

# Five-Year Comparison of Oxidized Zirconium and Cobalt-Chromium Femoral Components in Total Knee Arthroplasty

## A Randomized Controlled Trial

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**Background:** In vitro analysis has shown that oxidized zirconium on ultra-high molecular weight polyethylene has better wear properties than cobalt-chromium on ultra-high molecular weight polyethylene. The purpose of this study was to determine if oxidized zirconium femoral components performed better than cobalt-chromium in vivo and if the use of oxidized zirconium components had clinical adverse effects.

**Methods:** Forty consecutive patients (eighty knees) underwent simultaneous bilateral cruciate-retaining total knee arthroplasty for primary osteoarthritis from January 2002 to December 2003. For each patient, the knees were randomized to receive the oxidized zirconium femoral component, with the contralateral knee receiving the cobalt-chromium component. Outcome measures included the Western Ontario and McMaster Universities Osteoarthritis Index, Knee Injury and Osteoarthritis Outcome Score, Knee Society score, and British Orthopaedic Association patient satisfaction scale. Radiographic outcomes include the Knee Society total knee arthroplasty roentgenographic evaluation and scoring system and measurement of radiographic wear. Patients and assessors were blinded to the treatment groups and results.

**Results:** There were no significant differences in clinical, subjective, and radiographic outcomes between the two implants at five days, six weeks, and one, two, or five years postoperatively. At five years following surgery, 38% of the patients preferred the cobalt-chromium knee compared with 18% who preferred the oxidized zirconium knee ( $p = 0.02$ ) and 44% had no preference.

**Conclusions:** Five-year outcomes after total knee arthroplasty with oxidized zirconium and cobalt-chromium femoral components showed no significant differences in clinical, subjective, and radiographic outcomes. Patients had no preference or preferred the cobalt-chromium prosthesis to the oxidized zirconium prosthesis at the time of the five-year follow-up. There were no adverse effects associated with the use of oxidized zirconium femoral implants.

**Level of Evidence:** Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

Polyethylene wear is one of the most common reasons for total knee arthroplasty failure after five years<sup>1-7</sup>. Phagocytosis of the polyethylene debris by macrophages incites an inflammatory response with the production of cytokines, which stimulates osteoclasts and leads to bone resorption, aseptic loosening, and subsequent implant failure<sup>2,8-12</sup>. The etiology of wear is multifactorial but usually occurs at the bearing surface<sup>2</sup>. Mechanisms of wear include adhesive, abrasive, third-body, and fatigue wear<sup>4,5,13</sup>. Recent advances in implant design have focused

on reducing the number of biologically active wear particles<sup>2</sup>. This can be achieved either by improving the polyethylene liner or by the use of alternative bearing surfaces to improve the wear characteristics of the femoral component<sup>2</sup>. Adhesive wear can be decreased by decreasing the coefficient of friction between the femoral component and the polyethylene<sup>8</sup>. Abrasive wear can be minimized if the bearing surface resists scratching<sup>8</sup>.

Femoral components are usually manufactured with a standard cobalt-chromium alloy with a polished articular

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surface. Scratches to this smooth metal surface can lead to increased polyethylene wear<sup>8</sup>. Ceramic components have the advantage of better wear properties than metals, but concern remains regarding the risk of implant fracture<sup>2,14,15</sup>. A novel bearing surface modification has been the manufacture of components made from a wrought zirconium alloy (Zr-niobium [Nb] 2.5%) oxidized by thermal diffusion to create a 5- $\mu$ m oxidized zirconium layer (Oxinium; Smith & Nephew, Memphis, Tennessee). The oxidized component is burnished to make the articular surface smooth. The surface oxide is a transformation of the underlying metal surface into zirconium oxide ceramic, resulting in an implant that combines the strength of metal with the wear properties of ceramic in terms of its superior lubrication properties, surface hardness, resistance to abrasive scratching, and immunity to corrosive roughening<sup>1,8,10,15-17</sup>.

Laskin previously reported a more rapid and significant return of flexion ( $p = 0.025$ ) and a more rapid attainment of functional outcomes ( $p = 0.04$ ) in patients with oxidized zirconium compared with cobalt-chromium femoral components in a small randomized prospective series of twenty-eight patients, followed for two years after surgery<sup>4</sup>. The purposes of the present study were to determine whether the findings of Laskin were similar in our study group and to determine whether the beneficial wear properties of oxidized zirconium *in vitro* were also present *in vivo*.

We hypothesized that there would be no difference in the short and mid-term clinical, subjective, and radiographic outcomes in patients with bilateral total knee arthroplasty with use of an oxidized zirconium femoral component in one knee and a cobalt-chromium femoral component in the other.

## Materials and Methods

### Study Design and Patient Selection

An independent ethical review board granted approval for this study. Written informed consent was obtained from all study patients. This study is a double-blind, prospective, randomized controlled trial completed in a single surgeon's practice. The patients and the assessors postoperatively were blinded to the type of implant used in each knee. Sixty-two consecutive patients underwent simultaneous bilateral cruciate-retaining total knee arthroplasty for primary osteoarthritis from January 2002 to December 2003. Forty patients (eighty knees) were eligible and enrolled in the study. Exclusion criteria included flexion contracture of  $>15^\circ$ , inflammatory arthritis, medical comorbidities precluding simultaneous bilateral total knee arthroplasties, and mental conditions that could interfere with the ability to provide informed consent or to fulfill the study requirements.

### Sample Size and Randomization

The primary outcome of flexion was based on the study by Laskin<sup>4</sup> and was used to determine the sample size. On the basis of a comparison of two independent groups, a sample size of thirty-three knees per group was estimated to have sufficient power ( $p = 0.90$ ) to detect a clinically important difference of  $10^\circ \pm 12^\circ$  (mean and standard deviation) in range of motion ( $p = 0.05$ ). A standard deviation of  $12^\circ$  was used on the basis of a previous study by Kawamura et al., in which the Genesis II implant was used<sup>18</sup>. Assuming a loss-to-follow-up rate of approximately 30%, we aimed to recruit fifty patients (fifty knees per group). Block randomization according to side was performed for fifty knees per group. During the recruitment period, the senior surgeon undertook a sabbatical, and recruitment was stopped at forty patients, as it was known that only thirty-three patients were required to have adequate power in

the study. Therefore, the study groups were unequal, with twenty-three patients randomized to the oxidized zirconium group in the right knee vs. seventeen patients with oxidized zirconium in the left knee.

For each patient, the knees were randomized to receive the oxidized zirconium femoral component, with the contralateral knee receiving a cobalt-chromium component. Randomization was performed with use of concealed envelopes according to a computer-generated randomization list. The envelope remained sealed until the patient entered the operating room, where it was opened by the surgeon just prior to starting the procedure.

### Surgical Technique and Postoperative Protocol

The senior author (L.P.) performed all procedures. Preoperative antibiotics and spinal and/or epidural anesthesia were used. The Genesis II Knee System prosthesis (Smith & Nephew) with a titanium alloy (Ti 6%-Al 4%-V) base plate and a conforming deep-dished ultra-high molecular weight polyethylene liner (ethylene-oxide-sterilized ram-extruded GUR 1050) were used. The femoral components were either Oxinium (Zr-Nb 2.5%) or cobalt-chromium (Co 28%-Cr 6%-Mo). All components were inserted with cement (Simplex P; Stryker, Kalamazoo, Michigan). The left knee was routinely approached first. A medial parapatellar incision and anteromedial approach was used. The presence of a posterior cruciate ligament (PCL) contracture was assessed intraoperatively and released as necessary for proper balancing. The need for patellar resurfacing was determined by preoperative symptoms and intraoperative articular cartilage wear, with resurfacing with an all-polyethylene onlay component bilaterally when indicated.

All patients received one preoperative and one postoperative dose of antibiotic prophylaxis. Postoperatively, sequential compression devices and warfarin for venous thromboembolism prophylaxis were used. A venous Doppler ultrasound of both legs was performed prior to discharge, and warfarin was discontinued if the results were normal. Immediate full weight-bearing was encouraged. Twice daily physical therapy began on postoperative day 1 and continued until discharge.

### Assessment

Assessments were performed by two experienced physical therapists. Patients and assessors were blinded to the treatment groups and results. Patient demographics and clinical outcomes included knee range of motion and alignment. Range of motion was assessed with a goniometer with the patient in a supine position. Subjective outcomes included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Knee Injury and Osteoarthritis Outcome Score (KOOS), the Knee Society score<sup>19</sup>, and the British Orthopaedic Association (BOA) patient satisfaction scale<sup>20</sup>. The KOOS, with subscales of pain, quality of life, symptoms, and activities of daily living, was administered at the one-year, two-year, and five-year postoperative time points. The WOMAC was only administered preoperatively. However, the KOOS activities of daily living subscale was developed as an extension of the WOMAC for younger and/or more active patients with knee injury and/or knee osteoarthritis<sup>21</sup>. The Knee Society score, evaluating pain, range of motion, stability, and function, was administered at the preoperative and one-year, two-year, and five-year postoperative time points. All patients were asked to complete two separate subjective assessment forms, one for each knee. Assessments were performed preoperatively, in the hospital prior to discharge, and postoperatively at six weeks, six months, and at one, two, and five years. At the time of follow-up visits, patients were also asked, "Which knee do you prefer?"

Radiographs were made preoperatively and postoperatively while the patient was hospitalized, at six weeks, and at one, two, and five years. A blinded, experienced orthopaedic surgeon (S.M.) evaluated the radiographs for radiolucencies and alignment using the Knee Society total knee arthroplasty roentgenographic evaluation and scoring system previously described by Ewald<sup>22</sup>.

Radiographic evidence of wear was assessed at two and five years with use of the metal-to-middle method previously described by Collier et al.<sup>23</sup>.

### Retrieval Analysis

Two patients required a second surgical procedure for bilateral patellar resurfacing, both at fifty-two months after implantation of the primary total knee

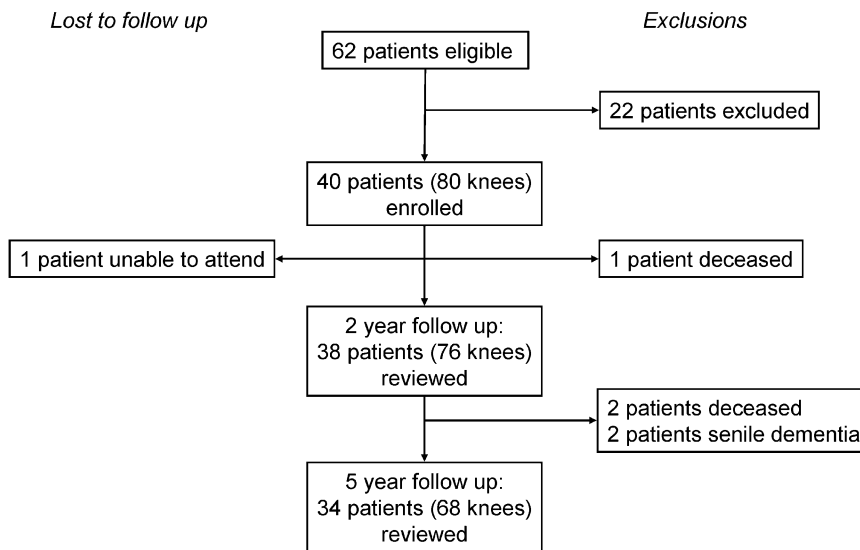


Fig. 1  
Participant flow through the trial.

replacement. Polyethylene liner exchange was performed concurrently in all four knees. Wear was assessed by the methods reported by Cornwall et al. in a blinded fashion<sup>24</sup>. All four implants were examined visually as well as with use of stereo zoom and environmental scanning electron microscopy (Hitachi TM-1000; Hitachi, Tokyo, Japan). Seven commonly reported mechanisms of surface degradation wear, including delamination, pitting, abrasion, scratching, burnishing, deformation, and embedded debris, were assessed as described by Cornwall et al.<sup>24</sup>. The inserts were carefully examined, and the mechanisms were documented on the implants as a wear map.

#### Statistical Analysis

The Mann-Whitney U test was used to compare the outcomes of the two femoral implants, and the Student t test was used to compare the outcomes

between the two-year and five-year time points. In all analyses,  $p < 0.05$  was considered significant.

#### Source of Funding

Institutional financial support for research was received from Smith & Nephew.

#### Results

##### Participant Flow and Adverse Events

The flow of participants through the trial is presented in Figure 1. Sixty-two patients were eligible for the study. Twenty-two were excluded, leaving forty patients (eighty

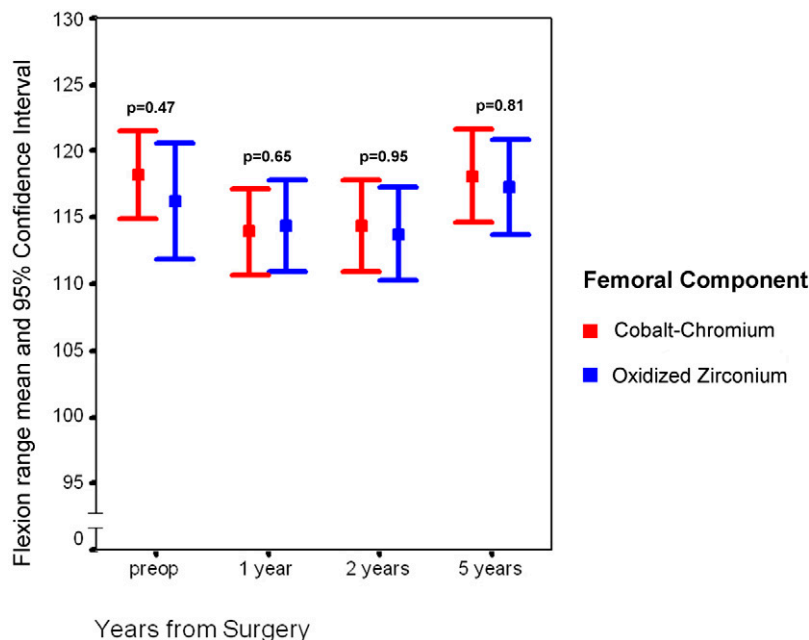


Fig. 2  
Mean and 95% confidence interval for knee flexion at each time point.

knees) enrolled in the study. At two years postoperatively, one patient had died from unrelated causes and one could not attend because of geographical reasons, leaving thirty-eight (97%) of thirty-nine patients for review. At five years postoperatively, two more patients had died of unrelated causes and two developed senile dementia and were excluded. One patient moved and could not return for assessment. Therefore, thirty-four (97%) of thirty-five patients completed the study and were included in the analysis.

Two patients had pulmonary embolisms that were treated with appropriate anticoagulation. No adverse events were related to the biomaterials of the implants.

#### *Baseline Demographics and Clinical Outcomes*

The groups were similar with no significant differences in any category preoperatively. There were fifteen men and twenty-five women. Twenty-three patients were randomized to receive oxidized zirconium in the right knee and seventeen patients had oxidized zirconium in the left knee ( $p = 0.18$ ). There was

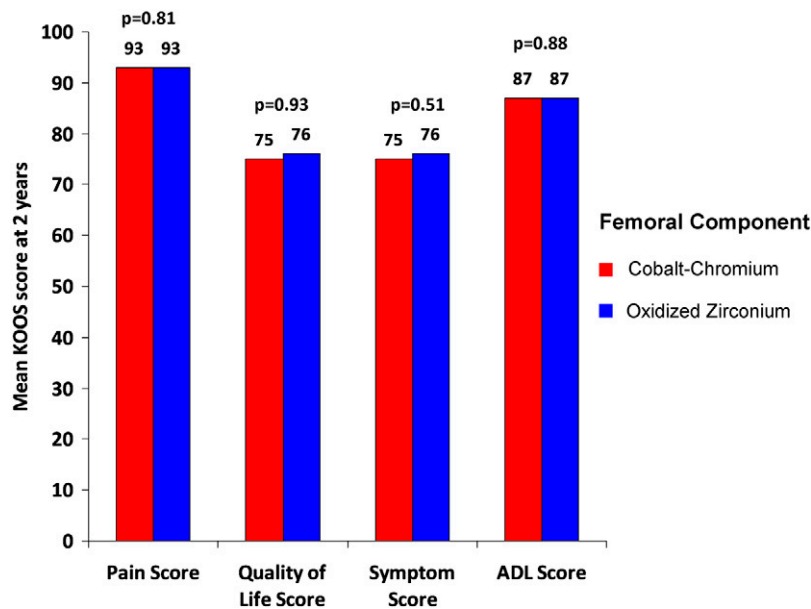


Fig. 3-A

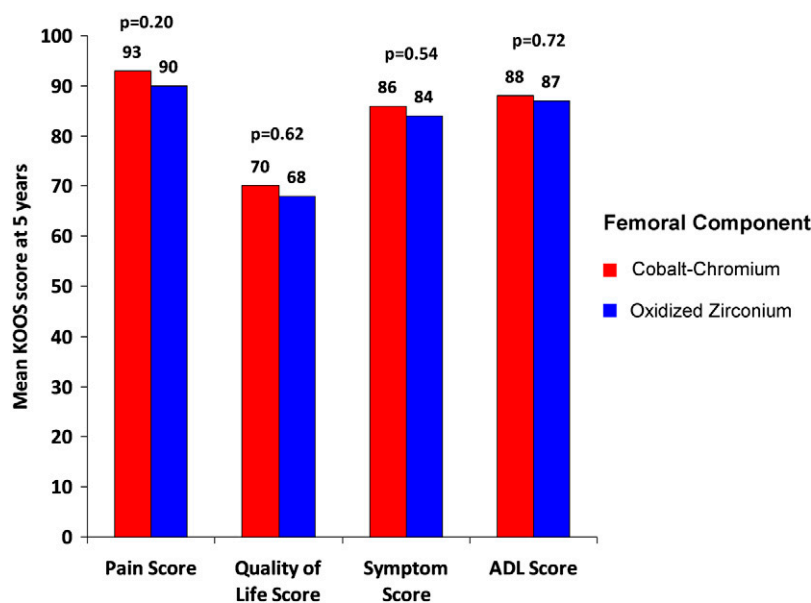


Fig. 3-B

**Figs. 3-A and 3-B** The mean Knee Injury and Osteoarthritis Outcome Scores (KOOS). ADL = activities of daily living. **Fig. 3-A** Two-year scores. **Fig. 3-B** Five-year scores.

TABLE I Radiographic Outcomes

	Oxidized Zirconium*	Cobalt-Chromium*	P Value
2 year			
Alignment†	184.7° ± 3.3°	185.0° ± 3.3°	0.711
Radiolucencies‡			
<4	36 (92)	35 (90)	0.692
5-9	3 (8)	4 (10)	
5 year			
Alignment†	183.4° ± 3.1°	184.5° ± 2.9°	0.147
Radiolucencies‡			
<4	31 (94)	28 (85)	0.213
5-9	2 (6)	5 (15)	

\*Radiographs were available for thirty-nine knees at two years and thirty-three knees at five years. †The values are given as the mean Knee Society total knee arthroplasty roentgenographic evaluation score and the standard deviation. ‡The values are given as the number of knees, with the percentage in parentheses.

no significant difference in the knee flexion (Fig. 2), extension, presence of a flexion contracture, extensor lag, effusion, or alignment at any time point.

#### Subjective Outcomes

There were no significant differences between the oxidized zirconium and cobalt-chromium groups for the functional Knee Society score at two years (mean, 88 for the cobalt-chromium group and 89 for the oxidized zirconium group;  $p = 0.80$ ) or five years (mean, 92 for the cobalt-chromium group and 89 for the oxidized zirconium group;  $p = 0.41$ ). There were no significant differences between the oxidized zirconium and cobalt-chromium groups for KOOS measured at any time point (Figs.

3-A and 3-B). When asked about which knee they preferred, the patients noted no differences at the immediate, one-year, and two-year postoperative time points. However, at five years following surgery, 38% of the patients preferred the cobalt-chromium knee compared with 18% who preferred the oxidized zirconium knee ( $p = 0.02$ ) and 44% had no preference.

#### Radiographic Outcomes

Radiographs were available for review at two years postoperatively for thirty-nine patients and for thirty-three patients at five years. There were no significant differences in the Knee Society total knee arthroplasty roentgenographic evaluation and score<sup>22</sup> for the alignment or presence of radiolucencies at two and five years postoperatively (Table I). No significant differences were seen regarding radiographic wear between the oxidized zirconium and cobalt-chromium knees (Fig. 4).

#### Patient Satisfaction

Patient satisfaction was assessed according to the BOA patient satisfaction scale<sup>20</sup>. Seventy-nine percent (twenty-seven) of thirty-four patients in both groups were enthusiastic about their outcome at five years postoperatively ( $p = 0.999$ ). Fifteen percent (five) of thirty-four patients were satisfied, and 6% (two) were noncommittal. No patients were disappointed with their knee arthroplasty outcome.

#### Retrieval Analysis

The four retrieved polyethylene inserts showed similar types and patterns of wear when analyzed (Figs. 5-A and 5-B). There were five main mechanisms of wear: deformation, scratching, abrasion, burnishing, and pitting. Backside wear was found in all specimens. There were no differences between the retrieved polyethylene liners under stereo zoom or environmental scanning electron microscopy.

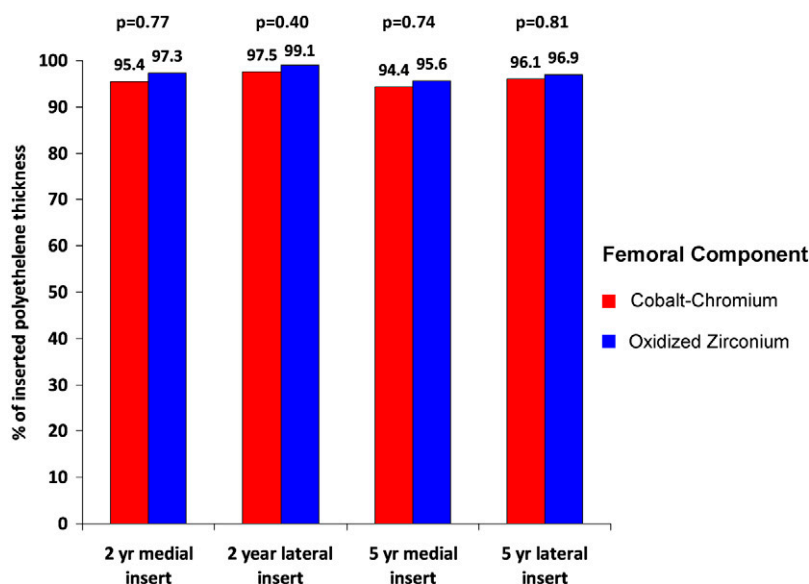


Fig. 4  
Radiographic wear analysis.



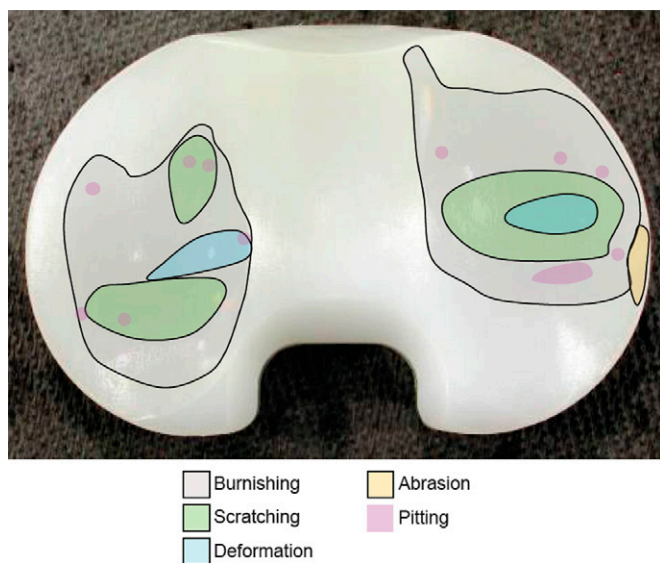


Fig. 5-A

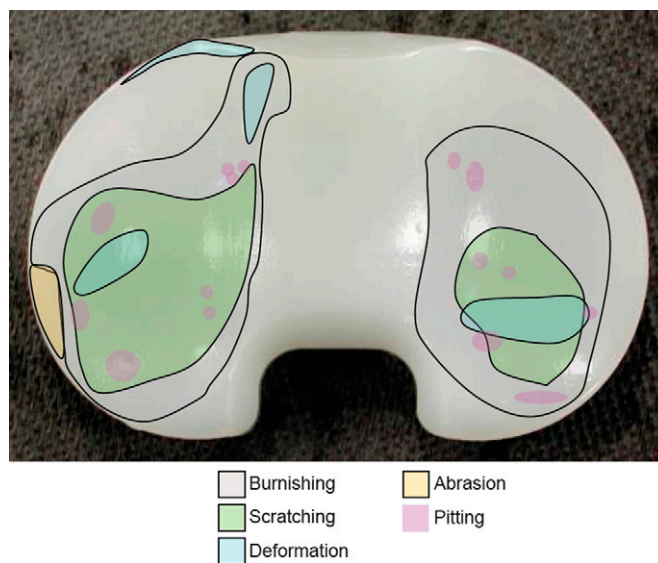


Fig. 5-B

**Figs. 5-A and 5-B** Wear maps of polyethylene from retrieval analysis. **Fig. 5-A** Wear map of retrieved cobalt-chromium polyethylene insert. **Fig. 5-B** Wear map of retrieved oxidized zirconium polyethylene insert.

## Discussion

There were no significant differences in clinical, subjective, and radiographic outcomes in patients who had bilateral total knee arthroplasty with use of an oxidized zirconium femoral component in one knee and a cobalt-chromium femoral component in the other in this prospective, double-blind, randomized controlled trial. This was consistent at both the short (two-year) and mid-term (five-year) end points. Mean differences between the groups were small, and 95% confidence intervals were narrow for all outcomes excluding the possibility that important differences exist. We did not observe the more rapid return of flexion or attainment of functional milestones in the oxidized zirconium group that were reported by Laskin<sup>4,5</sup>.

Patients had no preference or preferred the cobalt-chromium prosthesis to the oxidized zirconium prosthesis when asked at the five-year postoperative mark. We hypothesized that this may be due to differences in stress transfer from the implant to the bone between the two prostheses based on variations in the modulus of elasticity ( $E$ ) between oxidized zirconium and cobalt-chromium. However, the modulus of elasticity of Oxinium (approximately 100 GPa) is closer to that of cortical bone (approximately 15 to 20 GPa) than that of cobalt-chromium alloys (approximately 200 GPa)<sup>25</sup>. Therefore, this preference is an interesting finding that we cannot explain and needs to be followed to determine whether it remains significant at long-term follow-up.

No significant difference was detected in radiographic wear, nor was any difference seen in the retrieval analysis of the four polyethylene liners between the oxidized zirconium (two) and cobalt-chromium (two) implants. To our knowledge, this is the first report of analysis of polyethylene liners retrieved from oxidized zirconium femoral implants in total knee replacements. While it is difficult to draw firm conclusions from only four retrieved polyethylene liners, previous studies have all

been in vitro knee simulator studies. Those studies showed consistent reductions in polyethylene wear when ceramic femoral components were used instead of metal femoral components<sup>8,17</sup>. Oxidized zirconium surfaces develop less damage and produce less polyethylene wear under abrasive wear conditions in vitro<sup>8,26</sup>. We found no difference between the two prostheses in terms of detectable wear type and patterns, which may be due to the short implantation period.

Indications for the use of oxidized zirconium in total knee arthroplasty are not yet well defined. Currently, the main indication for the use of oxidized zirconium is metal sensitivity<sup>14</sup>. Metals within a biologic system undergo corrosion, releasing metal ions, which can cause a delayed-type cell-mediated hypersensitivity reaction<sup>14,27</sup>, eventually leading to early implant failure in these metal-sensitive patients<sup>27</sup>. The prevalence of metal sensitivity among the general population is 10% to 15%, with nickel sensitivity having the highest prevalence (approximately 14%), followed by cobalt and chromium<sup>27</sup>. Cobalt-chromium alloys can contain up to 1% Ni<sup>4,5</sup>, whereas surgical grade titanium alloy does not contain any Ni<sup>27</sup>. Metal sensitivity is generally to the material of the femoral component. Oxidized zirconium implants do not contain Ni and are a good alternative to the standard cobalt-alloy femoral components in these patients.

In Australia, the oxidized zirconium femoral implant costs approximately 25% more than the cobalt-chromium implant. On the basis of the results of this study, the additional cost of the routine use of oxidized zirconium implants in total knee arthroplasty cannot be justified in patients without metal sensitivity.

The strengths of this study include its rigorous design and adequate sample size such that the confidence intervals are narrow around treatment effects to exclude the possibility that important differences exist. Sample size was calculated with flexion used as the primary outcome, on the basis of the study by Laskin<sup>4</sup>, published in 2003. It was

conducted as a prospective, double-blind, randomized controlled trial, which minimizes potential bias. Bilateral simultaneous total knee arthroplasties were performed, which creates the optimal control group, with that being the contralateral leg. The patients were enrolled from the practice of single surgeon with standardized surgical technique and protocols.

The limitations of this study include the fact that there is no accurate method to determine polyethylene wear of implanted components without retrieval of the polyethylene liner. Therefore, subsequent failure of the implant is required as an end point in order to study polyethylene wear. There was no formal quantitative measurement of wear such as weighing of the retrieved liners. Wear was determined with use of radiographs, and they showed no difference between the two implants. However, a longer duration of follow-up is required to find any significant differences in wear. Synovial fluid analysis for polyethylene particles is a consideration to more accurately and objectively evaluate wear. This study was powered appropriately to detect a clinically important difference of 10° of knee flexion postoperatively, on the basis of the previous study by Laskin, which showed a more rapid return of flexion in the oxidized zirconium group. However, there are many factors influencing knee flexion that may bias this small randomized study, and it is possible that Laskin's finding was significant on the basis of chance. We recognize the inherent weakness in our study design using flexion to determine our sample size and as a primary outcome measure. Another weakness is that it is difficult for patients to distinguish functional status between left and right knees when completing the outcome scores. They were asked specifically to complete the score for each knee

separately, and we know of no better functional outcome measures that could have been used.

Polyethylene wear and osteolysis remain a major problem in the long-term survival of total knee replacements. Research has focused on methods to reduce polyethylene wear from the bearing surface such as the oxidized zirconium-polyethylene bearing couple examined in this study. There were no adverse events associated with the use of the oxidized zirconium femoral implants. Continued follow-up of this cohort of patients is planned to establish whether oxidized zirconium femoral implants will have an improved in vivo long-term survivorship, compared with the current standard of cobalt-chromium femoral implants in total knee arthroplasty, to warrant the additional cost. ■

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