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Does flexion of the femoral implant in total knee arthroplasty increase knee flexion: A randomised controlled trial

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ABSTRACT

Introduction: Prosthetic and operative modifications in total knee arthroplasty (TKA) have been proposed to maximise post-operative knee flexion as it is essential in routine functional activities.
Methods: We performed a double blind randomised controlled trial to compare clinical outcomes of primary cruciate-retaining TKA for osteoarthritis with the femoral component implanted in either 4° flexion in the sagittal plane (F) or in a neutral position (C). The primary outcome of knee flexion and secondary outcomes knee extension, quadriceps strength, WOMAC, SF-12v2, timed stand test, stair climb test and satisfaction were assessed at 1 year. Knee flexion and extension were also assessed intra-operatively. Implant flexion was measured from true lateral radiographs.
Results: Thirty-nine participants (40 knees) were recruited, 20 knees per group. Three subjects from the control group and two from the flexed group were lost to 1 year follow-up but numbers were sufficient to satisfy the sample size calculation. Significant differences were found between the groups in knee flexion (F: 113.6 ± 8.8° pre-operative, 122.4 ± 6.0° intra-operative, 110.2 ± 7.5° 1 year, C: 117.4 ± 11.7°, 117.4 ± 7.6°, 103.5 ± 10.7°. p = 0.031) and mental component score of the SF12-v2 (F 53.3 ± 13.2, C 61.1 ± 7.3, p = 0.009) but there were no significant differences in other outcomes and patients were equally satisfied.
Conclusion: Flexing the femoral implant in this cruciate retaining TKA system provided a significant difference in knee flexion compared to a neutral position. The improvement appears to occur predominantly at surgery and was not associated with a clinical or functional benefit at 1 year. (ACTRN12606000325505). Level of evidence: Level 1; randomised controlled trial.

1. Introduction

Knee flexion is traditionally one of the key outcomes in determining success of total knee arthroplasty (TKA) as it is critical to many routine daily activities. Up to 93° of knee flexion is required to rise from a chair, 117° to negotiate stairs or pick up an object off the floor, and 135° to get in and out of a bath [1,2]. Additionally, non-Western populations typically pursue activities such as squatting or cross-legged sitting for cultural or religious purposes which require knee flexion up to 165° [3]. Following conventional TKA however patients seldom exceed 110 to 115° [4–6].

Many variables affect knee flexion after TKA including patient factors such as gender, body mass index, age and pre-operative flexion [5–7]. Surgically modifiable variables such as implant sizing, ligament balancing, and osteophyte removal have also been well documented as important in optimising post-operative flexion [8]. Attention has turned recently to implant design with the emergence of "high-flex" prostheses but there is to date little consensus on their efficacy [9] and some concern with early loosening [10,11]. Moreover many studies investigating these designs which have demonstrated improvements in flexion were unable to show associated functional benefits [12,13].

Posterior condylar offset (PCO), first defined by Bellemans et al. [14] as the maximal sagittal plane thickness of the posterior femoral condyle relative to the posterior femoral cortex, is another surgical variable which has been reported to affect knee flexion. Thickened posterior femoral condyles are a common design feature in contemporary "high-flex" knee arthroplasty implants. Computer modelling [15], radiographic templating studies [16] and fluoroscopic studies [14] have shown PCO to be correlated with knee flexion, though there are some reports that it may only be helpful in offsetting the paradoxical anterior femoral translation reported in cruciate-retaining implants [17,18].

PCO can also be increased by flexing the femoral component in the sagittal plane [19]. Flexion of the femoral implant is an option with some knee systems to address flexion instability during surgery which can be caused by an inadequate restoration of PCO. Without this feature, surgeons may need to use a larger femoral component potentially leading to "overstuffing" of the patello-femoral joint and quadriceps mechanism tensioning, or medio-lateral overhang which may irritate soft tissue [19]. Only one previous trial was identified

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which has attempted to investigate the impact of implant position on post-operative ROM. In this retrospective study, Faris et al. [20] reviewed the sagittal plane orientation of 623 cruciate-retaining knee replacements and found no correlation between implant position and knee ROM. We are not aware of any studies evaluating the effect of electively flexing the femoral implant.

This study is a prospective randomised controlled trial of the clinical outcomes following cruciate-retaining TKA with a 4 degree flexed femoral component compared with a neutral resection. We hypothesised that subjects undergoing TKA with a flexed femoral implant would achieve significantly greater knee flexion compared to those with a neutral femoral implant.

2. Materials and methods

The study was granted approval by the institutional human ethical review board and was registered in the Australian New Zealand Clinical Trials Registry (trial number ACTRN12606000325505). All participants provided written informed consent.

2.1. Participants

Participants were recruited from a single surgeon's outpatient clinic by the surgeon or principal investigator between June 2006 and May 2009. Participants were eligible if they were scheduled for primary TKA with a diagnosis of osteoarthritis and were available for follow-up at 1 year but were excluded if they had undergone lower limb arthroplasty in the previous 12 months or were scheduled for bilateral TKA.

2.2. Procedure

All subjects underwent TKA with the Profix Total Knee System (Smith & Nephew, Memphis, TN) cruciate retaining implant. This device shares features common in "high-flex" designs such as a smaller radius of curvature in shorter and thickened posterior femoral condyles which aim to minimise edge loading and improve articular contact with deeper flexion. The instrumentation with this system allows the anterior femoral resection to be made at an angle of 0 or 4° flexion relative to the intramedullary axis in the sagittal plane. Flexion of the femoral component increases the PCO compared to a neutral resection (Fig. 1). Subjects were randomised on the day of surgery to flexed (4 degree flexed femoral component) or control (0 degree or neutral resection). Randomisation was performed by an independent research support service attached to the institution using a computer generated randomisation code (balanced block design of size 4) and sealed in opaque envelopes. The surgeon sequentially selected an envelope to reveal the grouping immediately prior to surgery. Participants and all other investigators were blinded to group allocation. All aspects of the surgery other than the intervention followed an identical procedure with a medial parapatellar approach, standard ligament balancing techniques and osteophyte removal. The patella was not resurfaced and the tibial slope resection was 0° for both groups. If any deviation from the standardised surgical procedure was required the participant was excluded. Reinfusion wound drains were routinely used and removed within 24 h of surgery.

The post-operative rehabilitation protocol for both groups was identical, following a standardised clinical pathway. Mobilisation without weight restriction, active and passive knee flexion and extension exercises and quadriceps strengthening commenced on post-operative day 1. Patients were discharged directly home when they were independently ambulating and were provided with a home exercise programme.

2.3. Outcomes

The primary clinical outcome of the study was knee flexion. Secondary outcomes included, knee extension, quadriceps strength, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [21], the Short Form Health Survey (SF-12v2) [22], physical function tests (stair climb test [23], timed stands test [24]) and patient satisfaction. Radiographic measurement of the femoral implant flexion in the sagittal plane was essential to verify two distinct groups were available for analysis. Clinical evaluations were conducted pre-operatively and at 1 year. Knee flexion and extension was also measured at the completion of surgery whilst the patient was still anaesthetised. A flow diagram for the study, in accordance with CONSORT guidelines [25] is presented in Fig. 2.

Knee flexion, extension and quadriceps lag were assessed with digital photographs using a 2-dimensional kinematic software analysis application adapted from telerehabilitation research [26]. This method has demonstrated validity (limits of agreement with universal goniometer measurements of −1.66 to 1.76°), intra-tester (ICC = 0.97 to > 0.99) and inter-tester reliability (ICC = 0.97 to > 0.99) [26]. Photographs were taken with the subject lying supine with the lens of the camera visually aligned with the horizontal axis of the knee. The measurements were performed by a blinded assessor. Knee flexion was

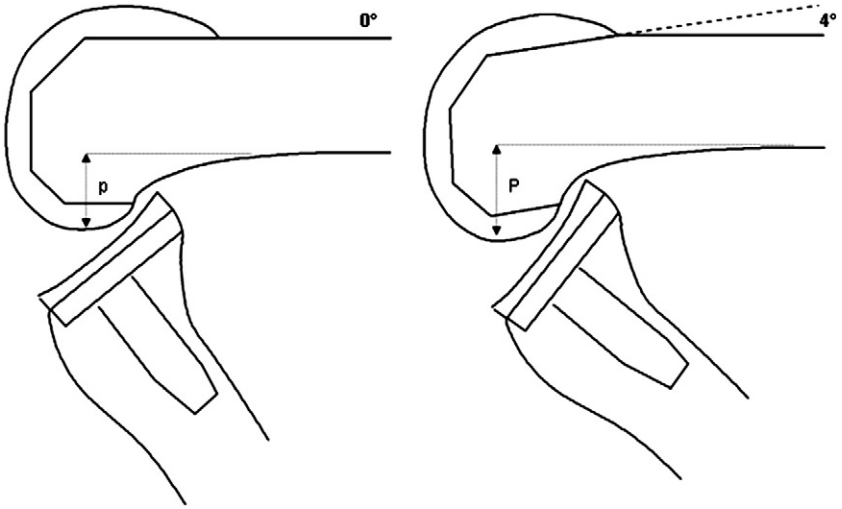

Fig. 1. Diagram representing the lateral view of the control (left) and flexed (right) groups. The posterior condylar offset is larger with the flexed group's 4° resection (P) than the control's 0° resection (p) accommodating greater knee flexion before tibial component impingement on the posterior cortex of the femur (Adapted from Bellemans, Banks et al. [14]).