Simultaneous cemented and cementless total knee replacement in the same patients

A PROSPECTIVE COMPARISON OF LONG-TERM OUTCOMES USING AN IDENTICAL DESIGN OF NEXGEN PROSTHESIS

The purpose of this prospective, randomised study was to evaluate the clinical and radiological results comparing the identical cemented or cementless NexGen total knee prostheses implanted bilaterally in the same patient. Sequential simultaneous bilateral total knee replacements were performed in 50 patients (100 knees). There were 39 women and 11 men with a mean age of 58.4 years (51 to 67) who received a cemented prosthesis in one knee and a cementless prosthesis in the other. The mean follow-up was 13.6 years (13 to 14). At final review, the mean Knee Society scores (96.2 (82 to 100) versus 97.7 (90 to 100)), the mean Western Ontario and McMaster Universities osteoarthritis index (34.5 (4 to 59) versus 35.6 (5 to 51)), the mean ranges of knee movement (124° (100° to 140°) versus 128° (110° to 140°)), mean patient satisfaction (8.1 (SD 1.9) versus 8.3 (SD 1.7)), and radiological results were similar in both groups. The rate of survival of the femoral components was 100% in both groups at 14 years. The rate of survival of the cemented tibial component was 100% and 98% in the cementless tibial component. No osteolysis was identified in either group. Our data have shown no advantage of cementless over cemented components in total knee replacement.

There is debate regarding the possible benefits of cementless fixation in total knee replacement (TKR).1 These include preservation of bone stock, ease of revision, the avoidance of complications of cementing, but most importantly, improved long-term survival of the prosthesis.1-5 Although it is now clear that aseptic loosening is mainly related to polyethylene wear debris rather than failure of cemented fixation,1-5 the question remains whether cementless TKRs have an improved long-term survival. This can only be answered by a randomised trial comparing the two methods of fixation. To date there have been few randomised, prospective trials in which cemented and cementless fixation in primary TKR have been compared in heterogeneous patient groups.1-5 We are unaware that comparison of the cemented and cementless TKR in the same patient has been examined. Such a strategy eliminates variability introduced by differences in gender, age, weight, comorbidities, bone quality, and activity level and permits more meaningful comparison of the impact of fixation on the outcome. The primary purpose of this prospective, randomised study was to evaluate the clinical and radiological results in the same patients after implanting NexGen posterior cruciate retaining (NexGen CR; Zimmer, Warsaw, Indiana) total knee systems that were identical in geometry but differed with regard to their fixation method (with or without cement) (Fig. 1). Secondly, rates of complication and revision were compared between the groups.

Patients and Methods
We enrolled 53 patients (106 knees) who underwent sequential simultaneous bilateral TKR between January 1997 and February 1998. The study had ethical approval and all patients provided informed consent. We excluded one patient because he declined to participate, leaving 52 patients available for evaluation. Two patients were lost to follow-up before two years, leaving 50 patients (100 knees) with a mean follow-up of 13.6 years (13 to 14) (Fig. 2). There were 39 women and 11 men.

The mean height of the patients was 155.3 cm (140 to 170) and the mean weight was 64.0 kg (48 to 80). The mean body mass index (BMI) was 26.6 kg/m² (24.5 to 27.7). The mean age at the time of the surgery was 58.4 years (51 to 67). All patients had a genu varum deformity of between 5° and 15° resulting from osteoarthritis with Ahlbäck grade6 III, IV or V in both knees. No patient in either group had undergone previous knee surgery.
Randomisation to a cemented or cementless NexGen CR Prosthesis was accomplished with use of a sealed study number envelope, which was opened in the operating theatre before a skin incision was made. Pre-operatively, there was no significant difference between the two cohorts in terms of the extent of the disease, pain, deformity, range of movement or bone loss (Table I).

All the procedures were performed by the senior author (YHK). A tourniquet was used for all patients. An anterior midline incision between 10 cm and 12 cm length was made with a medial parapatellar capsular incision. In both groups, femoral preparation was performed first. All patellae in both groups were resurfaced using a cemented polyethylene patellar component. In the knees with
Cementless fixation, the femoral and tibial components were inserted with a press-fit. The stability of the components was confirmed manually and in full flexion and extension as well when varus and valgus stress was applied. In the cemented fixation, implants were cemented after pulsed lavage, drying and pressurisation of cement. The dedicated cemented femoral component was not available due to inventory problems and the cementless femoral component was used and fixed using cement in the cemented group.

On the second post-operative day, patients started passive range-of-movement (ROM) exercises with a continuous passive motion machine. They also started active mobilisation under the supervision of a physiotherapist.

Routine post-operative assessment was undertaken at three months, one year, and annually thereafter. Pre- and post-operative Knee Society (KSS) scores were recorded at each visit and pre- and post-operative Western Ontario and McMaster Universities osteoarthritis index (WOMAC) scores were also determined at each visit. The active ROM of the knee in the supine and weight-bearing position was determined for all patients on two occasions by two of the authors (YHK, JWP) using a standard (60 cm) goniometer pre-operatively (in the supine position only) and at each review. The patients were asked to bend their knees as much as they could when lying supine and when bearing weight.

Satisfaction was assessed with a visual analogue scale ranging from 0 to 10 where 0 was the most dissatisfied and 10 the most satisfied. At each follow-up visit, we obtained anteroposterior hip-to-ankle radiographs with the patient standing and supine, lateral radiographs and skyline patellar radiographs. The radiographs were evaluated by one observer (SML) who was not a member of the operating team, to determine the femorotibial angle (between the anatomical axis of femur and that of tibia), the alignment of the components (femoral angle and tibial angle), percentage area of tibial surface covered by implant, the joint line (determined on the anteroposterior (AP) radiographs obtained before and after surgery by measuring the distance between the tip of the fibular head and the distal margin of the lateral femoral condyle pre-operatively and between the tip of the fibular head and distal margin of the lateral femoral component post-operatively), the posterior condylar offset (evaluated on pre- and post-operative lateral radiographs by measuring the maximum thickness of the posterior condyle projected positively to the tangent of the posterior cortex of the femoral shaft), radiolucent lines (RLLs) (depth in millimetres in each zone) and the angle of the patellar component (the angle between a line joining the medial and lateral edges of the patella and the horizontal line). The chance-corrected kappa coefficient, calculated to determine intra-observer agreement for measurements for all radiological parameters, ranged from 0.69 to 0.86.
Statistical analysis. In order to detect an effect size of 0.5, corresponding to an anticipated difference of four points in the KSS score and a standard deviation (SD) of eight points, with a power of 85% and a level of significance of 5%, we calculated that 40 participants were required. In anticipation of a small dropout rate, we aimed for 50 patients.

We calculated descriptive statistics (mean, SD and proportions) for continuous study variables. KSS and WOMAC scores were analysed with a paired t-test. The pre-operative Knee Society pain score was compared between the two groups with the Fisher’s exact test. Post-operative Knee Society pain scores were compared between the two groups with use of the Mantel–Haenszel chi-squared test. ROM of the knee was compared between the two groups with use of a paired t-test, radiological data were compared with a paired t-test and complication rates were compared with a chi-squared test. We used Kaplan-Meier curves in the analysis of the rate of survival of the prostheses with revision for any reason as the end point, and the 95% confidence interval (CI) at certain times was calculated with the formula of Greenwood.

Results

The pre- and post-operative knee and function scores, pain scores, WOMAC scores, walking distance, ROM, walking support and ability to negotiate stairs in both groups were not significantly different (Tables I and II). The difference in pain scores between the cemented and cementless knees according to both scoring systems was not statistically significant at the latest follow-up (Table II).

The range of knee movement in the two groups was not statistically different either before or after operation (Tables I and II). The mean pre-operative ranges of movement in the supine position were 120.8° (85° to 140°) and 122.5° (95° to 135°) in the cemented and cementless groups, respectively. The mean post-operative ranges of movement in the supine position were 124° (100° to 140°) and 128° (110° to 140°), respectively, and the mean post-operative ranges of movement in the weight-bearing position were 109° (90° to 130°) and 113° (100° to 130°), respectively. No patient underwent a post-operative manipulation to improve the ROM. All patients except three obtained > 90° of flexion.

At the latest follow-up, patient satisfaction was similar in both groups, with a mean satisfaction score of 8.1 points (SD 1.9) for the cemented group and 8.3 points (SD 1.7) for the cementless group (p = 0.728; paired t-test). In all 42 patients (84%) expressed no preference, four patients preferred the cemented prosthesis, and four patients preferred the cementless prosthesis.

There were no significant differences between the groups with regard to radiological parameters, including the alignment of the limb (femorotibial angle), the position of the
femoral and tibial components, the tibial surface covering, the level of the joint line, posterior condylar offset, RLLs or patellar tilt angle (Table III). We observed no radiolucency at the bone-cement or cement-implant or implant-bone interface in 46 knees (92%) with cemented components and in 45 knees (90%) with cementless components (Fig. 3). In all, four knees (8%) with cemented components and five knees (10%) with cementless components had an incomplete radiolucent line measuring < 1 mm in width at the interface between the tibia and tibial component. No knee had a complete radiolucent line measuring > 1 mm in width around any component in the cemented implant group. One knee in the cementless group had aseptic loosening of the tibial component and it was revised to a cemented component one year post-operatively. The mean patellar tilt angle both before and after TKR did not differ significantly between the groups (Table III). No knee in either group had subluxation or dislocation of the patella or underwent lateral retinacular release.

The Kaplan-Meier survivorship analysis revealed that the rate of survival of the femoral components was 100% (95% CI 0.93 to 1.0) in the cemented group and 98% (95% CI 0.91 to 1.0) in the cementless implant group at 14 years with loosening or revision considered the end point for failure. The rate of survival of the tibial component was 100% (95% CI 0.93 to 1.0) in the cemented group and 98% (95% CI 0.91 to 1.0) in the cementless implant group at 14 years with loosening or revision considered the end point for failure.

The complication rates were low and were similar in both groups. The mean peri-operative blood loss (including intra-operative blood loss and blood collected in a suction drain was 1010.8 ml (SD 585.7; 180 to 2680) in the cemented group and 1154.6 (SD 325.6, 210 to 2760) in the cementless group. This difference was significant (paired t-test, p = 0.006). One knee in each group had a deep infection; both were treated with open debridement followed by intravenous administration of antibiotics for six weeks. There was no subsequent recurrence of infection in either knee.

Discussion
Our study has shown that the long-term survival of the cemented and cementless TKRs was good irrespective of the method of fixation. The 14-year survival rates, using loosening or revision for all causes as the endpoint, were 100% for the cemented femoral and tibial components and the cementless femoral component and 98% for the cementless tibial component.
Baker et al reported rates of survival of 80.7% for the cemented press-fit condylar knee (PFC; DePuy, Warsaw, Indiana) and 75.3% for the cementless PFC knee (DePuy) at 15 years. The ten-year survival rates for other cemented prostheses range from 92% to 99%. The ten-year survival rates for other cementless prostheses range from 93.4% to 97%. Rand reported similar results when comparing the short-term outcome of cemented and cementless PFC knees. However, a longer-term study on these patients showed a significant deterioration in the survival of cementless prostheses and the survival rate at ten years was 94.2% and 72.7% in the cemented and cementless groups, respectively. These groups, however, contained small numbers of patients and were not well matched with regard to age; the cementless group was significantly younger, by about ten years.

Rorabeck, Bourne and Nott reported better results with cemented fixation but unlike the present study, their implants were of two different designs, which might account for the difference in survival. Collins et al compared the method of fixation using implants of similar design and reported no difference in the short-term outcome. Albrektsson et al showed significantly less migration of cemented components at one year. More cementless components required revision at three years in this series. In addition, Chockalingam and Scott reported on the same design in a non-randomised study and found cemented fixation to be superior for the femoral component. Onsten et al showed cemented fixation to be superior to porous-coated cementless components at one to two years, but equivalent to cementless hydroxyapatite-augmented porous-coated components. Berger et al reported that, at an average of 11 years follow-up, cementless fixation yielded poor results. Accordingly they abandoned cementless fixation in TKR.

Gandhi et al suggested in their meta-analysis of cemented and cementless TKRs that cemented fixation offers equivalent clinical outcomes and at least as good as, if not better survival than cementless fixation at medium-term follow-up of two to 11 years.

In our series, both cemented and cementless TKRs had an improved long-term survival and there was no significant difference between the two groups either for survival or clinical outcome at a mean of 14 years. Despite the patients’ active lifestyles, aseptic loosening that necessitated revision was not a notable problem in either group in this series. We believe that the good results in this series are attributable to the small stature and light weight of our patients, the design of the prosthesis, improvement in the quality of polyethylene compared to earlier series, and surgical technique.

Smith, Naima and Freeman observed that RLLs around the tibial component were due to a failure to inject cement into sclerotic bone. These lines were non-progressive and did not affect fixation. In the current series four knees in each group had tibial or femoral RLLs which were not progressive. One knee in the cementless group had a progressive tibial RLL and the tibial component was loose. Differentiation of the scores between the knees of one individual posed some difficulties. The components of pain, support and range of movement were easily differentiated but the components of distance walked and the ability to climb stairs were more difficult to separate. In these domains, if the patients had difficulties they could always identify the knee that most limited their activities.

### Table III. Radiological results

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Cemented</th>
<th>Cementless</th>
<th>p-value*</th>
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</thead>
<tbody>
<tr>
<td>Mean alignment (*) (range)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Pre-operative</td>
<td>10.2 (5 to 17)</td>
<td>10.0 varus (7 to 15)</td>
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<tr>
<td>Post-operative</td>
<td>5.8 (3 to 7)</td>
<td>5.3 valgus (3 to 7)</td>
<td>0.150</td>
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<td>Mean femoral component position (femoral angle (°)) (range)</td>
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<td>Coronal</td>
<td>96 (92 to 102)</td>
<td>97 (94 to 102)</td>
<td>0.269</td>
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<tr>
<td>Sagittal</td>
<td>3.7 (-0.5 to 10)</td>
<td>3.8 (1 to 9)</td>
<td>0.902</td>
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<tr>
<td>Tibial component position(*) (range)</td>
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<tr>
<td>Coronal</td>
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<td>89 (84 to 92)</td>
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<tr>
<td>Sagittal</td>
<td>84 (79 to 90)</td>
<td>84 (79 to 98)</td>
<td>0.657</td>
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<tr>
<td>Tibial surface capping (%) (range)</td>
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<td></td>
<td></td>
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<tr>
<td>Pre-operative</td>
<td>98 (91 to 103)</td>
<td>98 (93 to 103)</td>
<td>0.418</td>
</tr>
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<td>Tibial alignment (°) (range)</td>
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<td>Pre-operative</td>
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<td>15.2 (8 to 24)</td>
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<td>Tibial surface capping (%) (range)</td>
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<td>Pre-operative</td>
<td>25.6 (21 to 33)</td>
<td>25.7 (18 to 31)</td>
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<td>Post-operative</td>
<td>25.3 (16 to 30)</td>
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<td>Tibial surface capping (%) (range)</td>
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<td></td>
<td></td>
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<tr>
<td>Pre-operative</td>
<td>4 (8)</td>
<td>5 (10)</td>
<td>-</td>
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<tr>
<td>Post-operative</td>
<td>2 (4)</td>
<td>3 (6)</td>
<td>-</td>
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<tr>
<td>Tibial surface capping (%) (range)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative</td>
<td>11.9 (4.2)</td>
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<tr>
<td>Post-operative</td>
<td>3.8 (5.6)</td>
<td>3.5 (3.2)</td>
<td>0.964</td>
</tr>
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</table>

* paired t-test
Goldberg and Kraay\textsuperscript{31} reported that 24 tibial components (21\%) and 20 femoral components (17\%) of the 113 knees they studied showed osteolysis. They indicated that osteointegration of cementless tibial components can be successful with screw fixation, although there was a worrying incidence of tibial and femoral osteolysis. Berger et al\textsuperscript{28} reported a 10\% (13 of 131 knees) incidence of osteolytic lesions around cementless tibial components. On the other hand, Kim, Choi and Kim\textsuperscript{32} recently reported that the incidence of osteolysis (1.6\%, 14 of 894 knees in the fixed-bearing knees, compared with 2.2\%, 18 of 816 knee in the mobile-bearing knees) was very low after contemporary fixed- and mobile-bearing cemented TKRs. In the current series no knee in either group had osteolysis, which we attribute the quality of the polyethylene.

Khaw et al\textsuperscript{1} reported that the incidence of deep infections in the cemented group was higher than in the cementless group without establishing a reason. In the current series, the incidence of deep infection was low and similar in both cemented and cementless groups and the two knees with infection were treated uneventfully with open debridement and the administration of intravenous antibiotics for six weeks.

The strength of this study is the lack of confounding variables by examining a single surgeon’s experience with a consecutive group of patients in whom simultaneous bilateral TKR was performed. The limitation of this study was the small sample size and lack of interobserver comparisons, and this could produce bias in interpreting the radiological results. Other limitations included the low weight of

Fig. 3a

Radiographs of a 65-year-old woman with bilateral osteoarthritis of the knee, in a) standing anteroposterior view and b) lateral views 12 years post-operatively, showing the cemented (right knee) and cementless (left knee) NexGen CR prostheses firmly secured in a satisfactory position, with no radiolucent lines and no osteolysis around the components in either knee.
the patients, the good pre-operative range of knee movement and the relatively young age of this ethnic group of patients which might limit general applicability to other groups of patients. On the other hand, although the patients in this study had low weight, daily activities including farming, squatting and lifting were vigorous.

Although cementless TKRs are justified by their satisfactory outcome it should be appreciated that our data have shown no evidence of their benefit over cemented components.

The authors would like to thank S.-M. Lee for assistance with the radiological study and the relatively young age of this ethnic group of patients in this study had low weight, daily activities including farming, squatting and lifting were vigorous.

References


