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ORIGINAL ARTICLE

Comparative study of intraoperative knee flexion with three different TKR designs

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Total knee arthroplasty;
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Range of motion;
Navigation

Summary

Introduction: Substantial flexion after total knee arthroplasty (TKA) is required for certain categories of patients who wish to squat or kneel in their daily life. Many factors influence this postoperative flexion, including the prosthesis design. It is therefore valuable to in vivo analyze these factors on three knee prosthesis designs through a study of their intraoperative flexion.

Hypothesis: The posterior-stabilized (PS) knee prostheses provide better intraoperative flexion than the ultracongruent (UC) model. Of the currently available PS models, the high-flexion ones have better intraoperative flexion than standard models. Our main focus endpoint was the intraoperative flexion achieved, before soft-tissues closure, during TKA surgical procedure.

Patients and methods: This was a controlled study. Seventy-two osteoarthritic knees requiring TKA were included to compare three selected prosthesis models: the SAL ultracongruent and two PS models (the standard LPS and the LPS Flex). This was a single-operator study, with patients divided into three homogenous, comparable groups, in which intraoperative measurement of flexion was performed using computer-assisted navigation. Statistical analysis allowed comparison of the three models.

Results: Intraoperatively, after prosthesis implantation, before soft-tissues closure, the mean flexion of the LPS-Flex was 134° versus 124° for the SAL ($p = 0.0004$); the mean flexion of the standard LPS model was 130° versus 124° for the SAL ($p = 0.14$); the PS Flex model showed no significant difference ($p = 0.26$) in flexion (134°) compared to the standard model (130°). The SAL ultracongruent model seemed to be a factor reducing the intraoperative flexion by 8° compared to the PS models ($p < 10^{-4}$).

Discussion: In this study, the PS designs (standard or Flex) provided better intraoperative flexion than the SAL ultracongruent design. However, the LPS Prosthesis did not demonstrate superiority over the standard LPS Prosthesis.

Level of evidence: Level III, low-power prospective study.

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Introduction

Postoperative flexion after total knee arthroplasty (TKA) is an essential parameter for certain categories of patients who use squatting or kneeling for their activities such as in certain religions or ethnic groups (Indians, Chinese, Japanese, Muslims, etc.). For these activities, knee flexion between 111° and 165° is necessary [1]. Many factors influence this postoperative flexion [2]: they are related to the patient, the surgical technique, and the prosthesis chosen. Patient-related factors are difficult to modify. The factors related to surgical technique should be considered so as to optimize postoperative flexion.

The philosophy of TKA has evolved over the years while being based on biomechanical data to reduce deficiencies and better reproduce the knee's kinematics and therefore improve flexion: hence the emergence of posterior cruciate ligament substitution prostheses: the posterior-stabilized (PS) and the ultracongruent (UC) devices. Within these knee prostheses, the prosthetic design, in particular of the femoral component, has evolved to improve postoperative flexion.

It is interesting to study the isolated role of prosthesis design in vivo, attempting to eliminate as many confounding factors as possible. Using computer-assisted navigation during the surgical procedure, we tested the passive mobility of three different knee prosthesis models (two PS and one UC). These three models were all PCL substitution with a rotatory mobile bearing design.

Hypothesis

Our main hypothesis was that the PS models provided better intraoperative flexion than the UC prostheses. Of the PS prostheses, the high-flexion models have better intraoperative flexion than the standard models. We therefore conducted a controlled study in which the main endpoint

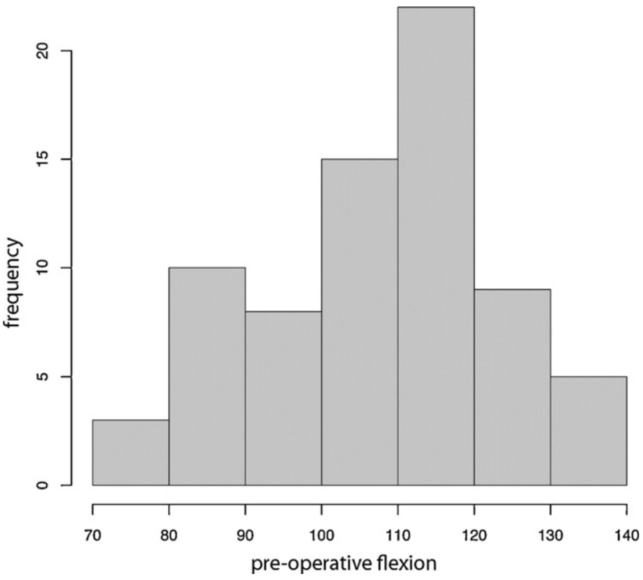


Figure 1 Distribution of flexion values measured preoperatively using a goniometer.

Table 1 Preoperative data for the three groups of patients distributed according to the prosthesis chosen.

	n	M	F	Age (years)	Size (cm)	Weight (kg)	BMI	HKA	Extension (goniometer)	Flexion (goniometer)
SAL	26	5	21	73.5 (55.8—84.2)	164.4 (150—180)	74.1 (54—120)	27.5 (20—46.9)	176.3 (160—197)	−5.6° (−15°—0°)	113.2° (90°—135°)
Standard LPS	24	7	17	76 (60.7—86.8)	164.7 (149—182)	77.3 (51—103)	28.5 (20.7—37.4)	176.1 (160—195)	−10.1° (−30° to 0°)	105.4° (70°—140°)
LPS-Flex	22	3	19	74.6 (52—86.7)	158 (142—179)	71.7 (51—103)	28.7 (21.2—44.6)	176.2 (165—193)	−6.6° (−30° to 10°)	115.7° (70°—140)
Total	72	15	57	74.8 (52—86.8)	162.4 (142—182)	74.8 (51—120)	28.4 (20.1—46.9)	176.4 (160—197)	−7° (−40° to 10°)	111.3° (70°—140°)

n: number of knees; M: males; F: females; BMI: body mass index; HKA: hip, knee, ankle angle. Ranges are given for all values, except flexion/extension when they are in 1st and 3rd quartiles.

was intraoperative flexion, knee open, after implantation. Our secondary objective was to demonstrate the predictive factors of this intraoperative flexion.

Patients and methods

This was a single-blind, controlled study. All patients undergoing a TKA by a single senior operator (PB) between January 2006 and January 2007 were included in the study. All the patients provided informed consent before the intervention. The inclusion criteria were invalidating gonarthrosis of any etiology, resistant to appropriately conducted medical treatment, with deformation of the limb's axis less than 20° of varus or valgus. The exclusion criteria were substantial valgus or varus deformation (> 20°) and irreducible deformations requiring hinge prosthesis, TKA revisions, and desarthrodesis prostheses.

The series included 70 patients (15 males and 55 females), 72 operated knees. The mean age at surgery was 74.8 years (range, 52—86.8 years) with a mean body mass index (BMI) of 28.4 (range, 20.1—46.9) for a mean height and weight of 162 cm (range, 142—182) and 75 Kg (range, 51—120), respectively. The preoperative clinical axes, ±2°, of the operated knees showed varus in 43 cases, valgus in 15 cases, and normal values in 14 cases, with a mean HKA angle of 176° (range, 160°—197°). The mean mobility values of the knee to be operated on as evaluated by the goniometer, during preoperative consultation, were −7° of extension (range, −40°—10°) and 111° of flexion (range, 70°—140°). The normal distribution of preoperative flexions is presented in Fig. 1. Three groups of patients, depending on the type of prosthesis to implant, were created. The three groups were homogenous and comparable in terms of age, sex, BMI, the longest axes, and preoperative mobility measured on the goniometer during the consultation (Table 1).

Three types of PCL substitution prostheses, all with a rotatory mobile bearing design were retained for this study: the SAL UC (Zimmer, Warsaw, IN, USA), the standard NEXGEN LPS PS (Zimmer, Warsaw, IN, USA), and the NexGen LPS Flex PS (Zimmer, Warsaw, IN, USA) (Fig. 2).

The SAL (self-aligning mobile bearing knee) UC presents a relatively flat femoral component in the coronal plane, with a total congruence between 0° and 75° of flexion; beyond this, congruence is only partial. The UC tibial insert has a medial eminence, particularly at the back, designed to provide mediolateral stability and limit the range of motion in flexion. It also provides a higher elevation to prevent excessive anterior translation of the tibia given the absence of the anterior cruciate ligament, without limiting range of motion in flexion, also with a high anterior elevation.

The standard NexGen Legacy-PS prosthesis has tibiofemoral conformation such that a wide zone of contact on the condyles is obtained. In the sagittal plane, the curve of the femoral component is the same for both the medial and lateral condyles. The NexGen Legacy-PS Flex mobile prosthesis has developed posterior femoral condyles, so that contact between the femur and the tibia in up to 155° of flexion can be obtained. This requires increasing the posterior offset with an additional 2-mm cut from the posterior femoral condyles. The design of the posterior-stabilization cam and the intercondylar eminence was modified so as to provide contact, even in hyperflexion, and to limit the tilt stresses on the tibial component. An anterior cut on the tibial articular surface reduces stresses at this level, providing greater freedom for the extensor apparatus in flexion.

The surgical technique was identical for all patients and all prosthesis models implanted. The anesthesia was either general anesthesia without curare or spinal anesthesia. A femoral block was always associated. All interventions were conducted without a tourniquet so as not to disturb intraoperative flexion measurements. The medial parapatellar approach was used in 55 cases and the lateral approach in 17 cases. All interventions took place with navigation (Navitrack-Orthosoft). The navigation pins were placed percutaneously. The femoral pins were placed through the quadriceps, the knee in maximum flexion, in the femoral diaphysis at mid-thigh to facilitate the intraoperative tests. On the tibia, the pins were placed on the anteromedial side of the diaphysis. This atypical positioning of the navigation pins made it possible to preserve the pins at the end of the intervention so that the navigation measurements of the operated knee could be taken even after skin closure. The bone cuts were made with the ancillary instruments of the chosen prosthesis guided by the navigation system. In all cases, a system of independent bone cuts was used. The femoral cuts were made first, with a distal cut such that the joint space was perpendicular to the femur's mechanical axis and the cutting thickness was calculated on the healthy compartment; then the posterior and anterior cuts

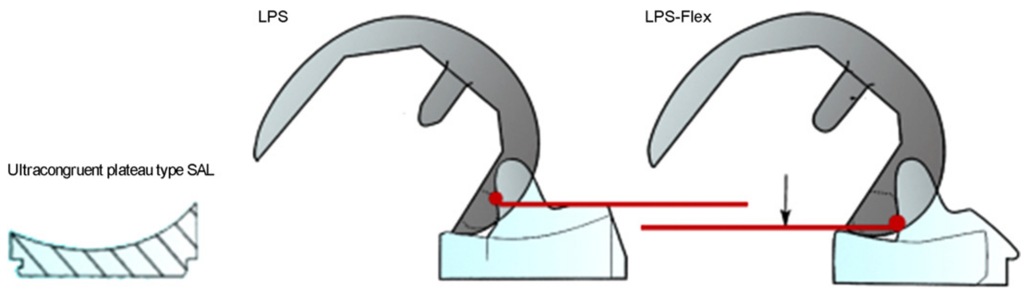


Figure 2 The polyethylene of the SAL Ultracongruent presents an anterior lip developed without a central stud (left). The LPS-Flex femoral implant (right) has larger posterior condyles than those of the standard LPS (middle) as well as a polyethylene insert with an anterior bevel (right). Implantation of the LPS-Flex requires cutting an additional 2 mm of bone in the posterior femoral condyles (right).

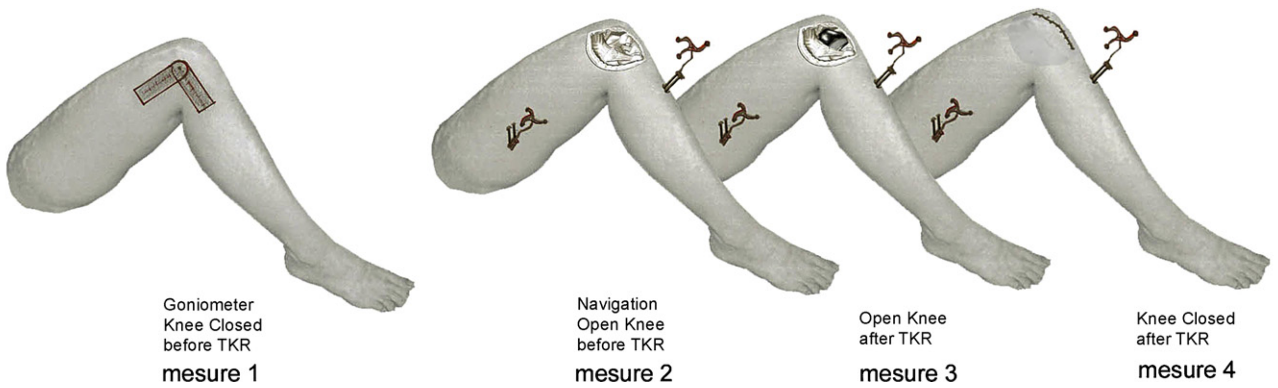


Figure 3 Methodology of intraoperative mobility measurement.
Measurement 1 is taken using the goniometer, under anesthesia. Measurements 2, 3, and 4 are taken during the surgery using the navigation system. Measurement 3 is the main endpoint.

were made. The reference of the anteroposterior cut was posterior. The external rotation of the femoral compartment was based on a preoperative CT analysis of distal torsion of the femur [3]. The distal cut was also guided by the navigation system, perpendicular to the tibial axis and resecting the thickness of the tibial implant on the nonworn side. When the trial femoral component and tibial baseplate were placed, increasingly thick polyethylene tibial plateaux were tested until the best coronal balance was obtained, usually the plateau corresponding to the thickness of the tibial cut. In case fixed flexion deformity persisted, releasing the posterior capsula was always sufficient to obtain the desired extension without ever having to resort to additional femoral cutting. The patella was systematically resurfaced and the final implants sealed to the tibia and femur. The skin was closed plane by plane using separated stitches on a Redon drain catheter.

Four flexion measurements were taken during surgery with the patient under anesthesia (Fig. 3) and in the dorsal decubitus position, with no tourniquet, on the knee in maximum flexion against gravity:

- before implantation, knee closed, with the goniometer;
- before implantation, knee open, with the navigation system;
- after implantation, knee open, with the navigation system (main endpoint);
- after implantation, knee closed, with the navigation system.

Statistical analysis

The quantitative variables were reported as means, range, and interquartile range (IQR); the qualitative variables were reported as proportions. A difference between the flexion measurements was sought between the three groups using analysis of variance with a significance level of 0.05; if the overall difference between the three groups was significant, two-by-two comparisons using the Wilcoxon rank test were carried out at a significance level of 0.01.

Linear regression models were constructed searching for predictive variables of the different flexion values after prosthesis implantation. The linearity of the effects was verified using splines. Multivariate analyses with a descending step-by-step selection procedure based on the Akaike information criterion (AIC) were used to identify a set of independently prognostic variables of these different flexions.

All of the analyses were carried out using R software [4]; all the tests were bilateral formulations.

Results

Mobility measurements

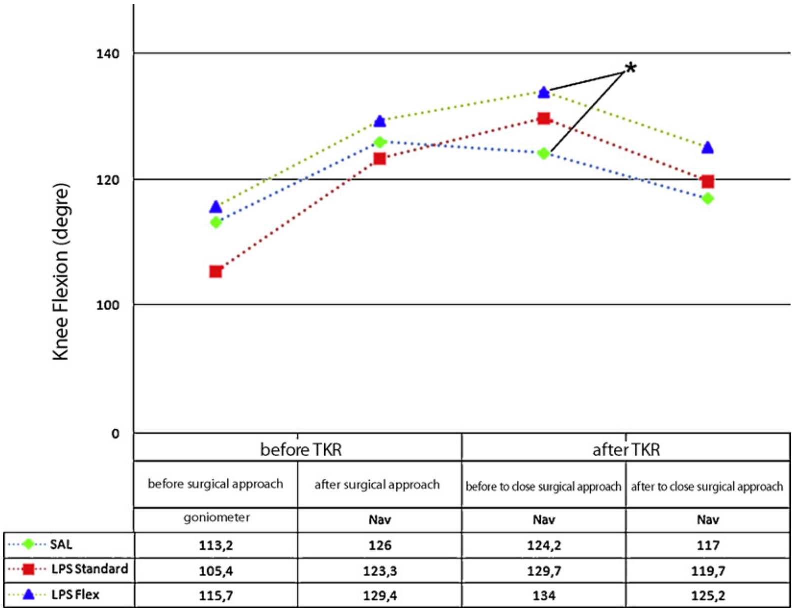
A difference was found in intraoperative flexion between the three knee prosthesis models, with better flexion for the LPS-Flex prosthesis compared to the SAL UC; however, there was no difference in intraoperative flexion between the LPS Flex and the standard LPS.

For the overall series, measured intraoperatively on the goniometer with the patient under anesthesia, the mean flexion before implantation, knee closed, was 115° (IQR, 80°;140°); with the navigation system, before implantation, knee open, it was 126° (IQR, 121°;133°); with the navigation system, after implantation, knee open, it was 129° (IQR, 123°;136°); and with the navigation system, after implantation, knee closed, it was 120° (IQR, 115°;128°).

Since there was a significant difference in flexion between the three groups ($p < 0.05$), we were able to compare the models two by two. The series of measurements for each of the knee prosthesis models are reported in Fig. 4. Using the navigation systems, after implantation, knee open, there was a significant difference in knee flexion between the LPS-Flex and SAL models ($p = 0.0004$); however, there was no difference between the standard LPS and SAL models ($p = 0.14$) or between the two PS models ($p = 0.26$).

Analysis of the predictive factors of flexion

Intraoperatively, using the navigation system, knee open, after implantation, high BMI was a factor in low knee flexion ($p = 0.0003$), the SAL UC model was a factor causing an 8° loss of flexion compared to the PS models ($p < 10^{-4}$) (Table 2). High preoperative flexion was a factor of high flexion after



	before TKR		after TKR	
	before surgical approach	after surgical approach	before to close surgical approach	after to close surgical approach
	goniometer	Nav	Nav	Nav
◆ SAL	113,2	126	124,2	117
■ LPS Standard	105,4	123,3	129,7	119,7
▲ LPS Flex	115,7	129,4	134	125,2

Figure 4 Intraoperative flexion by prosthesis model, under anesthesia.
Nav: navigation measurement; all measurements are in degrees.

Table 2 Univariate and multivariate linear regression models with intraoperative flexion, knee open, as the variable to predict.

	Univariate model		Multivariate model	
	Estimate [SD]	*p*	Estimate [SD]	*p*
Age	−0.002 [0.17]	0.99	-	-
Females	0	-	-	-
Males	5.23 [2.97]	0.083	-	-
Weight	−0.22[0.07]	0.00292*	-	-
Size	0.11 [0.14]	0.42	-	-
BMI	−0.72 [0.19]	0.0003 *	−0.44 [0.12]	3.10^{-4}*
Preoperative flexion	0.76[0.09]	$< 1.10^{-4}$*	0.66 [0.075]	$< 1.10^{-4}$*
LPS-FLex	0	-	0	-
SAL	−9.85 [2.72]	$< 1.10^{-4}$*	−8 [1.66]	$< 1.10^{--4}$*
Standard LPS	−4.4 [2.8]	0.12	−0.41 [1.72]	0.8

BMI: body mass index. *: statistically significant.

prosthesis implantation, knee open ($p < 10^{-4}$). No difference was found between the standard LPS model and the LPS-Flex model in univariate ($p = 0.12$) or multivariate ($p = 0.8$) analysis.

Overall, in intraoperative measurements, all the prosthesis models improved flexion of the operated knee: the LPS-Flex had significantly better flexion than the SAL UC; on the other hand, no significant difference was found between the standard LPS and the SAL UC, or between the standard LPS and the LPS-Flex. Therefore, the high-flexion Flex model did not demonstrate superiority over the standard model in intraoperative measurements. These results are confirmed by the intraoperative univariate and multivariate analyses: only the SAL UC was a negative predictive factor of knee flexion, and the standard LPS and the LPS-Flex models showed no significant difference in the different steps of intraoperative flexion measurements.

Discussion

The strengths of this study stem from its methodology: this was a single-blind, controlled, single-operator trial. The only parameter that varied from one group to another was the prosthesis design.

Many factors other than the prosthesis design influence postoperative flexion [2], related to the patient or the surgical technique. The most important factor found in the literature is preoperative flexion [5—8]: the better this is, the better the postoperative flexion will be. Patient-related factors as well as factors related to the intraoperative environment are also reported: obesity [6], soft tissues [6], preoperative rehabilitation, patient motivation, rehabilitation [9,10], and postoperative analgesia [11]. The surgery-related factors are technical errors: absence of posterior osteophyte resection [12], absence of posterior offset restoration, modification of joint space height [13], insufficient tension and ligamentous balancing, an oversized implant, implant malalignment, inverted tibial slope, an increase in patellar thickness, and more generally an increase in the sagittal overstuffing of the femoropatellar joint.

All the patient-related factors are difficult to modify: this study attempts to eliminate them. Anesthesia induces identical release of muscular tone during general anesthesia without curare or with spinal anesthesia. The loss of muscular tonicity makes it possible to take measurements with no muscular constraints, thus revealing the role played by the joint alone. The cutaneous opening of the parapatellar approach allows one to free the anterior soft tissues that can obstruct flexion. The patients' perioperative environment was not considered in this intraoperative study. All the factors related to the surgery were reduced by all patients being treated by a single experienced surgeon who did not modify the operative technique and encountered no intraoperative technical problems. Only PCL substitution prostheses were used with rotatory mobile bearing tibial inserts. The patient groups were homogenous. The values measured by the navigation system are reproducible and observer-independent. Most of the factors influencing intraoperative flexion were neutralized in this study, sufficiently isolating prosthesis design for its intrinsic study without excessive bias.

The main weakness of this study was the moderate number of patients in each group, reducing the power of the results. Another weakness is that the SAL femur design is not the same as the LPS.

After prosthesis implantation, knee open, the factors predictive of knee flexion are high BMI; the SAL UC model is a negative predictive factor. High preoperative flexion is a positive predictive factor.

With a mean BMI of 28.4, this study found this parameter to be a negative intraoperative predictive factor. BMI was also a prognostic factor found in the literature [6]: the higher the BMI, the lower the postoperative flexion. This can be explained by earlier contact of the posterior soft tissues of the thigh on the calf during knee flexion. This mechanical model was not challenged by our study. Preoperative flexion is the most important predictive factor found in the literature [5—8]: the higher the value in preoperative measurements, the better the flexion will be after arthroplasty. This factor seems to be independent of the anterior soft tissues as well as the extensor apparatus, because intraoperatively, the knee open, it is also found to be an important positive predictive factor.

The literature reports no intraoperative comparisons of prosthesis models, but only clinical studies with long-term revisions comparing the different implants. Laskin [14] found no significant difference in postoperative flexion, with 117° and 116° flexion between the UC and PS models, respectively. However, Parsley et al. [15] found a significant difference favoring PS implants (119.98° vs. 116.78°) at 1 year of follow-up ($p = 0.04$). As for the standard LPS and Flex (Zimmer) models, only Huang et al. [16] found significantly better flexion in the Flex model, with 138° vs 126° in the standard model in a retrospective study. For Kim et al. [17] and Nutton et al. [18], there was no significant difference between these two models in prospective randomized studies.

To better understand the role played by prosthesis design in knee flexion, the most interesting data in the literature are the biomechanical data. To improve flexion, they must be analyzed in the native joint. It seems that the posterior rolling—translation movement of the femur, called rollback, is one of the key aspects of flexion. According to Dennis et al. [19], this rollback is constant in the kinematics of the PS prostheses; for Matsuda et al. [20], rollback imposed by the PS protheses is better than that with the UC model. These biomechanical data point in the same direction as our results applied to flexion.

The other aspect studied is the relation between posterior offset of the femoral condyles and flexion of the knee: Bellemans et al. [21] analyzed the importance of restoring this posterior offset of the femoral condyles during arthroplasty. Guided by fluoroscopy, they reviewed 29 patients with a total knee prosthesis in the squatting position: 72% showed direct posterior contact between the tibial insert and the distal posterior femur, constituting a mechanical block to flexion. They then studied this factor in a series of 150 patients and they found a correlation between postoperative flexion and the posterior offset of the condyles. Based on these studies, the high-flexion models appeared in which the femoral design increased the femoral condyles for greater flexion, but at the price of a greater posterior femoral cut. Our study did not demonstrate this improvement in flexion between the standard LPS model and the LPS Flex model during the surgical intervention, perhaps because the flexion of the patient knees around 120° did not bring out this modification and flexion was limited by factors that were extrinsic to the prosthesis before the intrinsic factors come into play.

Conclusion

In this study, the isolated analysis, from a purely mechanical point of view, of the influence of prosthesis design on knee flexion at implantation showed that the PS Flex prosthesis had better intraoperative flexion than the SAL UC model. On the other hand, the LPS Flex model was not demonstrated to be superior to the standard LPS model, at least for patients whose preoperative flexion will likely not permit great flexion after TKA. This raises the question of the opportunity to use the LPS Flex model, which requires resection of more bone for the posterior femoral cut than the standard LPS model. To answer this question, it would be interesting to investigate the clinical mobilities of these patients over the long-term to assess the behavior of this different prostheses in a physiological environment that includes the whole patient with all the factors limiting flexion.

Conflict of interest statement

A.Wajsfisz; D.Biau; P.Boisrenoult: none.

P. Beaufils. Clinical trials as co-investigator, nonprincipal investigator, for Zimmer Company, Warsaw, IN, USA.

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