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Hearing Outcomes After Ossiculoplasty With Bone or Titanium Prostheses—A Nationwide Register-Based Study

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ABSTRACT

Objectives: This study compares hearing outcomes of two prosthesis materials, bone and titanium, used in ossiculoplasty.

Design: This retrospective nationwide registry-based study uses data systematically collected by the Swedish Quality Registry for Ear Surgery (SwedEar).

Setting: The data were obtained from clinics in Sweden that perform ossiculoplasty.

Participants: Patients who underwent ossiculoplasty using either bone or titanium prostheses were registered in SwedEar between 2013 and 2019.

Main Outcome Measures: Hearing outcome expressed as air–bone gap (ABG) gain.

Results: The study found no differences between bone and titanium for ABG or air conduction (AC) for either partial ossicular replacement prostheses (PORP) or total ossicular replacement prostheses (TORP). In a comparison between PORP and TORP for ABG and AC outcomes, regardless of the material used, PORP showed a small advantage, with an additional improvement of 3.3 dB (95% CI [confidence interval], 0.1–4.4) in ABG and 2.2 dB (95% CI, 1.7–4.8) in AC. In secondary surgery using TORP, titanium produced slightly better results for high-frequency pure tone average. The success rate, a postoperative ABG ≤20 dB, was achieved in 62% of the operations for the whole group.

Conclusion: Both bone and titanium used to reconstruct the ossicular chain produce similar hearing outcomes for both PORP and TORP procedures. However, titanium may be a preferable option for secondary surgeries involving TORP. The success rate, a postoperative ABG ≤20 dB, is consistent with other studies, but there is room for improvement in patient selection criteria and surgical techniques.

Summary

- The prostheses materials bone and titanium yield comparable hearing outcomes in ossiculoplasties.
- A majority of cases (62%) attained a postoperative air–bone gap (ABG) of ≤20 dB.
- After surgery, 57% achieved hearing improvement, 36% had unchanged hearing and 7% had worsened hearing.
- In secondary surgeries using total ossicular replacement prostheses (TORP), titanium showed slightly better results for high-frequency hearing.
- The study reflects real-world outcomes as it involves results from an entire country with a diverse group of surgeons, ranging from senior consultants to residents.

1 | Introduction

Ossiculoplasty is used to treat conductive hearing loss resulting from fixation or discontinuity of the ossicular chain. This can be caused by various factors, including chronic otitis media (COM) with or without cholesteatoma, trauma, congenital ossicular malformation or neoplasms [1, 2]. Depending on the extent of the ossicular damage, the ossicular chain can be reconstructed using a partial ossicular replacement prosthesis (PORP) or a total ossicular replacement prosthesis (TORP). In up to 30% of COM without cholesteatoma, ossicular chain injuries typically involve damage to the incus, followed by the stapes and malleus [3–6].

In Sweden, the most commonly used materials for ossiculoplasty prostheses are bone and titanium [7]. However, only a few studies have compared these two materials, and no consensus has been reached about which material yields the best hearing results [8–10].

Since 2013, ossiculoplasties performed in Sweden have been systematically recorded in the Swedish Quality Registry for Ear Surgery (SwedEar). This national registry for ear surgery was initially created in 1997 for myringoplasty and was expanded to include ossiculoplasty surgeries in 2013. Subsequently, cholesteatoma procedures were added to the registry in 2020. SwedEar is funded by the state and Sweden's municipalities and regions.

This study compares hearing outcomes following ossiculoplasty using bone and titanium prosthesis materials for both PORP and TORP. Data were collected from the SwedEar database for 675 patients who underwent surgery between 2013 and 2019.

2 | Materials and Methods

2.1 | Design and Settings

This retrospective nationwide registry-based study uses data systematically collected by SwedEar.

2.2 | Data Source

Between 2013 and 2019, patients in SwedEar were included based on the type of surgery, myringoplasties and ossiculoplasties. Concomitant mastoidectomy could be carried out and was noted only in 29 patients. The registered pathologies primarily consisted of COM without cholesteatoma, but also included trauma-related damage and congenital ossicular malformation. Cholesteatoma and deep retraction pockets were excluded. The registry included both primary and secondary surgeries, where previous ear surgery could involve various middle ear procedures, including staged ossiculoplasty after cholesteatoma surgery. The surgeon registered the objective of the operation as either hearing improvement or infection prophylaxis.

2.3 | Selection of Participants

This study includes patients who received either bone or titanium prostheses. Patients with missing audiogram data, follow-up visits, unhealed tympanic membrane or missing covariates were excluded. Patients with multiple surgery registrations for the same ear had only their first recorded surgery included, regardless of whether it was a primary or secondary operation.

Material and prosthesis type, PORP or TORP, were documented in the registry, but information regarding the variant of prosthesis or the manufacturer was not available. A PORP was used when the stapes were preserved, while TORP was used when the stapes suprastructure was absent. The bone prostheses primarily comprised of autologous bone with a few instances of homologous bone. Myringoplasties were performed with conventional underlay technique using autologous graft material, with fascia being the most commonly used.

SwedEar collects the data both at the time of surgery and at the follow-up visit, which is recommended 6–18 months after surgery.

2.4 | Audiometry and Outcome Measures

The audiometry was performed according to the International Standard Organization (ISO) (ISO 8253-1:2010) and the hearing levels were measured in decibels (dB). In the present study, the four-tone pure tone average (PTA_4) of frequencies 0.5, 1, 2 and 4 kHz was used to calculate mean air conduction (AC) and bone conduction (BC) thresholds. The air–bone gap (ABG) was determined by subtracting PTA_4BC from PTA_4AC [10]. When a numerical value for a single frequency was missing from the audiogram, an approximation to the nearest 5 dB value of the two adjacent frequencies was used. A clinically relevant change in gain was defined as >10 dB in accordance with the ISO standard norms of audiometric test methods.

The main outcome of this study was ABG gain. Improvement or gain was determined by assessing the change in PTA_4 between the pre- and postoperative audiograms [11]. A successful ossiculoplasty was defined as a postoperative ABG ≤20 dB. To evaluate high-frequency hearing, we computed the high-frequency pure tone average (HPTA) using the mean AC levels for the frequencies 4, 6 and 8 kHz. ABG gain for hearing outcome were categorised as follows: improved, when exceeding 10 dB; unchanged, when between 10 and −10 dB and worsened, when less than −10 dB.

2.5 | Statistical Methods

The study used a comparative analysis of hearing outcomes for two prosthesis materials, bone and titanium, within the PORP and TORP groups. Additionally, the impact of stapes presence or absence on hearing results was also analysed by comparing the type of the prostheses, PORP and TORP.

Two statistical methods were used: linear mixed-effect model (LMM) and logistic regression analysis (LRA). Both methods were adjusted for the covariates age, time to follow-up, gender, myringoplasty, prior ear surgery, perioperative infection and postoperative infection. The LMM using repeated measures was used to estimate the difference in hearing gain measured in dB between the prosthesis materials. LRA was employed to evaluate the categorical outcome of the success rate, which was defined as a postoperative ABG of ≤20 dB. The paired *t*-test was used to determine whether there was a significant difference between the pre- and postoperative hearing results. Sensitivity analyses were conducted for the variables age, gender, myringoplasty and prior ear surgery to assess the robustness of the study results. A stratified analysis was conducted for each variable, with estimates calculated for each stratum and subsequently compared with the primary analysis. All analyses were performed using IBM SPSS, V27 (IBM, Armonk, NY). The significance level was set at 5%, with a confidence level of 95%.

2.6 | Ethics and Guidelines

The study was approved by the Regional Ethical Committee at Stockholm University and performed in accordance with the Declaration of Helsinki (D-nr 2014/2203-31/4). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were followed.

2.7 | Bias

To prevent potential bias in the audiogram recordings, we developed an algorithm aimed at detecting potentially flawed or inaccurately recorded data. This algorithm initially flagged 270 patients with audiogram that raised suspicion of errors. To address this concern, we retrieved the original audiograms from the hospitals and cross-referenced them with our database. The majority of incorrect registrations were found to contain minor discrepancies, which were subsequently corrected in the database. We found that these incorrect registrations had a mean impact of 0.6 dB on the PTA_4.

3 | Results

3.1 | Participants

Between October 2013 and December 2019, 1179 patients who underwent ossiculoplasty were registered in SwedEar. Of these, 675 were considered eligible for inclusion in the study (Figure 1). The mean follow-up was 13 months (SD 5.4). The ages of the participants ranged between 6 and 86 years (mean 38 years). Gender distribution was fairly balanced (51% females).

The characteristics of the patients and the distribution of prosthesis materials within the respective groups are presented in Table 1. Of the 675 cases, 473 cases (70%) involved preserved stapes and therefore a PORP was used. In 202 cases (30%), the stapes suprastructure was absent, and reconstruction was performed using a TORP.

In the PORP group, bone prostheses were used in 351 cases (74%) and titanium prostheses in 122 cases (26%). These conditions were reversed in the TORP group, where the distribution was 59 (29%) for bone and 143 (71%) for titanium. In the majority of all operations (71%), a myringoplasty was concurrently performed alongside the ossiculoplasty. Approximately half of the operations were primary surgeries (52%), and the remaining patients had previously undergone various forms of middle ear surgeries. Postoperative infection was recorded for 7% of patients.

3.2 | Outcome Data

Before surgery, 14% of all patients had an ABG ≤20 dB. Following surgery, the overall success rate, defined as postoperative ABG ≤20 dB, was 62%.

The ABG gain for the entire group was divided into three distinct categories of hearing outcome: improved, unchanged and worsened. After surgery, 57% of cases had improved hearing, with the mean ABG changing from 37.2 dB preoperatively to 15.2 dB postoperatively. Hearing remained unchanged in 36% of the cases, with a mean ABG of 26.5 dB preoperatively and 23.3 dB postoperatively. In 7% of cases, hearing worsened, with the mean ABG increasing from 24.8 dB preoperatively to 42.5 dB postoperatively.

Figure 2a,b displays the distribution of ABG gain for both bone and titanium prostheses in the PORP and TORP groups. In both figures, bone and titanium exhibited a similar pattern relative to each other. The majority of operations in both groups fell within the 0–10 dB and 11–20 dB gain ranges. Additionally, these figures illustrate the number of cases where hearing outcomes were not successful. These cases resulted in an ABG gain of less than −10 dB, indicating a decline in hearing following surgery.

The mean improvement in the ABG was 12.5 dB, and the mean improvement in the AC was 15.0 dB for the entire group. However, at the higher frequencies (HPTA) in AC, the improvement was somewhat smaller, 6.4 dB. In BC, the mean improvement was 2.6 dB. Tables 2 and S1 present a comprehensive overview of the mean hearing outcomes, including gains for PTA_4 ABG, AC, BC and HPTA for all operations and by prosthesis group.

The rate of sensorineural hearing loss, a decrease in PTA_4 BC of >10 dB, was 4% ($n = 29$) of which the majority was found in the PORP group ($n = 24$). In one case, the patient was postoperatively found to be deaf in the operated ear.

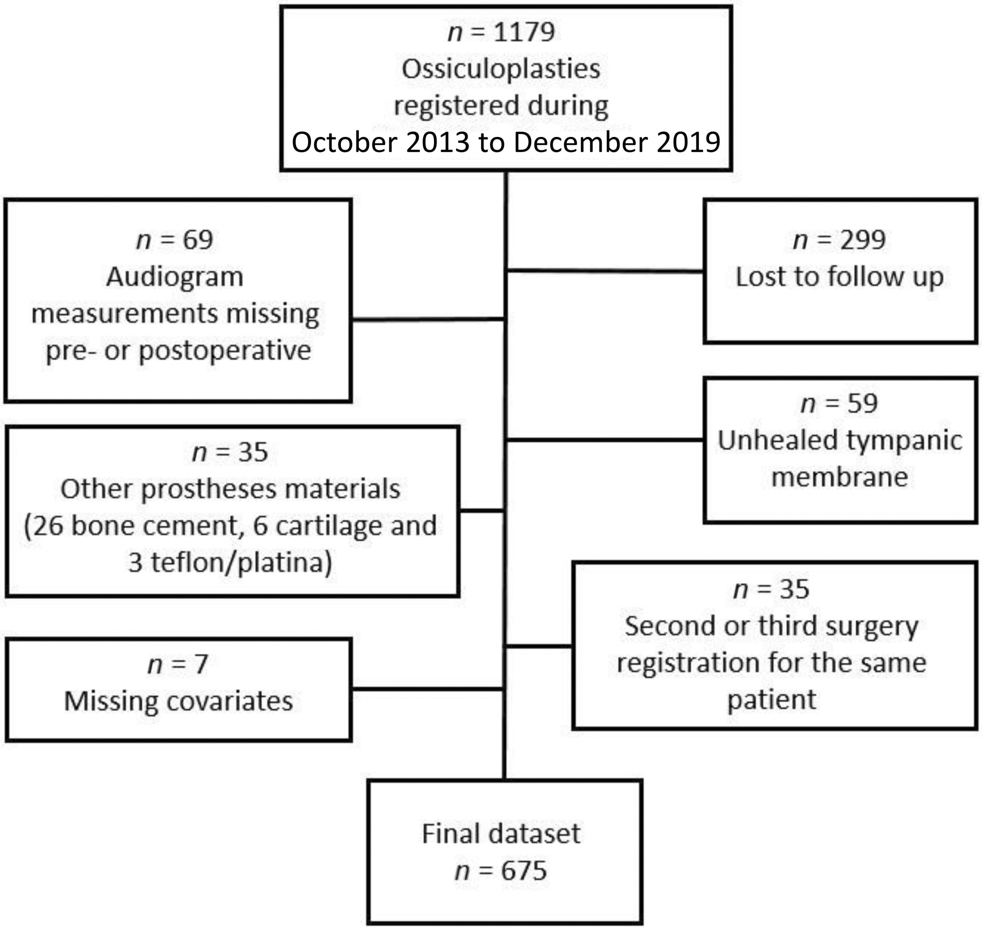


FIGURE 1 | Flow chart.

3.2.1 | PORP Bone vs. PORP Titanium

The mean ABG gain for PORP bone was 12.2 dB and for PORP titanium was 12.9 dB. The LMM analyses showed no significant differences between the two materials, including ABG, AC, BC and HPTA (Table 3). The success rate of surgery was 68% for bone compared with 66% for titanium, and LRA found no statistical significant difference between the two groups.

3.2.2 | TORP Bone vs. TORP Titanium

In the TORP group, the mean ABG gain was 10.5 dB for bone and 13.8 dB for titanium. However, as shown in the LMM analysis (Table 3), this difference was not statistically significant as were the results for the other mean value analyses. The success rate was 37% for bone and 55% for titanium, with significantly better odds for titanium compared with bone (odds ratio [OR] 2.5; 95% confidence interval [CI], 1.3–4.9, $p = 0.009$).

3.2.3 | PORP vs. TORP

When comparing the type of prostheses, regardless of the material used, the ABG gain improved by 12.4 dB for PORP, and a similar improvement of 12.5 dB was observed for TORP. However, after adjusting for covariates using LMM, a small but significant difference in estimates was found in favour of the PORP group. The PORP group exhibited lower dB values for PTA_4 AC (2.2 dB), PTA_4 ABG (3.3 dB) and HPTA (2.7 dB) compared with the TORP group (Table 3). Additionally, using LRA, we found that PORP had a significantly better success rate compared with TORP, with rates of 67% and 50%, respectively (OR 1.9; 95% CI, 1.3–2.7, $p = 0.001$).

3.2.4 | Sensitivity Analyses

Sensitivity analyses were conducted for the variables age, gender, myringoplasty and secondary surgery. These analyses did not reveal significant differences in age, gender or myringoplasty between the prosthesis groups. However, the sensitivity analysis conducted for secondary surgery indicated that HPTA had a higher estimate, 8.7 dB (95% CI 2.2–13.8, $p < 0.001$), for TORP bone compared with TORP titanium.

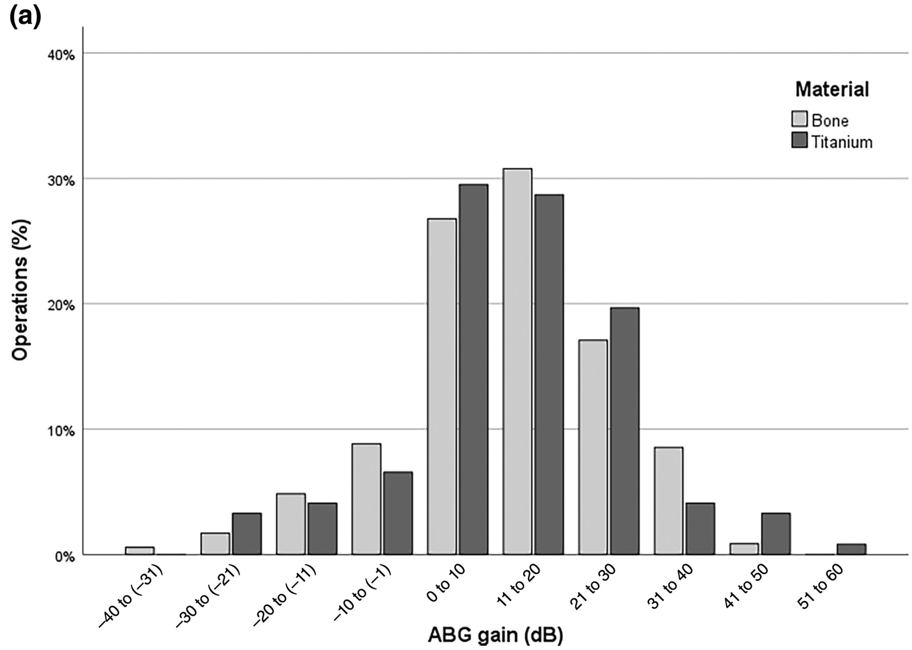
4 | Discussion

The current study found no significant differences in hearing outcomes when comparing the two prosthesis materials, bone and titanium, for either the PORP or TORP groups. Although some minor differences were observed, they were not deemed

TABLE 1 | Demographic data.

	Total, $n = 675$	All PORP[a], $n = 473$	All TORP[b], $n = 202$	PORP[a] bone, $n = 351$	PORP[a] titanium, $n = 122$	TORP[b] bone, $n = 59$	TORP[b] titanium, $n = 143$
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age at surgery (years)	37.8 (18.8)	37.2 (19.1)	39.3 (18.0)	37.0 (19.3)	37.7 (18.5)	38.6 (19.0)	40 (17.6)
Follow-up (months)	13.2 (5.4)	13.2 (5.4)	13.4 (5.5)	12.9 (5.2)	14.0 (6.0)	12.0 (4.3)	14.0 (5.9)
	n (%)[c,d]	n (%)[c,d]	n (%)[c,d]	n (%)[c,d]	n (%)[c,d]	n (%)[c,d]	n (%)[c,d]
Gender, female	346 (51)	257 (54)	89 (44)	190 (54)	67 (55)	30 (51)	59 (41)
Myringoplasty performed	476 (71)	364 (77)	112 (55)	277 (79)	87 (71)	40 (68)	72 (50)
Primary surgery	351 (52)	280 (59)	71 (35)	222 (63)	58 (48)	27 (46)	44 (31)
Perioperative infection	53 (8)	43 (9)	10 (5)	32 (9)	11 (9)	6 (10)	4 (3)
Postoperative infection[e]	50 (7)	32 (7)	18 (9)	22 (6)	10 (8)	5 (9)	13 (9)

[a]PORP, partial ossicular replacement prosthesis.
[b]TORP, total ossicular replacement prosthesis.
[c]Percentage calculated relative to the total number in the column.
[d]Categorical variables categorised as 'yes' or 'no'.
[e]Postoperative infection within 6 weeks after surgery.



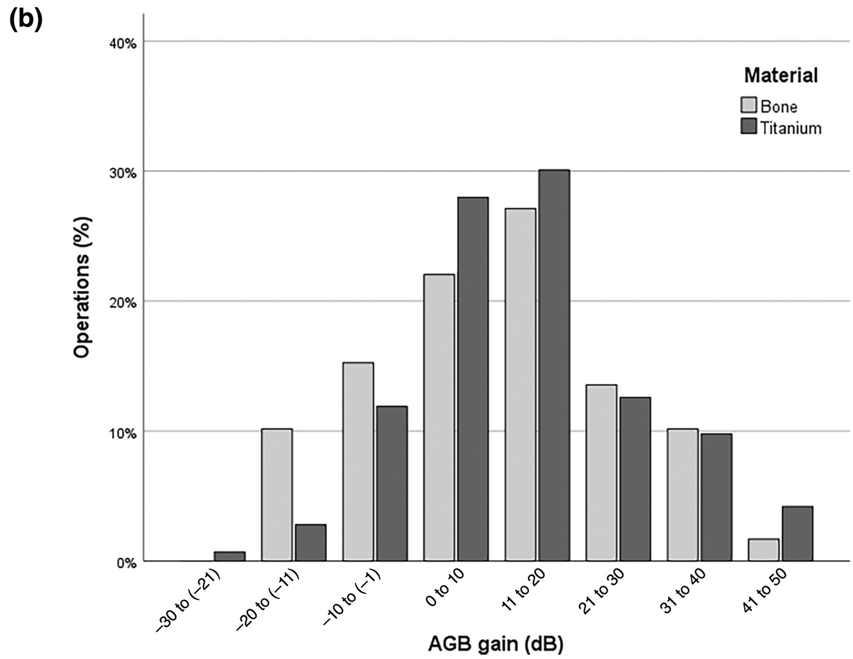


FIGURE 2 | (a) PORP bone versus PORP titanium. (b) TORP bone versus TORP titanium.

clinically relevant. When analysing PORP and TORP, PORP yielded slightly better hearing results irrespective of the material used. In the subset of patients who underwent secondary surgery, there was a slight advantage in high-frequency hearing observed with TORP titanium compared with TORP bone. However, it is important to note that these differences were <10 dB, and may not be considered clinically relevant. Additionally, there were no significant differences in age, gender or cases of concurrent myringoplasty.

Unexpectedly, our study shows that titanium exhibited a higher success rate in the TORP group, as determined by LRA. However, when it comes to the actual difference in dB between the two materials, LMM did not detect any statistically significant differences. This discrepancy arises from the use of categorical data, where the choice of the cut-off point for binary analysis falls between the means of the two groups.

The comparison of the two prosthesis materials, bone and titanium, has been a subject of limited research, often involving a small number of participants. Many of these studies employ criteria such as ABG gain and success rate as primary outcome measures. In previous studies, the number of included patients varied between 40 and 153; in some of these studies, the comparative groups were very small. In two studies comparing bone and titanium materials for PORP, one found bone

TABLE 2 | Pre- and postoperative hearing results.

	PORP[a] bone				PORP[a] titanium			
	Pre mean (SD)	**Post mean (SD)**	p[b]	**Gain (SD)**	**Pre mean (SD)**	**Post mean (SD)**	p[b]	**Gain (SD)**
PTA_4 AC	49.3 (16.9)	34.2 (18.7)	<0.001	15.1 (15.5)	49.9 (17.5)	34.9 (21.3)	<0.001	15.0 (19.9)
PTA_4 BC	18.1 (14.3)	15.1 (14.4)	<0.001	3.0 (8.2)	18.0 (14.7)	15.9 (15.6)	0.037	2.1 (11.1)
PTA_4 ABG	31.2 (10.9)	19.0 (10.9)	<0.001	12.1 (13.9)	31.9 (11.1)	19.0 (12.6)	<0.001	12.8 (14.7)
HPTA	55.3 (22.1)	49.4 (24.5)	<0.001	6.0 (17.6)	56.7 (23.2)	50.1 (25.8)	<0.001	6.6 (21.3)
	TORP[c] bone				**TORP[c] titanium**			
	Pre mean (SD)	**Post mean (SD)**	p[b]	**Gain (SD)**	**Pre mean (SD)**	**Post mean (SD)**	p[b]	**Gain (SD)**
PTA_4 AC	53.2 (15.0)	40.7 (17.6)	<0.001	12.5 (16.5)	52.3 (17.0)	36.4 (18.2)	<0.001	15.9 (16.4)
PTA_4 BC	18.8 (14.3)	16.8 (14.7)	0.080	2.0 (8.6)	17.1 (13.7)	14.9 (13.6)	<0.001	2.1 (6.8)
PTA_4 ABG	34.5 (11.1)	24.0 (10.2)	<0.001	10.5 (15.4)	35.2 (10.6)	21.5 (11.7)	<0.001	13.8 (14.3)
HPTA	60.0 (20.9)	57.4 (22.0)	0.194	2.6 (15.3)	61.5 (23.6)	52.5 (25.4)	<0.001	9.0 (15.8)
	PORP[a] total				**TORP[c] total**			
	Pre mean (SD)	**Post mean (SD)**	p[b]	**Gain (SD)**	**Pre mean (SD)**	**Post mean (SD)**	p[b]	**Gain (SD)**
PTA_4 AC	49.4 (17.0)	34.3 (19.4)	<0.001	14.2 (16.5)	52.5 (16.4)	37.7 (18.1)	<0.001	14.9 (16.5)
PTA_4 BC	18.1 (14.1)	15.3 (14.7)	<0.001	2.5 (8.9)	17.5 (13.9)	15.5 (13.9)	<0.001	2.1 (7.4)
PTA_4 ABG	31.3 (10.9)	19.0 (11.3)	<0.001	11.7 (14.2)	35.0 (10.7)	22.2 (11.3)	<0.001	12.8 (14.7)
HPTA	55.8 (22.4)	49.6 (25.0)	<0.001	5.0 (17.8)	61.1 (22.8)	54.0 (24.5)	<0.001	7.2 (15.9)

[a]PORP, partial ossicular replacement prosthesis.
[b]*T*-test was used to calculate the significant difference, $p < 0.05$, between the pre- and postoperative hearing results.
[c]TORP, total ossicular replacement prosthesis.

TABLE 3 | Linear mixed model analysis.

	Model 1[a]		Model 2[b]		Model 3[c]	
	Estimates (95% CI)	*p*	Estimates (95% CI)	*p*	Estimates (95% CI)	*p*
PORP[d] titanium vs. PORP[d] bone[e]						
PTA_4 AC	−0.7 (−3.5 to 2.3)	0.65	−0.3 (−3.0 to 2.3)	0.80	0.0 (−2.7 to 2.6)	1.00
PTA_4 BC	−0.3 (−2.4 to 1.8)	0.79	0.1 (−1.6 to 1.7)	0.92	0.1 (−1.6 to 1.8)	0.92
PTA_4 ABG	−0.4 (−2.2 to 1.5)	0.69	−0.4 (−2.3 to 2.4)	0.65	0.0 (−1.9 to 1.8)	0.97
HPTA	−0.7 (−4.2 to 2.8)	0.69	0.0 (−2.9 to 2.9)	0.98	0.5 (−2.4 to 3.5)	0.73
TORP[f] titanium vs. TORP[f] bone[e]						
PTA_4 AC	2.4 (−1.6 to 6.5)	0.23	3.0 (−0.6 to 6.7)	0.10	3.5 (−0.3 to 7.3)	0.07
PTA_4 BC	1.8 (−1.2 to 4.7)	0.25	2.3 (0.0 to 4.5)	0.05	2.5 (0.2 to 4.8)	0.03
PTA_4 ABG	0.8 (−2.0 to 3.5)	0.59	0.7 (−2.0 to 3.4)	0.59	0.9 (−1.9 to 3.8)	0.50
HPTA	1.6 (−3.5 to 6.8)	0.53	3.0 (−1.4 to 7.3)	0.18	4.0 (−0.5 to 8.4)	0.08
PORP[d] vs. TORP[f,g]						
PTA_4 AC	3.2 (1.0 to 5.5)	0.01	2.4 (0.3 to 4.4)	0.03	2.2 (0.1 to 4.4)	0.04
PTA_4 BC	−0.2 (−1.9 to 1.5)	0.82	−1.2 (−2.5 to 0.1)	0.08	−1.1 (−2.4 to 0.3)	0.13
PTA_4 ABG	3.4 (1.9 to 4.9)	<0.001	3.5 (2.1 to 5.0)	<0.001	3.3 (1.7 to 4.8)	<0.001
HPTA	5.1 (2.3 to 7.8)	<0.001	3.4 (1.1 to 5.7)	0.00	2.7 (0.3 to 5.2)	0.03

[a]Main model.
[b]Model 1 adjusted for gender and age.
[c]Model 2 additionally adjusted for myringoplasty, prior ear surgery, preoperative infection, postoperative infection and days to revisit.
[d]PORP, partial ossicular replacement prosthesis.
[e]Titanium as reference.
[f]TORP, total ossicular replacement prosthesis.
[g]PORP as reference.

material to provide better hearing outcomes, which is contrary to our findings [8]. In the second study, no significant difference was observed between the prosthesis materials, which is in line with our results [9]. In studies analysing hearing outcomes in TORP, a trend was seen where titanium was better than bone. However, in both of these studies, the comparison groups were small [9, 10]. Consequently, drawing definitive conclusions from these results is challenging. In our results on TORP, a potential advantage for titanium was only seen for secondary surgery.

While the studies mentioned above have provided mixed results, a systematic review comparing PORP bone to a combination of other materials found no significant difference in ABG gain. In this review, the ABG gain was reported to be 12.8 dB (SD 15.0) for bone compared with 11.8 dB (SD 15.0) for the group of other materials [12]. This result aligns with the findings observed in our study. Three meta-analyses show consistent results with our study concerning higher success rate and better ABG gain for PORP compared with TORP, and an agreement of separate analyses on PORP and TORP [13–15].

Patients undergoing ossiculoplasty present with a heterogeneous disease profile, exhibiting a wide range of middle ear pathologies. Several factors influence the hearing outcome, including the status of the middle ear mucosa, tympanosclerosis, tubal dysfunction, presence of residual ossicles, infection status and surgical factors [16, 17]. In recent years, instruments such as Middle Ear Risk Index (MERI), Ossiculoplasty Outcome Parameter Staging (OOPS) and Surgical, Prosthetic, Infection, Tissue, Eustachian (SPITE) have been developed to assess prognostic factors [18–20], but their usage varies. Additionally, there is no universally accepted protocol for describing hearing outcomes. Although the 'Committee on Hearing and Equilibrium' guidelines from 1995 exist, they are not comprehensive enough [11, 16, 17]. Therefore, comparing and deriving generalised conclusions from various clinical reports on ossiculoplasty is challenging.

The stated goal of the operations in this study was hearing improvement in the majority of cases, 92%. However, despite this, 36% did not experience a clinically relevant hearing improvement, defined as an ABG gain >10 dB. In the 'unchanged' group, the mean ABG changed from 26.5 dB preoperatively to 23.3 dB postoperatively, whereas in the 'improved' group, the preoperative ABG was higher at 37.2 dB, and postoperative ABG was 15.2 dB. This suggests that the potential for hearing improvement was smaller for the 'unchanged' group. Possible reasons for this could include a middle ear pathology that hindered improved sound transmission, or the presence of sufficient transmission preoperatively, such as myringopexy or a damaged incus with retained contact with the stapes, where ossicular reconstruction did not improve hearing.

The strength of the present study lies in involving a nationwide coverage with a substantial number of patients. To the best of our knowledge, this is the largest study comparing bone and titanium materials for ossiculoplasty. The surgeons ranged from residents operating under guidance to senior consultants. It is worth noting that SwedEar has undergone a validation process, which has demonstrated excellent data coverage and reliability [21]. Consequently, SwedEar offers a realistic reflection of the outcomes of ossiculoplasties in Sweden and serves as a valuable resource for informed patient counselling.

However, registry studies are constrained by the recorded information. SwedEar does not document several prognostic factors known to influence the hearing outcome in ossiculoplasty [18–20]. Additionally, it does not record the variant of titanium PORP or TORP. This latter limitation is unlikely to significantly impact the findings, as suggested by the limited number of studies addressing this issue and their results [20, 22]. Furthermore, specific disease diagnoses could not be grouped together for separate analysis. In the present study, only 57% of the operated patients were included in the final dataset. However, it is essential to acknowledge that several valid reasons led to exclusions, such as the use of other types of prosthesis materials, unhealed tympanic membrane and statistical considerations such as repeated operations on the same individual and missing single covariates. Although this could potentially introduce selection bias, it is noteworthy that the success rate in our study aligns with the results of other studies [23–25].

5 | Conclusion

Our results suggest that there are no significant differences in hearing outcomes between bone and titanium prosthesis materials. However, in cases involving TORP in secondary surgery, titanium may be a preferable option. Additionally, the need for concurrent myringoplasty does not appear to substantially affect the hearing outcome. It is also reassuring that age and gender do not seem to influence the result. The chance of achieving a successful hearing result was 62%, leaving room for improvement in terms of surgical techniques and patient selection criteria for those with the potential of hearing improvement.

Author Contributions

Planning of the article: SO, MB, JK, EW, POE, ÅB. Data processing: SO, MB, JK, EW, POE, ÅB. Data analysis: SO, MB, JK, EW, POE, ÅB, TT. Writing of the article: SO, MB, JK, EW, POE, ÅB, TT. All authors have read and accepted the text in its present form.

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Ethics Statement

The study was approved by the Regional Ethical Committee at Stockholm University and performed in accordance with the Declaration of Helsinki (D-nr 2014/2203-31/4). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were followed.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Peer Review

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/coa.14191.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.