Physiologic Reestablishment of Ossicular Continuity During Excision of Retraction Pockets

Use of Hydroxyapatite Bone Cement for Rebridging the Incus

Mohamed Nasser Elsheikh, MD; Hosam Elsherief, MD; Sayed Elsherief, MD

Objective: To analyze the results obtained from hydroxyapatite bone cement repair of ossicular discontinuity between the incus and stapes during surgery of retraction pockets.

Design: Clinical study of a case series.

Setting: Otolaryngology Department, Tanta University Hospitals, Tanta, Egypt.

Patients: A total of 62 previously untreated patients (82 ears) with retraction pockets.

Interventions: Hydroxyapatite bone cement was used to repair defects at the incudostapedial connection in 82 ears with retraction pockets. The ears were divided into 2 groups: group 1 included 48 ears with a small defect in the long process of the incus; group 2 included 34 ears with a large defect in the long process of the incus. In addition, 20 control patients underwent surgery using plastipore partial ossicular replacement prostheses. Hearing results were reported in 4 frequencies (0.5, 1, 2, and 3 kHz). Analysis of the results was performed using the paired t test with significance level at .05.

Main Outcome Measures: Anatomic and audiologic results.

Results: Significant postoperative improvement of pure-tone air conduction threshold averages and air-bone gap averages were reported in the 3 studied groups. The postoperative air-bone gap averages showed significantly better outcome in groups 1 and 2 compared with controls ($P<.001$), while there was no statistically significant difference between groups 1 and 2 ($P>.05$).

Conclusions: Bone cement ossiculoplasty offers cost-effective and significant improvement in conductive hearing loss. It provides an excellent alternative to ossiculoplasty with preformed prostheses. We believe the indications for bone cement were validated by these results.

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The objectives for treatment of retraction pockets are to eliminate disease, improve the anatomic conditions that favor recurrence, and, whenever possible, preserve or improve hearing while maintaining near-normal anatomy of the middle ear.

Disintegration in the incudostapedial joint represents the most common ossicular separation encountered in otology; this defect can lead to an air-bone gap (ABG) of up to 60 dB. Reconstruction using a variety of ossicular replacement prostheses 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.1 Alternatively, bone cements and acrylics, which were initially popularized in the dental field, have also been used in ossicular chain reconstruction and for fixation of various implants.1-3

In an attempt to more closely mimic the normal middle-ear sound-transformer mechanism, we used HA bone cement to rebridge incus defects during excision of retraction pockets. We herein analyze the anatomic and audiologic results of HA in comparison with partial ossicular replacement prostheses (PORPs) for the reconstruction of similar ossicular chain defects.

METHODS

PATIENTS

Between January 2002 and May 2004, HA bone cement (Bone Source; Howmedica Leibinger Inc,
Dallas, Tex) was used to repair defects at the incudostapedial connection in 65 previously untreated patients (82 ears) with retraction pockets. The ears were divided into 2 groups: group 1 included 48 ears with a small defect (<2 mm) in the long process of the incus or at the lenticular process; group 2 included 34 ears with a large defect (≥2 mm) in the long process of the incus. Results were compared with those of the control group, which included 20 patients who underwent surgery during the same period using plastyore PORPs (Shea modification of a PORP; Smith & Nephew Richards Inc, Memphis, Tenn). The patients were observed for more than 1 year after surgery (range, 13-40 months). Study protocol and consent forms were approved by the research review committee of Tanta University.

Exclusion criteria included cholesteatoma, absent incus, and inadequate follow-up. All surgical procedures were performed by the authors. The individual patients’ charts were reviewed. Data regarding their preoperative and postoperative morphologic and auditory status and details of the surgical procedure performed and disease-specific complications were collected with a standardized form.

SURGICAL TECHNIQUE

All patients underwent general anesthesia, and postauricular incision was used to explore the middle ear. Localized atticotomy was performed to allow precise dissection of the pocket. The tendon of tensor tympani was severed to allow release of the severely retracted malleus.

Following the HA manufacturer instructions, the surgeons mixed the 2 components of the bone cement together (powder and setting solution) to form cement of a pastelike consistency. This mixing process requires 45 to 60 seconds, and the chemical reaction is mildly exothermic. A fine needle was used for application to the area of the defect. When the defect in the long process of the incus or in the lenticular process was found to be smaller than 2 mm (group 1), HA cement alone was used to bridge the defect (Figure 1). When the defect in the long process of the incus was larger than 2 mm (group 2), a platinum wire was used to bridge the gap. The wire was twisted on itself to fashion a ring at one end, which was attached to the head of the stapes, and the other end of the wire was rested on the body of the incus. The HA cement was then applied to fix the wire skeleton between the incus and stapes (Figure 2).

All other middle ear work was completed before applying the cement. 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. Absorbable gelatin sponge (Gelfoam; Pfizer Inc, New York, NY) was used to protect other middle ear structures from inadvertent spillage of cement. This Gelfoam was then removed after the HA had set and hardened.

In all patients, tragal cartilage with perichondrium was used for tympanic membrane (TM) reconstruction. A U-shaped complete strip of the cartilage was removed vertically to accommodate the entire malleus handle. As the incus was preserved, an additional triangular piece of cartilage was removed from the posterior-superior quadrant to accommodate the incus. This excision prevented the lateral displacement of the posterior portion of the cartilage graft that sometimes occurs because of insufficient space between the malleus and incus. A small semilunar piece of cartilage was placed to reinforce the attic to prevent recurrence. The entire graft was placed in an underlay fashion, with the malleus fitting in the groove and actually conforming to the perichondrium. The cartilage was placed toward the promontory, with the perichondrium immediately adjacent to the TM remnant. Middle-ear packing was avoided on the promontory and in the vicinity of the ossicular chain. One piece of Gelfoam was placed lateral to the reconstructed TM, and antibiotic ointment was placed in the ear canal. Typically, the packing material of Gelfoam and antibiotic ointment was completely suctioned from the external canal 1 to 2 weeks after the surgical procedure. Antibiotic steroid-containing drops were used for an additional 2 weeks to clear the ear of residual ointment and Gelfoam.

HEARING RESULTS

A postoperative audiogram was obtained 3 months after the procedure, and the TM was examined macroscopically and microscopically. If the hearing result was good and the TM was clear, the ear was examined at 6 months and again at 1 year from the date of surgery. Hearing results 1 year postoperatively were analyzed according to the guidelines of the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology—Head and Neck Surgery. Accordingly, we calculated the mean, standard deviation, and range of each of the following: the postoperative ABG, the number of decibels of ABG closure, the change in high pure-tone bone-conduction level in decibels of hearing loss, and the preoperative and postoperative air-conduction thresholds. Thresholds at the frequencies 0.5, 1, 2, and 3 kHz were used for calculation. The postoperative ABG was calculated as the postoperative air-conduction pure-tone average minus the postoperative bone-conduction pure-tone average. The number of decibels of ABG closure was calculated as the preoperative ABG minus the postoperative ABG. The change in high pure-tone bone-conduction level was calculated as the preoperative high pure-tone bone-conduction average (mean of thresholds at 1, 2, and 4 kHz) minus the postoperative one.
STATISTICAL ANALYSIS

Analysis of the results was performed by the paired t test with significance level at .05.

RESULTS

Hydroxyapatite bone cement was used in 82 previously untreated ears with retraction pockets to repair defects at the incudostapedial connection. The control group included 20 patients who underwent prosthetic ossicular reconstruction. Demographic data of the study population are summarized in Table 1.

The preoperative and postoperative hearing results are summarized in Table 2. Significant postoperative improvement of pure-tone air-conduction threshold averages and ABG averages were reported in the 3 studied groups. However, there was no significant difference between the preoperative and postoperative word discrimination score in any group (P>.05).

The postoperative ABG averages, which are taken as an indication of ABG closure by surgery, showed significantly better outcome in groups 1 and 2 than in controls (P<.001), while there was no statistically significant difference between groups 1 and 2 (P>.05).

Patients in group 1 showed the best ABG closure, with 92% of patients (n=44) showing mean closure to 20 dB or lower; 82% of group 2 patients (n=28) reached this level of ABG closure; and only 55% of controls (n=11) showed mean ABG closure to 20 dB or lower (Table 3).

The postoperative bone-conduction thresholds were unchanged in all patients, and no patient showed sensorineural hearing loss postoperatively. Recurrent conductive hearing loss was reported in 3 patients (9%) in group 2. Among controls, extrusion of the prosthesis occurred in 2 cases (10%) between 15 and 21 months after tympanoplasty, and recurrent conductive hearing loss was reported in 4 patients (20%).

COMMENT

Most ossiculoplasty techniques have focused on replacing or bypassing the defects of the incudostapedial joint with an autograft, homograft, or allograft. The most common technique using an autograft is the incus transplantation in which the extracted incus is firmly held, and a hole of sufficient size to receive the head of the stapes is made. Failure of this technique results from ankylosis of the transposed incus to nearby bony surfaces or incus displacement from the head of the stapes, both of which cause a deterioration of the sound transmission in the long term. On the other hand, ossiculoplasty using homografts has now been abandoned by many surgeons because of the concern over the possible transmission of diseases such as acquired immunodeficiency syndrome.

Many artificial prosthetic materials such as plastics, ceramics, metals, and porous plastics have been used by surgeons and heavily advertised by manufacturers. However, surgeons’ experiences with ossicular necrosis, prosthetic displacement and extrusion, and unsatisfactory hearing restoration have caused disenchantment with many of these prostheses.

Many investigators have used bone cements to reconstruct total and partial ossicular defects in both experimental and clinical trials, and most cements have proven to be biocompatible and biostable over time, easy to handle, well tolerated by bone and soft tissue, and workable without splintering. In the present study, HA cement was used to rebridge small defects of the incus and reestablish articulation between the incus and stapes during surgery to treat retraction pockets. When the defect in the long process of the incus was larger than 2 mm (group 2), platinum wire formed an artificial skeleton for the long process of the incus and was fixed with the HA cement to reconnect the incus to the stapes. It should be emphasized that the rationale of using bone cement is to augment bone, not to replace it. Hydroxyapatite cement cannot be used to replace the entire long process of the incus. There must be enough native bone or a template on which to apply the HA.

The present technique was easy to perform and did not add to the time of surgery; moreover, the improvement in hearing was satisfactory and stable compared with the results obtained from placement of plastipore PORPs.

Table 1. Demographic and Clinical Data of the Study Groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group 1 (n = 48)</th>
<th>Group 2 (n = 34)</th>
<th>Control (n = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD, y</td>
<td>39 ± 7.8</td>
<td>42 ± 9.3</td>
<td>41 ± 8.2</td>
</tr>
<tr>
<td>Men/women, No.</td>
<td>30/18</td>
<td>20/14</td>
<td>11/9</td>
</tr>
<tr>
<td>Complications, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNHL</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>CHL</td>
<td>0</td>
<td>3 (9)</td>
<td>4 (20)</td>
</tr>
<tr>
<td>Extrusion</td>
<td>0</td>
<td>0</td>
<td>2 (10)</td>
</tr>
</tbody>
</table>

Abbreviations: CHL, conductive hearing loss; PORP, partial ossicular replacement prostheses; SNHL, sensorineural hearing loss.

Table 2. Results Analysis

<table>
<thead>
<tr>
<th>Study Group</th>
<th>PTA, dB</th>
<th>ABG, dB</th>
<th>WDS, %</th>
<th>Improvement, dB</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-op</td>
<td>Post-op</td>
<td>P Value†</td>
<td>Pre-op</td>
</tr>
<tr>
<td>1</td>
<td>40.5 (8.5)</td>
<td>15.2 (7.3)</td>
<td>.001</td>
<td>26.7 (7.6)</td>
</tr>
<tr>
<td>2</td>
<td>53.9 (11.2)</td>
<td>27.9 (8.9)</td>
<td>.001</td>
<td>37.3 (9.7)</td>
</tr>
<tr>
<td>Control</td>
<td>59.2 (8.9)</td>
<td>37.9 (7.7)</td>
<td>.001</td>
<td>52.3 (8.5)</td>
</tr>
</tbody>
</table>

Abbreviations: ABG, air-bone gap; post-op, after surgery; pre-op, before surgery; PTA, pure tone average; WDS, word discrimination score.

*Unless otherwise indicated, data are presented as mean (SD) values.
†Paired t test.
In accordance with these findings, recent publications on HA cements attest to its utility and safety. Babu and Seidman report the use of HA cement for reconstructing incudostapedial disarticulation with statistically significant hearing improvement and no complications. Kveton and Coelho used HA to reconstruct temporal bone defects and report stability over the course of a 10-year follow-up. They conclude that HA is the preferred biomaterial for reconstruction of temporal bone defects. Goebel and Jacob report the use of HA cement for difficult ossicular reconstruction. In particular, they recommend the use of Mimix (OtoMimix; Walter Lorenz Surgical Inc, Jacksonville, Fla) HA for its rapid mixing and quick setting times and the fact that it develops a puttylike consistency that is malleable for several minutes and can be applied precisely. In their study, no cases of infection or extrusion were reported.

Alternatively, glass ionomer cements have been successfully used for bridging the incudostapedial joint, in-cus augmentation, and for fixation of stapes implants. However, the histologic evidence of delayed foreign body reactions and potential neurotoxic effects have limited the use of these cements.

With the use of HA bone cement in the present study, significant hearing improvement was realized in each pathologic group, and the results compared favorably with those of ossiculoplasty using PORPs. The better results achieved with HA cement may be due to the fact that HA cement is sculpted to conform to the middle ear anatomy. Similarly, Maassen and Zenner report that in the case of a missing crus longum of the incus, a tympanoplasty type 2 (ionomeric cement or titanium-gold-angle prosthesis) achieved a significantly better hearing gain than an autograft interposition. However, the 2 type 2 procedures were not equal. In addition, the authors restricted prosthesis ossiculoplasty to cases with a sufficiently long incus process, whereas their cement technique was also applicable when only a short part of the long incus process remained.

In the present study, no complications were encountered in relation to HA cement application in middle ear in group 1, while 3 (9%) of 34 patients of group 2 (cement and wire) developed conductive hearing loss. However, none of our cases showed sensorineural hearing loss postoperatively. Although reconstruction of the TM with cartilage was performed in conjunction with ossiculoplasty, prosthesis extrusion occurred in 2 control patients (10%) in addition to the 4 control patients (20%) who developed conductive hearing loss. Gjuric and Schagerl reported prosthesis extrusion in 19% of their patients with gold prosthesis ossiculoplasty and recommended staging the surgery for atelectatic ears or using different shaping of the prosthesis to overcome prosthesis extrusion. Similarly, Babu and Seidman report that the use of PORPs carried the risk of prosthesis migration and resultant recurrent conductive hearing loss, while using bone cement to reconstruct the ossicular chain restored the integrity of the ossicular chain in the most natural of ways with results that persist.

Although the present study demonstrates stability of the repair for at least 13 months, with an average follow-up of 21 months, we continue to observe these patients to assess the longer-term results.

In conclusion, in the retraction pockets, HA bone cement provided an immediate anatomic reconstruction. Significant hearing improvement was realized in each pathologic group, and the results compared favorably with those of ossiculoplasty using plastipore PORPs.

Reconstruction of the ossicular chain with HA cement is recommended over the use of PORPs because the HA procedure is easy to perform, presents less risk of damage to the stapes and cochlea, requires less extensive surgery, and does not exclude other surgical methods if re-operation is needed. We believe the indications for HA cement are validated by these results.

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Correspondence: Mohamed Nasser Elsheikh, MD, PO Box 34, Tanta, Egypt (mnel_sheikh@hotmail.com).

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REFERENCES