S.A.; and the Division of Surgery (J.K., C.J.), University of Western Australia, Perth, Western Australia, Australia.

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Send correspondence to Michael B. Gluth, Section of Otolaryngology-Head and Neck Surgery, University of Chicago, 5841 S. Maryland Ave, Chicago, IL 60637. Email: michaelgluth@mac.com

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common sentiment that perhaps synthetic prostheses were inherently unfit for use in chronic middle ear disease. Thus, throughout the latter half of the twentieth century, advancements in ossiculoplasty were heavily focused on the key issue of biocompatibility.[11] Autograft ossiculoplasty with sculpted native ossicles arose as a viable alternative concept—but with limitations related to technical complexity and unique risk of prompting recidivism in patients with cholesteatoma.[5] A noteworthy breakthrough in this realm involved high-density porous polyethylene implants, which were popularized in the 1970s to eventually attain broad use worldwide.[12–14] Although high density porous polyethylene still had shortcomings such as long-term stability,[15,16] its general biocompatibility helped promote confidence in the concept of synthetic implants.

Yet, another major obstacle in the realm of ossiculoplasty was the issue of high prosthesis extrusion rates (10%–30%).[17–19] Prostheses often did not fare well when directly interfacing the tympanic membrane, especially in the presence of ongoing negative middle ear pressure; thus, it was not until cartilage tympanoplasty techniques were refined and applied alongside ossiculoplasty that extrusion rates improved.[20,21] This work, in the 1980s and 1990s, came about alongside modern biomaterials such as hydroxyapatite (HA), a bioactive porous ceramic,[22] and titanium[23] that, not only had superior biocompatibility, but also were acoustically-favorable. In the modern era, HA and titanium remain the two dominant ossicular replacement prosthesis biomaterials, and most long-term reports depict extrusion rates of under 5% using either material with application of an overlying protective cartilage cap.[24–27]

As the biomaterial problem was reasonably solved, an explosion of prosthesis designs occurred with intent to improve stability, fit, and ease of use.[28–32] The resultant wide variation of prosthesis shapes and sizes that emerged arguably exceeds need given the relative simplicity of the procedure itself. Considering the thrilling innovations achieved with biomaterials and design, it has been natural for otologic surgeons to focus upon the merits of a given prosthesis and surgical technique as the essential key to achieve favorable outcomes. To what degree, if any, various innovations in design have improved hearing outcomes is still unclear.

A more recent, but no less critical, development in ossiculoplasty has been the observation that hearing outcomes are generally worse when reconstruction is performed in a middle ear that has been remodeled by the effects of chronic disease, as compared to execution of the identical procedure in an ear that is healthy and more normal.[33–37] The critical implication of this concept is that, to validate new ossiculoplasty surgical techniques or prosthesis innovations, there must be a means to account for patient-specific ear risk to assure that groups undergoing comparison have been sufficiently risk-stratified and are therefore considered roughly equivalent. Unfortunately, there are still limits in understanding which ear environment risk factors definitively impact long-term ossiculoplasty outcomes, how such factors interplay with each other, and how much weighted impact each risk factor imparts upon a given ear.[38] Although useful grading scales of ear risk such as middle ear risk index (MERI)[39] or ossiculoplasty outcome scoring parameter (OOPS)[35] have emerged, each existing scale has distinct shortcomings with respect to application, validation, and generalizability as they are either based on a limited dataset from a single surgeon or not based on actual surgical outcomes at all.[38] This troublesome reality continues to render most of the existing literature on ossiculoplasty hindered and ambiguous.

In the current report, extensive new data relating to ossiculoplasty outcomes is presented while keeping the important concept of ear environment in focus. This effort includes presentation of a large dataset on ossiculoplasty outcomes derived from a multi-center effort involving numerous otologic surgeons. The objective of this study is to report the hearing outcomes that may be expected using modern ossiculoplasty techniques—including analysis of how outcomes can change over time. Further, this study aims to evaluate the impact of the underlying ear environment on hearing outcomes, with intent to generate a novel statistically-based ear risk grading scale that allows simple quantification of ear risk in scoring that better correlates with long-term hearing outcomes than existing grading systems.

METHODS

With institutional review board approval at each participating site, a multi-center database for ossiculoplasty outcomes was created with the participation of six tertiary-care academic medical centers, each having subspecialty expertise in otologic surgery. Standardized data entry at each site was facilitated via a case entry portal using a common secure online RedCap survey.[40] Data from subjects who underwent ossiculoplasty between 2011 and 2019 by a total of 11 otologic surgeons were included, each surgeon having subspecialty training in complex otologic surgery. This included patients that underwent procedures that involved synthetic ossicular replacement prostheses, autograft ossicular replacement prostheses, incudostapedial joint prosthesis, ossicular repair via bone cement, and ossicular mobilization procedures for malleus head fixation with preserved ossicular chain. We did not include cases of classic type III stapes columella tympanoplasty wherein the tympanic membrane graft is applied directly onto the stapes capitulum. Patients who underwent stapedotomy or stapedectomy for stapes footplate fixation were excluded.

For data acquisition, all factors that were previously utilized in the existing published MERI, OOPS, and surgical prosthetic infection tissue eustachian tube (SPITE) middle ear grading systems[33,35,39] were included alongside numerous additional factors deemed to be potentially impactful by the consensus of the senior authors—including input from every participating site.[38,41] Thus, for each ossiculoplasty case, we collected information on demographics, preoperative medical conditions, preoperative otologic history and exam, intraoperative findings, and postoperative follow-up information. Details on specific information collected are portrayed in Tables I and II.

Ossiculoplasty and mastoidectomy/epitympanectomy type were defined using The International Otology Outcome Group SAMEO-ATO framework (www.ioog.net). Austin's classification was used to classify ossicular status.[42] Severely diseased middle ear mucosa health status was defined by presence of tympanosclerosis, significant adhesions, or presence of middle ear polyp. Patients who smoked most or all days of the week at

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TABLE I.
Ossiculoplasty Case Profile.

A. Ossiculoplasty	*N* (%*)
Ossiculoplasty type	
Major and minor columella reconstruction with autograft or synthetic PORP (Osm & Ost)	984 (58.6)
Major and minor columella reconstruction with autograft or synthetic TORP (Ofm & Oft)	609 (36.3)
IS joint reconstruction (Osi)	39 (2.3)
Ossicular mobilization (On)	47 (2.8)
PORP ($n = 967$)	
Autograft	101 (10.4)
Titanium only	390 (40.3)
Titanium + hydroxyapatite	217 (22.4)
Polyethylene	247 (25.5)
Other[b]	12 (1.2)
TORP ($n = 604$)	
Autograft	3 (0.5)
Titanium only	274 (45.3)
Titanium + hydroxyapatite	163 (27.0)
Polyethylene	159 (26.3)
Other[b]	5 (0.8)
Cartilage in tympanoplasty ($n = 1623$)	
Yes	1511 (93.1)
No	112 (6.9)
Revision ($n = 1661$)	
Yes	527 (31.7)
No	1134 (68.3)
Revision number ($n = 510$)	
First	392 (76.9)
Second	89 (17.5)
Third	29 (5.7)
Status of past prosthesis at time of surgery ($n = 419$)	
Displaced	273 (65.1)
Fixed	85 (20.3)
Extruded	61 (14.6)
B. Concurrent surgery	**N (%*)**
Tympanic membrane perforation	
Repaired at time of ossiculoplasty	857 (51.8)
Repaired in past (staged)	291 (17.6)
Never required repair	507 (30.6)
Cholesteatoma	
Never	631 (38.2)
In the past (not current)	368 (22.3)
Concurrent removal	652 (39.5)
Mastoidectomy	
Never (Mx)	674 (40.8)
In the past (not current)	736 (44.5)
Concurrent	243 (14.7)
Mastoidectomy type ($n = 965$)	
Intact canal wall (M1a/M1b)	681 (70.6)
Canal wall down (M2c)	284 (29.4)

(Continues)

TABLE I.
Continued

B. Concurrent surgery	*N* (%*)
Canalplasty	
Yes	229 (13.8)
No	1430 (86.2)
Epitympanectomy	
Yes (M2a/M2b)	215 (13.0)
No	1442 (87.0)

Ossiculoplasty and mastoidectomy/epitympanectomy type depicted in parentheses according to IOOG SAMEO-ATO framework (www.ioog.net).

IS = incudostapedial joint; PORP = partial ossicular replacement prosthesis; TORP = total ossicular replacement prosthesis.

*% Indicates percentage of total for the number of patients who had data available for that field unless otherwise indicated.

the time of surgery were considered current and active smokers. When the surgical note did not implicitly mention drainage or lack of drainage, the most recent clinical note was used. Additional data related to surgical factors, such as prosthesis characteristics and the use of bone cement, were included in the survey, but that data and analysis will be reported in a separate article involving the impact of modifiable surgical factors on ossiculoplasty outcomes.

A minimum of two and a maximum of three audiograms were collected for each case: a preoperative audiogram closest to surgery (collected for all cases), an early (short-term) postoperative audiogram performed within 4 months after surgery, and/or the most recent audiogram to date (if further out than 4 months). The following data were collected: air and bone conduction thresholds at 500, 1000, 2000, 3000, and 4000 Hz and word recognition score (WRS). When results were not available at 3000 Hz, an average of the air or bone conduction at 2000 and 4000 Hz was used.[43] For audiograms where bone conduction was not available, the bone conduction was assumed to be the same as the most recent available audiogram. The pure tone average air-bone gap (PTA-ABG) was the main outcome of interest and was calculated by averaging patients' ABG for 500, 1000, 2000, and 3000 Hz.[44] Patients without a suitable postoperative audiogram available for review were excluded. Non-reliable audiograms were excluded and defined as bone conduction greater than 60 dB at 500 Hz or greater than 70 dB at 1000, 2000, 3000, or 4000 Hz due to presumed incomplete masking and inaccurate assessment of ABG. Additionally, patients with a preoperative WRS <50% were excluded. PTA-ABGs were classified into four groups based on the following classification scheme from Kartush: 0–10 dB = excellent; more than 10–20 dB = good; more than 20–30 dB = fair; more than 30 dB = poor.[34] Scattergrams of pre- and post-treatment PTA-ABG by WRS were created in compliance with the Reporting Hearing Outcomes for Clinical Trials available on the web (http://hearingoutcomes.stanford.edu/).

Univariate analysis was conducted using *t*-test for two-group comparison and ANOVA for three-group comparison to determine individual significant associations between all collected ear risk factors and most recent postoperative PTA-ABG. Ear risk factors with $p < 0.05$ on univariate analysis were, in turn, included in a multivariable linear regression analysis. All factors with significant correlation in the multivariable model were ultimately included in creation of a novel Ear Environment Risk (EER) scoring system. To account for the relative impact of each included EER factor, the multivariable correlation

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TABLE II.
Univariate Associations between Patient and Middle Ear Risk Factors and Most Recent Postoperative PTA-ABG.

A. Patient factors	*N* (%*)	Mean PTA-ABG (SD)	*p*-Value
Age category			
Pediatric (<18 years old)	459 (27.4)	23.7 (14.6)	<0.001
Adult	1214 (72.6)	20.3 (11.9)	
Sex			
Male	854 (50.9)	21.8 (12.9)	0.052
Female	825 (49.1)	20.6 (12.7)	
History of bilateral middle ear disease			
Yes	622 (38.2)	22.5 (13.0)	0.005
No	1007 (61.8)	20.7 (12.7)	
BMI category (pediatric cases excluded) ($n = 853$)			
Obese (BMI > 30)	278 (32.6)	20.0 (12.2)	0.481
Non-obese	575 (67.4)	20.6 (12.1)	
Smoking status			
Never smoker	792 (64.8)	21.4 (12.6)	0.310
Former smoker	218 (17.8)	20.0 (11.7)	
Current, active smoker	213 (17.4)	20.5 (11.4)	
Diabetes			
Yes	90 (5.4)	19.8 (9.8)	0.155
No	1577 (94.6)	21.3 (12.9)	
Major immunosuppression			
Yes	13 (0.8)	25.5 (13.0)	0.261
No	1649 (99.2)	21.2 (12.8)	
History of radiation therapy			
Yes	16 (1.0)	20.3 (11.9)	0.749
No	1640 (99.0)	21.3 (12.8)	
Middle ear tumor†			
Yes	95 (5.7)	19.2 (12.2)	0.089
No	1563 (94.3)	21.4 (12.8)	
Intracranial complication			
Yes	31 (1.9)	20.0 (11.7)	0.571
No	1627 (98.1)	21.3 (12.8)	

B. Ossicular status	*N* (%*)	Mean PTA-ABG (SD)	*p*-Value
Ossicular status			
M + I + S+	155 (9.3)	18.7 (12.5)	<0.001
M + I − S+	515 (31.0)	18.7 (11.0)	
M − I − S+	311 (18.7)	20.6 (12.5)	
M + I − S−	378 (22.8)	21.8 (12.9)	
M – I − S−	301 (18.1)	27.0 (14.0)	
Stapes			
Present	1000 (59.5)	19.8 (12.0)	<0.001
Absent	679 (40.4)	23.7 (13.6)	
Malleus			
Present	1067 (63.5)	19.4 (11.8)	<0.001
Absent	612 (36.5)	14.2 (13.6)	

(Continues)

TABLE II.
Continued

B. Ossicular status	*N* (%*)	Mean PTA-ABG (SD)	*p*-Value
Stapes footplate fixation			
Yes	73 (4.4)	25.7 (14.7)	0.009
No	1576 (95.6)	21.0 (12.6)	
Lateral chain fixation			
Yes	188 (11.3)	19.8 (12.0)	0.093
No	1469 (88.7)	21.4 (12.8)	

C. Middle ear envelope	*N* (%*)	Mean PTA-ABG (SD)	*p*-Value
Bellucci score			
Dry (I)	785 (48.2)	20.2 (13.0)	<0.001
Occasionally wet (<50%) (II)	538 (33.0)	20.8 (11.9)	
Usually wet (>50%) or wet with cleft palate (III or IV)	306 (18.7)	24.8 (13.3)	
Mucosa severely diseased			
Yes	636 (38.3)	22.1 (12.7)	0.025
No	1023 (61.7)	20.7 (12.8)	
Cholesteatoma			
Yes	1023 (61.9)	21.6 (12.4)	0.111
No	631 (38.1)	20.6 (13.2)	
Granulation tissue present			
Yes	183 (11.0)	22.0 (11.4)	0.384
No	1476 (89.0)	21.2 (12.9)	
Middle ear effusion			
Yes	89 (5.4)	21.0 (12.1)	0.830
No	1570 (94.6)	21.3 (12.8)	
Tympanic membrane lateralized/blunted			
Yes	102 (6.2)	26.7 (15.5)	<0.001
No	1556 (93.8)	20.9 (12.5)	
Myringitis			
Yes	44 (2.6)	21.5 (11.7)	0.895
No	1619 (97.4)	21.2 (12.8)	
Revision surgery			
No	1134 (69.0)	20.0 (12.3)	<0.001
First	392 (23.8)	22.9 (12.7)	
Second or greater	118 (7.2)	27.8 (15.2)	
Mastoidectomy			
Never (Mx)	674 (41.1)	19.6 (12.7)	<0.001
Intact canal wall (M1a/M1b)	681 (41.5)	21.5 (12.5)	
Canal wall down (M2c)	284 (17.3)	24.6 (13.4)	

Austin M_I_S_ = malleus, incus, stapes status[42]; BMI = body mass index; PTA-ABG = pure tone average air-bone gap; SD = standard deviation.

*% Indicates percentage of total for the number of patients who had data available for that field unless otherwise indicated.

†Middle ear tumor includes: papilloma, glomus tumor, adenoma (not cholesteatoma).

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coefficient was used as a starting point to estimate a weighted numerical score for each factor using whole numbers above and below the coefficient as possibilities. An initial total of 32 potential new EER scoring systems were applied to the database and the system with the highest resulting Kendall's tau correlation with most recent PTA-ABG was initially selected. Further modeling and modification of the chosen EER system was ultimately undertaken that went beyond the confines of whole numbers above and below the multivariate correlation coefficients based on correlation trends, resulting in selection of a final scoring system with the highest possible Kendall's tau that could be created and modeled. Mean and standard deviation of PTA-ABG for each EER score (minimum 0 [lowest risk] to maximum 16 [highest risk]) was calculated. EER scores were then divided into four EER risk categories based on distribution of PTA-ABG. PTA-ABG between EER risk groupings was compared using t-test.

Following creation of the EER scoring system, the strength of association between EER scores and PTA-ABG was compared to that of existing MERI and OOPS scoring systems. Of note, the SPITE system does not provide specific instructions for grading individual cases with a quantified score. The association between each scoring system and postoperative PTA-ABG was calculated using Kendall's tau coefficient. The strength of correlation between different scoring systems was compared using Bootstrap normal approximation. All statistical analyses were complected using Stata 15 (StataCorp, College Station, TX). p-values < 0.05 were considered statistically significant.

RESULTS

A total of 1827 individual surgeries were entered into the database. One hundred forty-eight were excluded for the above-mentioned exclusion criteria, and 1679 (91.9%) were included in the primary analysis. A detailed profile of the surgeries performed is portrayed in Table I. Rarely, select blank responses were present in the dataset for individual surgical case entries; thus, all 1679 cases are not necessarily accounted for in every single category depicted in the table. At most recent follow-up, 94.5% of prostheses were clinically deemed to still be in place ($n = 1294$) with 2.1% extruded and 3.4% displaced.

Mean preoperative PTA-ABG was 33.3 dB (SD: 13.8). Mean postoperative PTA-ABG from the most recent audiogram was 21.2 dB (SD 12.8) having a mean time after surgery of 33.6 months (SD 36.3). Hearing outcomes by traditional bracketed groupings is depicted in Table III, and both pre-treatment and post-treatment scattergrams of PTA-ABG and WRS are presented in Figure 1.

Among cases with a preoperative bone conduction hearing in the normal (<25 dB) range and preoperative AC-PTA in the moderate hearing loss or worse range (>40 dB), 54.1% were corrected by ossiculoplasty back into the normal range and an additional 29.3% to the mild hearing loss range.

When comparing 1015 cases for which a short-term (under 4 months) and longer-term follow-up audiogram were both available, the mean short- and long-term PTA-ABG were 21.2 dB (SD: 14.2) and 21.6 dB (SD: 13.3), respectively, which was not significantly different

TABLE III.
Pre- and Postoperative Audiologic Outcome Groupings.

	Preoperative PTA-ABG *N* (%)	Postoperative PTA-ABG (most recent available) *N* (%)
Excellent (0–10 dB)	46 (2.9%)	252 (15.0%)
Good (10–20 dB)	215 (13.3%)	644 (38.4%)
Fair (20–30 dB)	436 (27.1%)	442 (26.3%)
Poor (>30 dB)	914 (56.7%)	341 (20.3%)

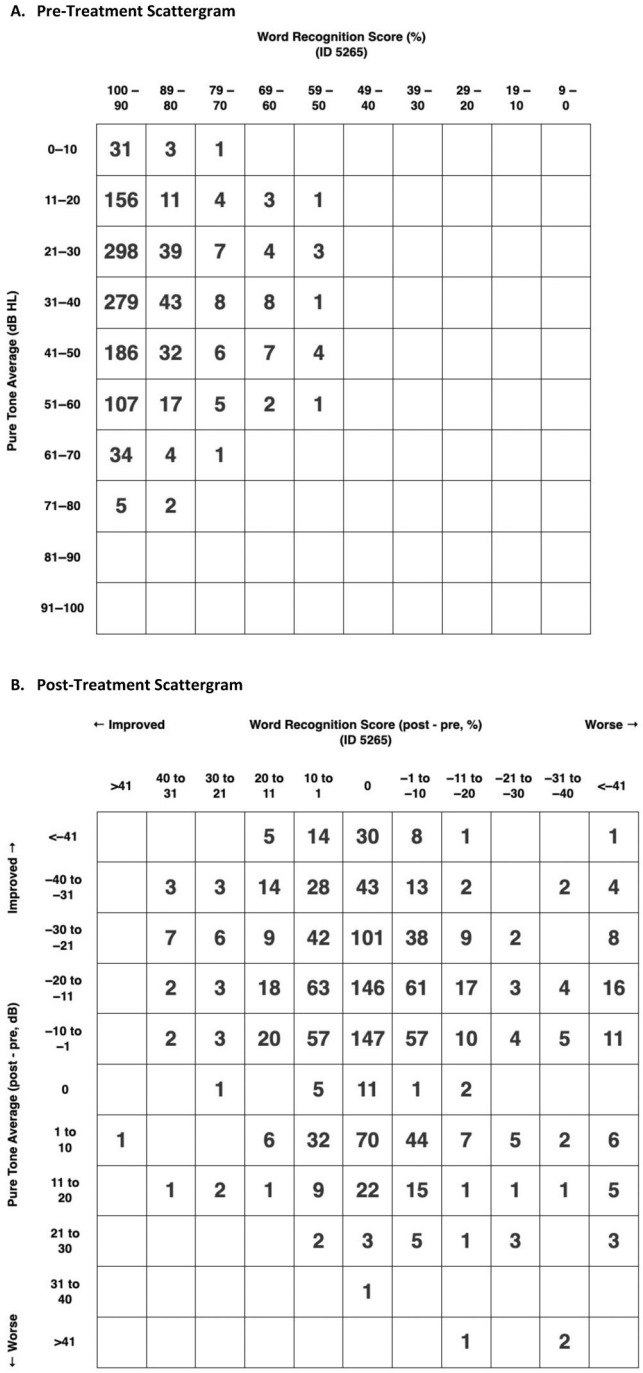

Fig. 1. Pre-treatment (A) and post-treatment (B). Scattergrams of pure tone average air-bone gap by word recognition score.

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($p = 0.287$). Overall, as defined by PTA-ABG ± 5 dB, 449 (44.2%) had no difference between short-term and long-term hearing outcome; whereas for 303 (29.9%), the long-term hearing was worse and, for 263 (25.9%), the long-term hearing outcome was better.

Of the 1350 patients with both a preoperative and short-term (<4 months) postoperative audiogram, 193 (14.3%) had an increase in PTA bone conduction >5 dB, and 180 (13.3%) had a decrease in PTA bone conduction >5 dB. Median change in bone conduction was a decrease of 1.9 dB (IQR: −6.9 to 1.9).

Univariate associations between potential ear environment risk factors and most recent postoperative PTA-ABG are shown in Table II. In summary, pediatric age grouping, history of bilateral middle ear disease, ossicular status, stapes footplate fixation, Bellucci score, severely diseased mucosa, lateralized or blunted tympanic membrane, revision surgery, and mastoidectomy were significantly associated with higher postoperative PTA-ABG ($p < 0.05$).

The significant variables in the univariate analysis were included in a multivariable analysis to affirm them as independent risk factors ($n = 1547$), which is shown in Table IV. In summary, revision surgery (both first and multiple revision), canal wall down mastoidectomy, pediatric age grouping, Bellucci score of III or IV, tympanic membrane lateralization/blunting, absent or damaged malleus, and absent or damaged stapes were independently associated with higher postoperative PTA-ABG ($p < 0.05$).

Among 32 potential weighted models for EER, the model ultimately accepted had a Kendall's $\tau = 0.193$. This model is shown in Table V. Mean postoperative PTA-ABG for each EER score was calculated (Fig. 2, Table VI). Based on the distribution of PTA-ABG by EER score, EER scores were divided into four risk groupings: favorable (EER 0), low risk (EER 1–4), intermediate risk (EER 5–8), and high risk (EER 9+). PTA-ABG was significantly higher in each risk group (Table VII) compared with each lower risk group (all $p < 0.001$). Kendall's τ for MERI and OOPS were both less favorable than EER at 0.149 and 0.164, respectively. Thus, comparison of correlation demonstrated that EER had a significantly stronger association than MERI (mean difference −0.04 [95% CI −0.07 to −0.01], $p = 0.003$) and OOPS (mean difference −0.03 [95% CI −0.06 to −0.01], $p = 0.032$). Table VIII portrays the mean and median postoperative ABG according to each EER risk grouping, including a depiction of median quartile ranges.

TABLE IV.
Multivariable Linear Regression Analysis ($n = 1,547$).

	Correlation coefficient (Standard Error)	*p*-Value
Revision		
First (vs none)	2.25 (0.77)	0.004
Multiple (vs none)	6.03 (1.28)	<0.001
Mastoidectomy		
Intact canal wall (M1a/M1b) (vs never [Mx])	−0.20 (0.75)	0.792
Canal wall down (M2c) (vs never [Mx])	2.30 (0.99)	0.020
Adult (vs pediatric)	−2.85 (0.72)	<0.001
History of bilateral middle ear disease	1.05 (0.66)	0.110
Stapes footplate fixation	2.01 (1.55)	0.193
Bellucci score		
II (vs I)	0.15 (0.73)	0.840
III or IV (vs I)	2.49 (0.94)	0.008
Severely diseased mucosa	0.95 (0.66)	0.152
Tympanic membrane lateralization	3.84 (1.30)	0.003
Malleus absent	2.99 (0.70)	<0.001
Stapes absent	1.67 (0.70)	0.016

Ossiculoplasty and mastoidectomy/epitympanectomy type depicted in parentheses according to IOOG SAMEO-ATO framework (www.ioog.net).

DISCUSSION

This report shows that modern ossiculoplasty is an effective means of improving hearing due to ossicular dysfunction. This large series of 1679 cases reports a mean improvement in PTA-ABG of 12.1 dB over a mean follow-up time of 33.6 months. In the context of traditional bracketed groups of hearing outcomes, 15.0% had PTA-ABG closure of 10 dB or less, 53.4% 20 dB or less, and 79.7% 30 dB or less. For many patients, the outcome that matters most is the postoperative air conduction hearing threshold, and in this respect, ossiculoplasty is also successful in the majority cases. For example, cases involving purely conductive hearing loss in the moderate or worse range were corrected into the normal range in 54%

TABLE V.
Ear Environment Risk (EER) Scoring System.

Risk Factor	Point(s)
Revision	
No	0
Yes, first	1
Yes, multiple	5
Canal wall down mastoid cavity present	
Yes	2
No	0
Age	
Pediatric	1
Adult	0
Malleus	
Present	0
Missing or damaged	2
Stapes superstructure	
Present	0
Missing or damaged	1
Drainage (Bellucci classification)	
Dry or occasional otorrhea	0
Wet >50% of the time or wet with cleft palate	1
Tympanic membrane	
Lateralized or blunted	4

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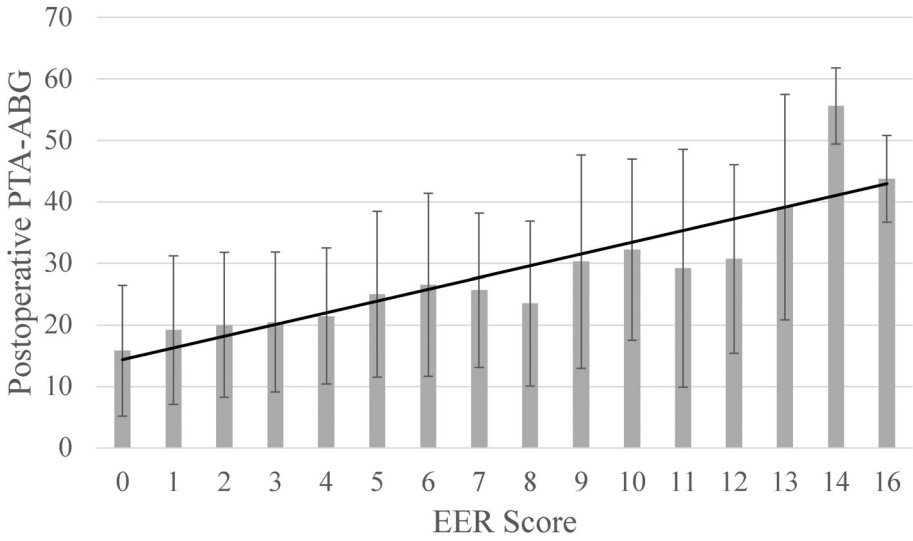

Fig. 2. Postoperative pure tone average air-bone gap versus EER score with brackets depicting standard deviation. Line of best fit added to show linear relationship.

TABLE VI.
EER Risk Groupings According to Postoperative PTA-ABG.

EER score	*N* (%)	Postoperative PTA-ABG (SD)
0	220	15.8 (10.6)
1	323	19.2 (12.0)
2	267	20.0 (11.7)
3	241	20.5 (11.4)
4	205	21.5 (11.0)
5	172	25.0 (13.5)
6	78	26.6 (14.9)
7	50	25.7 (12.5)
8	36	23.5 (13.4)
9	45	30.3 (17.3)
10	17	32.3 (14.7)
11	8	29.2 (19.3)
12	10	30.8 (15.3)
13	3	39.2 (18.3)
14	2	55.6 (6.2)
15	0	–
16	2	43.8 (7.1)

EER = Ear Environment Risk; PTA-ABG = pure tone average air-bone gap; SD = standard deviation.

TABLE VII.
Association between EER Risk Grouping and Postoperative PTA-ABG.

EER risk group	*N* (%)	Mean postoperative PTA-ABG (SD)	Kendall's τ
Favorable (0)	220 (13.1)	15.8 (10.6)	0.193
Low risk (1–4)	1036 (61.7)	20.2 (11.6)	
Intermediate risk (5–8)	336 (20.0)	25.3 (13.6)	
High risk (9+)	87 (5.2)	31.8 (16.7)	

PTA-ABG = pure tone average air-bone gap; SD = standard deviation; EER = Ear Environment Risk.

TABLE VIII.
Postoperative ABG Mean and Median Quartile Ranges by EER Risk Group.

EER risk	*N*	Mean	SD	Median	Q1	Q3
Favorable	220	15.8	10.6	13.8	8.8	20.0
Low	1036	20.2	11.6	18.1	11.9	26.3
Intermediate	336	25.3	13.6	22.5	15.0	32.5
High	87	31.8	16.7	29.4	18.1	42.2

SD = standard deviation; Q1 = first quartile; Q3 = third quartile.

of attempts, and hearing was corrected into the mild or normal range in over 80% of attempts. These results strongly suggest that ossiculoplasty holds the potential to mitigate need for amplification in a large percentage of patients with conductive hearing loss.

Complications, which plagued the early era of synthetic prosthesis use for ossiculoplasty,[5,7,16] were uncommon in this large cohort. The rate of known prosthesis extrusion was a mere 2.1%, with an additional 3.4% of cases suspected to have a shifted prosthesis. However, these data regarding prosthesis positioning are admittedly unreliable because they are based on clinicians' impression, not radiologic confirmation. Nevertheless, low rates of extrusion in this series and several other past publications[20,21] have likely been achieved by routine application of a cartilage cap, which appears to be fairly standard practice in modern ossiculoplasty as 93% of cases in this work of numerous surgeons involved such a cap. Use of cartilage even appears routine for hydroxyapatite prostheses, which are theoretically more suitable for direct engagement of the tympanic membrane as compared to titanium implants. Hearing complications, namely failure to close AB gap or a

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new postoperative sensorineural hearing loss, were also uncommon as a decline in postoperative bone conduction was not a prominent feature in this large case series.

Changes in Ossiculoplasty Outcomes Over Time

This series is composed of cases having a mix of short-term and longer-term hearing outcome data. Analysis of hearing outcomes over time within this cohort suggests general stability of outcomes over time as the mean short-term PTA-ABG (21.15 dB) was not significantly different ($p = 0.29$) to the mean most recent PTA-ABG (21.61 dB). However, stability in ossiculoplasty hearing outcomes (defined as within 5 dB) did not always occur as 29.9% of cases had a worse PTA-ABG (>5 dB) over time, while 44.2% were the same, and 26.0% improved.

Ear Risk Factors Impacting Hearing Outcomes

A major goal of this effort was to better define risk factors that impact ossiculoplasty hearing outcomes and also the manner in which middle ear risk is objectively graded. To this end, sequential univariate and multivariate analyses were applied. Among these, multiple revision status was identified as overwhelmingly having the greatest independent negative impact on ossiculoplasty hearing outcomes. Although single ossiculoplasty revision status also imparted a significant negative impact, this was far less robust. Thus, otologic surgeons should be particularly grounded in expectations when confronted with an ear that has undergone several unsuccessful prior ossiculoplasty attempts. It seems feasible that repeated surgical manipulation of the middle ear cleft bears the potential to impart negative consequences in the form of scarring and adhesion formation.[35,38,45–48] Yet, it is also possible that unique factors not detected in the framework of this current study account for repeated ossiculoplasty failure—including behavioral factors such as habitual manipulation of the ear via Valsalva or other means as one speculative example.

The presence of a canal wall down mastoid cavity is also a major independent risk factor for poor ossiculoplasty hearing outcomes. Although cadaveric experiments using laser vibrometry suggest that the presence of an open mastoid cavity does not seem to have inherent negative impact on the sound transfer function,[11,49,50] such ears bear the consequence of having undergone a reduction in volume of the middle ear space, which is known to have potential negative consequences.[51] Furthermore, a canal wall down surgery renders the undersurface of the tympanic membrane in close proximity to the cochlear promontory and other middle ear boundaries, which may increase the likelihood of developing adhesions between the drumhead and these structures that can yield stiffness loading.[11,52,53] In contrast to some other publications based on small populations,[35,54] this study has shown that the presence of a canal wall-up mastoid defect did not impart a negative impact on hearing outcomes; an epitympanectomy defect also did not negatively impact hearing.

In this series, pediatric patients had worse hearing outcomes. Certainly, children are known to be at unique risk for impaired middle ear ventilation based on possible anatomic immaturity of the Eustachian tube and other potential risk factors such as frequent upper respiratory tract infection.[55–59] It may be that a surgeon's practice pattern with respect to concurrent ossiculoplasty and tympanostomy could impact the effects of age on hearing outcomes, but there may be other unique factors relating to growth and inflammation as well as challenges inherent to postoperative care in children that might impact outcomes. Indeed, pediatric cholesteatoma recidivism outcomes reported in the medical literature also seem to be similarly worse than adults.[60,61]

Independent of age, infection status at the time of surgery also impacted results. Infection present >50% of the time or infection with underlying cleft palate (Belucci score of 3 or 4) had a negative impact on hearing outcome. However, rare infection (Belucci score of 2) was not impactful. Infection can theoretically prompt formation of adhesions, result in otitis media with tympanic membrane perforation, or negatively impact graft viability.[62,63] However, active infection at the time of surgery was not rare within this series and the relatively low rate of prosthesis extrusion seems to suggest that ossiculoplasty prostheses seem relatively resistant to long-term infection-related complications or other associated failure.

Ossicular status appears to also have an impact on hearing outcomes, with the worst outcomes not surprisingly associated with concurrent absence of the malleus, incus, and stapes superstructure. Worsening Austin ossicular status was associated with worse outcomes and independent assessment of malleus and stapes superstructure status identified each of these as unique risk factors for poor hearing outcomes—with absent malleus being the relatively more impactful of the two, as has been suggested in other publications on this subject.[35,38,48,64–68] It is also perhaps worth noting that intact ossicular status (M + I + S+), which would have been present for ossicular mobilization procedures, was no different than isolated incus deficiency (M + I − S+) in terms of hearing outcome.

Notable factors that were not associated with hearing outcomes included: concurrent or past tympanic membrane repair, effusion at time of repair, tobacco use, middle ear granulation, concurrent epitympanectomy, and concurrent canalplasty. Other published studies on long-term ossiculoplasty hearing outcomes have also noted diseased middle ear mucosa,[33,35–37] stapes footplate fixation,[34,67] smoking status,[33,39] tympanic membrane perforation,[34,46] and cholesteatoma[33,34,46] to be significant risk factors; yet, the current study did not yield confirmatory results for any of these factors. As already noted, this work intentionally did not focus on modifiable surgical factors such as prosthesis characteristics, incorporation of the malleus, or use of bone cement to name a few examples, and those factors are the subject of another study that is a current work in progress using this same database. This work also excluded cases where stapedotomy was performed to address footplate fixation.

Ear Environment Risk (EER) Scoring System

The risk factors impacting ossiculoplasty hearing outcomes were statistically weighted to generate a novel

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EER scoring system. The EER system, depicted in Table V, has a range of 0–12 and is reasonably simple to administer. As compared to other scoring systems that already exist, the EER scale is based on a much larger number of cases, depicts the work of numerous surgeons from multiple centers, is derived from a cohort with a mean follow-up of over 3 years, and includes a diversity of ossiculoplasty techniques. All cases in this series were graded according to this new EER scale, as well as the existing MERI and OOPS scoring systems,[35,39] and by comparison, the EER is shown to objectively better predict ossiculoplasty hearing outcomes. Given the elements of diversity inherent within the dataset from which it is derived, the statistical superiority of the EER may reflect improved generalizability. However, it is important to note that the correlation between EER and PTA-ABG having a Kendall's tau of 0.193 is still considered weak. This highlights the reality that numerous other factors aside from ear environment, such as surgical technique, surgeon experience, surgeon skill, prosthesis characteristics, and other factors, may impact outcomes.

The development of EER reveals shortcomings of the simplistic traditional approach to interpreting ossiculoplasty results that has used somewhat arbitrary bracketed groupings of postoperative PTA-ABG that do not take ear environment risk status into account. For example, a hypothetical question of whether a 14-dB postoperative PTA-ABG is an especially favorable result can be raised. According to traditional interpretation, this result falls within the "good" outcome range, and PTA-ABG closure under 20 dB has, in fact, been widely touted as a benchmark for ossiculoplasty success. However, Table VIII presents a range of expected PTA-ABG outcomes for each EER risk grouping. This allows particular ossiculoplasty hearing outcomes to be then interpreted as "falling within the expected range" or "better or poorer than expected" considering standard deviation from the mean for each group and calculation of the cohort quartile outcome cutoffs. In this context, a 14-dB postoperative AB gap is in the expected range for cases having a favorable or low EER risk grouping, but better than expected for cases falling in the intermediate- or high-risk groupings because it falls within the first quartile and also one standard deviation from the mean for both. In other words, the answer to the question of whether a 14-dB postoperative AB gap is an expected or particularly favorable ossiculoplasty result is "maybe," since this question can only be answered in the context of underlying ear risk.

The extensive and heterogeneous ossiculoplasty dataset put forth in this report has the potential to facilitate future ossiculoplasty outcomes research by controlling for the middle ear environment and comparing with benchmark outcomes derived from a large rigorously studied dataset. Conducting placebo-controlled or blinded clinical trials for surgery such as ossiculoplasty is not feasible due to the inability to ethically create a placebo control group. Further, while existing cohort studies may compare a particular aspect of ossiculoplasty with another such as technique or prosthesis, yet there is no accepted gold standard approach to act as a universal control to validate superiority in ossiculoplasty. As such, it may be sensible to use the risk grouping hearing outcome quartiles in this report (Table VIII) as normative data since not only it is among the largest reports of long-term ossiculoplasty outcomes, but also it portrays the work of a multitude of surgeons, techniques, prostheses, and pathologies that allow it to reasonably be considered a general outcome standard. Future investigators hoping to research a new ossiculoplasty technique or prosthesis innovation can score the middle ear risk of their cases according to EER and then determine if their hearing outcomes fall within the expected ranges by using the EER Expected Hearing Outcome worksheet presented as Appendices S1 and S2. This worksheet is designed to portray whether a reported ossiculoplasty cohort has outcomes that are "within, below, or exceeding expected range" per each EER risk grouping and for the total cohort. Presentation of data in this manner may suggest unique virtues or weaknesses of a particular ossiculoplasty innovation. For example, if the total percentage of outcomes falling within the "poorer than expectation" range are well below 25%, this may suggest an innovation is uniquely adept at avoiding particularly poor hearing outcomes—as may be the case with prosthesis instability and resultant shifting or extrusion. Conversely, if the percentage of outcomes within the "better than expectation" are markedly above 25%, this may suggest an innovation that is particularly optimized from an acoustic engineering standpoint at sound transfer.

This study has several strengths and weaknesses. Strengths include: largest ever report of ossiculoplasty outcomes to support robust statistical analysis, wider breadth of the data points evaluated as compared to prior published efforts, incorporation of numerous surgeons applying variable techniques at multiple tertiary-care medical centers to enhance external validity, mean follow-up relatively long-term, and application of robust statistical techniques to identify and weight various significant ear risk factors. Weaknesses include retrospective methodology in data acquisition, lack of case input from non-expert ear surgeons, and relatively low case numbers for particular ear risk factors under scrutiny such as stapes footplate fixation, history of radiation, or intracranial complication to name a few.

CONCLUSION

In summary, this is a large case series that confirms the efficacy of ossiculoplasty as a means to correct conductive hearing loss due to ossicular dysfunction. Ossiculoplasty hearing outcomes tend to be stable over the long-term, while prosthesis extrusion appears uncommon. Among ear risk factors that impact hearing outcomes, multiple revision status appears to be most impactful, while the presence of a canal wall down mastoidectomy cavity, tympanic membrane lateralization/blunting, severe infection status, pediatric age grouping, absent malleus, and absent stapes superstructure also appear to independently impact outcomes. By statistically weighting these risk factors into a novel EER scoring system, surgeons are able to risk stratify ossiculoplasty

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hearing outcomes and scoring ossiculoplasty cases by EER risk may have utility in the field of otology as a means to frame future ossiculoplasty outcome reporting and facilitate objective analysis of new materials and techniques.

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