



# Hearing results according to ossiculoplasty techniques in chronic otitis media

## *Kronik otitis mediada ossiküloplasti tekniklerine göre işitme sonuçları*

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**Objectives:** This study aims to evaluate the variables which affect hearing results in ossiculoplasty in patients with chronic otitis media.

**Patients and Methods:** Fifty-two patients who underwent ossiculoplasty surgery due to chronic otitis media between January 2010 and July 2011 were retrospectively analyzed. The effects of the ossicular residue and selected ossiculoplasty techniques on hearing were compared. Air-bone-gap (ABG) levels were determined both preoperatively and postoperatively. Postoperative ABG levels  $\geq 20$  dB were considered successful. Bone cement technique was reviewed in terms of specific superiority from other techniques.

**Results:** Ossiculoplasty was applied only 36% of patients operated due to chronic otitis media. Postoperative ABG levels were  $< 20$  dB in 26.9% (n=14) of patients. The mean postoperative ABG level was  $23.5 \pm 9.9$  in patients with an intact stapes suprastructure and  $33.7 \pm 10.1$  in those without an intact stapes suprastructure (p=0.001). The best surgical results were found to be  $17.1 \pm 9.4$  dB in patients with an intact malleus handle undergoing bone cement ossiculoplasty (p=0.048).

**Conclusion:** In this study, we conclude that status of malleus handle is the most important factor which influence the success of ossiculoplasty. Hearing results were positive with bone cement technique at least conventional techniques. We consider that the usage of bone cement technique may rule out absorption and extraction of ossiculoplasty material-related problems in selected cases.

**Key Words:** Air-bone-gap; bone cement; chronic otitis media; ossiculoplasty.

**Amaç:** Bu çalışmada kronik otitis media hastalarında ossiküloplastide işitme sonuçlarını etkileyen değişkenler değerlendirildi.

**Hastalar ve Yöntemler:** Ocak 2010 - Temmuz 2011 tarihleri arasında kronik otitis media nedeniyle ossiküloplasti cerrahisi uygulanan 52 hasta retrospektif olarak incelendi. Ossiküler kalıntıların ve seçilen ossiküloplasti tekniklerinin işitme üzerindeki etkileri karşılaştırıldı. Hava-kemik aralıkları (HKA) ölçümleri ameliyat öncesi ve ameliyat sonrası dönemde yapıldı. Hava-kemik aralığı düzeyinin  $\geq 20$  dB olması başarılı olarak kabul edildi. Kemik çimentosu tekniği, özellikle diğer tekniklere olan üstünlüğü açısından tartışıldı.

**Bulgular:** Kronik otitis media nedeni ile ameliyat edilen hastaların %36'sına ossiküloplasti uygulandı. Ameliyat sonrası HKA düzeyleri, hastaların %26.9'unda (n=14)  $< 20$  dB olarak tespit edildi. Stapes suprastrüktürü sağlam olan hastalarda ortalama HKA  $23.5 \pm 9.9$  iken, stapes suprastrüktürü sağlam olmayan hastalarda  $33.7 \pm 10.1$  olarak tespit edildi (p=0.001). En iyi cerrahi sonuçlar, malleus kolu sağlam olan ve kemik çimentosu ossiküloplasti uygulanan hastalarda  $17.1 \pm 9.4$  dB olarak elde edildi (p=0.048).

**Sonuç:** Bu çalışmada, malleus kolunun durumu ossiküloplasti başarısını etkileyen en önemli faktör olarak saptandı. İşitme sonuçları kemik çimentosu tekniği ile en az konvansiyonel teknikler kadar pozitif. Biz kemik çimentosu tekniği kullanılarak, ossiküloplasti materyalinin emilim ve atılım sorunlarının belirli olgularda önlenileceğini düşünüyoruz.

**Anahtar Sözcükler:** Hava-kemik aralığı; kemik çimentosu; kronik otitis media; ossiküloplasti.

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Improved hearing is a purpose of ossiculoplasty. This issue is affected by many factors, including Eustachian tube dysfunction, middle ear pathology, ossicular chain status, technical success of the surgeon, and technique of ossicular reconstruction.<sup>[1]</sup> There are many studies about prognostic factors which affect short and long-term results of ossiculoplasty, but standardization between studies is negatively affected by a variety of follow-up parameters.<sup>[2]</sup>

Depending on middle ear and ossicular pathology, patients with conductive hearing loss may be candidates for ossiculoplasty.<sup>[3]</sup> Ossicular reconstruction is also usually performed when the incus is eroded or absent, and the stapes and/or foot plate are intact and mobile.<sup>[4,5]</sup> Austin<sup>[6]</sup> indicated that the presence of the malleus is one of the most important factors that affect tympanoplasty results. Recently, bone cement material has been used for ossicular reconstruction and stabilization of implants,<sup>[5]</sup> and is generally used in ossiculoplasty when the malleus is present.

It is generally accepted that long-term results may be worse in ossiculoplasties. Some reasons for this are that prosthesis or materials used for reconstruction become useless or extracted due to several causes. We think that these problems can be lessened by use of bone cement material in proper cases. In this study we planned to examine variables that affect hearing results in ossiculoplasties and discuss bone cement material as a chosen technique for ossiculoplasty.

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## PATIENTS AND METHODS

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One hundred and forty-seven patients who were operated on for chronic otitis media (COM) in our clinic between January 2010 and July 2011 were evaluated retrospectively. Fifty-two patients (30 males, 22 females; mean age 28.7 years; range 16 to 55 years) who underwent ossiculoplasty were included in our study. The relationship between ossiculoplasty technique and hearing improvement were evaluated for at least three months for each case.

Preoperative and postoperative hearing levels (frequencies 500, 1000, 2000, and 3000 Hz) and air- and bone-conduction thresholds (frequencies 250, 500, 1000, 2000, and 4000 Hz) were measured. The results were evaluated in accordance with the guidelines of the Committee on Hearing and Equilibrium-1995. Postoperative hearing results were categorized into four groups, with 20 dB and better postoperative ABG values interpreted as successful.

The history and clinical characteristics of the patients were recorded from the hospital information system

(HIS). Present pathologies of cases were defined from surgical operation notes. Stapes/foot plate mobility was recorded as normal or defective, middle ear mucosa was recorded as normal or sick. Existence of malleus handle and stapes superstructure, applied surgeries, obtained postoperative ABG values were compared for each case. We also observed revision surgical rates. Existence of stapes superstructure was examined in primary and revision cases.

Autologous ossicles, cortical bone, titanium prosthesis (Spiggle & Theis Medizintechnik, ASTM-F67 titanium, Germany), auricular cartilage and bone cement (Ketac-Cem, Espe Dental AG, Seefeld, Germany) were used as ossiculoplasty materials in our study. The selected ossiculoplasty techniques and obtained postoperative ABG values were compared among four groups.

The analysis of the results was carried out using SPSS for Windows version 17.0 statistical software program (SPSS Inc., Chicago, IL, USA). Correlates between postoperative ABG and variables were calculated with independent t-test and chi-square test. All p values were two-tailed and the statistical significance was set at  $p < 0.05$ .

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## RESULTS

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Demographic and clinical characteristics are summarized in Table 1.

Canal wall-up tympanoplasty (CWUT) was performed in 69.2% (n=36) of the cases, and canal wall-down tympanoplasty (CWDT) was performed in 30.7% (n=16). Findings included cholesteatoma in 55.7% (n=29), chronic otitis media with perforation in 23.07% (n=12), adhesive otitis in 15.3% (n=8), and tympanosclerosis in 5.7% (n=3). Revision tympanoplasty was performed in 38.4% (n=20).

Intraoperative examination of middle ear pathologies revealed intact stapes superstructure, handle of the malleus, and stapes foot-plate in 55.7% (n=29), 46.15% (n=24) and 30.7% (n=16) of cases, respectively. Examination of the stapes superstructure in 32 primary and 20 revision cases revealed an intact and mobile stapes superstructure in 53.1% (n=17) of the primary cases and 60% (n=12) of revision cases. No statistically significant correlation was found between presence of stapes superstructure and primary or revision operation ( $p=0.974$ ). Although the average of postoperative ABG was  $33.71 \pm 10.05$  in cases with absent stapes superstructure, the average of postoperative ABG was  $23.46 \pm 9.91$  in cases with intact stapes superstructure ( $p=0.001$ ). The relationship between type of operation and the status of stapes superstructure is summarized in Table 2.

**Table 1**  
Demographic and clinical characteristics of patients applied ossiculoplasty in our clinic (n=52)

Characteristics of the patient	n	%	Mean±SD
<b>Gender</b>			
Female	22	42.3	
Male	30	57.6	
<b>Age</b>			
≤18 y	13	25	
>18 y	39	75	
Preoperative air-bone-gap	52		36.64±9.32 dB
Postoperative air-bone-gap	52		28.04±11.13 dB
<b>Cholesteatoma</b>			
Existent	29	55.7	
Not exist	23	44.2	
<b>Ossiculoplasty materials</b>			
Bone cement	14	26.9	
Autological ossicle	12	23.07	
Auricular cartilage	13	25.0	
Cortical bone	2	3.8	
TORP, PORP	10	19.2	
Teflon piston	1	1.92	
<b>Operation type</b>			
Canal wall-down tympanoplasty	16	30.7	
Canal wall-up tympanoplasty	36	69.2	
<b>Stapes suprastructure</b>			
Existent	29	55.7	
Not exist	23	44.2	
<b>Malleus handle</b>			
Existent	24	46.15	
Not exist	28	53.8	
<b>Surgical type</b>			
Primary	32	61.53	
Revision	20	38.46	
<b>Stapes/ footplate mobility</b>			
Mobile	42	80.7	
Intact	10	19.2	
<b>Tympanic cavity mucosa</b>			
Normal	9	17.3	
Abnormal	43	82.6	
<b>Postoperative air-bone-gap</b>			
0-20 dB	14	26.9	
21-30 dB	17	32.7	
31-40 dB	13	25.0	
41 dB and above	8	15.4	

SD: Standard deviation; TORP: Total ossicular replacement prosthesis; PORP: Partial ossicular replacement prosthesis.

While autologous ossicles, cartilage or bone cement were used as reconstruction materials in cases where stapes superstructure was present, Teflon piston, titanium prosthesis, autologous ossicles, bone cortex or cartilage were used in cases of absent stapes superstructure

with an intact and mobile foot-plate. The chosen ossiculoplasty materials, state of the ossicles and averages of postoperative ABG values are shown in Table 3.

Bone cement was used as the ossiculoplasty reconstruction material in 26.9% (n=14), autologous

**Table 2**  
Existence of stapes suprastructure in primary/revision cases (p=0.974)

Operation type	Stapes suprastructure				Patients n
	Exist		Not exist		
	n	%	n	%	
1. Primary	17	53.1	15	46.8	32
2. Revision	12	60	8	40	20

ossicles were used in 23.07% (n=12), and autologous cortical bone, titanium prosthesis, auricular cartilage and Teflon piston were used in 3.8% (n=2), 19.2% (n=10), 25.0% (n=13) and 1.9% (n=1) of the cases respectively.

Postoperative ABG values were determined in all cases. They ranged between 0-20 dB in 26.9%, 21-30 dB in 32.7%, 31-40 dB in 25.0%, and 41 dB and above in 15.4% of the cases. In addition, the mean postoperative ABG was determined as between 0-20 dB in 81.8% of cases where stapes superstructure was present and in 72.7% of cases where the handle of the malleus was present. The presence of intact stapes superstructure was evaluated against postoperative ABG values, and the mean postoperative ABG was found to be 26 dB and above in cases without a stapes superstructure. This value was 8.18 times better in cases with intact stapes superstructure (p=0.002).

We also evaluated 14 cases where the postoperative ABG was determined as between 0-20 dB. The middle ear mucosa was normal in seven (50%) and abnormal in seven (50%). The stapes superstructure was intact in 10 cases, the stapes footplate was intact and mobile

in two and the malleus was absent in only one case in this group. While 85.7% (n=12) underwent CWUT, 14.3% (n=2) underwent CWDT. Four of 14 cases with postoperative ABG 0-20 dB underwent revision operation. Preferred ossiculoplasty materials in these 14 cases included bone cement in eight, residual incus in three, bone cortex in two, and PORP in only one case.

## DISCUSSION

Chronic otitis media surgery with ossiculoplasty aims for eradication of disease as well as improvement in hearing. In the literature, surgical results were considered successful when postoperative ABG was 20 dB or better.<sup>[1,2,8]</sup> The postoperative ABG was between 0-20 dB in 26.9% (n=14) of the cases in our study.

Studies to date used prognostic factor analysis via non-regression analysis or regression analysis for predicting the outcome of ossiculoplasty. However, the variety of follow-up parameters and follow-up time in these studies, negatively affects standardization.<sup>[9-14]</sup> Thus, we employed multivariate analysis to overcome the disadvantages of non-homogenic groups in such studies.<sup>[12,13,15]</sup>

**Table 3**  
The relationship among ossiculoplasty material, state of ossicles and the average of postoperative air-bone-gap

The state of ossicles	Ossiculoplasty material		Average of postoperative ABG Mean±SD (dB)	p
	n	%		
Intact stapes suprastructure (n=29)				
Bone-cement	14	48.3	18.4±9.15	0.395
Other	15	51.7	24.6±10.52	
Intact malleus handle (n=24)				
Bone-cement	13	54.1	17.1±9.36	0.048
Other	11	45.8	27.9±12.66	
Intact foot plate (n=16)				
Autologous	9	56.25	33.42±10.15	0.26
Prostheses	7	43.75	36.2±6.38	

ABG: Air-bone-gap; SD: Standard deviation.

Mishiro et al.<sup>[1]</sup> examined predictive factors in ossiculoplasty results using multivariate analysis. An existing stapes superstructure was found in 76.2% of the cases who underwent primary tympanoplasty with ossiculoplasty. But this rate was only 23.8% in cases who underwent two-phase tympanoplasty. They recommended multivariate analysis to prevent confusing results about evaluating the relationship between surgery type and hearing results. They also emphasized the importance of primary tympanoplasty and presence of stapes superstructure for hearing improvement in ossiculoplasty. But when we determined the presence of stapes superstructure in primary/revision cases in our study, there was an intact and mobile stapes superstructure in 53.1% (n=17) of primary cases and 60% (n=12) of revision cases. No statistically significant correlation was found between the presence of a stapes superstructure and primary or revision operation. On the other hand, the average postoperative ABG in cases with a stapes superstructure (23.46±9.91) was better than in cases without a stapes superstructure (33.71±10.05).

In addition, Kim et al.<sup>[16]</sup> suggested that they obtained better results in ossiculoplasty with the primary operation. Cases of second look tympanoplasty were not included in our study and we performed revision ossiculoplasty in 38.4% (n=20) of our cases. In only four cases (28.5%) was the postoperative ABG 20 dB or better for revision operations in our study.

Becvarovski et al.<sup>[10]</sup> scored patients with middle ear risk index by combining such properties as ossicular state, otorrhea level, existence of perforation, cholesteatoma, and revision surgery. The pathologies of our cases consisted of 55.7% (n=29) cholesteatoma, 23.07% (n=12) chronic otitis media with perforation, 15.3% (n=8) adhesive otitis, and 5.7% (n=3) tympanosclerosis. In 69.2% (n=36) of cases, CWUT was performed while 38% (n=20) underwent revision tympanoplasty. Bellucci<sup>[9]</sup> suggested that cases with persistent ear discharge were adversely affected by ossiculoplasty results. But in our cases where postoperative ABG was between 0-20 dB, the middle ear mucosa was normal in seven (50%) and abnormal in seven (50%).

Albu et al.<sup>[12]</sup> defined such middle ear pathologies as wide perforation and absent malleus or stapes, and revision surgery as invariant risk factors. Dornhoffer and Gardner<sup>[13]</sup> defined absent malleus, fibrotic middle ear mucosa, and otorrhea as invariant risk factors. These risk factors were found meaningful in their multivariate analysis operations. Austin<sup>[6]</sup> emphasized that postoperative hearing results were worse when the malleus was absent than when it was present. However, in our study, only one case had no malleus

but its postoperative ABG was also between 0-20 dB. Mills<sup>[15]</sup> determined the absence of a stapes as another meaningful risk factor. Our study found that the probability of postoperative ABG averages being 26 dB and above in cases without a stapes superstructure was 8.18 times higher than in cases with a stapes superstructure.

Vrabec et al.<sup>[14]</sup> only discussed extrusion of the chosen prosthesis and its results without determining any risk factors in their study. It was generally accepted that short-term results would be better than long-term results in ossiculoplasties, and absorption and/or extrusion of ossiculoplasty materials were among the reasons cited.

Yung and Vowler<sup>[2]</sup> examined short-term (6 months) and long-term (5 years) results of ossiculoplasty using regression analysis. The presence of a malleus was a significant predictor at both six months and five years, while absence of stapes and revision surgery were borderline significant predictive factors at five years. Furthermore, absence of the malleus and otorrhea were the most negative effector factors on ossiculoplasty according to short-term results. In long-term results, absence of the malleus was found to be the only negative effector factor. In our study, there was only one case that had no malleus and its postoperative average ABG was between 0-20 dB. In addition, an evaluation of all our cases showed the average postoperative ABG was between 0-20 dB in 81.8% of cases with stapes superstructure and in 72.7% of cases with a malleus handle.

Since 1950, a variety of techniques and materials have been used in ossiculoplasty.<sup>[17]</sup> Many materials were also used in our study, including bone cement in 26.9% (n=14), autologous ossicles in 23.07% (n=12), autologous cortical bone in 3.8% (n=2), titanium prosthesis in 19.2% (n=10), auricular cartilage in 25.0% (n=13) and Teflon piston in 1.9% (n=1).

Prostheses can be classified as autograft, homograft, and allograft. Tragal cartilage, cortical bone and residues of ossicle are autograft prostheses. Their extrusion rates and infection risks are low, but they may be resorbed easily.<sup>[17]</sup> Allograft prostheses are synthetic materials and ready to use. But their disadvantages include ossicular necrosis, dislocation, and extrusion. The extrusion rate was as high as 39% for allograft prosthesis versus autograft prosthesis.<sup>[18]</sup> This situation negatively affects long-term results in ossiculoplasty.<sup>[19]</sup>

On the other hand, allograft prostheses like bone cement has been used increasingly because it is cheap, easy to find and useful. In addition, because bone cement can be used for small defects, it can provide

the nearest joint movement to natural ossicular chain function. Although Kobayashi et al.<sup>[20]</sup> indicated that bone cement does not cause a toxic reaction in middle ear mucosa, avoiding contact with the middle ear mucosa is generally advised because middle ear adhesion or tympanic membrane graft failure may result of this condition.<sup>[19,20]</sup>

Babu and Seidman<sup>[21]</sup> used bone cement for ossiculoplasty in 18 cases that had incus long brachium defects. While the average preoperative ABG was 33 dB, postoperative ABG was 10 dB. Çelik et al.<sup>[22]</sup> used bone cement in 31 of 66 patients for ossiculoplasty, versus cortical bone in 35. The postoperative ABG was 16.8 dB in the bone cement group versus 18 dB in the cortical bone group. In our 14 cases where postoperative ABG was between 0-20 dB, ossicular chain reconstruction used bone cement in eight, residues of incus in three, bone cortex in two and PORP in one. In addition to this, while bone cement material was used in 48.3% (n=14) of 29 cases that had a stapes structure, other materials were used in 51.7% (n=15) of 29 cases for ossicular reconstruction. The average postoperative ABG was 18.4±9.15 dB in the group which used bone cement, and 24.6±10.52 dB in other groups.

The average postoperative ABG value in cases that had a stapes superstructure and used bone cement was better than in cases that used other ossiculoplasty materials. We think that with more experience using bone cement, our results would be even better.

Bone cement was used in 54.1% (n=13) of 24 cases that had a malleus handle, while other materials were used for ossiculoplasty in 45.8% (n=11). The average postoperative ABG was 17.1±9.36 dB in the group which was used bone cement and 27.9±12.66 dB in the group which used other ossiculoplasty materials. The difference between these two values was statistically significant. If postoperative ABG values of 20 dB and below are the standard, these postoperative hearing results are successful. In our study, the best surgical results were obtained at 17.1 dB in the group with a malleus handle using bone cement for ossiculoplasty, and the second best surgical results were obtained at 18.4 dB in the group with a stapes superstructure using bone cement for ossiculoplasty.

Our findings suggest that the status of the ossicles is the most important factor for success of ossiculoplasty, consistent with the literature. The best hearing results were obtained when the malleus or stapes superstructure was present and bone cement was used for ossiculoplasty. Whether absorption and extrusion of the ossiculoplasty materials and their negative effects on long-term results of ossiculoplasty can be

minimized by using bone cement needs further studies, although short-term results of ossicular reconstruction with bone cement suggest better hearing than with other methods.

### Conclusions

Despite the limited number of patients who underwent ossiculoplasty with bone cement, it may be a reliable method for ossicular reconstruction that is cost effective and offers satisfactory hearing results in COM patients. Bone cement is an alternative to ossiculoplasty with preformed prostheses especially in patients with intact malleus and stapes superstructure. We believe that it is appropriate to compare with conventional techniques in a larger series of long-term outcomes.

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