Hearing outcomes in ossiculoplasty: comparison between materials using the Ear Environment Risk Score

Original Article

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Abstract

Introduction: Chronic otitis media frequently involves destruction of the ossicular chain, resulting in disruption of sound conduction between the tympanic membrane and the oval window. Ossiculoplasty aims to restore sound transmission between these two structures.
The assessment of hearing outcomes after ossiculoplasty is challenging due to the heterogeneity of the middle ear environment. The Ear Environment Risk (EER) score was developed to stratify this risk and allow a more objective comparison of surgical outcomes.
Objectives: The aim of this study was to evaluate the impact of reconstruction materials (autologous vs titanium) on functional success using an EER-adjusted approach.
Methods: A retrospective cohort study was conducted including patients who underwent ossiculoplasty between 2014 and 2024.
The primary outcome was late functional success (≥6 months after surgery) based on the EER index. Comparisons between reconstruction materials were performed using the chi-square (χ^2) test or Fisher's exact test, as appropriate. Multivariable logistic regression was performed to assess the independent association between reconstruction material and outcome, adjusting for ossiculoplasty type (PORP vs TORP) and canal wall down mastoidectomy. A secondary sensitivity model additionally adjusted for the presence of cholesteatoma.
Secondary analyses evaluated early (<6 months) versus late (≥6 months) outcomes and the stability of results over time using transition analysis.
Results: A total of 120 ears were included, of which 102 (85.0%) had a late postoperative audiogram (≥6 months).
EER-based functional success was achieved in 65.8% of cases, with no significant difference between autologous reconstruction (61.7%) and titanium reconstruction (70.0%; p=0.413). These findings were consistent across subgroup analyses.
In the multivariable analysis, reconstruction material was not independently associated with EER-based functional success (adjusted OR

1.44; 95% CI 0.54–3.81). These results remained unchanged after adjustment for ossiculoplasty type (PORP or TORP) and the presence of a radical mastoidectomy cavity. Additional adjustment for the presence of cholesteatoma did not materially alter the findings.
EER-based early success rates (at T1) also did not differ significantly between materials. Transition analysis in the 95 ears with complete follow-up showed that 61.5% maintained functional success from the early to the late postoperative period. The overall distribution of functional outcome transitions did not differ significantly between materials (p=0.234).
Conclusions: Evaluation of ossiculoplasty using an EER-based risk-adjusted model demonstrated comparable hearing outcomes between autologous materials and titanium.
Keywords: Ossiculoplasty; Chronic otitis media

Introduction

The goal of ossiculoplasty is the durable restoration of the sound-conduction mechanisms of the middle ear.[1] Despite several advances over time, this procedure continues to yield variable functional outcomes.[2] In an effort to optimize these outcomes, otologic surgeons must frequently choose among the surgical techniques and types of prostheses available to them. Faced with these choices, surgeons need a robust body of literature enabling comparisons that are as realistic and reliable as possible. In addition to these technical factors, it is now known that the functional success of ossiculoplasty is strongly determined by the middle ear environment.[3] Therefore, any comparison of ossiculoplasty outcomes must be adjusted for middle ear environmental factors to assess the true impact of a given intervention on these outcomes.[4] To meet this need, the Ear Environment Risk (EER) score was developed as a middle ear risk stratification tool based on prognostic factors independently associated with postoperative hearing outcomes and weighted according to their cumulative negative impact on ossiculoplasty success.[5] The EER permits ossiculoplasty outcomes to be interpreted within the range of values expected for each risk category, enabling fairer comparisons between different ossicular reconstruction strategies. In this context, the present study aimed to compare the functional outcomes of ossiculoplasty conducted with autologous materials vs titanium prostheses using an EER-based risk-adjusted approach.

Materials and methods

We conducted a retrospective cohort study of patients with chronic otitis media who underwent ossiculoplasty in our department between January 2014 and December 2024.
The procedures were conducted under general anesthesia with orotracheal intubation, using a Carl Zeiss OPMI Sensera S7 operating microscope, by multiple surgeons experienced in otologic surgery. Patients undergoing any type of ossiculoplasty were included, except those undergoing stapedotomy or stapedectomy. Patients without a preoperative audiogram or without at least one postoperative audiogram were excluded. Patients with a postoperative clinical follow-up of <1 year were also excluded. The operated ear served as the unit of analysis. The electronic medical records of each selected case were reviewed, and information was collected on several parameters of interest related to the surgery and the disease.
For each operated ear, we evaluated the preoperative audiogram closest to surgery, the first postoperative audiogram conducted within the first 6 months after surgery (T1), and/or the most recent postoperative audiogram performed after the first 6 months (T2). The mean air-bone gap (mABG) was calculated for each audiogram as the arithmetic mean of the air-bone gaps at 500, 1000, 2000, and 3000 Hz. When 3000-Hz thresholds were not recorded on the audiogram, they were estimated as the mean of the 2000-Hz and 4000-Hz thresholds. The speech reception threshold (SRT) and word recognition score (WRS) values from each speech audiogram were also recorded.
For each operated ear, the EER score was calculated as originally described (Table 1), and ears were subsequently categorized according to the predefined risk groups (0 = favorable, 1–4 = low risk, 5–8 = intermediate risk, and 9–16 = high risk) (Table 2).[5]

Table 1
Ear Environment Risk Score

Fator de risco		Points
Revision (previous surgery)	No Yes, 1st revision Yes, multiple revisions	0 1 5
Canal wall down mastoidectomy cavity	Yes No	2 0
Age	Pediatric (<18 years) Adult	1 0
Malleus	Present Absent or damaged	0 2
Stapes superstructure	Present Absent or damaged	0 1
Otorrhea (Bellucci classification)	Dry ear or occasional otorrhea Otorrhea >50% of the time or otorrhea with cleft palate	0 1
Tympanic membrane	Lateralized Nonlateralized	4 0

Table 2
Operational definition of a hearing outcome within the EER-expected range

EER risk group	EER range	Q3 of the postoperative mABG (dB)	Outcome within the EER-expected range
Favorable	0	20.0 dB	mABG ≤ 20 dB
Low risk	1–4	26.3 dB	mABG ≤ 26.3 dB
Intermediate risk	5–8	32.5 dB	mABG ≤ 32.5 dB
High risk	≥9	42.2 dB	mABG ≤ 42.2 dB

EER: Ear Environment Risk; mABG: mean air-bone gap.
Note: The thresholds shown were derived by the authors of this study from the Q3 values of the postoperative mABG reported by Gluth et al. for each EER risk group. This categorization is a study-specific operational definition for identifying hearing outcomes within the EER-expected range; it does not correspond to a formal definition of functional success proposed in the original article.

The primary finding was a late hearing outcome within the EER-expected range, assessed on the postoperative audiogram performed >6 months after surgery (T2). Because the EER contextualizes the postoperative mABG according to the baseline middle ear risk but does not formally propose a dichotomous definition of functional success or failure, we adopted an operational definition to classify outcomes as within or above the expected range for the corresponding risk group. A hearing outcome was considered within the EER-expected range when the late postoperative mABG was less than or equal to the upper quartile (Q3) reported in the original EER validation cohort for the corresponding risk group. Q3 was chosen because it represents a pragmatic upper bound for the expected outcomes in each risk category, so that only cases in the worst-outcome quartile of the corresponding distribution were identified as above the expected range (unfavorable). Q1 and the median (Q2) were not used because these thresholds would be too restrictive for this classification: Q1 would select only the quartile with the best outcomes, whereas the median would classify approximately half of the cases in the original cohort as outside the expected range, even though several of these outcomes would still fall within the expected distribution for the corresponding EER group. The primary analysis compared the proportion

of ears with a late hearing outcome within the EER-expected range between the different ossiculoplasty materials (autologous vs titanium). Ossiculoplasty cases using autologous material were grouped regardless of the specific material used (cortical bone, sculpted ossicle, or cartilage). Exploratory subgroup analyses were conducted according to the ossiculoplasty type (partial ossicular replacement prosthesis [PORP] vs total ossicular replacement prosthesis [TORP]). The χ^2 test or Fisher exact test was used in these analyses, as appropriate. Multivariable logistic regression was conducted to assess the independent association between the material used in ossiculoplasty and attainment of a late hearing outcome within the EER-expected range. The primary model was adjusted for the type of ossiculoplasty (PORP vs TORP) and for the presence of a canal wall down mastoidectomy cavity. A secondary sensitivity model included additional adjustment for cholesteatoma. Except for canal wall down mastoidectomy, the variables included in the EER were not entered into the regression models, to avoid collinearity. The mastoidectomy variable was retained in the model because it was considered a potential independent influence on the ossiculoplasty outcome. The type of graft used for tympanic membrane reconstruction was not included as a covariate in the sensitivity analysis because cartilage use was closely associated with the reconstruction material (it was used in all patients undergoing ossicular reconstruction with titanium prostheses), and its inclusion would have resulted in collinearity and model overfitting. As a sensitivity analysis, multiple linear regression was conducted using the late postoperative mABG (T2) as a continuous dependent variable to evaluate the association between reconstruction material and audiometric outcome independently of the dichotomous categorization based on the EER Q3. The model included the reconstruction material, total EER score, and type of ossiculoplasty (PORP vs TORP) as independent variables.

The other secondary analyses evaluated the early hearing outcomes (T1) and outcome stability over time using a transition analysis. Early and late outcomes were compared descriptively. The transition analysis was conducted in cases in which both postoperative audiograms were available. The transitions were categorized as "within the expected range" → "within the expected range," "within the expected range" → "worse than expected," "worse than expected" → "within the expected range," or "worse than expected" → "worse than expected," according to the EER-defined thresholds for each risk group. These analyses were performed using the χ^2 test or Fisher exact test, as appropriate.

Follow-up bias was evaluated by comparing the baseline EER distribution and several variables of interest between operated ears with and without a late audiogram using the χ^2 test or Fisher's exact test.

A statistical analysis was conducted using IBM SPSS Statistics software (version 29.0.1.1). A P-value < .05 was considered statistically significant.

Results

Initially, 171 cases were selected. After applying the exclusion criteria, the final sample comprised 120 operated ears (corresponding to 114 patients), equally distributed between the autologous-material and titanium-prosthesis ossicular reconstruction groups (hereafter, the autologous group and titanium group; 60 each). The characteristics of the overall cohort and of each study group are exhibited in Table 3. Both groups were comparable in terms of age, sex distribution, number of pediatric cases, and availability of early and late postoperative audiograms. The proportions of PORP and TORP ossiculoplasty were similar between the two groups, as was the median postoperative follow-up period.

There were significant differences in the distribution of EER components between the two groups. A canal wall down mastoidectomy cavity (created previously or during the same procedure) was more frequent in the

Table 3
Characterization of the study cohort

	Cohort (n = 120)	Autologous materials (n = 60)	Titanium prostheses (n = 60)	P value
A. A. Demographic characteristics and follow-up				
Age, years, median (IQR)	51 (25,8)	52 (25)	48.5 (27)	0.581
Male sex, n (%) Female sex, n (%)	49 (40.8) 71 (59.2)	28 (46.7) 32 (53.3)	21 (35.0) 39 (65.0)	0.194
Early audiogram (T1) available, n (%)	114 (95.0)	56 (93.3)	58 (96.7)	0.679
Late audiogram (T2) available, n (%)	102 (85.0)	52 (86.7)	50 (83.3)	0.609
Follow-up duration, median (IQR)	58.5 (58.5	60.0 (58)	53.5 (63)	0.508
B. B. Type of ossiculoplasty				
PORP, n (%)	84 (70.0)	43 (71.7)	41 (68.3)	0.690
TORP, n (%)	36 (30.0)	17 (28.3)	19 (31.7)	0.690
C. EER components				
Revision surgery, n (%)	25 (20.8)	13 (21.7)	12 (20.0)	0.822
Canal wall down mastoidectomy, n (%)	9 (7.5)	9 (15.0)	0 (0.0)	**0.003**
Pediatric ears, n (%)	8 (6.7)	3 (5.0)	5 (8.3)	0.717
Absent or damaged malleus, n (%)	64 (53.3)	38 (63.3)	26 (43.3)	**0.028**
Absent or damaged stapes superstructure, n (%)	39 (32.5)	19 (31.7)	20 (33.3)	0.845
Frequent otorrhea (Bellucci III–IV), n (%)	37 (30.8)	23 (38.3)	14 (23.3)	0.075
Lateralized tympanic membrane, n (%)	2 (1.7)	1 (1.7)	1 (1.7)	0.879
D. Ear Environment Risk (EER)				
EER score, median (IQR) Favorable (EER = 0), n (%)	2 (7) 33 (27.5)	2 (7) 15 (25.0)	1 (7) 18 (30.0)	**0.041**
Low risk (EER 1–4), n (%) Intermediate risk (EER 5–8), n (%)	75 (62.5) 12 (10.0)	36 (60.0) 9 (15.0)	39 (65.0) 3 (5.0)	0.183
High risk (EER ≥9), n (%)	0 (0)	0 (0)	0 (0)	
E. Baseline audiometric results				
Preoperative mABG (dB), median (IQR)	28.7 (47.5)	27.5 (45.6)	31.8 (45.6)	0.055
Preoperative WRS (%), median (IQR)	100 (40)	100 (40)	100 (25)	0.526
Preoperative SRT (dB), median (IQR)	60 (85)	60 (85)	60 (80)	0.665

Sample characterization: overall and by ossiculoplasty material used (autologous vs heterologous). Data are presented as mean (standard deviation), median (interquartile range [IQR]), or frequency (percentage), as appropriate. Between-group comparisons were performed using the Mann–Whitney U test for continuous variables and χ^2 test or Fisher exact test for categorical variables. EER: Ear Environment Risk; mABG: mean air-bone gap; WRS: word recognition score; SRT: speech reception threshold.

autologous group (P = .003). The malleus status also differed between the two groups: the malleus was more frequently absent or damaged in the autologous group (P = .028).

The median EER was significantly higher in the autologous group (P = .041); however, the distribution across EER risk categories was similar between the two groups, with most cases classified as low risk. The preoperative audiometric results were comparable between the two groups, although there was a nonsignificant trend toward higher mABGs in the autologous group.

A comparison between ears with and without a late postoperative audiogram (T2) revealed no significant differences between the groups, indicating a low risk of follow-up bias.

At late follow-up (T2), 78 of the 102 ears with an available audiogram (76.5%) had a hearing outcome within the EER-expected range. There were no significant differences between the autologous and titanium groups (71.2% vs 82.2%, respectively; P = .197). When stratified by the type of ossiculoplasty, there were also no significant differences between materials in the proportions of hearing outcomes within

the EER-expected range (Table 4). The primary multivariable logistic regression model was adjusted for the ossiculoplasty type and presence of a canal wall down mastoidectomy cavity. No independent association was found between the type of material used in ossiculoplasty and late EER-adjusted functional outcome (P = .459). This finding was consistent in a secondary model adjusted for the presence of cholesteatoma (Table 5).

In the secondary analyses, when the late hearing outcome was evaluated as a continuous variable, the mABG in the overall cohort was 17.9 dB (IQR, 16.3); it was higher in the autologous group than in the titanium group [21.9 dB (IQR, 40.0) vs 14.4 dB (IQR, 25.0), respectively; P = .041]. To evaluate whether this difference persisted after adjustment for potential confounders, multiple linear regression was performed using the late mABG as a continuous dependent variable. In this model, reconstruction material was not independently associated with the late postoperative mABG (B = −2.87; P = .133; Table 6). The other secondary analyses were conducted only in cases in which both postoperative audiograms (T1 and T2) were available (96 ears).

In the overall sample, 71 ears (73.9%) had a functional outcome within the expected range at T1. As in the T2 analysis, there were no significant differences in the proportion of ears with an early hearing outcome within the EER-expected range between the autologous and titanium groups (66.7% and 81.3%, respectively; P = .104).

The results of the transition analysis are shown in Table 7. This analysis showed that, in most cases, the EER-based hearing-outcome classification remained stable over time, with restricted bidirectional transitions between T1 and T2. Although stability was numerically greater in the titanium group, the overall distribution of functional-outcome transitions did not differ significantly between the two groups (P = .234).

Table 4
Risk-adjusted late hearing outcomes (T2) according to the material used in ossiculoplasty

	Cohort (n = 102)	Autologous materials (n = 52)	Titanium prostheses (n = 50)	P value
Overall				
Outcome within the expected range, n (%)	78 (76.5)	37 (71.2)	41 (82.2)	0.197
Stratified by ossiculoplasty type				
– PORP Outcome within the expected range, n (%)	55 (79.7)	27 (75.0)	28 (84.8)	0.310
– TORP Outcome within the expected range, n (%)	23 (69.7)	10 (62.5)	13 (76.5)	0.465

Note: This analysis compared functional outcomes at late follow-up (T2); therefore, only operated ears with an available late audiogram (102 ears) were included.
Data are presented as frequency (percentage). The χ^2 test or Fisher's exact test was used for comparisons between the two groups.

Table 5
Multivariable logistic regression models (at T2)

Variable	Model 1			Model 2		
	Adjusted OR	95% CI	P-value	Adjusted OR	95% CI	P-value
Material (autologous vs titanium)	1.44	0.540-3.814	0.469	1.59	0.59-4.32	0.360
Type of ossiculoplasty (TORP vs PORP)	0.79	0.292-2.135	0.642	0.68	0.24-1.90	0.460
Canal wall down mastoidectomy (yes vs no)	0.30	0.063-1.375	0.120	0.21	0.04-1.08	0.061
Cholesteatoma (yes vs no) [Model 2 only]				2.29	0.79-6.66	0.129

Table 6
Multiple linear regression for late postoperative mABG

Variable	B	P-value
EER	2.01	.003
Type of ossiculoplasty (TORP vs PORP)	4.10	.104
Reconstruction material (Autologous vs titanium)	−2.87	.133

Table 7
Analysis of outcome transitions between T1 and T2

Transition category	Overall (n = 96)	Autologous materials (n = 48)	Titanium prostheses (n = 48)	P-value
Within the expected range → Within the expected range	59 (61.5)	25 (52.1)	34 (70.8)	0.234
Within the expected range → Worse than expected	12 (12.5)	7 (14.5)	5 (10.4)	
Worse than expected → Within the expected range	14 (14.6)	8 (16.7)	6 (12.5)	
Worse than expected → Worse than expected	11 (11.4)	8 (16.7)	3 (6.3)	

Discussion

Chronic otitis media frequently includes osteitis, necrosis, and bone resorption, which can affect different components of the ossicular chain and impair normal sound transmission between the tympanic membrane and oval window.[6, 7] Ossiculoplasty aims to restore the energy transmission between these structures by reconstructing, replacing, or bypassing the affected ossicle(s).[2] Since its initial description in the 1950s, ossiculoplasty has benefited from multiple innovations in surgical techniques and in the materials and designs of available prostheses.[2] While the wider range of resources available to the otologic surgeon can provide more tools for addressing the challenges of ossicular reconstruction, it can also make choosing among them difficult.

Several previously published studies comparing different materials and prosthesis designs overlooked a key determinant of the functional outcome of ossiculoplasty: the environment of the operated ear.[4] Indeed, middle ear conditions can be highly heterogeneous and can strongly influence the hearing outcomes of ossiculoplasty.[3] These outcomes must therefore be adjusted for the middle ear environment to enable more realistic and reliable comparisons between different types of prostheses and reconstruction strategies.[4] The EER was developed to meet this need. By stratifying operated ears according to independent weighted risk factors identified in a large multicenter cohort, the EER allows ossiculoplasty hearing outcomes—in this case, mABGs—to be interpreted within the range of values expected for each risk category.[5] Importantly, the EER was developed not as a dichotomous scale of surgical success or failure, but as a tool for prognostic stratification and contextualization of the hearing outcomes after ossiculoplasty. In the present study, the Q3 values reported in the original cohort were used to create an operational definition identifying hearing outcomes within the expected range for the corresponding EER risk group. This method made it possible to compare the outcomes across different ossicular reconstruction materials using thresholds based on the baseline middle ear risk, rather than applying a uniform absolute cutoff to groups with potentially different middle ear environments.

The autologous materials typically used in ossicular reconstruction are bone (cortical bone or sculpted ossicles) and cartilage. These materials have the advantages of being free of charge and widely available. In addition, their biocompatibility ensures low extrusion rates.[2] In our sample, we

grouped the different subtypes of autologous materials to avoid small subgroups, thereby preserving statistical power and the stability of the analytical models. As for heterologous materials, several synthetic options are available, such as hydroxyapatite, plastic, and titanium prostheses. These prostheses usually offer greater structural stability and durability.[8] Only titanium prostheses were included in the present study, reflecting the institution's clinical practice during the study period.

The type of material used for ossicular reconstruction was not independently associated with the attainment of a late hearing outcome within the EER-expected range. In the unadjusted analysis of late mABG as a continuous variable, the autologous group had a higher mABG than the titanium group. However, this association was no longer present in the multiple linear regression analysis after adjustment for EER score and ossiculoplasty type, reinforcing the importance of interpreting audiometric outcomes in light of the baseline middle ear risk. These results indicate that the difference observed in the unadjusted analysis may reflect, at least in part, the unequal distribution of prognostic factors between the groups, and not necessarily an independent effect of the material used. Although exploratory and limited by the sample size, subgroup analyses by ossiculoplasty type also showed no significant differences between materials.

Published comparisons of the functional outcomes of ossiculoplasty with autologous materials vs titanium prostheses have yielded conflicting results.[8-14] These inconsistencies largely reflect the marked methodological heterogeneity and lack of uniform adjustment for the middle ear environment in most studies, making it difficult to compare and interpret the true impact of different materials on ossiculoplasty hearing outcomes. In the present study, the EER allowed outcomes to be contextualized according to the baseline middle ear risk. This was particularly evident in the continuous analysis of late mABG: although the unadjusted comparison numerically favored titanium prostheses, the difference was no longer significant after adjustment for the EER and ossiculoplasty type. Some of the secondary analyses evaluated early functional outcomes and outcome transitions over time. During the first 6 postoperative months, there was also no significant association between hearing outcomes and type of material used in ossicular reconstruction. One of the main concerns in ossiculoplasty is the long-term durability of outcomes. One cited advantage of titanium prostheses is their greater strength and structural integrity compared with autologous materials, which can theoretically undergo resorption and atrophy over time.[2, 15] A transition analysis was conducted to assess the temporal stability of outcomes for each material type. This analysis showed that most ears classified as within the expected range at T1 retained this classification at T2. Numerically, the titanium group had a higher proportion of outcomes maintained within the expected range; however, transition patterns did not differ significantly between materials, indicating comparable stability over time.

This study has several limitations that should be acknowledged. First, its retrospective design carries an inherent risk of selection bias. In addition, the relatively small sample size limited the feasibility and power of some subgroup analyses. Another methodological limitation is that the categorization “outcome within the EER-expected range” is an operational definition adopted by the authors of the present investigation. Although this definition is based on the quartiles reported in the original EER validation cohort, the original article did not formally propose a dichotomous threshold to classify hearing outcomes. Additionally, dichotomizing a continuous variable such as the mABG can lead to loss of information and dependence on the selected threshold. To mitigate this limitation, a sensitivity analysis was performed using the late mABG as a continuous variable. A further limitation relates to the temporal heterogeneity of audiometric follow-up. Although late follow-up was defined as >6 months and the median postoperative follow-

up was 58.5 months, late audiograms were not conducted at the same standardized time point in all patients. In most cases, the late audiogram analyzed was the one closest to the last available clinical evaluation. Nevertheless, this variability may limit the direct comparison of long-term functional stability between the groups. Finally, this was a single-center study, which may limit the generalizability of the results.

Conflicts of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

Data Confidentiality

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

Protection of humans and animals

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the 2013 Helsinki Declaration of the World Medical Association.

Privacy policy, informed consent and Ethics Committee Authorization

The authors declare that they have written consent for the use of photographs of patients in this article.

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Availability of scientific data

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During the preparation of this work, the authors used the OpenEvidence artificial intelligence platform for the literature search. After using this tool/service, the authors reviewed and edited the content as necessary and take full responsibility for the content of the publication.

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