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Prospective comparative clinical study of ceramic and metallic femoral components for total knee arthroplasty over a five-year follow-up period

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ABSTRACT

Background: The aim of this prospective comparative study was to evaluate the clinical and radiological outcomes of a TKA system, comparing a ceramic (BIOLOX® *delta*) and metallic (Co28Cr6Mo) femoral component over a five-year follow-up period.
Methods: Forty-three TKA patients (17 metallic and 26 ceramic femoral components) were enrolled in the study. Clinical and radiological evaluations were performed preoperatively and at three, 12, 24 and 60 months postoperatively, using the HSS-, WOMAC- and SF36-Scores, in addition to standardized X-rays.
Results: The HSS-Score improved significantly from 58.7 ± 12.7 points preoperatively to 88.5 ± 12.3 points at five-years postoperative in the ceramic group, and 60.8 ± 7.7 to 86.2 ± 9.4 points in the metallic group. WOMAC- and SF-36-Scores showed significant improvement over time in both groups. There were no significant differences between groups for HSS-, WOMAC- and SF-36-Scores, nor for range of motion ($p \leq 0.897$) at any follow-up evaluation. Furthermore, radiological evaluation showed no implant loosening or migration in either group.
Conclusions: Mid-term outcomes for the ceramic femoral components demonstrated good clinical and radiological results, as well as comparable survivorship to the metallic femoral component of the same total knee system, and to other commonly used metallic total knee systems. Therefore, ceramic knee implants may be a promising solution for the population of patients with osteoarthritis and metal sensitivity. Long-term studies are required in order to confirm the positive mid-term clinical results, and to follow the implant survival rate in regard to the enhanced wear resistance of ceramic implants.

1. Introduction

A rising number of total knee arthroplasties (TKA) have been performed over the number of years, improving confidence that the treatment is of benefit to patients [1,2,3]. However, particle-induced aseptic implant loosening still remains a major cause of total joint endoprostheses failure. Particles released from the wear of polyethylene inserts can trigger the well-known cascade of osteolysis, associated with the debonding of the components [4]. Polished ceramic surfaces as an articulating partner in general demonstrate excellent tribological aspects relating to their hardness, smooth surfaces, low friction, hydrophilic properties to water based-fluids (low contact angle) and wettability [5,6]. Since hypersensitivity reactions to metallic implant materials (*e.g.* chromium, cobalt and nickel) can cause implant failure, bioinert ceramic materials are a desirable alternative material for TKA [3,7–10]. Today, ceramics are successfully used as an articulation partner in total hip arthroplasty, and may also be a promising and eligible material for TKA [3,9–12].

The first experimental and clinical studies to investigate retrieved polyethylene inserts demonstrated that ceramic-on-polyethylene bearings used for TKA resulted in up to four to five times less wear compared to metal-on-polyethylene bearings [13,14]. The use of ceramics in TKA should not be expected to increase the functional outcome. However, by minimizing the generation of debris from wear, the use of the low-wear ceramic bearing may reduce osteolysis and implant loosening, and thus, provide better long-term survival of the total knee implants [9]. There is currently no clear clinical evidence that the use of ceramic femoral components would increase the survivorship of total knee replacement by reducing polyethylene wear.

Previous results (short-term) of composite ceramic femoral components suggest successful clinical implementation, and to date, there have been no reports of implant failures due to wear processes [11,12]. Studies on different alternative knee bearings (oxidized zirconium

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femoral component) in TKA showed excellent survival rates and good clinical and radiological outcomes over the first 10 years following implantation [9]. Furthermore, short-term clinical results have not demonstrated any differences for aseptic and septic revision rates between alternative knee bearings, when comparing ceramic-polyethylene and conventional metallic-polyethylene bearings [16].

Mechanical loosening in ceramic components is a cause of concern. However, a recent published *in vitro* study rejected the hypothesis that cemented ceramic TKA femoral components are more prone to mechanical loosening in a validated assessment protocol for the fixation of TKA femoral components [17,18]. Furthermore, reduced adhesive strength during a pull-off test after mechanical loading *in vitro* has previously been described [19]. Metallic femoral components displayed an average pull-off force of 4769 N, whereas the ceramic femoral components were shown to achieve a lower average pull-off force of 2322 N. Clinical relevance to this fact has not been shown so far.

The first implant of a femoral component made of composite ceramic material (BIOLOX® *delta*) for a Multigen Plus Knee system occurred in 2006 [12]. The aim of this comparative prospective study was to evaluate the clinical and radiological outcomes of the Multigen Plus Knee system with a ceramic femoral component, compared to a metallic femoral component, over a five-year follow-up period.

2. Materials and methods

2.1. Study design

The study was performed as a prospective comparative study for the functional and radiological evaluation of the bicondylar Multigen Plus Knee system using femoral components made of different materials (ceramic *vs.* metallic), and was classified as EBM (Evidence Based Medicine) Level 3. The study was approved by the local Ethics Committee, and all patients gave their informed consent. Inclusion criteria were indication for primary TKR, due to primary and secondary osteoarthritis or rheumatoid arthritis.

2.2. Implant system

The Multigen Plus Knee System (Lima Corporate, Villanova di San Daniele del Friuli, Italy) was used for all cases. The total knee system provides an unconstrained bicondylar cruciate-retaining (CR) design.

The femoral component of the Multigen Plus Knee system is available in two different materials. The metallic femoral component is made from a cobalt-chromium alloy (Co28Cr6Mo) and was first introduced in 1997, whereas the ceramic femoral component is made of a composite ceramic (BIOLOX® *delta* ceramic, CeramTec GmbH, Plochingen, Germany). The design of the femoral component is identical for both types of materials, with the exception of the anterior flange (symmetric ceramic *vs.* asymmetric metallic femoral component). Both the femoral and tibial (Ti6Al4V) components were fixed with bone cement. A fixed-bearing ultra-high molecular weight polyethylene liner (UHMWPE) was used for all cases.

2.3. Study group

Forty-one patients were enrolled in this study over two years. In total, 43 TKA were included in the study, three patients underwent bilateral TKA over a period greater than six months. Two of the bilateral cases were treated with the Multigen Plus knee system using a metallic femoral component within a period of six to 18 months, whereas one bilateral case had firstly undergone TKA with a different metallic knee system, followed by the ceramic Multigen Plus knee one year later. Severe instability or deformity without the possibility for a stable cruciate-retaining surface replacement was determined as contraindication.

The experimental group was dependent on the material type of the femoral component used. The choice of material was sequential and not randomized. The metallic femoral component of the Multigen Plus Knee system was used in 15 patients (17 TKA), and the ceramic femoral component was used in 26 patients (26 TKA). There were no significant differences regarding demographic data (Table 1) identified between the two study groups.

2.4. Intra- and postoperative management

All total knee implants were inserted in a standardized manner using the Payr's approach by two experienced orthopaedic surgeons. Before the tourniquet (300 mm Hg) was applied, all patients received a single-shot of Cefuroxime 1.5 g i.v. as perioperative antibiotic prophylaxis. Smoothing of the lateral patella facet and denervation was carried out. Patella resurfacing was not performed in any case. In all cases the positioning of the implant components was achieved with respect to biomechanical aspects. The correct positioning of the components was verified by intraoperative fluoroscopy. Both the femoral and the tibial components were fixed using PMMA cement (Refobacin Plus Bone Cement, Biomet Deutschland GmbH, Berlin, Germany).

Postoperatively, all patients underwent our standard regimen including analgesia, physiotherapy and thromboembolism prophylaxis with low-molecular heparin and compression stockings. In all cases, mobilization began on the second day after surgery, using two forearm crutches and a four-point gait with full weight-bearing for a period of six weeks.

2.5. Clinical and radiological evaluation of the patients

Evaluation of the functional outcome and quality of life were undertaken preoperatively and at three, 12, 24 and 60 months postoperatively, using the HSS-Score (Hospital for special surgery), WOMAC-Score (Western Ontario and McMaster Universities) and SF-36-Score (short-form 36). The HSS-Score is a joint specific score, giving a maximum of 100 points to consider both the subjective functional (62%) and objective examination criteria (38%). The categories include pain (30 points), function (22 points), motion (18 points), muscular strength (10 points), deformity (10 points) and instability (10 points). Ranawat and Shine consider an HSS-Score to be "excellent" between 85 and 100, "good" between 70 and 84, "fair" between 60 and 69 and "poor" below 60 [20].

Standardized radiographs (anterior–posterior (a.p.), lateral and merchant view) were made preoperatively and on day five postoperatively to serve as the baseline, and at each follow-up evaluation during the study. Radiolucent lines, osteolysis and implant position were assessed by an independent observer in accordance with the "Knee Society Roentgenographic Evaluation and Scoring System" [21]. The evaluation of the implant position included measurement of the medial distal femur angle (MDFA), medial proximal tibia angle (MPTA), distal femur angle (PDFA) and posterior proximal tibia angle (PPTA).

2.6. Data and statistical analysis

All data were analysed using the SPSS statistical package 15.0 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics were determined for each of the continuous and categorical variables, including mean, standard deviation (SD) and ranges of continuous variables, frequencies and relative frequencies of categorical factors.

The HSS-, SF-36- and WOMAC-Scores were analysed to assess the trends and differences among the scoring at different follow-up visits. Comparisons between the different time-points for clinical and radiological evaluations were performed using an ANOVA F-test with cluster sandwich (Huber–White) variance–covariance estimator. A p-value of <0.05 was considered to be statistically significant for all analyses.