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Ten year comparison of Oxidized Zirconium & Cobalt Chrome Femoral Components in Total Knee Arthroplasty- a randomised controlled trial

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Disclosures

Leo Pinczewski has received institutional research support from Smith and Nephew

Justin Roe is a stock holder with Optimised Ortho Pty Ltd

Introduction

- PE wear leading to osteolysis is a major cause of failure of total knee replacements, accounting for 29.1% of revision TKRs after 13 years in Australian NJR Registry
- Oxidized Zirconium (OxZr, Smith+Nephew) as a material for femoral implant
 - Lower coefficient of friction
 - Favourable low wear rates in laboratory studies
 - Safe and effective in medium term clinical studies
- No medium to long term studies showing clinical superiority of OxZr to Cobalt-Chromium (CoCr) femoral components in TKR

Aim

To compare the clinical outcome of OxZr and CoCr femoral components with respect to

- Clinical and subjective outcomes
- Incidence of adverse events or complications
- Clinical signs of wear



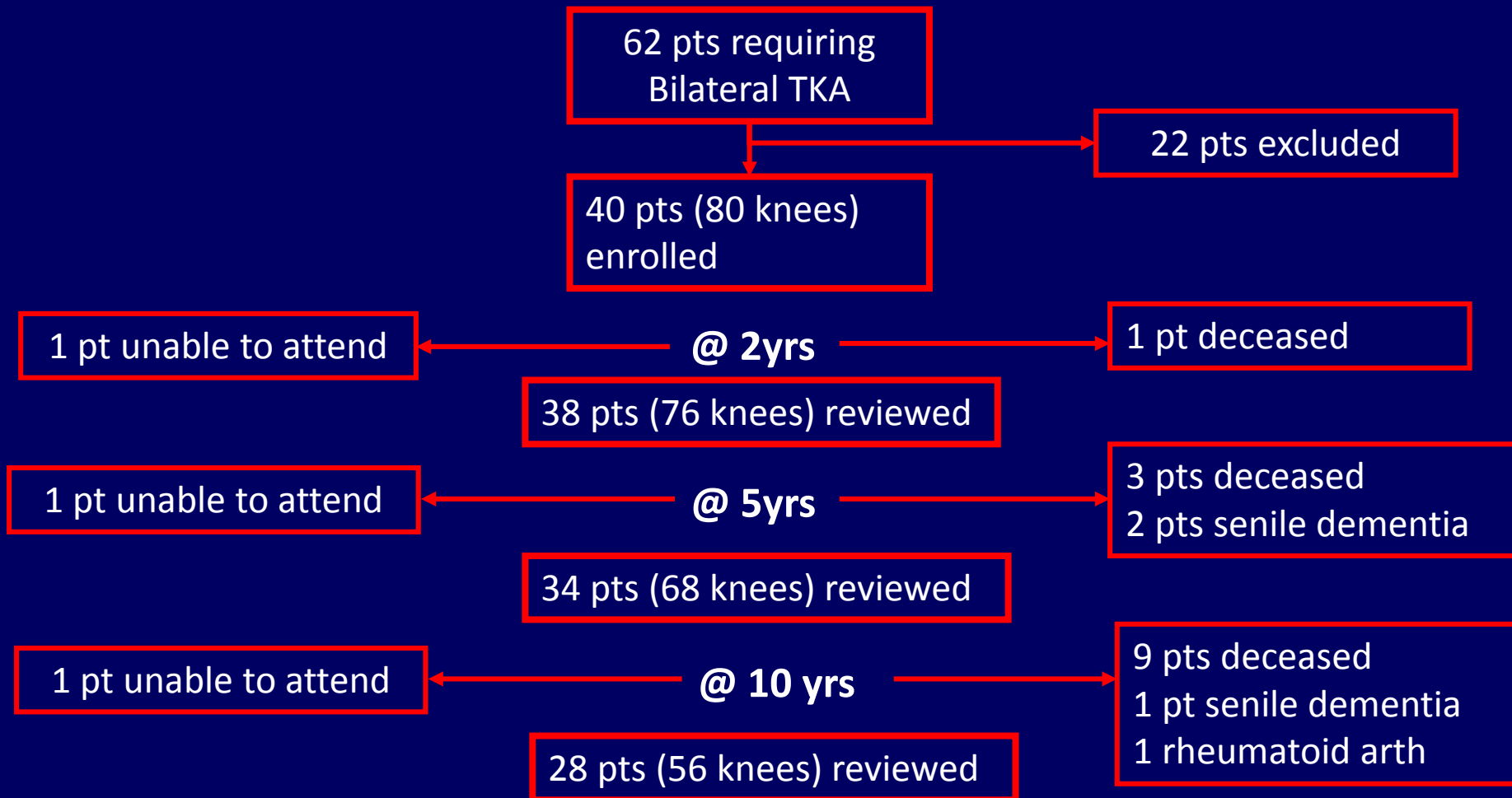
Study Design

- Double Blind Randomised Controlled Trial
- Single surgeon
- January 2002-December 2003
- Patients undergoing Simultaneous Bilateral TKA
 - Cemented Genesis™ II CR TKA, deep dished tibial PE (not XLPE)
- Patellae “selectively” resurfaced bilaterally
- Patients were randomized at the time of consent to receive OxZr Femoral component into LEFT or RIGHT knee

Outcome Measures

- Clinical: Examination (supine ROM)
- Subjective:
 - WOMAC, Knee Society Score, Knee Osteoarthritis Outcome Score (KOOS), BOA Patient Satisfaction Scale, separate subjective assessment forms for each knee
- Radiographic:
 - Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System (Ewald CORR 1989)
 - Clinical assessment of polyethylene thickness, Metal-to-middle method (Collier J Arthrop 2003)

Participant Flow



Demographics

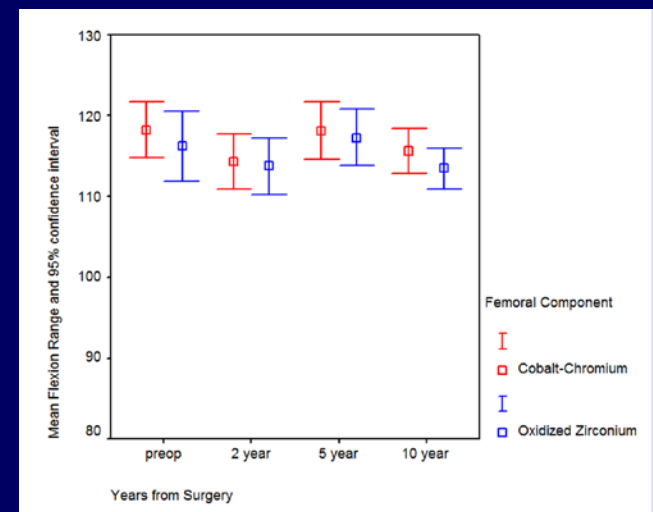
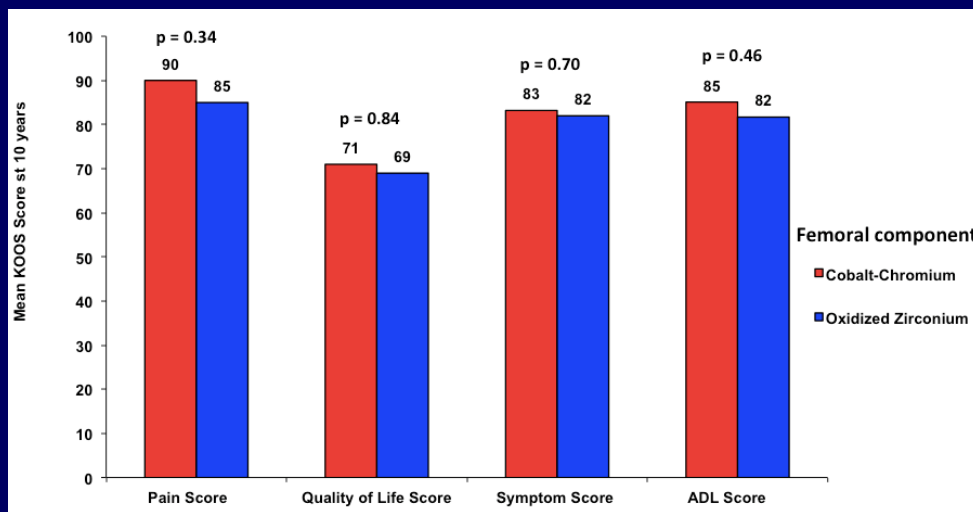
- 40 patients
 - No SD in any pre-op category
- 15 Female: 25 Male
- Mean age 68 years (range 55-85)
- 23 OxZr in RIGHT knee / 17 OxZr in LEFT knee
- 11 underwent bilateral patellar resurfacing

Further Surgery and Adverse Events

- 2 patients required bilateral patellar resurfacing @ 5 years
- PE liner exchange performed at time of resurfacing. allowed subsequent retrieval analysis to be performed
- 1 patient underwent unilateral patellar resurfacing (OxZr TKA) @ 7 years
- No adverse events documented over 10 years

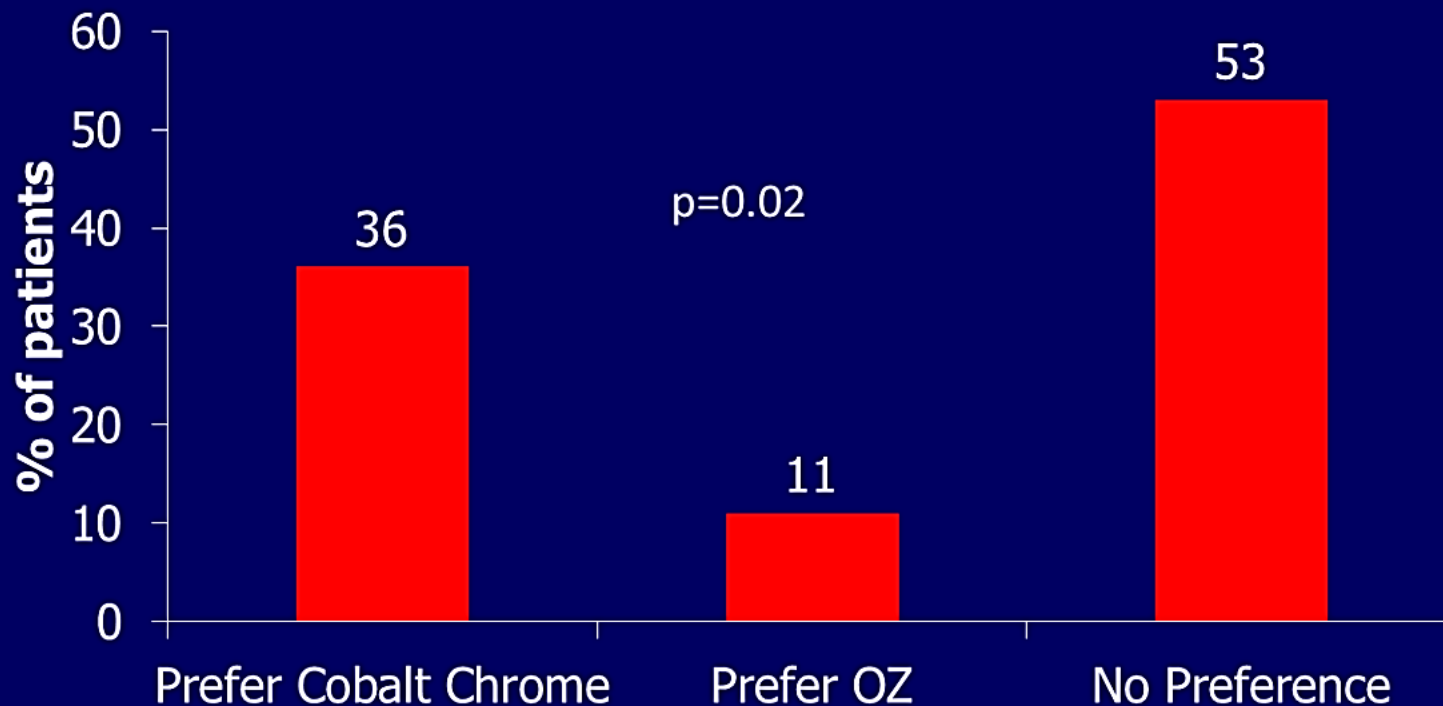
Results: 10 years

- No significant difference in KOOS Scores
- No significant difference in ROM at any time



IS ONE KNEE BETTER THAN THE OTHER?

- Significantly more patients reported a preference for the CoCr knee than the OxZr knee ($p=0.02$)



Results: Radiological Examination

No significant difference

- Radiological alignment ($p=0.82$)
- Knee Society Graded Radiolucenies <4
64% Cobalt Chrome and 32% OZ ($p=0.77$)
- Polyethylene thickness medial ($p=0.75$) or lateral ($p=0.64$) as per Collier et al 2003

Conclusion

- This study confirms that no adverse events were associated with the use of cemented OxZr femoral components over 10 years
- No difference in clinical, subjective and radiographic findings at mid-term follow up to 10 years.
- No evidence to support routine use of OxZr over CoCr femoral components
- Improved in vivo survivorship of OxZr has yet to be established