

Effectiveness of Ossiculoplasty with Adjustable Classical Titanium Prostheses and Titanium Prostheses with Porous Hydroxyapatite in Patients with Chronic Otitis Media

K.M. Diab^{1,2,*}, N.A. Daikhes^{1,2}, O.A. Pashchinina¹, A.G. Zukhba¹ and O.S. Panina¹

¹Federal Research Clinical Center of Otorhinolaryngology of Federal Medical Biological Agency of Russia, 123182, Moscow, Russia

²Department of Otolaryngology, Faculty of Postgraduate education, Pirogov Russian National Research Medical University, 117197, Moscow, Russia

Abstract: The aim of this investigation is the comparison of anatomical and functional results in case of reconstruction of middle ear bones' chain using classical titanium prosthesis and titanium prosthesis with hydroxyapatite layer. Retrospective analysis was performed.

In modern otosurgery performing the main stage of surgery (scar resection, elimination of retraction pockets, elimination of tympanic membrane defects, sanitation) and reconstruction of middle ear bony chain during one procedure is an actual standard. In this case effectiveness of middle ear sound conducting system's reconstruction is quite unpredictable. Different factors can influence the results of surgery: etiology of pathological process, intraoperative findings and peculiarities of surgical technique, design and mechanical properties of prosthesis, ways of ventilation in tympanic cavity or artificially created small tympanic cavity, intensity of scar processing in early and late post-operative period etc.

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

Starting from the 20th century investigations have been performing with the aim to choose the best method of anatomical ear structures' reconstruction and creation of ideal middle ear bones' prosthesis. Periodically preferences were made to some of materials: auto cartilage, allograft model.

Ideal ossicular prosthesis ought to produce sound characteristics very similar to those reproduced by human middle ear bones' chain, it ought to be biologically inert (not to cause inflammatory reaction or neoplasia), at the same time it ought to keep its structural integration and stability in its fixed position for a long-term period, it ought to be resistant to the changes of static pressure in middle ear cavities.

There are more than 18 companies producing prostheses worldwide, and there are more than 80 modifications. Ossicular prosthesis can be differentiated according to the form of bones they replace, materials (titanium, hydroxyapatite, bony cement, polyethylene composite, strengthened with hydroxyapatite (HAPEX), composition of materials etc), number of elements, length and openness of construction, some prostheses are differentiated by the way of preparation and installation, by methods of

fixation. In spite of big variability none of modern prostheses gives predictable result of full coverage of air-bone interval. Absence in literature of long term (2 years and more) outcomes in large samplings for titanium prostheses and bio-compound materials is conditional on low patients' engagement to the treatment process (especially in cases of distinctive results and therefore life quality) and difficulties in proper follow up. Taking into consideration quite a large number of factors, influencing the outcome of surgical intervention (anatomical and functional ones) the results of investigations observed in literature are also very heterogeneous and difficult for comparison

In our investigation we chose the group of patients who underwent the procedure of ossiculoplasty with titanium prostheses with and without hydroxyapatite head.

MATERIALS AND METHODS

Design of Investigation

All patients included in this investigation were operated during the period of January 2016 – February 2019 by one surgeon in the department of ear diseases in Scientific Clinical Center of Otorhinolaryngology Federal Medical Biological Agency of RF.

The investigation is approved by ethical committee of medical establishment; informational consents for

*Address correspondence to this author at the Department of Otolaryngology, Faculty of Postgraduate education, Pirogov Russian National Research Medical University, 117197, Moscow, Russia; Tel: +79191013300; E-mail: hasandiab@mail.ru

data processing were signed. 360 surgical procedures, 300 patients were included into the investigation. General clinical, standard ENT examination, pure tone threshold audiometry, temporal bone CT-scan was performed at pre-operative stage. Titanium prostheses of indicated modifications were used in all cases. Post-operative examination included evaluation of anatomical and functional results and complications.

During audiological examination air-bone gap difference at 500, 1000, 2000 and 4000 Hz was evaluated in pre-op and post-op periods. Average time for post-op follow up was 18 months.

Repeated audiological examinations were performed after 2-3 and 12 months post-op depending on patients' appearance.

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 Scientific Clinical Center FMBA RF

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, cholesteotoma recurrence)

Limitations of the Study

We encounter certain limitations of the study, the most important is regarding the sample size as each middle ear is different and there are many different situations that sufficient representation in each group cannot be ensured. Also the middle ear findings unfolds while progressing the surgery so the situation and conditions changes. The next is duration of follow-

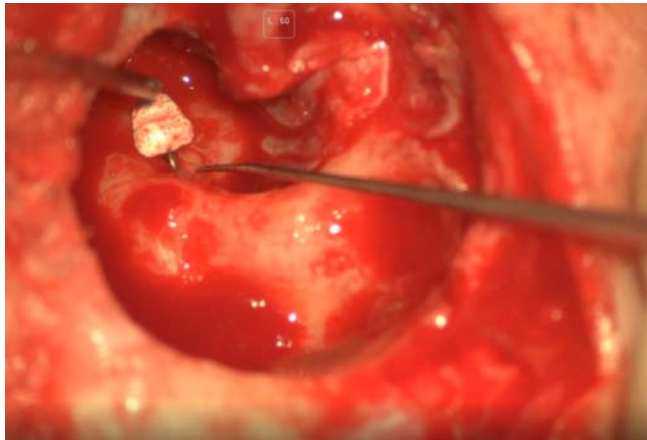
up, long term results and analysis of different implants and situation are necessary to improve our knowledge and understanding of stability and durability of ossiculoplasty. Third is inability to follow strict randomization.

Surgical Treatment

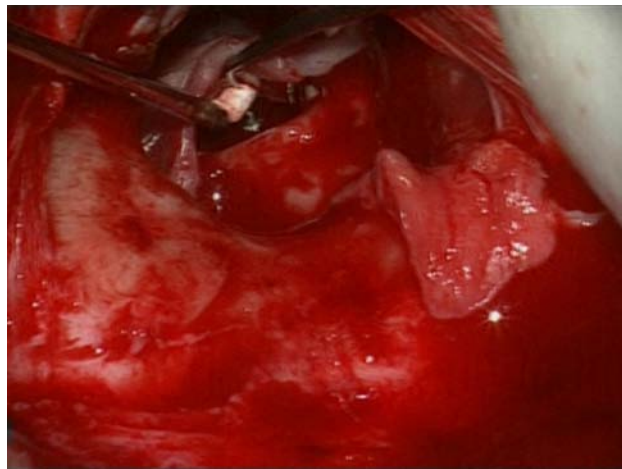
All surgeries were performed via retro-auricular access using trans-meatal, trans-mastoid or combined approach controlled with the help of surgical microscope. Steps of surgical intervention were documented. In all cases the etiological agent was chronic otitis media with or without cholesteotoma, which caused ossicular chain destruction, so on 1st stage of surgery sanitation of all structures and zones of middle ear was performed. Volume of surgical intervention was defined by localization, occurrence of pathological process, anatomical peculiarities of middle ear structures, condition of mucosa, ossicular chain, level of mastoid pneumatization and was varied from transcanal atticotomy, to canal wall up and canal wall down surgeries.

Reconstruction of sound conducting system was performed in one stage, even in case of cholesteotoma presence. 2 types of extensible total and partial prosthesis manufactured by Audio Technologies were used in investigation: classical fully titanium prosthesis and prosthesis with proximal part made of porous hydroxyapatite and distal part made of titanium. Partial titanium prosthesis was placed at stapes' head in case of its preservation and positive transmission to secondary cochlear window membrane. Total titanium prosthesis was placed directly to stapes footplate in case of stapes' supra-structure absence. Presence or absence of malleus or its part was alternative and did not influence the choice of prosthesis' type. The length of prosthesis was determined in the operation room using microscopic magnification and taking into consideration anatomical features of patient's middle ear structure. Extensibility of prosthesis' stem allowed to make length's correction for several times (from 1,5 to 5,5 mm PAP classical titanium; PAP with hydroxyapatite 2,5 – 5,0 mm; from 3 to 8 mm TAP classical titanium, TAP with hydroxyapatite 4-8 mm).

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)



Picture 1: Reconstruction of ossicular chain with total titanium prosthesis with hydroxyapatite head.



Picture 2: Reconstruction of ossicular chain with partial titanium prosthesis with hydroxyapatite head. Layer of auto-cartilage was placed on the head of titanium partial or total prosthesis without hydroxyapatite for all patients from group B. The final stage of surgery was placement of temporal muscle fascia to close perforation (overlay, underlay) meatus-panum flap, skin flap.

T-shaped plastic procedure for external auditory channel's skin was performed in case of sanitation reconstructive surgery. Packing of external auditory channel with gauze swab using Levomikol ointment or hemostatic swab. All patients used ear drops Ofloxacin+Dexametazon for 2 weeks locally in 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.

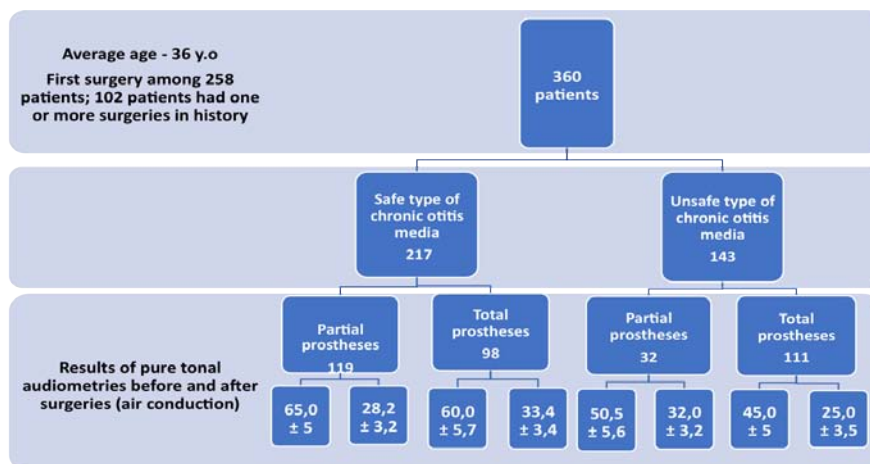
RESULTS

247 adults and 113 children, 162 men and 85 women. Mean age of patients was +36 y.o. (from 7 y.o. to 58 y.o). Etiology of the process was divided into two principal groups safe type and unsafe type.

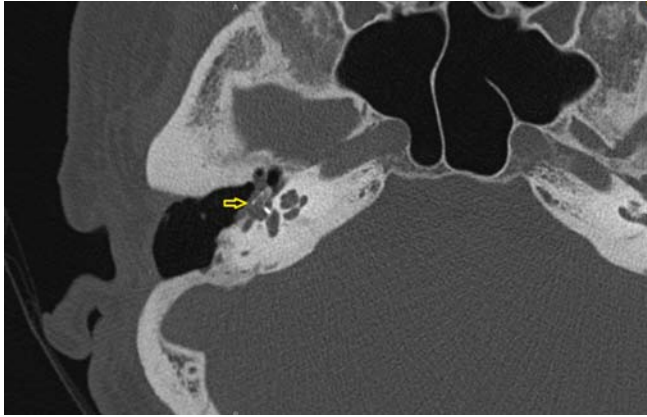
Ossiculoplasty was performed during the first surgical intervention in 258 cases (71,67%) , during the secondary surgical interventions in 102 cases (28,33%). In 217 cases (50%) partial titanium prostheses were used, in 143 cases (50%) total titanium prostheses were used due to the absence of stapes supra-structures.

Operational findings: incus was absent in 94 cases (26, 11%), lyses of long process of incus was observed in 143 cases. Malleus was intact in 82 cases (22, 78%), malleus erosion was in 278 cases (77,2%). Stapes was absent in 4 cases (13, 33%). (Average length of prosthesis was 2,5 mm in case of using partial titanium prosthesis, and 4 mm in case of using total titanium prosthesis).

Table 1: Patients Characteristics



ANATOMICAL RESULTS



Picture 3: CT after reconstructive surgery with ossiculoplasty on the right ear using titanium prosthesis 8 months postoperatively.

It was agreed to consider sustainable neo-tympanic membrane flexible during inflation as a satisfactory anatomical result and defects' formation, retraction of neo-tympanic membrane – as non-satisfactory result.



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



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

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



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



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



Picture 8: Condition after tympanoplasty with ossiculoplasty using partial titanium prosthesis with auto-cartilage layer (6 month post-op).



Picture 9: Condition after tympanoplasty with ossiculoplasty using partial titanium prosthesis with hydroxyapatite head without cartilage layer (1 year post-op).

FUNCTIONAL RESULTS

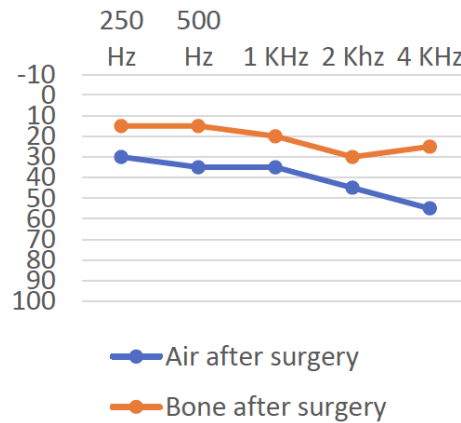
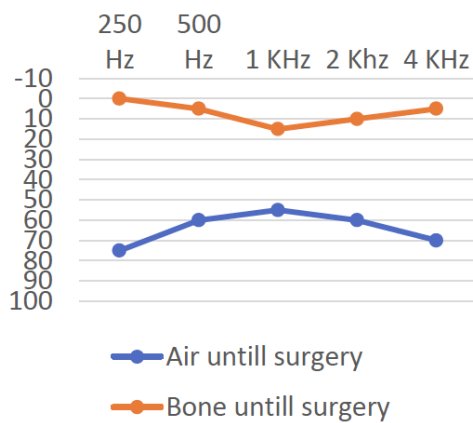
In case of middle ear pathology sound transmission from outer ear to inner ear is compromised, due to this air conduction hearing thresholds are increased. At the Audiological results are represented in diagram

same time, bone conduction thresholds are at normal levels due to inner ear structures and neural pathway preservation. Difference in thresholds between air and bone signal transmission is indicated in audiogram as air-bone gap.

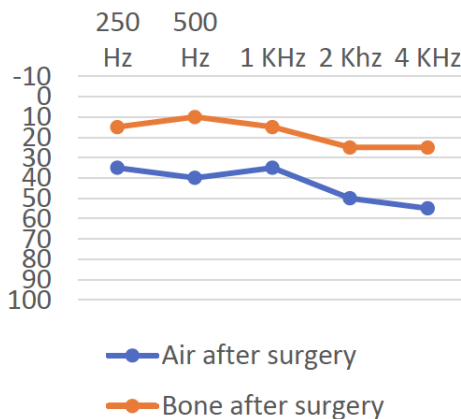
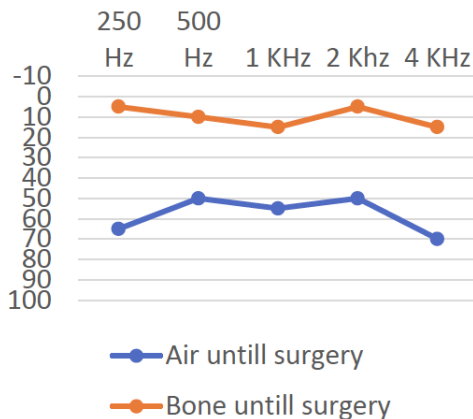
Decrease of air-bone gap in 20 dB and more is considered to be good and perfect results. Decrease of air-bone gap less than 20 dB is considered as satisfactory result. Air-bone gap without dynamics is considered as non-satisfactory result.

Mean value of air-bone gap was 20-25 dB 6-8 months post-operatively. Good result (in case of air-bone gap decrease in 20 dB and more) was achieved in 75% of patients, 40, 2% - in group A, 25, 8% - in group B.

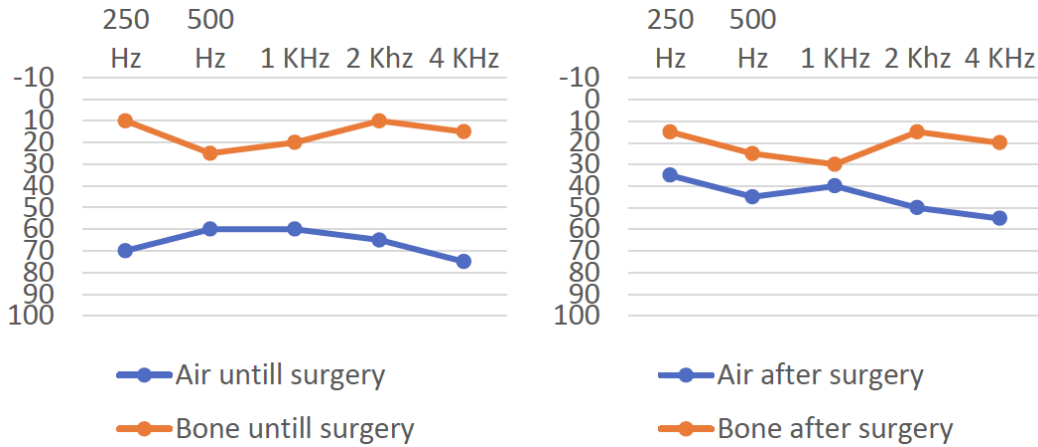
Statistically meaningful difference was found in cases of using partial and total prostheses in both groups 6-8 months post-operatively:



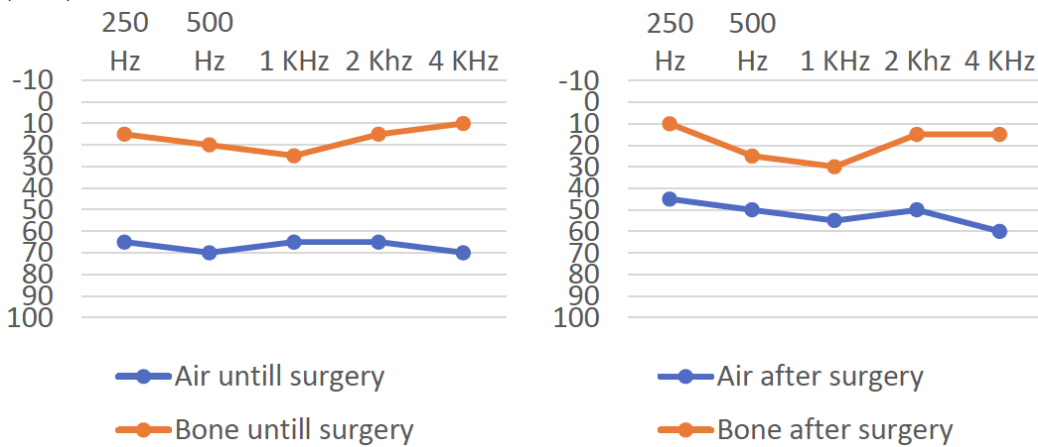
Average air conduction was at $60 \pm 5, 6$ dB before surgery and significantly decreased to $32, 0 \pm 3, 2$ dB in 6-8 months post-operatively among the patients who underwent tympanoplasty with reconstructive intervention and installation of total and partial prostheses with hydroxyapatite (n=30).



Average air conduction was at 50 ± 5 dB before surgery and decreased to $30, 0 \pm 3, 5$ dB in 6-8 months post-operatively 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 post-operatively 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 post-operatively 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-tympanicmembrane perforation	0,83%	0,56%	0,28%	0,28%	0	0,28%	3,33%	1,94%
Neo-tympanicmembrane 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, with and without cholesteatoma, still represents a large percentage in every day otologic practice. It frequently results in disruption of the ossicular chain and different types of hearing loss. For these patients surgical treatment could be provided during one operation, consisting of sanation, tympano- and ossiculoplasty. Success in ossiculoplasty is determined by duration of pathological process, its extension and aggression, surgeries in history, surgical technique, technical abilities and experience of the surgeon. With the evolution of new surgical techniques and advances in the instruments available to the otologists, the hearing outcome of ossiculoplasty has shown a noticeable improvement during last decades of years. Equally important for success - type of ossicular chain reconstruction. A wide range of prosthesis designs and materials has been used for reconstruction in middle-ear surgery. But until this time there is no ideal prosthesis, providing full stable closure of air-bone gap. The present study was designed to compare the outcome using titanium prostheses with hydroxyapatite head and fully titanium prosthesis in two groups of suitable patients presenting with chronic suppurative otitis media for middle ear reconstructive surgeries. Titanium has insignificant weight and construction's robustness, and what is most important – good sound conduction. Patients with titanium prostheses can undergo 1,5-3 Tesla MRI procedures of brain, what is very important in cases of extended cholesteatoma process. In case of fully titanium prosthesis use it is necessity to place the cartilage between the prosthesis head and the neotympanic membrane. Meanwhile cartilage interposition between the prosthesis and the tympanic membrane is able to reduce but not eliminate extrusion in alloplastic materials. In the present study, we noted implant extrusion in two cases (1.7%) in group B. The size of cartilage cover could be also variable depending on the surgeon. Increasing cartilage size does not improve the acoustic results, and can even make them worse at low frequencies. Smaller cartilage pieces seem to have a better acoustic result. Experimental studies suggested that a thickness between 0.3 and 0.5 mm is optimal, as vibration values are then similar to those of a natural tympanic membrane. We have used a conchal cartilage of 0.5 mm thickness in every case. On the other side, insufficient length of the construction (prosthesis with cartilage), especially TORP, explained poorer functional results and secondary displacement. Using titanium prostheses with hydroxyapatite head and extensible length allows

decreasing the time of surgical intervention, additional taking of material is not required. Prostheses with head from bioactive ceramics on the basis of calcium hydroxyapatite do not require installation of auto-cartilage layer; neo-tympanic membrane is placed directly on the head of prosthesis. No cases of prosthesis' extrusion were registered in group A during the period of patients' observation (12 months and more post-operatively) who underwent ossiculoplasty using titanium prosthesis with hydroxyapatite head. Forming of sustainable signal transmission system using titanium middle ear prostheses allows to achieve stabile hearing improvement. In our studies there're was division among the groups on partial and total prostheses. All studies including ours have found better results with PORP compared to the TORP prosthesis. Compared to canal wall up procedures and the use of PORP prostheses, combination of the canal wall down situation and the TORP prosthesis is associated with lower rates of success. The preservation of the posterior canal wall and the stapes superstructure are both factors in our material that promote stability for the middle ear prosthesis.

CONCLUSION

Our study showed some difference in postoperative hearing results and benefits in use of titanium prostheses with hydroxyapatite head. But both types of prostheses gave good functional results and surgeon can choose any types of prostheses by personal preference, experience and availability. Further randomized controlled long-term trials with large sample sizes are needed to establish the difference exactly.

DISCLOSURE OF INTEREST

The authors declare that they have no competing interest.

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