The Journal of International Advanced Otology

J Int Adv Otol 2022; 18(5): 415–419 • DOI: 10.5152/iao.2022.21360

Original Article

Functional Outcomes of Single-Stage Ossiculoplasty in Chronic Otitis Media With or Without Cholesteatoma*

Seongbin Park, Kang Hyeon Lim, Sung Jin Lim, Dong Heun Park, Yoon Chan Rah, June Choi

Department of Otorhinolaryngology-Head and Neck Surgery, Korea University College of Medicine, Ansan Hospital, Ansan, Republic of Korea

ORCID IDs of the authors: S.P. 0000-0002-1079-6351, K.H.L. 0000-0002-5064-2138, S.J.L. 0000-0002-5885-061X, D.H.P. 0000-0002-9671-7393, Y.C.R. 0000-0003-1559-5396, J.C. 0000-0002-6330-279X.

Cite this article as: Park S, Lim KH, Lim SJ, Park DH, Rah YC, Choi J. Functional outcomes of single-stage ossiculoplasty in chronic otitis media with or without cholesteatoma. *J Int Adv Otol.* 2022;18(5):415-419.

BACKGROUND: Two-stage ossiculoplasty has been widely used for hearing improvement in chronic otitis media with or without cholesteatoma. However, the outcomes of single-stage ossiculoplasty have not been fully clarified.The aim of this study is to determine whether the outcomes of single-stage ossiculoplasty are comparable with those of 2-stage ossiculoplasty in chronic otitis media with or without cholesteatoma.

METHODS: Medical records of 191 cases (187 patients) who underwent single-stage ossiculoplasty from January 2011 to May 2018 at our hospital were retrospectively reviewed.

RESULTS: Polycel and titanium were used in 56 and 135 cases, respectively. In chronic otitis media without cholesteatoma, the success rate of polycel and titanium partial ossicular replacement prosthesis was 80.7% and 81.6%, respectively. In chronic otitis media with cholesteatoma, the success rate of polycel and titanium partial ossicular replacement prosthesis was 63.6% and 64.6%, respectively, while that of polycel and titanium total ossicular replacement prosthesis was 45.9% and 47.8%, respectively.

CONCLUSION: These results suggest that single-stage ossiculoplasty is a suitable option for recovering postoperative hearing in chronic otitis media with or without cholesteatoma. Thus, if middle ear inflammation can be sufficiently treated in the first stage, single-stage ossiculoplasty is a suitable option for chronic otitis media with or without cholesteatoma.

KEYWORDS: Chronic otitis media, ossiculoplasty, single-stage, titanium, polycel

INTRODUCTION

Since the first ossiculoplasty was performed in the 1950s, there has been a great deal of practice to restore hearing function in patients with chronic otitis media (COM) with or without cholesteatoma.[1,2] Two-stage ossiculoplasty has been performed to remove the inflammatory tissue in the middle ear during the first stage, ossiculoplasty followed by the second stage after stabilization of the middle ear condition. Two-stage ossiculoplasty has been considered to be effective in improving the postoperative hearing outcome.[3,4]

On the other hand, single-stage ossiculoplasty means performing ossiculoplasty at the same time. In previous reports, 2-stage ossiculoplasty has shown better functional outcomes than single-stage ossiculoplasty.[5-8] However, patients who have decided on a 2-stage ossiculoplasty are inevitably required to undergo 2 surgeries, as well as to endure hearing loss until the second operation.

Various materials for ossiculoplasty have been used to obtain ideal postoperative hearing results.[1,2,9,10] Many researchers have considered the degree of sound propagation and long-lasting stability as important factors for using external materials.[1,2,9-13] Although titanium has been recently suggested as a suitable material for ossiculoplasty because of its superior biocompatibility,[2] previous studies have been controversial about significant differences between titanium and other materials including polycel, hydroxyapatite, autologous cartilage, etc.[2,8,12,14-17]

*Some data of this study were presented at the 25th Annual Congress of the Korean Society of Otorhinolaryngology- Head and Neck Surgery, October, 17, 2019, Yeosu, Republic of Korea.

Corresponding author: June Choi, e-mail: mednlaw@korea.ac.kr

Received: April 29, 2021 • **Accepted:** December 12, 2021 • **Available Online Date:** August 10, 2022

Available online at www.advancedotology.org

This study aimed to compare the postoperative hearing outcomes in patients with COM with or without cholesteatoma who had undergone single-stage ossiculoplasty using polycel or titanium. In addition, we analyzed the hearing outcomes according to the length of the material used for ossiculoplasty.

METHODS

Study Population and Surgical Procedures

We enrolled 191 cases (187 patients) who underwent single-stage ossiculoplasty for COM with or without cholesteatoma, performed by 1 surgeon, at our hospital from January 2008 to May 2018. Ethical committee approval was received from the Ethics Committee of Korea University Ansan Hospital (Approval no: IRB No. 2018AS0133).

All patients underwent complete removal of the inflammatory tissue and cholesteatoma in the middle ear at the initial surgery, and ossiculoplasty with polycel or titanium was performed to obtain prompt hearing recovery in the same surgical field simultaneously. Polycel was used from 2008 to 2011, and titanium was chiefly used from 2012.

Partial ossicular replacement prosthesis (PORP) and total ossicular replacement prosthesis (TORP) were planned based on the surgeon's judgment and condition of the ossicles, assessed according to the stapes superstructure in the surgical field. Partial ossicular replacement prosthesis was used if the incus was absent or eroded but the stapes were intact. Total ossicular replacement prosthesis was used if the stapes superstructure was eroded or absent. In all cases, the cartilage was interlaced between the prosthesis and the tympanic membrane. The prostheses were supported by a gel form to minimize tilt. The study was approved by the Institutional Review Board (IRB) of our hospital (IRB no. 2018AS0133).

Assessment of Functional Outcomes

The medical records of the patients were retrospectively reviewed to assess the postoperative hearing outcomes and extrusion rate according to the material type and length used for ossiculoplasty.

The average threshold for air conductive pure-tone audiometry (AC PTA) and bone conductive pure-tone audiometry (BC PTA) were recorded by averaging the hearing thresholds at the frequencies of 500, 1000, 2000, and 4000 Hz preoperatively and at 3, 6, and 12 months postoperatively. In addition, the air-bone gap (ABG), the difference between AC PTA and BC PTA, was evaluated. The last measured postoperative PTA (8.1 ± 3.3 months) finding was considered for each case.

MAIN POINTS

- Single-stage ossiculoplasty is a suitable surgery for recovering postoperative hearing in chronic otitis media with or without cholesteatoma.
- There was no significant correlation or weak correlation between the length of the material and functional outcomes.
- Although there is no significant difference between the use of polycel and titanium, the use of titanium may lead to better outcomes.

We used the modified Korean Society of Otorhinolaryngology-Head and Neck Surgery's standard guidelines for reporting the hearing outcomes after COM surgery.[18]

Postoperative hearing success was considered if any 1 criterion was satisfied—(1) postoperative AC PTA value ≤30 dB, (2) postoperative ABG ≤ 20 dB, or (3) difference between the preoperative and postoperative AC PTA ≥ 15 dB. In addition, we identified whether the material was extruded using endoscopy during follow-up.

Statistical Analysis

The Statistical Package for the Social Sciences version 21 (IBM SPSS Corp.; Armonk, NY, USA) was used to analyze the data. The Mann–Whitney test and independent *t*-test were used to compare the functional outcomes of each material type used for ossiculoplasty in COM with or without cholesteatoma. The Spearman's rank correlation was used for assessing the correlation between the length of the material and functional outcomes. A *P* value of <.05 was considered significant. In addition, Spearman's correlation coefficient (rho) of 0.10-0.39 was interpreted as a weak correlation.[19]

RESULTS

Clinical Characteristics of Single-Stage Ossiculoplasty Cases

Single-stage ossiculoplasty was performed in 191 cases (187 patients). The average patient age was 49.6 ± 1.3 years. There were 123 (64.4%) cases of COM with cholesteatoma and 68 (35.6%) cases of COM without cholesteatoma. The average preoperative AC PTA and ABG were 48.8 ± 19.4 and 28.1 ± 13.3 dB, respectively. Of the total cases, 134 (70.1%) cases underwent PORP and 57 (29.9%) cases underwent TORP. Polycel was used in 56 (29.3%) cases, and titanium was used in 135 (69.7%) cases (Table 1).

Table 1. Clinical Characteristics of Single-Stage Ossiculoplasty Cases

Clinical Factors	N = 191
Age (years)	49.6 ± 1.3
Sex (male:female)	71 (38%) : 116 (62%)
Side (right:left)	100 (52.3%) : 91 (47.7%)
Diagnosis (%)	
COM with cholesteatoma	123 (64.4)
COM without cholesteatoma	68 (35.6)
Preop ABG (dB)	28.1 ± 13.3
Preop AC PTA (dB)	48.8 ± 19.4
Ossiculoplasty type (%)	
PORP	134 (70.1)
TORP	57 (29.9)
Material type (%)	
Polycel	56 (29.3)
Titanium	135 (60.7)
Duration of follow-up	8.1 ± 3.3 months

COM, chronic otitis media; Preop, preoperative; ABG, air-bone gap; AC PTA, air conductive pure-tone audiometry; PORP, partial ossicular replacement prosthesis; TORP, total ossicular replacement prosthesis.

Table 2. Functional Outcomes According to the Material Type and Ossiculoplasty Type in COM With or Without Cholesteatoma

	Polycel		Titanium		*P* PORP (Polycel Versus Titanium)	*P* TORP (Polycel Versus Titanium)
	PORP	TORP	PORP	TORP		
COM with cholesteatoma (123, 64.4%)	22	7	48	46		
Postop ABG (dB)	18.5 ± 11.2	30.5 ± 9.6	19.5 ± 11.2	23.4 ± 11.1	.735	.120
Preop AC PTA - Postop AC PTA (dB)	8.4 ± 12.8	11.2 ± 14.5	2.9 ± 13.6	4.3 ± 14.8	.116	.207
Postop AC PTA (dB)	35.1 ±17.3	68.3 ± 14.7	36.7 ± 18.2	45.4 ± 18.1	.722	.004
COM without cholesteatoma (68, 35.6%)	26	1	38	3		
Postop ABG (dB)	21.5 ± 11.3	25	17.1 ± 9.8	25.6 ± 6.8	.081	
Preop AC PTA - Postop AC PTA (dB)	9.3 ± 17.5	5	10.2 ± 13.2	25.6 ± 9.2	.819	
Postop AC PTA (dB)	45.2 ± 15.7	50	42.3 ± 19.4	51.3 ± 5.8	.988	

COM, chronic otitis media; Postop, postoperative; ABG, air-bone gap; Preop, preoperative; AC PTA, air conductive pure-tone audiometry; PORP, partial ossicular replacement prosthesis; TORP, total ossicular replacement prosthesis.

Functional Hearing Outcomes According to the Material Type and Ossiculoplasty Type in Single-Stage Ossiculoplasty Cases

In single-stage ossiculoplasty cases, the functional outcomes based on the criteria for postoperative hearing success did not show differences based on the material type (polycel vs. titanium) and ossiculoplasty type (PORP vs. TORP) in COM with or without cholesteatoma. However, titanium showed significantly better postoperative AC PTA outcomes than polycel in COM with cholesteatoma (P = .004) (Table 2).

In COM with cholesteatoma, PORP showed a better success rate than TORP. The success rate of polycel (intact canal wall mastoidectomy (ICW) was performed in 14% of cases with cholesteatoma and open cavity mastoidectomy (OC) in 86%) and titanium (ICW: 23%, OC: 77%) was 63.6% and 64.6%, respectively, in PORP. Although there was little meaningful difference in the success rates of polycell and titanium, it was statistically significant in titanium PORP success rate. (P = .02). The success rate of polycel (ICW: 14%, OC: 86%) and titanium (ICW: 4%, OC: 96%) was 45.9% and 47.8%, respectively, in TORP. Likewise, although there was no marked difference in the success rates of polycell and titanium, it was statistically significant in titanium TORP success rate. (P = .007) (Figure 1A).

In COM without cholesteatoma treated with PORP, the success rate of polycel (ICM: 96%, OC: 4%) was 80.7%, while that of titanium (ICM: 84%, OC: 16%) was 81.6%. Although there was no noticeable difference in the success rates of polycell and titanium, it was statistically significant in titanium PORP success rate. (P = .01) (Figure 1B). However, TORP was rarely performed and was not analyzed in COM without cholesteatoma.

In addition, regardless of the type of material, PORP surgery was able to confirm statistically significant results that were higher than the success rate of TORP surgery.

Association Between the Functional Hearing Outcomes and the Length of the Material in Single-Stage Ossiculoplasty Cases

There was no significant correlation between the length of the material and functional outcomes for postoperative ABG (Spearman's rho = 0.029, P = .690). The correlation differences between the length of the material and functional outcomes including preoperative and postoperative AC PTA findings (Spearman's rho = 0.212, P = .003) and postoperative AC PTA findings (Spearman's rho = 0.206, P = .004) were significant but were weak (Figure 2).

Extrusion Rate According to the Material Type and Ossiculoplasty Type

The material used for ossiculoplasty was rarely found extruded during the follow-up period (8.1 ± 3.3 months). Of the 56 and 135 cases in which polycel and titanium were used, respectively, 1 case each showed extrusion (Table 3).

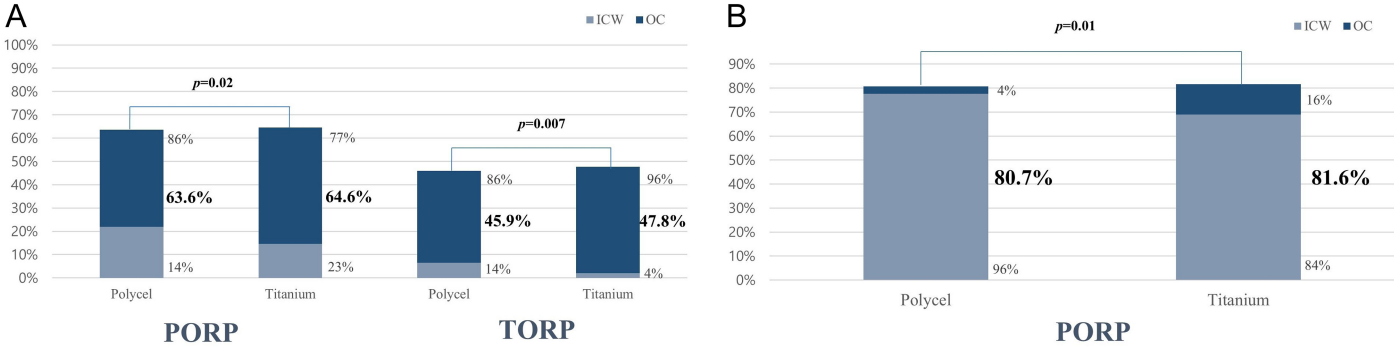

Figure 1. Success rate of functional outcomes according to material type and ossiculoplasty type in COM with cholesteatoma (A) and without cholesteatoma (B). COM, chronic otitis media; PORP, partial ossicular replacement prosthesis; TORP, total ossicular replacement prosthesis; ICW, intact canal wall; OC, open cavity.

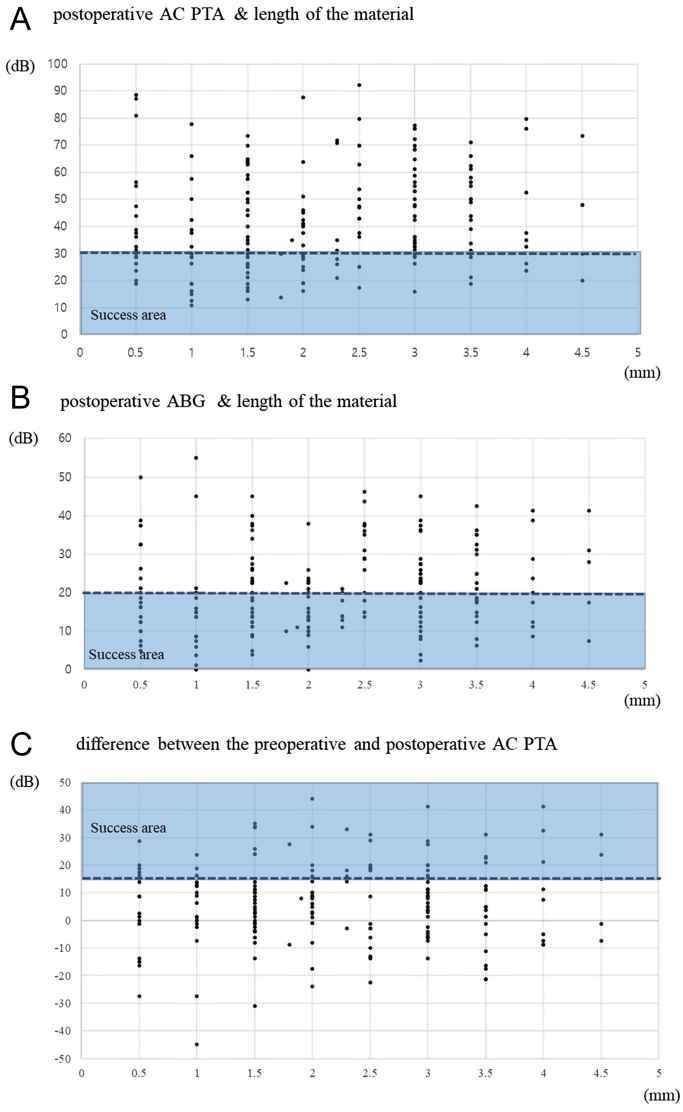

Figure 2. A-C. Association between the functional hearing outcomes and the length of the material in single-stage ossiculoplasty cases. There was no significant correlation or weak correlation between the length of the material and functional outcomes, including postoperative AC PTA findings (Spearman's rho = 0.206, *P* = .004), postoperative ABG (Spearman's rho = 0.029, *P* = .690), and the difference between the preoperative and postoperative AC PTA findings (Spearman's rho = 0.212, *P* = .003). AC PTA, air conductive puretone audiometry; ABG, air-bone gap.

DISCUSSION

The study results show that single-stage ossiculoplasty in COM with or without cholesteatoma is highly effective and that its functional hearing outcomes are comparable with those of 2-stage ossiculoplasty.

In a previous study, the success rate of single-stage and two-stage ossiculoplasty was 20% and 50%, respectively, when a postoperative ABG of <20 dB was considered a success.[5] In another study, when the postoperative ABG was <20 dB, the success rate of 2-stage ossiculoplasty with polycel and titanium TORP was 65% and 64.4%, respectively.[12] However, patients inevitably have to undergo 2 surgeries and have severe hearing loss until the second-stage ossiculoplasty. In addition, patients have to bear an increased socioeconomic burden. From a surgeon's perspective, performing single-stage ossiculoplasty is beneficial if it could achieve similar functional hearing outcomes to 2-stage ossiculoplasty. Moreover, if hearing improvement is not achieved after single-stage ossiculoplasty, a revision ossiculoplasty may be performed. Therefore, removal of the inflammatory tissue in the middle ear and ossiculoplasty simultaneously during the first stage have been performed for immediate postoperative hearing gain. In our study, the success rate of polycel and titanium PORP was 63.6% and 64.6%, respectively, in COM with cholesteatoma. The success rate of polycel and titanium TORP was 45.9% and 47.8%, respectively, in COM with cholesteatoma. The success rate of polycel and titanium PORP was 80.7% and 81.6%, respectively, in COM without cholesteatoma. The single-stage ossiculoplasty outcomes, especially ABG, reported in our study were similar to the 2-stage ossiculoplasty outcomes reported in previous studies.[6-8,19]

Although several materials have been used for ossiculoplasty in various ways, it is unclear which material is ideal. Since titanium was first used in 1993, it has been found that titanium is not significantly different from polycel and hydroxyapatite, which have been used before, and that it is biocompatible.[1,2,6,9-12,14,20] Our study results are consistent with those of earlier studies, which have shown that titanium is a suitable material for ossiculoplasty. Although there is no significant difference, the functional hearing outcome is better in ossiculoplasty with titanium than with other materials. In addition, long-term follow-up was required, and 2 cases of extrusion 1 each of polycel and titanium were identified in our single-stage ossiculoplasty (duration of follow-up: 8.1 ± 3.3 months), respectively, which were significantly lower than the extrusion rates previously reported.[6]

An adequate length of the material contributes considerably to the stability of the ossicles after surgery. We analyzed the correlation between the length of the material and any functional outcomes and found that there was no significant correlation between the length of the material and postoperative ABG (Spearman's rho = 0.029, *P* = .690). Although the length of the material and postoperative AC PTA were statistically correlated and the length of the material and the difference between the preoperative and postoperative AC PTA were correlated, the correlation was weak (Spearman's rho = 0.206, *P* = .004, and Spearman's rho = 0.212, *P* = .003, respectively). These findings might imply that a shorter material length may be sufficient

Table 3. Extrusion Rate in Single-Stage Ossiculoplasty Cases

	Extrusion of Polycel		Extrusion of Titanium	
Group	**PORP (48)**	**TORP (8)**	**PORP (86)**	**TORP (49)**
COM with cholesteatoma (123, 64.4%)	1	0	0	1
COM without cholesteatoma (68, 35.6%)	0	0	0	0

COM, chronic otitis media; PORP, partial ossicular replacement prosthesis; TORP, total ossicular replacement prosthesis.

for patients with mild hearing loss before ossiculoplasty (cases of mild ossicular damage), but a longer material length may be needed for patients with severe hearing loss before ossiculoplasty (cases of severe ossicular damage). In contrast to the findings of previously published reports, which indicate that PORP and TORP have similar outcomes,[1,2,6,9-12,14,20] the functional outcomes of PORP were significantly higher than that of TORP in our study. These results imply that TORP will be performed in severe conditions of the middle ear, such as erosion of the stapes superstructure.

The advantage of our study is that a single surgeon performed all ossiculoplasties at a single institution. In addition, the criteria for postoperative hearing success are modified according to standard guidelines of the Korean Society of Otorhinolaryngology-Head and Neck Surgery. Since this was a retrospective study and ossiculoplasty for restoring hearing is determined by the surgeon's judgment, the direct comparison between single-stage and two-stage ossiculoplasty is difficult to establish. The results may vary depending on the postoperative success criteria of ossiculoplasty. In addition, the follow-up period is relatively short (8.1 $\pm$ 3.3 months). These might limit the interpretation of our results.

However, we can confirm that the functional outcomes of single-stage ossiculoplasty are comparable with those of 2-stage ossiculoplasty. We suggest that if the surgeon sufficiently removes the inflammatory tissue and cholesteatoma in the middle ear during the first stage, single-stage ossiculoplasty can be a suitable option for immediate hearing gain.

CONCLUSION

Single-stage ossiculoplasty is a suitable surgery for recovering postoperative hearing in COM with or without cholesteatoma. Although there is no significant difference between the use of polycel and titanium, the use of titanium may lead to better outcomes. In addition, there is no significant correlation or weak correlation between the length of the material and functional outcomes. Further studies are needed to investigate the long-term follow-up outcomes of single-stage ossiculoplasty in COM with or without cholesteatoma.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of Korea University Ansan Hospital (Approval no: IRB No. 2018AS0133).

Informed Consent: N/A.

Peer-review: Externally peer-reviewed.

Author Contributions: Conception – S.B.P., K.H.L., J.C.; Design – S.B.P., K.H.L., J.C.; Supervision – Y.C.R., J.C.; Funding – J.C.; Materials – S.B.P., K.H.L., J.C.; Data collection and/or processing – S.B. P., K.H.L., S.J.L., D.H.P., and J.C; Analysis and/or interpretation – S.B.P., K.H.L., Y.C.R., and J.C.; Literature Review – S.B.P., K.H.L., S.J.L., D.H.P., and J.C.; Writing – S.B.P., K.H.L., J.C.; Critical review – S.B.P., K.H.L., J.C.

Declaration of Interests: The authors have no conflict of interest to declare.

Funding: This work was supported by the Korea University grants and the National Research Foundation of Korea (NRF) grant funded by the Korea government (MSIT) (No. 2020R1F1A1069424).

REFERENCES

1. Zeitler DM, Lalwani AK. Are postoperative hearing results better with titanium ossicular reconstruction prostheses? *Laryngoscope*. 2010;120(1):2-3. [CrossRef]
2. Zhang LC, Zhang TY, Dai PD, Luo JF. Titanium versus non-titanium prostheses in ossiculoplasty: a meta-analysis. *Acta Otolaryngol*. 2011;131(7):708-715. [CrossRef]
3. Shelton C, Sheehy JL. Tympanoplasty: review of 400 staged cases. *Laryngoscope*. 1990;100(7):679-681. [CrossRef]
4. Sheehy JL, Crabtree JA. Tympanoplasty: staging the operation. *Laryngoscope*. 1973;83(10):1594-1621. [CrossRef]
5. Lim JH, Park JM, Han JJ, Kim SI, Park SY, Park SN. Superiority of second stage ossiculoplasty. *Otol Neurotol*. 2018;39(10):1271-1276. [CrossRef]
6. Lahlou G, Sonji G, De Seta D, et al. Anatomical and functional results of ossiculoplasty using titanium prosthesis. *Acta Otorhinolaryngol Ital*. 2018;38(4):377-383. [CrossRef]
7. Şevik Eliçora S, Erdem D, Dinç AE, Damar M, Bişkin S. The effects of surgery type and different ossiculoplasty materials on the hearing results in cholesteatoma surgery. *Eur Arch Otorhinolaryngol*. 2017;274(2):773-780. [CrossRef]
8. Meulemans J, Wuyts FL, Forton GE. Middle ear reconstruction using the titanium Kurz Variac partial ossicular replacement prosthesis: functional results. *JAMA Otolaryngol Head Neck Surg*. 2013;139(10):1017-1025. [CrossRef]
9. Shah KD, Bradoo RA, Joshi AA, Sapkale DD. The efficiency of titanium middle ear prosthesis in ossicular chain reconstruction: our experience. *Indian J Otolaryngol Head Neck Surg*. 2013;65(4):298-301. [CrossRef]
10. Chavan SS, Jain PV, Vedi JN, Rai DK, Kadri H. Ossiculoplasty: a prospective study of 80 cases. *Iran J Otorhinolaryngol*. 2014;26(76):143-150.
11. Lee JI, Yoo SH, Lee CW, Song CI, Yoo MH, Park HJ. Short-term hearing results using ossicular replacement prostheses of hydroxyapatite versus titanium. *Eur Arch Otorhinolaryngol*. 2015;272(10):2731-2735. [CrossRef]
12. Faramarzi M, Jahangiri R, Roosta S. Comparison of titanium vs. polycel total ossicular replacement prosthesis. *Iran J Otorhinolaryngol*. 2016;28(85):89-97.
13. Kotzias SA, Seerig MM, Mello MFPC, et al. Ossicular chain reconstruction in chronic otitis media: hearing results and analysis of prognostic factors. *Braz J Otorhinolaryngol*. 2020;86(1):49-55. [CrossRef]
14. Kong JS, Jeong CY, Shim MJ, Kim WJ, Yeo SW, Park SN. Comparative study of new autologous material, bone-cartilage composite graft, for ossiculoplasty with Polycel((R)) and titanium. *Clin Otolaryngol*. 2018;43(2):434-439. [CrossRef]
15. Mishiro Y, Sakagami M, Adachi O, Kakutani C. Prognostic factors for short-term outcomes after ossiculoplasty using multivariate analysis with logistic regression. *Arch Otolaryngol Head Neck Surg*. 2009;135(8):738-741. [CrossRef]
16. Mulazimoglu S, Saxby A, Schlegel C, Linder T. Titanium incus interposition ossiculoplasty: audiological outcomes and extrusion rates. *Eur Arch Otorhinolaryngol*. 2017;274(9):3303-3310. [CrossRef]
17. Demir UL, Karaca S, Ozmen OA, Kasapoglu F, Coskun HH, Basut O. Is it the middle ear disease or the reconstruction material that determines the functional outcome in ossicular chain reconstruction? *Otol Neurotol*. 2012;33(4):580-585. [CrossRef]
18. Kim HJ. Classification and hearing result reporting guideline in chronic otitis media surgery. *Korean J Otorhinolaryngol-head Neck Surg*. 2006;49(1):2-6.
19. Schober P, Boer C, Schwarte LA. Correlation coefficients: appropriate use and interpretation. *Anesth Analg*. 2018;126(5):1763-1768. [CrossRef]
20. Lailach S, Zahnert T, Neudert M. Data and reporting quality in tympanoplasty and ossiculoplasty studies. *Otolaryngol Head Neck Surg*. 2017;157(2):281-288. [CrossRef]