Functional and Anatomical results using Titanium Prostheses and Titanium Prostheses with Porous Hydroxyapatite in middle ear surgery

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Abstract: The objective of this investigation is to compare the anatomical and functional outcomes of middle ear ossicular chain reconstruction using two different prosthetic materials: conventional titanium prostheses and titanium prostheses coated with hydroxyapatite. This study employs a retrospective analysis of patient data.Modern otosurgical practice has embraced a single-stage approach that combines initial surgical interventions, such as scar removal, retraction pocket elimination, tympanic membrane defect repair, and sanitation, with middle ear ossicular chain reconstruction. However, achieving predictable success in restoring middle ear sound conduction remains challenging. A multitude of factors can influence surgical outcomes, including the underlying pathology, intraoperative findings, variations in surgical techniques, prosthesis design and mechanical properties, tympanic cavity ventilation methods, and the extent of scar management during both the early and late postoperative periods.

Keywords: Ossiculoplasty, ossicular prosthesis, tympanoplasty, biocompatible materials.

Introduction

A century of research has focused on developing optimal methods for reconstructing the anatomical structures of the ear, and creating ideal middle ear prosthesis. Material choices have fluctuated, including autologous cartilage and allografts. An ideal ossicular prosthesis should closely mimic the acoustic properties of the native middle ear ossicular chain, be biologically inert (avoiding inflammation or neoplasia), maintain structural integrity and stability over time, and withstand fluctuations in middle ear pressure.

Globally, over 18 companies manufacture more than 80 variations of ossicular prosthesis. These prosthesis differ by the bones they replace, materials (e.g., titanium, hydroxyapatite, bone cement, polyethylene composites, hydroxyapatite-reinforced [HAPEX]), number of components, design (length, openness), preparation/implantation methods, and fixation techniques. Despite this variability, no current prosthesis consistently predicts a complete closure of the air-bone gap. The scarcity of long-term (2 years or more) outcome data in large cohorts using titanium prostheses and bio-composite materials is attributed to low patient engagement in follow-up, particularly when outcomes are variable and affect quality of life. Furthermore, the numerous anatomical and functional factors influencing surgical outcomes make it

challenging to compare findings across different studies.

This investigation focuses on a cohort of patients who underwent ossiculoplasty with titanium prostheses, both with and without a hydroxyapatite head.

Materials and methods

Design of Investigation

All patients in this study underwent ossiculoplasty between January 2016 and February 2019 by a single surgeon at the National Research Center for Otorhinolaryngology of the Federal Medical Biological Agency of Russia. The study protocol was approved by the institution's ethics committee, and informed consent was obtained from all patients. A total of 300 patients undergoing 360 surgical procedures were included. Pre-operative assessments included general clinical evaluations, standard otolaryngological examinations, pure-tone audiometry, and temporal bone CT scans. All procedures utilized specified titanium prosthetic modifications. Post-operative evaluations assessed anatomical and functional outcomes and complications.

Pre-operative and post-operative audiological assessments included evaluation of the air-bone gap at frequencies of 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz. The mean follow-up duration was 18 months. Post-operative audiological assessments were performed at 2-3 months and 12 months, with the timing adjusted based on individual patient follow-up schedules.

Inclusion Criteria

Chronic otitis media; period of post-op follow-up is not less than 6 months; revision procedure at different time periods after first surgical procedure was performed on the basis of NRC for Otorhinolaryngology of the FMBA of Russia.

Exclusion Criteria

First surgical procedure with titanium prosthesis was performed in other medical establishments; extensive destructive processes associated with damage of middle ear structures, absence of dynamic checkup, defined by this investigation.

Primary Parameter of Investigation

Patient's age and gender; type of prosthesis used; etiology; type of surgical intervention

Follow-Up Parameters of Investigation

Consistency of neo-tympanic membrane, audiological results, complications (neo-tympanic membrane perforation, neo-tympanic membrane retraction, prosthesis extrusion, prosthesis dislocation, cholesteatoma recurrence).

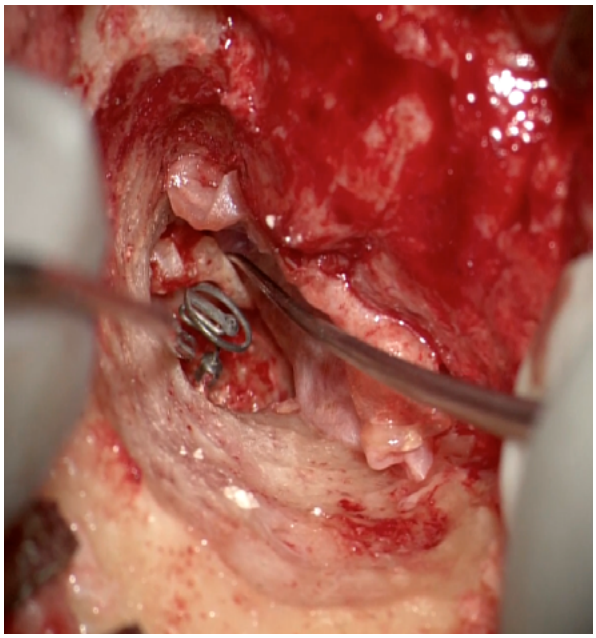
Surgical Treatment

All surgeries were performed using retroauricular access, employing either transmeatal, transmastoid, or combined approaches, all guided by surgical microscope. Detailed surgical procedures were meticulously documented. All patients presented with chronic otitis media, with or without cholesteatoma, resulting in ossicular chain destruction. Accordingly, the initial surgical stage involved thorough sanitation of the middle ear structures. The extent of the surgical intervention, ranging from transcanal attico-aditotomy to canal wall up or canal wall down procedures, was determined by the specific location and extent of the pathology, individual anatomical variations, the condition of the mucosa, ossicular chain, and mastoid pneumatization.

One-stage reconstruction of the ossicular chain was performed, even in cases with cholesteatoma. Two types of Audio Technologies prosthesis were employed: a fully titanium prosthesis and a prosthesis with a porous hydroxyapatite proximal section and a titanium distal section. Partial prostheses were used when the stapes was preserved, and a total prosthesis was implanted in cases where the stapes superstructure was absent. The presence or absence of the malleus did not affect the prosthesis type selection. The prosthesis length was intraoperatively determined via microscopic evaluation considering the patient's specific middle ear anatomy. The prostheses' extensibility allowed for adjustments in length from 1.5 to 5.5 mm (full titanium) to 2.5–5.0 mm (hydroxyapatite-titanium), and from 3 to 8 mm (full titanium) to 4–8 mm

(hydroxyapatite-titanium), depending on the specific needs of each patient.

Patients with titanium prosthesis with hydroxyapatite head (group A) were divided into 3 sub-groups: placing the soft tissue between facial tissue and the head of prosthesis (thinned layer of auto-cartilage (A1) or perichondrium (A2)) without using any additional materials (A3).



Fugure 1: Reconstruction of ossicular chain with partial titanium prosthesis

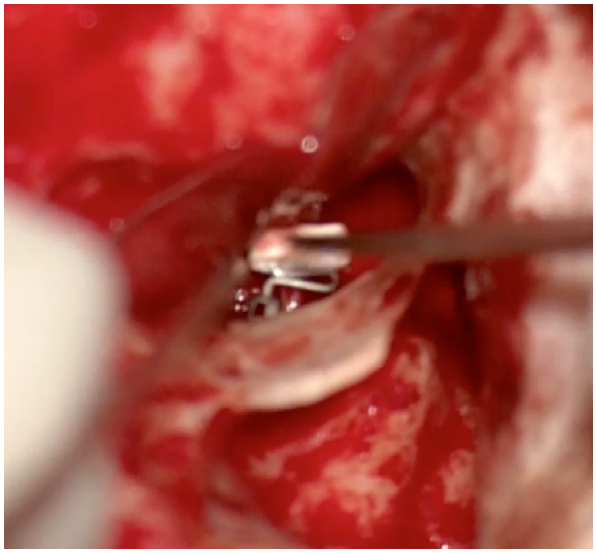


Figure 2: Reconstruction of ossicular chain with partial titanium prosthesis with hydroxyapatite head.

In all group B patients, a layer of autologous cartilage was placed over the head of the titanium (partial or total) prosthesis, which did not contain hydroxyapatite. The surgical procedure concluded with the application of temporal muscle fascia to seal any perforations (using an overlay or underlay technique) and the closure of the meatus and tympanic flap with skin.

A T-shaped plastic procedure was performed on the external auditory canal skin for patients undergoing sanitation and reconstruction. The external auditory canal was packed with gauze swabs soaked in Levomekol ointment or hemostatic swabs. All patients received topical otic drops containing Ofloxacin and Dexamethasone for two weeks in the operated ear.

Statistical Analysis

Results are represented as an average value +- standard deviation. Statistical analysis was made using software STATISTICA. The value of validity coefficient $p<0.05$ was considered as statistically meaningful.

Results

A total of 360 patients (247 adults and 113 children; 162 men and 85 women) were studied. The mean patient age was approximately 36 years (range 7-58 years). Patient groups were categorized based on the safe/unsafe type of the underlying disease process. Ossiculoplasty was performed as the primary procedure in 258 cases (71.7%) and as a secondary procedure in 102 cases (28.3%). Partial titanium prostheses were used in 217 cases (50%), and total titanium prostheses in 143 cases (50%), reflecting the absence of stapes supra-structures in the latter group.

Surgical findings revealed incus absence in 94 cases (26.1%) and lysis of the incus long process in 143 cases. Malleus integrity was observed in 82 cases (22.8%), while 278 cases (77.2%) demonstrated malleus erosion. Stapes absence was noted in 4 cases (1.1%). The mean prosthesis length was 2.5 mm for partial prostheses and 4 mm for total prostheses.

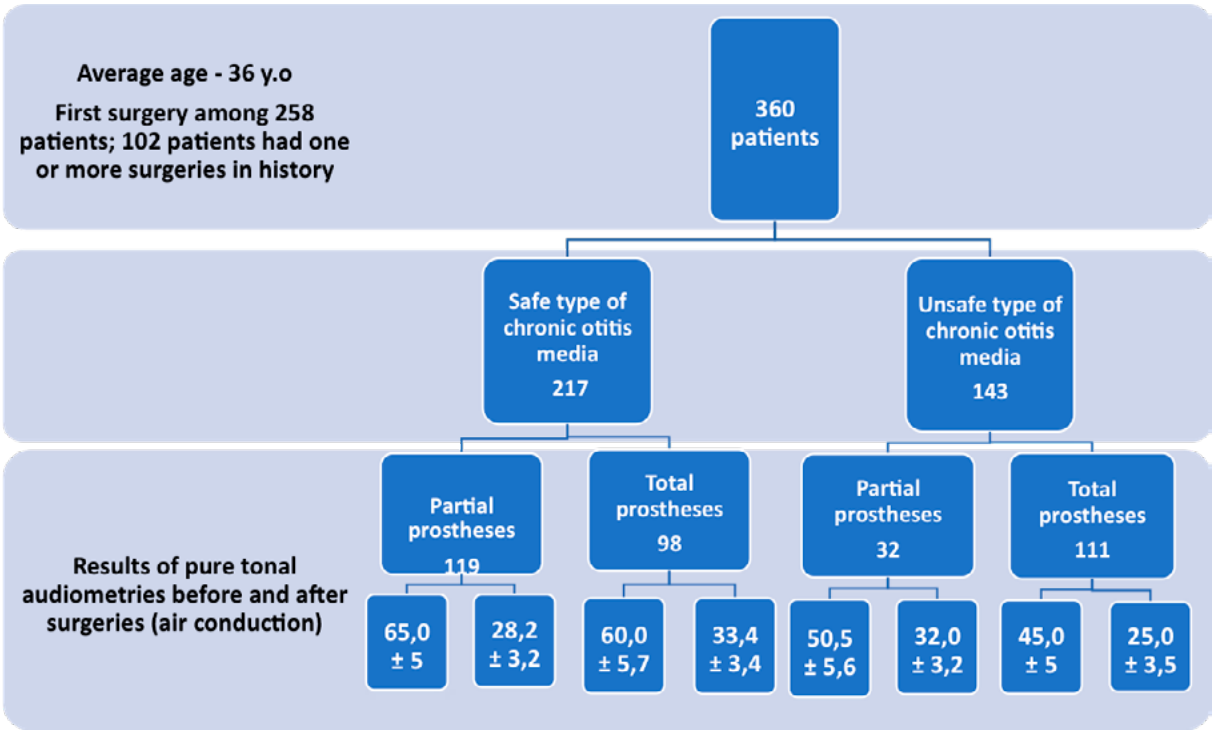


Table 1: Patients Characteristics

Anatomical results

A satisfactory anatomical outcome after surgery was defined as a flexible, inflated neo-tympanic membrane, while membrane defects or retraction were considered unsatisfactory.

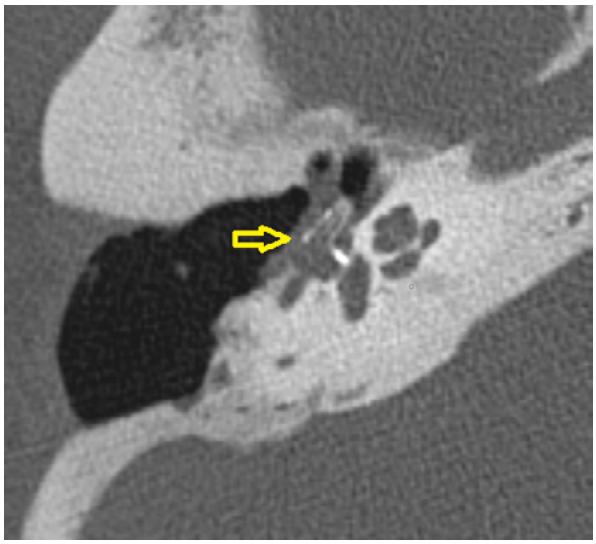


Figure 3: CT scan of the right ear, performed 8 months after ossiculoplasty using a titanium prosthesis.

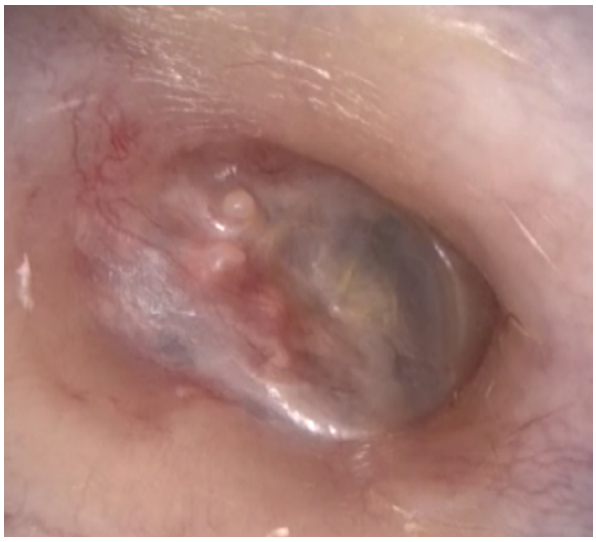


Figure 4: Condition after reconstruction surgery with ossiculoplasty using total titanium prosthesis with hydroxyapatite head (TAP-A3).

Otomicroscopic examination showed the Migration of auto-cartilage layer from the head of the prosthesis in 6 cases. Sustainability of neo-tympanic membrane during the whole period of observation was registered in 333 cases .

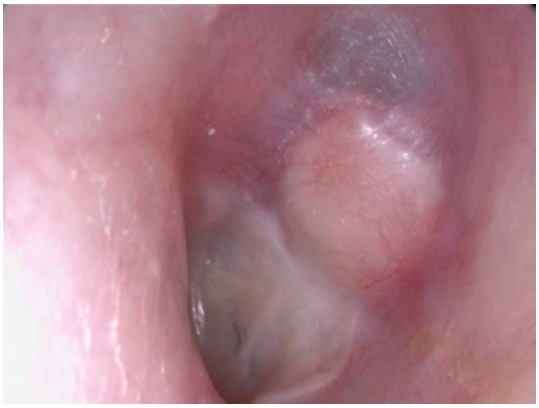


Figure 5: Condition after tympanoplasty using titanium prosthesis with auto-cartilage layer (8 month post-op).

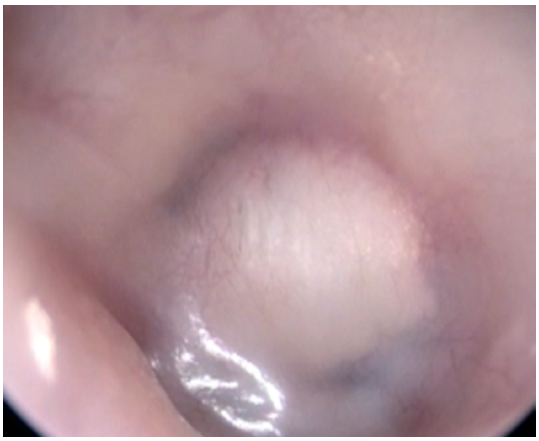


Figure 6: Condition after tympanoplasty with ossiculoplasty using partial titanium prosthesis with auto-cartilage layer (1 month post-op).

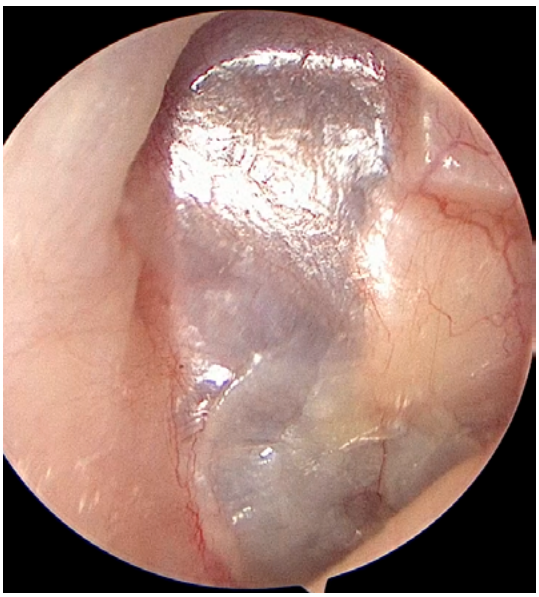


Figure 7: Condition after tympanoplasty with ossiculoplasty using partial titanium prosthesis with auto-cartilage layer (1 year post-op).

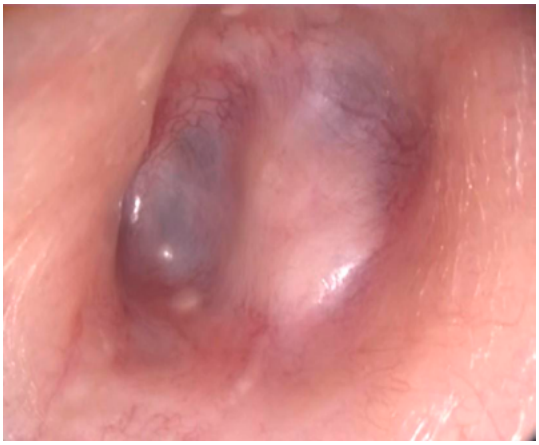


Figure: Condition after tympanoplasty with ossiculoplasty using partial titanium prosthesis with auto-cartilage layer (6 month post-op).

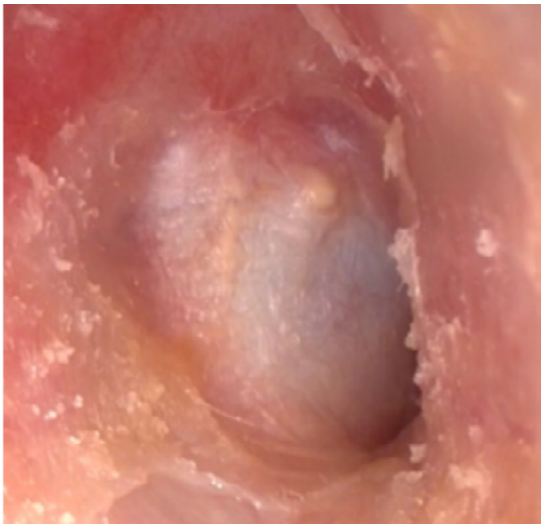


Figure: Condition after tympanoplasty with ossiculoplasty using partial titanium prosthesis with hydroxyapatite head without cartilage layer (1 year post-op).

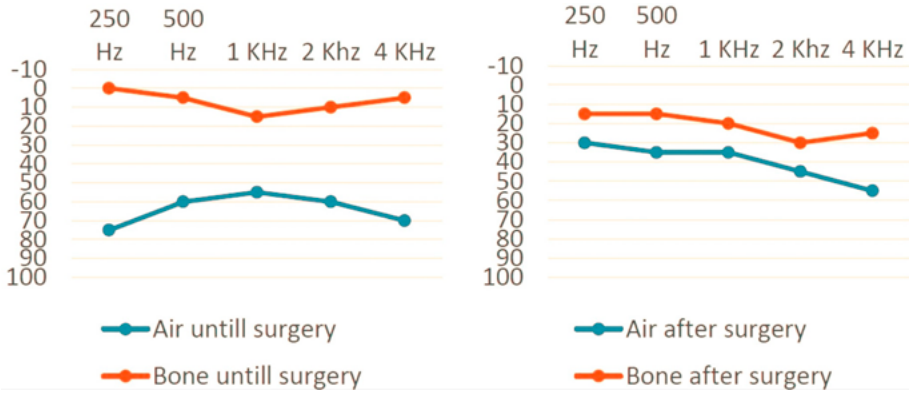
Functional results

Middle ear pathologies impair sound transmission from the outer to inner ear, leading to elevated air conduction hearing thresholds. However, bone conduction thresholds remain normal due to preserved inner ear and neural pathways. This difference in thresholds, known as the air-bone gap, is depicted on audiograms. A significant reduction in the air-bone gap (20 dB or more) signifies a positive outcome, while a gap of less than 20 dB is considered satisfactory. A static air-bone gap indicates an unsatisfactory outcome.

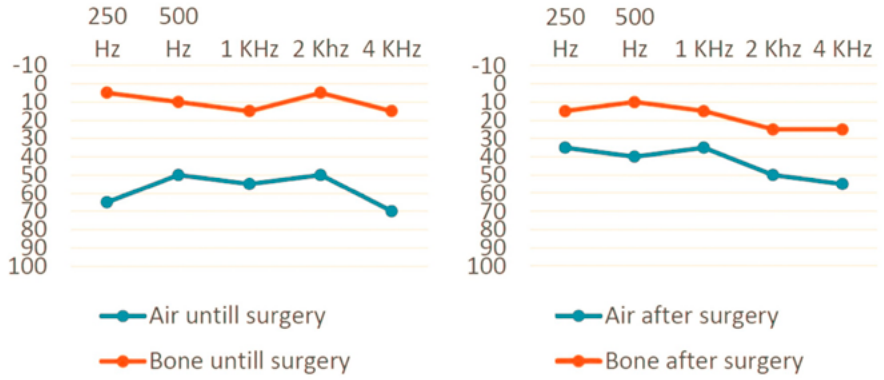
Six to eight months post-operatively, the average air-bone gap was 20-25 dB. A clini-

cally significant improvement (air-bone gap reduction of 20 dB or greater), indicating a positive result, was achieved in 75% of all patients. Within group A, 40.2% and in group B, 25.8% demonstrated this improvement. Furthermore, statistically significant differences were observed in the use of partial and total prostheses in both groups after 6-8 months, suggesting an important correlation between prosthesis type and outcome.

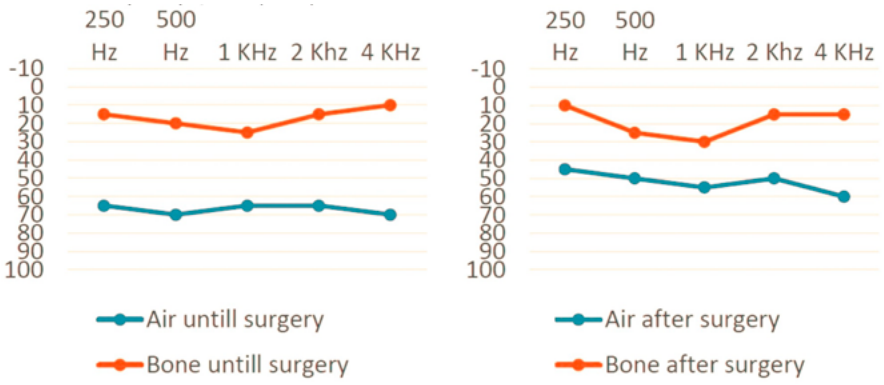
Average air conduction was at 60 ± 5, 6 dB before surgery and significantly decreased to 32, 0 ± 3,2 dB in 6-8 months postoperatively among the patients who underwent tympanoplasty with reconstructive intervention and installation of total and partial prostheses with hydroxyapatite (n=30).



Average air conduction was at 50 ± 5 dB before surgery and decreased to 30, 0 ± 3, 5 dB in 6-8 months postoperatively among the patients who underwent tympanoplasty with reconstructive intervention and installation of total prostheses without hydroxyapatite (n=90).



Average air conduction was at 65 ± 5,6 dB before surgery and decreased to 27,3 ± 3,2 dB in 6-8 months postoperatively among the patients who underwent tympanoplasty with reconstructive intervention and installation of partial prostheses with hydroxyapatite (n=30).



Average air conduction was at 65 ± 5,6 dB before surgery and decreased to 25,0 ± 5 dB in 6-8 months postoperatively among the patients who underwent tympanoplasty with reconstructive intervention and installation of partial prostheses without hydroxyapatite (n=90).

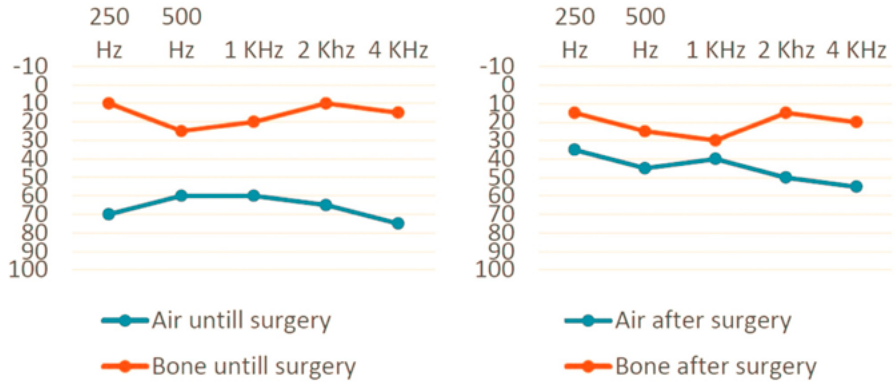


Table 2: Post-Operative Complications

Complications depending on the type of prosthesis	Group A (with hydroxyapatite)						Group B (fully hydroxyapatite)	
	TAP (A1)	PAP (A1)	TAP (A2)	PAP (A2)	TAP (A3)	PAP (A3)	TAP	PAP
Neo Tympanic Membrane perforation	0,83%	0,56%	0,28%	0,28%	0	0,28%	3,33%	1,94%
Neo Tympanic Membrane retraction	0,56%	0	0,28%	0	0,28%	0	0,83%	0,56%
Prosthesis extrusion	0	0	0	0	0	0	1,11%	1,67%
Prosthesis dislocation	0	0	0,28%	0	0	0	0,28%	0,56%
Cholesteatoma recurrence	0,28%	0	0,28%	0,28%	0	0	1,39%	0
Repetition of tympanoplasty	0,83%	0,56%	0,56%	0,28%	0	0,28%	4,17%	2,5%
Revision surgeries	1,11%	0	0,83%	0	0,28%	0	2,78%	0,56%

Discussion

Chronic suppurative otitis media, often complicated by cholesteatoma, remains a significant clinical challenge, frequently leading to ossicular chain disruption and hearing loss (Sevik et al., 2017). Surgical intervention for these cases can encompass sanitation, tympanoplasty, and ossiculoplasty in a single procedure (Lahlou et al., 2018). The success of ossiculoplasty depends on factors including the duration and severity of the disease, prior surgeries, surgical technique, and surgeon expertise. Advances in surgical techniques and instrumentation have improved hearing outcomes in recent decades. The chosen os-

sicular reconstruction method is also crucial, with various prosthesis designs and materials available (Sitnikov et al., 2006). However, no single prosthesis consistently and completely closes the air-bone gap (Lee J-I et al., 2015). This study aims to compare the effectiveness of titanium prostheses with hydroxyapatite heads versus fully titanium prostheses in patients undergoing middle ear reconstruction for chronic suppurative otitis media. Titanium's light weight, strength, and excellent sound transmission properties are advantages in this application (Coffey et al, 2008). Patients with titanium prostheses can safely undergo 1.5-3 Tesla MRI scans of the brain, a crucial consideration for individuals with extensive cholesteatoma (Mileshina et al., 2011). When using fully titanium prostheses, cartilage interposition between the prosthesis head and the neotympanic membrane is necessary. While cartilage interposition helps reduce, it does not completely eliminate extrusion of alloplastic materials. This study observed implant extrusion in two cases (1.7%) within group B. The amount of cartilage used can vary based on surgeon preference, but increasing its size does not consistently improve acoustic outcomes and may even worsen low-frequency performance (Truy et al., 2007). Smaller cartilage grafts appear to correlate with better acoustic outcomes (Hales et al., 2007). Experimental data suggest that an optimal cartilage thickness of 0.3 to 0.5 mm, similar to the natural tympanic membrane, yields optimal vibration values. This study consistently used 0.5 mm thick conchal cartilage. Insufficient prosthesis length, particularly for TORP implants, was associated with poorer functional results and secondary displacement (Zhang et al., 2011). Using titanium prostheses with hydroxyapatite heads and adjustable length reduces surgical time and avoids the need to obtain additional material (Pringle et al., 2014). Bioactive ceramic prostheses (calcium hydroxyapatite) do not require a separate layer of autologous cartilage; the neo-tympanic membrane is placed directly onto the prosthesis head (Rondini-Gilli E. et al., 2003). No prosthesis extrusion was observed in group A (using titanium prostheses with hydroxyapatite heads) during the 12+ months of follow-up. The use of titanium middle ear prosthesis facilitates a stable and improved hearing outcome (Lee J-I et al., 2015) (Lahlou et al., 2018) (Rondini-Gilli E. et al., 2003). Our study, like others, found better results with partial ossicular prostheses (PORP) than with total ossicular replacement (TORP) (Vincent et al., 2011). Canal wall down procedures with total ossicular replacement (TORP) prostheses, compared to canal wall up procedures and partial ossicular replacement (PORP), show lower success rates (Daikhes et al., 2017). Preservation of the posterior canal wall and the stapes superstructure is crucial for stable middle ear prosthesis placement, as demonstrated in this study.

Limitations of the Study

Several limitations affect this study. A primary limitation is the relatively small sample size. Individual middle ear anatomy and surgical scenarios vary considerably, making it difficult to ensure adequate representation of different cases within each group. Furthermore, surgical findings often evolve during the procedure, dynamically altering the situation and complicating comparisons. Finally, a longer follow-up period, along with analyses of different implant types and patient characteristics, are necessary for a more comprehensive understanding of the long-term stability and durability of ossiculoplasty. The lack of strict randomization further limits generalizability.

Conclusions

Our study found some differences in postoperative hearing outcomes with titanium prostheses featuring hydroxyapatite heads, but both types of prostheses yielded good functional results. Surgical preference, experience, and availability of materials can guide prosthesis selection. Further, large-scale, long-term, randomized controlled trials are necessary to definitively establish the differences between the two types of prostheses.

Disclosure of interest

The authors declare that they have no conflicts of interest.

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