Incudostapedial rebridging ossiculoplasty with bone cement

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ABSTRACT

OBJECTIVE: The purpose of this study is to evaluate hearing results of our experience with ionomeric bone cement repair of ossicular discontinuity between incus and stapes.

STUDY DESIGN: Case series with chart review.

SETTING: Tertiary referral center.

SUBJECTS AND METHODS: One hundred thirty-six patients who underwent incudostapedial rebridging ossiculoplasty with ionomeric bone cement were included in the study. Preoperative and postoperative audiologic results of incudostapedial rebridging ossiculoplasty with bone cement were evaluated. One year of follow-up is provided.

RESULTS: The postoperative air-bone gap was less than 20 dB in 81.6 percent after one year. The mean preoperative and postoperative pure-tone averages of the patients were 52.82/11006 5.59 and 32.81/11006 7.18 dB, respectively (P<0.01). The mean preoperative and postoperative air-bone gaps were 35.83/11006 4.73 and 16.54/11006 5.01, respectively (P<0.01). There were no statistically significant differences among the hearing results of different types of surgeries (P>0.05). No complications in the middle ear related to bone cements were encountered.

CONCLUSIONS: Incudostapedial rebridging ossiculoplasty with ionomeric bone cement is a reliable method for ossicular reconstruction that is cost effective and offers satisfactory hearing results in selected patients.

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The goals of surgery for chronic ear disease are eradication of the disease and reconstruction of a sound transformer mechanism.1 Numerous ossiculoplasty techniques have been used to reconstruct the ossicular chain. The ideal ossiculoplasty material should be biocompatible, stable, safe, and easily applied.

Erosion of the incudostapedial joint with an intact, mobile malleus is the most common ossicular defect encountered in chronic middle ear disease.2 Reconstruction of this type of defect may be accomplished by several means. Among different management options to reconstruct incudostapedial continuity, the application of incudostapedial rebridging ossiculoplasty (ISRO) with bone cement has been used increasingly.

Bone cements are substances that have been used in dentistry as filling and luting material.3 The formulated powder mixed with the dissolving liquid results in a mixture that hardens within minutes through an exothermic reaction. The glass ionomer bone cement (Ketac Cem Radiopaque, ESPE, Dental Products D-82229, Seefeld, Germany) used in this study contains a powder composed of glass powder, polycarboxylic acid, and pigments, as well as a liquid composed of water, tartaric acid, and conservation agents. After a quick mixing of the two components the material hardens to a bonelike consistency in five to 10 minutes. The cement can be shaped within a few minutes before hardening. The cement bonds directly to bone, and once the cement has set, it is no longer sensitive to surrounding fluids. These features make this material potentially useful in ossiculoplasty procedures.3

The use of bone cements in ossiculoplasty has been shown by several studies3-6 to be a reliable method. Our preliminary results with this technique have been previously reported.4,5 The purpose of our present study was to evaluate the audiologic results of 136 patients who underwent incudostapedial rebridging ossiculoplasty with ionomeric bone cement.

MATERIALS AND METHODS

A retrospective chart review of 136 patients who underwent incudostapedial rebridging ossiculoplasty between March 2000 and September 2007 was performed to evaluate the hearing results. Institutional Review Board approval for this study was obtained. One year of follow-up was provided. Patients who met the inclusion criteria of having disease-free or cleansed middle ear and mastoid, no cholesteatoma, and intact ossicular chain except for discontinuity between

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the long process of the incus and the head of the stapes; intact tympanic membrane after the operation; and adequate follow-up data were enrolled in the study.

There were 72 female and 64 male patients, whose ages ranged from 14 to 62 years (mean 30.96). The indications were chronic otitis media with perforation in 94 patients and conductive hearing loss with small retraction pocket in 42 patients. The patients were followed up for at least one year. Pure-tone air- and bone-conduction thresholds were obtained preoperatively and postoperatively. The preoperative audiometric results were compared with the audiometric results obtained after one year. Audiometric pure-tone thresholds by air conduction were recorded at 0.5, 1, 2, 3, 4, and 8 kHz and by bone conduction at 0.5, 1, 2, 3, and 4 kHz. Thresholds at 0.5, 1, 2, and 3 kHz were used to calculate the pure-tone averages (PTAs). The air-bone gap (ABG) was calculated for each test. Based on the American Academy of Otolaryngology—Head and Neck Surgery Committee on Hearing and Equilibrium guidelines a closure of the air-bone gap to within 20 dB was considered successful. Using the Statistical Package for the Social Sciences 11.0 for Windows (SPSS, Inc, Chicago, IL), a paired t test was used to compare the preoperative and postoperative results.

**Techniques**

The middle ear was exposed with a postauricular, endaural, or transmeatal approach. A mastoidectomy and removal of the granulation tissue was performed when necessary. The ISRO was performed when there was a discontinuity in the ossicular chain between the incus and stapes.

Preparation of bone cement is easy and has been previously well described. Included in the sterile package of Ketac Cem Radiopaque are a powder and a dissolving liquid. The powder and liquid were mixed on a metal plate, causing a minimal exothermic reaction. The mixture became muddy before it hardened in a couple of minutes, making it imperative that rebridging be performed within this period of time. With use of a needle, the cement was taken piece by piece, and the ossicular gap between the incus and stapes head was reconstructed. The new bridge hardened at this stage and allowed for stable continuity between the ossicles. After completion of the tympanic membrane grafting, the ear was closed in the standard fashion.

**RESULTS**

Incudostapedial rebridging ossiculoplasty with bone cement was applied in 136 previously unoperated cases suffering from conductive hearing loss. Patients who had graft failure and required revision surgery were excluded from the study. There was no serious complication such as facial palsy or sensorineural hearing loss.

The postoperative ABG less than 20 dB was achieved in 81.6 percent of patients. The mean preoperative and postoperative pure-tone averages of the patients were 52.82 ± 5.59 and 32.81 ± 7.18 dB, respectively (P < 0.01). The mean preoperative and postoperative air-bone gaps were 35.83 ± 4.735 and 16.54 ± 5.01, respectively (P < 0.01) (Fig 1).

The mean change of preoperative and postoperative PTA was 20.01 ± 5.472 with 95 percent confidence interval (t = 42.636, df = 135, P = 0.01) and mean change of preoperative and postoperative ABG was 19.29 ± 5.578 with 95 percent confidence interval (t = 40.339, df = 135, P = 0.01).

Among 136 patients, 42 (30.8%) underwent exploratory tympanotomy, 58 (42.6%) underwent tympanoplasty, and 36 (26.4%) underwent tympanoplasty with mastoidectomy. There were no statistically significant differences among the hearing results of different types of surgeries (P > 0.05).

**DISCUSSION**

This study demonstrated a statistically significant hearing improvement after ISRO with ionomeric bone cement (P < 0.01). Various techniques are available for reconstruction of continuity between incus and stapes secondary to incus long arm necrosis. Total (TORP) or partial ossicular replacement prostheses (PORP), otogen bone grafts, homogen bone grafts, or cortical bone grafts are materials that have been used for years. Problems with these materials are high extrusion rates and risk of dislocation, which may result in recurrent conductive hearing loss. ISRO with bone cement has some advantages such as satisfactory hearing results, ease of application, and cost effectiveness. Hearing results with bone cement ossiculoplasty are satisfactory. In our study, a postoperative air-bone gap less than 20 dB was achieved in 81.6 percent of patients. Bone cements are cost effective because they are cheaper than other ossiculoplasty materials.
The application of bone cement is easy. Nevertheless, there are some important points that should be considered during cement application. It should be performed within minutes before the mixture becomes hard. Any hemorrhage should be controlled before application of bone cement because it may interfere with hardening of the cement. Mucosal covering over ossicles should be removed and bone cement should be applied directly over denuded bone since bone cement does not adhere to soft tissue.6,8

Ionomeric bone cement should not come into contact with neural structures, perilymph, or dura because of its potential neurotoxicity.4,8,9 In case of contamination immediate aspiration of cement and multiple irrigation and aspiration with serum is necessary to remove the cement. To prevent contamination, bone cement should be applied in its most suitable consistency. Also, small pieces of gelfoam can be placed over facial nerve and stapes footplate during application.5 Aluminium encephalopathy and death due to glass ionomer bone cements have been reported.10,11 These are cranioplasty cases where ionomic bone cement was used in large amounts and in direct contact with cerebrospinal fluid. The amount of cement used in ossiculoplasty is very small when compared with cranioplasty. There have been no reported cases of toxicity secondary to glass ionomer cement ossiculoplasty. There are also hydroxyapatite (HA) bone cements. HA bone cements have better tissue tolerance than ionomic bone cements, which makes them preferred material in the reconstruction of cranioplasty defects. The main problem with HA bone cements in ossiculoplasty was their prolonged setting time. Recently, HA bone cement with shorter setting time used in ossiculoplasty was reported.12 Since such a small amount is used during ossiculoplasty, the set time of HA cement is no more than five minutes and in many cases the cement is set and waterproof at two minutes.

Bone cement does not interfere with graft take rate.5 We perform tympanic membrane grafting after cement sets. Also, we use an over-underlay technique and use standard gelfoam support during grafting. This prevents contact between cement bridge and eardrum.

Extrusion of prosthesis is still a challenge in ossiculoplasty with alloplastic materials, especially in patients with poor eustachian tube function.13 We had no case of extrusion since there is no contact between bone cement and eardrum.

Patient selection in bone cement ossiculoplasty is essential to obtain satisfactory postoperative hearing results and also to avoid possible undesired complications. Bone cement ossiculoplasty is not advocated in canal wall down surgeries, in atelectatic ears, and in the presence of a cholesteatoma.5

The distance between the remnant of necrotic incus and the stapes head is also important when selecting patients. Cases that have gaps less than one-third of incus long arm are ideal candidates for this technique. Larger defects up to two-thirds of incus long arm may be treated with this technique by repeated application of the cement. Defects larger than two-thirds of incus long arm should be treated by other techniques such as incus interposition or PORP ossiculoplasty.

Severe mucosal disease and eustachian tube dysfunction may contribute to poorer hearing results after ossiculoplasty.5 Mastoidectomy is usually performed when there is severe mucosal inflammation or granulation. No statistically significant difference was observed between the functional results of different types of surgeries applied in our study group (P > 0.05).

While incudostapedial rebridging ossiculoplasty is the most common indication of bone cement ossiculoplasty, bone cements also can be used in different situations such as between malleus and stapes in the absence of incus,5 in case of incus long arm necrosis in stapedotomy cases,5 to secure ossiculoplasty prostheses like TORP or PORP,12 and in incus subluxations.6

There is still controversy about the long-term results of bone cement ossiculoplasty. Some authors claim that bone cement bridge will be broken in the long run and revision surgery will be needed. Although one-year follow-up is enough to obtain hearing results, we continue to follow up these patients in order to assess longer-term results.

CONCLUSION
Ionomeric bone cement is a reliable material for use in ossicular reconstruction because of its ease of application, cost effectiveness, tissue tolerance, and satisfactory hearing results. Patient selection is mandatory to obtain good hearing results.

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Tekin Baglam, MD, substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; Erkan Karatvas, MD, drafting the article or revising it critically for important intellectual content; Cengiz Durucu, MD, analysis and interpretation of data; Ali Kilic, MD, acquisition of data; Enver Ozer, MD, substantial contributions to conception and design; Semih Mum-buc, MD, final approval of the version to be published; Muzaffer Kanlikama, MD, final approval of the version to be published.
DISCLOSURES

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REFERENCES