Comparison of outcomes after bilateral simultaneous total knee arthroplasty using posterior-substituting versus cruciate-retaining prostheses

Hong-Guang Liu, MD, Wei Zhu, MD, Zhen-Xiang Zhang, MD, PhD.

ABSTRACT

الأهداف: مقارنة النتائج من ناحية السلامة والفعالية بعد عملية رأب المفصل الكامل بين طريقة الاستبدال الخلفي من جهة و طريقة التثبيت الصليبي للطرف الاصطناعي لكامل مفصل الركبة من جهة أخرى وذلك بعد التحكم بالمتغيرات الدخيلة.

الطريقة: أجريت هذه الدراسة خلال الفترة من يناير 2008م إلى يونيو 2012م، وشملت الدراسة 32 مصاباً بالتهاب مفصل الركبة المزدوج. قبل بعض المرضى إجراء عملية رأب المفصل بطريقة الاستبدال الخلفي، في حين قبل البعض الآخر بطريقة التثبيت الصليبي للطرف الاصطناعي لكامل مفصل الركبة. ولقد قمنا بتقييم المضاعفات الجراحية بعد العلمية بالإضافة إلى نتائج الطريقتين الطبية قبل العملية الجراحية (معيار جمعية الركبة، ونطاق الحركة، ومؤشر التهاب المفاصل لدى جامعتي أونتوريو الغربية وجامعة ماكماستر، ونتائج التصوير الفوتوغرافي)، وكذلك أثناء فترة المتابعة بعد مرور أسبوعين، و3 أشهر، و12 شهراً و24 شهراً.

النتائج: لم يلاحظ وجود فرق في نتائج رضا المرضى، والتقييم الوظيفي، والمضاعفات الجراحية بين طريقة التثبيت الصليبي للطرف الاصطناعي لكامل مفصل الركبة وطريقة الاستبدال الخلفي لكامل مفصل الركبة وذلك بعدر مرور 24 شهراً خلال فترة المتابعة. غير أن طريقة الاستبدال الخلفي قد أظهرت تحسنا ملحوظا من الناحية الإحصائية فيما يخص نطاق الحركة وذلك عند مقارنتها بطريقة التثبيت الصليبي للطرف الاصطناعي لكامل مفصل الركبة.

الخاتمة: في حين لم يكن هناك فرقا في النتائج الطبية بين طريقتي الاستبدال الخلفي من جهة والتثبيت الصليبي للطرف الاصطناعي لكامل مفصل الركبة، فقد أدت طريقة الاستبدال الخلفي إلى تحسنٍ ملحوظ من الناحية الإحصائية وذلك فيما يخص نطاق الحركة مقارنةً بطريقة التثبيت الصليبي للطرف الاصطناعي لكامل مفصل الركبة.

Objectives: To compare the effectiveness and safety of posterior-substituting (PS) with cruciate-retaining (CR) total knee prostheses after the elimination of confounding variables.

Methods: Between January 2008 and June 2012, a total of 32 subjects who had bilateral arthritis of the knees agreed to have one knee replaced with a PS total knee design and the other with a CR design. In addition to postoperative complications, clinical outcomes (Knee Society Score, Range of Motion, Western Ontario and McMaster Universities Arthritis Index, as well as radiographic findings) were evaluated preoperatively, and at 2-week, 3-month, 12-month, and 24-month follow-up.

Results: At the 24-month follow-up interval, no benefit of CR design was observed over PS design regarding functional assessment, patient satisfaction, or postoperative complication. However, the PS total knee design did display statistically significant improvements in range of motion as compared with the CR design.

Conclusion: While comparable regarding supporting good clinical outcomes, the PS design does appear to support significantly improved postoperative range of motion when compared with the CR design.

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From the Department of Orthopedics, The Affiliated Taizhou People's Hospital of Nantong University, Taizhou, Jiangsu, People's Republic of China.

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Address correspondence and re-print request to: Dr. Zhen-Xiang Zhang, Orthopedic Department, The Affiliated Taizhou People's Hospital of Nantong University, Taizhou, Jiangsu 225300, People's Republic of China. E-mail: kafeimao1982@126.com

The posterior cruciate ligament (PCL) is recognized as an essential anatomical structure, which controls stability of the knee. The PCL is the strongest ligament in the knee, connecting the medial condyle of the femur to the posterior intercondylar area of the tibia. The primary functions of the PCL are to prevent posterior

translation of the tibia on the femur, and prevent the femur from falling off the anterior edge of the tibia.[1,2] On the basis of the PCL being retained or excised, total knee prostheses can be divided into cruciate-retaining (CR) design and posterior-substituting (PS) design. The main differences between the 2 types of implants are that the PS prostheses, compared to the CR prostheses, attempt to replace the role of the PCL with a femoral cam and polyethylene post that interact to prevent anterior translation of the femur on the tibia and allow femoral rollback during knee flexion.[3,4] Advocates of PS prostheses have regularly stated a more stable component interface, increased knee flexion as well as a less technically demanding procedure.[5,6] Proponents of CR prostheses firmly believe the potential advantages of preservation of bone, more normal knee kinematics, increased proprioception, femoral rollback on the tibia during flexion, and greater stabilization of the prosthesis, with the PCL preventing anterior translation of the femur on the tibia.[7,8] Varieties of clinical trials have been published to evaluate the effectiveness and safety of these 2 implants either in different patient groups or in the same patient who received both the implants.[5,7,9,10] However, no previous controlled comparison has been able to show any advantage of one implant over the other either in effectiveness or safety. Comparisons are more meaningful if confounding is minimal. In the present study, simultaneous bilateral total knee arthroplasty (TKA) using CR and PS variants of Genesis II total knee components (Smith and Nephew, London, England, UK) was performed in the same patient. The only variable was the design of tibial insert. We minimized confounding variables relating to disease, surgeon, bone quality, type of prostheses, and pain tolerance of individual and postoperative rehabilitation. The hypothesis is that CR total knee prostheses may achieve the same level of effectiveness and safety as compared with PS total knee prostheses in the same patients.

Methods. Between January 2008 and June 2012, 36 subjects suffering from bilateral knee arthritis were offered bilateral simultaneous TKA and were invited to have one knee replaced with a Genesis II PS prostheses and other with a Genesis II CR prostheses. Subjects were included if deformities of both osteoarthritic knees were similar and if the grade of the Kellgren-Lawrence grading scale was similar, less than 15°valgus or less than 10°varus deformity, less than 10°flexion deformity, range of motion (ROM) of greater than 80°, and BMI less than 28 kg/m^2. Simultaneous exclusion criteria included compromise of soft-tissue envelope, previously operated joint, and joints requiring a complex reconstruction with bone graft and/or prosthetic augmentation.

Subjects were assessed preoperatively and at 2-week, 3-month, 12-month, and 24-month follow-up, thereafter, according to the American Knee Society recommendation. However, the 2-week postoperative assessment was essentially associated with wound complications because no meaningful difference with regard to clinical performance of the 2 prostheses could be expected so early in the postoperative follow-up. The study was approved by the Regional Ethics Committee, and was carried out according to principles of the Helsinki Declaration.

Operative technique. The same surgeon conducted all of the operations with a similar surgical technique using the same instruments. The ligament balance was similarly performed. For the varus knees, the soft tissue releases included superficial medial collateral ligament, portion of pes anserinus, and the direct head of semimembranosus tendon. For the valgus knees, the releases included the conjoined tendon of lateral collateral ligament and popliteus tendon, and the iliotibial band. The magnitude of soft tissue releases was determined according to the severity of the deformity. The bone resections were performed using the standard cutting jigs and guides. The distal femoral cut was made with an intramedullary guide at 5° to 7° valgus. An additional central recess was made with the housing device for PS prosthesis. The proximal tibia cut was made perpendicular to the axis of the tibia using an intramedullary rod or an external cutting guide at the surgeon's preference. The patellar bone was cut using a cutting jig. The balance of flexion and extension gaps was conducted with a trial prosthesis. Press-fit condylar total knee prostheses were used in all subjects, and all components were cemented.

Post-operative evaluation. Subjects were assessed preoperatively and at 2-week, 3-month, 12-month, and 24-month follow-up using the Western Ontario and MacMaster Universities Osteoarthritis Index (WOMAC), knee society clinical rating system (KSS), as well as radiographic findings. The femorotibial angle, tibia angle, anteroposterior laxity, and mediolateral

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laxity were measured preoperatively and at 24-month follow-up. The 2-week post-operative evaluation was necessarily related to wound complications as no meaningful difference in terms of clinical performance of the 2 prostheses could be expected so early in the post-operative period (already previously stated, please include only once and amend accordingly). Radiographs were obtained in standing anteroposterior, lateral, as well as skyline views and analyzed by Ewald's classification. All postoperative complications were investigated to evaluate implant safety.

Statistical analysis. A complete statistical analysis was carried out on all data. Normality of data distribution was tested with the Kolmogorov-Smirnov and Shapiro-Wilk tests. Paired t test was used. However, if variables violated the normality assumption, Wilcoxon signed ranked test was employed. Categorical variables were analyzed by Chi square test or Fisher's exact test. The threshold for statistical significance was set at a p-value of less than 0.05. The statistical analysis was performed using Statistical Package for Social Sciences version 13.0 (SPSS Inc., Chicago, IL, USA).

Results. ***Demographics.*** Thirty-six subjects with similar ROM and deformity in both knees were invited to have one knee implanted with a PS and the other with a CR variant of the same TKA prosthesis. Clinical and radiologic parameters between the 2 designs were compared. At the 24-month follow-up, 32 subjects were available for assessment. There were 12 males (37.5%) and 20 females (62.5%). The mean age in the present study was 65.6 (range 59-78). Osteoarthritis was the

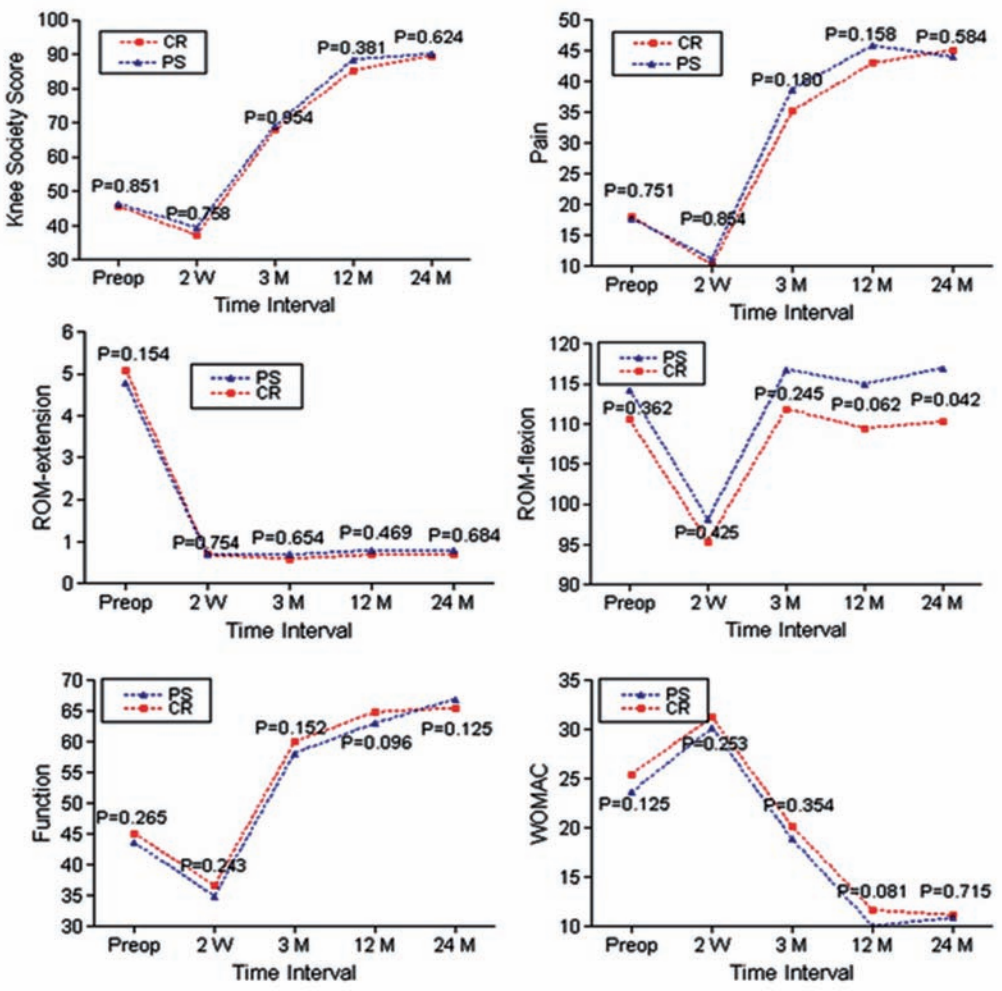

Figure 1 - Preoperative and postoperative assessment at each follow-up. Comparison of group mean values using the paired t-test or Wilcoxon signed ranked test. The threshold for statistical significance was set at a *p*-value of less than 0.05. CR - cruciate-retaining, PS - posterior-substituting, Pre-op - preoperative, ROM - range of motion, WOMAC - Western Ontario and MacMaster Universities Osteoarthritis Index.

Table 1 - Preoperative and postoperative characteristics of the operated knees.

Characteristics	CR			PS			*P*-value (CR versus PS)	
	Pre-op	Post-op	*P*-value	Pre-op	Post-op	*P*-value	Pre-op	Post-op
Kellgren-Lawrence grading	-	-	-	-	-	-	-	-
Grade 2	16	-	-	15	-	-	0.971	-
Grade 3	18	-	-	19	-	-	0.966	-
Grade 4	2	-	-	2	-	-	1.00	-
Mediolateral laxity*	13.2±1.4	13.3±1.5	0.956	13.4±1.7	13.8±1.8	0.562	0.851	0.547
Anteroposterior laxity†	9.1±0.8	8.9±0.5	0.847	8.9±0.8	7.7±0.8	0.038	0.854	0.033
Femorotibial angle (Valgus)	3.7±0.4˚	6.5±0.7˚	0.002	3.5±0.3˚	6.3±0.9˚	0.007	0.546	0.652
Tibia angle	82.1±6.1˚	88.6±7.3˚	0.248	83.9±5.5˚	89.1±6.2˚	0.321	0.625	0.862

Comparison of group mean values using the paired t-test or Wilcoxon signed ranked test; Categorical variables were analyzed by Chi square test or Fisher's exact test. The threshold for statistical significance was set at a *p*-value of less than 0.05. *For mediolateral laxity, 15 points was assigned for knee with 0 to 5˚, 10 points for 6˚ to 9˚, 5 points for 10˚ to 14˚ and 0 points for greater than 15˚ laxity. †For anterior laxity, 10 points was assigned for knee with 0 to 5 mm, 5 points for 6 to 10 mm, and 0 points for over 10 mm laxity. CR - cruciate-retaining, PS - posterior-substituting, Pre-op - preoperative, Post-op - postoperative

Table 2 - Radiographic assessment and postoperative complications.

Postoperative complications	CR	PS	*P*-value
Wound necrosis/discharge	1	2	1.00
Infection	0	0	-
Hemoarthrosis	1	1	1.00
DVT	1	0	1.00
Lucent line	1	1	1.00
Anterior knee pain	2	3	1.00
Stiff knee	2	0	0.492
Total	**8**	7	**1.00**

Comparison of complications using the Chi square test. The threshold for statistical significance was set at a *p*-value of less than 0.05. CR - cruciate-retaining, PS - posterior-substituting, Pre-op - preoperative, Post-op - postoperative, DVT - deep venous thrombosis

most common (29 subjects) diagnosis. All of these subjects had primary degenerative arthritis. Rheumatoid arthritis (3 subjects) was the other diagnosis.

Preoperative and postoperative clinical assessment. Preoperative and postoperative clinical assessments are displayed in **Figure 1**. At 24-month follow-up, the KSS averaged 89.5 points for CR knees and 90.1 points for PS knees, indicating an overall comparable recovery for both types of knees. No statistical significance was detected in terms of 24-month postoperative pain ratings between the CR and PS knees. Regarding ROM, a statistically significant difference was measured between mean flexion of the CR and PS knees at the 24-month follow-up. The preoperative mean function scores were 45.2 points for the CR knees and 43.7 points for the PS knees. At the 24-month follow-up, the score was 65.6 for the CR knees and 67.0 for the PS knees. The obtained results indicated that compared with the CR group, the PS group showed a trend toward higher functional scores. This difference was not notable. Although it appeared that the 24-month postoperative WOMAC assessment of the PS knees was superior to the CR knees, the difference was not significant.

Preoperative and 24-month postoperative clinical assessment. Preoperative and postoperative characteristics of the operated knees are summarized in **Table 1**. The differences in the preoperative degrees of the arthrosis, in terms of Kellgren-Lawrence grading were not statistically significant between the 2 groups. No significant difference in mediolateral laxity was detected. However, the difference in anterior laxity was statistically significant, favoring the subjects that underwent CR-TKA. There was no statistically significant difference in terms of the femorotibial angle and tibia angle.

Radiographic assessment and postoperative complications. Radiographic assessment and postoperative complications are shown in **Table 2**. One knee in the CR group and 2 knees in PS group developed persistent discharge from the wound within the early after-operative period (average fourth to fifth day). There was no significant difference between the 2 groups in terms of persistent discharge from the wound ($p>0.05$). Evaluation of the radiographs at the 24-month follow-up displayed a radiolucency smaller than 2 mm in one area of the tibia component in one subject in each group. No revision surgery was needed. The CR group had no stiff knee (defined in the present study as flexion values less than 90°), no infection, one deep venous thrombosis, one postoperative hemarthrosis,

and 2 knees with severe or moderate anterior knee pain. Postoperative complications in the PS group were one postoperative hemarthrosis, 3 knees with severe or moderate anterior knee pain, one DVT, no stiff knee, and no infected knee. No knee, however, was excluded from the 24-month analysis due to these complications.

Discussion. Current literature comparing CR and PS total knee designs is inconclusive, presenting variable results. Some authors demonstrated that the normal mechanics of the knee were lost as soon as one or both cruciates were removed and increased shearing forces at the prosthesis-bone interface and abnormal knee kinematics occurred.[11,12] While it is believed that PS prostheses possess a lower risk of luxation of the TKA,[13] some other authors[14,15] revealed that subjects who received PCL-sacrificing designs experienced difficulty in activities which required quadriceps power near full extension, such as descending or ascending stairs or rising from a chair. Many authors, on the contrary, demonstrated comparable outcomes for subjects that underwent CR TKA and PS TKA.[16,17] For instance, it was reported by Ritter et al[17] that there was no significant difference in terms of range of knee motion during stair ascent and stair descent, level of walking between subjects that received CR and PS TKA. Casino et al[16] reported that there was no significant difference in terms of knee scores between subjects with CR and PS designs. Nevertheless, subjects that ascended and descended stairs with one leg at a time tended to prefer the CR designs. However, those subjects who could use one leg in sequence to ascend and descend stairs did not display preferential dependence on either knee. The present study compared the CR total knee design with the PS design in the same patient who underwent simultaneous bilateral TKA. The obtained results of this investigation suggested that, when compared to the CR design, the PS total knee design seemed to support significantly improved postoperative ROM at the 24-month follow-up.

The KSS and Short Form 12 (SF-12) are physician scored tools that evaluate measures such as knee function, pain, and stability.[18] The WOMAC is disease specific measures completed by the patient.[18] All of the 3 scoring systems are the commonly used measures, aiming to valuate the effectiveness of TKA. A 10 points difference in scores can reasonably be recognised with clinical importance.[18,19] The obtained data of the present study indicated that the knees in both the 2 groups possessed a dramatic improvement in clinical outcomes after TKA. However, the mean postoperative knee scores between groups showed no statistical or clinical differences. The average KSS demonstrated excellent overall results in both the groups. The results are in line with other similar studies comparing the CR with PS prostheses, as well as the other competitive total knee prostheses. Range of motion is another important indicator of success of TKA, and is closely associated with subjects' satisfaction.[8,17,20] The results of our present study did support the suggestion that compared with the CR designs, the ROM may be improved by using the PS prostheses; this difference was statistically significant ($p<0.05$).

The relative safety of the designs was another purpose of the present investigation. We were aware of limited studies that detected the postoperative complications when comparing PS to CR total knee designs. Two knees with postoperative stiffness were investigated in the present study, and no stiff knee was detected in the PS group. The reason for the difference is unclear, one possible reason may be associated with the differences in knee kinematics between the 2 types of designs; specifically, the replication of PCL function with the PS design.[8,9,12,21] One knee in the CR group and 2 knees in the PS group developed persistent discharge from the wound within the early after-operative period. All these 3 subjects were taken into the operating theatre for debridement and irrigation of joints involved. Samples were collected from the joints and sent for culture and sensitivity. Subjects were continued on intravenous antibiotics for 14 days. Culture reports from all the three knees were sterile, and subjects were investigated for any possible coagulation defects. The incidence of wound complication with the numbers available is not significantly different on statistical parameters ($p>0.05$).

As the CR designs are not suited for severe knee deformity or the condition of the PCL was not intact, so those cases with a history of previous upper tibial osteotomy, septic arthritis, fixed varus or valgus deformity of more than 20° and patellectomy were excluded from the present comparisons. Narrowing of the inclusion criteria will further diminish any other confounding variables possibly contributing to the differences in outcomes.

Although we aimed to perform a well-designed study, some potential limitations must be acknowledged. First, only the common quantitative outcome indicators listed above were assessed in the current study, many other indicators such as gait analysis, patient satisfaction, proprioception, and so on, were not analyzed. Second, the number of patients was small, and the results might be different from studies with larger sample sizes, especially for the comparisons of complications. Third, the follow-up period was only 24 months. Therefore,

at the present time, we cannot speculate whether the conclusions will be different with regard to long-term outcome. In the future, we plan to conduct a long-term follow-up study to compare the results of the 2 types of total knee designs.

In conclusion, this study demonstrated that, while comparable in regards to supporting good clinical outcomes, the PS total knee design appears to support significantly improved postoperative ROM as compared with the CR design at a short-term follow-up. However, a longer follow-up is required to corroborate these findings.

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