A prospective randomised double-blind study of functional outcome and range of flexion following total knee replacement with the NexGen standard and high flexion components

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Modifications in the design of knee replacements have been proposed in order to maximise flexion. We performed a prospective double-blind randomised controlled trial to compare the functional outcome, including maximum knee flexion, in patients receiving either a standard or a high flexion version of the NexGen legacy posterior stabilised total knee replacement. A total of 56 patients, half of whom received each design, were assessed pre-operatively and at one year after operation using knee scores and analysis of range of movement using electrogoniometry. For both implant designs there was a significant improvement in the function component of the knee scores ($p < 0.001$) and the maximum range of flexion when walking on the level, ascending and descending a slope or stairs (all $p < 0.001$), squatting ($p = 0.020$) and stepping into a bath ($p = 0.024$). There was no significant difference in outcome, including the maximum knee flexion, between patients receiving the standard and high flexion designs of this implant.

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Recovery of function after total knee replacement (TKR) is dependent on a number of factors, including range of movement, muscle strength, joint stability and pain, as well as issues influencing the patient's general health, sense of wellbeing and expectations.¹⁻³ Range of movement, however, determines whether patients can manage high flexion activities such as crouching, kneeling and getting out of a low chair or a bath. Patient satisfaction with the outcome of TKR has been associated with the post-operative ability to kneel and crouch.⁴ In order to address this, modifications in the design of knee replacements have been proposed.⁵⁻⁷ By deepening the thickness of the posterior condyles of the femoral component, the offset between the posterior cortex of the femur and the articular surface of the tibial component is increased, which should allow a greater range of flexion before impingement between the femoral cortex and the posterior edge of the tibial bearing.⁸

The NexGen Legacy Posterior Stabilised total knee replacement (LPS; Zimmer, Warsaw, Indiana) is available in both a standard and high flexion design. The NexGen LPS-Flex system was designed to allow increased flexion by incorporating an extension of the posterior femoral condyles, along with modification of the cam and tibial spine. By extending the posterior

femoral condyles, contact of the articular surface in flexion is maintained, allowing posterior translation of the femur and flexion beyond 120° without tibiofemoral impingement. Increased offset in flexion is achieved by removing an extra 2 mm of bone from the posterior condyles of the femur in order to accommodate the thicker condyles of the femoral component. This extra resection of bone is the only difference in bone preparation between the NexGen LPS-Flex and the standard version of the implant.

This study is a prospective randomised comparison of the functional outcome in patients receiving either a NexGen LPS-Flex or the standard design.

Patients and Methods

Patients were enrolled from the waiting list of three consultants (RWN, PG, FAW) with a special interest in TKR between May 2004 and December 2005. The requirements for enrolment were the presence of unilateral osteoarthritis (OA) of the knee, a minimum pre-operative range of knee flexion of 90° and the ability to take part in the electrogoniometry assessments. Patients were excluded if they had inflammatory arthritis, OA of the hip causing pain or restricted mobility, a foot or ankle disorder which limited walking, dementia or a neurological disorder, including a past

Fig. 1

Flow diagram of participants according to the CONSORT guidelines.⁹

history of stroke which affected mobility. Previous hip replacement or contralateral knee replacement were not considered an exclusion criterion unless the patient had persistent pain or restricted function.

A total of 209 patients with OA were identified, of whom 86 were excluded, leaving 123 who were invited to take part in the study. Of these, 71 (58%) agreed to participate and 52 (42%) refused. A further 15 patients were removed from the study, of whom 11 did not receive a unilateral TKR at the participating hospital. Four were not able to attend the follow-up assessment; one because of mental illness, one because of an infected knee joint, one who was waiting for a total hip replacement and one who died. This resulted in a final study group of 56 patients. A flow diagram of the patients in the study, prepared according to the CONSORT Guidelines⁹ is shown in Figure 1.

The standard design was used for 16 female and 12 male patients and the LPS-Flex for 11 female and 17 male patients.

A control group of 40 volunteers matched for age and gender, with no history of OA of the knee or hip was also recruited.

Ethical approval was granted and all participants gave written consent to participate in the study.

Randomisation and surgical protocol. Computer-generated randomisation was employed to produce cards instructing

'standard' or 'high flexion' which were placed in sealed envelopes and opened in sequence. The envelope was opened when the patient was prepared and draped for surgery, immediately before proceeding with the operation. A total of 56 patients were randomised so that 28 received each design. The range of knee movement was recorded before and after surgery by holding the patient's thigh, without a tourniquet, and allowing the shank to drop down due to gravity (the 'drop test'). The range of movement from full extension to maximum flexion was recorded using a handheld goniometer (Physio Med Services, Glossop, United Kingdom) with the arms aligned along the midlines of the thigh and shank.

The TKRs were performed to accept either version of the NexGen-LPS design, using a medial parapatellar approach, with patella eversion. Soft-tissue balancing was performed using a sequence of tissue releases, as described by Ritter et al¹⁰ for medial, lateral and posterior structures. The extent of soft-tissue release was recorded and a simple scoring system derived, using the classification of Ritter et al,¹⁰ with the highest score for the highest degree of release. This scoring system was used to compare the degree of soft-tissue release in each group of patients.

The post-operative protocol for both groups was identical. We used our normal protocol for TKR which emphasises early weight-bearing and knee flexion exercises.

Fig. 2

Flexible electrogoniometer attached to the leg of a patient.

Discharge from hospital was dictated by the mobility of each patient and their circumstances at home, rather than by their range of knee movement. Out-patient physiotherapy was arranged on an individual basis if it was felt that the patient would benefit from extra rehabilitation.

Functional assessment. Functional assessment was performed by a research fellow (MLvdL) who had no involvement with the patient's care and who was blinded to the type of implant that the patient had received. The patients were also blinded to the type of implant used. Each patient was assessed pre-operatively within one month of their knee replacement. They were given a questionnaire to complete, which included the Short Form (SF)-36 health survey,¹¹ the Knee Society score (KSS)¹² and the Western Ontario and McMaster Universities (WOMAC) osteoarthritis index.¹³

The primary outcome was the functional range of knee movement as measured by electrogoniometry. Flexible electrogoniometers (M180, Biometrics Ltd, Gwent, United Kingdom) were aligned along the long axes of the femur and tibia (Fig. 2), allowing data on the range of movement to be recorded on a data logger carried in a holster attached to the patient's waist. Activities were divided into 'lower flexion' and 'higher flexion'. The

lower flexion activities were walking on a flat surface, ascending and descending a slope and a flight of stairs, and sitting and rising from a high chair. The higher flexion activities were sitting and rising from a low chair, getting in and out of a bath and bending the knee to the maximum range of flexion when standing, using a stool as a step. Finally, patients were asked to crouch and rise from a crouching position, using handrails for support. Patients were not asked to kneel, as they were anxious about performing this activity.

Active peak flexion and extension of the knee was measured with the patient sitting on a plinth, using a manual goniometer with the arms aligned along the long axes of the femur and tibia.

The questionnaires and assessments were repeated one year after operation.

Statistical analysis. The range of movement and the functional scores are presented as means with ranges and standard deviations (SD). Differences between the two groups of patients were analysed using a repeated analysis of variance (ANOVA) with two groups and two time points, before surgery and at one year. Student's *t*-test was used to compare differences between the two groups before surgery. 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

A comparison of the groups for age, pre- and post-operative SF-36, KSS and WOMAC scores is shown in Table I.

At one year after TKR, both groups had a statistically significant improvement in the physical component of the SF-36 score (ANOVA, $p < 0.001$), the knee function component of the KSS (ANOVA, $p < 0.001$) and improved pain, stiffness and knee function in the WOMAC score (ANOVA, $p < 0.001$).

Immediately after surgery, the drop test measurements for the standard design improved from a mean flexion of 111° (80° to 130°) to 121° (90° to 135°) compared with a mean of 119° (95° to 145°) to 127° (110° to 150°) for the high flexion design. The level of soft-tissue balancing required was the same for each group with a mean score of 3.07 (1 to 6) and 3.03 (1 to 5) for the standard and Flex design respectively (ANOVA, $p = 0.92$). There was no significant difference between the standard and high flexion designs for any of the outcome measures.

Electrogoniometry. The mean maximum pre- and post-operative ranges of movement for lower flexion activities for both study groups and the control subjects are shown in Figure 3. There was a significant improvement (ANOVA, $p < 0.001$) in the post-operative maximum range of flexion in both study groups for all low flexion activities, with the exception of rising from a chair. However, between the standard and high flexion designs there was no statistically-significant difference in the results for any of these activities.

Table I. Mean (standard deviation) of the pre- and post-operative measures for the standard, high flexion and control groups

	Age in yrs (range)	Active flexion (°)	SF-36* physical	KSS† function (max 100)	WOMAC‡		
					Pain (max 20)	Stiffness (max 8)	Function (max 96)
Standard	68 (52 to 85)						
Pre-operative		107 (15)	36.9 (4.0)	45.3 (15.4)	9.5 (3.1)	4.6 (1.3)	31.8 (10.8)
One year post-operative		106 (17)	47.7 (8.5)	84.3 (10.6)	3.8 (4.0)	2.3 (1.9)	14.7 (13.2)
High flexion	71 (38 to 87)						
Pre-operative		108 (15)	36.6 (5.6)	50.7 (15.9)	8.5 (8.5)	4.3 (1.3)	28.3 (10.7)
One year post-operative		110 (17)	45.0 (9.4)	76.9 (19.7)	3.0 (3.6)	2.1 (1.6)	13.1 (12.6)
Control	69 (54 to 79)	134 (6.4)	54.7 (5.9)				

* SF-36, Short Form-36

† KSS, Knee Society score

‡ WOMAC, Western Ontario and McMaster University osteoarthritis index

Fig. 3

Bar chart showing maximum knee flexion during lower flexion activities, before and after surgery for the patients in the standard and high flexion groups and control subjects.

The results for higher flexion activities are shown in Figure 4. With the exception of stepping into a bath (ANOVA, $p = 0.024$) and squatting (ANOVA, $p = 0.020$), there was no significant improvement in the maximum range of flexion for these activities and no difference between the standard and high flexion designs. Effect sizes for the differences between

the two implants ranged between 0.013 for walking down an incline and 0.29 for stepping into a bath.

Discussion

Patient satisfaction surveys following TKR suggest that the ability to crouch and kneel influences a patient's view of the

Fig. 4

Bar chart showing maximum knee flexion during higher flexion activities, before and after surgery for the patients in the standard and high flexion groups and control subjects.

outcome.^{4,5} In addition, kneeling and crouching are essential for cultural and religious purposes in some countries. The challenge of improving knee flexion after TKR has resulted in kinematic studies which have analysed the limitations of standard knee replacement designs for high flexion activities, particularly beyond 120° of flexion.⁶⁻⁸ It has been shown that reducing the posterior condylar offset by 3 mm will reduce knee flexion by 10° before the condyles impinge against the posterior edge of the tibial insert.¹⁴ Conversely, by increasing posterior condylar offset, tibiofemoral impingement may be avoided beyond 140° of flexion.¹⁵ The introduction of high flexion designs incorporate these modifications to the femoral component, with the expectation that this will allow a greater functional range of knee movement.

Clinical studies on the effectiveness of designs intended to provide high flexion following TKR have produced conflicting results. Gupta et al¹⁶ reported a significant improvement in the post-operative range of movement using a high flexion rotating platform design when compared with a standard design of rotating-platform TKR. Similarly, Bin and Nam¹⁷ found a significant improvement in knee flexion at one year after operation in patients receiving a high flexion design compared with a standard knee replacement,

particularly in patients with a pre-operative range of flexion of less than 90°. By contrast, Kim, Sohn and Kim¹⁸ were unable to show a significant improvement in knee flexion using a NexGen LPS-Flex knee replacement. In their study, the standard design was used in one knee and a high flexion prosthesis in the other. After a mean of 2.1 years the mean range of movement was 136° in the standard design and 139° in the high flexion design, compared with a mean pre-operative range of movement of 126° and 127°, respectively. In their Asian population, the pre-operative range of movement was greater than in the present series, despite which they were unable to demonstrate any advantage in using a high flexion design over the standard version. Other studies from Asian centres have failed to show an improvement in knee flexion using a high flexion design.^{19,20}

In our study, we used electrogoniometry, as well as knee scores, to assess active knee flexion. The advantages of electrogoniometry are that it is non-invasive, well accepted by patients and does not require exposure to radiation. It has been validated as an accurate and effective method of measuring the active, weight-bearing range of movement²¹ and allows patients to reproduce the physical activities of daily living. Electrogoniometry can be used to supplement knee function scores and to obtain more detailed informa-

tion about the range of flexion required for certain activities as well as whether patients are able to use this movement after a knee replacement.²² A recent study into the functional outcome of TKR seven years post-operatively showed opposing trends, with traditional knee scores which showed a decrease in function but the functional range of knee movement measured by electrogoniometry improving for some activities.²³

In our study at one year after TKR, all the patients had an improvement in knee function as assessed by the KSS function score, the WOMAC score, and the physical component of the SF-36. However, better functional scores can be attributed to improved mobility as a result of pain relief, rather than to a gain in movement. In our series, after TKR the range of knee movement observed during low flexion activities improved by approximately 10° on level walking and approximately 20° when negotiating stairs, suggesting that there was less inhibition of knee movement as a result of pain relief. However, there was no statistically-significant improvement in the functional range of movement after a knee replacement for the higher flexion activities except for stepping into a bath and squatting. In addition, it was not possible to demonstrate any significant difference in the maximum range of flexion used during lower and higher flexion activities, between the standard or high flexion design.

The results of the drop test demonstrated a similar immediate improvement in flexion after a knee replacement with both designs. The extent of the soft-tissue release did not appear to influence the outcome. There was no significant difference in the degree of soft-tissue release performed in each group and therefore it is reasonable to conclude that resurfacing the condyles alone resulted in a gain in knee flexion, but the increased offset in the high flexion design did not have an additional effect on movement.

An *a priori* power calculation was performed using a clinically relevant improvement of 7° and an SD of 11.²² This showed that to detect a statistical difference at $p < 0.05$ with a power of 80% would require 40 subjects in each group. However, we only had 28 subjects in each group, which means that the power to detect a difference in a measurement with an effect size of 0.64 (7 of 11) is just over 60%. However, the highest effect size for the difference between the two implants in the electrogoniometry results was 0.29 for the peak angle when stepping into a bath. Cohen²⁴ defined an effect size of less than 0.3 as small, meaning that the change is not perceptible to the eye.²⁵ Hence, we judged the differences between the implants to be clinically irrelevant.

We feel it likely that even with a higher number of patients in each group, this study would have failed to demonstrate any clinically-significant improvement in knee flexion when using a femoral component designed to maximise knee flexion.

Our results indicate that in patients with a mean pre-operative range of movement of $< 120^\circ$ and with the operative techniques used by the surgeons in this study, the high flexion design of the NexGen LPS will not improve the range of knee movement. It is generally considered that the pre-operative

range of movement is the best guide to the expected range of movement after a TKR.¹⁰

Supplementary Material

A further opinion by Mr S. Donell is available with the electronic version of this article on our website at www.jbjs.org.uk

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