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Titanium versus Hydroxyapatite Prostheses: Comparison of Hearing and Anatomical Outcomes after Ossicular Chain Reconstruction

Titanyum ve Hidroksiapatit Protezler: Kemikçik Zincir Onarımı Sonrası İşitme ve Anatomik Sonuçların Karşılaştırılması

Original Investigation
Özgün Araştırma

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Abstract

Objective: This study aimed to compare hearing and anatomical outcomes after ossicular chain reconstruction with titanium or hydroxyapatite prostheses.

Methods: In this study, patients who underwent tympanoplasty and ossicular chain reconstruction with titanium or hydroxyapatite prostheses at a university hospital from January 2007 to February 2013 were retrospectively reviewed; they had a minimum follow-up period of 6 months. Patients were divided into 4 groups according to the type of prostheses. The surgical procedure, follow-up examinations, preoperative, and postoperative audiometry results were noted and evaluated for partial and total prostheses. The results were compared both for titanium and hydroxyapatite prostheses.

Results: The study subjects included 51 patients. Titanium had better hearing results in partial prostheses ($p<0.05$), while the anatomical outcomes were similar. Nevertheless, both types had similar results in total prostheses ($p>0.05$). The extrusion rate was 5.8% for all patients.

Conclusion: Both types of prostheses had satisfactory functional and anatomical results and no preponderance could be stated, except for the hearing results of partial titanium prostheses.

Keywords: Titanium, hydroxyapatite, ossicular chain reconstruction, prosthesis

Özet

Amaç: Bu çalışmada titanyum veya hidroksiapatit protez kullanılarak kemikçik zincir onarımı (KZO) yapılan hastaların işitme ve anatomik sonuçları karşılaştırılmıştır.

Yöntemler: Bu özgün çalışmada bir üniversite hastanesinde Ocak 2007 ile Şubat 2013 yılları arasında titanyum veya hidroksiapatit ile KZO yapılan ve en az 6 ay takip edilmiş olan hastalar geriye dönük olarak incelendi. Hastalar kullanılan protezin çeşidine göre 4 gruba ayrıldı. Ameliyat şekli, takip notları, cerrahi öncesi ve sonrası odyometri sonuçları kaydedildi ve parsiyel ve total protezler için ayrı ayrı değerlendirildi. Tüm sonuçlar titanyum ve hidroksiapatit protezler arasında karşılaştırıldı.

Bulgular: Çalışmaya 51 hasta dahil edildi. Parsiyel protezler içinde titanyumun daha başarılı sonuçlar verdiği ($p<0.05$) ancak anatomik sonuçları benzer olduğu görüldü. Total protezler arasında ise gerek işitme gerekse anatomik olarak her iki grup arasında benzer sonuçlar alındı ($p>0.05$). Protez atılım oranı tüm hastalar için %5.8 olarak kaydedildi.

Sonuç: Her iki protezin de gerek işitme gerekse anatomik olarak benzer sonuçlar verdiği görüldü. Titanyumun parsiyel rekonstrüksiyondaki başarılı işitme sonuçları dışında, protezlerin birbirlerine karşı herhangi bir üstünlük sağlamadığı izlendi.

Anahtar Kelimeler: Titanyum, hidroksiapatit, kemikçik zincir onarımı, protez

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Introduction

Middle ear ossicles can be destructed by chronic middle ear disease, cholesteatoma, or tympanosclerosis (1). The main aim of a successful tympanoplasty is the eradication of disease; however, a satisfactory hearing result is as important as eradication of the disease. Ossicular chain reconstruction (OCR) has been a popular topic for over 100 years. The first published data was the myringostapediopexy of Matte in 1901 (2). Since then, numerous methods and prostheses have been tried. The use of hydroxyapatite (HA) in middle ear surgery was first introduced by Grote in 1984 (3). HA is a highly biocompatible material that can be derived from the mineral matrix of living bone. It is a rigid material for ossiculoplasty with favorable hearing results. The negative feature, however, is the formation of a big mass in the relatively small middle ear cavity. Titanium prostheses, which have similar biological features as HA, rather than having such a wide shaft were developed later. The density of titanium is lesser than 57% of

stainless steel, although it is a sufficiently rigid material. It is biocompatible and can be reshaped, according to the need of the surgeon. Most titanium prostheses have an open platform to provide convenience when placing the implant. The first data about the titanium ossicular chain reconstruction prostheses was published in 1999 by Stupp et al. (4).

The aim of this study is to evaluate anatomical outcomes and hearing results in OCR with titanium and HA prostheses. The surgical outcomes were compared for both protheses. OCR with titanium and with HA is discussed along with literature regarding the subject.

Methods

Study Design and Patient Population

A retrospective study was conducted for the patients who underwent tympanoplasty and OCR with HA or titanium prostheses at Ankara University from 2007 to 2013 with a minimum follow-up period of 6 months. Patients with other types of OCR prostheses were excluded. Signed consent form was obtained from all the participants.

Patients were divided into 4 groups: HA partial ossicular chain replacement prosthesis (HA-PORP), titanium partial ossicular chain replacement prosthesis (Ti-PORP), HA total ossicular chain replacement prosthesis (HA-TORP), and titanium total ossicular chain replacement prosthesis (Ti-TORP). All patients were grafted with temporalis muscle fascia that was reinforced with conchal cartilage. The surgical procedure, follow-up examinations, pre-, and post-operative audiometry results were noted and analyzed for each group. The results were compared for each group, for both HA and titanium prostheses. Intact graft material at the final follow-up examination was considered as a successful anatomical outcome. Audiometry results [air-bone gap (ABG) and gain in decibel hearing level] were evaluated for each group, and a final ABG of ≤20 dB was considered a successful hearing outcome, according to American Joint Committee on Hearing and Equilibrium (5). Pure tone audiometry was performed with the AD629® (Interacoustics, Copenhagen, Denmark) device for frequencies from 250 to 8000 Hz. The study was approved by the Ethics Committee of Ankara University Faculty of Medicine.

Statistical Analysis

All statistical analyses were performed with SPSS 15.0 for Windows (SPSS Inc.; Chicago, IL, USA) programme. A p value of <0.05 was considered statistically significant.

Results

The study group consisted of 51 patients with a mean follow-up period of 38.5 months. There were 15 female and 36 male patients with a mean age of 35.2 (range, 13-57 years). There were 18 patients in HA-PORP group, 15 in HA-TORP group, 8 in Ti-PORP group, and 10 in Ti-TORP group. Totally, 16 patients (31.3%) underwent revision surgery. PORPs were preferred in cases with an intact and mobile stapes with the absence of a steady incudomalleolar complex. TORPs were preferred in patients with no healthy middle ear ossicules but an intact and mobile stapes footplate. Malleus was absent or eroded in all cases. Middle ear mucosa was hypertrophic or sclerotic in most of the patients due to the presence of a cholesteatoma or chronic suppurative process.

Table 1. Summary of hearing results

	ABG (dB)		Gain (dB)	
	Mean±standard deviation	Median (min–max)	Mean±standard deviation	Median (min-max)
HA-PORP	13.94±6.91	5 (0-30)	16.72±7.63	17.50 (0-30)
Ti-PORP	8.25±6.11	10 (0-16)	25.50±6.25	25 (15-35)
HA-TORP	21.47±10.23	20 (0-40)	13.20±8.49	10 (0-30)
Ti-TORP	19.00±8.43	20 (5-35)	19.00±10.75	20 (0-35)

ABG: air-bone gap; std dev: standard deviation; HA-PORP: hydroxyapatite partial ossicular replacement prosthesis; HA-TORP: hydroxyapatite total ossicular replacement prosthesis; Ti-PORP: titanium partial ossicular replacement prosthesis; Ti-TORP: titanium total ossicular replacement prosthesis

Table 2. Hearing results in partial reconstruction prostheses

	ABG (dB)	Gain (dB)	Successful hearing
HA-PORP	13.94	16.72	83.3%
Ti-PORP	8.25	25.50	87.5%
p	0.001*	NS	NS

*: statistically significant; NS: non-significant; ABG: air-bone gap; HA-PORP: hydroxyapatite partial ossicular replacement prosthesis; Ti-PORP: titanium partial ossicular replacement prosthesis

Most of the patients underwent mastoidectomy (n=43, 84.3%). Of these 43 patients, only 4 had canal wall down procedure; all from HA-TORP group. Approximately 50% of the patients who underwent ossiculoplasty without mastoidectomy belonged to HA-PORP group. Intact wall mastoidectomy was performed in 83% of the patients who had titanium prostheses.

Final hearing status of all the study groups is summarized in Table 1. When partial ossicular replacement prostheses were compared in terms of hearing results, the mean ABG of all patients was <20 dB; it is inferred that a successful hearing result was obtained in both types of prostheses. However, titanium had significantly better hearing results when compared to HA prostheses (p=0.001). Increase in hearing thresholds, another parameter to assess hearing outcome, were similar between both groups (p=0.108) (Table 2). There were no significant differences between the two types of partial prostheses, in terms of anatomical outcomes. The anatomical success rates were 77.7% and 75% in HA-PORP and Ti-PORP groups, respectively.

When total ossicular replacement prostheses were compared in terms of hearing results, mean postoperative ABG was 21.47

dB in HA-TORP group and 19.00 dB in Ti-TORP group (p=0.190). The gain in hearing thresholds were better in HA-PORP group (p=0.024) (Table 3). Anatomical outcomes were similar between the groups.

Three prostheses were extruded in 51 patients: two were HA prostheses with an average extrusion time of 14 months and the other prosthesis was titanium, which was extruded on the 12th month. The total extrusion rate was 5.8% with a mean time of 13.3 months (Table 4).

Table 3. Hearing results in total reconstruction prostheses

	ABG (dB)	Gain (dB)	Successful Hearing
HA-TORP	21.47	13.20	66.6%
Ti-TORP	19.00	19.00	70%
P	NS	0.024*	NS

*: statistically significant; NS: non-significant; ABG: air-bone gap; HA-TORP: hydroxyapatite total ossicular replacement prosthesis; Ti-TORP: titanium total ossicular replacement prosthesis

Table 4. Extrusion rates of prostheses

	Extruded prostheses (n)	Mean extrusion time (months)
HA-PORP	2 (6%)	14
HA-TORP	0	-
Ti-PORP	1 (5.5%)	12
Ti-TORP	0	-
Total	3 (5.8%)	13.3

HA-PORP: hydroxyapatite partial ossicular replacement prosthesis; HA-TORP: hydroxyapatite total ossicular replacement prosthesis; Ti-PORP: titanium partial ossicular replacement prosthesis; Ti-TORP: titanium total ossicular replacement prosthesis

Discussion

Annually, middle ear diseases that cause erosion in ossicles affect millions of people. Erosion in ossicles leads to hearing impairment due to the lack of conduction mechanism. Chronic otitis media with/without cholesteatoma, tympanosclerosis, and adhesive otitis media are the most common causes of erosion.

The studies by Wullstein and Zollner (1) in the early 1950s started the modern era of ossiculoplasty. Homografts, autografts, xenografts, and allografts have been used since then. The most widely used materials in OCR are homografts and alloplastic materials. In a study by Huttenbrick and Beutner (6), the ideal middle ear implant was described as biocompatible, light weighted, rigid, functionally designed, a good conductor of sound energy and compatible with imaging techniques like magnetic resonance imaging.

In 1984, Grote proposed the use of HA implants for OCR (3). Two years later, the same author studied the biocompatibility of HA and found no damage or change in the growth rate of the middle ear mucosa epithelium (7). Hydroxyapatite was at that time the most preferred alloplastic material in most parts of the world (8).

One of the most common reasons for cessation of many ossicular chain prostheses in historical perspective is the high rate of extrusion. This is due to the fact that there is a risk of extrusion in every alloplastic material implanted in the human body. Although Grote (9) reported high biocompatibility and low extrusion rates of HA in the late 1990s, Vrabec et al. (10) reported 8% early and 14% late extrusion rates. Then, lower extrusion rates were reported with the use of a thin cartilage graft between the prostheses and membrane gained popularity (11). In our study, the extrusion rate of HA prostheses was 6%; the most common reason was postoperative atelectasis.

Satisfactory hearing results by HA prostheses were reported by numerous authors (12-14). In this study, successful hearing results with HA prostheses were recorded specifically for partial replacement prostheses because the most important factor for a successful ossiculoplasty is the presence of a steady stapes suprastructure.

Titanium is a light (specific gravity, 4.5 g/cm^3) and rigid material that is highly stable. Superior osseointegration was proved both in animal and human middle ear models (15, 16). The open platform model of titanium prostheses provides a wide field of vision for the surgeon while placement of the implant. Its excellent acoustic conduction can be attributed to the rigid and stable structure, inspite of having such a slim shaft. Titanium prostheses were first used in OCR in 1993, and the first clinical report was published in 1999 by Stupp et al. (4). Following this, titanium gained popularity and many studies have been performed since then (17-19). Chen and Tao (20) reported an 83.7% success rate in hearing results for Ti-PORP and a 71.4% success rate for Ti-TORP. Schmerber et al. (21) reported 14.3 dB postoperative ABG for Ti-PORP and 25.4 dB for Ti-TORP. In the same study, successful hearing results were elicited from 77% of Ti-PORP and 52% of Ti-TORP prostheses. However, a meta-analysis of 1388 patients in 12 studies reported that titanium prostheses did not have any advantages or superiorities to other types of prostheses, in terms of stability and hearing outcomes (22). According to our data, the success rate in hearing results were 87.5% in Ti-PORP and 70% in Ti-TORP group, which is consistent with the literature.

On the other hand, placing and manipulating the prosthesis can pose a problem during surgery. Yung et al. (23) administered a questionnaire to 14 surgeons with different seniorities about the differences between HA and titanium protheses. For partial reconstruction, the placement of titanium prostheses was found to be more difficult than that of HA because of the lightness of the implant; however, for total reconstruction, most of the surgeons preferred titanium prostheses because of the open platform that provides better vision when placing the implant.

Conclusion

Both types of prostheses can be considered as adequate enough and no preponderance could be shown, except for the hearing results of partial titanium prostheses. Our study suggests that titanium prosthesis has better hearing results for partial reconstruction. Nonetheless, there is no significant difference between the two types of prostheses in total reconstruction. Despite the limited number of patients in this study, we can conclude that surgeons must consider the characteristics of the patient and the operation type and then choose the most appropriate type of prosthesis for OCR.

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Informed Consent: Written informed consent was obtained from patients participated in this study.

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