



A 13- to 16-year clinical and radiological outcome study of the genesis II cruciate retaining total knee arthroplasty with an oxidised zirconium femoral component

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ABSTRACT

Purpose: The Genesis II Total Knee Arthroplasty with an oxidized zirconium (Oxinium™) femoral component (Smith & Nephew, Memphis, TN, USA) was introduced in an attempt to reduce polyethylene wear and osteolysis.

Methods: We retrospectively evaluated prospectively collected data from 245 consecutive patients (40 men and 205 women; mean age at surgery 70.1 years, range 44 to 85 years) who underwent 261 TKAs with a mean follow-up of 15.1 years (range 13 to 16 years). Implant failure rate, complication rate, clinical (both subjective and objective) and radiological outcomes were assessed.

Results: At final follow-up, 24 (9.8 %) patients (24 TKAs) were lost to follow-up and 35 (14.3%) patients (35 TKAs) had died for reasons unrelated to surgery. Four TKAs, in four patients, were revised because of aseptic loosening. In five TKAs (five patients) secondary patella resurfacing was performed because of patellofemoral pain. Survivorship analysis showed a cumulative success rate of 98.4% (95% CI, 94.3% - 100%) at 15 years with revision for aseptic loosening as an end point, and 95.6% (95% CI, 92.7% - 98.7%) at 15 years with revision for any reason as an end point. All patients showed a statistically significant improvement ($p = 0.01$) in the Knee Society clinical rating system, WOMAC Score, KOOS Score, Oxford Knee Score and EuroQol 5D Score. Surgery fulfilled patient expectations for 90.1% of patients; in 5.4% it did not, and 4.5% declined to answer.

Conclusion: This study demonstrates satisfactory long-term clinical results for this knee design.

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1. Introduction

Total knee arthroplasty (TKA) is one of the most satisfactory and popular orthopaedic procedures for the end stages of knee disorders due to long-term survival rates of greater than 90% at 10 years and improved functional outcomes [1–3]. The number of TKAs performed is expected to dramatically increase in the coming years, especially in young and active patients [4,5]. Polyethylene (PE) wear and osteolysis remain the main cause of TKA failure and revision [6–8]. In order to increase the longevity of TKA, various attempts have been made to improve implant design [9], accuracy of component placement [10,11] as well as the wear characteristics of the bearing surfaces [4,12].

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Standard TKAs use femoral components made of a cobalt–chromium alloy (Co-Cr). In order to improve the surface of the femoral component surface, metallic zirconium alloy femoral components (Zr-niobium 2.5%) are oxidised by thermal diffusion in order to create a five-micrometre oxidised zirconium (OxZr – Oxinium™) layer that covers the articular surface [13,14]. It is believed that OxZr implants combine the strength of metal with the superior wear properties of a ceramic surface [13,14]. This ceramized femoral component surface is combined with an ultra-high molecular weight polyethylene (UHMWPE) insert. Multiple in vitro studies have shown that OxZr bearings reduce PE wear by 43–89% compared to those made of Co-Cr [15,16]. Satisfactory clinical outcomes and survival rates have been presented by several centres at 10-year follow-up [17]. However, the in vivo performance of this bearing coupling beyond the first postoperative decade is still unclear.

The aim of this study is to present the long-term clinical outcomes of Genesis II cruciate retaining TKAs with OxZr femoral implants from the second decade, evaluating possible failures, complication rates, clinical (both objective and subjective) and radiological outcomes.

2. Patients and methods

From February 2002 to March 2005, 245 consecutive patients (261 knees) underwent a cemented OxZr Genesis II TKA (Smith & Nephew, Memphis, Tennessee, USA) in our department and were included in this study. There were 205 (83.7%) female and 40 (16.3%) male patients. The mean age at surgery was 70.1 years (range 44 to 85). One hundred and eighteen (45.2%) procedures were performed on the right and 143 (54.8%) on the left knee. Patients had a mean body mass index (BMI) of 33.4 (range 21.3 to 42.4). Sixteen patients underwent staged bilateral procedures. Criteria of patient selection were end stage knee arthritis, varus and valgus angular deformity of less than 20° and flexion contracture of less than 10°. Exclusion criteria were patients with severe knee deformities and either femoral or tibial bone defects requiring reconstruction. Written informed consent forms were obtained from all patients.

The Genesis II OxZr TKA (Smith & Nephew Orthopaedics, Memphis, TN, USA) was used in all patients (Figure 1). This is a modular system consisting of an anatomical OxZr femoral cemented component and an asymmetric titanium alloy tibial component with a short central stem. The polyethylene insert (deep dissed) was made of ultrahigh molecular weight polyethylene (ram-extruded, ethylene oxide-sterilised). The semi-constrained variant of the implant for posterior cruciate ligament retention was used. All procedures were performed by one orthopaedic surgeon (TK) via a mini mid-vastus approach [18]. Both femoral and tibial components were inserted with the use of high-viscosity Palacos® cement (Biomet, Warsaw, IN). Patellar resurfacing was not performed, and instead, patellar aponeurosis (a five millimetre all round patella retinacular release with a cautery) removal of osteophytes and patellar reshaping were performed on all patients. All patients had preventive pre- and postoperative intravenous (I.V.) antibiotics for two days, suction drain for two days and low molecular heparin administration for 30 days. Full weight bearing, as tolerated, with the use of a walking frame started from the second postoperative day and all patients followed a standard rehabilitation protocol.

Objective and subjective clinical and radiological data were prospectively collected preoperatively and at three weeks, six weeks, three months, six months, one year and every year thereafter, and stored in the Orthowave database (Aria Ltd., Lyon, France). The following validated scoring systems were used [19]: the Knee Society system (KSS, Knee score and Function score) [20]; the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) questionnaire (Likert version – range 96–0, 0 is best; 96 is worst) [21]; the original (60 to 12) Oxford Knee Score (OKS) [22] and the Knee Injury and Osteoarthritis Index (KOOS) [23]. The EuroQoL 5D questionnaire was also used in order to quantify parameters for the patients' quality of life [24]. The active range of movement (ROM), when sitting, was recorded using a goniometer. At the first, fifth, 10th and 15th postoperative year time interval, patients were also asked to subjectively judge relief of pain, their expectations of surgery and if they would like to repeat the same operation on another joint.

Standardised standing short anteroposterior and lateral radiographs were taken. The KSS was used for radiological evaluation [25]. Changes in alignment and migration (α , β , γ , σ and tibiofemoral angles) of the components were analysed comparing the angles of the first and last available radiographs. All radiographs were examined for progressive radiolucent lines (RLLs) according to Ewald [25] by two surgeons and, if both found RLLs, this was defined as a consensus. The gap width of RLLs (mm) was measured at specific areas along the implants. A score of four or less in one component was considered of no significance; a score of five to 10 required monitoring for progression; a score greater than 10 suggested impending failure of the implant [25]. Moreover, the presence of progressive RLLs greater than two millimetres, subsidence or change in alignment of a component was considered to indicate loosening. The criteria for failure were the need for revision, either performed or planned, aseptic loosening, infection, patellar resurfacing, dislocation or ligament instability.

2.1. Statistical analysis

Data were analysed for normal distribution using Kolmogorov–Smirnov analysis. Clinical scores (KSS, WOMAC, OKS), α , β , γ , σ and tibiofemoral angles were normally distributed. For statistical analyses, Student's *t*-tests and Mann–Whitney tests were used in order to evaluate possible statistical differences of values within the group of patients at different time intervals. Kaplan–Meier analysis with a calculation of 95% confidence intervals (CIs) was performed to calculate survivorship [26,27]. Revision of either component for aseptic loosening, revision for any reason and the “worst-case scenario” (the assumption that all lost to follow-up cases failed after last follow-up) were considered as end points. All statistical analyses were performed using SPSS version 12.0 (SPSS Chicago, Illinois) at the biostatistics department of the University of Thessalia. A *p*-value of ≤ 0.05 was considered significant.

3. Results

The patients in this series were followed up for a mean of 15.1 years (range 13 to 16 years). Between March 2018 and April 2018 a final evaluation was performed, and 186 (75.9%) patients with 202 (77.4%) TKAs were available for study. Twenty four

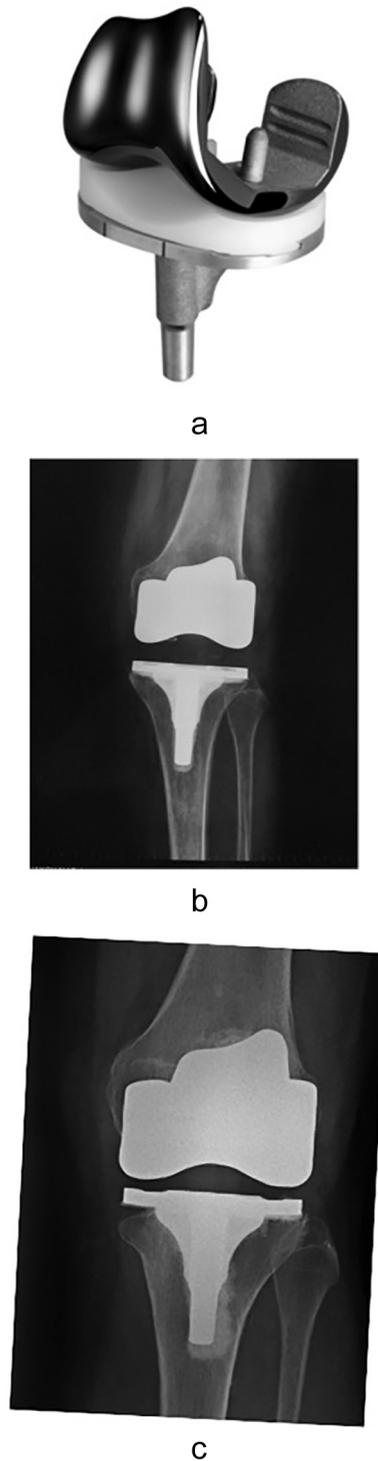


Figure 1. An OxZr Genesis II photograph (a), satisfactory anteroposterior radiological outcome at 15 years follow-up (b), and medial tibial plateau radiolucent line which led to implant revision (c), are shown.

(9.8%) patients (24 TKAs) were lost to follow-up, and 35 (14.3%) patients (35 TKAs) had died for reasons unrelated to surgery with their TKAs performing well.

Four (1.63%) TKAs, in four patients, were revised because of aseptic loosening (Figure 1). In one of them, patella resurfacing was also performed during revision. In five (1.92%) TKAs (five patients), secondary patella resurfacing was performed because of patellofemoral pain (subsequently, three TKAs became asymptomatic); in two of these, a PE insert was also exchanged in order to correct soft tissue balancing during the revision procedure. Two patients sustained femoral periprosthetic fractures of stable TKAs, after a fall, and underwent open reduction and internal fixation surgery. One patient underwent surgical soft tissue release because of joint stiffness, and another underwent surgical debridement because of superficial wound infection. Minor wound healing problems were recorded in 21 (8%) knees. Deep vein thrombosis was detected in eight (3.1%) TKA knees, which eventually fully recovered. In four (1.5%) knees, manipulation under anaesthesia was performed in order to improve post-operative flexion after the fourth postoperative week.

3.1. Survivorship analysis

Kaplan–Meier survivorship analysis showed a cumulative success rate of 98.4% (95% CI, 97.4%–99.9%) at 10 years, and 98.4% (95% CI, 94.3%–99.9%) at 15 years with revision for aseptic loosening as an end point (Figure 2). Kaplan–Meier survivorship analysis showed a cumulative success rate of 95.6% (95% CI, 92.8%–98.4%) at 10 years, and 95.6% (95% CI, 92.7%–98.7%) at 15 years with revision for any reason as an end point (Figure 2). Kaplan–Meier survivorship analysis also showed a cumulative success rate of 88.1% (95% CI, 83.9%–92.1%) at 10 years, and cumulative success rate of 85.1% (95% CI, 79.23%–96.2%) at 15 years with “worst-case scenario” revision as an end point (Figure 2).

3.2. Clinical outcome evaluation

Preoperative and postoperative at two, 10 and final follow-up 15 years mean values of the Knee Score, Function Score, OKS, WOMAC score, KOOS score and Euro-Qol 5D Score are shown in Table 1. Statistically significant improvement in all scores was observed (t -test $p \sim 0.01$). The OKS mean value reached a plateau at the third follow-up year and then showed a decline after the 10th follow-up year (Figure 3). A similar observation was made when the WOMAC Score's element of function was evaluated (Figure 4). In Figure 5, the pre- and postoperative elements of KOOS scores are shown. Surgery fulfilled patient expectations in 90.1% of patients; in 5.4% it did not, and 4.5% declined to answer. When patients were asked if they would like to repeat the same surgery in another joint, 67.4% of them replied definitely yes, 25.4% possibly yes, 1.1% probably not and 3.7% certainly not whilst 2.4% refused to reply. The range of movement rose from a preoperative mean of 82° (range 75° to 120°) to a final mean of 110.2° (range 85° to 135°) and no TKA had a postoperative fixed flexion deformity of more than five degrees.

3.3. Radiological evaluation

Postoperative and final follow-up mean values of implant alignment parameters of femoral valgus angle (α), tibial angle (β), femoral flexion (γ), tibial slope (σ) and knee alignment in both groups are shown in Table 2. No statistically significant changes developed when postoperative and final follow-up values were compared. At the second and 10th year time intervals, on anteroposterior radiographs of the tibial component, nonprogressive and less than two-millimetre RLLs were recorded in 32 (12.2%) TKAs (zones 1 and 5). At the same time intervals, on lateral radiographs of the femoral component, nonprogressive

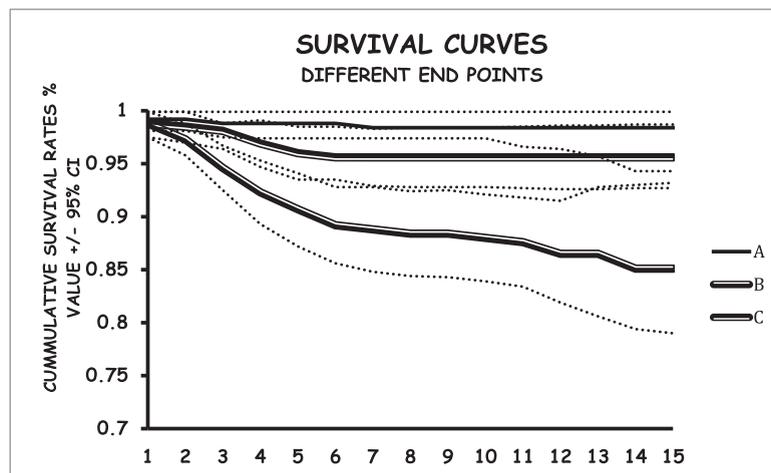


Figure 2. Survival curves with revision for aseptic loosening (A), revision for any reason (B), and revision for “worst-case scenario” (C) as end points are shown.

Table 1

Pre- and postoperative mean values at two, 10 and 15 years of objective and subjective clinical outcome rating scales, used in the study, are shown.

	PRE-OP	2Ys	10Ys	15Ys
EURO-QoL				
EURO-QoL 5D-3L	0.37	0.75	0.67	0.50
EURO-VAS HEALTH STATE	0.27	0.71	0.55	0.45
KNEE SOCIETY SCORE				
KNEE SOCIETY KNEE SCORE	33.9	93.1	84.2	72.0
KNEE SOCIETY FUNCTIONAL SCORE	50.4	88.0	73.1	58.4
OXFORD KNEE SCORE				
OXFORD KNEE SCORE	15.2	42.0	37.4	27.4
WOMAC				
PAIN	11.6	3.1	3.6	6.8
STIFFNESS	4.6	1.0	1.6	2.6
FUNCTION	39.3	9.0	12.0	22.5
TOTAL	55.4	13.1	17.2	31.9
KOOS				
SYMPTOMS	33.2	77.9	74.2	64.2
PAIN	30.6	86.3	82.7	73.8
FUNCTION	38.2	83.3	80.1	70.5
SPORTS	9.7	31.3	29.5	15.7
QoL	18.3	80.2	71.2	63.4
TOTAL	31.0	76.0	73.0	65.5

and less than two-millimetre RLLs were recorded in seven (2.7%) TKAs (zones 1, 2, 3). At final follow-up, there was no radiological evidence of progressive radiolucent lines or osteolysis due to polyethylene wear debris in all available TKAs.

4. Discussion

Despite satisfactory long-term clinical outcomes of cemented TKA, aseptic loosening remains one of the most common indications for revision [6–8]. Several risk factors related to patient selection, surgical approach, abnormal artificial joint kinematics, optimum biomaterials and ligament resection, substitution and retention have been identified, but their exact role and significance still remain controversial. Wear particle related osteolysis and aseptic loosening are the main overall reasons (approximately 20–25%) for TKA revision surgery according to the annual reports of registries [6,28,29]. Infection is the main reason for TKA revision during the first three postoperative years, whilst aseptic loosening is the main reason thereafter.

Oxidised zirconium (OxZr) femoral component combined with ultra-high molecular weight polyethylene (UHMWPE) insert is considered an alternative bearing for modern TKAs. It combines the desirable properties of a ceramic (low friction) and of a metal (strength), and it was introduced with the expectation that it will reduce both polyethylene wear rates and the incidence of aseptic loosening [13–17,30]. In vitro studies have verified the theoretical advantages of the material. Multiple studies performed in knee wear simulators showed that OxZr reduced the rate of polyethylene wear when compared to Co-Cr alloys [15,16,31,32]. Components retrieved from TKA revision surgery showed that the in vivo damage of both the femoral component and the

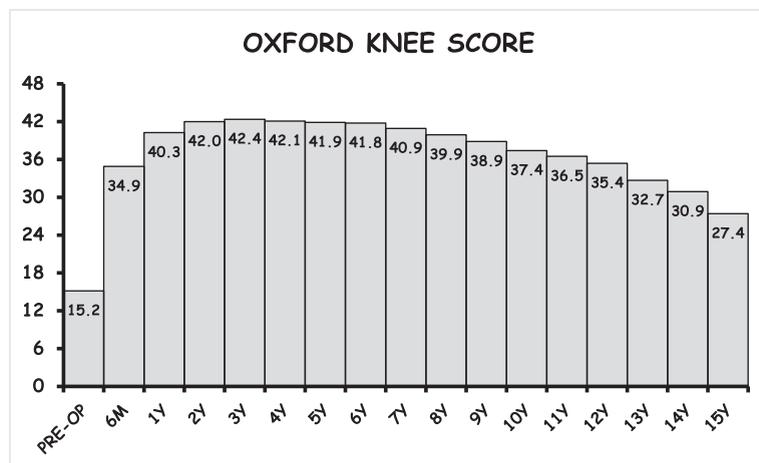


Figure 3. Oxford Knee Score mean values (bar graph) are shown.

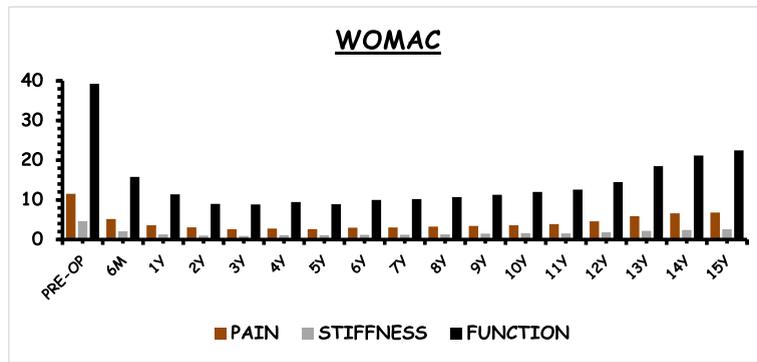


Figure 4. Mean values of all elements of WOMAC Score (bar graph) are shown.

polyethylene insert was lower in the case of OxZr compared to Co-Cr femoral components [33,34]. The present study reports the long-term survival, clinical and radiographic outcome of OxZr TKA.

Satisfactory long-term survival of the OxZr Genesis II prosthesis was recorded in this series. A survival rate of 98.4% at 15 years with revision for aseptic loosening as an end point and four recorded failures due to aseptic loosening is considered a satisfactory outcome at this length of follow-up. Even in the worst-case scenario, assuming that all patients lost to follow-up had failed, the 15 years survival rate of 85.1% can be considered a good outcome. Also, the incidence of 1.92% of secondary patella resurfacing is low and acceptable. The remaining failures were within the expected limits at this length of follow-up. We recorded no cases of severe PE wear, structural failure of all three components or late TKA instability. The OxZr Genesis II prosthesis has an anatomical bi-concave, three degrees externally rotated, femoral component and an asymmetric anatomical tibial tray for improved coverage of the tibia. It also has a deep and lateralized trochlear groove for improved patella tracking (patella “friendly implant”). It has recently been suggested that tibial asymmetric components result in a lower incidence of tibial tray malrotation, and this may partially explain favourable patella kinematics [35].

High survival rates do not necessarily mean patient satisfaction. Patient reported outcome measures (PROMs) and radiological evaluation are also useful and perhaps more important in order to evaluate the efficacy of TKA [19,36,37]. Functional recovery, as assessed by the Function score (objective), the OKS (subjective), WOMAC score (subjective) and KOOS Score (subjective), was also satisfactory. It has to be stressed that function improved up to the third postoperative year, then remained stable and started declining after the tenth postoperative year, perhaps due to senility. Surgery improved quality of life, with patients reporting satisfaction concerning pain relief, fulfilment of expectations and possible performance of a TKA in the contralateral knee.

The radiological appearance of the cemented interface of both implants was also satisfactory. Despite the fact that radiolucent lines were evident in the postoperative radiographs, at final follow-up, none of them were progressive. No implant change in alignment or migration was recorded in either group. No other adverse radiological signs were observed. This system also had a simple, comprehensive and easy to use instrumentation set, which allowed for easy and reliable performance of the surgical procedure.

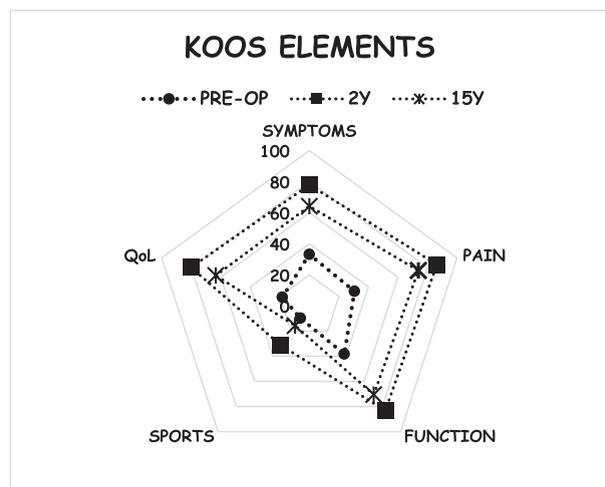


Figure 5. Mean values of all elements of KOOS Score (radar graph) are shown.

Table 2

Pre- and postoperative (last follow-up) mean values of alignment parameters for both components are shown.

	preop	postop
mean femoral valgus angle (α)	95.5 (93 to 100)	96.5 (93 to 102)
mean tibial angle (β)	89 (81 to 93)	88.5 (85–93)
mean femoral flexion (γ)	1 (–2 to 4)	1 (–3 to 3)
mean tibial slope (σ)	87 (83 to 91)	85 (83 to 90)
mean knee alignment	5 valgus (8 valgus to 3 varus)	4.8 valgus (7 valgus to 4 varus)

Limitations of the study are the relatively small number of patients and the lack of a control group. Although it is a consecutive cases study, the patients were not randomised, with a potential selection bias. The fact that all operations were performed in one hospital by a dedicated surgeon can be considered a weakness of the study. However, the low rate of patient loss to follow-up, the length of the observation period (15 years) and the use of subjective rating scales (patient reported outcomes) strengthen the findings of the study. Moreover, in order to improve the strength of the study's conclusions, we constructed a worst-case scenario for survival rates, assuming that all patients lost to follow-up had failed in the year after their last examination. Lessons learned from such studies are of considerable value in the assessment of newer devices, both in terms of quality and performance.

Several mid-term clinical outcome studies evaluating OxZr Genesis II cemented TKA have shown satisfactory clinical scores and survival rates greater than 99% at 5 years [13,38–43]. Only two reports have also shown survival rates at the level of 97–98% at 10 years [44,45]. Our study is perhaps the largest single centre cohort of patients with OxZr Genesis II TKAs that reports satisfactory clinical and functional outcomes with a survival rate of 98.4% (aseptic loosening as an end point) and no implant related failures recorded at the level of 15 years follow-up. However, in studies comparing OxZr to Co-Cr femoral components of Genesis II TKA similar results were reported in terms of rating scores and survival rates [39,40]. In the largest study, Kim et al. reported on 331 patients with bilateral TKA (in order to minimise inter-patient variability), one performed with OxZr and the other with a Co-Cr femoral component, followed up for a mean of 7.5 years [40]. They found no clinically significant difference, in terms of survival and clinical scores, whilst polyethylene wear particles analysed after aspiration of both knees did not reveal significant differences between the two bearing surfaces [40]. A recent study from the Australian Joint Replacement Registry reports comparable data and confirms these findings [46]. This cohort consisted of cemented cruciate retaining Genesis-II TKAs; 5,969 with OxZr femoral components and 11,608 with CoCr. No significant difference was found in terms of hazard ratio for revision risk between the two groups; although at 12 years, the cumulative revision rate was greater for the OxZr (7.7%) compared to the CoCr (4.8%) femoral components. Given the higher cost of OxZr, such data do not justify the widespread use of OxZr bearing surfaces in TKA, and their use should perhaps be limited to those patients with longer life expectancy [47]. Additionally, it is suitable for patients with metal sensitivity, as it contains untraceable amounts of nickel [48–50].

In conclusion, the cemented Genesis II cruciate retaining TKA with an oxidised zirconium femoral component and ultrahigh molecular weight polyethylene insert showed satisfactory survival rates, functional recovery and patient satisfaction at 15-year follow-up. Additionally, none of the components showed structural failure.

Conflict of interest statement

All authors state that they have not taken any financial support in order to perform this study, and they have no relationship with the company producing the prosthesis.

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