THE HISTOLOGY OF THE RADIOLUCENT LINE

LOUIS M. KWONG, MURALI JASTY, RICHARD D. MULROY,
WILLIAM J. MALONEY, CHARLES BRAGDON, WILLIAM H. HARRIS

From Massachusetts General Hospital and Harvard Medical School, Boston

The radiographic and histological features of radiolucent areas at the cement–bone interface were correlated in 15 specimens retrieved at post-mortem from patients who had undergone cemented total hip arthroplasty, two weeks to 15 years prior to death. All but one of the components were securely fixed, as demonstrated by direct measurements of micromotion.

Extensive radiolucencies were present in all but one case. In 11 of the 14 specimens with radiolucencies, histological examination showed that the radiolucent areas represented regions of osteoporosis and bone remodelling. The remodelling changes were characterised by osteoporosis, cancellisation and thinning of the endosteal cortex, and osteopenia of the trabecular bone. In two specimens the appearance of radiolucency was found to be due to fibrous tissue at the cement–bone interface and in one specimen there was a mixed picture of osteolysis and fibrosis.

The study demonstrates that radiolucent lines can occur with well-fixed components and that they may commonly represent osteoporosis rather than the presence of a fibrous membrane at the cement–bone interface.

Since the advent of radio-opaque cement in total hip arthroplasty, density changes at the cement–bone interface have been observed on plain radiographs of both the femoral and acetabular constructs, and have been variously described as radiolucencies, radiolucent lines, radiolucent zones, radiological demarcations and demarcation lines (DeLee and Charnley 1976; Salvati et al 1976; Reckling, Asher and Dillon 1977; Shine and O’Neill 1978; Gruen, McNeice and Amstutz 1979; Freeman, Bradley and Revell 1982).

Attempts have been made to correlate these radiographic changes with the histology of the tissue found at the interface and with stability of the implant (Charnley 1964; Charnley, Follacci and Hammond 1968; Willert and Semlitsch 1976; Bullough et al 1988). Radiolucency has been construed as evidence of fibrous tissue at the interface (Willert, Ludwig and Semlitsch 1974; Willert and Semlitsch 1976; Freeman et al 1982; Bullough et al 1988), occurring as a biological response either to the polymethylmethacrylate or to mechanical loosening (Goldring et al 1983; Goodman et al 1989). It may also be due to poor cement technique, failing to fill the canal (Charnley 1970; Jacobs et al 1989), osteoporosis (Charnley et al 1968; Willert et al 1974; Willert and Semlitsch 1976; Draenert 1981; Poss, Stahelin and Larson 1987; Comadoll et al 1988), fibrous membrane formation (Willert and Semlitsch 1976; Mirra, Marder and Amstutz 1982; Goldring et al 1983; Goodman et al 1989) and osteolysis (Carlsson, Gentz and Linder 1983; Harris and McGann 1986; Jasty et al 1986).

This study aims to correlate the radiographic and the histological appearance of the cement–bone interface and to assess the implication of radiolucencies for the long-term performance of an implant.

MATERIALS AND METHODS

Fifteen femurs from 13 patients who had undergone total hip replacement with radio-opaque cement were recovered at post-mortem. At the time of death the components of 14 of these specimens had been implanted.
for periods from two weeks to 15 years (0.5, 13, 40, 58, 82, 101, 102, 118, 119, 137, 144, 150, 156 and 180 months). The duration of service of one implant was not known. All but one of the implants appeared to be well fixed at the cement–bone interface; one was demonstrably loose.

The femoral stem designs used were Aufranc-Turner (4), CAD (3), HD-2 (3), Mueller (2), Harris I (2), and Omnipit (1). There were four male patients and eight females; the sex of one patient was unknown. The diagnosis was osteoarthritis in 11, femoral neck fracture in one, osteonecrosis in one, and unknown in two.

The ages of the patients at the time of the total hip replacement ranged from 40 to 87 years (average 71). Their ages at the time of death ranged from 43 to 90 years (average 77, Table I). There was good evidence from medical records, and from members of their families that all patients had satisfactory hip function up to the time of death.

The specimens were fixed in formalin immediately after removal and stripped of soft tissues. High contrast radiographs were taken in internal and external rotation as well as the standard anteroposterior and lateral views. The cement–bone interface was examined in each projection. We defined a radiolucency as any region of diminished density at the cement–bone interface; this included any difference in density between the cortical bone and the cement, areas of osteolysis, and regions of radiolucency surrounded by demarcation lines (lines of increased density). On the anteroposterior projection we recorded radiolucency in each of the seven zones described by Gruen et al. (1979). In addition, we calculated the percentage of the cement–bone interface which was radiolucent both on the anteroposterior and the lateral projections. The location of each radiolucency was recorded for later comparison with the histological cross-sections. The width of the radiolucency in each zone was noted as was its extent around the cement mantle as revealed by the anteroposterior and lateral radiographs.

In five specimens (from four patients) serial clinical radiographs were available from implantation to death; these films were also analysed to document the progression of changes.

When the radiographic evaluation was complete, the stability of each specimen was tested in simulated stance and stair-climbing loads using the methods described by Burke et al. (1992).

After biomechanical testing had been completed, each specimen was embedded in a block of methylmethacrylate cement and sectioned into 5 mm thick slices using a high speed, water-cooled saw with an aluminium ceramic blade. Contact radiographs were made of each section and examined under a dissecting microscope with 20× magnification. Each section was subsequently polished using a 600 grit silicon carbide paper on a surface grinder. Sections were then dehydrated with calcium chloride pellets and coated with a thin layer of gold in a sputter coater. The bone–cement interface of each specimen was examined with the electron microscope under secondary and backscatter imaging modes. The trabecular pattern and cortical porosity were assessed as well as the extent and thickness of any fibrous tissue. Sections from levels corresponding to the proximal, middle, and distal regions of the prosthesis were also prepared for histology by further grinding and staining with haematoxylin and eosin. The appearance of the cement–bone interface at the anterior, posterior, medial and lateral aspects in each of the 291 sections was assessed for evidence of porosis, lysis, or fibrous membrane formation.

RESULTS

Radiographic zonal analysis. The radiographs of the whole specimens prior to sectioning showed radiolucencies of various kinds at the cement–bone interface throughout the metaphyseal and diaphyseal regions in all but one case (specimen 1, obtained only two weeks after implantation). In three specimens (5, 10 and 15) the radiolucent areas were surrounded by thin, sclerotic, radiodense demarcation lines (DeLee and Charnley 1976). The maximum width of the radiolucencies in these cases ranged from 3.5 to 5.5 mm (average 4). In the other 11 cases, the radiolucency was due to a decrease in trabecular definition compared to regions of surrounding cancellous bone.

In specimens 5, 9, 12 and 15, the radiolucent areas were continuous in all zones and had a maximum width that ranged from 2 to 7 mm (average 4). In the other ten specimens, the radiolucencies were focal and discontinuous. They were found most often in zones 1, 3 and 6 on the anteroposterior projection, and in zones 1, 6 and 7 on the lateral projection. The maximum width ranged from 1 to 10 mm (average 3.5).

Using the criteria described by Harris and McGann (1986), we classified the implants as probably loose in four specimens (radiolucency surrounding all of the cement–bone interface); and possibly loose in nine (radiolucency surrounding 50% to 99% of the cement–bone interface).

In the five cases (3 to 5, 10 and 12) with serial clinical radiographs from implantation to post-mortem, the films showed progressive decrease in cortical thickness and density, and diminishing trabecular definition at the cement–bone interface. None of the clinical radiographs showed definite evidence of loosening or osteolysis. Specimens 5 and 10 had discontinuous demarcation lines, but specimens 3, 4 and 12 had none.

Mechanical testing. One of the 15 specimens was obviously loose and therefore was not tested. Of the remaining 14 specimens, two broke during testing.

In the 12 specimens from which data are available, the maximum elastic micromotion in simulated stance loading ranged from 4 to 90 μm (average 29). The maximum micromotion in simulated stair-climbing load-
# Table I. Details of 15 post-mortem specimens

<table>
<thead>
<tr>
<th>Number</th>
<th>Implant type</th>
<th>Time since implantation SVC (month)</th>
<th>Age: sex</th>
<th>Diagnosis</th>
<th>Radiolucency zone</th>
<th>Zonal distribution</th>
<th>Histology†</th>
<th>Micromotion‡ (microns)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>AP</td>
<td>Lateral</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td>HD-2</td>
<td>0.5</td>
<td>67: M</td>
<td>OA</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>Omnifit</td>
<td>13</td>
<td>87: F</td>
<td>Femoral fracture</td>
<td>60</td>
<td>60</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>3</td>
<td>HD-2</td>
<td>40</td>
<td>43: F</td>
<td>AVN</td>
<td>70</td>
<td>85</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>4</td>
<td>HD-2</td>
<td>58</td>
<td>90: F</td>
<td>OA</td>
<td>85</td>
<td>70</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>5</td>
<td>CAD</td>
<td>82</td>
<td>82: M</td>
<td>OA</td>
<td>100</td>
<td>100</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>6</td>
<td>A-T</td>
<td>101</td>
<td>73: F</td>
<td>OA</td>
<td>0</td>
<td>60</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>7</td>
<td>A-T</td>
<td>102</td>
<td>73: F</td>
<td>OA</td>
<td>30</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>A-T</td>
<td>118</td>
<td>87: F</td>
<td>OA</td>
<td>60</td>
<td>70</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>9</td>
<td>A-T</td>
<td>119</td>
<td>87: F</td>
<td>OA</td>
<td>85</td>
<td>100</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>10</td>
<td>CAD</td>
<td>137</td>
<td>82: F</td>
<td>OA</td>
<td>85</td>
<td>70</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>11</td>
<td>Harris 1</td>
<td>144</td>
<td>NK: M</td>
<td>NK</td>
<td>0</td>
<td>60</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>12</td>
<td>CAD</td>
<td>150</td>
<td>82: M</td>
<td>OA</td>
<td>85</td>
<td>100</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>13</td>
<td>Mueller</td>
<td>156</td>
<td>70: M</td>
<td>OA</td>
<td>60</td>
<td>60</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>14</td>
<td>Mueller</td>
<td>180</td>
<td>79: F</td>
<td>OA</td>
<td>70</td>
<td>85</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>15</td>
<td>Harris 1</td>
<td>190</td>
<td>NK</td>
<td>NK</td>
<td>100</td>
<td>100</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

*+, present, − absent, ± indeterminate
†N, normal, P, osteoporosis, M fibrous membrane, L osteolysis
‡A, maximum micromotion in simulated stance, B, maximum micromotion in simulated stair climbing
Figure 1 - Anteroposterior (a) and lateral (b) views of specimen 9 demonstrating circumferential radiolucency at the bone-cement interface; (c) radiograph of a section of the same specimen at diaphyseal level demonstrating a dense shell of new bone intimately associated with and surrounding the cement mantle. There is substantial osteoporosis of the adjacent cortex.

Figure 2a - Postoperative anteroposterior radiograph (specimen 10). b) Ten years after implantation there are new focal areas of radiolucency. Note the endosteal scalloping of the cortex. c) Contact radiograph of specimen 10 retrieved at post-mortem more than 11 years after implantation. d) Contact radiograph of a cross-section at the level of the mid-portion of the stem, demonstrating focal osteolysis, a dense shell of new bone around the cement mantle, and marked osteoporosis in the adjacent bone. Note also the focal osteolysis in the cortex.
Figure 3a – Postoperative anteroposterior radiograph of specimen 4. Note the area not filled with cement in zone 3. b) Contact radiograph of specimen 4 retrieved at post-mortem five years after implantation, demonstrating the development of increasing radiolucency at the cement-bone interface. c) Contact radiograph of a cross-section at the level of the junction of the middle and distal thirds of the stem demonstrating the presence of diffuse osteoporosis of the cortex.

Figure 4a – Postoperative anteroposterior radiograph of specimen number 12. b) Six years after implantation circumferential radiolucency has developed. c) Contact radiograph of specimen 12 retrieved at post-mortem more than 12 years after implantation demonstrating extensive circumferential radiolucency at the cement-bone interface. d) Contact radiograph of a cross-section at the level of the junction of the middle and distal thirds of the stem demonstrating the presence of diffuse osteoporosis. Note the absence of separation at the cement-bone interface.
ing ranged from 32 to 249 μm (average 84). The two specimens (3 and 13) with elastic micromotion of 155 and 249 μm both had severe osteoporosis of the cortex. All these deformations were elastic and spontaneously reversed, consistent with the performance of stable prosthetic components.

**Histology.** In specimen 1, which was retrieved two weeks after implantation, there was intimate apposition between the cement and the bone with no intervening membrane, osteoporosis, or osteolysis at the interface. No changes in cortical or trabecular bone architecture were seen.

In 11 specimens (2 to 4, 6, 7 to 9, 11 to 14), the radiolucent areas were found to represent regions of osteoporosis of the cortical and cancellous bone, and not fibrous tissue at the interface. Osteoporosis was most frequent in zones 1, 2 and 6 on the anteroposterior projection, and in zones 1, 6 and 7 on the lateral projection. Although extensive osteoporosis was found on histologic examination, and extensive radiolucencies were seen on the radiographs, these prostheses were not loose. In long-standing implants the cement mantle was supported by an intimately apposed shell of new bone, a 'neo-cortex', supported by a network of slender trabecular arising from the endostem. This neo-cortex could not be seen on the radiographs because it had the same density as the barium impregnated cement.

Cortical thinning was usually found along the whole length of the implant, but microscopy demonstrated no intervening fibrous tissue between the cancellous bone and the cement. Figure 1 illustrates how an X-ray beam passing through an area of osteoporosis surrounding the cement mantle will project the false appearances of a loose implant.

In one well-fixed specimen (number 10) that had been implanted for 13 years, both extensive osteoporosis and scattered areas of focal osteolysis were found. The areas of osteolysis were all secondary to granuloma formation and distally, they were related to regions in which the cement mantle was thin or incomplete and had fragmented (Fig. 2).

In only two cases (5 and 15) did we find a fibrous tissue membrane at the cement–bone interface. In specimen 5, the membrane was found principally in regions which corresponded with demarcation lines on the radiographs. The membrane did not completely surround the cement mantle at any level of section. The bone surrounding the intervening membrane was found to be porotic throughout the length of the implant.

Specimen 15, with a loose femoral component, had an extensive fibrous membrane up to 5 mm thick. This was the only case in which radiolucency was found to represent fibrous tissue at every site.

Of the five specimens in which serial clinical radiographs were available, the progressive radiolucencies in three (3, 4 and 12) represented only diffuse osteoporosis. The histological appearances were of extensive thinning of both the cortex and the trabeculae, and cancellation of the endostem. A dense circumferential shell of bone was intimately associated with the cement mantle with no intervening membrane (Figs 3 and 4). The retrieval findings in the remaining two specimens (5 and 10) were as described above.

**DISCUSSION**

Although the presence of a radiolucency at the cement–bone interface of femoral components has usually been thought to indicate a layer of fibrous tissue, the radiolucencies in our specimens were caused predominantly by osteoporosis. The bone changes were characterised by cortical osteoporosis, and cancellation and thinning of the cancellous trabeculae. Extensive osteoporosis was found in 14 of the 15 post-mortems and was the only factor contributing to radiolucency in 11 of them. Only the specimen obtained two weeks after implantation was without remodelling changes.

Charnley (1964) described six post-mortem specimens in which the radiographs suggested loosening of the implant but in which 'direct examination' revealed that "all the prostheses were held tight". He remarked that enlargement of the medullary canal secondary to osteoporosis did not cause loss of implant fixation. Histological studies of the interface of cemented femoral implants in dogs have shown an early remodelling phenomenon with cortical revascularisation, replacement of necrotic bone and late remodelling resulting in the cancellation of the cortex and the formation of a 'secondary medullary cavity' (Draenert 1981).

Jacobs et al (1989), reported four retrieved cemented femoral hip prostheses, and demonstrated that a lucent line at the cement–bone interface did not necessarily represent a layer of fibrous tissue.

The demonstration that localised osteoporosis can cause radiolucency at the interface has major implications for the long-term evaluation of cemented femoral implants.

This study was supported by the William H. Harris Foundation, Boston. One or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article. In addition benefits have also been or will be directed to a research fund, foundation, educational institution, or other non-profit institution with which one or more of the authors is associated.

**REFERENCES**


