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Original Article

Long-Term Durability of Ceramic Tri-Condylar Knee Implants: A Minimum 15-Year Follow-Up

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ABSTRACT

Background: Ceramic bearings are not commonly used in total knee arthroplasty (TKA). So far, little information is available about whether long-term survivorship and good clinical outcomes can be ensured with ceramic knee implants. The purposes of the present study were to evaluate the clinical and radiological outcomes, and to assess the long-term durability of a ceramic tri-condylar implant.
Methods: A total of 507 consecutive TKAs were carried out using a ceramic tri-condylar femoral implant. The posterior cruciate ligament was sacrificed, and all components were fixed with bone cement. Clinical outcomes were assessed retrospectively with the Knee Society scoring system. Kaplan-Meier survivorship was calculated to determine the cumulative survival rate.
Results: One hundred sixty-seven knees (114 patients) were available for clinical outcomes. The average range of flexion improved from 118.1° preoperatively to 123.7° at a minimum 15-year follow-up ($P < .001$). The average Knee Society knee score improved from 39.1 to 92.8 ($P < .001$). The functional score also improved from 36.0 to 47.0 ($P < .001$). With revision for any surgery or radiographic failure as the end point, Kaplan-Meier survivorship at 15 years was 94.0%. With revision of any component as the end point, the corresponding survivorship was 96.2%.
Conclusion: Clinically, the postoperative knee flexion range and Knee Society scores were good after long-term follow-up. The survivorship of the ceramic knee implant was excellent over the 15-year follow-up, and long-term durability was achieved, making ceramic a promising alternative material for the femoral component in TKA.

Metal-polyethylene (PE) bearings were initially used for total knee arthroplasty (TKA) and total hip arthroplasty (THA). However, microscopic debris from the bearings' surface can lead to periprosthetic osteolysis and consequent implant loosening [1-3]. Ceramic bearings were developed as an alternative to metal-PE articulation in total joint arthroplasty to reduce PE wear [4-7]. Ceramic bearings, including ceramic-on-ceramic bearings, are commonly used for THA. Recently, up to 20%-30% of THAs in registry data have been implanted with ceramic bearings [8,9]. Moreover, the superior wear characteristics of these materials have been verified in many clinical and experimental studies, with reports of less osteolysis in the proximal femur than with the metal-PE controls [4,5,10].

Compared with THA, ceramic bearings are not commonly used in TKA. However, ceramic femoral components with an all-PE tibial component are an established alternative for patients with a metal allergy [11]. Because of the mechanical properties of ceramic, several concerns have been raised, such as fracture of the implant [12-14] and decreased adhesive strength of the bone cement [15,16]. In some clinical studies, short-term results showed excellent clinical results and survivorship [17-21]. Further studies are needed to confirm the positive clinical results and durability after

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long-term follow-up with regard to the material properties of ceramic knee implants. So far, little information is available as to whether the long-term survivorship and good clinical outcomes would be sustained over 15 years with the ceramic femoral components.

The ceramic tri-condylar implant (Bi-Surface Knee System; Kyocera Medical, Osaka, Japan) was developed in 1989 to improve long-term durability after TKA. This implant has an alumina ceramic femoral component to reduce PE wear, as well as a unique design with a third condyle in the midposterior portion of the femoral component. As shown in previous biomechanical studies, this third condyle replaces the function of the postcam mechanism and works as a weight-bearing surface during deep knee flexion [22-25].

The purposes of the present study were to evaluate the clinical and radiological outcomes and to assess the long-term durability of a ceramic tri-condylar implant over 15 years. The hypotheses were that the tri-condylar ceramic knee implant could ensure good clinical results, a low rate of radiological failure, and a good survival rate after long-term follow-up, and that ceramic knee implants could be a promising option for TKA.

Fig. 1. Posterolateral view of the ceramic tri-condylar implant (left: type 1, right: type 2). The material of the tibial component and the congruity of the polyethylene were different.

Materials and Methods

A ceramic tri-condylar implant was developed to be compatible with the Asian lifestyle that involves frequent deep knee bending activities. This implant is a posterior-cruciate substituting prosthesis, with a ball-and-socket joint as a third condyle in the midposterior portion of the femoral component and the corresponding tibial insert. The third condyle works as a posterior stabilizing cam mechanism and as a load-bearing surface in flexion [22-26]. The third condyle contacts approximately 60° of knee flexion and provides large rotational freedom during deep knee bend activities. Therefore, when the knee is flexed more than 60°, the tri-condylar implant has 3 contact areas on the tibial articular surface: the medial and lateral condylar surfaces, and the third condyle.

The femoral component is mainly composed of alumina ceramic, including 7% yttria, with a central strut on the distal aspect to reinforce the component strength and to improve fixation to the femur with bone cement. In the original design of the tri-condylar implant (type 1), the tibial component was also made of alumina ceramic with a fixed PE insert. PE was initially made using the compression molding method, which was then changed to the ram extruded method in 1994. Neither type of PE was cross-linked. The articular surface of PE was completely flat in the medial-lateral direction, and the posterior condylar part was flattened in the anteroposterior direction to permit axial rotation of the femoral component (Fig. 1). In the next design (type 2), the material of the tibial component was changed to titanium alloy, and the design of PE was modified. The medial and lateral edges of the tibial insert were elevated to provide more congruity and better stability in the medial-lateral direction, because the medial-to-lateral stability was considered insufficient in the type 1 design. This implant with the ceramic femoral component is available with several minor modifications.

From 1989 to 1997, 507 consecutive TKAs were performed using a ceramic tri-condylar implant for 371 patients, and clinical outcomes were reviewed retrospectively. Informed consent was obtained from all patients. The study design was approved by the appropriate ethics review boards. One or more authors have received research grants from the implant manufacturer. Type 1 tri-condylar implants were implanted in the first 79 knees, and type 2 tri-condylar implants were implanted in the other 428 knees. A total of 52 men and 319 women with an average age of 68.5 years (39-91 years) were included at the time of the operation. The diagnoses for the TKA were osteoarthritis in 349 knees (254 patients) and rheumatoid arthritis in 158 knees (117 patients). The average height and weight were 148 cm and 54 kg, respectively, and the mean body mass index was 24.7 kg/m^2. Patients with the following conditions were not considered eligible for the tri-condylar implant: (1) patients with varus or valgus deformity of more than 30°; (2) a range of knee flexion limited to less than 60°; and (3) a knee with medial or lateral instability greater than 30°.

The surgery was performed in a uniform manner by 2 senior orthopedic surgeons at 2 institutions. The same surgical technique and postoperative rehabilitation programs were applied for all patients. The posterior cruciate ligament was sacrificed, and the bone was cut using the measured resection technique. The femur and tibia were resected perpendicular to the mechanical axis of the femur and tibia, respectively. Postoperative alignment was oriented such that the mechanical axis of the lower limb passed through the center of the knee joint. The medial or lateral collateral ligament was released to obtain as equal a medial-lateral balance as possible. The patella was resurfaced for all rheumatoid patients and for osteoarthritis patients with severe cartilage loss at the patella. All components, including the stem of the tibial component, were fixed with CMW-1 bone cement (DePuy Synthes, Warsaw, IN). The incision was closed with the knee in 100° of flexion. Aggressive knee flexion exercises were continued in routine rehabilitation programs with physical therapists for 1 month. Following rehabilitation, the patients were free to carry out deep flexion activities and were not restricted from performing any activities, including deep flexion, by the physicians.

Physical examination and knee scoring were conducted preoperatively, 1 year after surgery, and annually thereafter using the Knee Society's knee scoring system (knee score and knee function score) [27]. Range of flexion was passively measured with a goniometer in the supine position. Yearly follow-up was carried out by observers who were independent of the surgeons who had performed the surgeries. The patients were followed-up for a mean of 18.1 years (range 15.0-24.7 years). The mean age at the final follow-up was 83.9 years (range 55-103 years).

Standard anteroposterior, lateral, and skyline views were obtained preoperatively and at the final follow-up (Fig. 2). Radiographs were analyzed by independent orthopedic surgeons who had not performed the surgeries. The presence and location of radiolucent lines at the implant-cement and bone-cement interfaces were evaluated according to the Knee Society