Range of motion and function are similar in patients undergoing TKA with posterior stabilised and high-flexion inserts

Aamer Malik · Antonio Salas · Judith Ben Ari ·
Yan Ma · Alejandro González Della Valle

Received: 18 May 2009 / Revised: 18 August 2009 / Accepted: 19 August 2009 / Published online: 20 October 2009
© Springer-Verlag 2009

Abstract It is debatable whether high-flexion (HF) total knee arthroplasty (TKA) designs will improve postoperative flexion and function or will diminish the need for manipulation under anaesthesia (MUA). We retrospectively analysed range of motion (ROM), flexion, Knee Society Score (KSS), and rate of MUA in a consecutive group of patients who underwent TKA with a conventional posterior stabilised (PS) insert or an HF insert using identical surgical technique, implant design, and postoperative care. Fifty TKAs with a standard PS insert were matched for patient's age, gender, preoperative ROM, and KSS with 50 TKA performed with an HF insert. The patient's ROM and KSS were evaluated at six weeks, four months, and one year postoperatively. The outcome variables (flexion, ROM, KSS, and manipulation rate) in both groups were compared using the generalised estimating equations method. A second

analysis of patients with preoperative flexion $\geq 120^\circ$ was performed. The ROM, flexion, and patient-reported KSS was similar in both groups at each time period. The rate of MUA was also similar. Patients with a preoperative ROM of at least 120° showed similar results. Our study found that one year after surgery, patients who underwent TKA with a PS or an HF insert achieved similar flexion, ROM, and function.

Introduction

Since the introduction of modern total knee arthroplasty (TKA), there have been substantial improvements in anaesthesia, surgical technique, prosthetic design, and perioperative care in an attempt to diminish perioperative complications, accelerate recovery, and improve postoperative function. Among the early complications of surgery, stiffness remains a serious concern. In an analysis of seven studies reporting the results of 16,299 primary TKAs, manipulation under anaesthesia (MUA) was required in 4.5% of patients [5, 12, 16, 19, 30, 36, 40]. Postoperative range of motion (ROM) is influenced by preoperative, intraoperative, and postoperative factors [7]. There has been a recent interest in the development and use of TKA designs capable of accommodating the kinematics of high flexion [2, 10, 26, 35, 37]. The design features that have been introduced in the high-flexion (HF) knee replacements include changes in the geometry of the polyethylene insert [2, 18] with or without changes in the femoral component [10, 35, 37]. The design changes aim at facilitating flexion by improving the TKA kinematics in high flexion. It remains debatable whether the design changes in the so called HF TKA will not only facilitate but also increase postoperative flexion and diminish the manipulation rate [1, 8, 10, 14, 17, 18, 22, 27, 29, 37].

A. Malik · J. Ben Ari · A. González Della Valle
Department of Orthopaedic Surgery, Hospital for Special Surgery,
New York, NY, USA

A. Malik · J. Ben Ari · A. González Della Valle
Weill Medical College of Cornell University,
New York, NY, USA

Y. Ma
Department of Public Health, Weill Medical College
of Cornell University, Hospital for Special Surgery,
New York, NY, USA

A. Salas
Hospital of Orthopedics and Traumatology No. 21,
Monterrey, Mexico

A. González Della Valle (✉)
Hospital for Special Surgery,
535 East 70th Street,
New York, NY 10021, USA
e-mail: gonzaleza@hss.edu

The aim of this study was to answer the following research questions: Are the ROM, flexion, Knee Society Score (KSS) [11], and manipulation rate different in patients who undergo TKA surgery with a standard posterior stabilised (PS) insert or an HF design?

Material and methods

This study received institutional review board approval. We retrospectively reviewed office and hospital charts and pre- and postoperative radiographs of all patients receiving a primary TKA by the senior author (AGDV). There were 135 patients who underwent 154 primary TKAs between 23 January 2006 and 25 January 2008. Bilateral surgery was performed in 19 of the 133 patients (11 patients had a single-stage bilateral and eight patients had staged bilateral surgery). In all but two patients (two knees), the author used the same prosthetic design (Genesis 2, Smith and Nephew, Memphis, TN, USA). A different prosthetic design was used in only two patients (two knees) who presented with a severe, fixed valgus deformity. They received stemmed, constrained TKAs of a different design and were not included in the analysis.

The Genesis 2 prosthetic design includes a femoral component with symmetrical posterior condyles and an asymmetrical tibial tray. The tray and the femoral component accept a standard PS insert, an HF insert, and a constrained (CCK) insert that can be selected during surgery based on the surgeon's preference and the joint stability. The polyethylene in the HF design has been trimmed in the anterior portion of the insert and the post to increase clearance of the extensor mechanism in high flexion. In addition, a lowered posterior lip reduces contact stresses and edge loading in deep flexion while moving the flexion contact point anterior and distal to the proximal edge of the posterior condyles. The polyethylene has also been trimmed in the posterior–central region to avoid impingement in deep flexion (Fig. 1).

Fig. 1 Standard posterior stabilised (PS) (*left*) and high-flex (HF) (*right*) polyethylene inserts

Of the 133 patients with 152 TKAs, 21 patients (21 knees) received a CCK insert due to the presence of ligamentous instability and were excluded. Of the remaining 112 patients (131 knees), 54 (62 knees) received a standard PS insert, and 60 (69 knees) received an HF insert (two patients with staged bilateral TKA received a PS insert in one knee and an HF insert in the other). All 112 patients (131 knees) were considered for this study. The PS and HF inserts were used according to availability with a tendency to routinely use PS inserts at the beginning of the study period and HF inserts at the end.

Of the 112 patients (131 knees) with PS or HF inserts, 18 patients (20 knees; - 12 PS/8 HF) were subsequently excluded: four patients (5 knees 3 PS/2 HF) were lost to follow-up before the first year. Nine patients (10 knees 7 PS/3 HF) would not come for follow-up but had a good result when contacted over the phone. Two patients (2 knees 1 PS/1 HF) would not come to follow-up and were unhappy with the result due to persistent knee pain. Two patients (2 knees 1 PS/1 HF) developed aseptic loosening of the patella, and one patient (1 knee HF) developed a deep infection. The remaining 96 patients (111 knees) were studied. For our matched-pair study that focused on endpoints pertinent to TKA (ROM, flexion, and need for MUA), the knee and not the patient was considered the unit of study. Consequently, 50 knees with a PS insert were matched with 50 knees with an HF insert for patient's age, gender, body mass index (BMI), and preoperative ROM. In addition, the preoperative diagnosis, preoperative flexion, patient-reported and physician-reported sections of the KSS, and the limb alignment as measured in the preoperative radiographs were similar between the two groups (Table 1).

Outcome variables studied in the matched-pair group were passive ROM and gravity-assisted flexion, which were measured with a goniometer, and the patient- and physician-reported KSS at six weeks, four months, and one year after surgery. All measurements were obtained by the operating surgeon (AGDV). The incidence of manipulation was recorded and compared between groups. In order to determine whether HF TKA provides benefit to a selected group of patients with high preoperative flexion [18], a separate analysis was performed for the subgroup of patients with high preoperative flexion (120° or more) (Table 2). Twenty-six patients (28 knees) with an HF insert and 26 (26 knees) with a PS insert were included in the secondary analysis. The preoperative variables analysed were similar in the two groups with high preoperative flexion (Table 2).

All operations were performed using a combined spinal epidural anaesthetic supplemented by a femoral nerve block. Under tourniquet control that ranged between 200 and 300 mmHg, a standard midline incision measuring

Table 1 Comparison of preoperative variables (50 pairs)

	Variable	PS mean $\pm$ SD (range)	HF mean $\pm$ SD (range)	<i>P</i> value
	Age (years)	62.8 $\pm$ 10.7 (46–87)	66.4 $\pm$ 9.6 (51–85)	0.8
	Gender: female/Male	38/12	38/12	1
	BMI	33.0 $\pm$ 6.6 (19–51)	32.6 $\pm$ 5.6 (20–50)	0.72
	Preoperative ROM ^a	112 $\pm$ 15 (70–140)	114 $\pm$ 22 (80–140)	0.64
	Preoperative flexion ^a	114.6 $\pm$ 13.4 (70–140)	115 $\pm$ 21.3 (80–140)	0.91
	Preoperative diagnosis OA/RA	49/1	50/0	1
	Patient-reported KSS	41.7 $\pm$ 16.1 (18–92)	43.2 $\pm$ 13.3 (10–67)	0.59
	Physician-reported KSS	35.6 $\pm$ 15.8 (6–84)	36.9 $\pm$ 18.1 (8–80)	0.69
	Preoperative AP limb alignment ^{a,b}	5.2 $\pm$ 3.5 (–4.8 to 10.9)	5.9 $\pm$ 2.8 (–1.6 to 11.4)	0.32

^a Measurement in degrees^b Valgus has a negative value and varus a positive value

between four and seven inches (10–20 cm) and a standard medial parapatellar arthrotomy without patellar eversion was used in all patients. The tibial cut was made using an extramedullary guide referencing off the most normal side. The surgeon used a posterior tibial slope that approximately matched the patient's anatomy. The femur was prepared with an intramedullary guide set at 5° of valgus and using anterior referencing jigs. Rotation was determined by the posterior femoral condyles and using the epicondylar axis and Whiteside's line [39] in patients with anatomical abnormalities. Flexion and extension soft-tissue gap balancing was done with the use of spacer blocks in an attempt at obtaining equally symmetrical gaps. Resurfacing of the patella was performed in all cases. All implants were cemented.

Postoperative pain control was achieved with an epidural patient-controlled analgesic of a local anaesthetic and fentanyl for the first 24 hours postoperatively, progressing to oral analgesics as tolerated. Drains were used in all cases and removed on the first postoperative day. Rehabilitation was initiated on the day of surgery, with a continuous passive motion machine set at 0 to 60°, and patients were weight bearing, as tolerated. All patients received antibiotic prophylaxis. Pharmacological thromboprophylaxis included aspirin in 60% of patients. The remaining 40% who were considered at high risk of thromboembolism or were receiving Coumadin prior to surgery received Coumadin

with a goal international normalized ratio (IRN) between 1.8 and 2. Pharmacologic thromboprophylaxis was similar in the two groups ($p=0.68$). Patients were discharged home or to inpatient rehabilitation units within three to four days after surgery and were seen in the surgeon's office at six weeks, four months, and one year after surgery. ROM and patient- and physician-reported KSS were obtained by the operating surgeon (AGDV) at each visit. In addition, to further assure comparability between the two groups, the standard radiographs in anteroposterior, lateral, and axial views that were obtained at the six week and one year visits were evaluated by an independent observer (AM). Postoperative radiographs were evaluated using the Knee Society Roentgenographic Evaluation System [4]. The PS and HF groups had similar femorotibial limb alignment ($p=0.32$), femoral component lateral alignment ($p=0.22$), and tibial slope ($p=0.27$).

Statistical analysis Propensity scores of receiving PS and HF given patient's age, gender, BMI, and preoperative ROM were obtained. Samples in the PS and HF groups with nearly equal propensity scores were selected and matched. The purpose of matching analysis was to remove bias in the background covariates and generate comparable PS and HF pairs [3]. Chi-square tests/Fisher's exact tests and two sample *t* tests were used to evaluate the significance of comparison between these two groups for discrete variables

Table 2 Comparison of preoperative variables in patients with high preoperative flexion

	Variable	PS mean $\pm$ SD (range)	HF mean $\pm$ SD (range)	<i>P</i> value
	Age (years)	67.1 $\pm$ 9.9 (46–87)	65.1 $\pm$ 9.9 (51–84)	0.45
	Gender: female/Male	18/8	20/8	1
	BMI	31.2 $\pm$ 5.4 (19–45)	31.4 $\pm$ 4.9 (20–45)	0.92
	Preoperative ROM ^a	122 $\pm$ 10.1 (100–140)	125 $\pm$ 8.1 (105–140)	0.27
	Preoperative flexion ^a	125 $\pm$ 6 (120–140)	127 $\pm$ 6.2 (120–140)	0.25
	Preoperative diagnosis OA/RA	26/0	28/0	1
	Patient reported KSS	46 $\pm$ 19.4 (18–92)	46 $\pm$ 13.3 (20–67)	0.95
	Physician reported KSS	40 $\pm$ 17.3 (20–84)	41 $\pm$ 18.9 (8–80)	0.94
	Preoperative AP limb alignment ^{a,b}	6.1 $\pm$ 3.1 (–1.6 to 10.9)	5.5 $\pm$ 3.1 (–1.6 to 11.4)	0.53

^a Measurement in degrees^b Valgus has a negative value and varus a positive value.

and continuous variables, respectively. Matching analysis was carried out using the R software platform, a language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0, URL <http://www.R-project.org>). Statistical analyses were performed using SAS 9.1.3 (SAS Institute, Cary, NC, USA). Continuous variables were summarised by mean $\pm$ standard deviation (SD) of mean and range. Discrete variables were presented by frequency. We set the statistical significance at $\alpha=0.05$. Power analysis was conducted, and 50 patients per group were required in order to detect an increase in ROM of 10% in the HF group at one year follow-up and achieve a power of 80%.

Results

When 50 pairs were considered, the ROM and flexion were similar between the two groups at each one of the postoperative visits (Table 3). Both the total ROM and the flexion showed a sharp increasing trend from six weeks to four months but with an almost indiscernible change after four months. The patient- and physician-reported portions of the KSS were similar between the two groups at each one of the postoperative assessments, with the exception of the physician-reported portion of the KSS at six weeks, which was higher in the PS group ($p=0.03$) (Table 3). Both the patient- and physician-reported portions of the KSS showed a steep increasing trend from six weeks to four months but with an almost indiscernible change after four months. There was a nonsignificant difference in the incidence of MUA between the two groups (0/50 in the PS vs 3/50 in the HF, $p=0.24$).

The analysis of patients (28 knees in the HF and 26 knees in the PS) with a preoperative flexion $\geq 120^\circ$ revealed that the total ROM and the flexion were similar between the two groups at each time period (Table 4). Both ROM and flexion showed a sharp increasing trend from six weeks to four months but with an almost indiscernible change after four months. The patient- and physician-reported portions of the KSS were similar between the two groups at each one of the time periods, with the exception of the physician-reported portion of the KSS at four months, which was higher in the PS group ($p=0.003$) (Table 4). Both the patient- and physician-reported portions of the KSS showed a steep increasing trend from six weeks to four months but with an almost indiscernible change after four months. There was no difference in the incidence of MUA between the two groups (0/26 in the PS vs 2/28 in the HF, $p=0.5$).

Discussion

The modifications introduced in HF TKA designs are aimed at improving knee kinematics in high flexion. Most of the design changes in HF implants have been made on the polyethylene insert, which is the case of the TKA design used in our study. The most frequent changes in HF TKA designs can be summarized as follows: First, a deep recess on the anterior aspect of the insert and post reduces impingement with the extensor mechanism in high flexion [2, 23, 35]. Second, removal of polyethylene from the posterior aspect of the articulating surface relaxes the posterior slope of the insert, opens the flexion gap while maintaining the bone stock of the tibia, facilitates femoral roll back [2, 13], and reduces the torsional constraint that limits rotation of the components [15, 35]. Third, some

Table 3 Postoperative results at 6 weeks, 4 months, and 1 year of all patients (50 matched pairs)

Outcome	Postoperative visit							
	6 weeks			4 months			1 year	
	Group		<i>P</i> value	Group		<i>P</i> value	Group	<i>P</i> value
	PS mean $\pm$ SD (range)	HF Mean $\pm$ SD (range)		PS mean $\pm$ SD (range)	HF mean $\pm$ SD (range)		PS mean $\pm$ SD (range)	HF mean $\pm$ SD (range)
Arc of motion ^a	107 $\pm$ 15.2 (80–140)	104 $\pm$ 19.4 (60–145)	0.41	116 $\pm$ 12.6 (85–140)	116 $\pm$ 14.5 (87–140)	0.98	117 $\pm$ 15 (65–140)	119 $\pm$ 12.5 (90–140)
Flexion ^a	108 $\pm$ 14.5 (80–140)	105 $\pm$ 18.9 (60–145)	0.42	117 $\pm$ 12.1 (85–140)	117 $\pm$ 14.2 (87–140)	0.96	118 $\pm$ 14.1 (70–140)	120 $\pm$ 12.1 (90–140)
Patient-reported KSS	68 $\pm$ 11.6 (49–100)	68 $\pm$ 10.7 (38–91)	0.92	86 $\pm$ 11.7 (59–100)	88 $\pm$ 11.5 (59–100)	0.41	92 $\pm$ 8.2 (59–100)	93 $\pm$ 8.2 (59–100)
Physician-reported KSS	83 $\pm$ 12.5 (59–100)	77 $\pm$ 13.9 (35–100)	0.03	93 $\pm$ 9.7 (68–100)	90 $\pm$ 10.1 (56–100)	0.18	95 $\pm$ 6.9 (70–100)	93 $\pm$ 11.4 (32–100)

PS posterior stabilised insert, HF high-flexion insert, KSS Knee Society Score, SD standard deviation

^a Measurement in degrees

Table 4 Postoperative results at 6 weeks, 4 months, and 1 year of patients with high preoperative range of motion (ROM)

Outcome	Postoperative visit								
	6 weeks			4 months			1 year		
	Group		<i>P</i> value	Group		<i>P</i> value	Group		<i>P</i> value
	PS mean $\pm$ SD (range)	HF mean $\pm$ SD (range)		PS mean $\pm$ SD (range)	HF mean $\pm$ SD (range)		PS mean $\pm$ SD (range)	HF mean $\pm$ SD (range)	
Arc of motion ^a	113 $\pm$ 14.5 (80–140)	109 $\pm$ 20.5 (60–145)	0.39	121 $\pm$ 10.9 (100–140)	121 $\pm$ 14.5 (87–140)	0.94	123 $\pm$ 10 (100–140)	123 $\pm$ 11.7 (100–140)	0.95
Flexion ^a	113 $\pm$ 14.2 (80–140)	109 $\pm$ 15.7 (60–145)	0.45	121 $\pm$ 10.6 (100–140)	121 $\pm$ 13.9 (87–140)	0.23	118 $\pm$ 14.1 (70–140)	120 $\pm$ 12.1 (90–140)	0.43
Patient-reported KSS	71 $\pm$ 11.6 (49–100)	70 $\pm$ 12.3 (38–91)	0.77	88 $\pm$ 11.2 (69–100)	88 $\pm$ 13.1 (59–100)	0.90	94 $\pm$ 6.4 (76–100)	93 $\pm$ 9.6 (59–100)	0.64
Physician-reported KSS	87 $\pm$ 11.1 (62–100)	76 $\pm$ 14.9 (35–100)	0.004	96 $\pm$ 10.2 (68–100)	90 $\pm$ 10.7 (56–100)	0.07	96 $\pm$ 7.7 (70–100)	93 $\pm$ 11.7 (32–100)	0.30

PS posterior stabilised insert, HF high-flexion insert, KSS Knee Society Score, SD standard deviation

^a Measurement in degrees

prosthetic designs have introduced modifications to the femoral component that include thicker posterior femoral condyles with a tighter radius of curvature [23, 35]. This modification increases the articulating surface on the posterior aspect of the femoral condyles and consequently reduces the contact pressures in high knee flexion. This prevents posterior “edge loading” of the prosthetic condyles on the tibial insert and increases the arc of flexion. Fourth, in some HF designs, there are modifications of the cam-post mechanism to increase resistance to subluxation [10] and enhance posterior tibial translation [14, 35]. Some cruciate-retaining HF TKA designs include a chamfered medial border of the lateral femoral condyle to provide clearance to the posterior cruciate ligament in high flexion [22].

Despite the improved knee kinematics in high flexion introduced by the previously mentioned changes, it is still unclear whether these HF designs will actually improve clinical ROM and function [6]. It is also questionable whether they provide better flexion to all patients or if they benefit only a selected group of patients with high preoperative flexion [18]. Our study was designed to address these questions. We found no differences in postoperative knee flexion, ROM, or KSS between the two groups one year after surgery. The prevalence of MUA was also similar. The results were not significantly different when only patients with high preoperative flexion were analyzed.

Our study has limitations First, it was retrospective, and therefore, the potential for selection bias cannot be excluded. However, selection bias is unlikely, as the senior author (AGDV) used PS inserts routinely at the beginning of the study and gradually started to use HF inserts

routinely according to availability. Moreover, all preoperative variables analysed in the PS and HF groups were similar, discrediting the possibility of selection bias. To overcome this limitation, we performed a computer-generated matched-pair analysis based on age, gender, BMI, and preoperative ROM; and a strict comparison of diagnosis, preoperative KSS, and deformity between the groups (Tables 1 and 2). Second, the postoperative KSS and angular measurements were obtained by the operating surgeon (AGDV). The use of a single-observer eliminates interobserver variability in the measurements. However, it introduces the possibility of recollection bias. The senior author is a high-volume surgeon, and it is unlikely that he would remember the type of insert used for each patient at each one of the follow-up time periods. Third, we used passive (gravity-assisted) flexion as the final outcome measure. Maximum flexion achieved during kneeling or squatting was not evaluated and may differ in patients who receive PS or HF TKAs. Coughlin et al. [2] analysed patients who achieved high flexion following TKA with PS and HF designs and showed that although clinical gravity-assisted flexion was similar in both groups (128° and 129°, respectively), maximum weight-bearing flexion measured during kneeling or squatting was better in the high flexion group (118° and 125°, respectively, $p < 0.05$) [2]. Fourth, no patient outcome measures for satisfaction were analysed. Patient satisfaction may not be accurately reflected by the KSS and the ROM measured in our study. Outcome measures more sensitive than the KSS may be required to assess the clinical benefits of high flexion [21, 38]. Finally, anterior knee pain, which may be associated with deep-flexion activities, was not analysed, as it is not distinguished in the KSS. However, the KSS evaluates activities that involve the use of the patellofemoral joint. In our study,

the patient-reported scores for climbing stairs, descending stairs, raising from the sitting position, and pain while negotiating stairs were no different between the two groups at six weeks ($p=0.68$; 0.74, 0.13 and 0.14, respectively), four months ($p=0.82$; 0.63; 0.41 and 0.15) and one year after surgery ($p=0.83$; 0.68; 0.35 and 0.38).

The strengths of this study include the fact that it consisted of a consecutive series of patients operated upon by a single surgeon with a standardized surgical technique and identical implant design; and the rigorous matched-pair analysis and comparison of preoperative and postoperative variables. Based on the previous discussion of our shortcoming and strengths, we believe that our analysis allowed us to adequately address our research questions.

Our study and five others in the literature [14, 20, 22, 27, 29] failed to prove an increase in flexion with the use of HF TKAs. However, there is evidence that suggests that HF TKA designs may improve intraoperative passive ROM and postoperative maximum weight-bearing flexion. These variables were not evaluated in our study. Klein et al. used computer navigation to measure the intraoperative ROM of 27 TKAs and demonstrated that the use of an HF insert was associated with an increase in extension, flexion, and overall ROM when compared with a standard PS insert [15]. In addition, the previously discussed study of Coughlin et al. [2] showed that an HF TKA design achieved higher maximum weight-bearing flexion, such as the one required

for kneeling and squatting, than did a standard PS-design TKA. On the other hand, the modifications introduced in the HF TKA designs have potential downsides: The increase in the relative posterior slope of the insert achieved by removing material from the posterior aspect of the insert can result in anterior insert impingement [2], particularly if the surgeon inadvertently implants a tibial tray with excessive posterior slope. The removal of polyethylene from the posterior aspect of the insert may increase polyethylene contact stresses. Nagura et al. found that deep-flexion activities generate one to 13 times larger net quadriceps moments (average five) than does walking [25]. This may increase patellofemoral joint stresses, with the potential for causing pain, excess wear, patellar fracture, and loosening [9, 32]. Han et al. reported a 38% prevalence of femoral component loosening in the LPS HF TKA at a mean follow-up of 2.7 years in patients engaging in weight-bearing, high flexion activities [9]. Some HF femoral components also require a larger bone resection [32, 33]. Finally, high flexion may be associated with TKA cam-post instability: Moynihan et al. studied the in vivo knee kinematics of six patients who achieved high flexion after seven LPS HF TKAs (Zimmer, Warsaw, IN, USA) using dual-plane fluoroscopy. They found that cam-post engagement occurred at high-flexion angles, beginning at a mean of 100° and ending at a mean of 127° . At maximum flexion, five of the seven TKAs demonstrated cam-post disengagement and lateral femoral condylar lift-off

Table 5 Results of comparative studies between standard posterior stabilised (PS) inserts and high-flexion (HF) total knee replacement designs

Author	Year	Study design	Implant	Number of knees (PS + HF)	Mean follow-up	Preop flexion (control)	Preop flexion (HF)	Final flexion (control)	Final flexion (HF)	<i>P</i> value
Huang et al. [10]	2005	Retrospective match pair	Zimmer LPS vs LPS flex	25+25	28 months	112	110	126	138	<0.05
Kim et al. [14]	2005	Prospective randomised	Zimmer LPS vs LPS flex	50 bilateral	2.1 years	126	127	136	139	NSD
Gupta et al. [8]	2006	Retrospective match pair	PFC RF and PFC RP-F	50+50	12 months	110	110	116	125	0.0001
Bin et al. [1]	2007	Retrospective	Zimmer LPS vs LPS flex	90+90	12 months	122	123	124	129	<0.05
Laskin [17]	2007	Prospective cohort	Genesis 2 PS and HF	40+40	24 months	116	117	118	133	<0.01
Weeden et al. [37]	2007	Prospective randomised	Zimmer LPS vs LPS flex	25+25	12 months	121	122	120	133	<0.05
Ng et al. [27]	2008	Prospective cohort	Zimmer LPS vs LPS flex	35 bilateral	≥ 18 months	105	104	105	106	NSD
Minoda et al. [22]	2008	Consecutive series	Zimmer CR and CR HF	89+87	12 months	101	99	112	115	NSD
Nutton et al. [29]	2008	Prospective randomised	Zimmer LPS vs LPS flex	28+28	12 months	107	108	106	110	NSD
MacDonald et al. [18]	2009	Prospective cohort	S&N Genesis 2 CR, PS, CRHF	260+1913+360	12 months	n/a	n/a	n/a	n/a	<0.0001*
Present Study		Prospective match repair	Genesis 2 PS and HF	50+50	12 months	114	115	118	120	NSD

References: * Regression modeling revealed that patient with high preoperative flexion ($>120^\circ$) were more likely to have postoperative flexion gain than those with a PS insert ($p<0.0001$). *Preop* preoperative, *NSD* Not statistically different

[23]. Despite the previously mentioned concerns, the use of HF TKA designs has become popular, and the literature reporting on their clinical and biomechanical aspects is encouraging (Table 5).

Though intuitively patient satisfaction following surgery may be associated with the achievement of high flexion, the literature has proven otherwise [10, 13, 14, 29, 31]. Park et al. analysed ROM and clinical outcomes as measured by KSS, WOMAC, and SF-36 in 207 Korean patients (333 knees) one year following TKA. There was only a weak correlation between postoperative maximum flexion and pain relief, function, and quality of life [31]. In our KSS analysis, the patient-reported portion regarding pain while walking, while negotiating stairs, and at rest was similar in the PS and HF groups one year after surgery ($p=0.68$; $p=0.37$; $p=0.35$; $p=0.57$, respectively). Huang et al. evaluated the function and ROM of PS and HF TKA and reported that patients with HF TKA were able to squat more frequently than those with a PS TKA (80% vs 32%, respectively). However, none of the patients who were able to squat adapted to activities that demanded high flexion; moreover, 43% of those who were able to squat could not stand up without support. They concluded that squatting and other high-flexion activities played no role in patient's satisfaction from surgery [10].

The literature results comparing HF and PS TKA designs continue to be inconclusive and are probably design and surgeon dependent [6, 10, 13, 18, 20, 21, 28, 29, 38]. Table 5 outlines results from different studies comparing PS and HF TKA designs. Three of the four prospective randomised trials that compared the use of a PS and an HF TKA design failed to show differences in ROM [14, 20, 29]. The remaining study by Weeden et al. did report better flexion in the HF group compared with the PS group (133° and 120°, $p<0.05$) [37].

MacDonald et al. suggested that larger series of patients and registry data may demonstrate benefits of the HF designs better than smaller studies [18]. The authors studied a consecutive cohort of 2,523 patients using the Genesis 2 CR, PS, and HF designs. They found that preoperative flexion remained the most significant factor affecting postoperative ROM. However, the use of the HF inserts improved the chances of patients with high preoperative flexion to regain flexion postoperatively [18]. In a randomised controlled trial of 100 patients receiving a Genesis 2 TKA with a standard or HF insert, the same authors failed to demonstrate a clinically significant difference between the two groups [20]. A recent meta-analysis by Gandhi et al. concluded that HF implant designs improve the overall ROM compared with traditional implants but offer no clinical advantage in primary TKA [6]. In a systematic literature review focusing on outcomes after HF TKA, Murphy et al. found that there

was insufficient evidence to support the view that these new TKA designs improved ROM or functional performance [24]. This review included nine studies [1, 8, 10, 14, 17, 27, 29, 34, 37] with 399 HF TKAs in 370 patients. They conclude that the claims of greater flexion, ROM, and function for HF TKA reported in some of those studies were not supported due to poor study designs, short follow-up periods, inadequate blinding, and use of functional outcome measures that lacked sensitivity [24].

Our retrospective study found that at one year after surgery, both PS and HF inserts allow achievement of adequate flexion, ROM, and function in the majority of patients. Flexion, ROM, KSS, and MUA rate at one year of follow-up were similar in both groups.

Acknowledgements We are grateful to Mrs. Victoria Bidwell, Mr. Richard Sorgini, the Eleanor Jennings Myatt Memorial Fund, Dr. Eduardo Salvati and Dr. Thomas Sculco who provided funding for this study. We are grateful to Dr. Stephen Haas for his collaboration in the description of the high-flexion implant design used in our study.

Conflict of interest None.

References

1. Bin SI, Nam TS (2007) Early results of high-flex total knee arthroplasty: comparison study at 1 year after surgery. *Knee Surg Sports Traumatol Arthrosc* 15:350–355
2. Coughlin KM, Incavo SJ, Dooehen RR, Gamada K, Banks S, Beynnon BD (2007) Kneeling kinematics after total knee arthroplasty: anterior-posterior contact position of a standard and a high-flex tibial insert design. *J Arthroplasty* 22:160–165
3. D'Agostino R (1998) Tutorial in biostatistics propensity score methods for bias reduction in the comparison of a treatment to a non-randomized control group. *Stat Med* 17:2265–2281
4. Ewald FC (1989) The Knee Society total knee arthroplasty roentgenographic evaluation and scoring system. *Clin Orthop Relat Res* 248:9–12
5. Gandhi R, de Beer J, Leone J, Petruccioli D, Winemaker M, Adili A (2006) Predictive risk factors for stiff knees in total knee arthroplasty. *J Arthroplasty* 21:46–52
6. Gandhi R, Tso P, Davey JR, Mahomed NN (2009) High-flexion implants in primary total knee arthroplasty: a meta-analysis. *Knee* 16:14–17
7. Gonzalez Della Valle A, Leali A, Haas S (2007) Etiology and surgical interventions for stiff total knee replacements. *HSS J* 3:182–189
8. Gupta SK, Ranawat AS, Shah V, Zikria BA, Zikria JF, Ranawat CS (2006) The P.F.C. sigma RP-F TKA designed for improved performance: a matched-pair study. *Orthopedics* 29:S49–52
9. Han HS, Kang SB, Yoon KS (2007) High incidence of loosening of the femoral component in legacy posterior stabilized-flex total knee replacement. *J Bone Joint Surg Br* 89:1457–1461
10. Huang HT, Su JY, Wang GJ (2005) The early results of high-flex total knee arthroplasty: a minimum of 2 years of follow-up. *J Arthroplasty* 20:674–679
11. Insall JN, Dorr LD, Scott RD, Scott WN (1989) Rationale of the Knee Society clinical rating system. *Clin Orthop Relat Res* 248:13–14

12. Keating EM, Ritter MA, Harty LD, Haas G, Meding JB, Faris PM, Berend ME (2007) Manipulation after total knee arthroplasty. *J Bone Joint Surg Am* 89:282–286
13. Kim YH, Choi Y, Kwon OR, Kim JS (2009) Functional outcome and range of motion of high-flexion posterior cruciate-retaining and high-flexion posterior cruciate-substituting total knee prostheses. A prospective, randomized study. *J Bone Joint Surg Am* 91:753–760
14. Kim YH, Sohn KS, Kim JS (2005) Range of motion of standard and high-flexion posterior stabilized total knee prostheses. A prospective, randomized study. *J Bone Joint Surg Am* 87:1470–1475
15. Klein GR, Parvizi J, Rapuri VR, Austin MS, Hozack WJ (2004) The effect of tibial polyethylene insert design on range of motion: evaluation of in vivo knee kinematics by a computerized navigation system during total knee arthroplasty. *J Arthroplasty* 19:986–991
16. Kucera T, Urban K, Karpas K, Sponer P (2007) Restricted motion after total knee arthroplasty. *Acta Chir Orthop Traumatol Cech* 74:326–331
17. Laskin RS (2007) The effect of a high-flex implant on postoperative flexion after primary total knee arthroplasty. *Orthopedics* 30:86–88
18. MacDonald SJ (2009) Factors the affect patient outcome - the influence of a high flexion design. In *Proceedings of The Knee Society Meeting, Las Vegas, NV*
19. Maloney WJ (2002) The stiff total knee arthroplasty: evaluation and management. *J Arthroplasty* 17:71–73
20. McCalden RW, MacDonald SJ, Bourne RB, Marr JT (2009) A randomized controlled trial comparing hi-flex versus standard posterior cruciate substituting polyethylene tibial inserts in total knee replacement. In *Proceedings of The 18th Annual Meeting of AAHKS, Dallas, TX*
21. Meneghini RM, Pierson JL, Bagsby D, Ziemba-Davis M, Berend ME, Ritter MA (2007) Is there a functional benefit to obtaining high flexion after total knee arthroplasty? *J Arthroplasty* 22:43–46
22. Minoda Y, Aihara M, Sakawa A, Fukuoka S, Hayakawa K, Ohzono K (2009) Range of motion of standard and high-flexion cruciate retaining total knee prostheses. *J Arthroplasty* 24:674–680
23. Moynihan AL, Varadarajan KL, Hanson GR, Park SE, Nha KW, Suggs JF, Johnson T, Li G (2009) In vivo knee kinematics during high flexion after a posterior-substituting total knee arthroplasty. *Int Orthop E-pub ahead of print*. DOI: [10.1007/s00264-009-0777-2](https://doi.org/10.1007/s00264-009-0777-2)
24. Murphy M, Journeaux S, Russell T (2009) High-flexion total knee arthroplasty: a systematic review. *Int Orthop* 33:887–893
25. Nagura T, Dyrby CO, Alexander EJ, Andriacchi TP (2002) Mechanical loads at the knee joint during deep flexion. *J Orthop Res* 20:881–886
26. Nagura T, Otani T, Suda Y, Matsumoto H, Toyama Y (2005) Is high flexion following total knee arthroplasty safe?: evaluation of knee joint loads in the patients during maximal flexion. *J Arthroplasty* 20:647–651
27. Ng FY, Wong HL, Yau WP, Chiu KY, Tang WM (2008) Comparison of range of motion after standard and high-flexion posterior stabilized total knee replacement. *Int Orthop* 32:795–798
28. Noble PC, Gordon MJ, Weiss JM, Reddix RN, Condit MA, Mathis KB (2005) Does total knee replacement restore normal knee function? *Clin Orthop Relat Res* 431:157–165
29. Nutton RW, van der Linden ML, Rowe PJ, Gaston P, Wade FA (2008) A prospective randomized double-blind study of functional outcome and range of flexion following total knee replacement with the NexGen standard and high flexion components. *J Bone Joint Surg Br* 90:37–42
30. Pariente GM, Lombardi AV Jr, Berend KR, Mallory TH, Adams JB (2006) Manipulation with prolonged epidural analgesia for treatment of TKA complicated by arthrofibrosis. *Surg Technol Int* 15:221–224
31. Park KK, Chang CB, Kang YG, Seong SC, Kim TK (2007) Correlation of maximum flexion with clinical outcome after total knee replacement in Asian patients. *J Bone Joint Surg Br* 89:604–608
32. Ranawat CS (2003) Design may be counterproductive for optimizing flexion after TKR. *Clin Orthop Relat Res* 416:174–176
33. Ritter MA (2006) High-flexion knee designs: more hype than hope? In the affirmative. *J Arthroplasty* 21:40–41
34. Seon JK, Song EK, Lee JY (2005) Comparison of range of motion of high-flexion prosthesis and mobile-bearing prosthesis in total knee arthroplasty. *Orthopedics* 28:s1247–1250
35. Sultan PG, Most E, Schule S, Li G, Rubash HE (2003) Optimizing flexion after total knee arthroplasty: advances in prosthetic design. *Clin Orthop Relat Res* 416:167–173
36. Walton NP, Jahromi I, Dobson PJ, Angel KR, Lewis PL, Campbell DG (2005) Arthrofibrosis following total knee replacement. Does therapeutic warfarin make a difference? *Knee* 12:103–106
37. Weeden SH, Schmidt R (2007) A randomized, prospective study of primary total knee components designed for increased flexion. *J Arthroplasty* 22:349–352
38. Weiss JM, Noble PC, Condit MA, Kohl HW, Roberts S, Cook KF, Gordon MJ, Mathis KB (2002) What functional activities are important to patients with knee replacements? *Clin Orthop Relat Res* 404:172–188
39. Whiteside LA (2002) Soft tissue balancing: the knee. *J Arthroplasty* 17:23–27
40. Yercan HS, Sugun TS, Bussiere C, Ait Si Selmi T, Davies A, Neyret P (2006) Stiffness after total knee arthroplasty: prevalence, management and outcomes. *Knee* 13:111–117