Journal of
Otorhinolaryngology, Hearing and Balance Medicine

MDPI

Article

Comparing the Long-Term Stability of Titanium Clip Partial Prostheses with Other Titanium Partial and Total Ossicular Reconstruction Prostheses

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Abstract: Background/Objectives: Long-term prosthetic stability in ossicular chain reconstruction (OCR) surgery may be affected by multiple factors, including prosthesis type. We compared audiometric outcomes including air–bone gap (ABG) and air conduction pure-tone average (AC PTA) over a multi-year period in titanium clip partial prosthetics and other titanium partial and total ossicular reconstruction prostheses. **Methods:** This was a retrospective study of 92 adult patients (19–74 years) receiving primary, second-look, or revision OCR at a single institution between 2017 and 2021. ABG and AC PTA at short (3–6 months) and long-term (>12 months) postoperative follow-up were compared among patients receiving clip partial prosthetics, traditional PORPs, and TORPs. **Results:** Overall, AC PTA and ABG were significantly improved in the short term and did not significantly deteriorate in the long term. Clip partial prostheses had significantly lower AC PTAs and ABGs than TORPs in both the short and long term and no difference with PORPs. There was also no significant deterioration in audiometric outcomes in either clip partials, PORPs, or TORPs over time. Clip partials had the highest rate of short- and long-term surgical success (i.e., ABG $\leq$ 20 dB) with 62.2% and 54.1%, respectively. Cholesteatoma and revision status were not independent predictors of long-term ABG success. **Conclusions:** The clip partial prosthesis seems to demonstrate similar, and potentially increased, resilience compared to the PORP and TORPs in both the short and long term. They may have comparable effects on audiometric outcomes to PORPs, demonstrating postoperative ABG and AC PTAs that reflect the previous literature. Clip partials appear to be a safe and effective prosthetic for OCR in patients with intact stapes regardless of cholesteatoma or revision status.

Keywords: hearing loss; OCR; prosthesis

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Academic Editor: Agnieszka Szczepek

Received: 27 February 2025
Revised: 14 March 2025
Accepted: 18 March 2025
Published: 1 April 2025

Citation: Leahy, J.; Yang, A.; Wong, K.; Perez, E.R.; Wanna, G.B.; Cosetti, M.K. Comparing the Long-Term Stability of Titanium Clip Partial Prostheses with Other Titanium Partial and Total Ossicular Reconstruction Prostheses. *J. Otorhinolaryngol. Hear. Balance Med.* **2025**, *6*, 7. https://doi.org/10.3390/ohbm6010007

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1. Introduction

The success of ossicular chain reconstruction (OCR) surgery is dependent on numerous factors, including, but not limited to, the extent of middle ear disease, preoperative ossicle status, prosthesis type, and patient age [1–4]. While many studies have shown safe and effective outcomes in the short to intermediate postoperative period with OCR [2,5,6], the extended long-term, multi-year efficacy of the procedure is less certain. Given the possibility of extrusion and revision surgery in OCR, it is critical to understand what characteristics of either the patient or the prosthesis predict long-term stability of audiometric results, such as air–bone gap (ABG) and air conduction pure-tone average (AC PTA). In this study,

we assessed the short- and long-term performance of the CliP® Partial Prosthesis Dresden Type Titanium (Heinz Kurz GmbH, Dusslingen, Germany) (clip partial) [7] in comparison to the other titanium partial and total ossicular reconstruction prostheses (PORPs and TORPs, respectively).

Many available PORPs have a wide, cage-like end to facilitate visualization of the stapes superstructure during placement. The design of the titanium clip partial, Dresden type, allows a malleable fixation mechanism onto the stapes capitulum, which may provide improved coupling and sound conduction and potentially reduce the risk for extrusion [8,9] (Figure 1). However, the placement of the clip requires more precision and may theoretically inflict damage to the stapes in the process [8]. While a few studies have documented the performance of clip partials over time [8–10], comparison between other types of titanium PORPs and TORPs in the short- and long-term postoperative period is lacking.

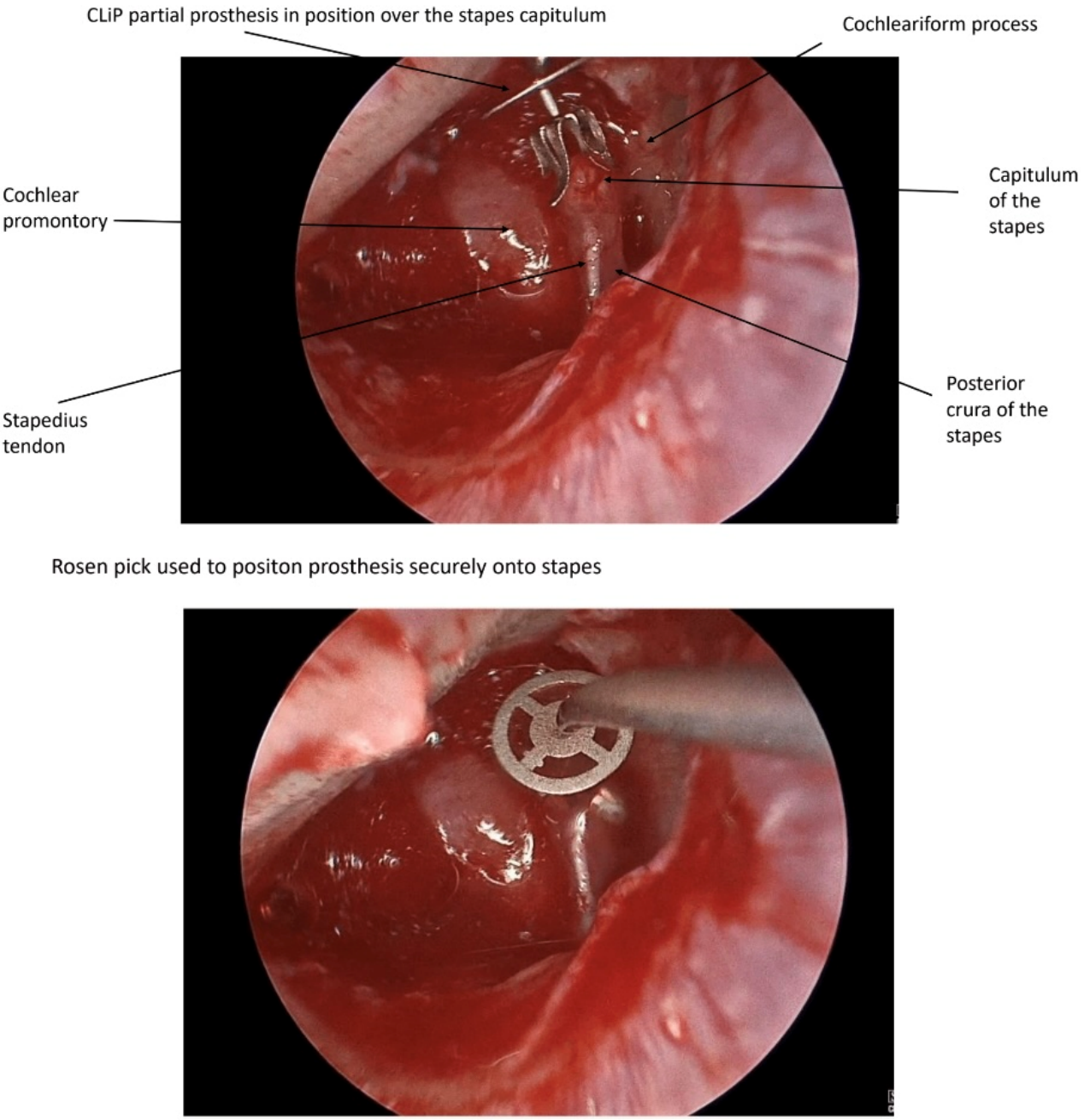


Figure 1. Intraoperative photos of clip partial.

Another important consideration for long-term stability is whether the ossicular chain has been replaced in its entirety by a TORP or in part by a PORP. In general, patients with more severe disease tend to require TORPs, often meaning that they start from larger preoperative ABGs and AC PTAs [11]. As a result, rates of surgical success in TORP patients tend to be lower than in PORP patients [2,5,11]. There is considerably more debate about the long-term durability of TORPs versus PORPs, with some studies claiming PORPs have earlier deterioration than TORPs [12] and vice versa [13,14].

Other factors, such as the status of the middle ear, eustachian tube function, and cholesteatoma, also play a critical role in the success of OCR over time, no matter which prosthesis type they receive. In particular, cholesteatoma is considered a major risk factor for revision surgery given the high rate of disease recurrence [15]. The destructive nature of cholesteatoma may lead to prosthetic extrusion or erosion of the remaining ossicles. It remains unclear what type of prosthesis is most beneficial for this population, and it is dependent on preoperative ossicle status. For example, patients with chronic middle ear disease with intact stapes superstructures may achieve similar audiometric results with a variety of PORPs and TORPs [16]. Research is needed to investigate if the clip partial may perform better or worse with cholesteatoma patients.

In our study, we investigate titanium OCR prosthetic stability over the short and long term by analyzing the change in ABG and AC PTA between first and second follow-up audiograms. We also included an analysis of prosthesis performance among patients with cholesteatoma given their predisposition to aggressive disease.

2. Methods

2.1. Study Design

This was a retrospective study of 92 adult (age $\geq$ 18 years) patients who received primary or second-look/revision OCR at the same tertiary care institution between 2017 and 2021. All surgeries were performed by one of three neurotologists. Short-term follow-up was defined as audiograms occurring roughly between 3 and 6 months and no later than 11 months after surgery. Long-term follow-up was defined as $\geq$12 months postoperatively.

In addition to basic demographic information, data were recorded on each patient's preoperative diagnosis (e.g., cholesteatoma), ossicle status (i.e., absent or eroded), and prosthesis type (i.e., PORP, TORP, clip partial). Primary audiometric outcomes included ABG, PTA, speech reception threshold (SRT) and word recognition scores (WRSs). Perioperative complications were also recorded.

2.2. Statistical Analysis

Descriptive statistics were applied to characterize the study population across demographic and clinical variables. The paired Mann–Whitney U test was used to identify significant changes in PTA and ABG in the short-term interval and postoperative follow-up interval to assess OCR outcome stability. ANOVA was used to assess differences in the magnitude of PTA and ABG changes across prosthetic types (i.e., clip partial, PORP, and TORP). We also investigated these differences for patients with and without cholesteatoma. All statistical analyses were performed using R version 4.3.1. A p-value of $\leq$0.05 was considered significant.

3. Results

3.1. Demographics

Sample characteristics are described in Table 1. Cholesteatoma was the predominant preoperative diagnosis (n = 54, 64%). Incus erosion was the most common ossicular defect found on preoperative imaging (n = 52, 57%).

Table 1. Demographic and preoperative information.

Age, Median (Range), Years	**47 (19–74)**
Sex, n (%)	
Male	41, 45%
Female	51, 55%
Ethnicity, n (%)	
Caucasian	29, 32%
African American	5, 5%
Hispanic	4, 4%
Asian	6, 7%
Other	47, 51%
Missing	1, 1%
Ear, n (%)	
Left	40, 43%
Right	52, 57%
Preoperative diagnosis, n (%)	
Cholesteatoma	54, 64%
Tympanic membrane perforation	46, 54%
Malpositioned or extruded prosthesis	6, 7%
Otitis media	16, 19%
Tympanosclerosis	3, 4%
Encephalocele	1, 1%
Congenital aural atresia	1, 1%
Preoperative ossicle status per imaging, n (%)	
Malleus erosion	26, 29%
Incus erosion	52, 57%
Stapes erosion	16, 18%

3.2. Preoperative and Surgical Information

Overall, average preoperative ABG and AC PTA were 31.0 dB (range 10.0–63.8 dB) and 49.4 dB (range 13.8–97.5 dB), respectively. There were 26 (28%) TORPs, 29 (32%) non-clip PORPs, and 37 (40%) clip partials. One-third of surgeries were performed with a transcanal exclusively endoscopic approach, while the rest were carried out microscopically without use of the endoscope for prosthesis placement. There were 67 primary cases (73%) (Table 2). For 20 patients receiving revision surgeries, 15 had their prior surgeries carried out at an outside institution (Table 2). The mean number of prior ear surgeries in second-look and revision cases was 1.3.

Table 2. Surgical information.

Surgery, n (%)	
Primary surgery	67, 73%
Planned second-look	5, 5%
Revision (prior surgery at same institution)	5, 5%
Revision (prior surgery outside of institution)	15, 16%
CWU	59, 64%

Table 2. *Cont.*

Surgery, n (%)	
CWD	3, 3%
Tympanoplasty	26, 28%
Prosthesis type, n (%)	
PORP	29, 32%
TORP	26, 28%
Clip partial	37, 40%
Prosthesis length, mode (range), mm	2 (0.75–5.5)

CWU = canal wall up, CWD = canal wall down, PORP = partial ossicular replacement prosthesis, TORP = total ossicular replacement prosthesis.

3.3. Short-Term Follow-Up

Overall, there were 84 total patients with short-term follow-up. Average ABG and AC PTA were 20.0 dB and 36.3 dB, respectively (Figure 2). There was minimal change in bone conduction, with the average difference in BC PTA being −2.2 dB.

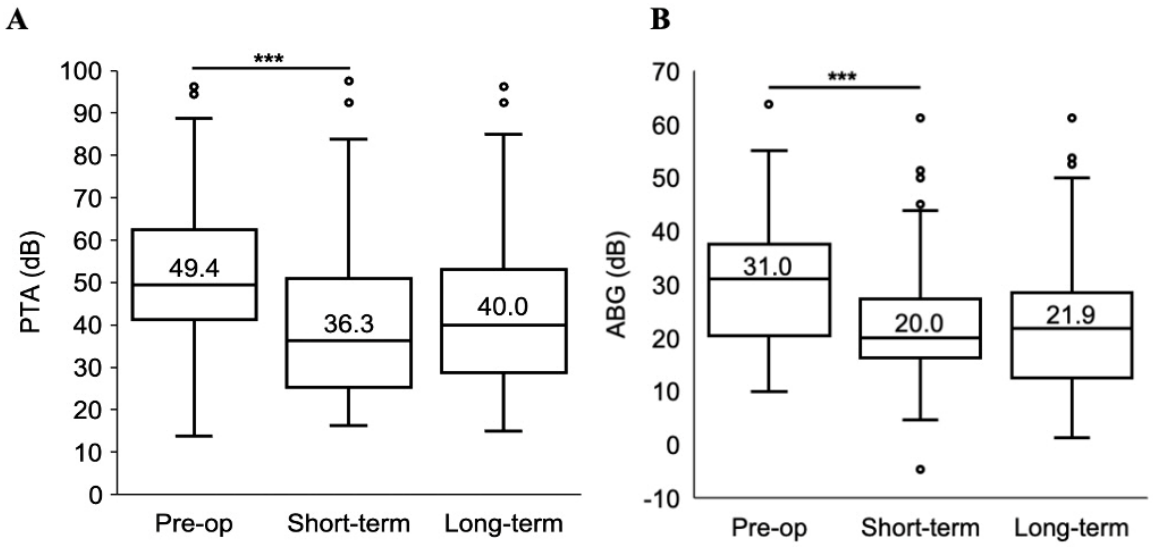


Figure 2. PTA (**A**) and ABG (**B**) observed at preoperative, short-term, and long-term time points. Significance levels were determined by $p < 0.001$ (***).

For clip partials specifically, 62.2% of patients had an ABG of ≤20 dB and 32.4% had an AC PTA of ≤25 dB postoperatively (Table 3). For PORPs, 48.4% of patients had an ABG of ≤20 dB and 19.4% had an AC PTA of ≤25 dB postoperatively. For TORPs, 20.8% of patients had an ABG of ≤20 dB and 12.5% had an AC PTA of ≤25 dB postoperatively. PORPs and clip partials both achieved an average ABG of 18.8 dB, while TORPs were 27.5 dB (Table 4).

Table 3. Number of patients with PTA ≤ 25 Hz and ABG ≤ 20 dB at short- and long-term follow-ups by prosthetic type.

	Clip Partial (n = 37)		**PORP (n = 31)**		**TORP (n = 24)**	
	PTA ≤ 25 dB	**ABG ≤ 20 dB**	**PTA ≤ 25 dB**	**ABG ≤ 20 dB**	**PTA ≤ 25 dB**	**ABG ≤ 20 dB**
Short-term follow-up	12 (32.4%)	23 (62.2%)	6 (19.4%)	15 (48.4%)	3 (12.5%)	5 (20.8%)
Long-term follow-up	9 (24.3%)	20 (54.1%)	5 (16.1%)	14 (45.2%)	3 (12.5%)	4 (16.7%)

Reported as N (%).

Table 4. Median hearing outcomes before and after OCR stratified by prosthetic type.

	Clip Partial (n = 37)		PORP (n = 31)		TORP (n = 24)		Kruskal-Wallis *p*-Value	
	PTA (dB)	**ABG (dB)**	**PTA (dB)**	**ABG (dB)**	**PTA (dB)**	**ABG**	**ΔPTA**	**ΔABG**
Preop	46.3 (13.8–96.3)	32.5 (10.0–46.3)	50.0 (21.3–87.5)	23.8 (12.5–63.8)	55.0 (35.6–97.5)	35.7 (12.5–55.0)	0.09	0.16
Short-term follow-up	30.0 (16.3–92.5)	18.8 (−4.6–38.8)	33.8 (16.3–83.8)	18.8 (5.0–61.3)	47.5 (20.0–97.5)	27.5 (8.8–51.3)	0.01 *	<0.01 **
Long-term follow-up	35.0 (17.0–96.3)	18.8 (1.3–48.8)	41.3 (15.0–83.8)	21.3 (5.0–50.0)	42.5 (20.0–92.5)	23.8 (7.5–61.3)	0.06	0.03 ***
Stability (Δ LT-ST)	+2.50 (−16.3–16.3)	+1.25 (−11.7–15.0)	1.88 (−20.0–36.3)	0 (−25.0–40.0)	0 (−47.5, 17.5)	−1.25 (−26.9, 23.8)	0.77	0.70
p-value	0.57	0.87	0.24	0.67	1.00	0.70	-	-

* PTA short-term follow-up: TORP significantly greater than clip partial ($p = 0.013$). ** ABG short-term follow-up: TORP is significantly greater than clip partial and PORP ($p < 0.001$ and $p = 0.02609$, respectively). *** ABG long-term: TORP is significantly greater than clip partials ($p = 0.037$).

3.4. Long-Term Follow-Up

There were 85 patients with long-term follow-up. Mean time to long-term follow-up was 30 months (range 12–65 months). Median ABG and AC PTA were 21.9 dB and 40.0 dB, respectively (Figure 2). Clip partials maintained the same average ABG as the short term (18.8 dB), while the average ABG increased to 21.3 dB for PORPs and improved to 23.8 dB for TORPs. For clip partials, 54.1% of patients had an ABG of ≤20 dB and 24.3% had an AC PTA of ≤25 dB in the long term (Table 3). For PORPs, 45.2% of patients had an ABG of ≤20 dB and 16.1% had an AC PTA of ≤25 dB postoperatively. For TORPs, 16.7% of patients had an ABG of ≤20 dB and 12.5% had an AC PTA of ≤25 dB postoperatively. See Figure 3 for further breakdown of audiometric data.

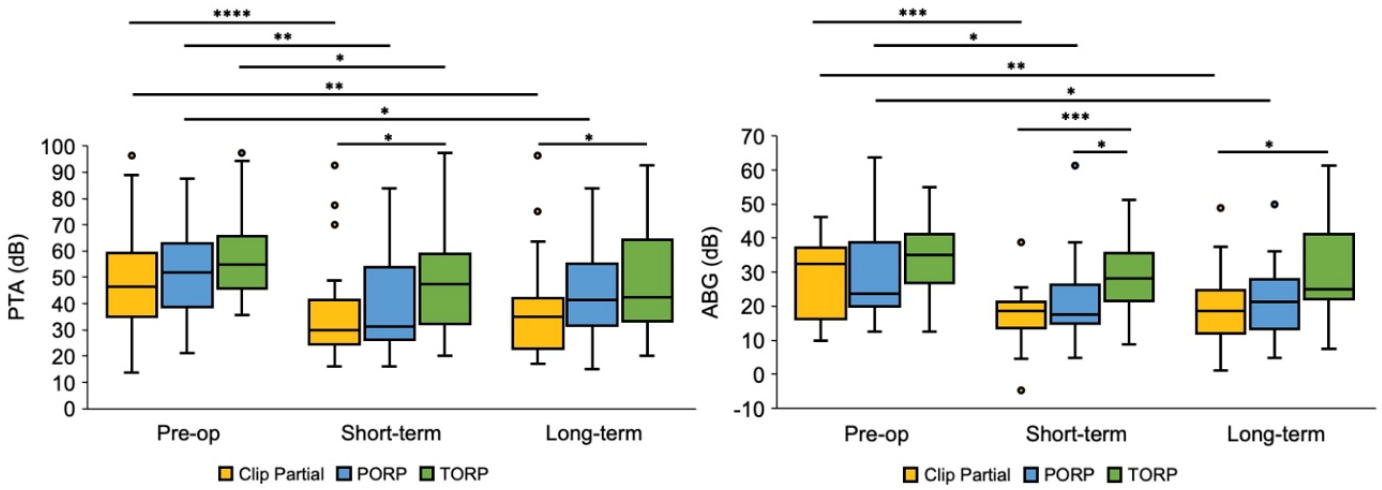


Figure 3. PTA (**Left**) and ABG (**Right**) observed at preoperative, short-term, and long-term time points stratified by prosthetic type. Unpaired Mann-Whitney U-tests were used to identify significant differences in PTA and ABG between clip partial, PORP, and TORP. Paired Mann-Whitney U-tests were used to identify significant differences within each prosthetic brand across time. Significance levels were determined by $p < 0.05$ (*), <0.01 (**), <0.001 (***), and <0.0001 (****).

3.5. Stability Analysis

There were 77 patients with both short- and long-term follow-up documented in their medical chart, enabling them to be included in the stability analysis of their prosthetic between the two visits. Mean time between short- and long-term follow-up was 24 months (range 5–65 months). Overall, there was no change in ABG between short- and long-term

audiograms. ABG increased by 0.9 dB on average for clip partials, decreased by 1.3 dB for PORPs, and was unchanged in TORPs between short- and long-term follow-ups. There was no significant difference between short- and long-term ABGs or PTA for clip partials, PORPs, and TORPs (Table 4).

3.6. Cholesteatoma Patients

There were 54 adults with cholesteatoma (ages 19–74, mean 47 years) with OCR via PORP (n = 17 traditional; n = 21 clip partial) or TORP (n = 16). Overall, there was no significant change in postoperative ABG over time (median short-term = 20 dB; long-term = 23 dB). Long-term ABG was significantly improved from preoperative (23 vs. 46 dB, $p = 0.04$). No patient experienced worsening of the bone line postoperatively. Patients with PORP were significantly more likely to achieve short-term postoperative ABG $\leq$ 20 than patients with TORP (71% vs. 20%, $p < 0.01$). In adjusted analyses, TORPs were negatively associated with short- and long-term ABG $\leq$ 20 with odds ratios (95% confidence interval) of 0.06 (0.01–0.30) ($p < 0.01$) and 0.21 (0.04–0.84) ($p = 0.04$), respectively. Clip partials demonstrated equivalent short- and long-term audiometric results as traditional PORPs. In analyses adjusting for age, primary vs. revision surgery, cholesteatoma vs. other preoperative diagnosis, and prosthetic type, cholesteatoma status was not found to be an independent predictor of long-term ABG success.

3.7. Revision Cases

Among the 25 revision cases, eight patients received a clip partial, nine received a PORP, and eight had a TORP. Of those receiving a clip partial, 50% achieved a short-term postoperative ABG $\leq$ 20 and 37.5% in the long term. For PORPs, ABG surgical success remained stable at 44.4% in both the short and long term. There was no significant difference in short- and long-term audiometric outcomes between patients who received a clip partial versus a PORP. Of note, no TORP patients achieved an ABG $\leq$ 20 or a PTA $\leq$ 25 in the long term. In analyses adjusting for age, primary vs. revision surgery, cholesteatoma vs. other preoperative diagnosis, and prosthetic type, revision status was not found to be an independent predictor of long-term ABG success.

3.8. Perioperative Complications

Only two patients (2.1%) had reported perioperative complications. Both patients received a clip partial. The complications included possible perilymphatic fistula and tympanic membrane perforation. The patient with the potential fistula presented with recurrent vertigo and sensorineural hearing loss and was ultimately taken to the OR for middle ear exploration 4 months after their initial OCR. The prosthesis was removed, and no leak was ultimately appreciated intraoperatively. Her symptoms had only mild improvement postoperatively, suggesting an alternative etiology for her symptoms than the procedure or prosthesis itself. The second patient presented with headaches, ear pain, and a small pinpoint perforation three months after surgery. No other patients had reports of dizziness, tinnitus, or sensorineural hearing loss in their postoperative notes.

4. Discussion

Data from the present study demonstrate equivalent audiometric results and long-term audiometric stability among various titanium OCR prostheses. Our audiometric results for clip partials support previous studies. The average short-term ABG of 18.8 dB in our cohort of clip partials is comparable to the short-term ABG of 18 dB found by Rivas et al. [8]. Though there are fewer long-term studies for comparison, our average long-term ABG of 18.8 dB is similar to multi-year studies, which have shown that clip partials tend to yield long-term postoperative ABGs between 11 and 20 dB [8–10]. Importantly, our study

showed that clip partials had no significant difference in outcomes between the short and long term, indicating stability of the prosthesis, a finding that has only been previously demonstrated in a few select studies [8,9]. We also demonstrated that revision cases status and presence of cholesteatoma may not affect the performance of the clip partial when compared to PORPs.

In our cohort, patients who received traditional PORPs also had outcomes that mirror the prior literature in both surgical success rates and objective audiometric measures, such as ABG and AC PTA [5,12,17]. Surgical success as defined by ABG $\leq$ 20 dB in both the short and long term for PORPs is estimated in these studies between 50% and 60%, which is similar to our findings. We found clip partials had a higher success rate than PORPs, though the difference was not significant. This may be due to enhanced adherence of the prosthesis to the stapes. When compared to PORPs, clip partials displayed no difference in their stability over time, indicating that the theoretical damage to the stapes during prosthesis insertion may be minimal.

Both clip partials and PORPs had higher rates of surgical success than TORPs in the short and long term. This may be affected by low sample size or higher preoperative baselines in TORP patients. Contrasting clip partials directly with TORPs may be imperfect due to the differences in preoperative ossicle status that necessitates replacing the entire ossicular chain. When using TORP for ossicular reconstruction, patients may be more likely to receive a staged procedure and revisions. There may also be demographic and clinical indication differences for a TORP. While this is the first study to compare TORPs to clip partials, previous studies comparing the efficacy of TORPs and PORPs have been conflicting. A systematic review and meta-analysis found that children who received a PORP had better preoperative hearing and postoperative hearing improvement when compared to children who received a TORP [10]. However, other studies have found that TORP ossiculoplasty has proven to be an effective means of ossicular reconstruction regardless of ossicle status or spatial arrangement [18]. The few studies that have compared the long-term audiometric outcomes for patients who received a TORP versus a PORP procedure found that there is no significant difference between the two [16,17,19].

Limitations

As with any retrospective, single-institution study, we are limited in our ability to generalize the results to the larger patient population. Though the majority of our patients had cholesteatoma, our cohort had a variety of different ear pathologies that could have potentially influenced the success of the OCR. Furthermore, 15 patients were lost to follow-up in the long term, which may have biased results. For example, it is possible that patients with excellent results may not have felt a need to return for follow-up appointments. Documentation in the medical record may also not be uniform across patients. Future longitudinal studies on this topic should have prospective designs with large sample sizes in order to facilitate long-term follow-up analysis.

5. Conclusions

The clip partial prosthesis demonstrates similar, and potentially increased, resilience compared to the PORP and TORPs in both the short and long term. They may have comparable effects on audiometric outcomes to PORPs, demonstrating postoperative ABG and AC PTAs that reflect the previous literature. Choice of OCR technique, including use of autologous bone, type, composition, and prosthesis, is often dependent on surgeon preferences. Newer prostheses, such as the clip partial, provide theoretical benefit in stability due to the improved coupling on the capitulum. Our study suggests that the clip partial may provide some benefit in audiometric outcomes, thereby warranting its

use over other types of ossicular reconstruction. However, large cohort or prospective studies in which patient variables are more tightly controlled are needed to definitively change practice patterns. Clip partials appear to be a safe and effective prosthetic for OCR in patients with intact stapes regardless of cholesteatoma presence or revision status.

Author Contributions: Conceptualization, J.L., K.W. and M.K.C.; methodology, J.L., A.Y. and M.K.C.; software, A.Y.; formal analysis, A.Y. and J.L.; data curation, J.L., K.W. and A.Y., writing—original draft preparation, J.L., A.Y. and M.K.C.; writing—review and editing J.L., A.Y. and M.K.C.; visualization, J.L., A.Y. and M.K.C.; supervision, E.R.P., G.B.W. and M.K.C.; project administration, E.R.P., G.B.W. and M.K.C. All authors have read and agreed to the published version of the manuscript.

Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Institutional Review Board Statement: These data were derived from clinical observations in human subjects. The institutional affiliation of the Institutional Review Board is the Icahn School of Medicine, Mount Sinai Medical Health System. The application number is 21-017868, and the Principal Investigator is Maura Cosetti. Approval date was 24 November 2021.

Informed Consent Statement: Not applicable.

Data Availability Statement: This study used healthcare data from medical charts of patients. The data are not publicly available due to privacy or ethical restrictions.

Acknowledgments: The authors would like to thank the Department of Otolaryngology at Mount Sinai for their continued support.

Conflicts of Interest: Cosetti is a member of the advisory board of Cochlear Americas. She participates in sponsored research with Cochlear Americas and MedEL. Cosetti and Perez are research consultants with Acclarent.

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