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ORIGINAL STUDY

Flexion and anterior knee pain after high flexion posterior stabilized or cruciate retaining knee replacement

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Background : **Special high-flexion prosthetic designs show a small increase in postoperative flexion compared to standard designs and some papers show increased anterior knee pain with these prosthesis.**

Methods : **A prospective double blind randomized controlled trial investigates the difference in flexion and anterior knee pain between standard and high-flexion total knee arthroplasty. In total 47 patients were randomly allocated to a standard cruciate retaining fixed bearing design (CR) in 23 patients and to a high-flexion posterior stabilized mobile bearing design (HF-PS) in 24 patients.**

Results : **The HF-PS did show a significantly higher passive postoperative flexion ; 120.8° (SD 10.3°) vs. 112.0° (SD 9.5°) for the CR group (p = 0.004). The active postoperative flexion, VAS-pain score and Feller score did not show significant differences between both groups. Sub analysis with the HF-PS group showed a higher VAS-pain for the patients achieving ≥130° of flexion ; 30.5 (SD 32.2) vs. 12.2 (SD 12.5) (p = 0.16).**

Conclusion : **The present study showed a significant higher passive flexion in the high-flexion prosthesis compared to the standard prosthesis. However this difference disappeared when comparing active flexion. No difference in anterior knee pain was found between both groups.**

Keywords : total knee arthroplasty ; RCT ; high-flexion ; anterior knee pain.

INTRODUCTION

Total Knee Arthroplasty (TKA) is a successful procedure, however most patients do not regain full flexion (*29,33*). Higher postoperative flexion is related to higher patient satisfaction (*1,11,24*). Especially in Asia, kneeling and squatting is essential for cultural and religious reasons. To help in these needs, manufactures have designed new implants to accommodate higher flexion. A study by Gupta *et al* (*16*) showed a 10 degrees increase in postoperative flexion after high flexion TKA when compared to a cohort receiving a standard posterior stabilized TKA. Another study compared a posterior stabilised high flexion (HF-PS) design to a cruciate re-

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taining (CR) design (*26*) and concluded that the HF-PS allowed for a higher non weight bearing knee flexion. However, patients in this group did not use this additional flexion range during activities of daily living. Furthermore, they reported more pain in the HF-PS group one year after surgery.

This difference in pain can be caused by two factors related to the implant design of HF TKA. The HF-PS designs typically have increased rollback to prevent impingement of the posterior aspect of the femur on the tibia plateau. More femoral rollback results in an increased angulation of the patellar tendon and patella in the sagittal view (*7*). This results in a different contact between the patella and femoral component, which might result in a difference in postoperative pain. Anterior knee pain is a common complication after TKA (*6,36*), with incidences ranging from 0-45% of patients (*2,9,32*). A second explanation for the increase in anterior knee pain in patients with different TKA designs is the type of bearing. Current total knee prosthetic systems can be divided into two groups : fixed bearing and mobile bearing devices. Tibia rotations are essential to achieve deep flexion in the normal knee. With increasing knee flexion, the tibia internally rotates relative to the femur and the lateral femoral condyle sometimes subluxes posterior relative to the tibia plateau (*15*). Since the mobile bearing devices typically allow for more tibia rotation, several studies have reported the mobile bearing devices to better recreate native knee kinematics than the fixed bearing devices (*12,13,28*). This can also lead to improved patellar tracking and lower patellofemoral contact stresses, which might reduce anterior knee pain (*31,36*). So, one would expect a decrease in anterior knee pain after rotating platform prosthesis.

To assess difference in passive and active postoperative flexion and anterior knee pain we performed a randomized clinical trial including the two extremes of knee arthroplasty designs, being a high flex posterior stabilized rotating platform prosthesis versus a traditional cruciate retaining fixed bearing prosthesis. We hypothesised that the HF-PS design would allow more flexion, due to increased femoral rollback with less anterior knee pain than the CR design. We specifically assessed the following hypotheses :

1. Patients have increased flexion after HF-PS TKA compared to CR TKA, both passive and active.
2. Patients show an increased femoral rollback in the HF-PS TKA as compared to the CR TKA.
3. Patients receiving a HF-PS TKA design report reduced anterior knee pain relative to those receiving the CR TKA.

PATIENTS AND METHODS

To test the hypotheses we used a patient cohort which was included in a double blind randomized controlled trial with a HF-PS prosthesis (posterior-stabilized PFC Sigma RP-F, rotating-platform TKA system, DePuy International, Leeds,UK) and a CR prosthesis (cruciate retaining PFC Sigma, fixed bearing TKA system, DePuy International, Leeds, UK). The study protocol was approved by the institutional review board at our hospital and it was carried out in line with the Helsinki Declaration. The study was registered in the ClinicalTrials.gov Protocol Registration System (Identifier : NCT 00899041). All patients who were scheduled to undergo primary total knee arthroplasty because of severe osteoarthritis were considered for inclusion and were enrolled prospectively. Exclusion criteria were dementia, hemophilia, juvenile rheumatoid arthritis, contralateral osteoarthritis or total knee arthroplasty, BMI < 25 kg/m^2 and ligament insufficiency that needed a posterior-stabilized or otherwise more constrained type of design. The minimal BMI was 25 to resemble the mild obesity in earlier studies (*16,26*) for realistic comparison. Between October 2008 and December 2011, 88 consecutive patients were assessed for eligibility.

After written informed consent had been obtained, 67 knees were randomly allocated to 2 groups. Thirty knees were selected to receive the HF-PS prosthesis and 37 knees to receive the CR prosthesis. The patients were randomised by a nurse practitioner using a blinded envelope technique.

Identical surgical techniques were used in the groups according to the manuals of the designers. Four experienced surgeons were involved in the study. A pneumatic tourniquet was used for all patients. The surgeries were performed using a standard medial parapatellar approach. The same type of instruments (PFC Sigma) was used in all cases, incorporating a posterior referencing guide for sizing the femoral component. Sequential soft-tissue release was performed after careful evaluation of the flexion/extension gaps with the spacers included in the surgical instruments. Releases were undertaken to obtain

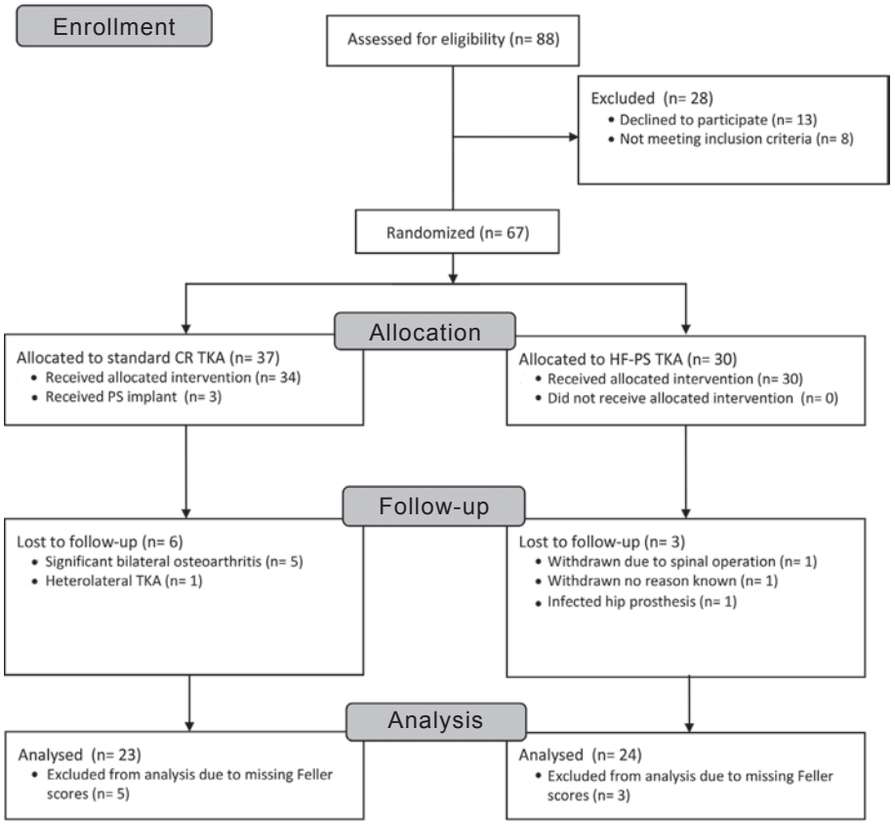

Fig. 1. — CONSORT 2010 Flow diagram

quadrilateral flexion/extension gaps. All components were cemented. No patellar components were used in any case. Circumferential electro cautery of the patella was performed in all cases.

Active range-of-motion exercises and walking were started under the supervision of a physiotherapist on the day of surgery. Follow-up evaluation was scheduled one year postoperative.

Preoperative and postoperative review data were recorded by a nurse practitioner who was blinded regarding patient allocation.

To investigate passive postoperative flexion, a standard goniometer measurement was performed with the patient in supine position. To investigate active postoperative flexion and rollback, a lateral maximum active flexion roentgen photograph was made (*22*). This maximum flexion lateral photograph was used to measure maximal active flexion, femoral rollback and posterior condylar offset as described by Laidlaw *et al* and Bellemans *et al* (*5,22*) as shown in Figure 2. All measurements were performed by one person (SvdG). The intra-observer variability was determined by measuring the rollback on 20 photographs twice with an interval of one month. The maximal variation was 3 mm, the average variation between both measurements was 1.0 mm (SD 0.79). To investigate anterior knee pain, the Visual Analogue Scale was used ranging from 0 mm (no pain) and 100 mm (worst pain imaginable) for the pain during a knee bend and the Feller anterior knee pain score was used (*14*). Preoperatively the quadriceps strength was considered normal in both groups in the Feller score to maximise the effect of the intervention. So, to summarize, we measured passive and active non-weight bearing flexion, femoral rollback, posterior condylar offset, VAS pain score during a squat and Feller score.

Statistical analysis

The primary outcome measure described in the current article is the difference in postoperative flexion angle. An a priori sample size calculation showed that 16 patients in each group would allow the detection of a

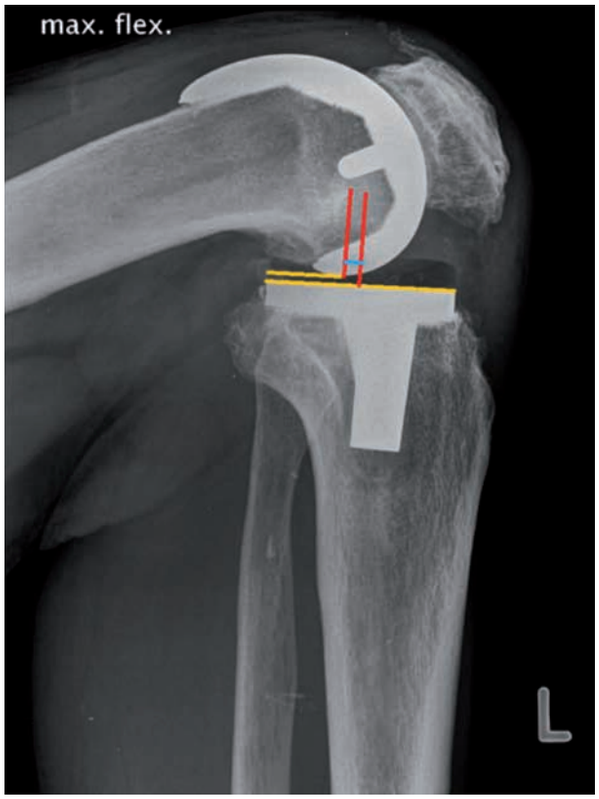

Fig. 2. — Example of a maximum flexion roentgen photograph of the CR prosthesis. The difference between the midpoint of the tibia plateau and contact point of the posterior condyle is the femoral rollback (indicated with the blue line).

difference of 10° (power = 0.8, $\alpha = 0.05$) with a standard deviation of 10° in postoperative flexion of the knee between the two groups. So, this study is adequately powered. The difference in rollback, posterior condylar offset, VAS and Feller score were considered as secondary outcome measures of the current study.

All data was analysed using SPSS 17.0. A two-sample *t*-test was used to compare differences between the groups before and after surgery for those outcome parameters that were normally distributed. For non-parametric data the Mann-Whitney U test was used. Differences were considered significant at the $p < 0.05$ level. We did not correct for testing multiple variables. The Pearson's test was used to determine correlations.

RESULTS

During surgery of three patients in the CR group the posterior cruciate ligament was regarded by the surgeon as insufficient. For this reason a posterior stabilised standard fixed bearing prosthesis was implanted and the patients were excluded from the study. At the three month analysis, six patients in the HF-PS group and three patients in the CR group were excluded since they turned out to meet exclusion criteria. These patients were registered as lost to follow up. The final group included therefore 47 patients, 24 patients in the HF-PS group and 23 patients in the CR group ; see figure 1 for CONSORT flow chart. The demographic results and clinical status at baseline of both groups are presented in Table I. The baseline results show similar mean values for almost all parameters.

In one patient, who received the HF-PS prosthesis, the preoperative Feller score was not documented. In one patient with the HF-PS prosthesis and two patients with the CR prosthesis, a maximum flexion roentgen photograph was missing and therefore the maximal active flexion angle and rollback could not be measured in these patients.

In the CR group one patient had less than 90° of flexion at short term follow-up and therefore the knee was manipulated under anaesthesia at 12 weeks follow-up. There were no further complications in any of the patient groups.

With postoperative passive flexion as the defined primary outcome measure in this paper, there was a significant difference between groups in favour of the HF-PS group. The HF-PS group had 120.8° (SD 10.3°) of flexion compared to 112.0° (SD 9.5°) of flexion for the CR group ($p = 0.004$). The patients with the HF-PS prosthesis gained on average 6° of flexion and the patients with the CR prosthesis lost on average 4° of flexion compared to preoperative flexion. So, when comparing the groups the difference in flexion was 10°. Eight patients in the HF-PS group and none of the patients in the CR group had a flexion of ≥ 130°. All patients achieved full extension. The correlation between pre- and postoperative passive flexion is poor ($r = 0.09$; $p = 0.56$).

The active maximum flexion as measured on the roentgen photograph was not significantly different for both groups ($p = 0.17$), but it was considerably lower than the measured passive range of motion ; in the HF-PS group the difference was on average 14.3° and in the CR group 10.4°. The rollback in the

Table I. — Demographic results

Parameter	HF-PS (n = 24) mean (SD)	CR (n = 23) mean (SD)
Age	66.5 (8.0)	65.2 (8.2)
Female:Male	11:13	12:11
Body Mass Index (kg/m²)	32.1 (5.2)	30.8 (3.9)
Side Right:Left	10:14	13:10
Follow-up (months)	13.9 (4.8)	17.5 (6.1)
VAS	52.5 (24.4)	51.0 (21.2)
Feller score	11.1 (5.0)	9.4 (5.8)
Passive flexion	115.2° (11.4°)	115.9° (12.4°)
Posterior condylar offset	30.5 mm (4.0 mm)	30.5 mm (3.4 mm)

HF-PS group was significantly higher than in the CR group (8.4 [SD 2.1] mm vs. 4.4 [SD 3.0] mm ; $p < 0.001$). However, the correlation with postoperative flexion was relatively poor ($r = 0.37$; $p = 0.01$). The posterior condylar offset showed no significant difference between both groups ; HF-PS group 28.6 mm and CR group 29.2 mm ($p = 0.60$). In table II the results are summarized.

Evaluation of the VAS pain score during a knee squat movement showed no significant difference between the two groups. In the HF-PS group it was 18.3 mm vs. 18.8 mm in the CR group ($p = 0.95$). The Feller score was 27.2 in the HF-PS group and 27.3 in the CR group, with no significant difference between the two groups. The correlation between postoperative Feller score and VAS score was $r = 0.48$ ($p = 0.001$). Hence, no difference in anterior knee pain between the two groups was detected. When comparing patients with a flexion of ≥ 130° postoperative and < 130° within the HF-PS group, no significant difference in anterior knee pain was found. However, we did detect an interesting trend. The patients achieving a postoperative flexion ≥ 130° showed a higher, yet not statistically different, VAS score during a knee squat ; 30.5 (SD 32.2) versus 12.2 (SD 12.5) ($p = 0.16$) within the HF-PS group. The preoperative VAS was equal in both groups (53.5 [SD 22.3] in the ≥ 130° group and 51.9 [SD 26.0] in the < 130° group, $p = 0.88$). The postoperative Feller score did not show the same clear trend as the postoperative VAS score. The postoperative Feller score was 26.5 [SD 6.4] in the ≥ 130° group and 27.5 [SD 4.0] in the < 130° group, $p = 0.64$.

DISCUSSION

The first hypothesis tested was that patients would have increased flexion after HF-PS TKA compared to CR TKA. We found that there was a significantly higher passive postoperative flexion in the HF-PS group compared to the CR group (120.4° [SD 10.1°] versus 113.5° [SD 10.9°]). This is in concordance with literature (*16,26*). Despite the clear

Table II. — Results, $p < 0.05$ is indicated in bold

Parameter	HF-PS mean (SD)	CR mean (SD)	p-value
VAS	18.3 (22.2)	18.8 (23.2)	0.95
Feller score	27.2 (4.8)	27.3 (4.4)	0.95
Passive flexion	120.8° (10.3°)	112.0° (9.5°)	*0.004*
Active flexion	106.5° (10.5°)	101.6° (12.9°)	0.17
Rollback	8.4 mm (2.1 mm)	4.4 mm (3.0 mm)	*< 0.001*
Posterior condylar offset	28.6 mm (3.7 mm)	29.2 mm (4.0 mm)	0.60

difference in passive flexion, the active non-weight bearing flexion was not different between the two groups. This might be caused by the fact that flexion strength after total knee arthroplasty remains up to 32.2% lower after total knee arthroplasty compared to the healthy knee (*35*). Patients may therefore be not strong enough to actively flex the knee to the same extend as is possible passively.

The overall postoperative passive flexion in the HF-PS group was higher than in the CR group, with a mean of 120° compared to 112° of flexion. The prosthesis is designed to increase flexion up to 155° of flexion. In the present study only eight patients in the HF-PS group and none of patients in the CR group achieved a flexion of 130° or higher. In the HF PS group the gain was 6°, while in the CR group the patients lost 4° of flexion. This respective gain and loss in flexion is probably not clinically relevant. A 10° difference however, can be clinically relevant.

The second hypothesis was that patients would show an increased femoral rollback in the HF-PS TKA compared to the CR TKA. The present study showed a significantly higher rollback of almost 4 mm in the HF-PS group. The higher rollback in the HF-PS group is most likely the reason for the higher postoperative flexion in the HF-PS group (Pearson's correlation $r = 0.32$), because more rollback results in a better clearance of the posterior condyles from the tibia plateau, which prevents posterior impingement. In the posterior stabilized design the post on the insert dictates the rollback. In the cruciate retaining design, the rollback is depending on the tightness, the position and the stiffness of the posterior cruciate ligament. The posterior cruciate ligament can be difficult to balance. During preparation of the tibia plateau the posterior cruciate ligament can be damaged, which results in an insufficient function of the posterior cruciate ligament. This results in a reduction in posterior rollback, which leads to earlier posterior impingement and therefore less flexion (*3*). Furthermore, the posterior condyles of the HF-PS prosthesis are thicker than the condyles of the CR prosthesis. So, while preparing the bone cuts, more of the native posterior condyles of the femur has to be removed. This increases the accessibility of the posterior osteophytes. It is therefore easier to remove the posterior osteophytes in the HF-PS prosthesis than in the CR prosthesis. This might have positively influenced the postoperative flexion as measured in the HF-PS group. Nevertheless, it should be realized that, both groups achieved flexion above 110°, which is adequate for typical daily activities in western countries (*30*).

The last hypothesis was that patients receiving a HF-PS TKA design would report reduced anterior knee pain relative to those receiving the CR TKA. This hypothesis was assessed by the determination of secondary outcome measures. No difference was found between both groups in VAS pain scores during a squat movement, however both groups showed a considerable improvement of the VAS score (50 preoperatively and 18 postoperatively). Despite this improvement, the patients clearly have pain during the squat movement. Postoperatively, no significant difference was found between both groups regarding Feller knee score and VAS pain in flexion. This is in contrast to what one would expect. Previous studies have shown lower patellofemoral contact forces and better patellar tracking in mobile bearing compared to fixed bearing total knee arthroplasty (*31,36*). However, another cadaver study showed higher (but non-significant) patellofemoral forces in PS compared to CR designs (*34*). So, the positive effect of the mobile bearing design might be counteracted by the posterior stabilised design. Moreover, after total knee replacement the patellofemoral contact forces are overall higher than in the normal knee (*36*). Furthermore, patellar tracking after TKA differs significantly from the normal knee (*4*). This might be an explanation for the relatively high VAS score (about 18 mm) during squatting and the absence of difference between both groups for the Feller knee score. Interestingly, when comparing patients receiving the HF-PS TKA design and achieving postoperative flexion of $\geq 130°$ with patients achieving $< 130°$, the first group had a clearly (but not statistically significant) higher VAS during a squat (30.5 vs. 12.2). The Feller score did not show such a difference (26.5 vs. 27.5). The Feller score is a questionnaire, which provides a measurement of anterior knee pain during normal daily activities, such as getting out of a chair or walking the stairs. The VAS score was obtained during a

knee squat, so during higher flexion. This might be the explanation why a clear difference was found in the VAS score and not in the Feller score.

Unfortunately, at the time of the design of this RCT, a reliable and valid questionnaire to adequately assess the problem of AKP in patients following knee arthroplasty was lacking. Currently used questionnaires do not adequately assess AKP in patients following TKA. Nowadays, the Kujala Anterior Knee Pain Scale (AKPS), is a validated tool to evaluate patellofemoral pain or AKP (*10,21*) in TKA. Recently, the AKPS has been validated in Dutch for patients after joint replacement surgery of the knee (*20*). It was concluded that the AKPS is a reliable and valid score in patients after knee arthroplasty, with no ceiling and floor effects, and can be used to assess anterior knee pain in patients who underwent joint replacement surgery. The Feller score is therefore, in retrospect, probably not the best score to evaluate AKP in patients after TKA.

Our study has some advantages, as it was prospective and randomised with both the patient and investigator blinded to which TKA had been used. Both passive and active range of motion were measured. By obtaining maximum flexion roentgen photographs, we were able to quantify rollback in an objective manner. In our opinion, rollback is very important in the assessment of a cruciate retaining TKA since it is directly related to posterior cruciate ligament functioning and for PS prosthesis it provides information about the functioning of the post-cam mechanism.

Despite its advantages, the present study does have some limitations. First of all, the roentgen photographs at maximal flexion were often not taken exactly lateral to the femoral component. This was probably caused by the fact that patients were asked to actively bend the knee in a supine position without any further constraints. Therefore, the measurements were sometimes difficult to perform, however the main difference in rollback of 4 mm was much more than the average measurement error of 1.0 mm.

Another limitation is that no intraoperative control of posterior cruciate ligament tension was performed as proposed by Heesterbeek *et al* (*18*). This would have made it possible to determine whether the lower rollback values in the CR groups could be related to laxity of (or damage to) the posterior cruciate ligament or the prosthetic design itself. Another limitation is the short follow-up period and the significant difference in this period between both groups. Both groups have a follow-up of longer than one year. It has been reported that functional outcome plateaus by one year, with smaller, less measurable changes subsequently (*19,23*). Another issue of debate is the use of a patellar component. In the present study, and according to our surgical routine, the patella was not resurfaced. Based on the literature, we do not think that the use of a patella component influences anterior knee pain (*8,17,25,27*).

In conclusion, the present study showed a significant higher passive flexion in the Posterior Stabilised-High Flexion mobile bearing compared to a Cruciate Retaining fixed bearing prosthesis. However, this difference disappeared when comparing active flexion. The difference in passive flexion was probably related to a significantly lower rollback causing impingement in the CR prosthesis. No difference in anterior knee pain was found between both groups. However, a suggestion is raised that achieving high-flexion might lead to more patellofemoral complaints.

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