



Medium term outcome of Titanium Nitride, mobile bearing total knee Replacement.

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This retrospective study examined the medium term outcome of 305 Titanium Nitride (TiN) Mobile bearing total knee. At ten years after the start of the study, there was a significant improvement ($p < 0.0001$) in the post-operative knee scores. The ten year survival with revision for any reason as the end point was 95.1% (95% CI 92.4 to 97.8). The ten year survival rate with revision for aseptic loosening as the end point was 99.1% (95% CI 97.8 to 100%). A total of 15 knees (4.9%, overall) required revision. No cases were revised due to sepsis. Based on these results, the surface Titanium Nitride ceramic, mobile-bearing total knee replacement has proved to be a reliable implant at 10 years when used in primary knee replacement.

Keywords : titanium nitride ; uncemented ; knee replacement ; mobile bearing ; revision.

INTRODUCTION

The number of Total Knee Replacement (TKR) procedures recorded in national joint registry for England and Wales in 2011 was 84,653, a 3.3% increase compared to 2010 (22). The long term results of total knee replacement with a fixed bearing design have shown a high degree of clinical success. However, implant loosening and polyethylene wear became recognised as a long-term cause of late failure (12,28,29). Total knee replacements using mobile-bearings were designed to improve the congruency between the femoral component (particularly through the first 40 degrees of flexion)

and the polyethylene insert and to uncouple the multi-directional shear forces acting on the polyethylene ; there is also the theoretical reduction of stress across the bone-implant interface (4,12,20). TKR using mobile-bearing implants has produced good medium to long term survival (1,3,5,21) although this has not proved to be superior in the short to medium term as published in meta-analysis studies and the major joint registries (17,22,25). Titanium Nitride (TiN) surface modification (30 μm) was introduced to further minimise second order wear of the polyethylene as a result of a smoother, more scratch resistant and a possibly more wettable surface (10,19). Additionally, in the case of cementless application, the increased osteophilic properties suggest an improved bone ingrowth (8,24,33).

From 2003, we have continuously used a ceramic surfaced mobile bearing total knee replacement.

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In 2013, we initiated a retrospective study of this prosthesis and report our 10 year results with a minimum of 36 months as a lower cut-off, with particular emphasis on implant survival, the radiological incidence of component loosening and assessing the clinical outcome using current scoring systems. Our hypothesis was that design of a ceramic surfaced TKR (CCI, Implantcast, later renamed ACS, Implantcast, Buxtedhude, Germany) did not impede good early to medium term results and therefore would allow advantages TiN to be realised in longer term.

PATIENTS AND METHODS

Between January 2003 and January 2010, all patients who underwent a titanium nitride ceramic surfaced TKR were entered retrospectively into the study. A total of 263 patients were recruited of whom 42 underwent bilateral procedures (305 total knee replacements in total). 289 (97%) of procedures were carried out by the senior author or fellowship-trained surgeons at Morriston hospital in Swansea, Wales. The final follow-up cut-off date was designated as January 2013 so that all patients had a minimum follow-up of 36 months (mean 79 ; 36 to 122). The non-rigid, positive indications for using the Titanium Nitride surfaced, mobile bearing TKR, included a younger age (< 75) and high expected activity or heavy body build (BMI > 35 kg/m²) ; exclusions included severe osteoporosis requiring treatment, radiologically evident inflammatory arthropathy or valgus deformity of more than 25 degrees (due to anticipated loss of mechanical support for the medial tibial plateau). 1 patient included in the study underwent a conversion from a unicondylar knee replacement to a TKR. Excluded cases underwent a fixed bearing non-modular, tantalum metal mesh, posteriorly stabilised, uncemented NexGen (Zimmer, Warsaw, USA) prosthesis.

All patients had been reviewed within our follow-up protocol (6 weeks, 6 mth – optional, 1 yr, 2 yr, 3 yr, 5 yr, 8 yr, 10 yr) (31). After 6 weeks, the patients were routinely reviewed by a senior Surgical Nurse Practitioner where complications, scorings and radiology assessment were undertaken. The clinical data at follow-up were assessed according to the joint and function tools of the American Knee Society (AKS) (14) and Oxford knee score (6) as well as the recording of complications relating to the surgery.

The radiographs were standard weight bearing anteroposterior (AP) and lateral radiographs with the patella directed forwards (12), and were assessed according to the Knee Society rating system guidelines (7) by a single examiner (ABM). All radiographs were digitised and measured using the PACS software (Agfa, USA) and were evaluated for radiolucency at the bone-implant interfaces, the lateral and medial joint spaces, any change in the position of the component and osteolysis. Radiolucency at the bone-implant interface was rated in seven zones in the anteroposterior radiograph and three zones in the lateral radiograph of the tibial component and in seven zones in the lateral film of the femoral prosthesis. The width of observed radiolucency for each zone was added for the three components in order to generate a score. A score of ≤ 4 was considered insignificant, 5 to 9 as indicating that a patient should be followed closely for progression and ≥ 10 as possible or impending failure of the prosthesis.

A paired *t*-test was used to compare pre- and post-operative scores. Pearson correlation was used to test the association between radiological parameters and functional outcome measures. Survival was analysed by the Kaplan-Meier Method (15) using re-operation for any cause as the endpoint as well as further analysis curves for aseptic loosening and exclusion of femoral prosthetic fractures.

RESULTS

A Total of 263 patients (305 knees in 149 men and 114 women) underwent TKR using TiN surfaced prosthesis between January 2003 and January 2010. There was a mean age of 67 years (45 to 89) at operation. The predominant pre-operative diagnosis was osteoarthritis (94%) in physiologically young adult men with good bone stock. By ten years, 41 (15.6%) patients had died leaving 222 patients (84.4%) available for review ; One patient was suspected of having a pulmonary embolism three days post-operative, the remaining 40 patients died at minimum four months post-operatively (mean 56 months ; 4 to 108) for causes not thought to be related to the primary surgery. The knee replacements had been functioning well in all of these patients at the time of death.

Of the 222 patients, the outcome was known for 179 (80.6%). We directly contacted the remaining 43 patients (19.4%) via post ; all of them responded

to our request to attend dedicated arthroplasty follow up clinics in January 2013. By that date, the clinical and radiological outcomes of all the 222 patients were known. 15 knees (4.9%) were identified as requiring a further operation during the study period and these will be discussed separately.

The manual alignment instruments supplied by the company (Implantcast, Buxtehude, Germany) were used for the procedure. The posterior cruciate ligament was sacrificed in all study patients.

There were 297 (97.4%) uncemented, 3 (1%) cemented and 5 (1.6%) hybrid TKRs (cemented tibia, uncemented femur). The polyethylene components were sterilised with Ethylene Oxide.

The cemented (including hybrid) TKRs were used when concern was raised regarding tibial bone quality and the ability to support an uncemented prosthesis. The mean femoral component size was 4.44 (size 2 to 6) while the mean tibial size was 5.20 (size 2 to 7). Of the 305 knees, the inserts were 10mm thick in 187 (61.3%), 12.5 mm thick in 104 (34.1%) and 15 mm in 14 (4.6%) knees. The thickness of polyethylene liner increased with the size of tibial component. Patella implants were not routinely used (29): 5 knees (1.6%) in 5 patients underwent uncemented patella replacement as part of the primary procedure indicated by the severity and morphology of the degeneration observed at operation. No tourniquet was used throughout the operations. Most patients underwent a general anaesthetic, used Aspirin for two weeks and calf pump as a routine postoperative thrombo-prophylaxis. The latter was changed to calf pumps for three days followed by aspirin for 6 weeks (75-150 mg od, po) from 2007 onwards. All patients had peri-operative antibiotics. All patients had drains which were removed 24-48 hours post-operatively and mobilised the day after surgery. All patients had autologous cell salvage blood collected for up to 6 hours post-operatively which was reinfused when volumes permitted (95%).

At their final follow up review, the mean post-operative knee flexion was 101 degrees (78 to 125 degree) while the mean flexion contracture measured 3 degrees (0 to 6) compared with mean knee flexion of 83 degree (70 to 96) and flexion contracture of 5 degrees (0 to 10) pre-operatively.

All the knee scores showed a highly significant improvement compared with the pre-operative scores (*t*-test, $p < 0.0001$); The mean AKS score improved from 39 (35 to 43) pre-operatively to 77 points (73 to 79). The mean AKS function score improved from 31 (25 to 36) pre-operatively to 69 points (66 to 72), and the Oxford knee score from 17 points (8 to 28) to 40 (34 to 45) post-operatively.

Radiographs of a total of 259 knees in 222 patients were assessed. Of these, 20 knees (7.7%) showed minor radiolucency at the bone-prosthesis interface. None of the knees produced a total score of ≥ 4 in any of the three components measured. Radiolucency lines observed did not exceed 2 mm in any zone and none progressed over the period of review. There was no correlation ($r = 0.43$) between radiolucency and functional outcome measures. No radiolucency was noted at the bone-prosthesis interface of the 5 patellar components.

Revision procedures

Of the 305 cases, 15 knees (4.9%), required a further operation for: prosthetic fracture in 4 (1.3%), Mal-positioning in 4 (1.3%), loosening and subsidence in 2 (0.7%), pain in 2 (0.7%), function loss in 1 (0.3%), secondary patella resurfacing in 1 (0.3%) and traumatic medial collateral ligament rupture in 1 (0.3%).

Fracture of the prosthesis occurred in four knees at a mean 36.75 months (20 to 66 months). This involved size 5, right femoral components only. Intra-operatively, there was little metallosis debris but titanium nitride staining of the tissues observed. In all cases the posteromedial femoral flange was found to be detached and the polyethylene bearing worn through to expose the tibial medial base-plate to the femoral component. The fracture line was through the posterior bevel of medial side of the femoral component. The components were replaced through a single procedure and the knees re-attained intrinsic stability post-operatively.

Two patients were revised for aseptic loosening of the prosthesis at a mean 49.66 months after the operation (19 to 79 months). At revision, the femoral component was removed relatively easily

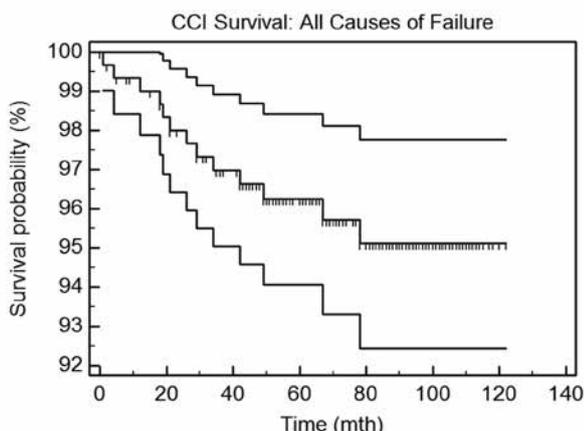


Fig. 1. — Survival curve for the study group using revision for any cause as a failure.

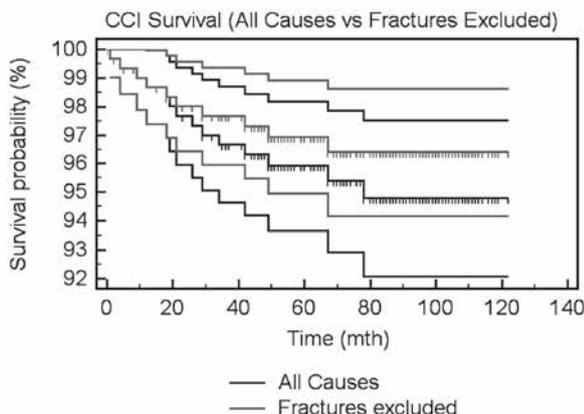


Fig. 2. — Survival curve comparing revisions due to all causes and with prosthetic fractures excluded.

in one knee and the tibia component was loose in the other revision. There were no indications of infection and the microbiology result of intra-operative fluid and soft tissue samples did not reveal growth on prolonged culture mediums.

There were four revisions for instability ; three of them revealed significant opening to valgus stress in mid-flexion and one knee was opening in ≥ 20 degree flexion. The stability was achieved by increasing the bearings to 15mm.

The 2 patients revised for unexplained pain did not demonstrate evidence for infection or loosening intra-operatively. Only one patient underwent secondary patella resurfacing for anterior knee pain

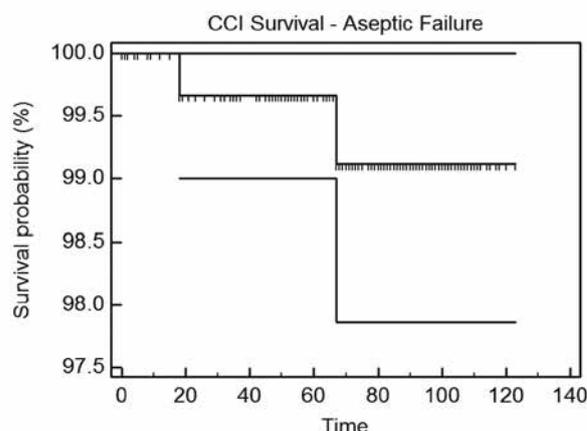


Fig. 3. — Survival curve using revision for loosening as a failure.

retaining the original knee components. One patient required revision for severe instability due to traumatic medial collateral ligament rupture and lateral femoral condyle fracture following a fall three months post-operatively. The components were found to be well fixed : demonstrates the bone ingrowth at retrieval. One patient required revision surgery for functional loss due to arthrofibrosis.

Survival analysis, using further revision for any reason, showed a 10 year survival of 95.1% (95% CI 92.4 to 97.8) (Fig. 1). Survival curves excluding prosthesis fractures gave a 10-year survival of 96.45% (95% CI 94.2 to 98.7) (Fig. 2). The ten year survival rate with revision for aseptic loosening only as the end point was 99.1% (95% CI 97.8 to 100) (Fig. 3).

DISCUSSION

Cobalt Chromium alloy, with its optimal wear characteristics and mechanical properties has been the material of choice for the majority of femoral and tibial components in TKRs. Adding a Titanium Nitride ceramic surface (30 μ m) will increase the smoothness and hardness of the bearing interface presented to the polyethylene spacer (19,23,34). This is applied via Physical Vapour Deposition (PVD) to the CrCoMo substrate. The value of PVD technology rests in its ability to modify the surface properties of a device without changing the underlying material properties and biomechanical functionali-

ty. TiN ceramic surfaces have shown up to 98% reduction in wear against polyethylene in hip simulator studies (23). The hard surface also provides protection in the presence of third body wear such as polymeric or cement debris and the surface scratch resistance prevents implant damage at excessive contact loads (19,23,30). The ceramic surface is more hydrophilic than bear CoCrMo and a better wettability will theoretically increase the lubrication, decreasing the coefficient of friction and the wear (19). The corrosion mediated release of cobalt and chromium ions has also shown to be reduced by the effective sealing of the surface TiN ceramic (10,16,34).

For cementless application, improved bony ingrowth has been observed and thought to be mediated through its stimulatory effect on osteoblast proliferation while maintaining a high degree of differentiation (24,33). TiN have also been shown to minimise bacterial proliferation and the corrosion action of bacteria on the alloy (27), and might provide a solution to metal allergy, protecting patients from adverse allergic reactions, particularly to Nickel present in low concentrations in the Chrom-Cobalt-Molybdenum (CrCoMo) substrate (18). The prevalence of radiolucent lines in our study was 7.7% at 10 years, however, all were insignificant according to the Knee Society guidelines and most radiolucencies on the tibial side were small and restricted to the extreme edges ; no radiolucency occurred around the central peg. The prevalence of radiolucent lines is reported to be between 20% and 60%, the higher rates being seen in studies with a more than ten-year follow-up (26, 32). The osteoconductive stimulatory effect of TiN on bone ingrowth is a possible reason for the absence of significant radiolucency in our series indicating good bony fixation.

The survival of our series at 10 years was 99.1% (95% CI 97.8% to 100%) for revision due to wear and loosening, supporting our hypothesis that the wear rate would be minimal at this stage with this design. Four knees (1.3%) required revision for prosthetic fracture. This complication occurred with a single size prosthesis, size 5, over the medial femoral condyle at the junction between the posterior and distal chamfer of the implant. The design

of this junction resulted in a narrow surface cross section, hence a high stress concentration. After the identification of a small number of failures overall, the design was modified to decrease the stress at the vulnerable junction and is currently marketed under the name of the ACS TKR (Implantcast, Buxtehude, Germany). There have not been any reported prosthetic fractures with the modified design. None of the ACS TKRs have been included in this study but there have been no failures, for any reason, in this group at our institution since the change.

The increased congruity and consequential reduction in pressure (load per unit area) necessitates a mobile bearing design of TKR to accommodate vertical axis rotation during the flexion cycle (4,11,20). However, the results from the UK National Joint Registry and other major registries does not reveal an increased survival rate over fixed bearing designs in the medium term (22,25). It is recognised that increased surgical skill is required to implant a mobile bearing design (2,13) which in the short term, increases failure rates which manifest as spinout, pain and loosening. This is supported by the shape of the KM survival curve which is concave initially. This represents a factor causing failure present at the time of surgery which becomes less influential as implant life increases. Failures due to wear or lyses tend to occur later and are related to implant life. This gives a later convex shape to the KM curve. Figure 1 shows the shape of the KM curve to be concave only which suggests that failures in this series are related to surgical technique and not implant life, as yet. It would not be expected that the TiN ceramic surface would give an increased implant survival until the onset of wear induced lyses would normally be expected. This study life-span is too short to observe this feature although it can still be hypothesised. There is no suggestion that the TiN surface reduces survival during the study period.

It is recognised that this study was subject to retrospective bias (9) and insufficient follow up duration to determine the longer-term outcome of this prosthesis. However, it is unique in that it represents the only reported series using TiN ceramic surfaced mobile-bearing TKRs showing a promis-

ing medium term functional and radiographic outcome. Continued follow-up of this prosthesis is being undertaken.

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