



CLINICAL STUDY

HEARING RESULTS ACCORDING TO OSSICULOPLASTY TECHNIQUES IN CHRONIC OTITIS MEDIA

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SUMMARY

Introduction: In our study, it was aimed to analyze the postoperative hearing data of the patients with chronic otitis media who were operated with different ossiculoplasty techniques and to compare ossiculoplasty techniques with each other and the literature.

Methods: Patients who were operated for chronic otitis media accompanied by hearing loss in Sakarya University Training and Research Hospital, Otorhinolaryngology Clinic between April 2013-December 2017 were retrospectively analyzed. Medical notes belonging to the patient were recorded. Thus, age, gender, surgical procedure and surgical findings of the disease, as well as the technique used for ossiculoplasty and audiometry test results at least 6 months postoperatively were determined.

Findings: A total of 203 ossiculoplasty files scanned by the retrospective method were included in the study. Among these cases, data on 131 operated ears who had no graft failure and whose files were fully accessible were included in the study. Fifty-seven (57%) percent of the patients were female, and 56 (43%) were male. There was no statistically significant difference between the ossiculoplasty methods and the absence of stapes, high middle ear risk index and secondary surgeries were among the factors that reduce the success.

Conclusion: As a result, we believe that it is important for the literature to demonstrate that open technique tympano-mastoidectomies can not be directly correlated with poor hearing outcomes and for the patients with intact manubrium mallei, audiological results of malleostapedopexy is as efficient as the patients implanted with partial ossicular replacement prosthesis (PORP).

Keywords: Chronic otitis media, hearing gain, ossicul, ossiculoplasty, air-bone gap

KRONİK OTİT MEDİA HASTALARINDA OSSİKÜLOPLASTİ TEKNİKLERİNE GÖRE İŞİTME SONUÇLARIMIZ ÖZET

Giriş: Çalışmamızda kronik otit media nedeniyle opere edilen ve farklı ossiküloplasti tekniklerinin kullanıldığı hastalara ait ameliyat sonrası işitme verilerinin analiz edilmesi ve ossiküloplasti tekniklerin birbirleri ve literatür ile karşılaştırılması amaçlanmıştır.

Yöntem: Nisan 2013-Aralık 2017 tarihleri arasında Sakarya Üniversitesi Eğitim ve Araştırma Hastanesi Kulak Burun Boğaz (KBB) Hastalıkları kliniğinde işitme kaybının eşlik ettiği kronik otit media nedeniyle opere edilen hastalar retrospektif olarak tarandı. Hastalara ait tıbbi notlar kaydedildi. Böylece hastalara ait yaş, cinsiyet, cerrahi prosedür ve cerrahi bulgular ile ossiküloplasti için kullanılan teknik ve ameliyat sonrası en az 6 ay sonrasında yapılan odyometri test sonuçları tespit edildi.

Bulgular: Retrospektif metod ile taranan toplamda 203 ossiküloplasti olgusundan greft başarısızlığı yaşanmayan 131 ine ait verilerin tümüne ulaşılabildi ve bu hastalar çalışmaya dahil edildi. Hastaların 75 i (%57) kadınlardan, 56 sı (%43) ise erkeklerden oluşmakta idi. Ossiküloplasti yöntemleri arasında istatistiksel anlamlı fark izlenmez iken, stapesin yokluğunun, yüksek orta kulak risk indeksinin ve ikincil cerrahilerin başarıyı azaltan faktörler arasında olduğu gösterildi.

Sonuç: Elde ettiğimiz verilerle açık teknik timpanomastoidektomilerin kötü işitme sonuçları ile direk korele edilemeyeceğinin gösterilmesinin ve intakt manubrium mallei varlığında malleostapedopeksinin parsiyel ossiküler replasman protezleri (PORP) kadar iyi odyolojik sonuçlara sahip olduğunun gösterilmesinin literatür katkısı açısından önemli olduğu düşüncesindedir.

Anahtar Sözcükler: Kronik otit media, işitme kazancı, kemikçik, ossiküloplasti, hava kemik aralığı

INTRODUCTION

For patients diagnosed with chronic otitis media, the primary goal of treatment is to achieve an effective postoperative hearing function as well as a disease-free tympanic cavity. For this purpose, in addition to an intact and functional tympanic membrane and middle ear cavity, an active ossicular system is the key goals of the surgery.

Of course, the main factors in reaching this goal are affected by mainly the surgical experience, but also the severity of the middle ear pathology, the mucosal structure, the technique used, the ossiculoplasty material, and whether the posterior wall of the external auditory canal is preserved¹

The most affected ossicular component of the middle ear is the lenticular part of the incus. However, there are also injuries that can result in total loss of the ossicular chain². Pathologies such as a short ossicular fissure can be easily corrected with bone cement, while the cases requiring the use of total ossicular replacement prostheses are also

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routinely encountered in the otorhinolaryngology (ORL) practice.

The aim of this study was to analyze the postoperative hearing functions of patients operated due to chronic otitis media and treated with different ossiculoplasty techniques, and to compare ossiculoplasty techniques with each other and the literature.

MATERIAL and METHODS

Research protocol was conducted after the approval of Sakarya University ethical committee of non-invasive experiments, and in accordance with ethical rules of the Helsinki Declaration and Turkish laws and regulations. Patients who were operated due to chronic otitis media with hearing loss at the Clinic of Otorhinolaryngology in Sakarya University Training and Research Hospital between April 2013 and December 2017 were retrospectively screened. Medical notes of the patients were recorded. Thus, the age, gender, surgical procedure, findings of the patients, the technique used for ossiculoplasty and audiological tests obtained at least 6 months postoperatively were determined.

Pure tone hearing thresholds obtained audiological at frequencies of 500, 1000, 2000 and 4000 Hz via airway and bone conduction were recorded and mean thresholds were determined by taking the average of these four frequencies. In order to assess the success of ossiculoplasty techniques, air-bone gap (ABG) values were determined by subtracting the thresholds of airway and bone conduction pathway from each other. Postoperative ABG values were analyzed in three groups (≤ 20 dB, 21-30 dB, 31-40 dB, and >41 dB) in a similar manner to the literature. Values of 20 dB or less were interpreted as successful results. [3]

Ossiculoplasty techniques were divided into the following groups: bone cement group where ossicular chain integrity is maintained by bone cement, autologous graft group where autologous grafts are used, TORP group where total ossicular replacement prostheses (TORP) are used, and PORP group where partial ossicular replacement prostheses (PORP) are used, and all statistical analyses were conducted on these groups.

The groups were further divided into open technical tympanomastoidectomies in which the posterior wall of the external auditory canal was removed and intact channel tympanomastoidectomies in which the wall was preserved, and the effect of the external auditory canal wall integrity on hearing function was assessed. The auditory effects of the presence of stapes and manubrium mallei, surgical

procedure being the primary or secondary surgical procedure, the presence of cholesteatoma, and to be in the pediatric age group were separately examined. Furthermore, middle ear risk index (MERI) was also assessed and MERI results were grouped as mild, moderate and severe, and the differences were compared statistically.

Statistical analysis was performed using the IBM SPSS 20.0 version statistical software program for Windows (IBM Corporation, Armonk, New York, USA). Mean \pm standard deviation was used for continuous variables and percentage values were used for categorical variables. Kolmogorov-Smirnov analysis was performed for normality distribution analysis and according to this analysis non-parametric tests were preferred. Mann-Whitney U and Kruskal Wallis tests were used in the intergroup comparisons. Chi-square test was used for comparison of categorical variables. P values less than 0.05 were considered statistically significant.

RESULTS

A total of 203 cases screened by retrospective method were included in the study. Mean follow up period for whole of the study group was 28.8 months (min: 9.3 months, max:61.5 months). Mean follow up period for prosthesis group was 28.3 months. Among these cases, data on 131 operated ears of a total of 123 patients who had no graft failure and whose files were fully accessible were included in the study. 75 of the operated ears (57%) were females and 56 were males.

Among the patients included in the study, the posterior wall of the external auditory canal was preserved in 108 (82%) of the cases and 23 patients required open technique tympanomastoidectomies. Comparison of these groups showed no statistically significant difference in the average values of any frequency and air-bone gaps. The majority of the patients (89%) were operated for the first time, while secondary surgical data was used in 15 patients. There was no significant difference in any middle ear ossicul when quantitative data of secondary surgeries were compared to secondary surgeries. However, comparison of the auditory outcomes showed that, hearing results were worse in primary surgeries and it was found that these differences were statistically significant (Table 1).



Table 1: Comparison results of different factors with air bone gap data

	n	%	ABG500Hz	p	ABG1000Hz	p	ABG2000Hz	p	ABG4000Hz	p	MeanABG	p
Gender												
Female	75	57	26.5±14.8	,03	24.6±13.9	,18	16.8±12.5	,37	25.5±12.1	,54	23.4±11.0	,15
Male	56	43	21.0±13.5		21.1±12.7		15.1±11.6		24.2±15.8		20.4±10.7	
Cholesteatoma												
+	31	24	27.7±14.9	,10	26.1±14.7	,20	18.3±15.7	,49	25.4±14.6	,73	24.4±12.9	,23
-	100	76	23.1±14.2		22.5±13.0		15.4±10.9		24.8±13.6		21.4±10.3	
Ossiculoplasty types												
Autologous graft	52	40	24.3±13.5	,27	23.7±13.4	,14	16.5±11.7	,29	24.6±14.7	,87	22.3±10.3	,19
Bone cement	39	30	21.0±14.3		19.6±13.5		14.1±11.5		23.0±12.8		19.4±10.8	
Prostesis	40	30	27.1±15.5		25.8±13.0		17.6±13.2		27.3±13.5		24.5±11.6	
Operation type												
Intact posterior wall	108	82	24.3±14.3	,756	23.0±13.0	,862	15.1±10.7	,189	24.5±13.4	,569	21.7±10.2	,856
Open technique	23	18	23.2±15.6		23.9±15.8		20.8±16.8		27.1±15.5		23.8±14.3	
Mastoidektomy												
+	64	49	27.3±15.7	,024	25.9±14.7	,041	18.2±13.1	,048	28.6±14.8	,005	25.0±12.2	,007
-	67	51	21.1±12.5		20.5±11.7		14.1±10.8		21.4±11.8		19.3±8.8	
Stapes Superstructure												
+	106	81	22.5±14.3	0.00	22.1±13.3	0.06	15.0±11.4	0.03	23.6±13.6	0.03	20.8±10.4	0.00
-	25	19	31.0±27.6		27.6±13.7		21.0±13.9		30.6±13.4		27.5±11.8	
Manubrium Mallei												
+	112	84	23.4±14.2	,18	2.7±13.8	,21	15.8±11.8	,56	24.4±14.0	,21	21.6±11.1	,12
-	19	16	28.4±15.5		25.5±11.5		17.8±14.0		28.1±12.4		25.0±10.1	
Surgical type												
Primary	116	89	23.0±14.1	0.01	22.1±13.2	0.01	15.3±11.8	0.02	24.3±13.7	0.1	21.2±10.7	0.00
Secondary	15	11	33.0±14.6		31.3±12.8		22.3±13.2		30.3±13.8		29.2±10.4	
Middle ear risk index												
Mild	55	42	18.4±12.2	0.00	18.6±11.5	,00	12.2±8.8	0.00	22.5±12.9	0.15	17.9±8.6	0.00
Moderate	63	48	28.4±14.4		26.8±14.0		19.0±12.9		26.7±14.7		25.2±11.5	
Severe	13	10	28.0±16.1		24.6±13.9		18.4±16.3		26.9±11.9		24.5±12.6	

Table 2. Comparison of the categorized air bone gap results according to the middle ear risk index

		Air Bone Gap Classification				Total
		<20dB	21-30 dB	31-40 dB	>41dB	
Middle Ear Risk Index	MILD	39 (79%)	11 (20%)	5 (9.1%)	0 (0%)	55
	MODERATE	22 (34.9%)	26 (41.2%)	6 (9.5%)	9 (14.3%)	63
	SEVERE	6 (46.2%)	3 (23.1%)	3 (23.1%)	1 (7.7%)	13



Table 3. Comparison of the categorized air bone gap results according to ossiculoplasty types

		Air-Bone Gap Classification				
		<20dB	21-30 dB	31-40 dB	>41dB	Total
Ossiculoplasty Type	Autologous graft	27 (51.9%)	16 (%30.8%)	6 (11.5)	3 (5.8%)	52
	Bone-cement	24 (61.5%)	9 (%23.1%)	4 (10.3)	2 (5.1%)	63
	PORP	10(52.6%)	6(%31.6%)	2(10.5)	1(5.3%)	19
	TORP	6 (28.6%)	9 (%42.9%)	2 (9.5)	4(19.0%)	21

PORP: Partial Ossicular Replacement Prosthesis

TORP: Total Ossicular Replacement Prosthesis

Table 4. Comparison of the air bone gap numeric results according to ossiculoplasty types

	ABG500Hz		ABG1000Hz		ABG2000Hz		ABG4000Hz		Mean ABG	
Bone-cement	21.0±14.3	.06	19.6±13.5	.10	14.1±11.5	.47	23.0±12.8	.60	19.4±10.8	.14
Autologous graft	24.3±13.5		23.7±13.4		16.5±11.7		24.6±14.7		22.3±10.3	
PORP	21.8±13.9		23.4±11.5		15.5±11.7		26.3±14.5		21.7±9.8	
TORP	31.9±15.6		28.0±14.1		19.5±14.3		28.3±12.9		26.9±12.8	

PORP: Partial Ossicular Replacement Prosthesis

TORP: Total Ossicular Replacement Prosthesis

Table 5. Hearing results of the patients with bone cement

	n	ABG500Hz		ABG1000Hz		ABG2000Hz		ABG4000Hz		Mean ABG
Bone cement (I-S)	27	24.2±14.9	.14	21.4±14.1	.54	15.9±10.7	.16	24.2±12.3	.56	21.4±10.4
Bone cement (M-S)	9	15.5±10.7		18.3±11.7		11.6±13.9		22.2±14.3		16.9±10.9

I-S: incudostapedial joint

M-S: Malleoincudal joint

The evaluation of the air-bone gaps obtained after surgery showed that; 51% of the patients had air-bone gaps under 20 dB, 30.5% between 21 and 30 dB, 10.5% between 31 and 40 dB and 8% above 41 dB. The patients were grouped according to the middle ear risk indexes, It was found that 55 (42%) patients had mild, 63 patients (48%) had moderate, and 13 (10%) patients had severe MERI scores. In this respect, comparison of the groups in terms of the numerical data (Table 1) and the categorized results revealed a positive correlation between disease severity and poor hearing results (Table 2).

The presence or absence of the middle ear ossicles were specially considered and the mean ABG was 20.8 dB in patients with stapes superstructure, whereas 27.5 dB in patients with damaged stapes. Statistical analyses of these results showed p values smaller than 0.05 for both numerical and categorical data. The presence of manubrium mallei did not lead to a significant difference. However it was found to lead to better ABG results compared to the defected group (p = 0.07) (Table 1). In addition, it was found that presence of cholesteatoma in the middle ear and being in the



pediatric age group did not present additional risk in terms of hearing outcomes (Table 1).

The study group was divided into subgroups according to ossiculoplasty techniques as; the cases of autologous graft, bone cement, and PORP and TORP were examined separately and no significant difference were found among the techniques for all frequencies (Table 3 and 4). The results of the PORP and malleo-stapedioplasty cases were compared specifically and the mean air-bone gaps were 21.7 ± 9.8 and 16.9 ± 10.9 , respectively. The difference was not significant at any frequency ($P < 0.05$). Moreover, the difference between the data of malleo-stapedioplasty and incudo-stapedioplasty groups was not statistically significant (Table 5).

DISCUSSION

The correction of hearing problems, which is an important health problem after the construction of a healthy middle ear in patients with chronic otitis media, is the main goal in these surgeries. Different materials have been used for a long time for hearing reconstruction. Currently, ossicular chain reconstruction with autografts, bone cement, allografts such as PORP and TORP are performed intensively in the ORL practice 1, as homografts previously used for this purpose are no longer used due to risk of infection. The results of our data showed that; all of the methods mentioned were effective and statistically indifferent from each other, and that all methods could be used in appropriate cases.

There are studies indicating that middle ear risk index, which consists of factors such as diseased mucosal state in the middle ear, ear effusion, cholesteatoma presence, advanced cases according to the Austin-Kartush classification and presence of previous surgeries could be used as a marker that affects ossiculoplasty outcomes. There are also authors that found no significant difference between MERI and hearing outcomes⁴⁻⁶. With the results of this study we can emphasize that better hearing results were obtained regardless of ossiculoplasty type in low risk groups when the groups were categorized and compared according to the numeric ABG values. Evaluation of the risk factors separately showed that secondary surgeries, presence of cholesteatoma, granulation and effusion in the middle ear, and advanced stage Austin/Kartush cases were independently associated with poor hearing outcomes.

Albu et al. thought that adding mastoidectomy to surgery could be an independent risk factor and showed that there was a significant

difference between cases with mastoidectomy and those without mastoidectomy. This situation was also proven by Dornhoffer et al.^{5,7}. The same authors also showed that not preserving the posterior wall of the external auditory canal was another risk factor. However, there are also authors who show that open technical tympanomastoidectomy does not constitute a risk factor^{8,9}. Analyses of our data showed that; although mastoidectomy could be considered as an additional risk factor, there was no significant difference between open technique tympanomastoidectomy and presence of intact external auditory canal in terms of hearing.

The presence of stapes superstructure is known to be one of the important factors affecting hearing success after ossiculoplasty for most of the authors.¹⁰⁻¹³. With the data of present study, it was seen that presence of stapes superstructure provided better ABG results. This situation is consistent with various studies in the literature. In our study, it was shown that the difference between ossiculoplasty techniques such as PORP, autologous grafts and bone cement, which can be used in the presence of intact stapes, were not statistically different.

The presence of manubrium mallei is one of the factors that affects auditory outcome positively as emphasized by many studies in the literature^{5,14-16}. Contrary to the literature, we found no significant difference in favor of this relationship. However, P value being close to 0.05 suggests that increasing the number of cases may result in statistical significance.

In the absence of an available stapes that can be used, using total ossicular replacement prostheses may be necessary. In this case, a sufficient tension between the tympanic membrane and the oval window needs to be created for a successful hearing outcome⁹. In a study conducted by Berenholz et al. TORP success was determined as 66% when an air-bone gap of 20 dB or less was accepted as a successful hearing outcome. This ratio increased to 86% when 30 dB or less was considered successful¹⁷. In the study conducted by Colletti et al., the success rate of TORP was 81% in the early period, but decreased to 35.7% after 5 years of follow-up¹⁸. In the study of Baker et al., the rate of patients who fell below 20 dB was determined as 60%¹⁹. Likewise, in the studies performed by Özdek, Bayazit and Martin et al., successful audiological outcomes were obtained in 44.8%, 43.1% and 30.4% of the cases reconstructed by TORP, respectively^{8,9,20}. In our study, this ratio was 28.6% when 20 dB or less was considered successful and 71.4% when 30 dB or less was considered successful. ABG for cases treated



with TORP was 26.9 dB. This value was reported as 27 dB in the study of Martin et al.²⁰.

Partial ossicular replacement prostheses are allograft materials used to join the stapes head with membrane or manubrium mallei. Similar to TORP applications, lateral support of prosthesis with cartilage grafts is important to prevent late prosthesis loss when PORP is used. Success rates in studies using PORP were 84% for Grote et al.²¹, 73% for Martin et al.²⁰, and 66% for Özdek et al.⁹. Our success rate was 52.6% and lower than the literature. However, the ABG values of PORP cases were found to be 21.7 dB which is very closer to 20 dB hearing level. This value was reported as 16.9 dB in the study of Martin et al. and 25.4 dB in the study of Elicora et al.²². Our average hearing results are consistent with the literature, while the number of patients below 20 dB is lower in our study compared to the literature.

CONCLUSION

The data of our study showed that; the difference between all the techniques used was not statistically significant when the results were compared statistically. These results show that autologous grafts and bone cement materials can also be used effectively for ossiculoplasty purposes just like allograft materials such as prostheses. Furthermore, we show that open technical tympanomastoidectomies cannot be directly correlated with poor hearing outcomes and that malleostapedopexy in the presence of intact manubrium mallei provides similarly good auditory outcomes as PORP. We believe that these results are important in terms of making a contribution to the literature.

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