Is the so-called ‘French paradox’ a reality?

LONG-TERM SURVIVAL AND MIGRATION OF THE CHARNLEY-KERBOULL STEM CEMENTED LINE-TO-LINE

F. El Masri, L. Kerboull, M. Kerboull, J. P. Courpied, M. Hamadouche

From the Centre Hospitalo-Universitaire Cochin-Port Royal, Paris, France

We have evaluated the in vivo migration patterns of 164 primary consecutive Charnley-Kerboull total hip replacements which were undertaken in 155 patients. The femoral preparation included removal of diaphyseal cancellous bone to obtain primary rotational stability of the stem before line-to-line cementing. We used the Ein Bild Roentgen Analyse femoral component method to assess the subsidence of the femoral component.

At a mean of 17.3 years (15.1 to 18.3) 73 patients were still alive and had not been revised, eight had been revised, 66 had died and eight had been lost to follow-up. The mean subsidence of the entire series was 0.63 mm (0.0 to 1.94). When using a 1.5 mm threshold, only four stems were considered to have subsided. Our study showed that, in most cases, a highly polished double-tapered stem cemented line-to-line does not subside at least up to 18 years after implantation.

A large body of orthopaedic literature clearly indicates that the cement mantle surrounding the femoral component of a cemented total hip replacement (THR) should be at least 2 mm thick.1-9 In the early 1970s, another concept was introduced, and is still upheld in France, which indicates that implantation of a canal-filling femoral component in a line-to-line manner is associated with a thin cement mantle.10 This principle which has given excellent long-term clinical and radiological results has been named the ‘French paradox’.11 An explanation of this phenomenon has been recently provided by in vitro studies which showed that a thin cement mantle in conjunction with a canal-filling stem was supported mainly by cortical bone and was subjected to low stresses.12,13 However, to the authors knowledge, a precise and accurate method has never been used to confirm the absence of in vivo migration of stems cemented according to the French paradox. The most accurate method of assessing migration of a stem is roentgen stereophotogrammetric analysis (RSA).14 This technique, however, is expensive and not available in all centres. In the late 1990s, Biedermann et al15 described the Ein Bild Roentgen Analyse femoral component (EBRA-FCA) method for assessing the migration of a femoral component. Its accuracy has been reported to be better than SD 1.5 mm (95% percentile), with a specificity of 100% and of sensitivity of 78% for the detection of migration of more than 1.0 mm, using RSA as the reference method.

Our aim was to evaluate the clinical results, the in vivo migration patterns using EBRA-FCA and survival of a consecutive series of contemporary polished femoral components cemented in a line-to-line manner.

Patients and Methods
Between January 1988 and December 1989, 164 consecutive primary THRs were performed in 155 patients by the two senior authors (MK, JPC). There were 93 women and 62 men with a mean age at the time of implantation of 63.7 years (26.6 to 91), a mean height of 165.6 cm (138 to 186), a mean weight of 65.0 kg (45 to 105), and a mean body mass index of 23.6 kg/m² (17.1 to 34.3). The right hip was operated on in 74 patients and the left in 72. The remaining nine patients had bilateral replacements. The initial diagnoses are summarised in Table I. Before THR 22 hips (13.4%) had undergone previous surgery including fixation of a fracture in three, a shelf procedure in four, femoral osteotomy in ten and surgical reduction of congenital dislocation during childhood in five.

Implants. All the prostheses were of the Charnley-Kerboull design (Kerboull MK III; Stryker-Benoist Girard, Hérouville Saint Clair, France) combining an all-polyethylene acetabular component and a 22.2 mm stainless-steel femoral head. The acetabular components were...
machined from compression-moulded GUR 415 ultra-high-molecular-weight polyethylene and were sterilised with 3 MRad of gamma irradiation in air. The monobloc double-tapered (5.9°) femoral component was made of 316L stainless steel with a highly polished surface (roughness (RA) 0.04 μm) and a quadrangular section. This contemporary version of the Charnley-Kerboull femoral component had a neck-stem angle of 130° (Fig. 1) and was available in six sizes with a stem length (shoulder to tip) ranging from 110 mm to 160 mm, and a neck length ranging from 24 mm to 56 mm. For each size, the femoral component was available in two to four different diameters to accommodate variations in the dimensions of the medullary canal. Hence, the entire range comprised a total of 18 standard femoral components. Preoperative planning using transparent templates was performed to determine the level of the neck section and the suitable neck length, offset and intramedullary size.

**Operative technique.** All the procedures were performed through a lateral approach with a trochanteric osteotomy as described previously.16 The acetabulum was prepared using curved gouges and/or reamers. The femur was prepared using straight femoral hollow reamers to remove diaphyseal cancellous bone in order to obtain rotational stability of the trial stem. The selected component which was cemented line-to-line was the same size as that of the last trial stem which was stable in rotation. Both components were cemented with CMW type-1 bone cement with gentamicin (Depuy, Exeter, United Kingdom). The cement was mixed manually in air. On the acetabular side, the cement was hand-packed while for femoral fixation it was packed with a rasp in the femoral canal which had been occluded with a bone plug.

**Post-operative treatment.** The post-operative regimen included the administration of systemic antibiotics (Cefamandol for 48 hours, thromboprophylaxis with coumadin until the time of full weight-bearing and anti-inflammatory medication (ketoprofen, 100 mg/day for five days) to prevent heterotopic ossification. Immediately after surgery, passive exercises were begun with the assistance of a physiotherapist and were continued until active movement of the hip was possible. The patients were free to walk after three days with crutches. Toe-touch weight-bearing was recommended until bone union had occurred at the trochanter, which was usually after six weeks.

Clinical and radiological evaluation was undertaken at six weeks, three and six months and at one year. The patients were reviewed every one or two years thereafter. At each follow-up visit, the patients had a physical examination by the operating surgeon and an anteroposterior (AP) radiograph of the pelvis with the patient supine was obtained.

**EBRA-FCA evaluation.** The primary method of evaluation was migration of the stem using EBRA-FCA.15 For each patient, all the available AP radiographs of the pelvis were digitised using the Vidar VRX-plus system (Vidar System Corporation, Herdon, Virginia) using a pixel density of 150 dots per inch, and linked to an IBM-compatible computer. The EBRA-FCA method consists of marking the femur and the femoral component with 19 reference points, with two additional lines to determine the axis of the component. Magnification, using the known size of the femoral head, was corrected for by the graphic program. The distance between the centre of the femoral head and the axis of the stem, the centre of the femoral head and the shoulder of the stem, and between the shoulder and tip of the stem were measured to assess the comparability of each pair of AP radiographs. The distance between the greater trochanter and the shoulder of the stem has been shown to be the most accurate measurement of migration of the stem,15 and was used in our study. An independent observer (FEM) recorded all the data. The baseline radiograph was that taken at the follow-up at six weeks after consolidation of greater trochanter.

**Clinical and radiological evaluation.** The functional results were rated according to the Merle d’Aubigné17 grading system in which an excellent result scored 18 points, a very good result 17, good 16, fair 15, poor 14, and a bad result

### Table I. Details of the initial diagnosis in the 164 hips

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number of hips (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary osteoarthritis</td>
<td>109 (66.5)</td>
</tr>
<tr>
<td>Congenital hip dysplasia</td>
<td>37 (22.6)</td>
</tr>
<tr>
<td>Avascular necrosis</td>
<td>10 (6.1)</td>
</tr>
<tr>
<td>Perthes’ disease</td>
<td>3 (1.8)</td>
</tr>
<tr>
<td>Femoral neck fracture</td>
<td>3 (1.8)</td>
</tr>
<tr>
<td>Ankylosing spondylitis</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Slipped capital femoral epiphysis</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Total</td>
<td>164 (100.0)</td>
</tr>
</tbody>
</table>
≤ 13. Standard radiological analysis was performed (MH) on serial AP radiographs of the pelvis. The position of the acetabular component relative to the horizontal and vertical tear-drop lines, its inclination angle and the presence and evolution of radiolucent lines according to DeLee and Charnley18 were evaluated on the pelvic side. Loosening of the acetabular component was defined as migration exceeding 3 mm, angular rotation exceeding 3° or a continuous radiolucent line wider than 2 mm. On the femoral side, the parameters investigated included the presence and evolution of radiolucent lines in any of the seven zones described by Gruen, McNeice and Amstutz,19 and the alignment of the stem which was referenced from the axial alignment of the femur. The latter was assumed to be neutral within 3° from co-linearity. Loosening of the femoral component was defined according to the criteria of Harris and McGann20 which included subsidence of the stem component was defined according to the criteria of Harris and Charnley.

Complications and revisions. Post-operative complications occurred in four hips (2.4%). An isolated dislocation occurred in one patient three weeks after surgery and there were two cases of nonunion of the greater trochanter. One of these latter hips was successfully treated using additional fixation with wires and a trochanteric claw plate three months after THR.24 One patient had a deep post-operative haematoma, which was treated by debridement with no further complications. Heterotopic ossification was observed in 16 hips (9.8%) and was classified as grade 1 in nine, grade 2 in five and grade 3 in two.

The mean time to revision for eight patients (eight hips in six women and two men) was 14.9 years (12.3 to 16.7). The mean age of these patients at the time of THR was 50.7 years (41.2 to 63). Of the eight revision procedures, seven involved both components and one the acetabular component only. All the revisions were performed because of acetabular wear and loosening associated with periacetabular osteolysis. Of the seven revised stems, three were loose at revision, the remaining four being removed for ease of acetabular reconstruction which was performed with allograft bone and the Kerboull acetabular reinforcement device.25

EBRA-FCA migration. A total of 1689 radiographs (a mean of 10.3 per hip) were digitised. Of these, 263 (15.6%) were excluded by the software since they did not meet set standards for comparability. Using this method, the length of follow-up was significantly shorter than the full observation period (Wilcoxon rank-sum test, p < 0.001). No migration curve could be obtained for 24 of the 164 stems (14.6%), including the two hips which had nonunion of the greater trochanter. The mean EBRA-FCA follow-up of the whole series was 9.4 years (0 to 18.4). At the last follow-up, the mean subsidence of the entire series was 0.63 mm (0 mm to 1.94 mm). When using a 1.5 mm threshold, in accordance with the accuracy of the EBRA-FCA method for subsidence, four of the 142 stems with adequate EBRA-FCA data were considered to have migrated (1.60 mm to 1.94 mm). Using a threshold of 2 mm for subsidence, none of the 142 stems was considered to have migrated. The patterns of migration were calculated every two years giving nine intervals. The results are summarised in Figure 2 and Table II. Of the three stems which were considered to be loose at revision, one had subsided 1.64 mm, but subsidence was < 1.5 mm for the remaining two.

Clinical. The clinical results were assessed for the 73 patients (50 women and 23 men, 77 hips) who were alive and had not undergone revision at the time of the last follow-up evaluation. The mean age of this group at the time of THR was 60.8 years (26.6 to 81.5). The mean age at the time of the last follow-up was 78.1 years (43.9 to 99.7). The mean Merle d’Aubigné functional hip score increased from 10.7 points (SD 2.4) pre-operatively to a mean of 17.6 (SD 0.4) at the time of the last follow-up.
IS THE SO-CALLED ‘FRENCH PARADOX’ A REALITY? 345

VOL. 92-B, No. 3, MARCH 2010

The clinical results were rated as excellent in 57 hips (74.0%), very good in 17 (22.1%), good in two (2.6%), and poor in one (1.3%). Radiological. The mean abduction angle of the acetabular component was 42.6° (25° to 55°). Placement of the acetabular component was considered to be anatomical in 132 (80.5%) of the 164 hips, whereas a minor malposition was seen in the remaining 32. The femoral component was in a neutral position in 132 hips (80.5%), while 28 components (17.1%) were in < 5° of valgus and four (2.4%) in < 5° of varus (Fig. 3). On the acetabular side, according to the criteria used in our study, 143 acetabular components (87.2%) were not loose, eight (4.9%) had probable or definite loosening (all being revised) and 13 (7.9%) possible loosening. On the femoral side, according to the criteria used in our study, 161 stems (98.2%) were not loose and three had definite or probable loosening (all being revised). Of these three stems, two had a complete radiolucent line greater than 2 mm and the third had tilted into varus. Periacetabular osteolysis was observed in 15 hips (9.1%), including the eight revised hips. On the femoral side, localised osteolysis in zone 7 was observed in 74 hips (45.1%).

Fig. 2

Table II. Details of the median (interquartile range) cumulative subsidence with time

<table>
<thead>
<tr>
<th>Follow-up (yrs)</th>
<th>Number of hips</th>
<th>Subsidence (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 2</td>
<td>142</td>
<td>0.43 (0.01 to 0.62)</td>
</tr>
<tr>
<td>2 to 4</td>
<td>103</td>
<td>0.63 (0.27 to 0.70)</td>
</tr>
<tr>
<td>4 to 6</td>
<td>93</td>
<td>0.70 (0.07 to 1.12)</td>
</tr>
<tr>
<td>6 to 8</td>
<td>72</td>
<td>0.76 (0.24 to 1.14)</td>
</tr>
<tr>
<td>8 to 10</td>
<td>67</td>
<td>0.66 (0.04 to 0.97)</td>
</tr>
<tr>
<td>10 to 12</td>
<td>48</td>
<td>0.55 (0 to 0.97)</td>
</tr>
<tr>
<td>12 to 14</td>
<td>44</td>
<td>0.50 (0 to 1.09)</td>
</tr>
<tr>
<td>14 to 16</td>
<td>31</td>
<td>0.37 (0 to 0.53)</td>
</tr>
<tr>
<td>16 to 18</td>
<td>31</td>
<td>0.46 (0.11 to 0.71)</td>
</tr>
</tbody>
</table>

(Fig. 2)

Graph showing the mean migration patterns as a function of time. The error bars indicate the sd.

Femoral cortical thickening in zones 3 and 5 occurred in 66 hips (40.2%). This phenomenon was not associated with proximal femoral stress shielding.

Survivorship analysis. With revision of either component for any reason as the endpoint (Fig. 4a), the cumulative survival rate at 17 years was 90.5% (95% CI 84.2 to 96.8). With radiological loosening of the femoral component as the endpoint (Fig. 4b), the cumulative survival rate at 17 years was 96.8% (95% CI 93.2 to 100).

In the ‘worst-case scenario’ in which all hips lost to follow-up were considered to be failures, the survival rate at 17 years was 82.4% (95% CI 73.8 to 91.0) and 90.4% (95% CI 85.3 to 95.5) when using revision of either component for any reason and radiological loosening of the femoral component as the endpoint, respectively.

The gender, initial diagnosis and previous surgery were not associated with a higher risk of revision (Wilcoxon log-rank test, p = 0.8). The cumulative survival rate at 17 years, using revision of either component for any reason as the endpoint, was 97.8% (95% CI 93.5 to 100) for patients older than 60 years compared with 82.2% (95% CI 70.1 to 94.3) for those younger than 60 years (Wilcoxon log-rank test, p = 0.016).

Discussion

Based on extensive in vitro clinical and post-mortem data, it is widely accepted in the United States and the United Kingdom that the cement mantle around a femoral component should be complete without any defects, the so-called white-out, and of at least 2 mm in thickness.1-9 This situation corresponds to the A grade of the classification of Barrack, Mulroy and Harris26 as modified by Schmalzried and Harris.27 Indeed, thin areas of cement mantle of less than 2 mm have been associated with fracture of the cement related to crack propagation by fatigue failure.2,4,6,28 These
findings which have been explained experimentally by high shear stresses and high peak strains at or near the tip of the femoral component, have been linked in vivo to an increased risk of debonding and loosening of the cemented femoral component. This phenomenon was first reported by Weber and Charnley, and was also observed by the senior author (MK) as early as 1971 in a series of 320 original Charnley THR (DePuy, Leeds, United Kingdom) carried out in our unit between 1969 and 1971. By two years, a debonding at the stem-cement interface in Gruen zone 1 associated with a distal transverse fracture of the cement mantle near the tip was observed in 16% of the hips. These findings have been reported in other series with rates ranging from 1.5% to 26%, and have been frequently observed in conjunction with subsidence of the stem. Although usually associated with a good clinical result including a pain-free hip, this condition, which rarely requires revision of the femoral component, has been widely regarded as a failure of fixation of the femoral component, and corresponds to the criteria of definite loosening of Harris and McGann. However, the interpretation and solution to this problem has been very controversial. Some authors have indicated that the initiation of loosening of cemented femoral components is debonding at the cement-prosthesis interface, and therefore postulated that an enhancement of the stem-cement bond through the introduction of various rough surfaces will ultimately improve the durability of cemented fixation. This has been ineffective in the mid- to long-term, and most controlled studies have clearly shown that matt stems perform notably worse than their polished counterparts, irrespective of the cementing techniques and designs of stem. In other studies modification of the design of the stem and/or cementing technique was proposed to reduce the occurrence of fracture of the stem and subsidence, and in others acceptance of migration of the stem was considered to be a positive event.

The solution introduced in 1972 in our department by the senior author was different. The evaluation of the initial series of Charnley stems showed that the first event was a longitudinal crack in the superomedial part of the mantle as a result of high stresses transmitted by a thin and therefore elastic stem, strongly curved with a long offset and a relatively closed (125°) stem-neck angle. Fracture of the cement in this location widened the proximal part of the cement mantle, decreased the shear stresses along the stem and increased the vertical force on the distal cement which broke under tensile stress and allowed the stem to subside. Our experience was that transverse cement fractures under tensile stress were frequent (36%) in hips with a wide femoral medullary canal and a thick cement mantle, but were rarely (6%) seen when the stem fitted a relatively narrow canal through a thin cement layer, and never noted when a narrow straight stem had been implanted in a dysplastic femur after reaming of the canal despite a very thin layer of cement. From this experience, modifications were made to the original Charnley prosthesis, including a wider and thicker proximal part to provide the stem with a double-tapered shape and a neck-stem-neck angle of 130°. Moreover, a large range of sizes was made available so that after removal of cancellous bone, the implant could restore the hip architecture and fit the medullary canal. Outcome studies using historical stems (Kerboull MKI and CMK2) have shown that this philosophy has produced excellent long-term survival, even in high-demand patients. Additionally, Skinner et al using a particular design of neck-retain ing stem found significantly fewer radiolucent lines at follow-up at five years when the canal was reamed to the same size as the prosthesis than with over-reaming by 2 mm. However, as indicated in the original annotation on the French paradox, the patterns and extent of subsidence of stems cemented line-to-line had never been evaluated using an accurate method.

A limitation of our study was related to the fact that the initial radiograph used for the measurement of migration of the stem was that taken at six weeks rather than that before discharge. This choice was made because subsidence of the stem was measured relative to the greater trochanter, and all hips were operated through a transtrochanteric approach. By six weeks, consolidation was obtained in all
except two hips which have not been included in the subsidence study. It seems doubtful that the exclusion of subsidence which would have occurred during the six first post-operative weeks during which the patients were toe-touch bearing, has led to a notable underestimation of total subsidence.

Another limitation was the inability of the EBRA-FCA software to account for rotation of the stem. We acknowledge that some stems such as the Elite Plus (DePuy) showed minor subsidence and also major posterior migration of the head,\(^40\) leading to an unacceptable rate of loosening in the medium term.\(^48\) However, our study was at a mean follow-up of 17.3 years (15.1 to 18.3), and if such posterior migration had occurred, the rate of loosening would have been much higher. The EBRA-FCA method used in our study is not as accurate as RSA. In the longer term, however, its accuracy has been shown to increase up to 91% at five years.\(^49\) Moreover, it is not as costly and is less cumbersome than RSA. A further advantage of EBRA-FCA is that the variability of the measured parameters is reduced by using only comparable radiographs, increasing the validity of our data. In our study 15.6% of the radiographs were rejected by the software since they did not meet standards set for comparability. These figures are consistent with those of previous studies.\(^49,50\) It should also be pointed out that in our study, both the stem and the cementing technique were evaluated, since no control group using the same stem with a thick cement mantle of 2 mm was used.

The clinical and standard radiological results obtained in our study using a current design of Charnley-Kerboull THR were similar to those obtained with the original stem (Kerboull MKI 1972, Stryker-Benois Girard) with excellent results being found in 96.2% of cases. The accuracy has been shown to increase up to 91% at five years.\(^49\) Moreover, it is not as costly and is less cumbersome than RSA. A further advantage of EBRA-FCA is that the variability of the measured parameters is reduced by using only comparable radiographs, increasing the validity of our data. In our study 15.6% of the radiographs were rejected by the software since they did not meet standards set for comparability. These figures are consistent with those of previous studies.\(^49,50\) It should also be pointed out that in our study, both the stem and the cementing technique were evaluated, since no control group using the same stem with a thick cement mantle of 2 mm was used.

Two recent studies have evaluated the in vitro behaviour of canal-filling Charnley-Kerboull stems cemented line-to-line to explain the French paradox further. Scheerinck et al\(^13\) used a validated measurement technique based on CT to examine the alignment of the stem and the thickness of the cement mantle in paired human cadaver femora after cementing line-to-line or using undersized stems. Their study indicated that stems cemented line-to-line were at least as well aligned as undersized stems with a centraliser. Areas of thin cement of less than 2 mm and very thin cement of less than 1 mm were present in 26.4% and 6.2% of the mantle, respectively. However, 90% of these areas were supported by cortical bone or cortical bone with less than 1 mm of cancellous bone interposed. A further study\(^12\) using a finite-element analysis model evaluated the effect of the size of the implant and type of bone supporting the cement mantle on the stability of the implant and the fatigue failure of the cement. The results showed that canal-filling stems cemented line-to-line produced fewer cracks in the cement mantle and had better rotational stability than the undersized counterparts. In addition, fewer cracks and better rotational stability were observed when the cement mantle was supported by cortical bone. This latter situation corresponds to the in vitro situation of our study. In our experience the cement mantle was rather thick anteriorly and posteriorly and thin or very thin medially and laterally, but never incomplete. Furthermore, the double-taper design allowed for transformation of the detrimental shear stresses into their compressive component.

We conclude that our findings show that a current design of the Charnley-Kerboull stem cemented line-to-line affords satisfactory long-term stability. These successful results rely on both the design of the stem including its highly polished surface finish and the cementing technique.


