

Audiological Results of Total Ossicular Replacement Prosthesis with Cartilage Shoe Technique

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Original Investigation

Abstract

Objective: The aim of this study was to investigate functional results of total ossicular replacement prosthesis (TORP) shaft stabilization with a cartilage shoe in chronic otitis media patients with cholesteatoma who had undergone canal wall down tympanomastoidectomy (CWDT). In addition, it was determined whether the presence of granular and edematous mucosa in middle ear altered functional outcomes.

Methods: Sixty patients, who had undergone CWDT with the use of TORP for the reconstruction of ossicular chain, were divided into two groups. Patients with cartilage shoe were classified as Group 1 (n=30) and those without the shoe were classified as Group 2 (n=30). Patients in both groups were classified into "A" and "B" subgroups according to the middle ear risk index (MERI). Air conduction (AC) and bone conduction thresholds were evaluated preoperatively and postoperatively.

Results: There was no statistically significant change between preoperative AC thresholds of the groups

and subgroups ($p>0.05$). There were statistically significant differences regarding AC thresholds and air-bone gap (ABG) values between Groups 1 and 2 at the postoperative 12th month ($p<0.05$). Postoperative AC thresholds and ABG values of Group 1B patients with a high MERI score were statistically significant at all frequencies than those of Group 2B patients ($p<0.05$). When ABG values were compared, it was observed that functional results were better in Group 1B, but a statistically significant difference was observed only at 2000 Hz ($p<0.01$).

Conclusion: The cartilage shoe method for titanium TORP stabilization that is used for ossicular reconstruction during CWDT has been found to have a beneficial effect on auditory outcomes. Cartilage shoe application increases positive effects on hearing outcomes, particularly if the middle ear mucosa is granular and edematous.

Keywords: Cholesteatoma, tympanoplasty, ossicular prosthesis, cartilage

Introduction

Chronic otitis media involves chronic inflammation of the middle ear. Tympanic membrane perforation and/or otorrhea lasting for at least 3 months accompany chronic otitis media. Chronic otitis media with cholesteatoma (COMC) is a disease characterized by epithelial proliferation that causes keratin production in the middle ear, which may also be a source for irreversible alterations in the surrounding tissues. It is divided into two groups, congenital and sporadic, and its treatment is surgical. "Canal wall down" and "canal wall up" tympanomastoidectomies performed during surgical treatment of cholesteatoma have been compared for a long time with respect to hearing outcomes in terms of their recurrence and success rates. Both techniques have advantages and disadvantages. In canal wall down tympanomastoidectomy (CWDT), to completely remove the cho-

lesteatoma, the posterior wall of the external ear canal up to the level of the facial nerve is removed and the middle ear and mastoid cavity become one common cavity (1). It was reported that because of these structural changes, hearing outcomes might have been negatively affected (1, 2). However, Cook et al. (3), Kim et al. (4), and Azevedo et al. (5) reported that canal wall down and canal wall up mastoidectomy techniques were not superior to each other with respect to hearing outcomes, whereas Tos and Lau (6) determined that hearing outcomes were superior with the canal wall down technique.

During ossiculoplasty, the presence of stapes suprastructure increases auditory gains. In the presence of a mobile oval window (footplate) in patients without a stapes suprastructure, providing a columella between the graft/malleus and oval win-



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Cite this article as: Kaplankıran H, Ceylan ME, Aksoy Yıldırım G, Ceylan G, Dalğıç A, Olgun L. Audiological Results of Total Ossicular Replacement Prosthesis (TORP) with Cartilage Shoe Technique. Turk Arch Otorhinolaryngol 2018; 56(2): 95-101.

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Received Date: 08.01.2018

Accepted Date: 20.02.2018

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DOI: 10.5152/tao.2018.3200

dow is required. As a result of quests for prosthesis with high biocompatibility and functional advances, titanium prosthesis began to be used more frequently (7).

In cases without a suprastructure that were supposed to have less auditory gains, many techniques were defined for establishing and preserving hearing in the long-term. Fisch and May (8) recommended prosthesis with a spike-like protrusion on the base for strengthening footplate connection. Cox et al. (9) suggested the use of a titanium "footplate shoe" on an oval window. The main common feature of these techniques is to provide a more stable graft-footplate connection. After ossiculoplasty, decreases in auditory gain may be observed during early and late periods. In the healing period, disposition of the prosthesis due to contractures that may be seen in the middle ear is one of the main reasons for failure during the late period (10).

In this study, we investigated effects of titanium prosthesis shaft stabilization with a cartilage shoe in the oval window in patients with COMC who had undergone CWDT operation with the usage of total ossicular replacement prosthesis (TORP) on auditory functions in early and late periods. We also aimed to determine whether the presence of granular and edematous mucosa in the middle ear altered functional outcomes.

Methods

Participants

Patients who were operated for COMC in the department of Otorhinolaryngology of University of Health Sciences İzmir Bozyaka Research and Training Hospital, who were diagnosed with the destroyed stapes suprastructure during the preoperative period with otomicroscopic evaluation and/or during surgery, who had primary CWDT, and in whom TORP was used for hearing reconstruction were included. This study was approved by our local ethics committee and adhered to the principles outlined in the Declaration of Helsinki.

The patients were randomly divided into two groups: the group with the cartilage shoe technique performed for TORP or that with the cartilage shoe technique not performed. All surgeries were performed by the first and the sixth authors of the study. Informed consent was obtained from all patients during the preoperative period. Using the silent cabined audiometry device with the 125–12000 frequency area (IAC Acoustics IL, USA), tonal audiometry was performed; the measurement of the speech discrimination score was performed using a phonetically balanced monosyllabic word list. Axial and coronal section computed tomography of the temporal bone was performed. During surgeries, localization and dimensions of cholesteatoma and the conditions of the mesotympanum mucosa and ossicles were recorded. Because the condition of the middle ear mucosa was aimed to be the only variable between two patient groups, patients with chronic otitis media without cholesteatoma, patients with recurrent or residual cholesteatoma, and patients with complicated chronic otitis were not included in the study. A total of 60 patients were included in the study, and they

were divided into two groups depending on the usage of cartilage shoes. The group in which the cartilage shoe was used was named as Group 1 (n=30), whereas the group in which TORP was inserted using the classical method was named as Group 2 (n=30). Patients in both groups were classified according to the middle ear risk index (MERI), considering the condition of the middle ear mucosa and the presence of ongoing ear discharge (11). Groups 1 and 2 were further subgrouped as A and B. Subgroup "A" was classified as having low risk according to MERI, whereas subgroup "B" was classified as having high risk according to MERI, and the functional outcomes of the groups were compared.

For evaluation of localization and extent of cholesteatoma in patients, the system advised by Lau et al. (12) and Saleh et al. (13) was used.

Randomization

Randomization was performed in blocks of two using random numbers. Subjects with MERI <5 were assigned randomization numbers in an ascending sequential order using the lowest numbers available. Subjects with MERI >5 were assigned randomization numbers in a descending sequential order. Patients with MERI ≤5 were regarded as a low-risk group, whereas those with MERI >5 were regarded as a high-risk group.

Surgical technique

In all patients, mastoidectomy was performed, and the posterior wall of the external ear canal was removed to the level of the facial nerve. After completely cleaning the cholesteatoma, ossiculoplasty and tympanoplasty were performed. A perichondrium-cartilage composite graft was used for reconstruction of the tympanic membrane.

Cartilage peace was prepared from the conchal cartilage according to dimensions of the oval window. Using an aspirator tip with a lumen diameter of 0.25 mm, a hole was drilled in the middle of this cartilage to get into the TORP shaft (Figure 1). Cartilage shoe was prepared using the Huttenbrink method (14) after insertion of a titanium TORP into the cartilage shoe in a way that it could move easily (Figure 2). Subsequent to the exertion of the previously inserted perichondrium-cartilage composite graft, TORP with the shoe was inserted in the oval window niche (Figure 3).

In patients with stable manubrium mallei, contact of the prosthetic platform with manubrium was achieved. The prosthetic platform was completely covered by the island-shaped cartilage part of the perichondrium-cartilage composite graft or free cartilage graft (Figure 3). The graft was reposed, and the surgery was completed with a large meatoplasty.

Outcome measures

Results of audiometric examinations were evaluated using the American Academy of Otolaryngology Head and Neck Surgery (AAOHN) standards (15). In all patients, tonal audiometry and speech discrimination score (SDS) measurements were

performed. Patients were evaluated using the same physical and audiological examinations on postoperative 3rd, 6th, and 12th months. Audiological tests were performed using a silent cabined audiometry device with 125–12000 frequency area. On 500, 1000, 2000, 3000, and 4000 Hz frequencies, bone conduction and air conduction (AC) hearing thresholds were determined. SDS was determined using a Hacettepe monosyllabic phonetic, balanced word list. The air–bone gap (ABG) was calculated. Closure on ABG and postoperative AC thresholds were recorded. Similarly, differences between preoperative and postoperative values were recorded.

Statistical analysis

Statistical analysis of data obtained in this study was performed using Statistical Package for the Social Sciences, version 15.0 (IBM Corp., NY, USA). Normal distribution of groups was analyzed using the Shapiro-Wilk test before the comparison of groups. During preoperative and postoperative comparisons, Wilcoxon signed-rank test was performed. For comparison of groups, Mann-Whitney U test was performed. With a 95% significance level, $p < 0.01$ was regarded to be statistically important (highly significant), $p < 0.05$ was regarded to be statistically significant, and $p > 0.05$ was regarded to be statistically insignificant.

Results

Basic characteristics and preoperative hearing levels of participants and the stage, extension, and type of cholesteatoma in the two treatment groups are summarized in Tables 1 and 2.

Preoperative and postoperative 12th-month AC thresholds and ABG measurements for both groups are presented in Figure 5 and 6. The 12th-month AC thresholds and ABG measurements were statistically significant compared with preoperative values ($p < 0.01$).

There was no statistically significant change between the preoperative AC thresholds of groups and subgroups ($p > 0.05$). On the 12th month when the study was completed, it was determined that there were statistically significant differences in mean AC threshold values at 500, 1000, and 2000 Hz between Groups 1 and 2 ($p < 0.01$), and the difference at 4000 Hz was also statistically significant ($p < 0.05$) (Figure 5).

There was no statistically significant change between preoperative ABG values of groups and subgroups ($p > 0.05$), except between Group 1B and 2B only at 2000 Hz. ($p = 0.003$). At the end of the 1st year, changes in mean ABG values in patients in Group 1 were statistically significant (highly) compared with those in patients in Group 2 at 2000 Hz ($p < 0.01$) and at 500, 1000, and 4000 Hz ($p < 0.05$) (Figure 4).

At the end of the study, when the 12th-month mean AC threshold values of patients in Group 1A were compared with those of patients in Group 2A, it was observed that at 500, 1000, and 4000 Hz, differences were not statistically significant ($p > 0.05$), i.e., the difference was statistically significant only at 2000 Hz ($p < 0.05$) (Figure 5).



Figure 1. Cutting the cartilage shoe from the conchal cartilage, according to the dimensions of the oval window, using an aspirator tip and drilling a hole in the middle of this shoe by an aspirator tip with a lumen diameter of 0.25 mm that will get into the TORP shaft



Figure 2. Insertion of the TORP shaft into the shoe so that it can easily move back and forth



Figure 3. Position of TORP with the cartilage shoe on the basis and the insertion of cartilage graft on it

When the 12th-month mean ABG values of patients in Group 1A were investigated, it was observed that the correction at only 1000 Hz was statistically significant compared with that in patients in Group 2A ($p < 0.05$), whereas at all other frequencies, differences between the two groups were not statistically significant ($p > 0.05$) (Figure 4).

Table 1. Basic characteristics and preoperative hearing levels among the two groups

Parameter	Group 1 (n=30)	Group 2 (n=30)
	Group 1A, n= 17 Group 1B, n=13	Group 2A, n=16 Group 2B, n=14
Mean age (years)	31.2	40.2
Male/female	19/11	18/12
Middle ear granulation-fibrosis present	13	14
Average MERI	5.4	5.2
Mean PTA-air (dB):	52.9	44.9
Mean ABG (dB):	36.7	34.2
Malleus: Absent or extracted	6	7

Group 1: Cartilage shoe TORP stabilization method

Group 2: Classic TORP stabilization method

ABG: air bone gap; PTA: pure tone audiometry; TORP: Total ossicular replacement prosthesis; dB: decibel

Table 2. Stage, extension, and type of cholesteatoma in the two treatment groups

Parameter	Group 1 (n=30)	Group 2 (n=30)
Cholesteatoma type*		
Attic	8	10
Tensa I	16	13
Undefined	6	7
Cholesteatoma stage**		
S3	14	14
S4	10	9
S5	6	7
Attic, S3 extension: Attic, antrum, middle ear	4	6
Tensa I, S3 extension: Middle ear, antrum, mastoid	10	8
Attic, S4 extension: Attic, antrum, middle ear, mastoid	4	4
Tensa I, S4 extension: Middle ear, attic, antrum, mastoid	6	5
Attic/Tensa I, S5 extension: More than five sites extension	6	7

Group 1: Cartilage shoe TORP stabilization method

Group 2: Classic TORP stabilization method

*According to Lau and Tos (12)

**According to Saleh and Mills (13)

When the 12th-month AC threshold values of patients in Group 1B were investigated, it was observed that the correction at 500 Hz was statistically significant compared with that in patients in Group 2B ($p<0.01$); in addition, at 1000, 2000, and 4000 Hz,

differences between the two groups were statistically significant ($p<0.05$) (Figure 5).

Regarding these results, when postoperative ABG values of patients in Group 1B were compared with those of patients in Group 2B, there were no statistically significant ($p>0.05$) differences at 500, 1000, and 4000 Hz, whereas there was statistically significant (highly) difference at 2000 Hz ($p<0.01$) (Figure 4). This difference was not taken into consideration as it was present preoperatively at a frequency of 2000 Hz.

Discussion

In patients with COMC, different degrees of destruction in the ossicles may be observed and after complete eradication of pathology, in many patients, ossicle reconstruction may be performed with autograft ossicles or allograft materials (16). During chronic otitis media surgery, it is known that the stapes suprastructure provides a great advantage for ossicle reconstruction; with the use of an autograft or homograft incus, ceramic prosthesis, and titanium prosthesis of malleus head, quite satisfactory auditory outcomes have been obtained (17). On the other hand, the absence of the stapes suprastructure may prevent successful results during reconstruction. Even if initial results are satisfactory, during long follow-ups, hearing may get worse (18, 19). This condition occurs because of sliding of the prosthesis shaft out of the oval window, fixation of it to the neighborhood bony structures, and development of widespread fibrosis (20, 21).

Scar and fibrotic tissues that develop after surgical interventions particularly occur in ears with considerable infectious pathologies and may result in separation of the prosthesis from the basis (22). During the postoperative period, middle ear effusion or alterations in atmospheric pressure may cause dislocation of the prosthesis. Therefore, stable fixation of the prosthesis to the basis is of great importance (23). The cartilage shoe technique, which was performed for TORP stabilization, has been previously performed by Huttenbrink (14), and successful functional results were obtained. Babighian and Albu (24) modified this technique during establishment of TORP stabilization.

In this study, the cartilage shoe technique performed by Huttenbrink previously was used for TORP stabilization (14). At the end of the 1st year, in patients who had CWDT performed with titanium TORP with the cartilage shoe method, AC thresholds were determined to be improved and ABG was determined to be improved significantly compared with preoperative values (Figure 4, 5). In a study conducted by Fayad et al. (25) with the usage of a titanium shoe, ABG was reported to be better in patients who had canal wall down surgery with the shoe than in those operated without the shoe, similar to our results. However, there was no statistically significant difference between the patients.

During ossiculoplasty, based on the condition of the ossicles, there are different methods ranging from minimal applica-

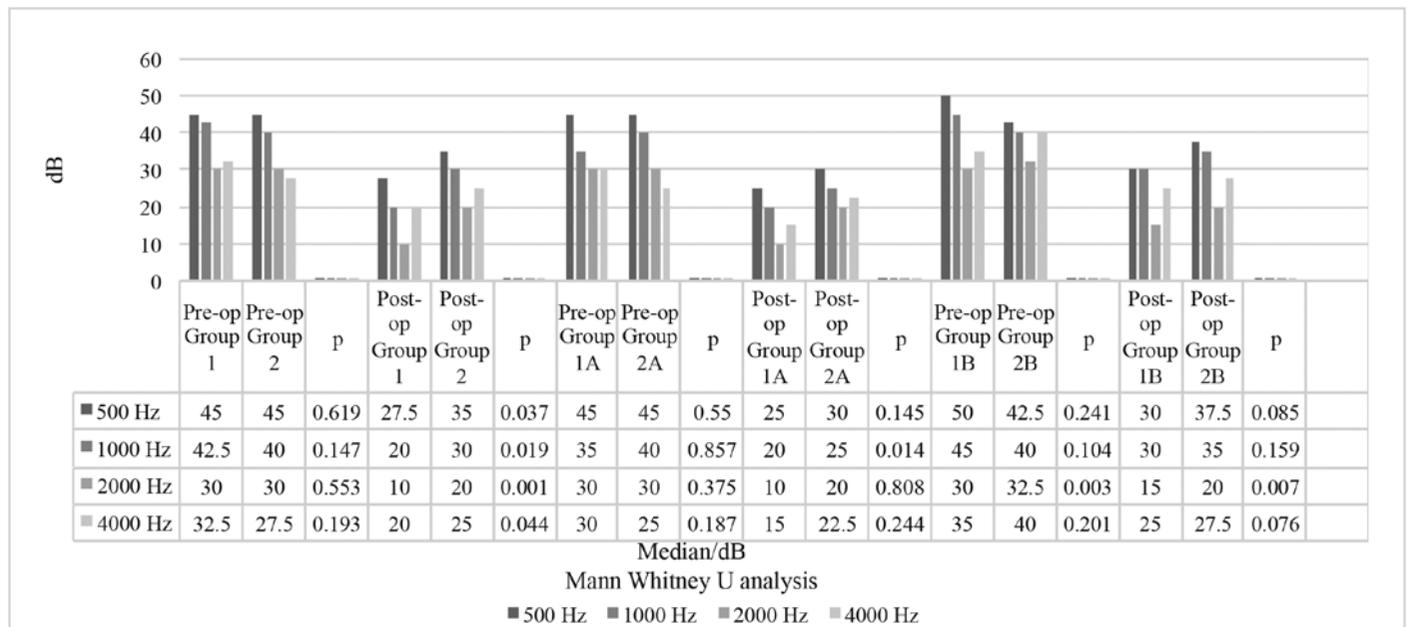


Figure 4. Pre- and postoperative ABG measurements and comparison of results between groups and subgroups at the 12th month
Group 1: Cartilage shoe TORP stabilization method, Group 2: Classic TORP stabilization method, Group A: Low-risk according to MERI, Group B: High-risk according to MERI, Pre-op: Preoperative, Post-op: Postoperative

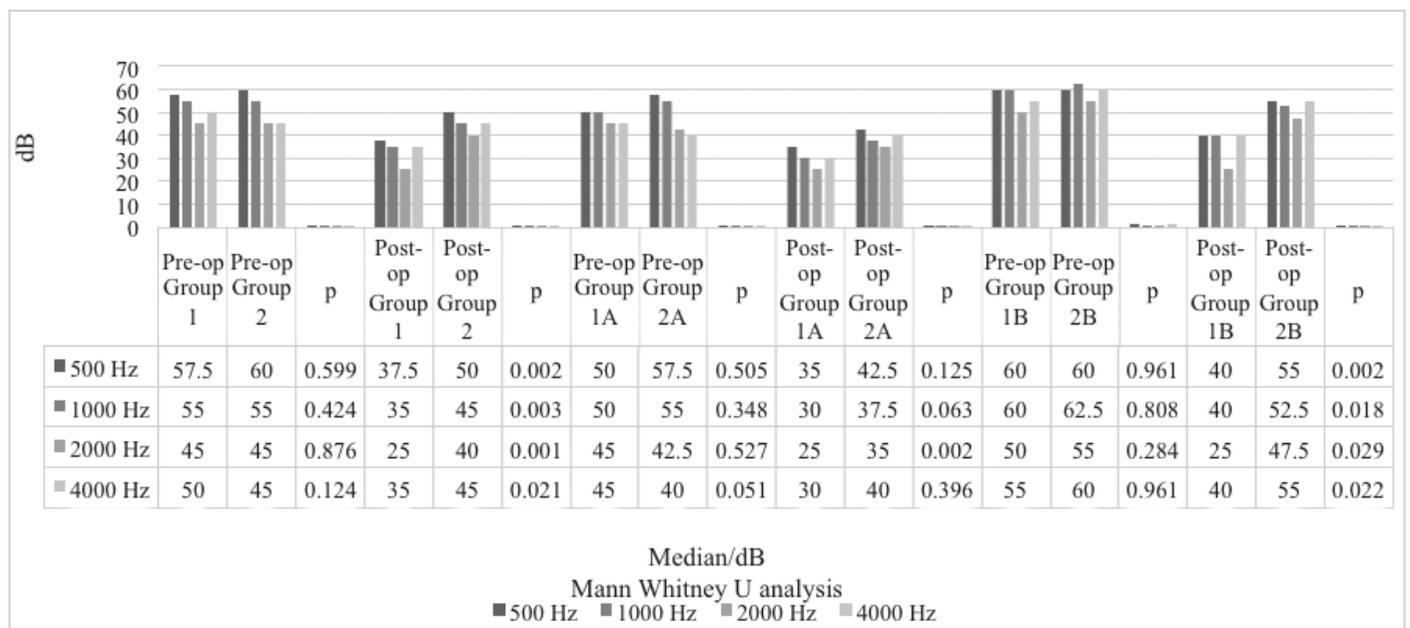


Figure 5. Pre- and postoperative air conduction thresholds and comparison of results between groups and subgroups at the 12th month
Group 1: Cartilage shoe TORP stabilization method, Group 2: Classic TORP stabilization method, Group A: Low-risk according to MERI, Group B: High-risk according to MERI, Pre-op: Preoperative, Post-op: Postoperative

tions, such as bone cement or prosthesis applications performed in the absence of ossicles. Other than the properly performed surgical method, auditory gain and its permanency may also be affected by tubal dysfunction, adhesive process, tympanic fibrosis, and presence of bilateral or recurrent diseases. In other words, the presence of disease on the middle ear mucosa and decreased or impaired ventilation in the middle ear may negatively affect the prognosis. For that reason, the two study groups were further subdivided based on the condition of the middle ear mucosa and functional outcomes were compared.

It has been shown that if the middle ear mucosa is near normal, positive effects of cartilage shoe application on hearing outcomes may be limited; however, if the middle ear mucosa is granular and edematous, cartilage shoe application has significant positive effects on hearing outcomes (Figure 4, 5). Therefore, TORP application with cartilage shoe was not affected by the negative condition of the middle ear mucosa.

Similarly, in a study conducted by Cox et al. (9) with titanium prosthesis, shoe application was reported to have significant advantages during early periods. Cox et al. (9) also evaluated

MERI in that study; however, in contrast to the results of our study, this index was used to determine whether patients who were operated using different surgical techniques, such as revision and primary, had similar risk indices.

In a study performed by Atila et al. (26) with cartilage shoe, there was less dislocation of prosthesis in the study group compared with that in classical TORP application technique group. However, the difference between two groups was not statistically significant. In our study, there was no dislocation of the prosthesis at the end of one year in both groups. We can then interpret that the cartilage shoe resists adverse effects of the middle ear mucosa and probably prevents the prosthesis from dislocation.

The results obtained from the patients who had TORP application with the classical method showed that hearing outcomes were worse in mid- or long-term patients with granular and edematous middle ear mucosa compared with those in patients with normal mucosa. These findings suggest that the prosthesis should be fixated with a cartilage block to the base of the stapes. Recently, Gostian et al. (27) reported the results of a 6.8-year follow-up of patients with cartilage shoe application. With these results, it may be thought that cartilage shoe application is a reliable method that is not negatively affected by the middle ear pathology.

During chronic otitis media surgery with ossicular reconstruction, postoperative hearing may be affected depending on the condition of the middle ear mucosa, features of the prosthesis, and surgical technique as well as the presence or absence of malleus (28). In this study, in both groups, presence or absence of malleus was approximately equal; however, a subgroup analysis based on the presence of malleus on auditory gains was not performed. This is one of the limitations of this study. Another limitation of this study is the absence of comparisons on the effects of preoperatively determined cholesteatoma extent on postoperative hearing results.

Conclusion

There are many factors affecting success rates of reconstruction interventions, such as the condition of middle ear mucosa, condition of ossicles, extent of the disease, surgical technique, patient age, or the surgeon's experience. During chronic otitis media surgery, there are different ossicle reconstruction methods to prevent hearing loss or reduce conductive loss. In this study, it was determined that the cartilage shoe method for titanium TORP stabilization used for reconstructing canal wall down tympanoplasties has positive effects on auditory gain. The use of cartilage shoe may provide audiological benefits and protect the prosthetic shaft from adverse effects of middle ear pathologies.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of İzmir Bozyaka Training and Research Hospital (15.09.2010/316).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - H.K., M.E.C., G.A.Y., G.C., A.D., L.O.; Design - H.K., M.E.C., G.A.Y., G.C., A.D., L.O.; Supervision - H.K., M.E.C., G.A.Y., G.C., A.D., L.O.; Resource - H.K., M.E.C., G.A.Y., G.C., A.D., L.O.; Materials - H.K., M.E.C., G.A.Y., G.C., A.D., L.O.; Data Collection and/or Processing - H.K., M.E.C., G.A.Y., G.C., A.D., L.O.; Analysis and/or Interpretation - H.K., M.E.C., G.A.Y., G.C., A.D., L.O.; Literature Search - H.K., M.E.C., G.A.Y., G.C., A.D., L.O.; Writing - M.E.C.; Critical Reviews - L.O., A.D.

Acknowledgements: The authors thank to Professor Hasan Cem İrkılata, M.D. for editorial supervising.

Conflict of Interest: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

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