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A Novel Method of Hybrid Ossiculoplasty: Ionomer Bone Cement Coated Mastoid Cortical Bone

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ABSTRACT

Objective: The development of otologic surgical techniques has significantly improved the functional results of surgery. However, the issue of the most effective ossiculoplasty material is still controversial. The study aimed to introduce a novel method of autologous ossiculoplasty, using "ionomer bone cement coated mastoid cortical bone" and to assess short-term and long-term results of this method.
Material and Methods: The study presented a retrospective, consecutive case series of twelve patients who underwent revision surgery as type IV tympanoplasty using Mastoid cortical bone coated with ionomer bone cement in our institution between January 2013 and December 2019. Coating with ionomer bone cement was performed to prevent the autograft from sticking to the surrounding bone tissue. The short- and long-term auditory functions and otologic examination findings of the patients were analyzed.
Results: Physical examination findings were satisfactory. Except one, all patients had a significant improvement in hearing outcomes, and the late-term results were also satisfactory. An average long term audiological gain of 19.9 dB (± 8.7 SD) was found.
Conclusion: A novel method of Hybrid Ossiculoplasty: Ionomer Bone Cement Coated Mastoid Cortical Bone is an effective and safe method of ossiculoplasty. It can be easily eliminated one of the major disadvantages of mastoid cortical bone by coating it with ionomer bone cement.

Keywords: Ossiculoplasty, graft material, mastoid cortical bone graft, ionomer bone cement, type IV tympanoplasty

INTRODUCTION

There are a lot of issues that have not yet been overcome despite the technological developments in otologic surgery. Combating cholesteatoma and long-term outcomes of hearing reconstruction are among the most critical issues of otology (1). Total ossicular replacement prostheses (TORP) are usually placed between the stapes footplate and the tympanic membrane graft when middle ear ossicles are absent or inappropriate to use (type IV tympanoplasty according to Wullstein classification) during middle ear surgery (1). Today, various alloplastic materials are used as TORP, among which primarily are the materialstitanium and polycel. However, long-term results may not be satisfactory due to the obstacles related to the biocompatibility of these materials (2, 3). Although the use of mastoid cortical bone (MCB) as an autologous graft material was described before, it did not gain popularity due to the possibility of resorption and /or adhesion to the surrounding bone tissues (4).

We propose that properly shaped autologous MCB is a suitable material for ossicular reconstruction that is comparable to other synthetic materials. We used properly shaped MCB, the medial half of which was coated with ionomer bone cement in the revision surgeries.

The clinical results of the patients who underwent ossiculoplasty using MCB coated with ionomer bone cement were assessed as a preliminary study.

MATERIAL AND METHODS

The medical records oftwelve patients who were diagnosed with chronic otitis media (COM) and underwent type IV tympanoplasty between January 2013 and December 2019

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were retrospectively reviewed. The inclusion criteria were to be between the age of 18 and 65, performed type IV tympanoplasty surgery using MCB coated with ionomer bone cement and to have at least a 12 month follow-up clinical and audiological examination.

Patients' preoperative, postoperative initial period (6-8 weeks) and late (at least 12 months after surgery) audiogram results, otoscopic examination findings, clinical course and complications were recorded. For patients who previously underwent ossiculoplasty and used alloplast prosthetics, but have worsened hearing and/or extrusion, we recommended Type IV tympanoplasty with ionomer cement coated MCB usage as a salvage surgery.

After the patients were informed of their diseases and treatment options, an informed consent form was obtained, and a treatment process was started.

The postoperative late results were assessed based on the most recent audiograms in the postoperative period, which varied between one and seven years. The hearing was assessed using a pure tone audiometry test. The air and bone conduction pure tone thresholds and air-bone gap (ABG) were assessed (500 Hz, 1000 Hz and 2000 Hz frequencies were considered when measuring the averages of pure tone thresholds). Changes over time in audiologic values were calculated. Cases with ABG values less than 20 dB and gain greater than 10 dB were considered functionally successful.

Surgical Technique

A single surgeon performed all surgeries. Surgical access was provided through a retro auricular incision. A Mastoidectomy was performed with the ''inside out'' technique. The middle ear and mastoid cavity were revised in those who had previously received a performed mastoidectomy. Any cholesteatoma, granulation tissue and /or sclerotic plaques were cleaned. The previously placed prosthesis was removed. The status of the oval and round windows was assessed and the stapes footplate was confirmed to be mobile. Underlay tympanoplasty was performed using a temporal fascia. The posterior part of the fascia graft was placed forward and preparation for hearing reconstruction was provided. After the tympanic cavity was made ready, a bone graft preparation was started. Bone graft with a diameter of 1 mm and a length of 8mm from the mastoid cortex was obtained by drilling and using a gouge and hammer (Figure 1a). The length and shape were arranged according to the depth of the oval window (Figure 1b). Half of the bone to be positioned medially was insulated with ionomeric cement (Glasspolyalkenoate [ionomer] cement, Voco/meron corresponds to EN 29917/150/9917/1994[CE 0482]) (Figure 1c). The prepared bone graft was placed between the stapes footplate and the graft membrane. The lateral part of the MCB graft was not coated, as it adheres to the grafted membrane.A sound transmission chain continuity was provided. A Tympanomeatal flap was laid on the fascia graft.

Postoperative Follow up

The patients were discharged the next day after surgery. Stitches were removed after a week. Tampons from the mastoid cavity were removed after seven days and checked every week for four to six weeks until cavity epithelialization occurred. The postoperative follow-up continued and controls were performed monthly in the first year, and annually after the first year. Hearing tests were conducted six to eight weeks after surgery, on the first year and on annual controls. During this period, the patients were requested to report immediately in case of any problems (e.g., hearing deterioration, discharge, pain).

Data Analysis

Data were analyzed using the SPSS 22.0 software program (IBM Corp. In Armonk, NY. The means and medians, ranges, and standard deviations were calculated. Data distributions were analyzed using the Kolmogorov-Smirnov test and the quantitative data were compared using paired t test. The Friedman test was used to analyze time-dependent changes of the hearing test results of the patients. Level of significance was set at $p>0.05$.

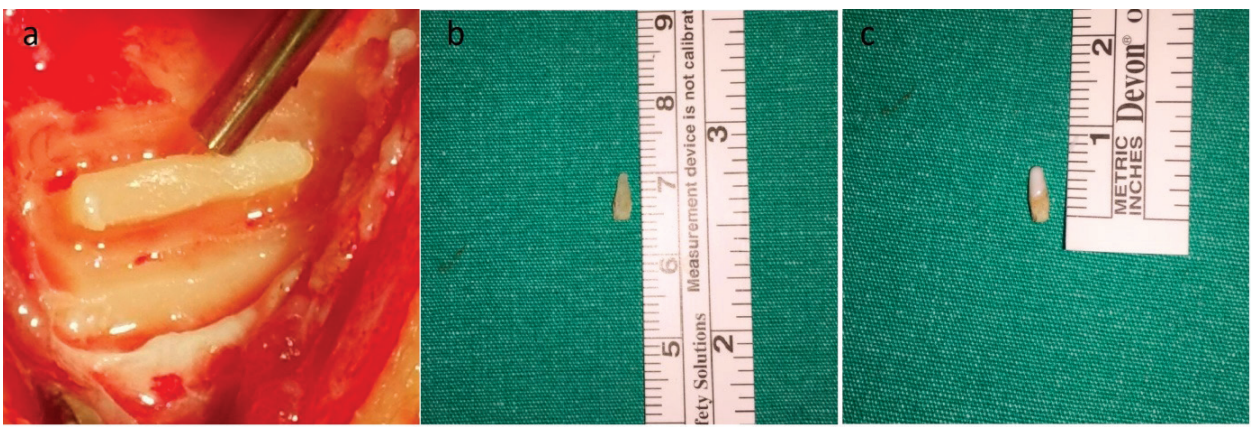

Figure 1: Demonstrates preparation process of Ionomer bone cement coated MCB graft. a: Image of bone extraction by drilling from the mastoid cortex. b: The length and shape of the graft were arranged according to the depth of the oval window. c: medial part of the graft was coated with ionomer bone cement

RESULTS

The mean ages of the cases included in the study at the time of surgical treatment were 43.17 (between the ages of 21 and 72). The demographic characteristics of the patients are given in Table 1.

Table 1: Demographic and paraclinical features of the patients

Patients	12 (100%)
Gender	
Male	7 (58%)
Female	5 (42%)
Average age	43.17 (21-72)
SID	
right	7 (58%)
left	5 (42%)
Postoperative average time	39 month (12-84)

Surgical indications were present in five of the patients due to the extrusion reaction of the prosthesis detected during examination, four of them due to recurred conductive hearing loss and three due to ear discharge and renewed conductive hearing loss. Of the twelve patients, eight (67%) had had surgery in our hospital before, while four (33%) had had prior surgeries in other centers. Three patients were found to have recurrent cholesteatoma in the sinus tympani region and one patient was found to have a displaced prosthesis. All patients had abundant granulation tissue (Table 2). Nine patients had previously had canal wall down tympanoplasty while the posterior canal walls of three patients were intact. In these three patients, thecanal walls needed to be removed by an ''inside out'' technique during the operation. The stapes footplates of all patients were mobile. No complication developed in any of the patients. In the early and late postoperative period after surgery the mastoid cavity epithelialization and middle ear healings were optimal (Figure 2). There was no improvement in the hearing of one patient although there was no problem in the examination and the patient refused revision surgery. Other patients' short- and long-term hearing results improved significantly (Table 3). There was no statistically significant difference between patients' short-term and long-term air conduction pure tone audiometry ($p<0.05$). The patients' long-term bone conduction pure tone audiometry thresholds were slightly elevated but the difference between the results was not statistically significant ($p<0.05$).

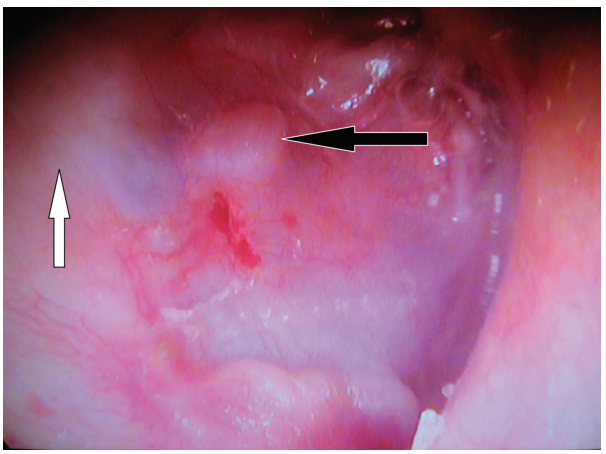

Figure 2: Postoperative 1-year otoendoscopic view (right ear). Black arrow points to the silhouette of the MCB graft. The white arrow points to the facial ridge

Table 2: Clinical findings of the patients

Patient №	Ear discharge	Prosthesis extrusion	Granulation tissue	cholesteatoma	Displacement of the prosthesis	Extracted prosthesis
1	+		+			Titanium PORP
2		+	+			Titanium TORP
3			+	+		Titanium TORP
4		+	+			Titanium PORP
5			+		+	Polycel TORP
6		+	+			Polycel TORP
7	+		+			Titanium TORP
8			+			Polycel PORP
9		+	+			Polycel TORP
10			+			Titanium PORP
11		+	+	+		Titanium TORP
12	+		+	+		Titanium TORP

TORP: total ossicular replacement prostheses; PORP: partial ossicular replacement prostheses.

Table 3: Audiologial examination results of the patients

Values	Pre-op	Post-op early	Post op late	Difference of	p#
	Average±SD	Average±SD	Average±SD	Averages*	
Air conduction	57.5±10.3	35.2±8.6	37.6±8.6	19.9	0.0040
Bone conduction	24.9±6.4	24.8±8.1	26.4±7.1	-1.5	0.905
Air bone gap	32.4±10.9	6.8±8.0	7.2±7.8	20.2	0.0030

#: Paired t test; SD:standart deviation; *: difference between the averages was calculated based on the postoperative late averages.

DISCUSSION

This study presented a novel method of type IV ossiculoplasty using a hybrid material (MCB + ionomer bone cement) to provide continuity of the sound transmission mechanism in the middle ear.Thus, the aim was to eliminate shortcomings of the MCB and ionomer bone cement.

There are many factors affecting the success of hearing reconstruction in middle ear surgery. Some of the most crucial factorsare the condition of the ossicles, extent of the surgical procedure, the condition of the mastoid cavity, the condition of the middle ear mucosa, the condition of the eustachian tube, the technique used during the surgery, the used prosthetic material, and the experience of the surgeon (5-7). The surgical technique and material used in hearing reconstruction have always been the subject of controversy. Chronic otitis media, with and without cholesteatoma, is one of the most important causes of disruption of the integrity of the middle ear ossicular chain (8). In this present case series, the primary diagnosis of all operated patients was COM with cholesteatoma. The posterior canal wall was drilled out in all patients to ensure complete clearance of the cholesteatoma (CWD mastoidectomy). It is a fact that such surgical procedures negatively affect the hearing results of the patients (9). Alaani et al. reported that long-term hearing results of CWD mastoidectomy are worse than canal wall up (CWU) mastoidectomy (10). However, they also emphasized that the functional difference was not statistically significant (10). In some cases, the posterior canal wall and stapes suprastructure were preserved and the MCB was placed between the stapes and the tympanic membrane. However, they were excluded from this study to maintain standardization.

The literature indicates that autologous cartilage, bone, vinyl-acryl, polyethylene, gold, plastipore, hydroxyapatite, bioglass, and titanium may be used to restore the continuity of sound transmission in the middle ear (6). Prosthetic materials used in otologic surgeries are expected to have biocompatibility, durability, good sound transmittance, accessibility and to be easy to use (6, 11). Today, although titanium and synthetic polycel prostheses are mostly used this issue remains controversial and indeed, none of them are considered perfect materials (12). Extrusion rates of allograft materials vary between 3% and 15% in the literature (6, 9, 12-14). However, because bioengineering is developing, the studies in this area are promising. Plastipore is the first alloplastic material that was used and commercialized (15). Although the early short-term result was promising, the long-term hearing results and extrusion rate were not acceptable (12).

One of the most popular alloplast materials today is hydroxyapatite (HA). HA is a natural component of bone tissue and shows high biocompatibility. It is still used in clinical practice and has proven itself in the time test (12, 16). Choi et al. reported the extrusion rate as 6.7% (12).

Polycel is another synthetic material that is widely used today. Moon et al. assessed long-term hearing results and reported that 51.1% of cases showed an ABG of ≤20 dB, and 158 cases (84.0%) had an ABG of ≤30 dB (14). They claimed that extrusion rate to be 3.8% (14).

One of the most interesting allograft materials since 1970s is titanium (17). Nowadays, titanium is widely used in orthopedics and craniofacial surgery (2). As it has been used in otologic surgery for many years, many reports have been published as a long-term result (18, 19). Despite being extremely dependable in terms of biocompatibility, long-term hearing results provide conflicting data in the literature (20). Lahlou et al. recently published a study investigating the anatomical and functional results of the titanium ossicular prosthesis where they reported that ABG ≤ 20dB to be in 65% of cases, displacement rate 6% and extrusion rate 3% (13).

Ulku et al.conducted an animal experimental study with vitallium which is used in orthopedic and orthodontic practice (2). They placed it in the rabbit middle ear and obtained results similar to titanium in terms of biocompatibility. They emphasized higher resistance to corrosion and lower probability of local debris than titanium (2). Studies have shown that both titanium and vitalium are safe in terms of toxicity, mutagenicity, and carcinogenicity (21).

Although homograft materials seem to be more advantageous in suitable cases in terms of both short- and long-term results, they are not preferred due to difficulties such as procurement and infection risks, etc. (2, 6, 18, 22).

Both autologous MCB and bone cement are not new in otology. They have been used in otologic surgery for a long time for a number of purposes and methods. Zeitler et al. stated that the use of autologous ossicles, cartilage, and MCB have advantages such as high biocompatibility, readily available, easy to shape, and low risk of extrusion (18). Malafronte et al. described the double–cartilage block ossiculoplasty method in cases where

stapes suprastructures were preserved and stated that it was a successful and easy method (23). Recently, Kong et al. reported a new technique using an autologous graft, which they describe as a bone cartilage composite graft (BCCG) (6). In their study, they shaped the patient's incus bone or MCB, carved to be a stalk of BCCG. They also harvested a piece of conchal cartilage and shaped it as a 5~6 mm circle to be the cap of the BCCG. Using the cartilage and bone they created a mushroom-shaped graft. Kong et al.compared the anatomical and functional results of these patients with results of patients that used allograft material (polycel and titanium) and suggested that this method had better long-term hearing results and the lowest extrusion rate (0%) (6).

The risk of the development of osteitis, bone resorption and adhesion possibilities to adjacent tissue are the major handicaps of the use of autograft material (24, 25). In this context, the middle ear ossicles seem more advantageous than MCB because they have a periosteum on them (25). However, in this kind of pathologies where CWD mastoidectomy is needed, middle ear ossicles are often absent or not suitable for use. It is also necessary to consider the possibility of re-implantation of cholesteatoma and infectious agents to the middle ear (24).

In fact, Bauer et al. also reported that they used the combination of MCB graft and ionomer cement for ossicular reconstruction, and they argued that this combination was efficient (26). However, they used ionomer cementas a kind of glue toprovide the continuity of the ossicular chain (26). The principle of our technique is completely different.Our purpose of using ionomer cement was to prevent MCB from sticking to the surrounding bone structures. In our clinical practice we have seen that the bone graft may be adhered to the promontorium. Bauer et al. also reported that they encountered this problem in one of their patients (26). To eliminate this problem, we coated the medial part of the bone graft with ionomeric bone cement, which has been used in otological surgery for many years and has been proven to be safe (27). In this way, direct contact of bone tissues was prevented.

In primary surgeries, especially in patients with cholesteatoma and/or infected middle ear, the choice for ossiculoplasty was in favor of alloplast materials. Ionomer Bone Cement Coated MCB was used only in selected clean revision surgeries where the allograft material was extruded. Ionomer Bone Cement seems to be an ideal solution in this sense due to advantages such as: good adhesion to bone, reliability in terms of toxicity, easy access, and easy application (27, 28). The long-term anatomical and functional findings were also favorable (Table 3). The disadvantages of using autograft material are that it prolongs the operation time and it is more difficult to prepare than using the ready-made prosthesis (2). It seems that by using these two materials together in a hybrid way, we can make-up for their disadvantages. We continue to follow up and collect the data of our patients and plan to conduct a study comparing the results of other allograft ossiculoplasty in the future.

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Ethics Committee Approval: As the study designed as retrospective data collection, ethical approval was waived in accordance with the Institutional Review Board of Istanbul Aydın University, Turkey.

Informed Consent: Written informed consent was obtained.

Peer-Review: Externally peer-reviewed.

Author Contributions: Conception/Design of Study- D.T., C.C.; Data Acquisition- C.C.; Data Analysis/Interpretation- D.T., C.C.; Drafting Manuscript- C.C.; Critical Revision of Manuscript- C.C.; Final Approval and Accountability- D.T.

Conflict of Interest: Authors declared no conflict of interest.

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