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Comparison of Autologous Malleus Head and Hydroxyapatite Partial Replacement Prosthesis in Ossicular Chain Reconstruction

Kemikçik Zincir Rekonstrüksiyonunda Otolog Malleus Başı ile Hidroksiapatit Parsiyel Replasman Protezinin Karşılaştırılması

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Abstract

Aim: A wide variety of materials are used as a partial ossicular replacement prosthesis in ossiculoplasty. Data on the use of the head of the malleus for partial ossicular reconstruction is quite limited in the literature. The main objective of our study is to compare the functional and anatomic outcomes of ossiculoplasty using an autograft head of the malleus and hydroxyapatite partial ossicular replacement prosthesis (HA-PORP) in Austin-Kartush type A ossicular chain defect.

Material and Methods: Patients who underwent surgery due to attic cholesteatoma and had Austin-Kartush type A ossicular chain defect (with intact and mobile stapes, no incus, or not used as an autograft in ossiculoplasty) were included in the study. The patients were divided into two groups according to the material used for ossiculoplasty: those with malleus head (Group I) and those with HA-PORP (Group II). The groups were compared in terms of hearing gains obtained from the results of pre-and post-operative hearing tests, prosthesis extrusion rates, and recurrent cholesteatoma development rates.

Results: Postoperative air-bone gap (ABG) values were significantly lower in group I. Postoperative ABG gains were also significantly higher in group I. Functional success rates (postoperative ABG ≤20 dB) were higher in Group I (65%) than in Group II (50%), but the difference was not significant. Prosthesis extrusion rates were significantly higher in Group II; there were no differences between the groups in terms of recurrent cholesteatoma.

Discussion and Conclusion: When the incus is not available for ossiculoplasty, the head of the malleus can be considered as the first choice because it is biocompatible, cost-free, and has low extrusion rates compared with HA-PORP.

Keywords: hydroxyapatite; ossicular replacement prostheses; ossiculoplasty; PORP

Öz

Amaç: Ossiküloplastide parsiyel kemikçik replasman protezi olarak çok çeşitli materyaller kullanılmaktadır. Literatürde parsiyel kemikçik rekonstrüksiyonu için malleus başının kullanımına ilişkin veriler oldukça sınırlıdır. Bu çalışmanın temel amacı, Austin-Kartush tip A kemikçik zincir defektinde otogreft malleus başı ile hidroksiapatit parsiyel kemikçik replasman protezinin (HA-PORP) fonksiyonel ve anatomik sonuçlarını karşılaştırmaktır.

Gereç ve Yöntem: Çalışmaya attik kolesteatomu nedeni ile ameliyat edilen ve Austin-Kartush tip A kemikçik zincir defekti saptanan (stapes'i sağlam ve hareketli, incus'u olmayan veya ossiküloplastide otogreft olarak kullanılabilir durumda olmayan) hastalar dahil edildi. Hastalar ossiküloplastide kullanılan materyale göre iki gruba ayrıldı: malleus başı kullanılanlar (grup I) ve HA-PORP kullanılanlar (grup II). Gruplar ameliyat öncesi ve sonrası işitme testi sonuçlarından elde edilen işitme kazançları, protez atılma oranları ve rekürren kolesteatom gelişme oranları açısından karşılaştırıldı.

Bulgular: Grup I'de postoperatif hava-kemik aralığı (HKA) değerleri istatistiksel olarak anlamlı düzeyde düşüktü. Postoperatif HKA kazançları da Grup I'de istatistiksel olarak anlamlı düzeyde yüksekti. Fonksiyonel başarı oranları (postoperatif HKA ≤20 dB) grup I'de (% 65), grup II'ye (% 50) göre daha yüksekti, ancak fark istatistiksel olarak anlamlı değildi. Grup II'de protez atılma oranı anlamlı olarak daha yüksekti, nüks kolesteatom gelişimi açısından gruplar arasında fark bulunmadı.

Tartışma ve Sonuç: Ossiküloplasti için inkus mevcut veya kullanılabilir durumda olmadığında malleus başı biyouyumlu, maliyetsiz ve HA-PORP'a göre düşük ekstrüzyon oranlarına sahip olduğu için ilk seçenek olarak düşünülebilir.

Anahtar Kelimeler: hidroksiapatit; kemikçik replasman protezi; ossiküloplasti; PORP

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INTRODUCTION

The management of chronic otitis media with cholesteatoma requires surgical intervention and is often a difficult process involving the reconstruction of the ossicular chain. Although several studies have been published examining different ossiculoplasty materials to date, no consensus has been reached (1). Due to its poor blood supply, the incus is vulnerable to trauma and infections; therefore, the most commonly encountered ossicular chain defect is the erosion of the incus long process. The defects of the incus can be corrected differently depending on the size of the defect and the decision of the surgeon. The grafts used for this purpose are divided into three main groups as allografts, homografts, and autografts.

Today, due to the risk of carrying infectious diseases such as hepatitis, HIV, and Creutzfeldt-Jacob's disease, homografts are not used frequently. Allograft products are bio-compatible synthetic materials. Hydroxyapatite (HA), polyethylene, Teflon, plastipore, ceramic, and a variety of metal prostheses (e.g. titanium, gold) are materials used to reconstruct the ossicular chain. In incus defects, partial ossicular replacement prosthesis (PORP), or in case of where the stapes superstructure lies towards the promontory a total bone replacement prosthesis can be used depending on the surgeon's preference. As an autograft, incus residue is often used and ossiculoplasty is performed by shaping and repositioning it (placing it between the manubrium mallei and the head of the stapes). Apart from the incus, the head of the malleus, cortical bone, and cartilage have also been used in ossiculoplasty (2,3).

The purpose of ossiculoplasty is to improve hearing in the presence of conductive hearing loss. Many factors may influence the outcome of the ossiculoplasty, such as the condition of the middle ear mucosa and ossicles, the surgical technique, and the function of the Eustachian tube. Other factors that affect postoperative hearing outcomes include patient age, tympanic membrane perforation, otorrhea, prosthesis length, revision surgery, and cholesteatoma (4). The present study was designed to compare the functional and anatomical results using the autologous head of the malleus and HA-PORP in two groups of suitable patients (patients who have intact and mobile stapes, and whose incus is not suitable to be used for ossiculoplasty) presenting with attic cholesteatoma.

Materials and Methods

The present study was conducted in line with the ethical standards specified in the "Helsinki Declaration of Good Clinical Practices." Ethics approval was obtained from the hospital's local Research Ethics Committee (REC protocol number 2019/253).

Patients and groups

The files of patients who had surgery in the Otorhinolaryngology Department of our tertiary referral center due to isolated attic cholesteatoma between August 2014 and May 2018 were retrospectively evaluated. The inclusion criteria were as follows: 1. patients who had surgery due to attic cholesteatoma and whose external auditory canal could be reconstructed with cartilage, 2. patients with Austin-Kartush type A ossicular chain defect, 3. patients in whom the head of the malleus and HA-PORP were used for partial ossicular reconstruction, 4. patients who were followed for at least 6 months postoperatively, 5. patients who had a pre-operative hearing test and who had a hearing test performed at the 6th postoperative month or later, and 6. patients with primary surgery. Those who underwent revision surgery, had severe sensorineural hearing loss (dead ear), those who were not followed up or who did not have sufficient follow-up time of the study were excluded. Temporal bone computed tomography (TBCT) is routinely performed in all patients scheduled for chronic otitis media surgery in our clinic. If the findings in TBCT or during surgery are consistent with advanced cholesteatoma and healthy middle ear mucosa is insufficient, these patients may not be suitable to perform functional reconstruction in the same session and a second stage may be needed. Second-stage patients were not included in our study. Also, we routinely perform diffusion magnetic resonance imaging (MRI) on our patients who underwent external auditory canal reconstruction to evaluate the recurrence of cholesteatoma at the postoperative 6th month, 1st year, and annually thereafter. All patients included in our study had MRIs performed at least in the 6th postoperative month. The demographic data (e.g. age, sex) of the patients, follow-up periods (time from surgery to the last control), pre-and post-operative pure-tone audiometry findings, whether there was prosthesis extrusion, and whether there was recurrent cholesteatoma were recorded. The patients were divided into two groups according to the material used in

the partial ossicular reconstruction, ossiculoplasty performed by the head of the malleus (Group I) and by the HA-PORP (Group II).

Surgical procedure

All patients received general anesthesia. The surgery was carried out under a microscope (Karl-Zeiss, Jena, Germany) and the retro auricular approach was used. The tympanomeatal flap was elevated, then the flap was placed anteriorly and the middle ear was exposed. The posterior border of the cholesteatoma was reached by drilling off the attic lateral wall retrogradely. The cholesteatoma sac was carefully elevated and removed from the epitympanic region. To check the supratubal recess for cholesteatoma, any incus/incus residue and malleus head were removed. When it was ensured that the cholesteatoma was completely removed and there was sufficient healthy middle ear mucosa, ossicular chain reconstruction was performed. All ossiculoplasties were performed in single-stage surgery. The incus was not suitable for ossiculoplasty in every patient included in the study because it was severely defective and/or tightly covered by a cholesteatoma matrix. Also, they had mobile footplates and stapes superstructures suitable for partial ossicular reconstruction. If the head of the malleus was intact, it was removed and used for ossicular reconstruction. While preparing the malleus head as a graft, microscopic stripping was performed and suspicious areas were burred over with a 0.6-mm diamond burr. The acetabulum was opened on the head, then it was placed on the stapes head (Figure 1,2). HA-PORP (partial 90°, round head, offset; Medtronic Xomed, Jacksonville, FL, USA) was used when the head of the malleus was eroded and it could not be used as a graft. A direct TM/TM graft was placed when the head of the malleus was used, and cartilage was placed between the prosthesis and the TM/TM graft when HA-PORP was used. In cases where the malleus head was short, a piece of cartilage was placed on it to increase the length of the graft. As the tympanic membrane graft, the perichondrium of the tragal cartilage was used (the perichondrium was stripped on only one side and the perichondrium on the other side was left intact). The defect in the external ear canal was restored using tragal cartilage, the side with perichondrium was placed laterally and the procedure was terminated after the flap was replaced.

Evaluation of hearing

An AC40 (Interacoustics, Middlefart, Denmark) audiometry device and TDH-39 supra-aural headphones were used for audiometric examination. Pure-tone audiometry (PTA) results were evaluated according to the guidelines of the American Academy Committee on Hearing and Equilibrium (1995) (5). The mean values of pure-tone air conduction (AC) and bone conduction (BC) thresholds at 0.5, 1, 2, and 4 kHz were calculated using pre-operative and post-operative sixth-month PTAs. The air-bone gap (ABG) was determined by calculating the difference between AC and BC averages. In addition, the hearing gain was obtained by calculating the difference between pre and postoperative ABG. Also, the number and rate of patients with postoperative ABG of ≤ 20 dB were calculated. Hearing results were considered successful if the postoperative ABG was ≤20 dB, due to the common acceptance

Table 1. Basic Parameters and Demographic Data of Groups

	Group I	Group II	P
Sex (female / male)	10/13	6/6	0.713
Side (right / left)	12/11	5/7	0.555
Age, mean ± SD (min-max)	42.2±10.1 (22-60)	39±12.5 (26-63)	0.413
Follow-up time (months), mean ± SD (min-max)	18.1±6.8 (10-36)	19.6±7.8 (12-36)	0.554
Prosthesis extrusion,% (n)	-	16.6 (2)	**0.044**
Recurrent cholesteatoma, % (n)	4.3 (1)	8.3 (1)	0.630

(SD: standard deviation, min: minimum, max: maximum)

Table 2. Comparison of Pre-Postoperative Hearing Data of the Groups

	Preoperative	Postoperative	p
Group I	mean±SD (min-max) dB	mean±SD (min-max) dB	
- AC thresholds	52.1±11.6 (30-70)	41.3±10 (30-60)	**0.002**
- BC thresholds	20±7.5 (10-35)	21.5±7.7 (10-40)	0.503
- ABG	32.1±7.5 (20-50)	19.7±6.4 (10-35)	**< 0.001**
Group II			
- AC thresholds	50±12.4 (30-75)	43.8±14.8 (25-70)	**0.044**
- BC thresholds	20.8±7.9 (10-35)	21.2±9.3 (10-35)	0.907
- ABG	29.1±7.6 (15-40)	22.5±8.9 (15-40)	**0.049**

(AC: Air conduction, BC: Bone conduction, ABG: Air-bone gap, SD: Standard deviation, min: minimum, max: maximum)

of achieved audiometric outcome for the ossicular reconstruction of postoperative ABG 20 dB (6,7).

Statistical analysis

Frequency analysis, t-test, and Chi-square tests were used to assess the data. $p < 0.05$ was considered statistically significant.

Results

Thirty-five patients were eligible for the study. There were 23 patients (10 females, 13 males) in Group I, and 12 patients (6 females, 6 males) in Group II. Patient demographics, follow-up periods, extrusion rates, and recurrent cholesteatoma rates are shown and compared in Table 1. The mean age was 42.2 ± 10.1 (range, 22-60) years in Group I and 39 ± 12.5 (range, 26-63) years in Group II. There were no statistically significant differences between the groups in terms of demographic data and follow-up periods ($p>0.05$). In the postoperative follow-up, no prosthesis extrusion was observed in Group I, but prosthesis extrusion was detected in two patients (16.6%) in Group II at the postoperative 8th and 13th months. There was a statistically significant difference between the groups in terms of prosthesis extrusion ($p = 0.044$). In Group I, recurrent cholesteatoma was detected in one patient in the postoperative 1st year and revision surgery was recommended, but the patient did not accept revision surgery at that time. The patient later accepted surgery due to the development of otorrhagia symptoms during follow-up and underwent revision surgery in the 18th postoperative month. In Group II, one patient underwent revision surgery in the 8th postoperative month due to the recurrence of cholesteatoma and prosthesis extrusion. For recurrent cholesteatoma, there was no statistically significant difference between the groups during the current follow-up periods. ($p = 0.630$). When patients were examined for preoperative and postoperative hearing data, there was a significant difference between preoperative and postoperative AC thresholds and ABG values in both groups; no significant difference was found between preoperative and postoperative BC thresholds in either group (Table 2).

Preoperative and postoperative hearing data of the groups were compared. For preoperative AC thresh-

Table 3. Comparison of Pre-Postoperative Hearing Data Between the Groups

	Group I	Group II	p
Preoperative			
- AC thresholds Mean±SD (min-max) dB	52.1±11.6 (30-70)	50±12.4 (30-75)	0.612
- BC thresholds Mean±SD (min-max) dB	20±7.5 (10-35)	20.8±7.9 (10-35)	0.762
- ABG Mean±SD (min-max) dB	32.1±7.5 (20-50)	29.1±7.6 (15-40)	0.272
Postoperative			
- AC thresholds Mean±SD (min-max) dB	41.3±10 (30-60)	45.8±14.8 (25-70)	0.292
- BC thresholds Mean±SD (min-max) dB	21.5±7.7 (10-40)	21.2±9.3 (10-35)	0.927
- ABG Mean±SD (min-max) dB	19.7±6.4 (10-35)	24.5±8.9 (15-40)	**0.047**
Hearing gain (ABG gain), Mean ± SD (min-max) dB	12.8±6.7 (-5-25)	7±4.9 (0-15)	**0.014**
Functional success, (ABG ≤20 dB), % (n)	65% (15)	50% (6)	0.383

(AC: Air conduction, BC: Bone conduction, ABG: Air-bone gap , SD: Standard deviation, min: minimum, max: maximum)

olds, BC thresholds, and ABG values, there were no significant differences between the groups (p>0.05). Postoperative ABG values were significantly lower in Group I (p = 0.047). Postoperative ABG gains were significantly higher in Group I (p = 0.014). Although functional success rates were found higher in Group I (65%) than in Group II (50%), the difference was not statistically significant (p = 0.383) (Table 3).

Discussion

This study compared the effects of the head of the malleus and HA-PORP on recurrent cholesteatoma, prosthesis extrusion, and hearing outcomes in patients with Austin-Kartush type A ossicular chain defect. Hearing results were better and prosthesis extrusion rates were lower in the head of the malleus than HA-PORP. We successfully demonstrated that the use of the head of the malleus for ossiculoplasty is feasible.

Cholesteatoma is a non-neoplastic lesion characterized by the migration of squamous epithelium into the middle ear and mastoid cavity. Ossicular chain erosion occurs below this epithelial layer (8). Surgery is the mainstay of management in cholesteatoma. The main purpose of surgical treatment is to eradicate the disease and prevent recurrence and obtain a dry and safe ear. Roux et al. investigated residual rates in patients with cholesteatoma in whom they reconstructed the canal wall and defined canal wall reconstruction as feasible and safe in cholesteatoma surgery. They reported that this approach offered a broad perspective to the cholesteatoma-affected area and reduced residual cholesteatoma rates (9). In our clinic, we prefer to reconstruct the canal wall in cases where the cholesteatoma does

Figure 1. The head of the malleus is reshaped and an acetabulum is created

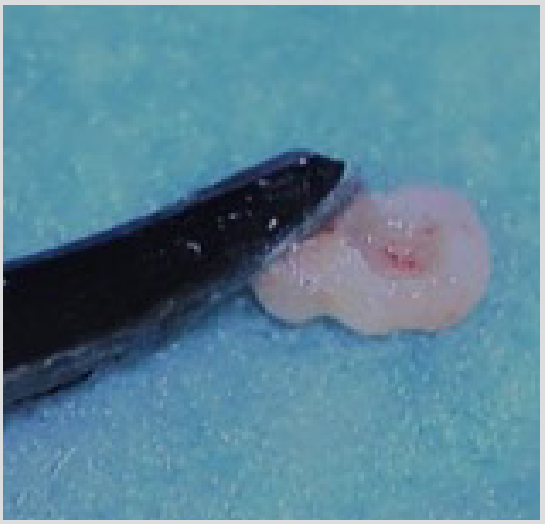
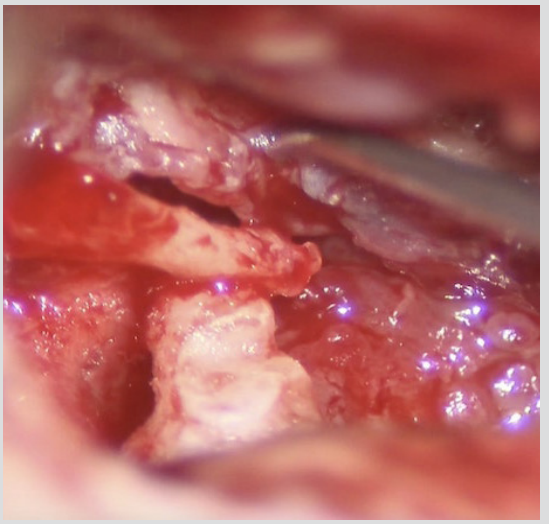


Figure 2. The head of the malleus interposed between the stapes and the manubrium mallei



not progress to the posterior of the horizontal semicircular canal and/or posterior mesotympanum.

In otologic surgery, ossicular chain repair and long-term successful physiologic and functional results remain a challenge, even for experienced otologists. Various materials such as homografts, autografts, and allografts have been used for ossiculoplasty, all of which have advantages and disadvantages. Autograft prostheses have advantages such as low extrusion rates, no risk of disease transmission, biocompatibility, and low cost; however, they also have disadvantages like complete absorption, displacement, and the ability to harbor microscopic disease and residual cholesteatoma (10). Ng et al. investigated the use of autografts for ossiculoplasty in cholesteatoma surgery and reported that they detected residual cholesteatoma only in ossicles that were badly eroded and could not be used in the reconstruction. They did not detect residual disease in usable ossicles, and it was safe to use autologous ossicles for ossiculoplasty that had retained body and bulk after stripping under a surgical microscope (11). Attanasio et al. rejected the theory that epithelial inclusions in the ossicles could cause the recurrence of cholesteatoma. As a result of their histologic study on 19 mallei and 15 incudes, which they obtained during cholesteatoma surgery, they suggested performing a safe cleaning procedure such as drilling, stripping, or autoclaving to make ossicular remnants utilizable in ossiculoplasty (12). When we used the head of the malleus as an ossiculoplasty material, we first performed microscopic stripping and then shaving with a diamond burr in the areas we found suspicious for epithelial inclusion while preparing the malleus head as a graft. In our study, the rates of recurrent cholesteatoma development in Group I and Group II were 4.3% and 8.3%, respectively, and no statistically significant difference was found between them ($p = 0.630$). We also think that autografts are safe to use in ossiculoplasty after an effective cleaning procedure such as microscopic stripping and drilling.

HA prostheses are widely used for ossicular reconstruction due to their excellent biocompatibility. Its disadvantage is that it forms a large mass in the relatively small middle ear space. There is a potential for extrusion of all alloplastic materials implanted in the human body. Kobayashi et al. reported a 1.9% prosthesis extrusion rate in patients in whom they placed cartilage between the HA prosthesis and TM (13). Ocak et al. reported this rate as 6% (14). In our study, HA prosthesis extrusion was observed in two (16.6%) patients, and we think that this high rate was due to our small number of patients in Group II. In Group I, no extrusion was observed. The difference was statistically significant ($p = 0.044$).

It is very difficult for researchers to compare studies in the literature because there is no universally accepted protocol to evaluate the results of ossiculoplasty. Os-

siculoplasty performed with the head of the malleus, in particular, is mentioned in a few publications in the literature (3,15). Iurato et al. compared audiological results of different ossiculoplasty materials in Austin-Kartush Group A patients and reported that they found no significant difference between incus interposition and the head of the malleus interposition (3). Moreover, Eliçora et al. noticed that the head of the malleus had the least success among autograft partial ossicular replacement prostheses in their study, where they examined the effects of different ossiculoplasty materials on hearing, but they reported that they found no significant difference between autograft materials (15). In another study, there was no difference between autologous material and PORP for hearing outcomes (16). In this study, the postoperative ABG values were slightly but statistically significantly lower in Group I ($p = 0.047$). Also, postoperative ABG gains were statistically significantly higher in Group I ($p = 0.014$). We believe that the better hearing results in Group I may be because the cholesteatoma was advanced in patients in whom we used HA-PORP, enough to erode the malleus head (but still did not exceed the attic).

Iurato et al. reported the rate of functional success (postoperative ABG ≤20 dB) as 85% in patients who underwent ossiculoplasty using autograft (3). Emir et al. reported the functional success rates as 58.1%, 71.4%, and 56.3% for autologous incus, cortex, and PORP, respectively (10). Kobayashi et al. found a functional success rate of 75% among their patients who underwent ossiculoplasty with HA-PORP (13). Our functional success rates for the head of the malleus and HA-PORP were calculated as 65% and 50%, respectively. Although the functional results of the head of the malleus appear better, there was no statistically significant difference between the two groups ($p = 0.383$).

Our study has some limitations. The main limitations are the small number of patients and the retrospective nature of our study. Data obtained from larger patient series, including patient groups using incus and bone cement, which are widely used for partial ossicular reconstruction, can provide a better interpretation of the effects of the head of the malleus on ossiculoplasty.

Conclusion

Compared with HA-PORP, hearing gains were significantly higher in patients using the head of the malleus for ossiculoplasty. There was no statistically significant difference among the groups over the current follow-up periods for recurrent cholesteatoma. The only disadvantage of ossiculoplasty performed with the head of the malleus compared with HA-PORP is the prolongation of the surgical time during ossicle reshaping and placement, where the incus is not usable for ossiculoplasty. If the head of the malleus is usable, it may be considered as the first choice because it is both biocompatible and costless and the rate of extrusion is lower than HA-PORP.

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