Metallurgical analysis of five failed cast cobalt-chromium-molybdenum alloy hip prostheses

STEPHEN D. COOK, Ph.D.; MARCUS A. KESTER, Ph.D.; AMANDA F. HARDING, B.S.; T. DESMOND BROWN, M.D.; PATRICIA M. SANDBORN, B.S.

Rehabilitation Research and Development, Veterans Administration Medical Center, New Orleans, Louisiana and Department of Orthopaedic Surgery, Tulane University School of Medicine, New Orleans, Louisiana

Abstract — The clinical and metallurgical characteristics of five cast cobalt-chromium-molybdenum alloy femoral hip prostheses which failed in vivo were evaluated. The devices included: two of the Howmedica Muller-Charnley design, two of the Howmedica Charnley design, and one of the Zimmer Aufranc-Turner design. Fractographic analyses demonstrated that the five devices had failed by fatigue which originated on the lateral aspect. Failure occurred after an average in vivo time of 80.4 months (approximately 6.7 years). Only two of the devices had Rockwell hardness values that were within the ASTM specifications for the alloy. Upon metallurgical examination, moderate to severe levels of gas porosity, interdendritic shrinkage, and nonmetallic inclusions were found in all of the devices. As expected, extremely large grain sizes also were observed in the devices examined. These results indicate that the metallurgical flaws and defects associated with the cast cobalt-chromium-molybdenum alloys used in these devices may preclude successful longterm performance and warrant manufacturer's attention.

INTRODUCTION

Total hip arthroplasty has proved to be a successful treatment modality for the restoration of daily activities and relief of pain in the disabled joints of the elderly. However, because of continuing problems, the procedure has not enjoyed the same degree of success in young or middle-aged patients. Device loosening and pain are the principle reasons for revision surgery. A late problem with total hip prostheses is fatigue failure of the femoral component. Charnley has reported a fracture incidence of 0.23 percent in his initial 6500 hip replacement procedures (1). Martens et al reported an incidence of 11 percent in a smaller group of 56 patients who had received Charnley-Muller devices of an earlier design (9). Iatrogenic factors, fixation methods, implant design, and metallurgical characteristics have all been implicated in causing fatigue failures in the femoral stems (1–9, 11).

Failure to obtain or maintain proper valgus positioning of the device is a primary factor in device mechanical failure. Varus positioning or migration can lead to increased stress on the lateral aspect of the device (2,3,5,7,9). Likewise, failure to remove enough of the calcar trabecular bone may lead to resorption and a loss of calcar support (1–3,5–8,11). If the device is properly seated distally, this situation can generate a cantilever effect on the device during daily activities (5,7,8). Such an alteration of stresses can produce catastrophic device failure through the fatigue mechanism.

Design flaws, which can lead to mechanical fatigue, are uncommon. Most manufacturers have abandoned such features as sharp corners and mechanically etched serial numbers on the devices. The use of better metal alloys has also significantly reduced the incidence of crack initiation. However, the use of cast cobalt-chromium-molybdenum in early hip designs has led to a number of problems. These problems arose from metallurgical flaws such as gas porosity, nonmetallic inclusion content, grain size variability and interdendritic shrinkage (2–5, 9,11,12). Such characteristics predispose the implant to crack formation and propagation. Normal daily activities such as gait cause fluctuating stresses on the implant (5). These fluctuations can produce small cracks that originate
principally along the lateral and anterior borders of the device which experience the highest tensile stresses (5,7,8,11). Once the crack is formed, loads producing mean tensile stresses significantly less than the material's nominal strength can lead to fatigue failure, due to the stress concentration at the leading edge of the crack.

As part of the ongoing Orthopaedic Implant Retrieval and Analysis Program sponsored by the Veterans Administration, all total joint prostheses removed from patients at Tulane-affiliated hospitals were evaluated for in vivo performance. It was the purpose of this study to review the clinical histories of five patients with fractured cast cobalt-chromium-molybdenum alloy femoral hip prostheses and correlate findings with the metallurgical properties and failure characteristics of the devices.

MATERIAL AND METHODS

Upon surgical removal, the five fractured femoral hip prostheses were forwarded to the Biomaterials Laboratory for mechanical failure and metallurgical evaluations. The hip components were removed between the years 1976 and 1985 from patients at Tulane-affiliated hospitals. All femoral prosthetic components were fabricated from cast cobalt-chromium-molybdenum alloy.

After removal, the devices were ultrasonically cleaned in a hydrogen peroxide bath, brushed with a mild detergent, and photographed. Proper care was taken to insure that the fracture surfaces of the broken femoral stems remained unharmed in order to facilitate determination of the mode of device failure. The fracture surfaces were viewed using light and scanning electron microscopes. Using an abrasion wheel cutoff saw, a transverse section was obtained from each component just below the distal fracture site. This section was mounted in epoxy and polished to a mirror image for metallurgical analysis. Using ASTM Standard techniques, each specimen was evaluated for Rockwell hardness, inclusion content, porosity, and grain size. Gas porosity, inclusion content, and interdendritic shrinkage were evaluated on a grading scale where 0 represented no significant levels, 1 represented moderate levels, and 2 represented severe levels. The controls incorporated in the grading scheme were similar cast cobalt-chromium-molybdenum prostheses, but were of current designs and materials.

Clinical histories also were obtained from each patient's chart. Parameters evaluated included patient age at implant insertion, insertion diagnosis, implant time in situ, and reason for implant removal.

The following is a typical case of a device failure: the patient, a 63-year-old white male, had a Muller-Charnley (32 mm head) type total hip arthroplasty inserted in 1972 for severe left hip pain due to avascular necrosis (Figure 1a). He had a history of chronic alcohol abuse. Following surgery, the patient had good relief of pain and returned to office work until 1982, when he began to have some left hip discomfort. The pain became more severe after December 1984 (Figure 1b) and by August 1985, the patient was only able to ambulate one-block distances with the aid of a cane. At that time, he had a painful range of motion of 0-90 Deg. flexion, 30 Deg. external rotation, 0 Deg. internal rotation, and 15 Deg. abduction. He also had a slight leg-length discrepancy of 1 cm and slight quadriceps atrophy. He had no flexion contracture and no drainage.

Figure 1a.
Postoperative radiograph of a Muller-Charnley total hip arthroplasty (prosthesis #1).
Radiographic review in August 1985 showed a transverse fracture of the femoral component at the junction of the distal and middle third of the stem (Figure 1c). There was solid fixation of the stem tip in cement, yet there was visible radiolucency around the proximal stem and resorption of bone in the calcar region. The acetabular component showed evidence of proximal migration, early protrusio and radiolucency at the cement-bone interface. Radiographs taken in May 1985 (Figure 1d) revealed evidence of the femoral stem fracture, although this remained undiagnosed until August 1985. An earlier film from December 1984 did not show the stem fracture or acetabular loosening.

In August 1985, the patient was taken to surgery for removal of the loose acetabular and femoral components. The fractured piece of the distal femoral stem was firmly fixed, necessitating a window cut in the bone for removal. The prosthesis was replaced with a non-cemented DuPuy type AML bipolar endoprosthesis (Figure 1e).
RESULTS

Femoral prostheses were removed from five patients (four males and one female) with an average age at insertion of 54.7 years (range: 50–67 years). The cases included three right hip arthroplasties and two left hip arthroplasties. Insertion diagnoses included avascular necrosis (three cases), joint dislocation (one case) and Paget’s disease (one case). All prostheses remained in situ for an average of 80.4 months (range: 37–158 months) and all were removed due to fracture of the femoral component with associated loosening. The clinical data are presented in Table 1.

All devices had metallurgical defects which could have contributed to their mechanical failure (Table 2). With the grading scheme employed, three (60 percent) of the devices had moderate levels of gas porosity, while the two (40 percent) remaining devices had severe levels (Figure 2). Three (60 percent) devices also exhibited moderate levels of nonmetallic inclusions, while two (40 percent) had severe levels (Figure 3). Interdendritic shrinkage voids were present in all prostheses examined and were judged to be severe in three (60 percent) devices and moderate in two (40 percent) devices (Figure 4).

ASTM guidelines suggest that cast cobalt-chromium-molybdenum alloy for implantation should have Rockwell “C” scale hardness values between 25 and 35 (11).

Figure 1. (above)
Radiograph at revision surgery showing the AML bipolar endoprosthesis, August 1985.

Figure 2. (below)
Photomicrograph showing severe levels of gas porosity in a fractured femoral stem component (prosthesis #1).
Figure 3.
Photomicrograph showing severe levels of nonmetallic inclusions in a fractured femoral stem component (prosthesis #3).

Table 1
Clinical Data for Patients with Fractured Hip Prostheses

<table>
<thead>
<tr>
<th>Prosthesis Number</th>
<th>Sex</th>
<th>Age (years)</th>
<th>Mfg./Head Diameter</th>
<th>Insertion Diagnosis</th>
<th>Removal Reason</th>
<th>Months in situ</th>
<th>Limb</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>50</td>
<td>H* (32mm)</td>
<td>Avas.Necr.</td>
<td>Breakage</td>
<td>158</td>
<td>L</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>50</td>
<td>H* (32mm)</td>
<td>Avas.Necr.</td>
<td>Breakage</td>
<td>43</td>
<td>R</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>67</td>
<td>H** (22mm)</td>
<td>Dislocation</td>
<td>Breakage</td>
<td>108</td>
<td>L</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td></td>
<td>H** (22mm)</td>
<td>Avas.Necr.</td>
<td>Breakage</td>
<td>56</td>
<td>R</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>52</td>
<td>Z*** (32mm)</td>
<td>Pagets Dis.</td>
<td>Breakage</td>
<td>37</td>
<td>R</td>
</tr>
</tbody>
</table>

H = Howmedica  
Z = Zimmer  
* Muller-Charnley: Model #6920-0  
** Charnley: Model #6924-0  
*** Aufranc-Turner: Model #4047-09

Table 2
Metallurgical Parameters for Fractured Hip Prostheses

<table>
<thead>
<tr>
<th>Prosthesis Number</th>
<th>Level of Fracture*</th>
<th>Rockwell C Hardness**</th>
<th>Gas Porosity***</th>
<th>Inclusions***</th>
<th>Interdendritic Shrinkage***</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Distal</td>
<td>15.0 (1.8)</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>Middle</td>
<td>22.0 (2.6)</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>Proximal</td>
<td>20.0 (2.2)</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Proximal</td>
<td>26.0 (1.5)</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>Middle</td>
<td>28.0 (4.7)</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

* See Figure 5  
** Mean (Standard Deviation)  
*** ASTM guidelines suggest Rockwell hardness in the range of 25-35 for RC values.

0 = None  
1 = Moderate  
2 = Severe
Figure 4.
Photomicrograph showing severe levels of interdendritic shrinkage voids in a fractured femoral stem component (prosthesis #1).

Figure 5.
Photograph showing the location of fracture sites along the femoral stems: A. Howmedica Charnley device, B. Howmedica Muller-Charnley device, C. Aufranc-Turner device.
Three of the five (60 percent) femoral components had mean hardness values less than 25 (Table 2). There were no consistent findings regarding the variation of hardness values across the sections, although in three (60 percent) devices, the hardness values increased in the center of the device.

The fractures of the femoral stems occurred in a variety of locations (Figure 5) (Table 2). Two (40 percent) of the devices broke in the area of the proximal third of the stem. The central third of the stem was the location of two (40 percent) device failures, while the remaining device fractured in the distal third of the stem. Both of the devices that fractured in the proximal third were the Howmedica Charnley total hip (Model 6924-0). Additionally, one device (prosthesis #2) had a secondary crack forming slightly distal (0.5 cm) to the level of the fracture site (Figure 6).

Due to in vivo fretting abrasion subsequent to fracture, it was extremely difficult to determine the precise origination site of the fatigue. The fracture surfaces normally showed a somewhat smooth or slow fatigue which encompassed the lateral one-third to one-half of the transverse cross-sectional area (Figure 7). This portion of the fracture surface had stress striations typical of fatigue failure (Figure 8). The remaining portion of the fracture surface had a rough appearance, which is typical of a brittle or fast fracture (Figures 7, 9). Fast fracture ultimately occurs when the effective cross-sectional area, already reduced due to slow fatigue, can no longer support the demands placed upon it.

**DISCUSSION**

The results of this study concerning the metallurgical defects present in many cast cobalt-chromium-molybdenum prostheses are in agreement with the findings of other researchers (3–6, 9–11). These flaws
include gas porosity, nonmetallic inclusions, and interdendritic shrinkage, which can all function as both crack initiators and intensifiers in the crack propagation process. The lateral bias of the fatigue initiation site is also in accord with other researchers (3,8). Gas pores or a string of pores as are present in interdendritic shrinkage are stress raisers and their presence near a surface warrants concern (11). Further, the frequency of nonmetallic inclusions has been demonstrated to have a detrimental effect on the endurance limit of cast materials (11). The effect of porosity on the hardness of a device can be appreciated by noting that device #1 (Figure 2, Table 2) had the greatest porosity and the lowest Rockwell hardness values of the five hips examined. Manufacturing processes can enhance the chances of prosthetic survival by including steps to reduce the chance of microstructural flaws being present. Such steps include hot isostatic pressing, forging, and remelting processes (3–5,11), as well as the use of other alloys such as titanium. These metallurgic flaws are particularly important when considering the fluctuating stresses that occur during the working life of a hip prosthesis.

The extreme proximal location of the fracture of the two femoral components of identical models illustrates the importance of design considerations in the performance of prosthetic devices (Table 2) (1,2,8–10). Device features such as sharp corners, tapers, small cross-sectional areas, and overly curved stems should be avoided. As shown in Figure 9, the stem on the Charnley (22 mm head) device is curved in such a manner that large bending stresses are generated at the shoulder of the device (1). The area of fatigue failure was in this shoulder region in both hip stems of this type.

Prosthetic parameters affecting mechanical and clinical failure rates include: iatrogenic factors such as cement techniques, device placement and selection, patient selection and education, as well as the surgical handling of the device. Proper calcar support of the device is extremely critical in obviating device fatigue. Although the proximal end of the device migrates medially with the
Figure 8.
Scanning electron microscope photograph showing slow fatigue striations on the lateral 1/3 to 1/2 of the transverse cross-sectional area (prosthesis #2).

Figure 9.
Scanning electron microscope photograph showing fast fracture striations on the fracture surface of a femoral stem (prosthesis #3).
loss of calcar support, the distal end remains fixed in the cement. Once the proximal load transfer is lost, the system resembles a bending cantilever and the device must resist enhanced cyclic bending stresses (7). Factors such as patient weight (3,5,6,8) and high levels of activities (5) can also increase these bending stresses and have been demonstrated to have a positive correlation with fatigue failure.

It is hoped that with the development of the newer alloys such as titanium and the use of new manufacturing techniques, the frequency of mechanical failures can be reduced. Education regarding the data generated through implant retrieval and analysis, along with these new alloys and techniques, should result in an enhanced survival rate for current hip devices.

REFERENCES