Original article

Survival and functional results after a mean follow-up of 9 years with the Ceragyr® highly congruent mobile-bearing TKA

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A B S T R A C T

Introduction: Fixed-bearing total knee arthroplasty (TKA) implants have excellent long-term survival. Mobile-bearing implants were developed to reduce bone–implant interface stresses and polyethylene insert wear. The primary objective of this study was to analyze the survival rate of a highly congruent mobile-bearing TKA implant (Ceragyr®) in patients having a minimum follow-up of 7 years. We hypothesized that the survival rate would be 95–100% at that time point.

Patients and methods: A single-center prospective study included all the patients operated for a primary TKA procedure with a Ceragyr® implant between 2000 and 2003. All the implants were cemented. Patellar resurfacing was not carried out systematically, but could be carried out secondarily in cases of persistent anterior knee pain. Clinical and radiological data were collected before the surgery, at 3 months postoperative, at 1 year and then at a minimum follow-up of 7 years. The primary endpoint was the overall revision-free survival rate. Secondary endpoints were the survival without mechanical failure, IKSS score, knee range of motion and implant positioning.

Results: One hundred and thirty-four patients (143 Ceragyr® TKA cases) were included; 9 patients (10 TKA) were lost to follow-up (6.7%) and the remaining 125 patients (133 TKA) were contacted. At the final review, 7 of the 133 TKA cases (5.3%) had been revised (6 men, 1 woman; P = 0.002), 2 (1.5%) because of mechanical failure and 5 (3.8%) because of an infection. The overall revision-free survival rate was 94.8% [95% CI: 89.3–97.5]; survival was 98.4% [95% CI: 93.8–99.6] with mechanical failure as an endpoint. An in-person assessment was conducted on 76 patients (80 TKA cases) (49 women; 27 men) who had an average age of 70.3 ± 8.4 years at the time of the arthroplasty procedure. The patella had been resurfaced during the initial procedure in 49 cases, and was either not resurfaced or secondarily resurfaced in 31 cases. The average follow-up was 8.7 ± 1.1 years. The IKSS score had significantly improved relative to the preoperative values (P < 0.00001). Knee flexion and the IKSS knee score remained stable over time (P > 0.05). Patients who underwent patella resurfacing during the initial TKA procedure had better clinical results (P = 0.03).

Conclusion: After a minimum follow-up of 7 years, the overall revision-free survival rate for the Ceragyr® was 94.8%; the survival was 98.4% with mechanical failure as an endpoint. The results were stable over time.

Level of evidence: IV, retrospective study of prospectively collected data.

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1. Introduction

Total knee arthroplasty (TKA) is the final option for a patient suffering from knee cartilage destruction. Patients expect their quality of life to improve after this procedure and their knee to be pain-free, stable and to function normally. They also expect that these results will be maintained over time and that their implants will be durable. Mobile-bearing TKA designs incorporate a mobile interface between the insert and tibial plateau to increase the tibiofemoral contact area. This congruence reduces the wear of the polyethylene insert and the stresses at the bone–implant interface, thus the risk of loosening, by allowing rotation [1].

The Ceragyr® (Ceraver-Osteal, Roissy, France) is a highly congruent mobile-bearing TKA implant with a single radius of curvature at the femoral condyles, which is identical in the frontal and sagittal planes. The polyethylene insert is free to move on the tibial
baseplate in rotation and anteroposterior translation. An in vivo fluoroscopy study was done to compare the knee kinematics of 17 patients with a Ceragyr® to that of 16 patients with a fixed-bearing TKA [2]. Patients with Ceragyr® implants had no separation of the condyles (high congruence), greater axial rotation and less posterior translation than patients who received a fixed-bearing TKA. After an average follow-up of 4.7 years, Munoz et al. [3] reported that this mobile-bearing implant had satisfactory clinical and radiographic outcomes, which were comparable to those of a fixed-bearing implant. Lemaire et al. reported a 99.5% survival after 5 and 8 years in a group of 181 Ceragyr® knees, with revision for any reason as the endpoint [4].

The objectives of the current study were to analyze the survival of the Ceragyr® after a minimum follow-up of 7 years with partial or total revision for any reason as the endpoint, and to determine the reasons for revision (septic, aseptic) and the function of the operated knee.

2. Patients and methods

A single-center retrospective study of prospectively collected data included all the patients operated between March 2000 and December 2003 who received a Ceragyr® implant (Ceraver-Osteal, Roissy, France) during a primary TKA procedure. During the study period, all patients who underwent a primary TKA procedure received this type of implant.

2.1. Surgical technique

The patients were operated by one of three senior orthopedic surgeons. The surgical procedure was performed without computerized navigation. A tourniquet was used during the implantation. A lateral approach was used in six cases where the knee valgus was greater than 10°. The typical approach consisted of medial parapatellar arthroscopy with lateral relocation of the extensor mechanism. The distal femoral cut was made first. The tibial cut was made using either intramedullary or extramedullary alignment guides. Ligament gap balancing was performed with extension wedges before the femoral cuts were finalized. The tibiofemoral gaps in extension were transferred to the 90° flexed knee to balance the flexion gap. The anterior and posterior femoral cuts were then performed with the knee flexed at 90°, the ligaments taught and using posterior landmarks. All the implants were cemented. In our early cases, the patella was not systematically resurfaced. Preventative anticoagulant therapy was prescribed to patients for 1 month, and antibiotics were initiated 1 hour before the procedure and continued for 48 hours.

2.2. Patient evaluation protocol

Clinical and radiological data were collected before the surgery, at 3 months postoperative, at 1 year and at the final review. All patients were contacted at least 7 years after the TKA procedure. At the final review, the patients who were still alive and had not undergone TKA revision were invited to return to the hospital for clinical and radiographic assessments by an independent surgeon.

The following demographic and clinical data were collected: age, gender, side, height, weight, history, TKA indication, active range of motion measured with a goniometer, sagittal laxity with a Rolimeter knee tester (Aircast Europe, Neubeuern, Germany), frontal laxity, IKS knee and function scores.

The radiological assessment at each follow-up visit consisted of an A/P view, lateral view in 30° flexion, 30° Merchant views of the patellofemoral joint and long-leg standing views.

2.3. Endpoints

The primary outcome was the overall survival with a minimum follow-up of 7 years, with the endpoint being partial or total TKA revision for any reason. The secondary outcomes were the survival without mechanical failure with a minimum follow-up of 7 years, with the endpoint being partial or total TKA revision for aseptic loosening and/or osteolysis, the IKS scores, knee range of motion, implant positioning and periprosthetic radiolucent lines according to the Knee Society classification on A/P and lateral X-rays [5]. The IKS total score was considered excellent if it was between 160 and 200, good if between 140 and 159, average if between 120 and 159, and poor if below 120 [6]. Implant positioning was evaluated on A/P long-leg standing views by measuring the hip-knee-ankle (HKA) angle (varus when HKA < 180° and valgus when HKA > 180°), femoral mechanical axis (FMA) and tibial mechanical axis (TMA). The survival rate was calculated for the entire cohort. The secondary outcomes were analyzed in the subgroups of patients who were still alive at the time of the review and had at least 7 years of follow-up.

2.4. Statistical methods

Survivorship was estimated after at least 7 years of follow-up using the non-parametric Kaplan-Meier method and 95% confidence intervals. The endpoint was total or partial TKA revision for any cause and for mechanical causes; patients who were lost to follow-up or had died before 7 years of follow-up were considered as right censored observations. The risk factors for revision were explored using the log-rank test. The Shapiro-Wilk test was used to determine if the data were normally distributed. If the normality assumptions were met, parametric tests were used: independent or paired Student’s t-test for quantitative variables and McNemar or Chi² test for qualitative variables. If the normality assumptions were not satisfied, non-parametric tests were used: Mann-Whitney or Wilcoxon test for continuous variable and the Fisher’s exact or McNemar test for binary variables. The Kruskal-Wallis test was used when more than two groups were being compared. A P value < 0.05 was considered as statistically significant.

3. Results

3.1. Description of population available for analysis

Between March 2000 and December 2003, 134 patients (89 women, 45 men) having an average age of 73.4 ± 8.8 years underwent primary TKA procedures, with 9 of them undergoing a bilateral procedure. This resulted in 143 knees receiving the Ceragyr® implant. The main indication for the TKA was knee osteoarthritis, typically primary. Nineteen of these 134 patients (6.7%) (10 knees) were lost to follow-up. For the final review, 125 patients (133 TKA) were contacted. Because some patients had undergone TKA revision and some had died, 80 patients (85 TKA) remained and were invited to the hospital for review. Of these patients, 76 (80 TKA, 95%) accepted and underwent the clinical and radiological assessments (Fig. 1).

3.2. Survival analysis

Twenty-nine of the 125 patients (23.2%) died before the 7-year follow-up from other diseases without having undergone TKA revision. The TKA implant was revised in 7 patients (6 men, 1 woman), or 5.3% (7/133 TKA). Two of the revisions were for mechanical failure (2/133, 1.5%) and five were for an infection (5/133, 3.8%).

At the final review, the overall revision-free survival rate for the series was 94.8% [95% CI: 89.3–97.5%]. If only revision for
3.3. Other complications

In addition to the five above-mentioned septic complications, there was one patellar tendon rupture, two cases of postoperative hemorrhathosis, one of postoperative deep vein thrombosis, one of necrosis on the lateral aspect of the leg and one of supracondylar fracture without implant loosening. There were no cases of insert dislocation or subluxation.

3.4. Clinical and radiological evaluation

The average follow-up in the subgroup of 76 patients (49 women and 27 men, 80 TKA) who underwent in-person clinical and radiological evaluation was 8.7 ± 1.1 years. Their average age at the time of arthroplasty was 70.3 ± 8.4 years and their average age at the final review was 79.1 ± 8 years. The average BMI was 27.7 ± 3. In terms of the patella, 49 had been resurfaced during the TKA procedure and 31 had not; of these, 5 were subsequently resurfaced an average of 3 years later due to persistent anterior knee pain.

The IKS scores (knee, function, total) had significantly improved 1 year after the procedure and at the final review. The total IKS score was good or excellent in 95% of cases at 1 year and 81% at the

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**Fig. 1.** Flow diagram summarizing the study design.

**Fig. 2.** Kaplan-Meier survival curve with 95% confidence intervals. A. Revision-free survival of the implant. B. Survival when only mechanical failures are taken into consideration.
Kaplan-Meier survival estimates

Fig. 3. Kaplan-Meier survival curve with 95% confidence intervals by age group and gender.

final review. However there was a significant reduction in the IKS function and total IKS scores between the 1-year time point and the final review (Table 1).

When compared to TKA cases where the patella was not resurfaced, or resurfaced secondarily, cases where the patella was immediately resurfaced had a significantly better IKS total score at the final review (172.6 ± 23.8 vs. 157.6 ± 31.8; P = 0.03). Among the five patients who underwent secondary patellar resurfacing, only one improved. None of the patients who had average or poor results at 1 year postoperative and at the final review had undergone patellar resurfacing. There were no significant differences in the IKS total score between men and women (P = 0.80), as a function of patient age (P = 0.38), or BMI (P = 0.37).

The average knee flexion was stable over time. Before the TKA procedure it was 109.1 ± 16.6°, at 1 year it was 107.3 ± 12.2° (P = 0.28) and at the final review it was 106.6 ± 16.1° (P = 0.82).

Ideal positioning (HKA: 180 ± 3°) was achieved in 75% of patients at 3 months postoperative, but in only 57% of cases at the final review. On average, in the subgroup of 80 TKA cases evaluated, the HKA was 178.7 ± 3.7° at 3 months and 178.2 ± 4.8° at the final review (P = 0.006). This significant difference between the 3rd month postoperative and the final review was not present in the average FMA (89.3 ± 3.3 vs. 89.3 ± 3.7, P = 0.11) and the average TMA (89.4 ± 2.6 vs. 89.3 ± 2.8, P = 0.10). At the final review, 44 TKA cases were in varus (21 varus ≤ 3° and 23 varus > 3°) and 22 were in valgus (16 valgus ≤ 3° and 6 valgus > 3°).

It was very difficult to identify radiolucent lines around the femoral component because of superimposition. There were six cases of patellar radiolucent lines after 1 year and seven at the final review. At 1 year postoperative, radiolucent lines were observed on A/P views of 47 tibial components and on lateral views of 34 tibial components. At the final review, the number of radiolucent lines increased to 63 and 56, respectively. These radiolucent lines were more extensive, but had not increased in thickness. Their presence was not related to implant loosening. At the final review, lateral tibial radiolucent lines were present in 17/22 (77.3%) of implants in valgus and medial tibial radiolucent lines were present in 33/44 (75%) of implants in varus on A/P X-rays.

4. Discussion

With a minimum follow-up of 7 years, this study found the survival of the Ceragyr® TKA implant to be 98.4% with revision for mechanical failure as the endpoint and 94.8% with revision for any reason as the endpoint. The clinical and radiological results were compared between the short- and medium-term, and remained stable. The reasons for implant failure were identified and spanned all reasons for implant revision. Few studies have had a sufficiently long follow-up to evaluate the outcomes of a highly congruent TKA implant with rotating-platform and anteroposterior movement [4,7,8].

The survival rate when fixed-bearing TKA implants are used is very good: 87–95% at 10 years [9,10]. In a prospective study, Kim et al. [11] included patients less than 51 years of age who had received a fixed-bearing TKA implant on one side and a mobile-bearing implant on the other because of bilateral knee osteoarthritis. After 16.8 years of follow-up, the survival rate of these implants was 95% (91–100) and 97% (93–100), respectively. Our results after an average of 8.7 years follow-up are comparable to those of other published studies (Table 2). In a recent meta-analysis of 19 mobile-bearing TKA studies, the survival was 97.8% at 5 years and 96.7% at 10 years [21]; however, this was an average follow-up and the definition of failure was not specified. In a French, multicenter, retrospective study of 846 TKA cases [22], the 199 highly congruent, mobile-bearing TKA implants that were included had a survival rate of 93% (88–95) at 10 years, which was comparable to the other implants in the study.

Table 1

<table>
<thead>
<tr>
<th></th>
<th>Preoperative (1)</th>
<th>1 year (2)</th>
<th>Final review (3)</th>
<th>P (1 vs. 2) (1 vs. 3)</th>
<th>P (2 vs. 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee score</td>
<td>37.1 ± 12.1</td>
<td>88.9 ± 11.2</td>
<td>87.9 ± 17</td>
<td>0.00001</td>
<td>0.46</td>
</tr>
<tr>
<td>Function score</td>
<td>53.4 ± 11.2</td>
<td>87.3 ± 9.2</td>
<td>79 ± 21.8</td>
<td>0.00001</td>
<td>0.0012</td>
</tr>
<tr>
<td>IKS total</td>
<td>90.6 ± 18.5</td>
<td>176.3 ± 17.9</td>
<td>166.9 ± 27.9</td>
<td>0.00001</td>
<td>0.0017</td>
</tr>
</tbody>
</table>
In our study, the knee flexion before the surgery and at the final review is comparable. In two other published studies about the Ceragyr®, the average knee flexion at the last review was 105° (90–120°) [3] and 113.6° (70–135°) [4]. This appears to be slightly less than the one reported with other mobile-bearing TKA implants [14,15]. Due to their design, highly congruent TKA implants seem to provide the patients with less knee flexion, especially without anteroposterior movement.

The course of action relative to the patella is still controversial. The mobile-bearing provides better tibial and femoral alignment when in rotation, which in theory results in better fit of the extensor mechanism in flexion and extension. In the Lemaire et al. study with the Ceragyr® [4], 7 of 54 knees underwent secondary patella resurfacing because of persistent anterior knee pain. In our study, 5 of 31 knees underwent secondary patella resurfacing. It is difficult to draw conclusions about the need for systematic patella resurfacing, because if resurfacing is not performed during the primary TKA procedure, this relative simple and limited procedure is often performed by the surgeon when the patient experiences persistent anterior knee pain [23].

At the final review, the IKS function score was significant lower in the group of reviewed patients, relative to the 1-year postoperative score, even though the IKS knee score was stable. This can be explained by the overall function of patients decreasing as they age.

As in the Hossain et al. study [24], infection was the most common revision for implant revision in our study. Deep infection occurred in 3.8% of patients in this study, which is comparable to published values. A 2.3% infection rate has been reported in a study of Swedish arthroplasty register [25]. Recent studies with other mobile-bearing TKA implants have reported an infection rate between 2 and 4% [15,18].

Our study has several limitations. Because there was only one patient cohort, we could not compare the results of the mobile-bearing TKA to those of a fixed-bearing TKA. Moreover, the minimum follow-up of 7 years only reflects on the medium-term period. The prospective evaluation of the data from this cohort is still ongoing.

5. Conclusion

With a minimum follow-up of 7 years, the overall revision-free survivorship for the Ceragyr® is 94.8% and 98.4% when only mechanical failures are taken into consideration. The clinical outcomes with this type of TKA implant are stable over time.

Disclosure of interest

SK received payments from Ceraver-Ostéal for acting as a clinical research consultant for this study. PH received payments from Ceraver-Ostéal and Zimmer for acting as a consultant. The other authors declare that they have no conflicts of interest concerning this article.

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