Total Hip Arthroplasty Using Bone Cement Containing Tri-n-butylborane as the Initiator

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Abstract: We performed total hip arthroplasty (THA) using a special acrylic self-curing bone cement (Bonemite®), which contains tri-n-butylborane as the initiator. Its maximum temperature at curing is lower than that of a conventional bone cement (CMW®). Fifty-eight THAs using Bonemite and 35 THAs using CMW were followed up for more than 8 years (12.5 years on average). At the 10-year follow-up, the survival rates, using revision surgery or aseptic loosening impending revision as the endpoint for failure, were 92.2% for the patients in the Bonemite group and 91.0% for those in the CMW group. No statistical differences were observed between the patients in these two groups with regard to survival rate (p = 0.39). Bonemite showed no clear superiority compared with CMW, although the results suggest that Bonemite is safe and reliable for clinical use and stable in situ for long time. © 1999 John Wiley & Sons, Inc. J Biomed Mater Res (Appl Biomater) 48: 759 –763, 1999

Keywords: bone cement; total hip arthroplasty; polymerization temperature; elasticity; cure initiator

INTRODUCTION

After Charnley in 19601 first used self-curing acrylic cement to fix the femoral component, total hip arthroplasty performed using bone cement has proved to be very useful for osteoarthritis of the hip. Recently, improved implant designs and operation techniques have been employed and the clinical results have also improved.2 But research on a new bone cement is scarce, and the clinical application of it is rarely reported.3

In 1972, we started to use a new type of bone cement (Bonemite®), which contains tri-n-butylborane (TBB) as the cure initiator. Bonemite is a self-curing acrylic cement, which contains poly(MMA-co-EMA) (1:1), 2-5-dimethylhexan-2-5-hydroperoxide and BaSO4 as a polymer contents, MMA monomer and hydroquinone as a monomer contents, and tri-n-butylborane (TBB) (Table I). TBB is the cure initiator and is provided in a syringe, and 2-5-dimethylhexane-2-5-hydroperoxide is the polymerization promoter. Before clinical use, TBB is added to the MMA monomer and stirred well; during this process TBB becomes a free radical (Fig. 1). The free radical acts on MMA monomer and polymerization begins.4 Immediately after that, poly(MMA-co-EMA) is added and stirred to form a dough. It becomes cured within 10 min at 21 °C. TBB is finally decomposed into boric acid and butylalcohol. On the other hand, CMW® contains benzoylperoxide (BPO) as the initiator and dimethyl-p-toluidine as the promoter. BPO first breaks down to a free radical coexisting with N,N-dimethyl-p-toluidine at room temperature, and then polymerization of MMA begins (Fig. 2).

Bonemite has, theoretically, an elastic modulus 3% lower than that of CMW, which is formed with all MMA. The setting temperature of Bonemite in vitro ranges between 60–70 °C, while that of CMW ranges between 85–90 °C.5,6

We report the results of THAs using Bonemite in patients with osteoarthritis, in comparison with those of THAs using a conventional bone cement (CMW), which were undergone at the same period.

MATERIALS AND METHODS

Total hip arthroplasties using Charnley implants (Chas. F. Thackley Ltd., Leeds LS6 2DP, UK) fixed with two types of
bone cements were performed. One was Bonemite® (Mochida Pharmaceutical Co, Tokyo, Japan) and the other was CMW® (C.M.W. Laboratories Ltd., Blackpool FY4 4QQ, UK). These two bone cements can be used in the same manner for clinical application. The mixing time of Bonemite is approximate 1 min, and the working and setting time are dependent upon the room temperature. The working time in a dough state of Bonemite begins after 3 min from the start of mixing and continues for approximately 2–3 min at 21°C. Both cements were inserted into the bone in a dough state during polymerization and final hardening occurs within 10 min at 21°C.

We treated 97 patients, who had undergone primary THAs using Charnley implants between 1976–1986. Thirteen patients have been lost to follow-up within 8 years postoperatively. Five patients died, 3 failed to attend for examination due to internal diseases, and 5 could not be contacted. We reviewed 84 patients, who were followed up for more than 8 years (Table II). Fifty-eight THAs used Bonemite and 35 THAs used CMW; the choice of cement used for each patient was randomized. The working time in a dough state of Bonemite begins after 3 min from the start of mixing and continues for approximately 2–3 min at 21°C. Both cements were inserted into the bone in a dough state during polymerization and final hardening occurs within 10 min at 21°C.

Operative Procedure

For all cases, we followed the lateral approach with detachment of the greater trochanter and then replaced the hip according to Charnley’s procedure. Cementing was done without a cement gun. A flanged socket and a cement restrictor for the femoral canal were used for most hips in the latter half of the series. After surgery, antibiotics were administered for prophylaxis to all patients.

Statistics

We examined the patients clinically and radiologically before and after the operation and then yearly during follow-up. The clinical results were evaluated using the Harris hip score, and the differences between the groups were analyzed using the t-test. Survival analysis was performed using the Kaplan–Meier method. The survival rate was calculated considering revision surgery (cup, stem, or both) or impending revision due to aseptic loosening, as the end point. We defined radiological aseptic loosening as a progressing component migra-

## Table I. Composition of Bone Cements

<table>
<thead>
<tr>
<th>Bonemite®</th>
<th>CMW®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monomer</td>
<td>MMA</td>
</tr>
<tr>
<td>Hydroquinone</td>
<td>Hydroquinone</td>
</tr>
<tr>
<td>N,N-Dimethyl-p-toluidine</td>
<td>Ethanol</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td></td>
</tr>
<tr>
<td>Polymer</td>
<td>Poly(MMA-co-EMA)</td>
</tr>
<tr>
<td>2-5-dimethylhexane-2-5-hydroperoxide</td>
<td>Benzoylperoxide</td>
</tr>
<tr>
<td>BaSO₄</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>Tri-n-butylborane</td>
</tr>
</tbody>
</table>

Bonemite®: monomer is 18.9 g, polymer is 48 g and TBB is 0.8 ml. CMW®: monomer is 18.4 g and polymer is 40 g. MMA: methyl methacrylate. EMA: ethyl methacrylate.

Bonemite to the other side. Of the 35 hips, 33 hips showed osteoarthritis and 2 had avascular necrosis. These operations were performed by or under the supervision of one surgeon.

## Table II. Details of the Patients

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>Bonemite® Group</th>
<th>CMW® Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males (No. of hips)</td>
<td>53</td>
<td>33</td>
</tr>
<tr>
<td>Females (No. of hips)</td>
<td>43 (47)</td>
<td>30 (32)</td>
</tr>
<tr>
<td>Age (yr.) (average)</td>
<td>57.2</td>
<td>57.0</td>
</tr>
<tr>
<td>Follow-up period (yr.) (average)</td>
<td>8.21</td>
<td>8.21</td>
</tr>
<tr>
<td>Body weight (Kg)</td>
<td>53.4 ± 5.6</td>
<td>54.5 ± 9.5</td>
</tr>
</tbody>
</table>
tion exceeding 5 mm in any direction, and revision surgery was recommended for patients who complained of severe pain or whose implant migrated progressively. The proportion of surviving hips was calculated and indicated on the survival curves using Stat View 4.5 (Abacus Concepts Inc, Berkeley, California), and the curves were compared by the log-rank method.

### RESULTS

The mean preoperative Harris hip score was 43.8 in Bonemite group and 42.2 in CMW group (Table III). The implants were in good conditions for 5 years, but clinically they started to deteriorate gradually after that in both groups. The mean postoperative hip score was 89.2 in Bonemite group and 86.7 in CMW group at 5 years, and slightly decreased to 86.1 and 84.2 at 10 years after the operation, respectively. There were no statistically significant differences between the scores in the two groups before and after the operation.

<table>
<thead>
<tr>
<th>Follow-up (yr.)</th>
<th>Number of Hips</th>
<th>Harris Hip Score</th>
<th>Pain</th>
<th>Gait</th>
<th>Activity</th>
<th>Deformity</th>
<th>ROM</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperatively</td>
<td>58</td>
<td></td>
<td>14.6</td>
<td>13.1</td>
<td>9.8</td>
<td>2.6</td>
<td>3.7</td>
<td>43.8±11.1</td>
</tr>
<tr>
<td>1</td>
<td>58</td>
<td></td>
<td>41.8</td>
<td>27.1</td>
<td>12.5</td>
<td>3.7</td>
<td>4.8</td>
<td>90.0±8.2</td>
</tr>
<tr>
<td>5</td>
<td>58</td>
<td></td>
<td>41.3</td>
<td>26.8</td>
<td>12.7</td>
<td>3.7</td>
<td>4.7</td>
<td>89.2±9.7</td>
</tr>
<tr>
<td>10</td>
<td>43</td>
<td></td>
<td>40.3</td>
<td>25.2</td>
<td>12.4*</td>
<td>3.7</td>
<td>4.4</td>
<td>86.1±12.1</td>
</tr>
</tbody>
</table>

### CMW Group

<table>
<thead>
<tr>
<th>Follow-up (yr.)</th>
<th>Number of Hips</th>
<th>Harris Hip Score</th>
<th>Pain</th>
<th>Gait</th>
<th>Activity</th>
<th>Deformity</th>
<th>ROM</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperatively</td>
<td>35</td>
<td></td>
<td>13.4</td>
<td>13.0</td>
<td>9.8</td>
<td>2.5</td>
<td>3.5</td>
<td>42.2±13.8</td>
</tr>
<tr>
<td>1</td>
<td>35</td>
<td></td>
<td>42.8</td>
<td>25.3</td>
<td>12.0</td>
<td>3.8</td>
<td>4.6</td>
<td>88.5±12.2</td>
</tr>
<tr>
<td>5</td>
<td>35</td>
<td></td>
<td>42.2</td>
<td>24.1</td>
<td>11.9</td>
<td>3.7</td>
<td>4.7</td>
<td>86.7±12.9</td>
</tr>
<tr>
<td>10</td>
<td>27</td>
<td></td>
<td>41.3</td>
<td>23.8</td>
<td>11.1*</td>
<td>3.7</td>
<td>4.2</td>
<td>84.2±14.1</td>
</tr>
</tbody>
</table>

The p values were more than 0.05 on all headings between the two groups except for the activity scores* at 10 years (p < 0.05) after the operation. There were no statistically significant differences in the total scores between the two groups.

Early postoperative infection never occurred and no serious complications occurred immediately after the operation in either group. Radiographically, no abnormal reaction between circumferential bone and tissue and bone cement was observed in either group (Fig. 5). No findings of massive osteonecrosis or tumor-like tissue were observed at revision surgery for either group.

### DISCUSSION

Although recent advancements in prosthesis designs and operative procedures have contributed to better clinical results...
after THA, several problems of acrylic bone cement remain and lead to the instability of implants after long-term use, and cause aseptic loosening.

The first problem of bone cement is its lower biocompatibility. Although a block of Poly(MMA) causes no active foreign body reaction,9 microparticles of Poly(MMA) might induce an inflammatory response and cause osteolysis of a circumferential bone.10 Recently, microparticles produced from the polyethylene cup are thought to be more harmful, 11 and prevention of polyethylene socket wear is now being actively studied.12

The second problem is fatigue fracture of the bone cement. While avoiding stress concentration, bone cement is applied to bone tissue with no defects using a cement gun or a vacuum mixing technique for bone cement,13 and the thickness of the cement mantle should be kept over 3 mm at least.14 For improvement of fatigue strength of bone cement, adding styrene to the polymer and making copolymer of MMA and styrene helps to increase the useful life of cement (Symplex P®).15

The third problem is the bad effect of heat during polymerization of the MMA monomer. Some authors think that heat developed during polymerization can be over the temperature at which proteins coagulate to damage the bone around the cement, but others think heat is well absorbed by the metal implant and does not injure the bone.16 Mjöberg17 said the radiolucent zone around the components could be explained by heat injury during the polymerization of bone cement and the initial rapid migration could be accounted for by the resorption of a layer of necrotic bone following heat injury during the polymerization. Regardless, a temperature over 70 °C is not safe for human tissue.

The forth problem is the elastic modulus of the bone cement for THA. Weightman et al.18 insisted that a bone cement with a lower elastic modulus and more ductile than the conventional one improved load transfer to the proximal femur to avoid the stress shielding around it. But there is no consensus regarding which is the best elastic modulus of bone cement for THA.

Bonemite was developed to solve the latter two problems. Polymerization of MMA in the presence of TBB does not occur too rapidly, and the highest temperature during polymerization is lower than that of conventional bone cement, but the application time is short enough for clinical use, namely, within 10 min at a room temperature of 21 °C. As for physical properties, Bonemite has a 3% lower elastic modulus and greater ductility than CMW (Fig. 6).6 These characteristics could also have some effect on radiological and clinical results. The present study showed that the stems fixed with Bonemite had a higher survival rate than those in the CMW group, but no statistically significant difference was observed. This might be attributable to the still-high temperature during polymerization and the still-high elastic modulus.

Pain or other kinds of discomfort around the hip were no different for the Bonemite group and the CMW group, and the clinical hip scores were nearly equal. And there were no statistically significant differences in the rate of revision surgery or radiological aseptic loosening between the two groups. Our results indicate that Bonemite is safe biologically and is mechanically stable for a long time, and further improvements, including the development of a low viscosity one for the cement gun or the adhesive one to bone,19 could lead to better results of THAs.

We thank K. Furuya, MD, Professor Emeritus, for his invaluable leadership.

Figure 4. Survival rate of stems fixed with Bonemite or CMW (p = 0.085).

Figure 5. Radiograph of a patient in the Bonemite group taken 21 years after THA. There are no signs of radiological loosening.

Figure 6.
REFERENCES


Figure 6. Fracture toughness of Bonemite and CMW in three point bending tests. Yielding points are 674 Kg/cm² (Bonemite) and 703 Kg/cm² (CMW).