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Better Flexion but Unaffected Satisfaction After Treatment With Posterior Stabilized Versus Cruciate Retaining Total Knee Arthroplasty — 2-year Results of a Prospective, Randomized Trial

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ABSTRACT

Background: Both the cruciate-retaining (CR) and posterior-stabilized (PS) implant systems are commonplace in modern total knee arthroplasty (TKA) practice. However, there is controversy regarding functional outcomes and survivorship. The aim of the underlying study was to evaluate differences between CR and PS TKA regarding knee function, patient-reported outcome measures (PROMs) as well as complication rates.

Methods: 140 patients with knee osteoarthritis scheduled for an unconstrained TKA were enrolled in a prospective, randomized study. Patients received either a CR or PS implant. Range of motion and PROMs (Oxford Knee Score, Knee Society Score, European Quality of Life 5 Dimensions 3 Level, University of California Los Angeles Activity scale and subjective satisfaction) were assessed prior to, 3 months, 1 and 2 years after surgery.

Results: We found minor differences between treatment groups regarding demographic factors. Within the PS group duration of surgery was longer (mean PS 81.4 min vs CR 76.0 min, $P = .006$). We observed better flexion (median PS 120.0° vs CR 115°, $P = .017$) and an overall better range of motion (median PS 120.0° vs CR 115.0°, $P = .008$) for the PS group. PROMs did not differ between groups. At 2-year follow-up there were no revisions in either cohort. Five patients needed reoperations. Three patients needed manipulation under anesthesia, 2 in the CR and one in the PS group.

Conclusion: While PS TKA achieved a better flexion capability, PROMs were similar in CR and PS TKA. The CR implant design continues to be a reliable option for patients with an intact posterior cruciate ligament.

Background

Total knee arthroplasty (TKA) is nowadays a routine procedure that is highly standardized. Yet, there are still procedural steps, components and implant designs that are controversial. Whether to sacrifice the posterior cruciate ligament (PCL) or not has been discussed intensively throughout the past decades [1–5]. In some patients, there is a need for substitution of the PCL (ie, if it is insufficient or unintendedly resected during the surgery), and therefore the implant choice is inherent. In most cases, however, the PCL is intact, leaving the decision of which implant to choose up to the surgeon. This choice seems to be a matter of preference, experience, philosophy, and geography rather than a profound evidence-based decision [6,7]. Several implant designs are available, including cruciate-retaining (CR) and posterior-stabilized (PS) designs. Each implant design offers relevant advantages. PS designs have displayed better kinematics and knee flexion [8]. However, the improved range of motion (ROM) comes at a cost, including the necessity for a larger bone resection and higher revision rates due to early femoral loosening [9–14]. Despite these facts, the number of PS implants used in Germany and other countries is rising

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continuously, although there is still no consensus on which implant is the better treatment option [14]. To date, numerous studies have failed to demonstrate the superiority of one implant design over the other.

The aim of the underlying randomized-controlled study was therefore to evaluate the functional and patient reported outcome as well as to compare the complication rate after TKA using the PS or CR design.

Materials and Methods

The study protocol was registered in the US National Institutes of Health's database registry (http://www.clinicaltrials.gov) under National Clinical Trial number 03873363. After institutional review board approval (EK 6012018) a prospective, randomized-controlled trial was initiated. A total of 140 patients scheduled for TKA due to primary or secondary osteoarthritis were enrolled between April 1, 2018, and June 1, 2020, after written informed consent. Exclusion criteria comprised patients with chronic pain, neuromuscular diseases, insufficiency of the PCL, the need for a constrained implant, known or suspected addictive diseases (ie, drugs, alcohol) and body mass index (BMI) > 40 kg/m^2. Initially 70 patients were randomized per group using a software algorithm. During surgery, one patient preoperatively planned for a CR implant, received a PS implant since the PCL appeared damaged. Four patients preoperatively planned for PS received a CR implant by error. One patient had to be excluded since a higher level of constraint was necessary during surgery. Overall, 72 patients were treated with a CR and 67 patients with a PS implant design (balanSys Bicodylar CR and PS, Fa. Mathys AG, Bettlach, Switzerland). The balanSys is a bicondylar knee system with some special design features which include a single-radius design, a 7° inclined anterior femur shield to prevent notching, a wide Q-angle and deep trochlea design for improved patellar tracking as well as a relatively narrow mediolateral femur dimension and a deep flexion possibility for the PS femur. It has demonstrated good results in several national arthroplasty registries [12–14]. Surgery was carried out under general or spinal anesthesia without a tourniquet. A total of 7 surgeons carried out the operations; however, 3 surgeons performed more than 90% of the operations. Prior to surgery, the following demographic parameters were assessed: age, sex, BMI, American Society of Anesthesiologists score. Furthermore, perioperative data (cut-sew-time, blood loss, transfusion rate, adverse events) were evaluated. Blood loss was calculated using Rosenchers formula [15]. Patients were clinically evaluated prior to, 3 months, 1 and 2 years after surgery. Knee function (ROM, stability) and patient reported outcome, including Oxford Knee Score, Knee Society Score, EuroQuol questionnaire (EQ-5D, EQ-VAS) and University of California Los Angeles activity scale as well as satisfaction with the results of the surgery on a visual analogue scale (VAS 0 to 10) were assessed. 132 patients completed the 2-year FU (Figure 1).

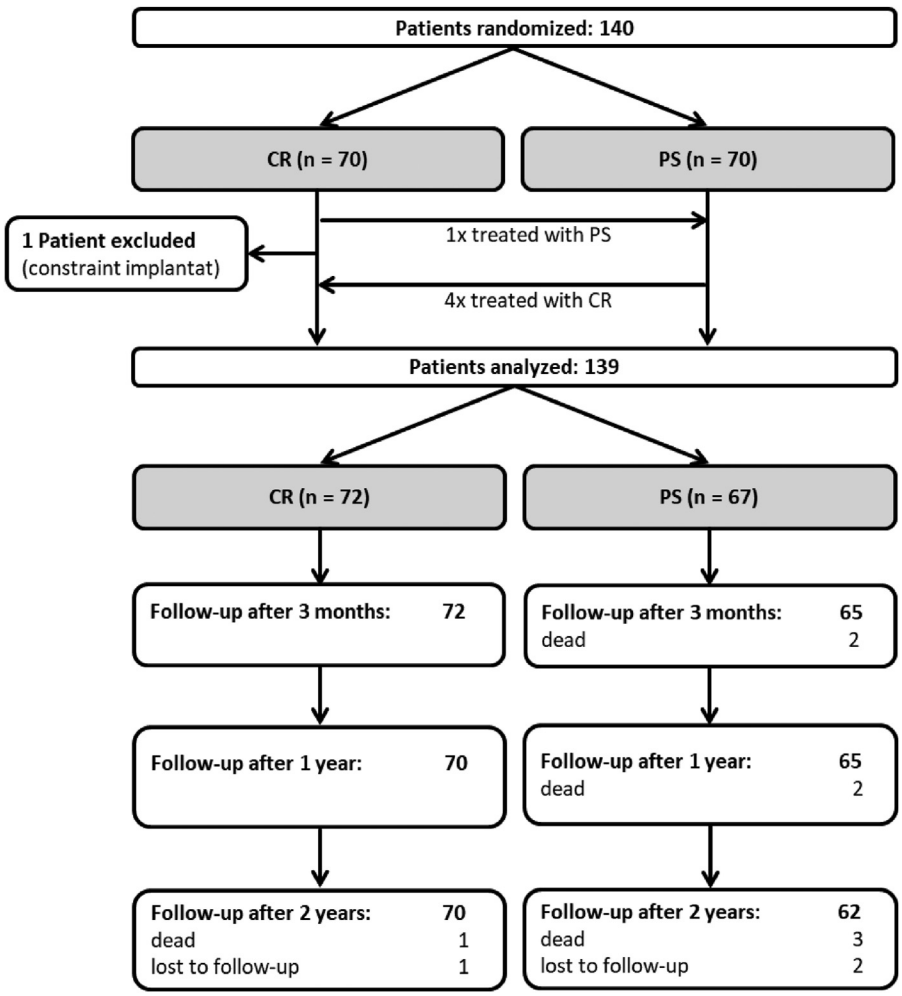

Fig. 1. Consort FlowChart.

Statistical Analysis

Sample size calculation was based on knee flexion. To detect a difference of 5° (estimated standard deviation of 10°) with a power of 0.8 and a significance level of $P < .05$ a minimum of 64 patients per group were necessary.

Data description was based on median and range for continuous values and absolute and relative frequencies for categorial values. Data was tested for normality using Kolmogorov-Smirnov-Test. Comparisons between treatment groups were done "as treated". Additionally an "intention-to-treat" analysis was performed. While Mann-Whitney-U-Test was used for continuous values in case of nonnormal distribution, *t*-test was used in case of normal distribution. *Chi*-Square test was used for categorial values. Significance level was set at $P < .05$. The software SPSS (release 26 for Windows) was used for data analysis.

Results

We found no differences between the treatment groups regarding gender, American Society of Anesthesiologists score, pathology leading to TKA and surgeon performing the operation. Despite randomization, patients of the PS group were significantly younger, while patients of the CR group had a significantly lower BMI. Total operative time was 5.4 minutes longer for the PS group. Blood loss was significantly higher in the PS group. In both groups no blood transfusions were necessary. (Table 1).

At 2-year FU 4 patients had died and 3 were lost to follow-up (FU). Overall, 70 patients in the CR group and 62 patients in the PS group completed the 2-year FU. There were no revisions performed in either cohort. However, 5 patients needed reoperations: one debridement, antibiotic therapy, and implant retention procedure due to periprosthetic joint infection, 2 superficial wound revisions, one open reduction and internal fixation in a periprosthetic fracture of the patella, one Baker`s cyst removal. Three patients needed manipulation under anesthesia, 2 in the CR and one in the PS group.

The evaluation of the functional outcome revealed a significantly better flexion at the 1- and 2-year FU in the PS group leading to an overall better ROM. The extension capability was slightly better for the CR group with a significant betterment at the 2-year FU (Table 2).

Regarding the evaluated patient-reported outcome measures (PROMs), there was a significant improvement in both groups, but no differences between the groups at any given FU (Table 3). The comparison between the preoperative and 2year results displayed significantly better results in both groups for all tested PROMs ($P = <.001$).

Discussion

Despite a high level of standardization in orthopedic surgery and especially in TKA, it is still a matter of philosophy and surgeons' preference which implant design is chosen [6,7,16]. Moreover, it seems to be a matter of geography. While in the Netherlands, the PS design is used in two thirds of the TKA procedures, surgeons in Australia and the UK prefer CR implants [12,13,17]. In Germany, PS implants are on the rise. There has been an increase in its use from 12.9 to 19.2% since 2014 [14]. Thus far, however, studies have demonstrated no clinically relevant differences between both designs [18–21]. Yet, PS implants have displayed a better ROM and better kinematics in various studies. However, this does not seem to have an impact on patients` satisfaction or activities of daily living [21–23]. The reasons have yet to be elucidated. Flexion capability and ROM itself on the other hand, have been investigated in depth. In synopsis, studies have demonstrated that a ROM of approximately 45 to 105° is necessary to perform typical activities of daily life (ie, ascending/descending stairs, rising from a chair, walking) [24]. And while patients with a flexion <70° have been shown to be severely impaired, a flexion of ~95° seems to be the cut-off point to pursue a somewhat normal life [25]. Less flexion seems to be accompanied by an increasing impairment. At the same time patient-reported outcome improves up to a flexion of approximately 110°. A further increase apparently does not lead to a further noticeable betterment for the patient [22]. Despite the significantly better ROM in patients who received a PS implant, the patient reported outcome in our study is not altered compared to the CR group. It might be plausible, that the slight advantages in ROM and flexion do not lead to a perceivable clinical benefit. The minimal noticeable change has yet to be determined. Within the PS group we found a significant improvement at the 2-year-FU regarding knee function, quality of life and level of activity compared to the preoperative assessment. While the improvement regarding quality of life and level of activity was also visible in the CR group,

Table 1
Pre- and Perioperative Demographic Characteristics of all Patients Who Completed the 2-Y Follow-Up as Treated Given as Median, Range and Interquartile Range.

Item	CR TKA (n = 70)	PS TKA (n = 62)	*P*-value
Age at surgery [years]	68.0 (43.3 to 84.4; 13.8)	62.6 (44.9 to 81.1; 15.4)	**.036**†
Total operative time [minutes]	74.5 (57.0 to 122.0; 13.0)	80.0 (62.0 to 111.0; 15.0)	**.006**†
BMI [kg/m^2]	28.4 (20.6 to 42.5; 6.0)	31.4 (24.2 to 43; 6.1)	**.0005**‡
Blood loss			
Hemoglobin preoperative [g/dl]	8.5 (6.7 to 11.4; 1.1)	8.7 (7.1 to 10.9; 0.9)	.137‡
Hemoglobin postoperative [g/dl]	6.9 (4.8 to 9.0; 1.0)	6.8 (4.6 to 9.0; 1.0)	.774†
Estimated blood loss [ml]	1.0 (0.1 to 2.1; 0.5)	1.1 (0.4 to 2.5; 0.5)	**.021**†
Female gender	38 (54.3%)	30 (48.4%)	.499*
Comorbidities			
ASA grade 1 or 2	43 (61.4%)	41 (66.1%)	
ASA grade 3 or 4	27 (38.6%)	21 (33.9%)	.575*
Pathology leading to TKA			.402*
Primary osteoarthritis	64 (91.4%)	57 (91.9%)	
Secondary osteoarthritis	6 (8.6%)	5 (8.0%)	
Performed procedures			.690*
Surgeon 1	33 (47.1%)	26 (41.9%)	
Surgeon 2	16 (22.9%)	19 (29.0%)	
Surgeon 3	15 (21.4%)	15 (24.2%)	
Others	6 (8.6%)	3 (4.8%)	

Statistical test used depending on distribution and parameter type: * = Chi^2, † = *t*-test, ‡ = MWU. $P < .05$.
Bold value results that are significant, $P < .05$.

Table 2
PROMs of Patients Given as Median, Range and Interquartile Range. Nonnormal Distribution. $P < .05$.

Plane of Motion	CR TKA (n = 70)	PS TKA (n = 62)	*P* Value (MWU)
Flexion			
Prior to surgery	115 (80 to 130; 10)	110 (70 to 140; 20)	.134
3 mo follow-up	105 (70 to 125; 15)	110 (90 to 140; 20)	.055
1 y follow-up	110 (85 to 135; 15)	120 (90 to 135; 10)	**.0002**
2 y follow-up	115 (90 to 130; 15)	120 (95 to 135; 10)	**.017**
Improvement [delta 2yrs - preoperative]	0 (−25 to 35; 15)	5 (−20 to 40; 15)	**.001**
Extension			
Prior to surgery	−5 (−15 to 0; 5)	−1.5 (−20 to 0; 5)	.394
3 mo follow-up	0 (−50 to 0; 3)	0 (−10 to 5; 5)	.548
1 y follow-up	0 (−15 to 5; 0)	0 (−10 to 5; 0)	.855
2 y follow-up	0 (−20 to 5; 0)	0 (−10 to 5; 0)	.384
Improvement [delta 2yrs - preoperative]	5 (−10 to 15; 5)	3 (−2 to 20; 5)	.865
ROM			
Prior to surgery	110 (75 to 130; 20)	110 (60 to 140; 17)	.296
3 mo follow-up	100 (40 to 125; 18)	110 (85 to 135; 20)	.071
1 y follow-up	110 (80 to 140; 20)	120 (89 to 135; 10)	**.0003**
2 y follow-up	115 (90 to 130; 15)	120 (90 to 135; 10)	**.008**
Improvement [delta 2yrs - preoperative]	2.5 (−20 to 40; 15)	10 (−20 to 55; 20)	**.003**

Bold value results that are significant, $P < .05$.

Table 3
PROMs of Patients Given as Median, Range and Interquartile Range.

Score	CR TKA (n = 70)	PS TKA (n = 62)	*P* Value
Oxford knee score [0 to 48]			
Prior to surgery	22 (8 to 32; 9)	21.5 (5 to 35; 12)	.492†
3 mo follow-up	32.5 (13 to 46; 11.9)	30.5 (10 to 44; 11)	.515†
1 y follow-up	39 (21 to 48; 8)	40 (11 to 48; 9)	.950‡
2 y follow-up	41 (14 to 48; 11)	40 (12 to 48; 7.6)	.470‡
Improvement [delta 2yrs - preoperative]	17.5 (−5 to 34; 10)	17 (−2 to 33; 10)	.651†
KSS Knee Society Score [0 to 200]			
Prior to surgery	101.7 (47 to 153; 32.5)	97.5 (39 to 145; 35.6)	.284†
3 mo follow-up	146.5 (43 to 197; 41)	149 (87 to 187; 41)	.747†
1 y follow-up	169 (91 to 200; 38)	164.5 (94 to 199; 35)	.406†
2 y follow-up	175 (95 to 200; 43)	169 (80 to 200; 36)	.834‡
Improvement [delta 2yrs - preoperative]	64.5 (3 to 114; 30.2)	70 (1.6 to 131.6; 37)	.441†
KSS Knee Score [0 to 100]			
Prior to surgery	45 (13 to 74; 21)	40.5 (10 to 79; 22)	.381†
3 mo follow-up	83.5 (13 to 98; 20)	81 (43 to 100; 23)	.476‡
1 y follow-up	91 (46 to 100; 13)	92 (44 to 100; 15)	.855‡
2 y follow-up	92.5 (45 to 100; 12)	92 (50 to 100; 16)	.905‡
Improvement [delta 2yrs - preoperative]	42 (6 to 80; 22.3)	48 (−8.4 to 81.6; 25)	.422†
KSS Function Score [0 to 100]			
Prior to surgery	60 (15 to 90; 20)	55 (10 to 80; 10)	.362‡
3 mo follow-up	65 (25 to 100; 30)	67.5 (25 to 100; 25)	.891‡
1 y follow-up	80 (40 to 100; 25)	75 (30 to 100; 30)	.179‡
2 y follow-up	80 (10 to 100; 40)	80 (30 to 100; 20)	.862‡
Improvement [delta 2yrs - preoperative]	20 (−20 to 60; 20)	20 (−20 to 65; 30)	.475‡
UCLA activity score [1 to 10]			
Prior to surgery	4 (2 to 9; 3)	3.5 (2 to 9; 2)	.161‡
3 mo follow-up	5 (2 to 8; 2)	5 (3 to 7; 3)	.100‡
1 y follow-up	5.5 (2 to 10; 2.5)	5 (2 to 9; 2)	.811‡
2 y follow-up	5 (2 to 9; 3)	5 (2 to 8; 3)	.784‡
Improvement [delta 2yrs - preoperative]	1 (−3 to 4; 2)	1 (−2 to 5; 3)	.331‡
EuroQol index			
Prior to surgery	0.8 (0.1 to 0.9; 0.5)	0.8 (0.1 to 0.9; 0.5)	.478‡
3 mo follow-up	0.9 (0.2 to 1.0; 0.1)	0.8 (0.3 to 1.0; 0.1)	.481‡
1 y follow-up	0.9 (0.4 to 1.0; 0.2)	0.9 (0.2 to 1.0; 0.2)	.698‡
2 y follow-up	0.9 (0.2 to 1.0; 0.2)	0.9 (0.2 to 1.0; 0.2)	.805‡
Improvement [delta 2yrs - preoperative]	0.2 (−0.5 to 0.8; 0.2)	0.2 (−0.6 to 0.9; 0.5)	.249‡
EuroQol visual analogue scale [0 to 100]			
Prior to surgery	55 (20 to 90; 25)	55 (10 to 90; 30)	.519‡
3 mo follow-up	70 (30 to 100; 20)	70 (35 to 97; 20)	.860‡
1 y follow-up	80 (17 to 100; 30)	75 (30 to 99; 25)	.591‡
2 y follow-up	80 (20 to 100; 20)	80 (16 to 100; 20)	.419‡
Improvement [delta 2yrs - preoperative]	20 (−45 to 67; 25)	20 (−40 to 69; 35)	.769‡
Satisfaction with the results of surgery [0 to 10]			
1 y follow-up	9 (2.5 to 10; 2)	9 (4 to 10; 2)	.782‡
2 y follow-up	9 (3 to 10; 2)	9.5 (4 to 10; 2)	.746‡

Statistical test used depending on distribution: † = *t*-test, ‡ = MWU. $P < .05$.
UCLA, University of California, Los Angeles.

flexion and overall ROM did not display a significant betterment. This is consistent with the results of other studies [26,27]. A recent metanalysis by Li et al displayed higher flexion in PS implants but also revealed no differences regarding PROM and gait parameters [28].

CR and PS implants have different mechanisms of restoring knee function. CR implants have an initial paradoxical anterior translation and less posterior femoral rollback [28]. There is, however, often a partial damage dealt to the PCL during the tibial cut which may lead to an increased risk of instability due to early tears [1]. PS implants on the other hand use a cam post mechanism, which is causing better femoral rollback and consequently superior flexion, but on the other hand make the implant vulnerable to additional polyethylene wear [1,19,29]. PS implants have been reported to have higher revision rates due to early loosening especially of the femoral component [10,13,14]. In the German Arthroplasty registry, revision and failure rates for PS implants were up to 50% higher at the 2-year-FU compared to CR systems [14]. This has also been observed in other arthroplasty registries [12,13,17,30]. Vertullo et al reported a 45% higher revision rate in patients when operated on by a surgeon who prefers PS implants compared with minimally stabilized CR implants. Several causes have been discussed for that higher revision rate, including increased polyethylene wear and the use in less stable knees [14,31].

Further disadvantages of the PS design include the necessity of a larger bone resection of the box, which leads to an increased cut-sew-time due to additional procedural steps and therefore an increase in costs. Additionally, the risk for femoral condylar fractures is increased. In the present study, the average cut-sew-time using the PS was 5.4 minutes longer compared to the CR group. This seems to be a negligible amount of time. However, considering an average cost of $36 to 62 per minute in the OR, this results in increased overall costs of $194 to 335 [32–34] per TKA. Especially in high volume clinics, this can lead to relevant additional costs.

A further factor concerning the cost-efficiency is the higher blood loss in the PS group. Within this group an additional blood loss of 150 mL compared to the CR group was observed. The cause is likely the additional bone resection, which leads to increased intraoperative and postoperative bleeding. In the underlying study, this had no impact on the transfusion rate and caused no difference in complication rate. While Mähringer-Kunz et al have presented similar results, there has also been a study by Cankaya et al which displayed no significant difference in perioperative blood loss [35,36].

Limitations

Limitations of our study include the aforementioned differences in patient demographics (age and BMI) between treatment groups despite randomization. However, even though the results are significant the actual differences are low with an age difference of 3.4 years and a difference in BMI of 2.7 kg/m^2. In the past, a correlation between implant survival-rate and the mentioned demographic criteria has been shown. While the probability of revision is decreasing with age, a higher BMI is associated with periprosthetic joint infections and a higher revision rate [14]. In the present study, only short-term survival has been investigated. A longer FU will be necessary to determine implant survival. It also needs to be mentioned that within our study 4 patients did not receive the randomized PS implant resulting in a slightly larger CR group. In order to address this issue an intention-to-treat analysis has been performed. The results, however, did not differ from the presented “as treated“ analysis.

Within this study, one specific implant design was used. All propositions can therefore only be made for these implants but are likely to yield similar results in comparable implant designs of other manufacturers.

Conclusion

Posterior stabilized and CR implants displayed similar results during short-term FU regarding patient reported outcome, levels of satisfaction and revision rates. Knee flexion was better in PS implants; however, this improvement did not translate into the daily life of the patients. The additional procedural steps of the PS implants are leading to an increased length of surgery and higher perioperative blood loss. However, this did not result in any clinical difference. The CR implant design therefore continues to be a reliable option for patients with an intact PCL.

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