The NexGen LPS-flex to the knee prosthesis at a minimum of three years

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We carried out a prospective study to assess the clinical outcome, complications and survival of the NexGen Legacy posterior-stabilised-Flex total knee replacement (TKR) in a consecutive series of 278 knees between May 2003 and February 2005. Mean follow-up for 259 TKRs (98.2%) was 3.8 years (3.0 to 4.8). Annual follow-up showed improvement in the Knee Society scores (paired t-test, p < 0.05). At the last follow-up, the mean maximum flexion was 135° (110° to 150°). Two knees showed radiolucent lines, but revision was not required because the patients were asymptomatic. Revision was required in one case because of infection, but there were no prosthesis-related revisions. There were no other complications. The estimated survival rate at four years with revision for any reason and prosthesis-related problems was 99.6% and 100%, respectively.

This relatively large study indicates that the legacy posterior stabilised-Flex design provides excellent short-term outcome but warrants ongoing evaluation to confirm the long-term durability and functioning of the implant.

The fundamental goal of a total knee replacement (TKR) is to provide relief of pain and a good post-operative range of movement. In the western world, 110° of flexion generally allows for normal function in most activities. However, a number of daily activities for Asians are performed while squatting, kneeling or sitting cross-legged, which require a higher degree of flexion. Some short-term increase in flexion after TKR in these patients has been reported. Most patients and surgeons believe that limited flexion restricts function after a TKR. As a result, modifications in the design of TKRs have been proposed. The NexGen Legacy posterior-stabilised (LPS)-Flex fixed TKR system (Zimmer, Warsaw, Indiana) was designed to achieve high flexion. The posterior condyles of the femoral component are extended and there are modifications in the cam and post-mechanism to maximise flexion whilst maintaining stability. An increased offset in flexion inevitably thickens the posterior condyles and increases the height of the posterior-stabilised box, both of which require removal of an additional 2 mm of bone from the posterior femoral condyles. This extra resection is the only difference in preparation of the bone between the NexGen LPS-Flex and the standard version of the implant. This modification and the perceived increase in flexion raised concerns regarding the possibility of implant loosening, excessive wear, instability, patellofemoral complications and difficult revisions. Recently, Han, Kang and Yoon also described a high incidence of loosening of the femoral component with this system and questioned the durability of the implant. It remains unclear whether this design does improve flexion and there is little information in the literature on this subject.

The aim of our study, therefore, was to prospectively assess the clinical outcome and survival of the LPS-Flex system with a minimum follow-up of three years.

Patients and Methods
A prospective consecutive series of 278 primary TKRs in 187 patients was undertaken using the NexGen LPS-Flex fixed prosthesis between May 2003 and February 2005. None of the patients were excluded from the final study. All the patients provided informed consent. There were 13 men (7%, 18 knees) and 174 women (93%, 260 knees) with a mean age of 69.9 years (52 to 88) and a mean body mass index (BMI) of 27.0 kg/m² (18.7 to 37.4). There were 96 unilateral and 91 bilateral procedures, which were performed two weeks apart. The pre-operative diagnosis was primary osteoarthritis in 267 knees (96%), osteonecrosis in seven (2.5%), post-traumatic osteoarthritis in three (1.1%) and rheumatoid
arthritis in one (0.4%). Of the 278 knees, only ten (3.6%) had a valgus deformity.

All the knees received the NexGen LPS-Flex prosthesis, which has a fixed bearing as a substitute for the posterior cruciate ligament (PCL). The extended posterior condyle enlarges the area of articular contact at high-flexion, and increases posterior femoral translation and the range of flexion. The cam of the femoral component has also been modified to increase the resistance to subluxation and the contact surface between the cam and the tibial post beyond that of a standard LPS design at angles of flexion of > 130°. An anterior cut from the polyethylene tibial insert has also been made to reduce the potential for impingement of the patellar tendon during high flexion.

Prior to the operation, full-length weight-bearing radiographs were obtained showing the hip, knee, and ankle joints. The angle of the femoral and tibial cuts, and the desired position of the entry hole, were planned before surgery. All operations were performed by a single surgeon (S-IB) using the same technique. An anterior midline incision measuring 12 cm to 14 cm was followed by a medial parapatellar arthroscopy. A medial soft-tissue release was performed to remove a thickness of bone equal to that of the patella, resection of the femoral condyles was performed in all but one knee. It consisted of a peripatellar synovectomy, electrocautery of the patellar rim to provide partial denervation, removal of osteophytes and reduction of size of the patella. The exception was a knee with rheumatoid arthritis, severely eburnated bone and inflammatory synovitis, which was resurfaced with an all-polyethylene dome-shaped component implanted with cement. All patients received prophylactic antibiotics and anticoagulation with low-molecular weight heparin for one week. They wore compression stockings for two weeks. A drain was used for 36 hours. Quadriceps-strengthening exercises and continuous passive movement were commenced immediately post-operatively. Weight-bearing was allowed from the second post-operative day, and a Zimmer frame was used as needed. Weight-bearing high-flexion activities such as squatting and kneeling were allowed as tolerated.

The patients were reviewed at six weeks, three months, six months, one year, and annually thereafter. Clinical parameters including the Knee Society scores (KSS), range of movement, post-operative clinical anterior knee pain and complications were recorded. In addition, patients were asked to squat or sit cross-legged at follow-up. All the data at follow-up examinations were recorded by the operating surgeon (S-IB) and compiled by an independent observer, who was not part of the surgical team and had no knowledge of the radiological findings. Pre-operative factors affecting the post-operative range of movement were also analysed including age, gender, BMI, flexion contracture, deformity and range of movement.

Maximum flexion was measured prior to surgery and at review using a manual goniometer with the arms aligned along the long axes of the femur and tibia on the lateral side of the knee joint. Patients were told to bend until they felt at most slight pain. Maximum flexion was measured on two occasions, by one of the authors (T-HK) as well as by another author (D-HL) who was blinded to the radiological findings, and the figure reported represents the mean of those two measurements. Flexion contracture was measured and reported similarly. Range of movement was calculated by subtracting the flexion contracture from maximum flexion.

**Radiological assessment.** Pre- and post-operative weight-bearing radiographs included anteroposterior, lateral and full-length anteroposterior films and a skyline patellar view. These were assessed for limb alignment, component positioning and the presence and location of radiolucent lines at the bone-cement interface. The width of the radiolucent line was measured on the basis of seven zones on the lateral radiograph of the femur, seven on an anteroposterior radiograph of the tibia, and three on a lateral radiograph of the tibia, as per the Knee Society roentgenographic evaluation system. All the radiographs were analysed by one author (T-HK) with no knowledge of the patient’s name, and the findings were recorded by a research assistant who again did know the identity of the patient. Intra- or inter-observer analysis of the radiological findings was not performed.

**Statistical analysis.** The life-table method was used for survival analysis. The endpoints were defined as revision for any reason and revision for prosthesis-related reasons only. Multiple logistic regression was used to analyse the pre-operative factors affecting range of movement follow-
ing surgery. The paired t-test was used to compare the pre-operative Knee Society scores and the range of movement with the final values. The level of statistically significant difference was set at p = 0.05, and the calculations were performed using SPSS version 12 (SPSS Inc., Chicago, Illinois).

**Results**

Of the 187 patients (278 knees), 172 (259 knees, 93.2%) were followed for a mean of 3.8 years (3.0 to 4.8). Of these patients, 14 (17 knees) underwent assessment by telephone because they lived in rural areas. Four patients (seven knees) died from causes unrelated to the operation, and one (one knee) underwent revision because of infection. Of the ten patients (11 knees) lost to follow-up, nine (ten knees) had changed their address and one (one knee) had emigrated.

Pre-operatively, the mean knee score was 30.9 points (SD 11.4) and the mean function score was 44.9 points (SD 17.4). Both scores improved after operation (p < 0.05) (Table I). At the latest follow-up, the clinical anterior knee pain scores were grade 0 (no pain) in 207 knees (79.9%), grade 1 (mild pain) in 31 knees (12%), and grade 2 (moderate pain) in 21 knees (8.1%); none were grade 3 (severe pain). None of the patients requested a revision because of anterior knee pain. A total of 108 patients (166 knees, 64.1%) could squat or sit cross-legged at the final follow-up, but of these, 78 (102 knees, 61.4%) could not stand up from these positions without support. Regression analysis showed that the pre-operative range of movement was an important factor affecting post-operative movement (p < 0.05), whereas age, gender, BMI, flexion contracture and degree of deformity had no effect on the post-operative movement (Table II).

Pre-operatively, the mean flexion contracture was 9.0° (0° to 30°), the mean maximum flexion was 121.9° (90° to 150°), and the mean range of movement was 117.3° (65° to 150°). At the final follow-up, the mean flexion contracture was 0.2° (0° to 3°; p = 0.041), the mean maximal flexion angle was 135.1° (110° to 150°; p = 0.028), and the mean range of movement was 134.7° (110° to 150°; p = 0.034). These outcomes each represent a statistically significant improvement (p < 0.05). Improvements in range of movement were retained over time (Table III).

**Radiological results.** Radiographs of 242 knees (89.3% of the 183 patients still alive) were available for analysis. The mean tibiofemoral angle was 8.5° (SD 6.9) of varus (32° of varus to 18° of valgus) pre-operatively and 5.4° (SD 2.2) of valgus (3° to 7° of valgus) at final follow-up. No change in alignment was observed at any post-operative radiological examination. Radiolucent lines were observed in two knees of two patients. One showed a radiolucent line approximately 1.2 mm wide in zone 1 on a lateral radiograph of the femur six months after surgery. However, the radiograph obtained four years post-operatively did not show any widening of the radiolucent line or migration of the component (Fig. 1). This patient remained asymptomatic.

### Table I. Annual post-operative Knee Society scores (KSS)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Follow-up year</th>
<th>Pre-operative</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>KSS score</td>
<td></td>
<td>30.9 (278)</td>
<td>94.2 (272)</td>
<td>94.7 (264)</td>
<td>95.4 (261)</td>
<td>95.0 (109)</td>
</tr>
<tr>
<td>Function score</td>
<td></td>
<td>44.9 (278)</td>
<td>84.7 (272)</td>
<td>85.4 (264)</td>
<td>86.3 (261)</td>
<td>81.3 (109)</td>
</tr>
</tbody>
</table>

### Table II. Variables associated with post-operative range of movement

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean (SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative flexion contracture</td>
<td>9.0 (9.4)</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Pre-operative alignment</td>
<td>8.5 (6.9)</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Pre-operative range of movement</td>
<td>117.3 (12.6)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>270 (3.7)</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>69.9 (6.3)</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td>&gt; 0.05</td>
</tr>
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</table>

### Table III. Range of movement of the knee over time

<table>
<thead>
<tr>
<th>Follow-up period</th>
<th>Pre-operative</th>
<th>6 months</th>
<th>1 yr</th>
<th>2 yrs</th>
<th>3 yrs</th>
<th>4 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>278</td>
<td>278</td>
<td>272</td>
<td>264</td>
<td>261</td>
<td>109</td>
</tr>
<tr>
<td>Mean (range) (°)</td>
<td>117.3 (65 to 150)</td>
<td>129.2 (105 to 150)</td>
<td>135.1 (110 to 150)</td>
<td>134.6 (110 to 150)</td>
<td>134.7 (110 to 150)</td>
<td>135.0 (110 to 150)</td>
</tr>
</tbody>
</table>
In contrast, the other patient had a radiolucent line approximately 1.2 mm wide in zone 1 of the femur six months after surgery, and radiographs at three years revealed that this had widened to 2.3 mm. However, revision was not indicated as there was no evidence of loosening of the femoral component (Fig. 2). There were no cases of tibial radiolucency.

Complications. One knee underwent a two-stage revision because of infection with *Staphylococcus aureus*, which was identified nine months after surgery. In another knee, a supracondylar fracture of the femur occurred two years after operation, and this was treated successfully with open reduction and plate fixation. The femoral component remained well fixed. There were no other complications.

Survival analysis. With revision of the implant for any reason as the endpoint, the survival rate was 99.6% (95% confidence interval (CI)) at four years (Fig. 3). This analysis includes the knee that was revised because of infection. With revision of the implant for any prosthesis-related reason as the endpoint, the survival rate was 100% at four years.

Discussion

The LPS-Flex prosthesis has been the subject of several trials. Huang et al. reported results from 25 cases with a mean follow-up of 28 months. Kim et al. performed a prospective comparative study of 50 cases for a mean of 2.1 years. Most recently, Nutton et al. described a one-year study involving 28 knees implanted with either LPS-Flex prostheses or standard LPS prostheses. These studies provide limited information because of the small numbers and short follow-up. Ours is the first study to report the results of a high-flexion prosthesis at a mean of 3.8 years. It represents a large study population with enrolment open to all and excellent compliance (93.2%).

Previous studies have produced conflicting findings. Huang et al. found that the mean flexion in patients with a high-flexion prosthesis was approximately 10° greater than in those with a standard posterior stabilised implant. We and Laskin have also previously indicated similar findings. However, some authors have not noted increased flexion when using high-flexion rather than conventional prostheses. In the present study, a post-operative mean range of movement of approximately 135° was obtained, and retained over time. For conventional implants, the range of movement following TKRs is reported to be approximately 110° and few patients can flex beyond 120°. The excellent range of movement observed in this study is consistent with the kinematic advantages of high-flexion implants demonstrated in several biomechanical studies.

Key factors which influence the range of flexion after TKR include body weight, flexion contracture, degree of deformity, pre-operative range of movement, surgical technique and rehabilitation. However, these factors were identified in studies that mainly used conventional prostheses. The present study, using the LPS-Flex prosthesis, showed that the pre-operative range of movement was the only factor affecting post-operative

Fig. 1a Lateral radiographs showing a left knee a) six months, and b) four years post-operatively. Radiolucency beneath the anterior flange of the femoral component is indicated by black arrows. Note the lack of change in the width.
movement. This result is consistent with our previous comparative study. Therefore, pre-operative range of movement appears to be the most useful indicator of range of movement after a TKR using either a high-flexion or conventional prosthesis.

The introduction of a high-flexion prosthesis has raised concerns that the increased flexion which enables patients to squat or kneel may compromise the long-term results. There is also concern regarding loosening of the implant, caused by design modifications requiring removal of more bone from the posterior femoral condyles and the intercondylar area. However, our study, which had the longest follow-up period of all reported *in vivo* studies relating to the high-flexion prosthesis, shows favourable results, with mean values of 135° flexion and excellent total and function Knee Society scores. The cumulative survival rate at four years was 99.6%. No revisions for aseptic loosening were required, and the life-table survival for any prosthesis-related failure was 100%. There were no incidents of instability or dislocation in deep flexion. No patient requested revision because of anterior knee pain on deep flexion.

Information regarding aseptic loosening of the LPS-Flex design has also been limited. Huang et al reported no evidence of component loosening or osteolysis in 25 cases with a mean follow-up of 28 months. Kim et al found that the LPS-Flex prosthesis in 50 knees required no revision for aseptic femoral loosening at a mean of 2.1 years. In the present study, two cases of radiolucency were found six months after surgery. Of
these, only one showed widening at the last follow-up (four years post-operatively). However, revision was not required as there was no evidence of prosthesis migration or loosening. By contrast, Han et al.\textsuperscript{10} reported a high incidence of loosening of the femoral component in a retrospective series of 72 knees. At a mean follow-up of 32 months, aseptic loosening of the femoral component was found in 27 (38\%) TKRs, with 15 (21\%) requiring revision at a mean of 23 months. They concluded that the high rate of loosening was associated with weight-bearing at maximum flexion and inadequate support of the posterior condyle of the prosthesis. However, these findings are contradictory to those previously reported\textsuperscript{10,16-18} and to the present study. All these studies used the same type of prosthesis, and all but one involved Asian patients. Moreover, the cohorts for three studies, including ours,\textsuperscript{10,17} were virtually identical in that the patients followed a traditional Korean lifestyle that involved working and sleeping on floors and demanded weight-bearing high-flexion activities in daily life. The post-operative mean range of flexion was 136° in the group that demonstrated loosening,\textsuperscript{10} which is similar to that reported for the other studies performed among Asian patients.\textsuperscript{16,17} It is necessary also to consider other factors that could have possibly been responsible for their outstanding number of cases of aseptic loosening. Loosening of the femoral component is a relatively infrequent complication of a TKR.\textsuperscript{34} Although no consensus has been reached regarding its mechanism, several previous studies have identified implant design, preparation of bone, cementing technique, implant positioning, and soft-tissue balancing as possible causes of femoral loosening.\textsuperscript{35-37} Therefore, it is possible that one or more of these factors could have been responsible for the higher rates of aseptic loosening in their series.

It is generally accepted that in an intact knee, high-flexion activities such as prolonged squatting or kneeling are risk factors for the development of tibiofemoral osteoarthritis, and increase peak tibiofemoral stresses by five to seven times body-weight.\textsuperscript{38-41} However, recently reported biomechanical studies \textit{in vivo} showed that the LPS-Flex design maintained sufficient tibiofemoral and cam-post contact area such that the contact stress values were well below the yield strength of the cross-linked polyethylene.\textsuperscript{42-44} The geometry of the femoral component of the LPS-Flex design was reported to improve posterior tibiofemoral contact in high angle of flexion.\textsuperscript{7} The present study had only one case of progressive radiolucency in 278 TKRs, which is a rate that may also be anticipated when using conventional prostheses. Therefore, we believe that the LPS-Flex design does not create additional problems that threaten the longevity of a TKR. However, a large random comparative study involving both conventional and high-flexion prostheses could answer this question.

The NexGen LPS-Flex prostheses used in the current study incorporated contemporary high-flexion design features that provided satisfactory results in a large series of TKRs at 3.0 to 4.8 years’ follow-up. The implant functioned well, and the extremely low incidence of adverse radiological findings and lack of prosthetic-related revision suggest that function can be satisfactorily maintained when combined with good surgical technique. These results warrant ongoing evaluation to confirm the long-term durability and functioning of this implant.

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References