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No difference in patient-reported outcomes with cruciate-retaining, anterior-stabilized, and posterior-stabilized total knee arthroplasty designs

A THREE-ARMED, BLINDED, RANDOMIZED STUDY WITH TWO-YEAR FOLLOW-UP

Aims

This study compared patient-reported outcomes of three total knee arthroplasty (TKA) designs from one manufacturer: one cruciate-retaining (CR) design, and two cruciate-sacrificing designs, anterior-stabilized (AS) and posterior-stabilized (PS).

Methods

Patients scheduled for primary TKA were included in a single-centre, prospective, threearmed, blinded randomized trial (n = 216; 72 per group). After intraoperative confirmation of posterior cruciate ligament (PCL) integrity, patients were randomly allocated to receive a CR, AS, or PS design from the same TKA system. Insertion of an AS or PS design required PCL resection. The primary outcome was the mean score of all five subscales of the Knee injury and Osteoarthritis Outcome Score (KOOS) at two-year follow-up. Secondary outcomes included all KOOS subscales, Oxford Knee Score, EuroQol five-dimension health questionnaire, EuroQol visual analogue scale, range of motion (ROM), and willingness to undergo the operation again. Patient satisfaction was also assessed.

Results

Patients reported similar levels of pain, function, satisfaction, and general health regardless of the prosthetic design they received. Mean maximal flexion (129° (95% confidence interval (Cl) 127° to 131°) was greater in the PS group than in the CR (120° (95% Cl 121° to 124°)) and AS groups (122° (95% Cl 120° to 124°)).

Conclusion

Despite differences in design and constraint, CR, AS, and PS designs from a single TKA system resulted in no differences in patient-reported outcomes at two-year follow-up. PS patients had statistically better ROM, but the clinical significance of this finding is unclear.

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Introduction

Total knee arthroplasty (TKA) is an effective procedure in patients with advanced osteoarthritis (OA).¹ However, some patients report dissatisfaction after primary TKA,² although historical data on the prevalence of patient dissatisfaction have recently been disputed.³ Through efforts to improve the procedure and clinical outcomes, several TKA designs have been produced. Currently, three TKA designs are commonly used: cruciate-retaining (CR), which preserves the posterior cruciate ligament (PCL); posteriorstabilized (PS); and anterior-stabilized (AS), the latter two being PCL-sacrificing designs. The decision of whether to keep or remove the PCL during primary TKA, and how to substitute it in case of removal, is still open to debate.

The effect of resecting the PCL on knee biomechanics post arthroplasty has not yet been fully clarified; however, supporters of retaining the PCL argue that keeping it intact maintains femoral rollback, prevents flexion-extension gap mismatch,

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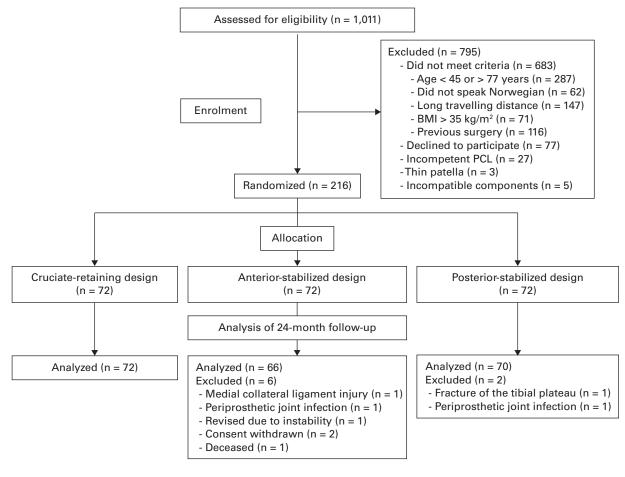


Fig. 1

CONSORT flow diagram depicting participant flow throughout the clinical trial, from eligibility assessment through enrolment, intervention, and completion of follow-up.

and improves knee flexion as well as extensor efficiency.^{4,5} In contrast, current evidence suggests that retaining the PCL does not significantly improve joint proprioception after TKA,⁶ and sacrificing the PCL in TKA achieves similar clinical outcomes compared to CR TKA.⁷

PCL substitution in primary TKA has traditionally relied on a cam-post restraint mechanism. Although this design has proven successful, complications including prosthesis dislocation,⁸ post breakage, and wear have been reported.9 More recently, a change in the sagittal plane conformity of the tibial insert, as an alternative to the PS cam post design, has been introduced. This is achieved with an AS design using a deeper dished polyethylene insert. The AS implant differs from the standard CR implant as the insert has an increased anterior lip, deeper trough, and more conforming articular surface, providing increased anteroposterior stability. Reported advantages of the AS design include the simplicity of replacing an absent or nonfunctional PCL, preservation of femoral bone, and elimination of cam post impingement.¹⁰ As part of our current study, we conducted a radiostereometric analysis highlighting how the AS design cannot fully restore normal knee kinematics.¹¹

The AS design shows favourable results in a few published reports compared with existing CR or PS designs.^{12,13} Some studies have compared the CR, AS, and PS designs on patient-reported outcomes or objective measures of knee function.^{14,15} However, these studies either had small numbers of patients, varying outcome measures, poor randomization, retrospective design, or compared different prosthesis brands.

This study aimed to compare clinical results using the Knee injury and Osteoarthritis Outcome Score (KOOS)¹⁶ among patients receiving CR, AS, or PS designs from the same primary TKA system. The primary hypothesis was that the KOOS would be equivalent between the three implant designs at two-year follow-up. Secondly, there would be no differences in the knees' range of motion (ROM).

Methods

We conducted a prospective, single-centre, blinded, threearmed, randomized controlled trial (RCT) with two-year follow-up. Study design and implementation followed CONSORT statement guidelines.¹⁷ The patients and physiotherapists who conducted the follow-up assessments were blinded

Inclusion criteria	Exclusion criteria
Primary osteoarthritis	Prior ligament surgery
Varus or valgus deformity $\leq 15^{\circ}$	Previous osteotomy
Intact posterior cruciate ligament	Flexion < 90°
Age 45 to 77 years	Flexion contracture > 10°
BMI < 35 kg/m ²	Live > 2 hours away from the hospital
ASA grade I to III	Peripheral neuropathy
	Malignancy
	Not fluent in Norwegian
	Rheumatic disease

ASA, American Society of Anesthesiologists.

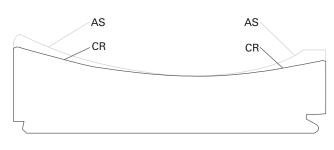


Fig. 2

Schematic drawing of the anterior-stabilized (AS) and cruciate-retaining (CR) inserts.

to the implant design throughout the study. The Regional Ethics Committee approved the study (2016/1981), and the protocol is registered in ClinicalTrials.gov (NCT03059927). All patients received written information and gave informed consent before surgery.

Patients. Patients were included from March 2017 to January 2020. Table I displays the inclusion and exclusion criteria. Of the 216 patients included in the study, 208 (96.3%) completed it, two withdrew consent, four were revised (2 infections, 1 instability, 1 tibia plateau fracture), one had a perioperative injury to the medial collateral ligament, and one died (Figure 1).

Surgical technique and randomization. The surgeries were performed by a team of 11 board-certified orthopaedic surgeons who specialize in joint arthroplasty surgery. All patients were operated on under spinal anaesthesia, and a consistent surgical technique was used, as described in Table II.

Low molecular weight heparin (LMWH) was given for two weeks postoperatively as prophylaxis against thrombosis. Patients on aspirin (75 mg daily) continued their medication and were not given LMWH. All patients were treated postoperatively using the same multimodal analgesia and mobilization protocols. Patients were mobilized on the day of surgery and received physiotheraphy from a therapist blinded to the prosthesis design.

Patients were randomly allocated to one of the three Legion TKA designs (CR, AS, or PS) (Smith & Nephew, USA). The tibial baseplate was identical in all three designs, and the shape of the tibial insert is the only difference between the CR and AS designs (Figure 2). The PS design relies on a post-cam mechanism to replace the role of the PCL. Randomization was computer-generated with a variable block size of three. Table II. Description of surgical technique.

All surgeries included a medial parapatellar arthrotomy, femur first, and a mechanical alignment technique.

The goal for coronal alignment was 5° valgus (anatomical axis) and 0° mechanical axis.

The tibia cut was neutral to the mechanical axis in the coronal plane and with 3° of posterior slope using an intramedullary guide.

The bone resection and the insert slope defined the composite posterior slope. CR and PS designs had a composite slope of 7°, while the AS slope was 6° .

The PCL was carefully protected using a Y-shaped retractor and preserving a bony island around the PCL tibial footprint.¹⁸

After tibial plateau resection, PCL integrity was evaluated visually and by palpation.

The PCL was assessed again during knee ligament balancing and deemed intact by a negative posterior drawer test, and the tibiofemoral contact point located at the middle of the tibial bearing.

Following randomization, the PCL was resected in the AS and PS groups.

The patella was resurfaced in all patients with a Genesis inset biconvex button (Smith & Nephew, USA).

The femoral component was uncemented in the CR and AS groups, and the patellar and tibial components were cemented using Palacos R + G cement (Heraeus, Germany). In the PS group, all components were cemented.

No wound drain or tourniquet was used.

First-generation cephalosporin (2 g \times 4) was administered as antibiotic prophylaxis. Patients allergic to penicillin received clindamycin (600 mg \times 3).

All patients received intravenous tranexamic acid (10 mg/kg) twice. A local infiltration analgesia mixture (ropivacaine, ketorolac, and epinephrine) was injected during surgery.

AS, anterior-stabilized; CR, cruciate-retaining; PCL, posterior cruciate ligament; PS, posterior-stabilized.

Baseline characteristics. Data on comorbidities, BMI, American Society of Anesthesiologists grade,¹⁹ age at surgery, sex, smoking status, length of surgery, and length of hospital stay were extracted from medical records (Table III).

Clinical outcomes. Patients independently completed the KOOS,¹⁶ Oxford Knee Score (OKS),^{20,21} and two health-related quality of life measures (EuroQol five-dimension five-level questionnaire (EQ-5D-5L) and EuroQol visual analogue scale (EQ-VAS))²² preoperatively, and one and two years postoperatively. At one-year follow-up visit, patients were asked to describe their TKA on a five-point Likert scale (1 = very dissatisfied to 5 = very satisfied). The primary outcome measure was the mean score of the five KOOS subscales (KOOS₅)²³ two years after surgery. Secondary outcomes were the five individual KOOS subscales, OKS, EQ-5D-5L, EQ-VAS, ROM, and patients' willingness to undergo the same operation again.

Clinical follow-up. Two physiotherapists (AMK; see Acknowledgements) performed clinical examinations preoperatively, at six weeks, three months, and annually for two years postoperatively. For the ROM examination, a long-arm goniometer was used to measure the angle to the nearest degree using anatomical landmarks such as the trochanter, lateral epicondyle, and lateral malleolus. Patients were positioned supine with a pad under their ankles to measure passive extension, and then seated on the treatment bench to measure flexion.

Plain weightbearing radiographs (anterior-posterior (AP) and lateral views) and hip-knee-ankle radiographs were obtained

Measure	CR	AS	PS	p-value	
Total, n	72	72	72		
Mean age at surgery, yrs (range)	69 (56 to 77)	68 (53 to 77)	67 (47 to 77)	0.471*	
Female sex, n (%)	38 (53)	41 (57)	38 (53)		
Mean BMI, kg/m² (range)	28 (19 to 35)	28 (19 to 35)	30 (22 to 35)	0.014†	
Kellgren-Lawrence grade					
Mean (SD)	3.3 (0.5)	3.4 (0.5)	3.2 (0.4)	0.083*	
Grade 1, n (%)	0	0	0		
Grade 2, n (%)	2 (3)	0	1 (2)		
Grade 3, n (%)	48 (67)	44 (61)	55 (76)		
Grade 4, n (%)	22 (30)	28 (39)	16 (22)		
Comorbidities, n (%)					
Atrial fibrillation	8 (11)	3 (4)	5 (7)		
Heart attack	4 (6)	1 (1)	4 (6)		
Stroke	6 (8)	2 (3)	2 (3)		
COPD	3 (4)	2 (3)	3 (4)		
Diabetes type 2	4 (6)	3 (4)	4 (6)		
Hypertension	35 (49)	36 (50)	32 (44)		
Smokers, n (%)	1 (1)	0	3 (4)		
Mean ASA grade (SD)	2.06 (0.37)	1.96 (0.52)	2.00 (0.44)	0.429*	
Mean operating time, mins (range)	79 (60 to 112)	82 (62 to 146)	92 (67 to 147)	< 0.001*	
Mean LOS, days (range)	3.03 (1 to 7)	2.88 (1 to 5)	2.85 (1 to 6)	0.878*	
Mean length of follow-up, days (range)	756 (719 to 915)	749 (723 to 929)	764 (722 to 1,182)	0.312*	

*Kruskal-Wallis test.

†Mann-Whitney U test.

AS, anterior-stabilized; ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease; CR, cruciate-retaining; LOS, length of stay; PS, posterior-stabilized; SD, standard deviation.

no more than three months before surgery. AP and lateral views were re-taken three months after TKA and then yearly. Osteoarthritis (OA) was graded using the Kellgren-Lawrence $(KL)^{24}$ classification. Complications were registered at each patient contact.

Statistical analysis. The minimal important change (MIC) of ten points for the KOOS₅ and KOOS subscales was considered clinically relevant.^{25,26} We calculated that a sample of 180 patients (60 per group) was needed to detect this MIC with 80% power using a two-sided test and 5% significance level.²⁷ To account for loss to follow-up, our target enrolment was 216 patients (72 per group). A per-protocol analysis was performed, including only patients who completed the two-year follow-up.

Descriptive statistics included frequencies or means with ranges and confidence intervals (CIs), and group comparisons were performed for the following outcomes: KOOS, OKS, EQ-5D-5L, EQ-VAS, ROM, satisfaction, KL grade, and "willingness to undergo the same operation again". Data were checked for normality using the Kolmogorov-Smirnov test. We used independent-samples *t*-tests, analysis of variance, Mann-Whitney U test, chi-squared test, and Kruskal-Wallis test to assess group differences. A p-value < 0.05 was considered statistically significant; all tests were two-sided. Data were analyzed using SPSS v. 24.0 software (IBM, USA).

Results

The three groups had similar baseline characteristics regarding age, sex, and KL grade, although the PS group had higher BMI (Table III). About half the patients were women (54%; n = 117), and most (98%; n = 212) were non-smokers. Mean operating

times in the CR and AS groups were 79 minutes (60 to 112) and 82 minutes (62 to 146), respectively, significantly shorter than the 92 minutes (67 to 147) for the PS group (p < 0.001, Kruskal-Wallis test). The mean hospital stay was approximately three days in all three groups (p = 0.878, Kruskal-Wallis test) (Table III).

Clinical outcomes. The primary outcome (KOOS₅) was not significantly different between the three groups preoperatively, and we found no difference between the groups at two years (Table IV). In addition, there were no statistically significant differences in the KOOS subscales between baseline and the two-year follow-up. Furthermore, there were no significant group differences on the KOOS subscales, OKS, EQ-5D questionnaire, and EQ-VAS at two years (Figure 3, Table IV). All three groups reported more than 90% satisfaction rates as defined as a rating \geq 3 on a 1 to 5 Likert scale (CR, 99%; AS, 91%; PS 99%; p = 0.911, Kruskal-Wallis test), and there were no disparities among them. Additionally, 66/72 (92%) of the CR group, 54/66 (82%) of the AS group, and 65/70 (93%) of the PS group were willing to undergo the same operation again; the difference was not statistically significant (p = 0.080, chisquared test). There was no group difference in mean postoperative knee extension angle (p = 0.976, Mann-Whitney U test), although mean knee flexion angle was significantly better in the PS group compared to the CR and AS groups (129° vs 122°; p < 0.001, Mann-Whitney U test) (Table V).

Complications. One patient in the CR group, four in the AS group, and five in the PS group failed to achieve flexion greater than 90° by six weeks and required manipulation under anaesthesia; all achieved sustained improvement in flexion

Measure	Preoperative				2-yr follow-up			
	CR (n = 72)	AS (n = 72)	PS (n = 72)	p- value	CR (n = 72)	AS (n = 66)	PS (n = 70)	p- value
Mean KOOS (95% Cl)*	39 (36 to 42)	40 (37 to 42)	36 (34 to 39)	0.117	76 (72 to 80)	76 (72 to 80)	76 (72 to 80)	0.961
Paint	46 (42 to 50)	46 (43 to 49)	42 (38 to 45)	0.159	84 (81 to 88)	85 (81 to 89)	84 (80 to 88)	0.723
Symptoms†	55 (51 to 59)	56 (53 to 60)	51 (48 to 55)	0.226	84 (80 to 87)	83 (80 to 87)	82 (79 to 85)	0.724
ADL†	52 (48 to 56)	54 (51 to 58)	49 (46 to 53)	0.176	84 (80 to 88)	87 (84 to 91)	85 (81 to 88)	0.369
Sport & Rec†	17 (14 to 20)	17 (13 to 20)	15 (12 to 18)	0.717	52 (46 to 58)	51 (45 to 57)	53 (47 to 59)	0.887
QoLt	26 (23 to 30)	26 (23 to 29)	23 (20 to 26)	0.342	74 (69 to 79)	75 (70 to 80)	75 (70 to 80)	0.832
Mean change from baseline (95% Cl)	1							
KOOS								
Pain†					39 (34 to 43)	39 (34 to 44)	42 (38 to 47)	0.431
Symptoms†					29 (24 to 33)	27 (22 to 32)	30 (26 to 35)	0.565
ADL†					32 (28 to 37)	33 (28 to 38)	35 (30 to 39)	0.634
Sport & Rec†					35 (28 to 42)	34 (28 to 40)	37 (31 to 43)	0.737
QoLt					47 (42 to 53)	48 (42 to 55)	51 (46 to 57)	0.521
OKS (0 to 48)*	24 (23 to 26)	25 (24 to 27)	23 (22 to 25)	0.152	41 (39 to 42)	41 (40 to 43)	41 (39 to 42)	0.563
EQ-5D-5L†	0.59 (0.54 to 0.64)	0.64 (0.59 to 0.69)	0.62 (0.58 to 0.67)	0.207	0.87 (0.83 to 0.91)	0.90 (0.87 to 0.93)	0.91 (0.88 to 0.93)	0.491
EQ-VAS (0 to 100)1	62 (57 to 68)	67 (61 to 72)	64 (59 to 69)	0.391	70 (63 to 77)	67 (60 to 75)	62 (55 to 69)	0.113
Patients who did not achieve MIC fo KOOS, n (%)	r				3 (4)	8 (12)	3 (4)	

Table IV. Patient-reported outcome measures preoperatively and at two-year follow-up.

*Analysis of variance.

†Kruskal-Wallis test.

ADL, activities of daily living; AS, anterior-stabilized; CI, confidence interval; CR, cruciate-retaining; EQ-5D-5L, EuroQol five-dimension five-level questionnaire; EQ-VAS, Euro Qol-Visual Analogue Scale; KOOS, Knee injury and Osteoarthritis Outcome Score; KOOS₅, mean score of the five KOOS subscales; MIC, minimal important change; PS, posterior-stabilized; QoL, quality of life.

Table V. Measurements of flexion and extension preoperative and two years after total knee arthroplasty for the three implant designs.

Range of motion	Preoperative			2-yr follow-up			
	CR (n = 72)	AS (n = 72)	PS (n = 72)	CR (n = 72)	AS (n = 66)	PS (n = 70)	
Mean flexion, ° (95% CI)	126 (124 to 128)	127 (124 to 129)	125 (123 to 127)	122 (121 to 124)	122 (120 to 124)	129 (127 to 131)*	
Mean extension, ° (95% CI)	-5 (-6 to -4)	-5 (-6 to -4)	-5 (-6 to -4)	-1 (-1 to -1)	-1 (-1 to 0)	0 (-1 to 0)	

*Significantly more flexion than cruciate-retaining and anterior-stabilized designs (p < 0.001 for both, Mann-Whitney U test).

AS, anterior-stabilized; CI, confidence interval; CR, cruciate-retaining; PS, posterior-stabilized.

range post-manipulation. Further, in the AS group, one patient was treated for periprosthetic joint infection (PJI), one was reoperated due to instability, and one had a perioperative injury to the medial collateral ligament. In the PS group, one patient was reoperated for a PJI, and another was treated for a pulmonary embolism. There were no significant group differences in complications.

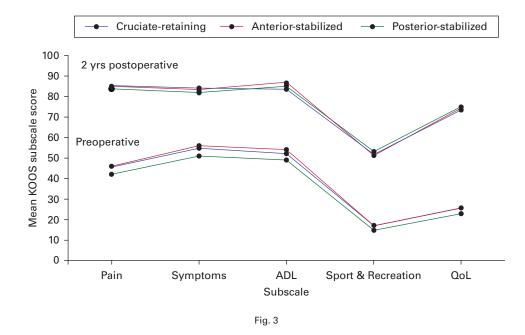
Discussion

In this RCT, we compared the clinical outcomes of patients who underwent TKA using three different implant designs from the same primary total knee system. Of particular interest was to explore whether a more conforming tibial insert (AS) was clinically as effective as a post-cam design (PS) in replacing a deficient PCL. A panel of validated patient-reported outcome measures (PROMs) assessing various outcomes was administered. After two years, we observed no significant differences in any of the PROMs between patients randomly assigned to receive CR, AS, or PS TKA. We also found no significant group

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differences in KOOS change scores from baseline to the twoyear follow-up. All three implant designs showed promising results, with good clinical and functional outcomes. Most (more than 90%) of the patients who underwent TKA reported being satisfied with the procedure. However, the patients receiving the AS design had a slightly lower percentage of patients who said they would be willing to undergo the same operation again. This difference, however, was not statistically significant compared to the other groups.

Our findings are similar to those reported in other studies showing no significant clinical differences between PCLretaining and PCL-sacrificing designs.^{12,28} However, previous trials had fewer participants than ours, or mostly compared only two designs. Raja et al²⁹ showed in a meta-analysis that AS TKA had similar functional outcomes to PS TKA, but was associated with less femoral rollback and increased sagittal laxity. Few studies have compared more than two TKA designs, and they had small sample sizes, short-term follow-ups, insufficient statistical power, or significant dropout rates.^{14,15}



Knee injury and Osteoarthritis Outcome Score (KOOS) profiles before and two years after total knee arthroplasty (TKA) for all three designs, and mean KOOS subscale scores at the preoperative assessment and at two-year follow-up. ADL, activities of daily living; QoL, quality of life.

Prosthesis survival is a common TKA outcome for comparing the performance of prosthesis brands or design subsets. In a registry study comparing the long-term survivorship of one manufacturer's CR, AS, and PS designs, Dalton et al¹⁵ found that AS and CR TKAs had comparable revision rates. However, the AS design resulted in a lower revision rate than the PS design. The authors proposed that this difference might be due to PS designs being selectively used in more complex TKA cases at higher risk of revision.

Our research findings indicate that the box cut and cementing of the femoral component required for PS cases resulted in longer operating times. This result is consistent with other studies.¹² Additionally, prior research has shown better flexion with a PS design. A meta-analysis of 1,114 patients revealed a significant difference in knee flexion in favour of the PS design.³⁰ In PS implants, the post-cam mechanism creates a posterior translation of the femur on the tibial plateau during flexion, increasing the rollback movement and, thus, the degree of flexion.¹¹ Studies have shown that greater ROM can improve functional scores.³¹ However, many daily activities, such as climbing stairs, only require knee flexion of about 90°. Nevertheless, whether the flexion difference (7°) observed in our study is noticeable or clinically significant for patients remains uncertain. According to the study conducted by Hancock et al,32 using a long-arm goniometer requires a minimum difference of 10° between measurements to ensure a valid difference. Further, our flexion and extension data were passive, and the force applied by the physiotherapists varied. In contrast, Hancock et al's³² data were active and subject-controlled, which may make them more reliable. The long-arm goniometer, however, had high inter-rater and intra-rater reliability.

A prerequisite for CR TKA is a functioning PCL. In the case of a tight PCL, some surgeons suggest balancing in terms of partially releasing the ligament,³³ which may increase the risk of later insufficiency. We believe it is essential to maintain an intact PCL during CR TKA, and no patient in the CR group was revised because of anteroposterior instability at two years. Wood et al¹⁸ showed a risk reduction of 50% for PCL insufficiency in a cadaver study where the same method to protect the PCL was employed as in the present study.

A potential cause of revision knee arthroplasty is late rupture of the PCL.34 An isolated tibial insert exchange (ITIE) is an option in revising a sagittally unstable CR knee prosthesis. This alternative can be appealing as it reduces surgical complexity, preserves bone stock, and may accelerate rehabilitation compared to a complete prosthesis revision. In the absence of infection, ITIE has been undertaken in patients for various indications, such as polyethylene wear, instability, stiffness, and effusion.35 A recent study by Tetreault et al³⁵ showed that ITIE yielded lower ten-year survival when performed for instability than isolated insert wear. ITIE is the second most common TKA revision procedure, accounting for almost 20% of cases in the USA,³⁶ but only a few extensive studies have analyzed its outcome. Therefore, patient selection for this procedure should be carefully made for indications other than early PJI.

There are situations where a CR TKA is challenging to perform, and the surgeon should therefore be capable of converting to an AS or PS design. For example, PCL insufficiency, coronal malalignment, and difficulty balancing often necessitate PCL resection.³⁷ Laskin³⁸ reported that CR TKA performed in patients with a coronal deformity of $> 15^{\circ}$ was associated with an increased risk of revision and pain. In addition, conversion from a CR to a PS design is reported to be more common in patients with flexion contracture $> 20^{\circ}$.³⁷ Prior knee injuries or surgery may reduce the quality of the remaining ligaments,³⁷ so accurate soft-tissue balancing would be easier with a sacrificed PCL in these patients.

TKA aims to restore as near as possible native knee kinematics, and as our understanding of knee kinematics evolves, so do knee implant designs. Intact cruciate ligaments are a prerequisite for normal knee kinematics, which change as soon as one or both cruciate ligaments are removed. A recent report from a subset of patients in the present study showed that CR and AS designs failed to restore physiological joint kinematics during a step-up movement, in contrast to the PS design in patients with a well-functioning TKA.¹¹ However, it is not clear whether this has any clinical significance.

The main strengths of our study were the prospective randomized controlled design, large sample, and high follow-up rate of 96% at two years. In addition, the inclusion and exclusion criteria were strict, and the surgical protocol for the initial preservation of the PCL was standardized. Furthermore, patients, and the physiotherapists performing the functional testing, were blinded to the TKA design.

Our trial had some limitations. Only a small proportion of patients met the rigorous eligibility standards, and while we used a TKA design from a single manufacturer, which helped to ensure we had a uniform and consistent group, this may limit the generalizability of our findings to the broader TKA population. The follow-up period was only two years, so the clinical results may not fully represent longer-term outcomes. Several surgeons performed the TKAs, so there may have been minor differences in surgical technique.

Our trial may be underpowered, as using MIC values to calculate sample size is not recommended,³⁹ despite the KOOS user guide indicating that it is feasible to do so. We did not conduct a postoperative radiological assessment, so we cannot rule out the potential impact of differences in alignment on the study outcomes. Lastly, using a hybrid TKA in the AS and CR groups may introduce a bias and further limit the generalizability of the results. However, the hybrid fixation method has been the leading procedure at our hospital for several years, and the Norwegian joint registry indicates better survival of hybrid TKAs than fully cemented prostheses.⁴⁰

To conclude, we have performed a blinded RCT comparing the CR, AS, and PS designs of the same primary TKA system and found no difference in PROMs after two years. More than 90% of patients in all three groups reported being satisfied with their knees. The PS design performed better in terms of flexion compared to the other designs. Nonetheless, the difference may not be large enough to have clinical relevance. All three designs are viable options for primary TKA in uncomplicated OA knees.

Take home message

 There is no difference in patient-reported outcomes for posterior cruciate ligament-preserving and -sacrificing total knee arthroplasty (TKA) designs.

- More than 90% of patients who underwent TKA reported high satisfaction levels.

Instagram

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