



## CLINICAL STUDY

# EFFECT OF THE PRESENCE OF EXTERNAL EAR CANAL WALL ON FUNCTIONAL OUTCOMES OF OSSICULAR RECONSTRUCTION WITH TITANIUM TOTAL OSSICULAR REPLACEMENT PROSTHESIS (TORP)

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### SUMMARY

**Objectives:** To investigate the effect of external ear canal wall on functional outcomes of ossicular reconstruction procedures with titanium total ossicular replacement prosthesis (TORP).

**Methods:** Patients who underwent middle ear surgery and ossicular reconstruction with TORP in a tertiary referral center between 2009-2014 were retrospectively searched in two groups; Canal Wall Up (CWU) + TORP and Canal Wall Down (CWD) + TORP. Functional results were evaluated.

**Results:** A total number of 89 cases were evaluated. CWU group included 25, CWD group included 36 patients who met inclusion criteria. In the CWU group, the mean pre-operative pure tone average (PTA) value was 58.1±11.2 dB; postoperative PTA was 44.1±17.9 dB, the mean increase was 13.9±14.3 dB. In the CWD group, the mean preoperative PTA was 56.6±15.3 dB, postoperative PTA was 50.6±21.3 dB, the mean increase was 6.0±15.6 dB. The mean air-bone gap (ABG) closure value was 14.4±11.5 dB in the CWU group and 6.4±10.5 dB in the CWD group. There was a significant difference in terms of PTA increase and ABG closure values between the two groups.

**Conclusions:** The external ear canal wall has a positive effect on postoperative hearing when an ossiculoplasty with Titanium TORP is performed. The removal of ECW leads to a hearing loss of about 9dB in PTA levels and 8dB in ABG closure values in these cases.

*Keywords: Ossicular prosthesis; titanium; ear canal; hearing*

### DIŞ KULAK YOLU ARKA DUVARI VARLIĞININ TİTANYUM TOTAL OSSİKULER REPLASMAN PROTEZİ (TORP) İLE KEMİKÇİK REKONSTRÜKSİYONU UYGULAMASININ FONKSİYONEL SONUÇLARINA ETKİSİ

#### ÖZET

**Amaç:** Mevcut çalışmamızda, titanium total ossikuler replasman protezi (TORP) kullanılarak ossikuloplasti yapılan olgularda dış kulak yolu (DKY) arka duvarının korunmasının fonksiyonel sonuçlara etkisini belirlemek amaçlandı.

**Yöntemler:** Kurumumuzda 2009-2014 yılları arasında kronik otitis media (KOM) nedeniyle orta kulak cerrahisi ve TORP kullanılarak ossikuler rekonstrüksiyon operasyonu geçiren hastalar iki grup altında incelenerek fonksiyonel sonuçlar karşılaştırıldı: Canal Wall Up (CWU) + TORP ve Canal Wall Down (CWD) + TORP.

**Bulgular:** Toplamda 89 olgunun verileri incelendi. Dahil olma kriterlerine uyan 61 hasta çalışmaya alındı: CWU grupta 25, CWD grupta 36 hastanın verileri analiz edildi. CWU grupta ortalama pre-operatif saf ses ortalaması (SSO) 58.1±11.2 dB; post-operatif SSO 44.1±17.9 dB, ortalama düzelme 13.9±14.3 dB olarak saptanırken, CWD grupta pre-operatif SSO 56.6±15.3 dB, post-operatif SSO 50.6±21.3 dB, ortalama düzelme 6.0±15.6 dB olarak saptandı. Ortalama hava-kemik aralığı (HKA) kapanma değerleri ise CWU grupta 14.4±11.5 dB, CWD grupta 6.4±10.5 dB olarak saptandı. SSO düzelme ve HKA kapanma değerleri açısından iki grup arasında istatistiksel olarak anlamlı fark saptandı.

**Sonuç:** Titanium TORP kullanılarak yapılan ossikuloplasti prosedürlerinde, DKY arka duvarının korunmasının fonksiyonel sonuçlara anlamlı etkisi mevcuttur. Bu olgularda DKY arka duvarının kaldırılması, SSO değerlerinde yaklaşık 9dB, HKA kapanma değerlerinde ise yaklaşık 8dB kayıba neden olacaktır.

*Anahtar Sözcükler: Ossiküler protez, titanyum, dış kulak yolu*

## INTRODUCTION

A defect in the ossicular chain is a common sequel of chronic otitis media (COM). Ossicular reconstruction is a crucial step of middle ear surgery that affects post-operative hearing. Different types of prostheses are present for ossicular chain reconstruction and titanium

prostheses are widely used in this area. The outcomes of these prostheses are reported in different studies and titanium is evaluated as an adequate material for decent sound transmission and is also a highly biocompatible metal<sup>1,2</sup>. On the other hand, mastoidectomy is also a critical part of the procedure and can be performed with two techniques related to the pathology: canal wall up (CWU) and canal wall down (CWD) mastoidectomies. The external ear canal wall's (ECW) positive effect on hearing is well described: it doesn't only direct sound waves to the tympanic membrane, also strengthens them. It acts as a filter to reduce low frequencies, a

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resonator to enhance mid frequencies (2.0 to 7.0 kHz) <sup>3</sup>. Previous studies about titanium total ossicular replacement prosthesis (TORP) indicated that functional outcomes were not satisfactory when a titanium TORP is used in a CWD procedure. This is likely a result of the deterioration in external ear acoustics <sup>4</sup>.

The subject of this study is to investigate the effect of the presence of the ECW on functional outcomes when titanium TORP is used for ossicular chain reconstruction. We aimed to determine the degree of hearing loss the patient will suffer when the ECW is removed in these cases. Functional outcomes of two groups of cases that have similar properties except for the presence of ECW were compared and evaluated.

## MATERIAL and METHODS

Patients who underwent middle ear surgery and ossicular reconstruction with TORP for chronic otitis media in a tertiary referral center between 2009-2014 were retrospectively searched in two groups; Canal Wall Up + TORP and Canal Wall Down + TORP. The research protocol was approved by the faculty's Research Ethics Committee and informed consents were collected from all participating patients by means of previously documented patient information leaflets and consent forms.

A total number of 89 cases were evaluated: 56 cases in the CWD group and 33 cases in the CWU group. Patients who were not under regular follow-up, six patients with perforated grafts and/or prosthesis extrusion, three patients with recurrent cholesteatoma, and patients who had other middle ear pathologies that may cause conductive hearing loss (otosclerosis, tympanosclerosis, or fixed footplate) were not included in the study; as these pathologies could cause additional hearing loss and complicate the analysis regarding the effect of ECW. CWU group included 25, CWD group included 36 patients who met inclusion criteria and none of the patients were operated on both ears. All patients had a defect in stapes but had an intact and mobile footplate and malleus. The TORP was placed between the malleus and the intact footplate in all cases during initial surgeries and patients with staged surgeries were

not included. If the malleus was defected or absent, one of the following two approaches was considered according to the case: the TORP was placed directly under the grafted tympanic membrane or a second surgery was planned for ossicular reconstruction (second-look). None of these patients were included in the study as well.

Otomicroscopic examinations, pure tone audiometry (PTA), and high-resolution CT scans were performed pre-operatively. Titanium TORP was used for ossiculoplasty in all procedures and conchal cartilage was used as a graft. All patients in the study group had a minimum of one year of follow up. Functional results were compared between two groups with pure-tone average (PTA), air-bone gap (ABG) at 4 frequencies (0.5, 1, 2, and 4kHz), increase in pure-tone average, and closure in ABG values <sup>5</sup>.

### Statistical analysis

Statistical analysis was performed with SPSS for Windows (SPSSversion 18.0; SPSS Inc., Chicago, USA). The distribution of the data was assessed with the Kolmogorov-Smirnov test. Student's t-test and chi-square test were used for statistical comparison of the audiologic data. The difference is accepted as statistically significant if the value of p was < 0.05.

## RESULTS

CWU group included 25 patients: 13 females and 12 males, the mean age was 43.7 years (range; 11-61). CWD group included 36 patients, 21 females, and 15 males, the mean age was 37.8 years (range; 11-63 years). There wasn't a statistically significant difference in terms of age between the two groups (p=0.53).

A retroauricular approach was used in all cases. In the CWU group, all 25 patients underwent cortical mastoidectomy. Cartilage tympanoplasty was performed in all cases to avoid extrusion of the prosthesis. A routine effort to place a shoe graft or soft tissue to stabilize the prosthesis on the footplate did not take place. Middle ear pathologies observed during surgeries in each group are presented in Table 1. The main indication for a CWD mastoidectomy was extensive cholesteatoma. Granulation tissue and middle ear atelectasis were the other pathologies observed.



For the CWU group, the mean postoperative audiometry time was 16.4 months. For the CWD group, it was 14.3 months. Audiometry tests that were performed earlier than six months after the surgery were not evaluated in the study and control tests were performed if necessary. There was no significant difference in terms of postoperative audiometry time between the two groups. ( $p=0.36$ )

In the CWU group, the mean pre-operative PTA was  $58.1 \pm 11.2$  dB; postoperative PTA was  $44.1 \pm 17.9$  dB with an increase of  $13.9 \pm 14.3$  dB. In the CWD group, mean preoperative PTA was  $56.6 \pm 15.3$  dB, postoperative PTA was  $50.6 \pm 21.3$  dB, with an increase of  $6.0 \pm 15.6$  dB. There was a significant difference in terms of PTA increase levels between the two groups. ( $p=0,039$ ) (Table 2).

In the CWU group, pre-operative mean ABG was  $39.9 \pm 10.7$  dB, post-operative mean ABG was  $24.8 \pm 10.9$  dB; the mean ABG closure was  $14.4 \pm 11.5$  dB. In the CWD group, pre-operative mean ABG was  $39.1 \pm 10.0$  dB, post-operative mean ABG was  $32.7 \pm 13.6$  dB, the mean closure value was  $6.4 \pm 10.5$  dB. There was a significant difference between the two groups in mean ABG closure levels. ( $p=0.021$ ) (Table 3).

Patients with post-operative ABG  $< 20$  dB were defined as successful with regards to previous studies. In CWU group 10 patients out of 25 (40.0%), in CWD group 10 patients out of 36 (27.7%) had postoperative ABG  $< 20$  dB (Table 4).

**Table 1.** Middle ear pathologies in each group

	<i>Cholesteatoma</i>	<i>Granulation Tissue</i>	<i>Middle ear atelectasis</i>
Canal wall-up (n=30)	20	4	1
Canal wall-down (n=36)	30	5	1

**Table 2.** Pre operative and post operative PTA (pure tone average) values and increase levels in both groups.

	<b>Canal wall up</b>	<b>Canal wall down</b>	<b>p</b>
Pre op. Mean PTA (dB)	$58.1 \pm 11.2$	$56.6 \pm 15.3$	<b>0.861</b>
Post op. Mean PTA (dB)	$44.1 \pm 17.9$	$50.6 \pm 21.3$	<b>0.091</b>
Increase in PTA (dB)	$13.9 \pm 14.3$	$6.0 \pm 15.6$	<b>0.031</b>



**Table 3.** Pre-operative and post-operative mean air-bone gap (ABG) values and closure levels in both groups

	Canal wall up	Canal wall down	p
Pre op. mean ABG (dB)	39.9±10.7	39.1±10.0	<b>0.798</b>
Post op. mean ABG (dB)	24.8±10.9	32.7±13.6	<b>0.020</b>
Closure in ABG (dB)	14.4±11.5	6.4±10.5	<b>0.018</b>

**Table 4.** Number and percent of patients with Air Bone Gap (ABG) < 20 dB

	<i>Patients with post operative ABG &lt; 20 dB</i>
Canal wall-up	10 (25), 40.0%
Canal wall-down	10 (36), 27.7%
Total	20 (61), 32.7%

## DISCUSSION

Chronic otitis media surgery aims to achieve a dry, disease-free middle ear with optimal hearing. In cases with a defect of the ossicular chain, titanium prostheses are frequently used<sup>6-8</sup>. A CWD mastoidectomy is a safe method that enables cleaning pathologic tissues totally from the middle ear and the mastoid cavity; especially in cases with extensive cholesteatoma. But an intact external ear canal wall plays an important role in hearing physiology and should be preserved or reconstructed if possible<sup>9</sup>. It acts as a resonator, which causes the acoustic pressure at the tympanic membrane to be greater than it is at the entrance of the ear canal. The increase is prominent near 3 kHz (the resonance frequency) where it is approximately 10 dB. When the canal wall is removed, the acoustic properties of the

new mastoid cavity will be different from a healthy external ear and the gain or the loss in hearing levels at different frequencies will depend on the resonance properties of the cavity. This could be considered as the first impact of the removal of ECW on hearing physiology. The second consequence of a CWD mastoidectomy is the decrease in the middle ear volume. In a healthy ear, the total volume of the middle ear and mastoid cells is about 6ml. If the total volume is lower than 1ml; a conductive hearing loss, which is evident in low frequencies, takes place. If the volume is lower than 0.4ml, the degree of conductive hearing loss is about 10 dB<sup>10</sup>.

Whittemore et al.'s report which studied the contribution of the middle ear air spaces to sound transmission through the middle ear in canal wall-up and canal wall-down mastoidectomies pointed that as long as the



middle ear air volume is greater than 0.7 ml, a canal wall-down mastoidectomy generally causes less than 10 dB changes in middle ear sound transmission compared to the canal wall-up procedure<sup>10</sup>. In our study, the mean increase in PTA levels is 13.9 dB in the CWU group and 6 dB in the CWD group; compatible with the findings of Whittemore et al.

The third effect of a removed ECW is the position of the reconstructed membrane. When the ECW is removed, the grafted tympanic membrane will be placed more medially, which brings the risk of contact with the promontorium or facial nerve canal. This contact can limit the vibration capability of the membrane and can also diminish the middle ear volume and aeration<sup>11</sup>.

Hearing results after following CWD Mastoidectomy and Tympanoplasty with TORP procedures are documented in various studies. Redaelli de Zinis stated that the mean postoperative air conduction gain was 5.5 dB in his series of cases who underwent CWD mastoidectomy and ossiculoplasty with titanium TORP when stapes suprastructure was absent and 28% of patients had an ABG < 20dB<sup>2</sup>. This finding is similar in our study, as the mean gain in the CWD group was  $6.0 \pm 15.6$  dB and 27.7% of patients had ABG < 20 dB. They also stated that results were frequently superior when the stapes superstructure was present.

Schmerber et al.'s study compared results of both CWD and CWU procedures when PORP or TORP was used and in the CWD + TORP group success rate (ABG < 20 dB) was 27,3% (3 out of 11 patients), in the CWU group it was 61.5% (24 out of 39)<sup>4</sup>. They stated that hearing gain was minimum when a TORP was used in a CWD procedure. Martin et al. presented the outcomes of ossicular reconstruction with titanium prosthesis and the authors reported that 36% of patients who underwent CWD mastoidectomy and ossiculoplasty with TORP or PORP had ABG < 20dB and the absence of stapes suprastructure or the canal wall were poor indicators<sup>7</sup>. Contrastingly, Iniguez-Cuadra et al. reported that 38 (68%) of 56 CWD and 24 (64%) of 37 CWU cases achieved a postoperative ABG between 0 and 20 dB in their series and the

authors concluded that here were no differences in the results between CWU and CWD<sup>12</sup>.

In Kim et al.'s study, %25 (2 out of 8) patients who underwent CWD mastoidectomy and ossiculoplasty with TORP had post-operative ABG < 20 dB<sup>13</sup>. In staged procedures, %68 (11 out of 16) patients had ABG < 20 dB. The authors stated that staged ossicular reconstruction yielded better hearing results when an open mastoid cavity was present and the stapes suprastructure was absent. Martins J et al's study revealed similar results after single staged ossiculoplasty with TORP<sup>8</sup>. They achieved in 15.3% (4 out of 26) of patients a post-operative ABG < 20 dB and stated that there was an audiometric improvement in the total reconstruction (TORP) in two stages, compared to surgery in a single stage. To increase functional success in CWD cases, Kaplankiran et al. suggested the stabilization of the TORP with a shoe graft and reported that the cartilage shoe method for titanium TORP stabilization used had positive effects on auditory gain<sup>14</sup>.

In the literature, post-operative mean ABG values after a CWD Mastoidectomy + TORP procedure vary from 22 dB to 28 dB<sup>2,4,7,12</sup>. In our study, post-operative mean ABG was  $32.7 \pm 13.6$  dB, but it should be considered that all surgeries were single staged, pre-operative ABG values were relatively high and the stapes suprastructure was not present in any case. In the CWU group, with the same conditions mentioned above; the mean postoperative ABG was  $24.8 \pm 10.9$  dB, with an average closure of  $14.4 \pm 11.5$  dB and 40.0% of patients had ABG < 20dB. Gardner et al.'s study, in which 102 ossicular reconstruction procedures were evaluated, successful rehabilitation<sup>15</sup>. Wood et al. reported the long term (two years) outcomes of total ossicular reconstruction with TORP and the mean postoperative ABG was  $26 \pm 13$  dB<sup>16</sup>. In different studies, closure of ABG values vary between 5dB - 13 dB with 11%-44% of patients have post-operative ABG < 20 dB<sup>7,8,13</sup>.

In this study, we aimed to define the effect of ECW on functional outcomes of ossiculoplasty with TORP procedures. Although



we tried to compare two homogenous groups in order to attribute the difference to ECW, it is not possible to assume that middle ear conditions were the same in both groups; as these patients have a long history of COM and the pathologies and healing processes of patients can vary. This subject can be considered as the main limitation of studies that compare the outcomes of ossiculoplasty procedures; including ours. But to our knowledge, our study is the only report that compares the outcomes of two to the utmost similar groups except for the presence of ECW. We concluded that the removal of ECW leads to a loss of approximately 9dB in PTA levels and 8dB in ABG closure values. We also observed that staged surgeries can be an option especially if a CWD mastoidectomy is planned for an extensive or complicated disease; as staged surgeries are documented to have better hearing results<sup>2,17</sup>.

## CONCLUSION

With this study, we documented that preserving the external ear canal wall has a positive effect on postoperative hearing when an ossiculoplasty with Titanium TORP is performed. The degree of hearing loss that occurs in the absence of ECW is also assessed. More studies investigating the effect of the shape, size, and volume of the mastoid cavity on the resonance properties of the external ear canal could be useful to better understand and predict the functional outcomes of ossiculoplasty with CWD mastoidectomy procedures.

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