ABSTRACT

Purpose. To report the early results of the Oxinium Genesis II prosthesis with an oxidised zirconium femoral component in 55 patients.

Methods. 71 knees in 21 men and 34 women aged 32 to 75 (mean, 55) years were evaluated; 16 of the patients had bilateral staged total knee replacements with a mean interval of 9 (range, 6–16) months between surgeries. The indications for surgery included osteoarthritis (n=57), rheumatoid arthritis (n=13) and revision from a unicompartmental knee replacement for osteoarthritis (n=1). Postoperatively, patients were evaluated using the Knee Society score (KSS), the modified Oxford Knee Score, and the SF-12 health survey, as were component position, leg and knee alignment, and prosthesis-bone interface or fixation on radiographs.

Results. The mean follow-up was 62 (range, 51–88) months. The mean KSS, Oxford Knee Score, and SF-12 physical component score improved significantly. Radiolucent lines (<2 mm) were noted in the tibial cement-bone interface in 17 knees (most commonly in zones 4 and 1) and in the femoral cement-bone interface in one knee. The alignment of the knees and positioning of the components were acceptable. There were no revisions for septic or aseptic loosening.

Conclusion. Early results of the Oxinium Genesis II prosthesis are comparable to the standard total knee prostheses.

Key words: arthroplasty, replacement, knee; zirconium oxide

INTRODUCTION

Most total knee replacement (TKR) prostheses consist of a cobalt-chromium femoral component and a tibial insert made of ultra-high molecular weight polyethylene (UHMWPE). The wear of the polyethylene generates submicron particles that are phagocytosed by macrophages and other cells. This leads to the synthesis and release of proinflammatory mediators that signal osteoclastic resorption and depress osteoblastic function and eventually lead to
osteoysis. Failure of the polyethylene components is less frequent and severe in TKR than total hip replacement. Nonetheless, the stress generated in a polyethylene tibial plateau is greater than in a polyethylene acetabular component. Oxidised zirconium is better than cobalt chromium in resisting roughening, frictional behaviour, biocompatibility, and reducing the wear of the polyethylene.

Ceramic femoral components have greater scratch resistance but are more brittle. Oxidised zirconium femoral components can reduce polyethylene wear substantially when used for fixed-bearing TKR. The Oxinium Genesis II (Smith and Nephew, Memphis [TN], USA) prosthesis consists of a femoral component made of zirconium and niobium (with the surface oxidised by thermal diffusion to transform the surface into zirconium oxide ceramic, approximately 5 µm in thickness), a patellar component made of polyethylene, and a modular tibial component with a conforming UHMWPE insert (compression moulded or ram extruded with annealing) in a titanium-aluminium-vanadium alloy base plate.

This study report the early results of the Oxinium Genesis II prosthesis with an oxidised zirconium femoral component in 55 patients.

MATERIALS AND METHODS

This study was approved by the ethics committee of our hospital, and informed consent was obtained from each patient. Between November 2003 and May 2006, 67 patients who underwent 84 TKRs using the Oxinium Genesis II prosthesis were prospectively recruited. Patients with active infection, malignancy in the involved knee, severe osteoporosis, chronic neuromuscular disease, significant ligamentous laxity in the knee, and severe fixed deformity (30° flexion, 30° varus/valgus) were excluded. 12 of the patients were lost to follow-up, despite attempts to trace them by reviewing hospital records, contacting their general practitioners, contacting their next of kin, and tracing them via telephone directories.

The remaining 21 men and 34 women (71 knees) aged 32 to 75 (mean, 55) years were evaluated. 16 of them had bilateral staged TKRs with a mean interval of 9 (range, 6–16) months between surgeries. The indications for surgery included osteoarthritis (n=57), rheumatoid arthritis (n=13) and failure of a unicompartmental knee replacement for osteoarthritis (n=1).

A medial parapatellar approach was used. The infrapatellar fat pad and any osteophytes were excised. Soft tissues were released as appropriate to achieve normal knee alignment. The femur was cut in 5° of valgus in men and 7° of valgus in women using intramedullary instrumentation. The tibia was cut using an extramedullary alignment guide. The patella was routinely resurfaced. Fixation was by cementation.

Full weight bearing was allowed one day after surgery. Patients were followed up at 6 weeks, 3, 6, and 12 months, and thereafter yearly. Functional outcome was assessed using the Knee Society scores, the modified Oxford Knee Score (range, 0–48), and the SF-12 health survey. Radiographic outcome was evaluated using the Knee Society scoring system described by Ewald by 2 assessors, one of whom reassessed the radiographs after 2 months. Standardised anteroposterior radiographs (with the patient bearing full weight) and lateral radiographs (with the knee flexed to 30°) were assessed for component position, leg and knee alignment, and prosthesis-bone interface or fixation.

It was assumed that the study population was not normally distributed and hence the Wilcoxon matched pairs signed-rank test was used to analyse the significance of improvement in the Knee Society scores, modified Oxford Knee Score, and SF-12 score. A p value of <0.05 was considered statistically significant.

RESULTS

The mean follow-up was 62 (range, 51–88) months. The mean Knee Society knee score improved from 39 (range, 0–70) preoperatively to 92 (range, 31–100) in the latest follow-up. The mean Knee Society functional score improved from 53 (range, 0–90) to 90 (range, 35–100). The mean modified Oxford Knee Score improved from 14 (range, 3–32) to 40 (range, 12–48). All these increases were significant (p<0.05, Wilcoxon matched-pairs signed-rank test). For the SF-12 health survey, the mean physical component score improved from 30 (range, 17–59) to 42 (range, 21–58), and the mean mental component score improved from 42 (range, 17–65) to 53 (range, 26–67); only improvement in the former was significant.

At the latest follow-up, radiolucent lines (<2 mm) were noted in the tibial cement-bone interface in 17 knees (most commonly in zones 4 and 1) and in the femoral cement-bone interface in one knee (Fig.). The knee alignment and positioning of the components were acceptable. The mean total valgus angle was 7.0° (95% confidence interval [CI], 6.8–7.2). The mean femoral flexion was 96.7° (95% CI, 96.3–97.1). The
The mean tibial angle was 88.7º (95% CI, 88.2–89.2). The mean femoral flexion on lateral radiographs was 0.8º (95% CI, 0.4–1.2) and the mean tibial angle on lateral radiographs was 87.8º (95% CI, 87.2–88.4).

There was no revision for septic or aseptic loosening. Six patients had complications: one had a superficial wound infection that resolved with oral antibiotics. Two underwent sequential lateral release and excision of the lateral facet for persistent knee pain. Two others underwent a manipulation under anaesthesia within 6 months for poor range of motion, and regained full extension and flexion (90º and 100º). They had had fixed flexion deformities of 20º and 30º with preoperative range of motion limited to 0º to 90º. One patient underwent a manipulation under anaesthesia and exchange of a smaller polyethylene insert. She had had a poor range of motion with a 20º fixed flexion deformity, further flexing to 60º. At the latest follow-up, her range of motion improved to 0º to 80º.

**DISCUSSION**

The outcomes in our series were superior to those reported for similar series using oxidised zirconium femoral components.14,21,22 Notably, our patient cohort was younger (mean age, 55 years) than other cohorts with mean ages of 59 years21 and 68 years.14 We offered younger and more active patients the oxidised zirconium femoral component, because of its decreased wear rates and potentially longer implant survivorship.

Wear debris from polyethylene tibial inserts can result in osteolysis and subsequent aseptic loosening. To tackle this problem, efforts have focused on improvement in implant design and quality of UHMWPE.3,23–25 Improvement in polyethylene has reduced the failure rate due to delamination, but submicron wear particles generated from the hard counterface of the femoral component result in adhesive and abrasive wear problems.26

Oxidised zirconium is better than cobalt chromium in resisting roughening, frictional behaviour, and biocompatibility.7 The surface of the femoral component is zirconium oxide ceramic (5 µm thick) and not simply an external coating.11,14 It has a lower wear rate under normal and abrasive conditions in a knee wear simulator.8,10,11 It also has superior scratch resistance in a knee wear simulator that allows 6º of freedom of motion over 4 million increased force cycles, and the wear of the UHMWPE is reduced 78%.9 Retrieval studies also show less damage to the femoral components and the polyethylene inserts.27–30 In 73 patients followed up for 2 years, no evidence of adverse effects was noted.14 In 95 knees followed up for 5 years, only one case of aseptic loosening was noted, and the survivorship was 99% at 7 years.21 In 34 patients (68 knees) having simultaneous bilateral TKRs randomised to receive an oxidised zirconium femoral component in one knee and a cobalt chromium femoral component in the contralateral knee,22 the mean functional KSS score was 89 at 2 and 5 years in knees with an oxidised zirconium femoral component, and there was no significant difference between left and right knees. However, the age range of the patient cohort was not reported.

In 99 knees with a press-fit condylar modular total knee system followed up for 4 to 6 years, non-progressive radiolucency lines were noted at the cement-bone interface in 39% of the knees, but there was no prosthesis loosening.31 Although every effort was made to standardise the radiographs, minor variations in tilt of the X-ray beam or a patient’s knee could obliterate a thin radiolucent line if the beam was not aligned perfectly. Conventional radiographs are considered unreliable as a means to identify radiographic interfaces, for which fluoroscopically-assisted radiography is recommended.32,33 Nonetheless, the presence of non-progressive, thin radiolucent lines in the early postoperative period do not seem to affect migration or presage loosening.34 These radiolucencies are defined by a layer of reactive sclerosis, which is visible as a white line and may
be due to failure to inject cement into the sclerotic cancellous bone.\textsuperscript{35}

One limitation of our study was that there was no randomisation or controls. The follow-up period was short, partly because the prosthesis was introduced relatively recently. Preclinical laboratory testing does not always concur with in vivo performance, for example, the early clinical failure of a highly crystalline UHMWPE (Hylamer)\textsuperscript{36} or the ASR hip resurfacing.\textsuperscript{37} Therefore, early clinical reports on the presence of any adverse events of a new prosthesis are necessary. In addition, 18\% of our patients were lost to follow-up, which may have caused a bias. However, patients lost to follow-up are not uncommon in medium-to-long-term outcome studies, despite attempts to trace them. Finally, inter- and intra-observer reliability of the radiographic assessment was not evaluated. Longer-term studies are needed to determine whether potential reduction in wear of the polyethylene translates into decreased wear particle-induced osteolysis, loosening and revision rates as well as better survival.

\section*{REFERENCES}