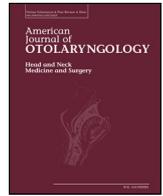




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# Titanium ossicular chain reconstruction in single stage canal wall down tympanoplasty for chronic otitis media with mucosa defect

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## ABSTRACT

**Purpose:** To evaluate surgical outcomes for chronic otitis media with mucosa defect underwent titanium ossicular chain reconstruction (OCR) in single stage canal wall down tympanoplasty (CWD).

**Methods:** A clinical retrospective study was performed on 83 cases of the chronic otitis media with mucosa defect and 123 ears with mucosa integrity according to intraoperative findings that underwent synchronous titanium OCR in single stage CWD from January 2012 to January 2018. Pre- and postoperative air conduction threshold (AC), air-bone gap (ABG) and ABG closure at 0.5, 1, 2, and 4 kHz were investigated.

**Results:** The overall mean AC threshold of  $53.4 \pm 16.5$  dB was lowered to  $41.2 \pm 15.9$  dB postoperatively ( $p < 0.01$ ). The mean pre- and postoperative ABG of all patients were  $27.9 \pm 9.9$  dB and  $17.2 \pm 9.3$  dB ( $p < 0.01$ ), respectively, with a mean ABG closure of  $10.7 \pm 8.4$  dB. The total rate of success, postoperative ABG  $\leq 20$  dB was achieved in 71.4%. In the mucosa defect group underwent TORP, the mean pre- and postoperative ABG were  $28.1 \pm 9.8$  dB and  $20.1 \pm 9.0$  dB ( $p < 0.01$ ), respectively, with the ABG closure was  $8.0 \pm 7.9$  dB. In the mucosa defect group underwent PORP, the mean pre- and postoperative ABG were  $27.9 \pm 10.1$  dB and  $16.5 \pm 9.1$  dB ( $p < 0.01$ ), respectively, with the ABG closure was  $11.4 \pm 8.6$  dB. Furthermore, in the mucosa defect group, there was significant difference in success rate of achieved postoperative ABG  $\leq 20$  dB between the TORP (48.9%) and PORP (77.5%) ( $p < 0.05$ ).

**Conclusion:** It is revealed PORP in single stage CWD tympanoplasty for the patients suffered from chronic otitis media with mucosa defect is favored.

## 1. Introduction

The ideal goals of surgical treatment of chronic otitis media are complete eradication of disease to produce a dry, safe ear and subsequent reconstruction of the sound conduction system to preserve or improve hearing, within a single stage surgical procedure if possible. Traditionally, canal wall down (CWD) and canal wall up (CWU) techniques are the most commonly used approaches by otologists. CWD mastoidectomy is considered to be the gold standard for this purpose, particularly in cases of chronic otitis media with cholesteatoma or granulation. CWD provides excellent intraoperative exposure of the tympanum and mastoid, and this aids in total disease elimination with low recurrence rate. Besides removing the disease and preventing the recurrence, procedures for restoration of social hearing is another important aim.

Ossicular chain reconstruction (OCR) is to establish ossicular continuity to restore the mechanical transmission of sound from the

tympanic membrane to the oval window with a well-aerated mucosa-lined middle ear. Manufactured partial and total ossicular prostheses (PORP and TORP) are popular choices for repairing of the ossicular chain defect during ossiculoplasty. To achieve better hearing outcomes, Sheehy et al. [1,2] advocated staged surgery when addressing a chronically draining ear. Mucous membrane problems were the most common reason for staging. Iseri et al. [3] reported that reconstruction with a titanium prosthesis offered good functional results when performed during CWD surgery for advanced cholesteatoma, as a single stage procedure. Staged operations with middle ear prostheses were significant cost and risks of a second procedure [4].

So there still exists significant difference in opinion regarding the optimal surgical strategy. The aim of this retrospective study is to evaluate the hearing results of titanium ossicular chain reconstruction in single stage canal wall down tympanoplasty for chronic otitis media with severe mucosa lesions.

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**Table 1**  
Hearing results according to the middle ear mucosa status.

Mucosa status	Type of OCR	Preoperative ABG	Postoperative ABG	ABG closure	<i>p</i>
Mucosa defect (n = 83)	TORP (n = 43)	28.1 ± 9.8	20.1 ± 9.0	8.0 ± 7.9	< 0.01
	PORP (n = 40)	27.9 ± 10.1	16.5 ± 9.1	11.4 ± 8.6	< 0.01
Mucosa integrity (n = 123)	TORP (n = 29)	28.0 ± 9.5	16.7 ± 9.4	11.3 ± 8.3	< 0.01
	PORP (n = 94)	27.8 ± 9.9	16.4 ± 9.6	11.6 ± 8.5	< 0.01

Abbreviations: OCR, ossicular chain reconstruction; ABG, air-bone gap; TORP, total ossicular replacement prostheses; PORP, partial ossicular replacement prostheses.

## 2. Materials and methods

### 2.1. Surgical methods

The primary canal wall down (CWD) mastoidectomies were performed. All ossiculoplasties were carried out in single stage surgery. Ossicular chain reconstruction (OCR) (n = 206) was performed using total ossicular replacement prosthesis (TORP, 4.0 mm, Spiggle & Theis, Overath, Germany) in the absence of stapes superstructure and partial ossicular reconstruction prosthesis (PORP, 1.0 mm, Spiggle & Theis, Overath, Germany) in the presence of stapes superstructure. The intraoperative status of the middle ear mucosa was recorded. According to the mucosa status in the surgery the patients were divided in two groups: the mucosa defect and the mucosa integrity. The mucosa defect group (n = 83) consisted of the middle ear with mucosa removal after complete eradication of disease with or without cholesteatoma. The mucosa integrity group (n = 123) consisted of the middle ear with normal or only thickened mucosa after complete eradication of disease with or without cholesteatoma. The tympanic membrane was reconstructed with the temporalis muscle fascia, and a generous piece of cartilage of the auricular concha was removed to allow wide exposure of the meatus. A retrospective study was performed on 83 cases of the chronic otitis media with mucosa defect (n<sub>TORP</sub> = 43, n<sub>PORP</sub> = 40) and 123 ears with mucosa integrity (n<sub>TORP</sub> = 29, n<sub>PORP</sub> = 94) according to intraoperative findings that underwent synchronous titanium OCR in single stage CWD at the Eye and ENT Hospital of Fudan University between January 2012 and January 2018. Approval was obtained from the Institutional Internal Review Board. All surgeries were performed by the first author.

### 2.2. Audiometric measures

Pre- and postoperative air conduction thresholds (AC), bone conduction thresholds (BC) and the air-bone gap (ABG) at 0.5, 1, 2, and 4 kHz were measured. The ABG closure was calculated as preoperative ABG minus postoperative ABG. Attaining a postoperative ABG ≤ 20 dB was generally cited as success in ossiculoplasty. Postoperative audiometry was performed at 6 months after the surgery. Pre- and postoperative audiometric data were assessed according to the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) standards.

### 2.3. Statistical analysis

Statistical analysis was performed with the SPSS software package (IBM SPSS Statistics 22.0; IBM, New York, NY). For continuous variables, comparisons between groups were done with *t*-test. Comparisons of categorical variables were performed with a Fisher exact test or chi-square test. A *p* value of < 0.05 was considered statistically significant.

## 3. Results

### 3.1. Patient demographics

A total of 206 patients were identified who had undergone titanium

ossicular chain reconstruction (OCR) in single stage canal wall down (CWD) tympanoplasty. One hundred and eighteen patients were men, and 88 patients were women. The age of patients varied from 15 to 70 years, and the average age at the time of surgery was 46 years. There were 106 right-sided affected ears and 100 left-sided affected ears. The follow-up duration was ranged from 6 months to 6 years, with an average of 30 months.

### 3.2. Anatomic outcomes

In general, a dry and spacious external auditory canal was successfully created within three months. Otic endoscopy showed epithelization and smooth in the radical cavity. The tympanic membrane was intact and maintained the natural angle. There were 5 cases with cavity infection including 3 cases in the mucosa defect group and 2 cases in the mucosa integrity group. There were 2 cases with prosthesis extrusion including 1 case in the mucosa defect group and 1 case in the mucosa integrity group in the postoperative follow-up. No significant differences were showed between the two groups.

### 3.3. Audiometric results

The overall mean AC threshold of 53.4 ± 16.5 dB was lowered to 41.2 ± 15.9 dB postoperatively (*p* < 0.01). The mean pre- and postoperative ABG of all patients was 27.9 ± 9.9 dB and 17.2 ± 9.3 dB (*p* < 0.01), respectively, with a mean ABG closure of 10.7 ± 8.4 dB. The total rate of success, postoperative ABG ≤ 20 dB was achieved in 71.4%.

The hearing results according to the middle ear mucosa status of the patients underwent concurrent OCR with either TORP or PORP are presented in Table 1. In the mucosa defect group underwent TORP, the mean pre- and postoperative ABG were 28.1 ± 9.8 dB and 20.1 ± 9.0 dB (*p* < 0.01), respectively, with the ABG closure was 8.0 ± 7.9 dB. In the mucosa defect group underwent PORP, the mean pre- and postoperative ABG were 27.9 ± 10.1 dB and 16.5 ± 9.1 dB (*p* < 0.01), respectively, with the ABG closure was 11.4 ± 8.6 dB. There were significant difference between the mean pre- and postoperative ABG in the mucosa defect group with both TORP and PORP (*p* < 0.01).

Similarly, in the mucosa integrity group, there were significant difference between the mean pre- and postoperative ABG with both TORP and PORP (*p* < 0.01). And in the mucosa defect group, there was significant difference in postoperative ABG and ABG closure between the TORP and PORP (*p* < 0.05). Furthermore, in the mucosa defect group, there was significant difference in success rate of achieved postoperative ABG ≤ 20 dB between the TORP (48.9%) and PORP (77.5%) (*p* < 0.05). In the mucosa integrity group, there was no statistical difference in postoperative ABG, ABG closure and success rate between the TORP (72.4%) and PORP (78.7%) (*p* > 0.05).

## 4. Discussion

According to the literature, the ossicular chain reconstruction (OCR) for patients underwent tympanoplasty could be performed at staged or concurrent procedure. It was reported that planned, staged

ossiculoplasty was helpful to establish an air-containing middle ear cavity and an intact tympanic membrane with a higher success rate of hearing results. Shelton and Sheehy reported that closure of the ABG to 20 dB or less occurred in 68% of 400 staged patients with intact stapes [2]. Ho and Kveton [5] suggested that a planned 2-stage procedure that used the posterior tympanotomy approach for the control of cholesteatoma was an effective technique. Average hearing gain at the completion of the second-stage procedure was 9 dB. However, Bedri and Redleaf [6] reported that the improvement of ABG was seen in 1-stage operations without mastoidectomy. Preoperative air bone gaps were  $44 \pm 7$  dB; postoperative air bone gaps were  $23 \pm 10$  dB, for an average improvement of 21 dB across all reconstruction types ( $p < 0.001$ ).

Crowson et al. [4] found that there was no significant difference in postoperative ABG for CWU patients between second look and single stage ( $p > 0.05$ ). Ravishankar and Datta [7] revealed that audiological results were same for both concurrent and staged reconstruction following CWD tympanomastoidectomy, however, they only compared the mean pre- and postoperative AC threshold. Qotb et al. [8] reported that single stage CWD with reconstruction of the posterior canal wall, ossicular chain, and tympanic membrane is a safe and reliable technique with the advantages of CWU. The mean preoperative and postoperative ABG was  $35.8 \pm 6.2$  dB and  $22.9 \pm 6.8$  dB, respectively. A moderate positive correlation was found between pre- and postoperative ABG ( $p < 0.001$ ). De Corso et al. [9] showed that hearing improvement was possible following cholesteatoma surgery with canal wall down tympanoplasty and ossicular chain reconstruction. The mean pre- and post-operative ABG was 28.83 and 13.94 dB, respectively. Almost 62.67% of patients closed their ABG to within 20 dB. Castro Sousa et al. [10] reported that the majority of the concurrent ossiculoplasties improved hearing status satisfactorily. Ossiculoplasty was successfully achieved in 113 patients (74%). The mean preoperative ABG was  $35.3 \pm 10.6$  dB and the mean postoperative ABG was  $14.0 \pm 10.5$  dB. These measurements represented a significant improvement over the preoperative values ( $p < 0.05$ ). In our study, the overall mean AC threshold of  $53.4 \pm 16.5$  dB was lowered to  $41.2 \pm 15.9$  dB postoperatively ( $p < 0.01$ ). The mean pre- and postoperative ABG of all patients was  $27.9 \pm 9.9$  dB and  $17.2 \pm 9.3$  dB ( $p < 0.01$ ), respectively, with a mean ABG closure of  $10.7 \pm 8.4$  dB. The total rate of success, postoperative ABG  $\leq 20$  dB was achieved in 71.4%. There was statistical difference between the mean pre- and postoperative hearing in concurrent OCR during CWD tympanoplasty for chronic otitis media. The possible reason is that the repaired ossicular chain can support the tympanic membrane well and facilitate the formation of the air-containing middle ear cavity. Kim et al. [11] reported that staged OCR was advantageous in those with most severe disease. Dornhoffer and Gardner [12] revealed that the mucosal condition rather than the disease status had a significant detrimental impact on postoperative hearing. Jahn [13] suggested that factor like extensive mucosa disease of middle ear dictated staged procedure to reconstruct the ossicular chain six months later.

It was found that the mucosal status of the middle ear was an important prognostic factor for hearing outcome by multivariate statistical analysis [2,10,14,15]. When the middle ear mucosa was intraoperatively evaluated as normal, it was a positive prognostic factor for the hearing outcome. Anyway, Aslan et al. [16] did not find any significant differences in the statistical comparison of these two subgroups (staged or concurrent OCR) of the extensive cholesteatoma disease underwent CWD tympanoplasty. In staged OCR, the mean preoperative ABG was  $32.3 \pm 12.1$  dB and the mean postoperative ABG was  $22.5 \pm 10$  dB. The mean ABG change was  $9.6 \pm 10.2$  dB. In concurrent OCR, the mean preoperative ABG was  $31.5 \pm 11.5$  dB and the mean postoperative ABG was  $27.3 \pm 11.1$  dB. The mean ABG change was  $4.3 \pm 11.2$  dB. Iseri et al. [3] found that the mean air-bone gap improved from  $30.38 \pm 11.12$  dB pre-operatively to  $15.62 \pm 9.65$  dB post-operatively, for both total and partial ossicular

replacement prosthesis groups combined during canal wall down surgery for advanced cholesteatoma. Our results showed that, in the mucosa defect group underwent TORP, the mean pre- and postoperative ABG were  $28.1 \pm 9.8$  dB and  $20.1 \pm 9.0$  dB ( $p < 0.01$ ), respectively, with the ABG closure was  $8.0 \pm 7.9$  dB. In the mucosa defect group underwent PORP, the mean pre- and postoperative ABG were  $27.9 \pm 10.1$  dB and  $16.5 \pm 9.1$  dB ( $p < 0.01$ ), respectively, with the ABG closure was  $11.4 \pm 8.6$  dB. There were significant difference between the mean pre- and postoperative ABG in the mucosa defect group with both TORP and PORP ( $p < 0.01$ ) during single stage canal wall down tympanoplasty. In cases of severe chronic otitis media, removal of irreversible lesions in the middle ear cavity leads to middle ear mucosa defect, resulting in adhesion of the new tympanic membrane graft and the naked promontory. Tympanic membrane is not easy to adhere to the regenerated mucosa because of the support of the reconstructed ossicular chain.

By our further comparison, in the mucosa defect group, there was significant difference in postoperative ABG and ABG closure between the TORP and PORP ( $p < 0.05$ ). In the mucosa defect group, there was significant difference in success rate of achieved postoperative ABG  $\leq 20$  dB between the TORP (48.9%) and PORP (77.5%) ( $p < 0.05$ ). In the mucosa integrity group, there was no statistical difference in postoperative ABG, ABG closure and success between the TORP (72.4%) and PORP (78.7%) ( $p > 0.05$ ). It is also found that reconstruction with titanium PORP offered better functional results when performed during CWD surgery for advanced cholesteatoma, as a single stage procedure. In their study, the presence of mucosal pathology had a statistically significant effect on functional results, when both PORP and TORP groups were considered together. However, when the PORP group was considered alone, the presence of mucosal pathology did not have a statistically significant effect on the postoperative ABG [3]. Kim et al. [11] reported no significant difference was seen when PORP ossicular reconstruction was performed in an open mastoid cavity, whether it was staged after tympanomastoidectomy or performed concurrently. A staged ossicular reconstruction with tympanomastoidectomy was significantly more advantageous than concurrent ossicular reconstruction when considering those cases in which a TORP was used in an open mastoid cavity. Yung and Vowler [17] regarded that the absent stapes was the possible unfavorable factors in the univariate analysis. We speculate that the reconstructed ossicular chain will not be disturbed by the regeneration of the middle ear mucous membrane when the stapes superstructure is present. Aslan et al. [16] thought that the positive effect of the presence of the stapes superstructure on hearing results was closely related to the quality of the mucosa. These results implied that the postoperative adhesions and fibrosis had an influence on the columella and the assembly built, and resulting in poorer hearing results. In our opinion, the PORP in single stage canal wall down tympanoplasty for the patients suffered from chronic otitis media with mucosa defect is favored.

## 5. Conclusion

It is revealed PORP in single stage CWD tympanoplasty for the patients suffered from chronic otitis media with mucosa defect is favored. And the concurrent TORP is available, though the final effect is not as good as PORP.

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