# The Relationship Between Individual Ossicular Status and Conductive Hearing Loss in Cholesteatoma

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**Objective:** To investigate and analyze the relationship between individual ossicular erosion and air-bone gap (ABG) among patients with cholesteatoma.

Study Design: Retrospective case review.

Setting: Tertiary referral center.

**Subjects and Methods:** Data from all patients undergoing an initial surgery for cholesteatoma were retrospectively reviewed to evaluate the relationships between preoperative pure tone audiometry data, intraoperative assessment of individual ossicular destruction, and clinical characterization of cholesteatoma. For each patient, the cholesteatoma was categorized as primary acquired, secondary acquired, congenital, or unable to discern. Ossicular destruction was graded, and ABG was calculated. For each ossicle, the relationship between degree of cholesteatoma involvement and ossicular erosion and the ABG was analyzed using univariate and multivariate linear regression.

**Results:** A total of 158 primary cholesteatoma surgeries were performed by the senior author between 1992 and 2009 that met

Patients with cholesteatoma often report hearing loss as one of their first symptoms. Hearing loss in these patients is thought to occur mainly as a result of destruction of the ossicles by cholesteatoma and the subsequent interruption of the ossicular chain's continuity. Numerous theories that attempt to describe the mechanism of ossicular erosion in the presence of cholesteatoma exist. These include enzymatic resorption due to products of cholesteatoma growth and direct pressure necrosis of ossicles by an impinging mass of cholesteatoma (1). Hearing loss in cholesteatoma may also be attributable to other factors such as loss of the pars tensa surface area and tympanosclerosis.

Although it would seem reasonable that progressive erosion of the ossicles by cholesteatoma and the discontinuity of the ossicular chain would cause a concordant increasing and progressive conductive hearing loss, this

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our inclusion criteria. The status of each ossicle was significantly associated with the ABG in a graded and independent manner; this association was most significant for the incus. Cholesteatoma abutting an intact ossicle did not significantly affect the ABG. Clinical categorization of cholesteatoma was not significantly associated with the ABG.

**Conclusion:** Previous assessments of ossicular destruction have provided limited information about the relationship between ossicular destruction and ABG in cholesteatoma patients. Through the use of a new and detailed grading scale, this study reveals that the erosion of each ossicle contributes in a graded and independent manner to the increase in ABG, with the status of the incus having the most statistically significant association with ABG. **Key Words:** Cholesteatoma—Conductive hearing loss—Ossicular erosion.

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remains a matter of debate. In fact, previous studies have found that, in cholesteatoma, the air-bone gap (ABG) is not a good predictor of ossicular chain discontinuity (2,3). These studies are limited by a simple classification of ossicular status: continuous or discontinuous. The main purpose of this study was to explore and analyze, in depth, the relationship between individual ossicle status and a conductive hearing loss that occurs in patients with cholesteatoma, using a more detailed grading system for the ossicular chain. To better achieve this, rather than the binary rating of the ossicular chain as continuous versus discontinuous used previously, a 4-step scale for each ossicle is proposed. This study is a continuation of a previously published work (4).

# **MATERIALS AND METHODS**

#### Patients

Records of all patients undergoing surgery for cholesteatoma by the senior author (S.H.S.) at Weill Cornell Medical Center from 1992 to 2009 were entered into a database that included epidemiological, clinical, treatment, and outcome data. A retrospective review was performed, which included all patients in this database, to evaluate the status of their ossicles, their preoperative pure-tone audiometry data, and the clinical categorization of their cholesteatoma—primary acquired, secondary acquired, or congenital. Patients were excluded from this study if they had a history of previous ear surgery, previous radiation treatment to the head and neck, trauma to their ear, or complete, total hearing loss. Nine patients were excluded from this study because of incomplete ossicle status data or incomplete preoperative hearing data. Institutional review board approval was obtained from the Weill Cornell Medical College Institutional Review Board.

#### **Preoperative and Intraoperative Findings**

Preoperative audiometric data were recorded following the Guidelines of the Committee on Hearing and Equilibrium (5). The pure-tone average and ABG average were calculated using frequencies 0.5, 1, 2, and 3 kHz. For some patients, hearing at 3 kHz was not recorded. In those cases, the recommendations by Monsell (6), which were implemented in previous studies, were followed, and the threshold at 3 kHz was estimated as the mean of the thresholds at 2 and 4 kHz (7–9).

For each patient, the status of each ossicle was evaluated and described intraoperatively. A unique, comprehensive scaled rating system was developed to quantify the level of erosion for each ossicle. With this rating, the relationship between ossicular destruction and conductive hearing loss can be explored at a greater level of detail than is possible using the binary classification of the ossicular chain as continuous or discontinuous. Ratings were assigned to each ossicle as follows: 1 indicates completely normal; 2, cholesteatoma abuts the ossicle but the ossicle is still intact; 3, the ossicle is partially eroded by cholesteatoma; and 4, the ossicle is completely absent (for the malleus and incus) or if the superstructure is eroded (for the stapes). Erosion of the footplate by cholesteatoma is rare, and this did not occur in our sample. Each patient received a 3-digit combination rating, in the order of malleus-incus-stapes, to create a complete, individual picture of ossicular erosion.

#### **Statistical Analysis**

The primary goal of this study was to delineate the association between the level of destruction of the 3 ossicles and the ABG. To do so, univariate regression analyses were performed using a general linear model. The independent variable was the categorical 1-to-4 rating of the status of each ossicle. The primary dependent variable was the average ABG. Secondary dependent variables were the ABG at the frequencies 250 Hz, 500 Hz, 1 kHz, 2 kHz, 3 kHz, and 4 kHz. The estimated regression parameters  $\pm$  SEs and *p* values, with *p* < 0.05 defined as significant, are reported. All analyses were performed in SAS 9.2 (SAS Institute, Cary, NC, USA) and in concert with a biostatistician.

Following the above univariate analysis, a multivariate general linear model was applied to determine whether each ossicle's destruction was an independent factor in the average ABG or, alternatively, whether there were interactions (e.g., synergistic effects). To increase the power of the multivariate analysis, adjacent categories were grouped together on the rating scale for each ossicle if the above univariate analysis showed that they were not significantly different. The grouping of data that has been shown not to be significantly different is a standard statistical method that improves the power of further analysis. The Akaike information criterion and p values were used to select a final model for multivariate analysis (10). As secondary anal-

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yses, the final multivariate model from the averaged ABG was applied to the ABG at each of the six frequencies individually.

The influence of the clinical type of cholesteatoma on the ABG was also investigated by univariate linear regression analysis and then by multivariate analysis. A separate congenital cholesteatoma analysis was not included because of its small sample size, although these patients were included in the initial analysis of ossicular status and ABG in the combined group of all patients in the study.

### RESULTS

A total of 155 patients were identified, with a total 158 primary surgeries. Three patients underwent cholesteatoma surgery for both ears on separate dates. There were 88 male and 67 female patients, ranging in age from 3 to 81 years (mean, 40.9 yr); however, age data were not available for 20 patients. The mean of pure-tone air conduction was 41.3 dB with SD of 18.8 dB. The mean ABG was 25.1 dB (SD, 12.7). Seventy-seven were primary acquired cholesteatomas, 56 were secondary acquired, 8 were congenital, and 17 could not be determined from the intraoperative evaluation owing to the extensive destruction of the local anatomy. The mean ABG for primary acquired, secondary acquired, and congenital cholesteatomas were 23.1 dB (SD, 12.7), 27.6 dB (SD, 11.3), and 23.1 dB (SD, 21.1), respectively.

The most common 3-digit combination rating, in the order of malleus-incus-stapes, was 232. This individual pattern of erosion, which represents cholesteatoma abutting an intact malleus, partial erosion of the incus, and cholesteatoma abutting an intact stapes, had an average ABG of 27.3 dB (SD, 9.7). The most common erosion patterns, in order of progressive cholesteatoma involvement and ossicular erosion, are shown in Figure 1. In general, the graph illustrates 1) an increase in ABG as the incus becomes partially eroded by cholesteatoma, 2) a minimal change in ABG for patients with an absent



**FIG. 1.** Preoperative average ABG (dB),  $\pm$ SD, for the most common patterns of ossicular erosion. This 3-digit combination rating is in the order of malleus-incus-stapes. Selection represents all groupings of  $n \ge 6$ .



FIG. 2. Preoperative average ABG (dB), ±SE, for ossicle ratings of 1 to 4.

incus as opposed to those with a partially eroded incus, 3) an increase in ABG in patients with a completely eroded stapes superstructure that occurs both in patients with a partially eroded incus and in patients with a completely eroded incus, and 4) a minimal change in ABG as cholesteatoma involves, but does not erode, more ossicles.

Of 155 patients, representing 158 ears undergoing primary surgeries, 41 ears had no ossicular erosion and completely intact ossicular chains; the remaining 117 ears had at least one ossicle with a rating of 3 or greater. Of 117 ears, 109 had significant erosion (at 1 or more ossicles) that caused ossicular discontinuity; only 8 ears had erosion of any ossicle (rating of 3) with an intact ossicular chain. In those 8 ears, mild erosion occurred primarily at the incus, with 1 patient also having mild erosion at the stapes in addition to the incus.

### **Univariate Analysis**

To begin to quantify these observations, each ossicle's effect was analyzed separately. Figure 2 illustrates the average ABG data for the malleus, the incus, and the stapes at each of the 4 ratings. For the malleus and the stapes, the greatest difference in average ABG occurred between a rating of 3 and a rating of 4. For the incus, the greatest difference in average ABG occurred between a rating of 2 and a rating of 3. In other words, for the malleus and stapes, the impact on ABG depends largely on whether there is complete versus partial erosion, whereas for the incus, the impact depends largely on whether there is any erosion at all.

Regression analysis was used to determine the extent of each ossicle's effect. For each ossicle, the degree of change in ABG was calculated by comparing the difference in ABG that occurred between a completely normal ossicle (rating of 1) and a completely eroded ossicle (rating of 4). Of the 3 ossicles, total erosion of the malleus (rating of 4) was found to have the greatest effect on average ABG, 19.25 dB, with SE of 5.88. However, for the transition between a completely intact with cholesteatoma abutting (rating of 2) and a partially eroded ossicle (rating of 3), the incus showed the greatest effect, 12.20 dB (SE, 2.24) (Table 1).

In addition, regression analysis was used to determine the significance of the difference in impact of each level of the rating scale for each ossicle. Results showed that cholesteatoma abutting any intact ossicle (rating of 2) did not significantly alter average ABG compared to a normal ossicle (rating of 1) (p = 0.79 for incus, p = 0.79 for malleus, p = 0.85 for stapes). Other findings depended on the ossicle.

For the incus, complete erosion (rating of 4) did not have a significantly different influence on ABG from partial erosion (rating of 3). Although the difference in average ABG was found to be significant for a rating of 3 versus a rating of 2 ( $p \le 0.0001$ ), an incus rating of 4 showed no significant difference in effect on ABG from an incus with a rating of 3 (p = 0.24).

However, the presence and degree of erosion of the malleus and of the stapes demonstrated a different relationship on ABG than did the incus. No statistically significant difference in average ABG for a rating of 3 versus a rating of 2 (p = 0.07 for the malleus and p = 0.6 for the stapes) was found. In contrast to the incus, a significant difference was found in effect on average ABG between a rating of 4 and a rating of 3 (p = 0.01 for malleus and p = 0.03 for stapes).

In sum, for the malleus and the stapes, partial erosion caused no significant increase in ABG from that of an intact ossicle with cholesteatoma abutting, but a significant increase in ABG did occur when the ossicle was completely eroded as opposed to partially eroded, with complete erosion of the stapes superstructure.

TABLE 1. Results of univariate linear regression analysis for sequential ratings

Rating	Malleus				Incus		Stapes		
	Estimates	SE	р	Estimates	SE	р	Estimates	SE	р
2 versus 1	-0.88	3.34	0.79	-1.24	4.67	0.79	0.43	2.31	0.85
3 versus 2	5.49	3.01	0.07	12.2	2.24	< 0.0001 <sup>a</sup>	2.18	4.11	0.6
4 versus 3	14.64	5.7	$0.01^{a}$	2.75	2.32	0.24	8.9	4.17	$0.03^{a}$
4 versus 1	19.25	5.88	0.0013 <sup><i>a</i></sup>	13.71	4.71	0.0041 <sup>a</sup>	11.5	2.42	< 0.0001 <sup>a</sup>

 $^{a}p < 0.05.$ 

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		Malleus		Incus			Stapes		
Rating	Estimates	SE	р	Estimates	SE	р	Estimates	SE	р
(3+4) versus $(1+2)$		_	_	12.87	1.99	< 0.0001 <sup>a</sup>	_		_
3  versus  (1+2)	5.39	2.98	0.0723				2.4	3.91	0.54
4 versus $(1 + 2)$	20.03	5.07	$0.0001^{a}$				11.3	2.16	$< 0.0001^{a}$
Overall p			< 0.0001 <sup>a</sup>			$0.0002^{a}$			< 0.0001 <sup>a</sup>

**TABLE 2.** Results of univariate linear regression analysis with combined ratings

 $^{a}p < 0.05.$ 

To improve the power of further univariate and multivariate analyses, adjacent ratings that showed no significant difference were then combined. Ratings of 1 and 2 were combined for all three ossicles and ratings of 3 and 4 were combined for the incus. Although the ratings of 2 and 3 were not significantly different for malleus and stapes, they were kept separate as they represent 2 distinct ossicular states, intact versus eroded.

The univariate analysis was then performed using the newly combined ossicle ratings: (1 + 2) and (3 + 4) for the incus and (1 + 2), 3, and 4 for the malleus and the stapes. The results showed that the separate overall status of each individual ossicle had a significant influence on the average ABG (Table 2). The overall effect for the incus, the malleus and the stapes were less than 0.0001, 0.0002, and less than 0.0001.

A separate univariate linear regression analysis was performed for the clinical categorization of cholesteatoma. The results showed that the type of cholesteatoma, primary acquired or secondary acquired, did not have a statistically significant effect on average ABG (p = 0.23). Although not significant in univariate analysis, the type of cholesteatoma was included in model testing for multivariate analysis, specifically to investigate its effects on the secondary dependent variables, the separate frequencies.

### **Multivariate Analysis**

To isolate the independent effects of each ossicle, a multivariate analysis was performed. A number of different models were tested for use in the multivariate lin-

**TABLE 3.** Results of multivariate linear regression analysis with combined ratings

	8								
	Malleus								
	3 versu	s (1 +	2)	4 vers	Overall effect				
ABG	Estimates	SE	р	Estimates	SE	р	р		
Average	0.777	2.73	0.78	12.47	4.67	0.01	0.0307		
250 Hz	0.55	4.06	0.89	12.04	6.94	0.08	0.224		
500 Hz	1.92	3.75	0.61	13.81	6.42	0.03 <sup><i>a</i></sup>	0.0995		
1 kHz	0.64	3.14	0.84	17.57	5.37	0.0013 <sup>a</sup>	0.0056 <sup>a</sup>		
2 kHz	2.17	3.14	0.49	10.26	5.38	0.06	0.1508		
3 kHz	-1.64	3.33	0.62	8.24	5.7	0.15	0.2795		
4 kHz	0.12	3.53	0.97	13.97	6.04	$0.02^{a}$	0.07		

Average ABG calculated with frequencies of 500 Hz, 1 kHz, 2 kHz, and 3 kHz.  ${}^{a}p < 0.05$ .

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ear regression analysis, some of which included possible interaction terms between the ossicles. Among all the possible interaction terms, only one was statistically significant, an interaction between the stapes and the incus. However, the level of significance was marginal, and the improvement in model was minimal. Therefore, the focus of further analysis was on a model that included terms for the status of each ossicle, but no additional terms for their interactions.

A summary of the results of multivariate analysis is shown in Tables 3, 4, and 5. The malleus, the incus and the stapes were all significantly associated with average ABG. The incus had by far the most significant association with average ABG ( $p \le 0.0001$ ), and patients with ratings of 3 and 4 had a 10.3 dB (SE, 2.02) greater ABG than patients with ratings of 1 and 2 (Fig. 3). The stapes had the next most significant association (p = 0.008), whereas the malleus had the least significant association with average ABG (p = 0.037). Complete erosion of the malleus had a greater effect on average ABG, 12.47 dB (SE, 4.64), than did the stapes, 6.48 dB (SE, 2.14).

Analysis of the secondary variables showed that the incus also had the most significant and consistent association with ABG across all the different frequencies, whereas the malleus and the stapes varied in the significance of their association among different frequencies. The malleus had the least significant association with ABG across all frequencies. All 3 ossicles, however, were significantly associated with ABG at 1 k Hz. The clinical type of cholesteatoma, primary or secondary acquired, was also tested and was found to have a marginally significant

**TABLE 4.** Results of multivariate linear regression analysis with combined ratings

	Incus (3 + 4) versus (1 + 2)						
ABG	Estimates	SE	р				
Average	10.3	2.02	< 0.0001				
250 Hz	12.7	3.05	$< 0.0001^{a}$				
500 Hz	9.87	2.77	$0.0005^{a}$				
1 kHz	11.33	2.32	$< 0.0001^{a}$				
2 kHz	9.85	2.32	< 0.0001 <sup>a</sup>				
3 kHz	10.15	2.46	< 0.0001 <sup>a</sup>				
4 kHz	11.45	2.62	< 0.0001 <sup>a</sup>				

Average ABG calculated with frequencies 500 Hz, 1 kHz, 2 kHz, and 3 kHz.

 $^{a}p < 0.05.$ 

**TABLE 5.** Results of multivariate linear regression analysis

 with combined ratings

	Stapes							
	3 versus (1 + 2)			4 vers	Overall effect			
ABG	Estimates	SE	р	Estimates	SE	р	р	
Average	-0.63	3.61	0.86	6.48	2.14	0.003	0.0088	
250 Hz	2.7	5.35	0.62	8.79	3.28	$0.0081^{a}$	0.0296 <sup>a</sup>	
500 Hz	-1.24	4.96	0.8	6.21	2.94	$0.04^{a}$	0.0892	
1 kHz	-0.41	4.15	0.92	7.62	2.46	$0.0024^{a}$	$0.0077^{a}$	
2 kHz	-2.57	4.16	0.54	4.94	2.47	0.05	0.0823	
3 kHz	1.71	4.4	0.7	7.15	2.61	$0.007^{a}$	0.0256 <sup>a</sup>	
4 kHz	1.64	4.67	0.73	7.86	2.78	0.005 <sup>a</sup>	0.0198 <sup><i>a</i></sup>	

Average ABG calculated with frequencies 500 Hz, 1 kHz, 2 kHz, and 3 kHz.

 $^{a}p < 0.05.$ 

effect on ABG only at 250 Hz and no significant effect at other frequencies.

# DISCUSSION

Physiological and anatomic studies of middle ear mechanisms have led to a degree of understanding of the mechanical and acoustic function of the middle ear structures. Simple models of middle ear function have been used to describe a conductive hearing loss associated with middle ear pathology (11). The investigations of different disease processes on middle ear function have relied on perturbations of models of normal ossicular coupling. The conductive hearing loss associated with the presence of cholesteatoma has been attributed, in part, to the erosion of the ossicles and disruption of the ossicular chain as well as on the presence of the cholesteatoma matrix within the middle ear. Classification systems of the ossicular chain that are based on models of normal ear function can provide only limited information about the relationship between cholesteatoma and conductive hearing loss.

Few clinical studies have carefully examined the relationship between ossicular erosion by cholesteatoma and conductive hearing loss. One study by Jeng et al. (2) in 2001 found that, in patients with cholesteatoma, preoperative ABG was not significantly correlated with ossicular discontinuity. In 2007, Carillo et al. (3) expanded on Jeng's work by exploring the association of ossicular discontinuity with ABG cutoff levels across different frequencies, and although the study found specific ABG cutoff values were associated with ossicular discontinuity in patients with chronic otitis media, no such association was found in patients with cholesteatoma. In both studies, however, the status of the ossicular chain was evaluated and classified only as either continuous or discontinuous, with each study using slightly different criteria for what was considered discontinuous. Although Jeng and Carrillo's aim was specifically to determine whether preoperative findings, such as ABG, ear discharge, mastoid pneumatization, and other parameters, were predictive of ossicular discontinuity, most studies that include cholesteatoma patients evaluate the status of the ossicular chain and the preoperative ABG for the purpose of describing or predicting the success of postoperative hearing results. These studies typically describe the preoperative status of the ossicles using standard classifications, such as the Austin-Kartush groups, that were created to facilitate the analysis of ossiculoplasty data (7,11-13). However, these classifications have limited power to adequately describe the pathological relationship of the degree of ossicular erosion and the resultant conductive hearing loss. The rating system used in this study was specifically developed to achieve a more in-depth examination of the pathophysiology of a conductive hearing loss caused by cholesteatoma growth and the frequent erosion of at least a portion of the ossicular chain. These data show that this refinement demonstrates a close relationship between hearing loss and ossicular status, in which destruction of each ossicle contributes, in a graded fashion, to clinical hearing loss.

It should be noted that an ABG can often be measured in patients with cholesteatoma but without any ossicular erosion. The present study has examples of such cases. One mechanism by which cholesteatoma could possibly cause an ABG in these patients is by limiting the vibratory capacity of an intact ossicle by its direct impingement by cholesteatoma. As cholesteatoma directly abuts an intact ossicle, the ossicle's ability to freely vibrate and, therefore, to transmit the force produced by the tympanic membrane should be affected, and an increase in ABG is expected. However, this study found that, overall, there is no significant change in ABG when cholesteatoma abutted any intact ossicle. In the case of patients with all ossicles intact, cholesteatoma may decrease the sound transmission that occurs by ossicular coupling through other mechanisms, such as by decreasing the aeration of the middle ear and



FIG. 3. The estimated marginal means of preoperative average ABG (dB), ±SE, for the combined ratings.

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the vibratory capacity of the tympanic membrane. Perforation or absence of the tympanic membrane may also contribute to a conductive hearing loss in patients with an intact ossicular chain. This study found that the effect of a cholesteatoma on ossicular coupling does not, however, seem to occur from the direct contact of the cholesteatoma with an intact ossicle. Only with some specific degree of ossicular erosion was there a statistically significant effect on the ABG.

This study also explored the frequency-specific relationship of ossicular status to ABG in cholesteatoma patients. In normal ears, the gain in hearing that occurs owing to ossicular coupling has been shown to be frequency dependent. Maximal gain has been shown to occur at 1 k Hz (14). The inverse is also expected, that is, the decibel increase in ABG as an ossicle is eroded should vary depending on the frequency. However, this study found that, in cholesteatoma, loss of hearing due to progressive destruction of the ossicles is not frequency specific. The amount of change in decibel that occurred with erosion of an ossicle was the same across all the frequencies (within SE). Other studies have qualitatively described the incus as the most frequently affected ossicle in patients with cholesteatoma (15,16). Previously published data that used the same 1 to 4 rating system used in this study for individual ossicles quantitatively demonstrated the incus as the most commonly eroded ossicle (4). The present study expands on those findings and reveals that the status of the incus is has the most statistically significant association with the average ABG and the ABG across all the tested frequencies. Furthermore, unlike the malleus and the stapes, partial erosion of the incus was sufficient to cause a significant change in ABG. The degree of erosion was not significant however. No significant change in ABG occurred when the incus was partially as compared to completely eroded.

Beyond the effects of the status of the individual ossicles, the rating system used also allowed for the exploration of the relationship between different clinical categories of cholesteatoma and a conductive hearing loss. Previously published data that used the same 1 to 4 rating system used in the present study found that patterns and severity of individual ossicular erosion varied for primary and secondary acquired cholesteatomas (4). A study by Stankovic (13) in 2008 found a significant difference in the preoperative ABG in tensa cholesteatomas compared with attic cholesteatomas. Although not entirely clear, tensa may be thought of as secondary acquired, whereas attic may be thought of as primary acquired. Yet, despite the differences in ossicular erosion between the 2 classifications, the present study found no significant difference in ABG exist between primary and secondary acquired cholesteatomas.

This study had a specific focus on exploring the relationship between individual ossicular destruction and the ABG in patients with cholesteatoma through the use of a new, detailed rating system. However, other factors, including the pars tensa surface area and ossicular fixation, can affect the ABG observed in patients with cholesteatoma. These factors were not directly measured in this study, which is a limitation of this work.

Understanding the anatomy and physiology of the ossicular chain in both health and disease states will only improve our ability to best recreate its function as we move forward.

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