Early experience with the NexGen® CR-Flex Mobile knee arthroplasty system: results of 2-year follow-up

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Abstract

We evaluated our initial results in 57 patients who received the NexGen® CR-Flex Mobile knee system using the standard anterior approach in a prospective study. The bicondylar surface implant was cemented in position (Palacos®) without posterior patellar resurfacing. The clinical outcome and perioperative and post-operative complications were documented over 24 months of its use. Overall, after two years, good results were obtained for the categories of pain and ROM (range of motion), and for the HSS (knee society score) (pre-operative: 42/57; post-operative: 87/80). No pathological radiological findings were made during this period. Two patients, however, felt that the primary operation had not been successful because of lateral patellar tilt. This was corrected with revision surgery. It was remarkable that our patients achieved greater than 100° flexion within the first 14 days of the immediate post-operative period. Evaluation and comparison of the scores with those of conventional bicondylar surface replacement systems showed no relevant differences.

Introduction

The development of bicondylar surface replacement systems started in 1972 with the Freeman and Swanson prosthesis. It took the form of a bonded double carriage which articulated in a trough-shaped tibia baseplate like a roller. Both cruciate ligaments were resected. Mediolateral stabilization was achieved via the natural capsular ligament apparatus. Insall et al. developed the total condylar knee (TCK), which also enabled retropatellar resurfacing and was the prototype for surface replacements in use today. This prosthesis had a so-called round-on-round design, which largely prevented rotation and shearing movements. This led in the 1980s to the development of systems with the so-called flat-on-flat design which, with preservation of the posterior cruciate ligament, resulted in more physiological knee kinematics. This design philosophy has been incorporated into numerous knee systems now available and gives good long-term results. One problem associated with this design is the high local polyethylene wear caused by the small contact area during weight-bearing. Modern designs, therefore, again attempted to ensure as large a contact area as possible between the femoral components and the polyethylene in all joint positions. This return to the round-on-round system can only be successfully achieved by systems that offer either meniscal bearing or mobile bearing (as is usually the case today).

Nowadays, replacement of the surfaces of the knee joint accounts by far for the largest proportion of endoprosthesis procedures on the knee. A Swedish collective study, as well as several international studies report good to very good long-term results with cemented surface prosthesis.1,2 Increasing efforts have been made over the past years to improve the flexion properties of knee implants by refining their design. The basic principle in doing so has been to reduce the back side radius of the condyle of the femoral component, which, in combination with partial posterior coupling, has achieved maximum flexion angles of over 120°.4 Although this means that resection of more bone from the posterior femoral condyle is unavoidable, this permits a range of motion extending to deep kneeling and squatting. Demographic developments mean that increasingly young patients require knee arthroplasty, and this means that the expectations of surgery (e.g. flexion over 120°) are also increasing. Nowadays, it is no longer enough to ensure freedom from pain and adequate movement to allow everyday activities. Patients now expect the knee to be completely functional with unrestricted ability to ride a bicycle, go hiking or skiing, and perform all everyday activities.

In the light of this, we performed a prospective study in 57 patients who received a NexGen® CR-Flex Mobile implant, a system offering extended flexion of the knee, and evaluated our initial findings. The clinical outcome (Knee Society Score [KSS], range of motion [ROM] and radiological finding) and perioperative and post-operative complications were documented in the first two years of its use in our hospital and were compared with those with other knee replacement systems.

Materials and Methods

Between January 2006 and January 2007, we implanted 57 NexGen® CR-Flex Mobile knee replacement systems (Zimmer, Warsaw, Indiana, USA) in patients with primary osteoarthritis. The NexGen® CR-Flex Mobile System implants were available in a range of sizes from femoral B-G and tibial 4-8, with a polyethylene thickness of 10-22 mm.

The ratio of men to women was 1:3, and the mean age was 63.8 years (52-79 years; SD: 9.6 years). None of the patients had undergone previous knee surgery, and none were lost to follow-up. All patients stated that they were normally active, and some also jogged, skied, or played tennis. The mean body mass index was 28 with a maximum of 35 (SD: 4.6). The KSS, ROM and radiological findings (knee in 3 planes) were documented before and six and 24 months after surgery. The KSS is a functionally orientated questionnaire that evaluates the objective clinical outcome and the subjective opinion of the patient on their ability to perform everyday activities, such as normal walking and climbing stairs. It includes scales that quantify the target variables pain, functionality and stability, also taking into account further clinical variables such as extent of movement and varus or valgus leg axis deviation. Radiographic assessment comprised a standing scanogram of the leg and lateral radiography to assess tibiofemoral alignment and component positioning. The Merchant’s view was used to assess patellar tracking. The axial patellofemoral position was defined as central (less than 5° tilted) or as having medial tilt (over 5° tilted, with the medial side depressed) or lateral tilt (over 5° tilted, with the lateral side depressed) as described by Bindelglass and Vince.5 The bicondylar surface replacement with a mobile bearing polyethylene inlay was implanted using the anterior Payr approach with medial arthrotomy. Both the femoral and the tibial component were completely cemented (Palacos®, none-vacuum technique). Primary
posterior patellar resurfacing was not performed in any of the patients. Interventions were performed by one surgeon.

Statistical methods
Pre-operative and post-operative findings of the KSS were compared using Student’s t-test with a level of significance of P<0.05. All values are presented as means and standard deviations (SD).

Results
Hospital care
All patients were inpatients and were observed post-operatively for one day on an intermediate care ward. The mean duration of hospitalization was 10.8 days (7-16 days). Physiotherapy was started on the day after surgery with walking exercises on two forearm crutches with maximum weight-bearing and exercise on CPM (continuous passive motion). Lymph drainage was added on the second post-operative day. None of the patients developed infections while in hospital.

Scores and range of motion
The mean pre-operative KSS was 42 (range 33-46) and the mean functional score was 57 (range 50-61). After six months, the mean KSS score had improved to 75 (range 68-79) and the mean functional score to 77 (range 68-83). The corresponding figures after 24 months were 87 (range 85-93) and 80 (range 76-85), indicating a further improvement. Sixty-three percent (36/57) of the patients had excellent results, 19% (11/57) a good result, 14% (8/57) a satisfactory result, and 3.5% (2/57) a poor result (Figure 1).

The ROM improved continuously over the first year, and a mean flexion of 122° was achieved (Figure 2).

Radiological results
The tibiofemoral angle was 5-8° valgus in 28 knee joints, 0-4° valgus in 12 joints, and 0-8° varus in 17 knee joints. The mean posterior slope of the tibia was 6.4° (range 4-10). No signs of aseptic loosening of tibial or femoral component could be found. The patella was centrally positioned in 47 cases, showed medial tilt in no cases, lateral tilt without subluxation in 8 cases, and lateral tilt with subluxation in 2 cases.

Complications
Three patients required treatment because of perioperative complications. Two of these patients had a deep vein thrombosis and needed treatment with anticoagulants for three months. The remaining patient developed acute renal failure which resolved completely.

Discussion
The main hypothesis in this work was to test whether a new multi-radius designed knee system (NexGen Cr Flex Mobile) demonstrates better ROMs than other knee systems. Compared with the predecessor model, the NexGen® CR, the new NexGen® CR-Flex Mobile total knee system offers significant, new design features. From the biomechanical point of view, different medial and lateral radius (Figure 3), together with the posterior cruciate ligament, support the axial rotation during the rollback (internal rotation and rollback of the femur). The cruciate retaining component allows up to 15° of internal or external rotation with no significant reduction in the contact area. Such a physiological rolling-sliding behavior is not achieved with conventional endoprostheses with medio-lateral symmetry (single-radius). Such single-radius endoprostheses have restricted flexion, the inflection point of the mechanical load increases on the sliding surface and the ends of the posterior condyle notch in the sliding surface which is associated with increased wear.

Also, at a high degree of flexion, the patellar tendon may be brought into sudden contact with the head of the tibia, and cause pain. The result of this is restricted flexion. The anterior sliding surfaces of the NexGen CR Flex Mobile have a groove to accommodate the patellar tendon with increasing flexion. The improved congruence of the tibiofemoral joint surfaces and the self-alignment of the mobile platform mean that flexion of more than 120° can be achieved without resulting in joint instability or increased polyethylene wear (Figure 4).

Patellofemoral pain syndromes in 9-20% of cases have been reported in some studies. 1,9 Provided the implant had been positioned correctly, we did not observe this problem in our group of patients who had received knee systems with extended flexion. This is presumably because of the revised design of the patellofemoral sliding surfaces of the NexGen® Cr Flex Mobile implant; although
the number of patients we treated is too small to draw a firm conclusion on this. A further factor is that resection of the lateral patella facet was performed in patients with Wiberg Type II and III patellas.

In the patients with an excellent and good outcome, the patella was not displaced in lateral X-rays or in the Merchant’s view. Patients with residual symptoms, however, showed lateral tilting of the patella. The 2 patients in our group with lateral tilting and subluxation of the patella had an inward rotation malpositioning of the femoral component. The minimal surgical revision approach here was retrotibial resurfacing with associated soft-tissue management to improve patellar tracking. Replacement of the femoral component was not performed in these cases. This highlights the importance of the correct positioning of the patella and exact positioning of the components in achieving a fully functional and pain-free artificial knee joint (Figure 5).

In addition to pain reduction and restoration of functionality, survivorship is also a decisive consideration in the success of total knee replacement. We achieved excellent and good KSS score results in 47 cases. Fourteen patients felt that the outcome of surgery was satisfactory, and only 2 patients felt that it had not been successful.

The KSS improved from a mean of 42 before surgery to a mean of 87 two years after surgery, and the functional score from 57 to 80. Our scores were similar to those of other knee systems.10-13 We did, however, observe a considerable difference to other knee systems in the ROM achieved. Our patients achieved greater than 100° flexion at an early stage within the first 14 days after surgery, and over the course of the subsequent two years flexion improved to a mean of 122°. Increasing numbers of younger patients will require total knee replacement in the near future because of demographic changes, and this means that more and more patients will be expecting an implant that restores complete functionality. However, survivorship, which is largely determined by wear on the sliding surfaces, must not be sacrificed for the increased freedom of movement. Thanks to its extended posterior condyle radius which has been widened all around, the NexGenCr-Flex Mobile System offers a larger contact surface on deep bending and therefore spreads the contact stress over a large area. It has been demonstrated in vitro that with a flexion of 155° this guarantees the optimum contact area and counteracts a high degree of polyethylene wear.

Despite positive results in the first two post-operative years, it remains to be seen how this new knee system stands up to stress in the medium and long-term, with the focus on the degree of polyethylene wear and the possible consequence of aseptic loosening.

**References**