Use of Mimix hydroxyapatite bone cement for difficult ossicular reconstruction

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OBJECTIVE: **To describe the advantages of using Mimix™ hydroxyapatite (HA) bone cement in reconstructing a variety of ossicular chain abnormalities.**

STUDY DESIGN AND SETTING: **Case series at a tertiary medical center.**

RESULTS: **Twenty-five cases of HA reconstruction are included in this series (ages 23-74; mean, 47 years). The examples presented include (1) HA as the sole reconstructive material for incus erosion, (2) HA for securing a total or partial ossicular replacement prosthesis, (3) incus augmentation after crimping for revision stapedotomy with incus erosion, (4) HA in primary stapedotomy to fix the crimped prosthesis to an intact incus, and (5) other unique situations. Preoperative and postoperative audiograms were evaluated for 4-tone pure tone average (PTA), speech reception thresholds, word recognition scores, and air–bone gaps (AB gaps). Mean follow-up was 11 months (range 2 to 22 months). The mean PTA improved from 57 dB to 37 dB, whereas the mean AB gaps decreased from 33 dB to 16 dB. There were no cases of infection or extrusion.**

CONCLUSIONS: **Hydroxyapatite bone cement is an excellent adjunct or alternative to ossiculoplasty with preformed prostheses. Easily malleable, rapidly setting, and rapidly hardening, Mimix is particularly well suited for middle ear work.**

SIGNIFICANCE: **Definitive fixation with bone cements during difficult ossicular chain reconstruction may ensure a more enduring successful outcome.**

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The native ossicular chain conducts sound efficiently from the environment to the inner ear. Diseases of the middle ear, however, can disrupt this energy transfer and cause a conductive hearing loss. Ossicular chain reconstruction using a variety of partial or total ossicular replacement prostheses (PORP or TORP) has revolutionized the treatment for this problem. Unfortunately, the surgeon must often rely on surface tension and packing to stabilize the operative repair. Without definitive fixation, the prosthesis can migrate over time and result in a less than optimal long-term hearing result.

Bone cements and acrylics have been used in otology and neurotology for several decades. Initially popularized in the dental field, they have been used in cranioplasty, tegmen and ear canal reconstruction, mastoid obliteration, ossicular chain reconstruction, and for fixation of various implants.[1-8] Unfortunately, such products have been associated with various complications, and most have not had the handling characteristics necessary for middle ear work. The ideal bone cement should be malleable, easily applied, rapidly setting, nontoxic, and fluid resistant; capable of osteointegration; and incite minimal inflammation.

Hydroxyapatite (HA) has proven itself as well tolerated in cranioplasty and for the production of preformed ossicular prostheses. We present our experience with a quick-setting hydroxyapatite bone cement (Mimix™; Walter Lorenz Surgical; Jacksonville, FL) used to repair a variety of complex ossicular problems in 25 patients undergoing ossiculoplasty, tympanomastoidectomy, or stapedotomy. We feel that this particular product offers particularly favorable handling characteristics for middle ear work.

MATERIALS AND METHODS

Twenty-five patients were included in this series from the otology and neurotology practice of one of the authors (J.A.G.) at Washington University in St Louis. They ranged from 23 to 74 years of age (mean 47 years). Thirteen were men, and 12 were women. All patients had a preoperative audiogram and were followed with microscope examinations of the ear and serial audiograms postoperatively. Each audiogram was assessed for 4-tone pure tone average (PTA), speech reception thresholds, word recognition scores, and air-bone gaps (AB gap). Mean follow-up was 11 months (range 2 to 22 months). All data collection and reporting was in compliance with established HIPAA guidelines. *(Please see Table 1 on the online version of this*

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Dr. Goebel has financial arrangements with Walter Lorenz, the manufacturer of Mimix. He is a paid consultant, and has a royalty agreement for OtoMimix, an otologic version of Mimix cleared by the FDA.

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Mimix is a calcium phosphate powder (TTCP/alpha TCP and Sodium Citrate Dihydrate) that forms hydroxyapatite (HA) bone cement when mixed with a setting solution (anhydrous citric acid in water). It was obtained from the manufacturer (Walter Lorenz Surgical) and used per their package instructions. The reaction is mildly exothermic. Mimix requires 30-45 seconds for mixing and develops a pastelike consistency. It can be applied with a Rosen needle, straight pick, or similar instrument. All other middle ear work was completed before applying Mimix. Care was taken to obtain as dry an operative field as possible, and all mucosa was stripped from the underlying bone where the HA was to be applied. Mimix is malleable for 3-4 minutes before setting and then requires only 4-6 minutes to harden completely. This is in contrast to other available products that may take hours to harden fully. Gelfoam was used to protect other middle ear structures from inadvertent spillage of Mimix. This gelfoam was then removed after the HA had set and hardened. No Mimix was ever applied directly onto the oval window.

Mimix was utilized in various difficult clinical scenarios. These included (1) HA as the sole reconstructive material for incus erosion, (2) HA for securing a total or partial ossicular replacement prosthesis, (3) incus augmentation after crimping for revision stapedotomy with incus erosion, (4) HA in primary stapedotomy to fix the crimped prosthesis to an intact incus, and (5) several other unique situations.

RESULTS

Information regarding the diagnosis, operative findings, and audiometric data for all 25 patients is presented in Table 1 (in the online version). The mean PTA improved from 57 dB to 37 dB, whereas the mean AB gap decreased from 33 dB to 16 dB (see Table 2). Figures 1 and 2 depict the change in preoperative to postoperative PTA and air–bone gaps graphically. Mean follow-up was 11 months (range 2 to 22 months). There were no cases of infection or extrusion. All but 1 patient reported subjective improvement in hearing (see discussion).

Below are several cases illustrating the diverse uses for Mimix.

Case 1: Mimix as the sole reconstructive material for incus erosion

This 53-year-old male had suffered right temporal bone trauma in 2001 as a result of a motor vehicle accident. Since that time, he had undergone middle ear exploration and ossiculoplasty twice for incudostapedial (IS) joint separation. An Applebaum prosthesis was used on the first try and a prosthesis plus fibrin glue on the second. The prosthesis had slipped both times leaving him with a persistent conductive hearing loss. His preoperative AB Gap was 49dB. During this most recent procedure, Mimix was used to bridge the IS joint separation without the need for a prosthesis (Fig 3). His postoperative audiogram demonstrated an AB Gap of 8. He has now been followed for 17 months without evidence of infection, extrusion, or worsened hearing.

Table 2. Pre- and postop pure tone average (PTA) and air bone (AB) Gap

Preop PTA	Postop PTA	Preop AB Gap	Postop AB Gap
30	18.8	20	7.5
65	18.8	49	7.5
43	33.75	12.5	12.5
43	26	31.25	20
67.5	50	34	10
59	35	49	24
51	47.5	43.75	40
81.4	70	46	30
58		28	
40	22.5	25	13.75
76	33	48.75	15
51	32	28	0
64	29	27.5	6
56	37.5	30	9
79	41	39	0
76	104	31	47.5
60	36	32.5	11
48	10	22	
40	17.5	21	2.5
79	60	46	11
36	19	14	8
43	6.25	28	0
64	48	45	32
53	60	33	41
54	56	44	44

Case 2: The eroded incus during revision stapedotomy

A 70-year-old female presented with a history of 2 prior stapedectomy procedures on her left ear for otosclerosis. She had experienced a delayed failure with each. The last procedure failed after only 6 months. Her audiogram demonstrated a maximal conductive hearing loss with an AB Gap of 49 dB. When we explored her middle ear, we found a displaced stapes prosthesis and a very tapered, partially eroded incus. We did not feel that this incus would support another tight crimp. Therefore, a new McGee prosthesis was lightly crimped onto the remaining incus, and Mimix was placed over the crimp to fasten it in position (Fig 4). This obviated the need for a firm crimp that might