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Comparison of hearing reconstruction techniques in tympanosclerosis with stapes fixation

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Ethics Committee Approval
The study was approved by Kocaeli University Ethics Committee of Non-Invasive Clinical Research with the approval number of GOKAEK 2021/3.30 on February 5, 2021, and informed consent was obtained from all patients. All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

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Abstract

Background/Aim: Surgery for tympanosclerosis with stapes fixation for hearing reconstruction is controversial, with many reports in the relevant literature advocate opposing suggestions. The primary aims were to evaluate hearing improvement with varied hearing reconstruction techniques performed for tympanosclerosis with stapes fixation.

Methods: Patients with tympanosclerosis and stapes fixation, whose hearing impairment was reconstructed surgically and who were followed for 1-5 years were reviewed in this retrospective cohort study. The audiological outcomes of reconstruction methods, including mobilization, partial ossicular replacement prosthesis (PORP), total ossicular replacement prosthesis (TORP), and teflon pistons (TP) were documented.

Results: The study included 76 ears of 76 patients; 29 ears in the mobilization technique group, 28 ears in the PORP technique group, 10 ears in the TORP technique group, and 9 ears in the TP technique group. When postoperative and preoperative hearing were evaluated, the mobilization and PORP techniques showed statistically significant improvement in both air conduction threshold gain and air-bone gap closure ($P<0.05$). Although some improvement was observed with the TORP and TP techniques, it was not significant ($P>0.05$). Bone conduction threshold showed no significant deterioration in any techniques.

Conclusion: For hearing gain, mobilization and PORP were effective in tympanosclerosis patients with stapes fixation after removal of sclerotic plaques, whereas the TORP and TP techniques did not show significant improvement. It can be concluded that, if a functionally mobile stapes cannot be achieved, it is not advisable to perform TORP replacement or a stapedotomy. However, these methods may still be used in carefully selected patients and be successful in some.

Keywords: Tympanosclerosis, Stapes fixation, Hearing reconstruction, Ossicular replacement prosthesis, Ossicular mobilization

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Introduction

The tympanic membrane, tympanic cavity, and mastoid cavity sometimes contain calcareous plaques, a condition known as tympanosclerosis. Dense fibrous and collagenous connective tissue with scattered calcification, hyaline degeneration, and few cells were observed in histological studies [1]. Deposition of calcareous plaques usually causes conductive-type hearing loss at lower frequencies, initially due to ossicular fixation. As the disease progresses, hearing loss may be detectable at all frequencies due to the mass effect of plaques. If the disease affects the cochlea, sensorineural hearing loss can also occur [2]. There is no proven and effective medical treatment for tympanosclerosis. Thus, to date, surgery is the only effective option to treat this pathology, although surgery remains controversial due to concerns about long-term refixation and sensorineural hearing loss during stapedotomy.

Ossicular mobilization is the initial step in all types of tympanosclerosis surgery. If total mobilization can be achieved, the procedure can be concluded. However, if total mobilization is not possible, a further appropriate hearing reconstruction technique should be selected. Placement of partial ossicular replacement prosthesis (PORP), total ossicular replacement prosthesis (TORP) or Teflon pistons (TP) are options for ossicular continuity [3, 4], but all these techniques carry the risk of hearing deterioration, especially after performing a stapedectomy. This makes the surgical decision-making challenging in some patients. Rehabilitation with hearing aids is an alternative choice [5], but it has its own disadvantages. Therefore, single stage surgery is still promising to obtain functional hearing in selected patients.

The aim was to evaluate hearing improvement following the use of a range of reconstruction techniques including mobilization only, PORP, TORP, and TP and to further compare subsequent postoperative hearing outcome when these techniques were performed for tympanosclerosis with stapes fixation.

Materials and methods

Patients with tympanosclerotic middle ears who were treated surgically between January 2016 and November 2018 at a tertiary center were retrospectively assessed. Patients who had stapes and/or oval window fixation, were Wielinga-Kerr Classification Groups 3 and 4 [6], who were treated surgically, had a hearing reconstruction performed at the same or second stage, and had been diagnosed as tympanosclerosis by pathological examination were included in this study. Wielinga-Kerr group 1 and 2 patients, patients who had less than 12 months of follow-up or who refused second stage operation were excluded. Patients whose stapes could not be mobilized and could not be replaced with a TP were also excluded.

The study was approved by Kocaeli University Ethics Committee of Non-Invasive Clinical Research with the approval number of GOKAEK 2021/3.30 on February 5, 2021, and informed consent was obtained from all patients.

Patients and reconstruction techniques

Patients were evaluated by sex, tympanic membrane status, presence of cholesteatoma, preoperative and the postoperative air-conduction thresholds (ACT), bone-conduction thresholds (BCT) and air-bone gap (ABG).

Patients were evaluated by four techniques depending on the method of hearing reconstruction: Technique 1- The mobilization technique, Technique 2- The PORP technique, Technique 3- The TORP technique, and Technique 4- The TP technique. All prostheses were Kurz® (Dusslingen/Germany) titanium ossicular prostheses.

Operative procedure

Tympanoplasty was defined as grafting of the tympanic membrane and exploration of the middle ear for the purpose of this study. After the removal of pathological tissues, all available ossicles were first mobilized. Then, additional hearing reconstruction(s), if needed, was performed according to the status of the middle ear and ossicular chain.

The evaluation of ossicular mobility began with the assessment of the malleus with a needle manipulation. If the malleus was not mobile, the incudostapedial joint was disrupted and the stapes was palpated individually. If attic fixation was detected, the incudomalleolar joint was detached, the incus was removed, and the prosthesis was positioned between the malleus and the stapes or footplate. Patients who had both attic fixation coupled with stapes fixation and where the mobilization of one or both was unsuccessful were excluded from the study. In patients undergoing TORP or PORP, the prosthesis was placed between the graft or malleus and stapes suprastructure or footplate. In all TP cases, the small fenestration technique was performed as a standard stapedotomy procedure.

The TORP was a further choice for ossicular reconstruction. Due to the nature of tympanosclerosis, destruction of ossicles is infrequent [6]. The reason for the use of TORP was usually absent or weakened stapes suprastructure.

Sclerotic plaques were removed under microscopic vision. Plaques between the stapedial crura and around the footplate were carefully and gently removed using a needle. When at all possible, the sclerotic mass was removed from the surgical field and stapes mobilization was assessed with round window movement under the highest magnification. The plaques over the lateral semicircular canal and the facial canal were dealt with using maximum precision. On the facial canal projection, as much of the plaque was removed as possible, with the help of a facial nerve stimulator, until it had no effect on the ossicular or ventilation system which was then restored. After removing all sclerotic plaques, additional hearing reconstruction techniques were performed, if ossicular continuity or mobilization could not be achieved.

In general, mobilization was the first step and also the only intervention for all patients if adequate motility was achieved. In the absence or weakness of stapes suprastructure, TORP was used. Ossicular discontinuity was managed with PORP. The patients whose stapes could not be mobilized were treated with TP, if feasible.

Audiological analysis

Audiometric evaluations were performed according to ISO standards using an Interacoustic AC40 (Interacoustic, Middelfart, Denmark) and obtained no earlier than one month before surgery, and postoperative measurements were made at the most recent recorded physical examination

after surgery. All techniques were evaluated according to hearing thresholds and the proportion of patients with a postoperative ABG less than 20 dB.

Statistical analysis

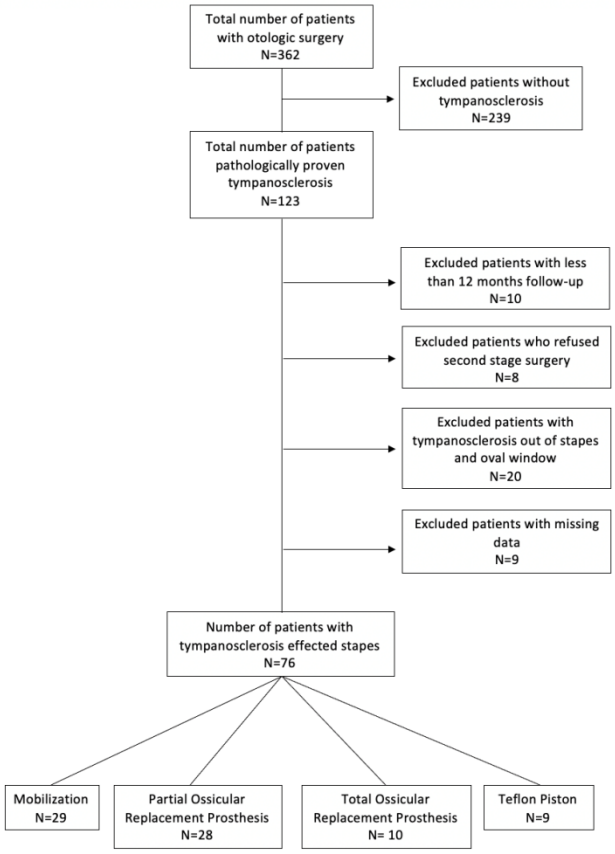
All statistical analyses were performed using SPSS for Windows, version 20.0 (IBM Corp., Armonk, NY, USA). Kolmogorov-Smirnov tests were used to test the normality of data distribution. Continuous variables were expressed as mean (standard deviation (SD)), median (25^{th}-75th percentiles, i.e., the interquartile range (IQR)). Categorical variables were expressed as counts (percentages). Comparisons of normally distributed continuous paired variables between the times were performed using the paired samples t-test and two-way ANOVA. Comparisons of non-normally distributed continuous variables between the times were performed using the Wilcoxon t-test, and Friedman analysis of variance by ranks. A *P* value <0.05 was considered statistically significant.

Results

General information

At a tertiary center, 123 patients with ears pathologically confirmed as tympanosclerosis were identified between the years 2016-2018. Of these, ten patients with a follow-up of less than 12 months, eight patients who refused second stage surgery, twenty patients falling into Wielinga-Kerr group 1 and 2 (tympanosclerosis not involving the stapes and oval window), and nine patients with missing data were excluded. Thus, a total of 47 patients were excluded. Seventy-six ears of 76 patients were included in the study and analyzed (Figure 1). There were no patients who had both ears operated in the study cohort.

Figure 1: Flow diagram of the study



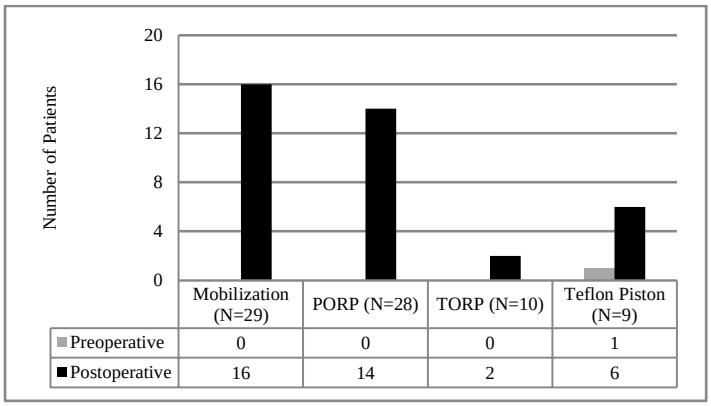
The patients were aged between 18 and 61 years with a median (IQR) age of 28.0 (22.0-35.6) years. Fifty-two (68.4%) were female, and 24 (31.6%) were male. The patients were followed for a median (range) of 41.8 (12-60) months.

Tympanic membrane perforation was detected in 65 patients (85.5%). There were seven patients (9.2%) affected by cholesteatoma, but no recurrence was observed during follow-up. Tympanoplasty without mastoidectomy was performed in 16 patients (21.1%), intact canal wall (CWU) mastoidectomy in 41 patients (53.9%), and canal wall down (CWD) mastoidectomy in 19 patients (25.0%).

Reconstruction methods and audiological assessment

There were 29 patients in the mobilization group, 28 patients in the PORP group, 10 patients in the TORP group, and nine patients in the TP group. The median follow-up time was 42 months for all groups. The mobilization group was followed for a median (IQR) of 42.0 (28.2-50.5) months, the PORP group for 39.0 (22.5-49.0) months, the TORP group for 40.5 (22.5-51.8) months, and the TP group for 49.7 (29.0-55.9) months. Follow-up times did not differ significantly between these groups (*P*>0.05). Figure 2 shows the pre-operative and the post-operative ABGs of all groups, and Table 1 summarizes the audiological and statistical results. The details of all groups are given below.

Figure 2: The preoperative and the post-operative ABG less than 20 dB of all groups



PORP: Partial ossicular replacement prosthesis; TORP: Total ossicular replacement prosthesis.

Table 1: The evaluation of average of hearing thresholds according to techniques

		Preoperative Median (25th-75th)	Postoperative Median (25th-75th)	*P*-value
Mobilization (n=29)	ACT	47.5 (45.0-54.4)	36.3 (24.5-56.9)	0.001
	BCT	17.5 (13.8-22.6)	15.0 (9.4-21.3)	0.130
	ABG	30.0 (26.9-35.0)	18.0 (13.9-32.9)	0.005
PORP (n=28)	ACT	53.8 (44.1-60.1)	43.9 (27.5-54.4)	0.002
	BCT	14.0 (10.0-20.0)	14.0 (11.5-21.9)	0.380
	ABG	34.4 (30.1-45.8)	22.0 (16.6-33.6)	0.001
TORP (n=10)	ACT	58.9 (48.4-63.8)	46.9 (31.3-53.8)	0.102
	BCT	20.0 (14.7-27.5)	16.8 (13.4-23.4)	0.343
	ABG	35.9 (28.4-45.2)	26.9 (18.4-33.8)	0.058
TP (n=9)	ACT	48.0 (45.0-48.9)	31.3 (25.6-46.3)	0.139
	BCT	15.0 (11.0-21.9)	12.0 (8.8-25.0)	0.888
	ABG	30.0 (23.8-39.0)	19.0 (16.4-24.4)	0.173

ACT: Air-Conduction Threshold BCT: Bone-Conduction Threshold ABG: Air-Bone Gap PORP: partial ossicular replacement prosthesis; TORP: total ossicular replacement prosthesis; TP: Teflon Piston; ACT: air-conduction threshold; ABG: air-bone gap. (Unit: dB) Data given as median (25. percentile; 75. percentile).

Group 1: Mobilization (n=29). In all surgeries in this study, mobilization was the first step. Patients who did not require additional reconstructions were included in this group. Adequate ossicular mobility were achieved in 29 patients (38.1%) with mobilization only. Four patients (13.8%) required revision surgery with the mobilization procedure. Tympanoplasty was performed in six (20.7%), CWU in 19 (65.5%), and CWD in four (13.8%) patients. The graft success

rate was 86.2% (25 patients). Cholesteatoma was present in three patients (10.3%).

A postoperative ABG <20 was achieved in 16 patients (55.2%). The ACT levels significantly improved from a median of 47.5 dB to a median of 36.3 dB (P=0.001). The ABG levels improved from a median of 30.0 dB to a median of 18.0 dB (P=0.005). The BCT levels tended to improve from 17.5 to 15.0 dB, but without statistical significance (P=0.130).

Group 2: PORP (n=28). In this cohort, the most applied prosthesis was the PORP. The PORP was positioned between the manubrium mallei and the stapes in 18 patients (64.3%), and between a cartilage under-graft and stapes in 10 patients (35.7%). Tympanoplasty was performed in five (17.9%), CWU in 12 (42.9%), and CWD in 11 (39.3%) patients within this group. Four revision surgeries (14.3%) were performed due to prosthesis displacement in two patients, and tympanic membrane perforation in two patients. Cholesteatoma were removed in two patients (7.1%).

The PORP group had a success rate of 50.0% (14 patients) with postoperative ABG less than 20 dB. The ACT levels improved from a median of 53.8 dB to a median of 43.9 dB (P=0.002). The ABG levels improved from a median of 34.4 dB to a median of 22.0 dB (P=0.001). There was no change in BCT levels with a postoperative median of 14.0 dB compared to preoperative levels of 14.0 dB (P=0.380).

Group 3: TORP (n=10). The TORP was positioned between the manubrium mallei and the stapes footplate in three patients (30.0%), and between a cartilage under-graft and the stapes footplate in seven patients (70.0%). Tympanoplasty was performed in two (20%), CWU in four (40%), and CWD in four patients (40%). Only one (10.0%) revision surgery for tympanic membrane perforation was carried out. Cholesteatoma was removed in two patients (20.0%).

There were two (20.0%) patients with less than 20 dB postoperative ABG (defined as success). In the TORP group, improvement was achieved in all three assessments (ACT, ABG, and BCT), with no statistical significance. The ACT levels improved from a median of 58.9 dB to a median of 46.9 dB (P=0.102), the ABG levels from a median of 35.9 dB to a median of 26.9 dB (P=0.058) and the BCT levels from 20.0 to 16.8 dB (P=0.343).

Group 4: TP (n=9). The least used prosthesis in our patients was TP. Stapedotomy was performed in nine patients (11.9%) who had no mobile stapes footplate. We removed all plaques wherever possible. After the middle ear and oval window were freed from plaques, we manually controlled the fixation. If stapes fixation persisted, we mostly preferred to wait and perform a second stage surgery. Two-stage surgery was performed in six patients (66.7%), and a single-stage surgery was performed in the remaining three patients (33.3%). Tympanoplasty was performed in three (33.3%) and CWU, in six patients (66.7%). Three (33.3%) revision surgeries (fat myringoplasties) for tympanic membrane reconstruction were performed in this group. Cholesteatoma was encountered in two patients (20.0%) in the first stage of their surgery.

A less than 20 dB postoperative ABG was achieved in six patients (66.7%). In the TP group, improvement was evident in all three assessments (ACT, BCT, and ABG) but there was again no statistical significance. The ACT levels improved from a median of 48.0 dB to a median of 31.3 dB (P=0.139), the ABG levels improved from a median of 30.0 dB to a median of 19.0 dB (P=0.173), and the BCT levels improved from 15.0 to 12.0 dB (P=0.888).

Complications

Graft failure occurred in 10 patients (13.2%) and prosthesis dislocation, in two patients (2.6%). Six were corrected with minor interventions, such as fat myringoplasty. The remaining graft failures and prosthesis dislocations were revised under general anesthesia with a tympanoplasty procedure, as described. No major complications, including total hearing loss or facial paralysis, were noted.

Discussion

Tympanosclerosis is a mass disease in the middle ear, affecting the tympanic membrane, and the mastoid cavity. Although the surgical treatment of tympanosclerosis remains controversial, especially when there is stapes involvement [7], surgery is justified for hearing reconstruction [8]. Surgery begins with the removal of calcareous deposits. When all irreversible or mobility-effecting deposits are removed, ossicular chain mobility should be assessed using at least basic methods. Our practice is to always palpate the ossicular chain with a needle, and if any movement of the round window after the mobilization was observed, the procedure for hearing reconstruction was considered complete without any further intervention. If no movement was observed, additional reconstruction strategies were used, depending on the status of the ossicular chain.

Mobilization, or sole use of mobilization, is a controversial procedure in the management of fixed stapes in tympanosclerosis. Some authors are opposed to the notion that the mobilized ossicles will become fixed again in a short time or that satisfactory hearing results cannot be achieved with mobilization alone [9, 10]. However, our results demonstrated no significant long-term deterioration in the mobilization group over a median 42 month-follow-up period, as previously reported [11, 12], and in support of this viewpoint. The concerns about re-fixation requirement in mobilized ossicles are somewhat allayed by these satisfactory results.

The limit for ossicular mobilization is also controversial. Having a mobile and healthy stapes without any intervention seems sufficient, but our major focus in this study was damaged and fixed stapes, due to tympanosclerosis. All stapes ossicles of patients in this study were damaged and no patient in the cohort had healthy stapes in the affected ear. After mobilization, if the movement of the round window appeared sufficient, it was deemed sufficient to finish the procedure. However, the main issue is an accurate evaluation of ossicular mobility. Although the round window reflex is not a reliable method, due to simplicity, economy, and practicality, it is certainly a pragmatic option for evaluation of stapes mobility. The implementation of new, objective techniques to assess ossicular motility will provide more detailed and precise information about which technique should be applied. Wales et al. [13] experimented with minimally invasive laser vibrometry for an objective evaluation of the ossicles in temporal bones. In the future, after mobilization, surgeons may utilize such methods

to decide whether to perform an additional hearing reconstruction.

After stapes mobilization, if the malleus and/or incus were defective or had to be removed, the PORP was the prosthesis of choice for hearing reconstruction in our patients. Wan *et al.* showed that the results of PORP for mobile stapes and attic fixation were statistically better than those of mobilization alone [14], but our results showed no significant difference between PORP and the mobilization group according to ACT gain, ABG gain, and BCT loss. Since our samples sizes were larger, we believe that our results are more reliable. Thus, we suggest that mobilization is as effective as PORP. Proper removal of the plaques and efficient mobilization are the key points. In addition, selection of patients in which mobilization is sufficient and for which a PORP is required are also important. We believe that it is particularly important to preserve anatomical structures as much as possible to utilize them in reconstruction, despite the fact that they may display a mass effect and causere-fixation [12].

TORP was the preferred prosthesis for ossicular reconstruction in our patients when the stapes suprastructure was absent or weakened, and the footplate was mobile. Although the likelihood of ossicular destruction in tympanosclerosis is considered low [6], we encountered relatively high rates of stapes suprastructure defects. The reason for this might be the high number of patients with cholesteatoma and the deleterious effect of late hospital admission. The TORP group did not show significant hearing improvement, which is in contrast to the study of De Vos *et al* [15]. These authors stated that the design of TORP increased stability and has equal performance with PORP. Stability was provided for the titanium prosthesis we used by placing gel foams around the TORP. Encouragingly, TORP displacement was not observed, although two dislocations in the PORP group were identified during follow-ups. In our patients, there was also a tendency to improve in both the ACT and the ABG levels in the TORP group, but this was not significant. It is our opinion that both PORP and TORP have their own advantages and disadvantages. PORP has functional superiority, but it also has a higher risk of re-fixation. TORP has a lower risk of ongoing sclerosis but is placed in a less favorable position in the middle ear. Our preference is for PORP rather than TORP when a functional stapes is present.

The TORP group had the least (Postoperative ABG <20 dB) hearing success (20%). The extraction of plaques on the oval window with a defective stapes suprastructure is more challenging due to the risk of footplate dislocation and worsened hearing. This restrains the surgeon from further removal causing the poorest ABG gain in the TORP group.

Prosthesis extrusion rates ranged from 0 to 5% in a previous report [16]. To overcome this complication, prostheses (PORP and_TORP) were placed under a cartilage graft or the manubrium mallei, which avoided direct contact with the fascia graft. We believe that the main reasons why we did not encounter any prosthesis extrusion were cartilage graft placement and meticulous surgical procedure. Only two patients required revision for non-functional hearing gain in the PORP group: One due to displacement towards the promontorium and the other due to synechia with the bony annulus.

The main question in the management of tympanosclerosis is whether to force mobilization or perform a stapedotomy. The reasons for this discussion are the risk of sensorineural hearing loss and facial nerve damage [17]. Some authors favor mobilization and others favor stapedotomy [3, 7, 8]. There was no hearing deterioration or facial nerve damage in any of our patients and we did not observe any significant improvement in the stapedotomy group, suggesting that further intervention was not necessary. A hearing aid may be a safer option than performing a stapedotomy, based on our results.

Stapedotomies were usually performed at the second stage (71.4%), as suggested by Bayazıt et al. [10]. Deciding whether to undergo second stage surgery may be difficult for patients. In our center, eight patients refused to undergo a second operation and were excluded from the study. The single-stage patients (33.3%) had dry ears with only sclerotic plaques with anterior small perforations. Thus, we could not compare single- and two-stage stapedotomy surgery statistically because of insufficient numbers of stapedotomies at the first stage of the operation. Future studies with higher number of patients would provide more data for this comparison.

In the TP group, ABG insignificantly decreased. Six out of nine patients (66.7%) had a postoperative ABG of less than 20 dB in the TP group and the median ACT was 31.3 dB, both of which are acceptable for communicative hearing. The low numbers of patients in this group may have made statistical analysis unreliable.

The general success rate in all groups was 50.0% in the long term (median 42 months), according to a success criterion of a postoperative ABG less than 20 dB. Teufert and De La Cruz compared short-term and long-term results for up to 9.5 years. They reported a success rate of 64.6% in the short term and 65.3% in the long term using this same criterion. They also showed no significant deterioration over the time [11]. Therefore, given the results of Teufert and De La Cruz's and the present study, we suggest that re-fixation of the ossicles and deterioration of the audiological results is unlikely to be of concern.

The co-existence of cholesteatoma with tympanosclerosis was 9.2% in our study. Our finding was consistent with the lower end of the rate (4-30%) reported by Kaur [18]. Of course, the presence of cholesteatoma in patients with tympanosclerosis complicates the surgery. However, we believe that, with appropriate surgical treatment, it should not hinder achieving hearing gain, as also reported by Weiss et al. [19].

Limitation

There are limitations to this study, including its retrospective and single-center design. A further limitation of the study was the small population of patients in the TORP and the TP groups compared to the other groups. It is also important to note the limitations inherent in gathering data through a hospital registry review process. Future research with higher number of patients and prospective design should be done for more certainty.

Conclusion

We recommend surgical intervention for these patients. To obtain a mobile stapes is the key point for hearing

improvement. If stapes mobilization cannot be achieved after removal of tympanosclerotic plaques, any additional intervention, such as TORP or stapedotomy, is generally not recommended. We suggest that these techniques may still be performed in some selected patients by our long-term hearing outcomes.

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