Concern about polyethylene wear and related osteolysis after knee arthroplasty has developed in the last years. Mobile-bearing knee prostheses were designed in order to reduce the influence of this critical factor on long-term success of total knee replacement. We present a prospective study comparing clinical and radiological results with a mobile-bearing (Ceragyr) and a fixed-bearing knee prosthesis (posterior stabilized Hermes). Clinical results did not show any significant differences in Knee Society scores. We found better results in the mobile-bearing group for pain scores and subjective preference, but the difference did not reach statistical significance. Within the time limits of this study, radiological analysis showed no osteolysis in either group, but longer follow-up will be needed to confirm this.

Keywords: mobile-bearing; posterior stabilized; total knee arthroplasty; fixed-bearing.

INTRODUCTION

A high degree of clinical success has been reported in literature with fixed-bearing knee prosthesis designs, especially in less active individuals (14). The Ceragyr mobile-bearing knee prosthesis (Ceraver-Ostéal, Roissy, France) features a high conformity of the articular surfaces in the coronal and sagittal planes (8,9,12,29,48). This results in a larger contact area (800-1000 mm²) than in other less conforming mobile designs, with contact stress under 21 MPa on the polyethylene bearing (48). Anteroposterior translation and rotation of the tibial insert also contribute to maintaining femorotibial congruence during knee movement (3,16,49).

Various studies have compared the clinical results of modern mobile-bearing and fixed-bearing TKAs and have not so far demonstrated any clear advantages in knee function for mobile-bearing designs. The present prospective study aimed at comparing the clinical results achieved following total knee arthroplasty with either a fixed-bearing Hermes or a mobile-bearing Ceragyr prosthesis.

MATERIALS AND METHODS

The fixed-bearing knee prosthesis used in this study was the Hermes posterior stabilized prosthesis (Ceraver-Ostéal); the mobile bearing prosthesis was the Ceragyr (Ceraver-Ostéal) which features full femorotibial congruence from 0° to 85° of flexion, with a fixed condylar

No benefits or funds were received in support of this study

radius (fig 1). The femoropatellar joint is similar in both designs, and has a deep anatomic trochlea with left and right femoral components that articulate with a 2-pegged all-polyethylene dome shaped patellar implant. The tibial tray of the Ceragyr has a central guiding mechanism that fits into an oblong slot of the polyethylene undersurface and allows the insert to rotate 12°-15° from the neutral position and to glide 5 mm in the AP plane.

A prospective trial involving patients undergoing primary TKA was started in January 2000. Two senior surgeons (FA and AS) performed all the surgeries and they used the design with which they felt more comfortable. Between January 2000 and December 2002 these two surgeons performed 140 primary total knee arthroplasties in 118 patients. A fixed-bearing Hermes total knee prosthesis was implanted in 71 knees (61 patients; 10 bilateral) and a mobile bearing Ceragyr total knee prosthesis was implanted in 69 knees (57 patients; 12 bilateral). No differences in demographic parameters or preoperative deformities were observed between the two groups (table I).

General or spinal anaesthesia was used according to patient or anaesthesiologist preference (56 general and 84 spinal). Antibiotic prophylaxis with intravenous cefazoline was given (1 g one hour before inflation of the tourniquet followed by 1 g every 24 hours for three days) and antithrombotic prophylaxis with subcutaneous enoxaparin (40 mg) or bemiparin (3500 UI) was started on the night after surgery and continued for the next four weeks. All the procedures were performed through a midline skin incision 12-14 cm in length, with a medial parapatellar approach. Both cruciate ligaments were resected in all knees and the patella was resurfaced in all the knees. Adequate soft-tissue release to realign and balance the knee was performed in both groups. Tibial resection was done using an extramedullary guide in the Hermes group and an intramedullary guide in the Ceragyr group. Approximately 10 mm of tibial bone was resected in the Ceragyr group and 11 mm in the Hermes group. The posterior slope of the tibial cut was 3° in the Ceragyr group and 0° in the Hermes group. The so-called no-thumb technique was used to assess patellar tracking and the need for lateral retinacular release (25). A lateral retinacular release was performed in 5 knees in the Ceragyr group and 3 knees in the Hermes group. All implants were cemented.

A splint in extension was applied for the first forty-eight hours. The knee was then placed in a continuous passive-motion machine, starting at 60°, with 10° daily increments, and ambulation was started with crutches or a walker on the third day after surgery. On the same day the physiotherapist taught the patient active and passive range-of-motion exercises. Hospital discharge was

Table I. — Preoperative parameters of the patients available at final follow-up

<table>
<thead>
<tr>
<th></th>
<th>HERMES GROUP</th>
<th>CERAGYR GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average age (years)</td>
<td>70 (44-82)</td>
<td>68 (54-85)</td>
</tr>
<tr>
<td>Male (number)</td>
<td>15</td>
<td>17</td>
</tr>
<tr>
<td>Female (number)</td>
<td>43</td>
<td>39</td>
</tr>
<tr>
<td>Side</td>
<td>Right : 33 / Left : 35</td>
<td>Right : 41 / Left : 27</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>74.82</td>
<td>80.32</td>
</tr>
<tr>
<td>Previous surgery (number)</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Radiological varus</td>
<td>56</td>
<td>54</td>
</tr>
<tr>
<td>Radiological valgus</td>
<td>12</td>
<td>14</td>
</tr>
</tbody>
</table>
allowed when the patients were able to bend the knee at least 90° and to walk independently with crutches, which occurred on average on the seventh postoperative day (range 6-10 days) in both groups.

Follow-up evaluation was done in the outpatient department at six weeks, three months, one year and then every two years. The average duration of follow-up was 4.7 years (range, 4 to 5 years). The follow-up was made by a senior surgeon who did not participate in the surgery. Each knee was rated preoperatively and postoperatively according to the Knee Society scoring system. In addition, each patient completed a self-administered questionnaire with a visual analog scale for the assessment of pain (0 no pain, 4 pain not controlled with opiates), the ability to climb stairs, to walk specified distances, and their level of satisfaction with the result (0 dissatisfied - 10 enthusiastic). Anteroposterior and lateral radiographs were taken to evaluate the alignment of the limb, the presence and location of radiolucent lines at the bone-cement interface according to the Knee Society roentgenographic evaluation system (26) and to measure angles alfa, beta, gamma and delta.

Statistical evaluation was performed using SPSS software 12.5 (SPSS, Chicago, Illinois). A power calculation was performed with a confidence level of 95%.

RESULTS

Evaluation of range of movement, postoperative pain, subjective preference, walking distance and support, ability to climb stairs and radiological angles for both groups was done at 6 weeks, three months, 1, 3 and 5 years, in more than 85% of the patients in both groups. Results are shown in table II. Two patients (2 knees; one in each group) died two years after operation. Two patients in the Hermes group required 2-stage revision for septic loosening (13 months and 24 months after surgery) caused by methicillin-resistant *Staphylococcus aureus* and *Enterobacter faecalis* respectively. This left 68 knees in 58 patients in the Hermes group and 68 knees in 56 patients available for study at final follow-up.

Before surgery, there was a mean flexion contracture of 5° (range -4° to 10°) in the Hermes group and 4° (range -4° to 12°) in the Ceragyr group. At 12 months follow-up, the mean knee extension improved to 0° in both groups (p = 0.20). The average knee flexion at three months was 95° (range 80° to 115°) in the Hermes group and 99° (range 85° to 120°) in the Ceragyr group (p = 0.25). The average flexion at 60 months follow-up was 112° (range 93° to 120°) in the Hermes group and 105° (range 90° to 120°) in the Ceragyr group (p = 0.30). Good pain relief was observed: at five-year follow-up, 86.5% of the patients in the Hermes group and 88.0% in the Ceragyr group reported no pain. Mild pain was present in 7.6% of patients in the Hermes group and 9.1% of patients in the Ceragyr group. Four patients in the Hermes group and two patients in the Ceragyr group complained of severe pain (p = 0.40).

The mean function score improved from 45 (range, 12-65) preoperatively to 80 (range, 55-100) at 60 months in the Hermes group and from 41 (range, 20-61) to 82 (range, 54-100) in the Ceragyr group.

Thirty-two patients (55.8%) in the Hermes group and 31 (58.8%) in the Ceragyr group could walk more than two hours. Twenty patients in the Hermes group and 19 in the Ceragyr group could walk more than one hour and 6 in both groups were able to walk only for thirty minutes (p = 0.30). Two patients in the Hermes group and one in the Ceragyr group were housebound and needed a wheelchair due to their health problems. No support was required for ambulation in 62 cases in the Hermes group (91.2%) and in 64 in the Ceragyr group (94.1%) after the third month following surgery. Eleven patients in the Hermes group and 9 in the Ceragyr group needed a banister to manage the stairs, while 80.9% in the Hermes group and 83.8% in the Ceragyr group managed the stairs without any help.

Pain at final follow-up scored 1.51 +/- 1.09 for the Hermes group and 1.31 +/- 0.67 for the Ceragyr group (analog scale from 0-4), which reflects marked pain relief in both groups (p = 0.25). On the other hand, worse results were obtained irrespective of implant design if the knees had previous surgery (1.79 +/- 1.13) (p = 0.20). Better subjective feeling was obtained in the Ceragyr group (8.21 +/- 1.47) than in the Hermes group (7.37 +/- 1.21) (p = 0.30) but the difference did not reach statistical significance; in the six bilateral cases with a different prosthesis in each knee we could not detect any subjective preference between the two implants.

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Measurement of the different radiological angles showed no significant differences between the two groups. Using the extramedullary guide in the Hermes group gave a beta angle of 90.14° (+/- 3.59°) versus 89.61° (+/- 3.44°) with the intramedullary guide in the Ceragyr group.

Duration of surgery was 70.9 +/- 4.6 minutes for the Hermes group and 76.5 +/- 4.9 for the Ceragyr group, however this included our learning curve with the Ceragyr knee, which we started using in this study. At an average of 60 months of follow-up, there were 85% excellent results, 11% good, 3% fair and 1% poor results for the Hermes group and 86% excellent results, 11% good and 3% fair results for the Ceragyr group (fig 2).

**DISCUSSION**

Mobile-bearing knee arthroplasty was introduced to minimize some of the potential disadvantages of the conventional fixed-bearing designs (9,29). Fixed-bearing TKA have been reported to face problems of wear and loosening especially in more active individuals, however several studies have shown survival rates of 95-97% at 10 to 15 years of follow-up (5,24). Analysis of different publications that compare fixed and mobile-bearing designs show similar clinical results and an annual revision rate of 1% for both implants (5,7,15,28,30,38,46,60,64).

Our aim was to assess some theoretical advantages (better clinical results and longevity) of the mobile-bearing design which we started using 6 years ago. For this purpose we compared it to our TKA gold standard, i.e. the Hermes prosthesis (Ceraver-Ostéal®) with which we have more than 20 years experience. The new design offers innovative features as the mobility of the bearing (rotation and AP translation), and the geometry of the components (fixed condylar radius and high femorotibial congruence), but has a similar femoropatellar joint.

The fixed radius of the femoral condyles with full femorotibial conformity up to 85° flexion results in a large contact area, with decreased

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**Table II. — Clinical results in both groups (Her = Hermes, Cer = Ceragyr)**

<table>
<thead>
<tr>
<th></th>
<th>Preoperative</th>
<th>3 months</th>
<th>1 year</th>
<th>3 years</th>
<th>5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 (%)</td>
<td>0</td>
<td>0</td>
<td>80.5</td>
<td>89.0</td>
<td>86.0</td>
</tr>
<tr>
<td>1 (%)</td>
<td>10.0</td>
<td>12.0</td>
<td>17.0</td>
<td>6.5</td>
<td>9.17</td>
</tr>
<tr>
<td>2 (%)</td>
<td>35.0</td>
<td>34.0</td>
<td>1.5</td>
<td>3.5</td>
<td>1.62</td>
</tr>
<tr>
<td>3 (%)</td>
<td>45.0</td>
<td>46.0</td>
<td>1.0</td>
<td>1.0</td>
<td>3.21</td>
</tr>
<tr>
<td>4 (%)</td>
<td>10.0</td>
<td>8.0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total function score</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>45</td>
<td>41</td>
<td>78</td>
<td>77</td>
<td>79</td>
<td>80</td>
</tr>
<tr>
<td><strong>Average ROM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-90°</td>
<td>4-89°</td>
<td>0-95°</td>
<td>1-99°</td>
<td>0-95°</td>
<td>0-102°</td>
</tr>
<tr>
<td><strong>Walking capability</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 2h (%)</td>
<td>2.0</td>
<td>0</td>
<td>50.3</td>
<td>52.4</td>
<td>55.8</td>
</tr>
<tr>
<td>&gt; 1h (%)</td>
<td>22.0</td>
<td>30.5</td>
<td>27.6</td>
<td>28.3</td>
<td>30.0</td>
</tr>
<tr>
<td>&lt; 30' (%)</td>
<td>75.0</td>
<td>68.0</td>
<td>19.2</td>
<td>17.8</td>
<td>11.3</td>
</tr>
<tr>
<td>Not walk (%)</td>
<td>1.0</td>
<td>1.5</td>
<td>2.9</td>
<td>1.5</td>
<td>2.9</td>
</tr>
<tr>
<td><strong>Walking support</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No support (%)</td>
<td>57.0</td>
<td>56.0</td>
<td>86.2</td>
<td>84.6</td>
<td>88.0</td>
</tr>
<tr>
<td>1 cane (%)</td>
<td>39.0</td>
<td>35.0</td>
<td>9.8</td>
<td>11.9</td>
<td>9.3</td>
</tr>
<tr>
<td>1 crutch (%)</td>
<td>4.0</td>
<td>8.0</td>
<td>4.0</td>
<td>3.5</td>
<td>2.7</td>
</tr>
<tr>
<td>2 crutches (%)</td>
<td>0</td>
<td>1.0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Stairs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal (%)</td>
<td>63.0</td>
<td>61.0</td>
<td>76.0</td>
<td>78.0</td>
<td>78.5</td>
</tr>
<tr>
<td>Banister (%)</td>
<td>37.0</td>
<td>39.0</td>
<td>24.0</td>
<td>22.0</td>
<td>21.5</td>
</tr>
</tbody>
</table>
contact stress, which is not achieved in less congruous mobile bearing designs. However, full conformity in flexion is less important than in extension (48). We prefer postero-stabilized implants because most of our patients have advanced disease and marked preoperative deformities, so that the LCP is incompetent in many cases. The Ceragyr knee has a stabilising mechanism that does not affect the geometry of the femoral trochlea and allows patellar resurfacing without conflict.

The design of the Ceragyr prosthesis, allows anteroposterior gliding which is meant to increase the range of motion, although it has been shown that only a small percentage of the knees reproduce the physiological rollback after arthroplasty (2,4,33). Most and D’Lima in an experimental study found that the kinematics of TKA’s with fixed and mobile bearings were similar with respect to femoral rollback although the designs were different (17,51). These authors state that the tibial insert stops moving before 90° of knee flexion, beyond which the prosthesis performs as the fixed-bearing designs. Our results showing similar ranges of motion seem to confirm that the in vivo kinematics of both designs are similar. Previous kinematic studies have rarely shown femoral rollback in association with designs allowing anteroposterior gliding (21,22,45), which does not support the idea that this type of bearing would improve the postoperative range of motion or would reproduce the natural knee kinematics (4,20,59). However, Delport et al have found that mobile-bearing posterior stabilized designs better reproduce internal tibial rotation during knee flexion than fixed-bearing designs (19). Theoretically, this could justify the use of mobile-bearing implants in active patients who practice sports such as golf or tennis. The freedom of rotation in mobile-bearing implants would reduce wear of the polyethylene at the interface of the post-cam mechanism and the intercondylar femoral housing during flexion, in this postero-stabilized design (36,54).

Laboratory studies have shown reduced linear wear for highly conforming mobile bearing implants compared with standard fixed-bearing designs (3,16) but in vivo kinematic analysis failed to show any advantages of mobile-bearings with respect to rollback and axial rotation patterns, range of motion and condylar lift-off (1,32,58,59). On another hand, the anteroposterior translation of the mobile-bearing design used in this study allows for variation in the centre of axial rotation during ascending or descending stairs, deep-knee bends, normal gait and knee twisting (62). A potential disadvantage of mobile-bearings is volumetric wear rate because of its large contact area (6,34,63). In vitro studies of torque stresses or component
malrotations show that mobile bearing knees are more forgiving in relation to contact stress distribution than fixed-knees (18,36,49).

Clinical results in both groups did not show any significant differences in Knee Society scores (41,42,43,44,47,53). We found better results in the mobile-bearing group for pain scores and subjective preference but the difference did not reach statistical significance.

We have noted no instance of synovitis and recurrent effusion with the Ceragyr prosthesis, although some authors have reported up to 60% of such problems with other mobile-bearing designs due to impingement with anterior tissues, which resolved after subsequent exchange of the tibial polyethylene bearing (52). There were no cases of bearing dislocations or soft tissue impingement as reported for other anteroposterior-gliding mobile-bearing designs (37,50). However, bearing dislocation or subluxation is a potential complication in cases with severe deformities requiring extensive release of soft tissues to balance the flexion and extension gaps (5).

Radiographic analysis showed no osteolysis in our cases, however our follow-up is too short to allow for relevant conclusions so we decided not to include this parameter in the statistical analysis. Osteolysis after TKA with fixed-bearing designs has been well documented (11,27,40,56) especially with cementless prostheses (23,31), but few cases of severe osteolysis related with polyethylene wear in a mobile-bearing prosthesis have been reported (35,57). The diagnosis of osteolysis is made by radiographic assessment and its true prevalence is difficult to evaluate because of the limitations of the imaging. Osteolysis on the femoral side is not easily detected until lesions are large enough, because the flanges of the femoral prosthesis make its visualisation difficult on standard radiographs (40,57), and specific views are required to evaluate the extent of the lesions before revision.

We routinely resurfaced the patella in both groups, and we have noted no patellar problems that might require a re-operation. It seems that a rotating platform mobile-bearing tibial component may help the patellar component to center itself in knees with 5 to 10º of rotational mismatch between the femoral and tibial component (13,48,61). The two prostheses compared have a patellofemoral groove deeper and longer than some other designs, which may account for the low prevalence of patellar problems and anterior knee pain. Lateral retinacular release was required in five cases with the mobile-bearing design and three cases with the fixed-bearing prostheses. They all had marked preoperative valgus deformities (5,39).

No benefit of the mobile-bearing knee over the fixed-bearing knee has been observed in this study regarding the postoperative range of motion. Better results have been noted in the first two evaluations (at six weeks and three months), but in the long run, motion is similar with both prostheses, slightly but not significantly better in the fixed-bearing knee. However, long-term follow-up will be needed to assess this impression.

Short-term results with mobile-bearing designs did not show any definite advantages in our experience, but long-term follow-up will be needed to evaluate the incidence of osteolysis, the rate of polyethylene wear and the longevity of the implants. Prosthesis design and meticulous technique minimize technical problems with respect to alignment of the components, such as rotational mismatch of the tibial and femoral components or balance of the flexion-extension gap. A mobile-bearing implant cannot anyway redeem an unsuitable surgical technique or pitfalls in the basic design, but mobile-bearing designs appear as an interesting alternative to fixed-bearings prosthesis (36).

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