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Novel post-cam endoskeleton-reinforced posterior-stabilized cement articulating spacer reduced the rate of mechanical complications in prosthetic knee infection

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Abstract

Background Posterior-stabilized cement articulating spacers (PS spacers) have superior knee scores and a greater range of motion in a two-stage exchange for chronic prosthetic knee infections (PKIs); however, mechanical complications are associated with the use of PS spacers. In the present study, we investigated a novel post-cam endoskeleton-reinforced PS spacer and its outcomes.

Methods This single-surgeon retrospective cohort study included patients with chronic PKIs treated with PS spacers between 2015 and 2022. PS spacers with three different configurations, based on endoskeleton reinforcement, were compared: non-reinforced (n-PS), cam-reinforced alone (C-PS), and post- and cam-reinforced (PC-PS). Rates of mechanical complications, reoperation, and infection eradication were evaluated. The constraint choice of the revision prosthesis and risk factors for mechanical complications were analysed.

Results In total, 186 patients, including 75 with n-PS, 61 with C-PS, and 50 with PC-PS spacers, were included. All patients were followed up for 2 years. The rate of overall mechanical complications was lowest in patients treated with PC-PS spacers, particularly in patients with unstable joints after femoral cam and tibial post fracture and tibial spacer dislodgement. Moreover, neither spacer exchange nor rotating-hinge knee revision prosthesis was required in PC-PS spacers. Independent risk factors for mechanical complications were body mass index ≥ 25 kg/m², femoral spacer size ≤ 2 , and intra-operative maximum flexion $\geq 110^\circ$.

Conclusion The novel PC-PS spacers prevented mechanical complications, spacer exchange, and the need for high-level constraint revision prostheses. We recommend the use of novel PC-PS spacers in two-stage exchange for chronic PKIs, especially in patients with a high body mass index, small femoral spacer size, and high knee flexion.

Keywords Post-cam, Endoskeleton, Posterior-stabilized spacer, Mechanical complications, Prosthetic knee infection

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Background

Prosthetic knee infection (PKI) is the most prevalent cause of early revision following primary total knee arthroplasty (TKA), with an incidence of 1–2% [1]. Two-stage exchange with an antibiotic-loaded cement spacer is the gold-standard treatment for chronic PKI, demonstrating infection eradication rates of 80–95% [2]. Articulating spacers show comparable results to static spacers in infection eradication rates; however, they demonstrate superior knee scores and greater range of motion in the interim and after reimplantation [3].

Numerous cement articulating spacer designs have been developed and are biomechanically categorized into cruciate-retaining (CR) and posterior-stabilized (PS) types [4]. CR spacers can cause mechanical complications such as spacer loosening, periprosthetic fractures, joint subluxation or dislocation, and extensor mechanism disruption [5]. In contrast, PS spacers are associated with lower rates of mechanical complications and reoperations [6].

Severe ligamentous deficiency and bony loss of the knee joint were observed after infection and resection [7]. A PS spacer with a post-cam design plays a crucial role in stabilizing the femoral and tibial components and achieving knee stability during motion. However, the cement composition of the post-cam design causes mechanical complications and leads to reoperation [6, 8]. To the best of our knowledge, there are only two studies on endoskeleton-reinforced PS spacers: one was on 49 PS spacers with a Kirschner wire-reinforced femoral cam alone to prevent fracture [8], and the other involved three PS spacers with a screw-reinforced tibial post alone to avoid breakage [9]. Moreover, there is no consensus on the optimal endoskeletal design for minimizing post-cam mechanical complications. Consequently, a study comparing the clinical outcomes of PS spacers with different endoskeleton configurations is crucial for optimizing the two-stage exchange.

Therefore, this study aimed to compare PS spacers with three different configurations based on endoskeleton reinforcement: non-reinforced PS (n-PS), cam-reinforced alone PS (C-PS), and novel post- and cam-reinforced PS (PC-PS) spacers. We hypothesized that the novel PC-PS spacers would result in a lower rate of mechanical complications and reoperation but no differences in infection eradication.

Methods

PS cement articulating spacer

The PS spacers were fabricated using a computer-aided design technique featuring a post-cam constrained system (CADAS; Ever Young BioDimension, Taichung, Taiwan) [4]. Silicone moulds made from thermosetting

polymers can be re-sterilized with hydrogen peroxide plasma and reused without any deformation. With six sizes of femoral and tibial trials available, surgeons can quickly select the appropriate silicone mould and fabricate articulating spacers.

Patients

This retrospective cohort study was approved by the Research Ethics Committee of our institution and conducted in accordance with the Declaration of Helsinki. All study participants provided informed consent. Clinical data were retrospectively collected from a database that included all adult patients treated for chronic PKI, based on the Musculoskeletal Infection Society criteria [10], who underwent a two-stage exchange using PS spacers between January 2015 and August 2022 and had a minimum follow-up of 2 years. The exclusion criteria were as follows: (1) incomplete radiographic data, (2) fungal or tuberculous PKIs, and (3) PKIs after revision TKA. The patients were divided into three consecutive cohorts based on endoskeleton usage: n-PS spacers between January 2015 and December 2017, C-PS spacers between January 2018 and June 2020, and PC-PS spacers between July 2020 and August 2022. All surgeries were performed by a single senior arthroplasty surgeon specializing in the treatment of prosthetic joint infections.

Surgical technique

A medial parapatellar approach and lateral retinaculum release were routinely performed. We preoperatively identified microorganisms using joint arthrocentesis under sterile conditions, and specimens were submitted for culture and sensitivity testing. All spacers were prepared using a 1:5 ratio of antibiotics to bone cement as the carrier (CMW3 without gentamicin; DePuy Synthes, Warsaw, IN, USA). When a specific microorganism was identified, targeted antibiotics were selected based on the sensitivity profiles. If the culture was negative, empirical antibiotics such as vancomycin and ceftazidime were added into the bone cement [11].

Both spacers were used to mark the appropriate coronal and rotational alignments. The tips were used to prevent tibial spacer varus malalignment, joint recurvatum deformity, and the use of a cement stem extension with a tibial spacer [12].

The n-PS spacers are shown in Fig. 1a–d. In the C-PS spacer, a bended, saddle-like 3.0 mm Kirschner wire was used within the femoral cam, engaging the bilateral posterior condyles anteriorly of the femoral spacer (Fig. 1e–h). Compared with the C-PS spacer, the additional procedure for the PC-PS spacer was the application of a 3.5-mm screw to reinforce the tibial post and merge the tibial spacer with the cement stem (Fig. 1i–l). A 2.5 mm

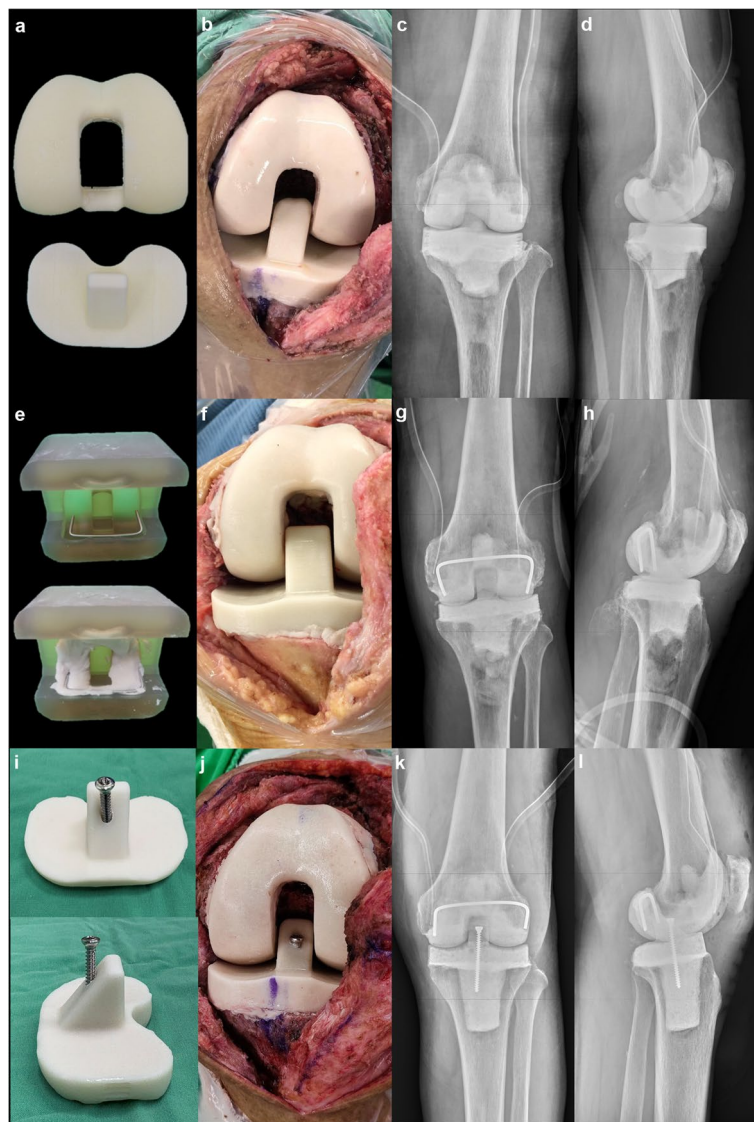


Fig. 1 **a-d.** The non-reinforced posterior-stabilized spacer. **a** The spacer after fabrication; **b** the knee joint with the spacer implanted; **c** anteroposterior and **(d)** lateral radiographs of the postoperative knee showing the spacer in situ. **e-h.** The cam-reinforced alone posterior-stabilized spacer. **e** A bended saddle-like 3.0-mm Kirschner wire within the cam and bilateral posterior condyles; **f** knee joint with the spacer implanted; **g** anteroposterior and **(h)** lateral radiographs of the postoperative knee showing the spacer in situ. **i-l.** The post- and cam-reinforced posterior-stabilized spacer. **i** A 3.5 mm screw with adequate length passed through the tibial post, spacer, and cement stem **(j)** knee joint with the spacer implanted; **k** anteroposterior and **(l)** lateral radiographs of the postoperative knee showing the spacer in situ

drilling bit was used to create an antegrade canal from the post through the spacer; one 40–60 mm screw, depending on spacer thickness, was partially driven into the bottom level of the spacer. We ensured that the drill point was not close to the tip of the post to prevent cement cracking. In addition, the screw length was adequate, with a length of at least 10 mm, to anchor the cement stem. After the implantation of the tibial spacer into the proximal tibia, with the cement in the setting phase, the remaining half of the screw was fully embedded in the

post. The compression screw was “locked” after cement stem curing.

Postoperative protocol

Postoperative care was consistent regardless of the spacer used; weight bearing was tolerated with a walker, and no knee brace was used. Intravenous antibiotics were administered for a minimum of 4 weeks following the recommendations of an infectious disease consultant. Oral antibiotics were continued until normalization of

the C-reactive protein levels and erythrocyte sedimentation rates. Radiographic examinations, including anteroposterior, lateral, and merchant views of the knee, were evaluated postoperatively every subsequent month, and pre-replantation evaluation was performed whenever patients experienced knee pain, swelling, or deformity.

Before reimplantation, negative clinical signs of infection, C-reactive protein and erythrocyte sedimentation rates within the normal range, and negative culture of arthrocentesis were observed for at least 2 weeks of antibiotic holidays [13].

Evaluation

Patient demographics and microorganism data at the time of resection arthroplasty were recorded. Information regarding the spacers and surgical times was documented. The range of motion was measured after spacer insertion and wound closure. The interim and follow-up periods were extracted from medical records.

Data on spacer exchange and unexpected early reimplantation for mechanical complications during the interim and constraint choice of revision prostheses were extracted from the operation records. These collated data were reviewed by one author blinded to the surgeries.

Any radiographic coding on INFINITT Picture Archiving and Communications System was considered a mechanical complication [4, 6, 8, 14], including femoral spacer dislodgement, unstable joint (subluxation or dislocation) after femoral cam fracture, tibial spacer dislodgement, unstable joint after tibial post fracture, spacer fracture besides post or cam, peri-spacer fracture, and extensor mechanism disruption. Mixed complications were considered major complications only once in each patient. All radiographic data were assessed and recorded by a musculoskeletal radiologist and two arthroplasty surgeons.

Infection eradication was defined according to the Delphi criteria following reimplantation [13].

Data analyses

Data were analysed using the Statistical Package for the Social Sciences software (version 24.0; SPSS Inc., Armonk, NY, USA). Data were presented as means, ranges, and 95% confidence intervals for continuous variables and as numbers and percentages for categorical variables. Differences among the three cohorts were evaluated using the chi-square test for categorical variables. Between-cohort comparisons were performed using a one-way analysis of variance for continuous variables. The reliability of the radiographic coding of mechanical complications was examined using

intraclass correlation coefficients. Univariate and multivariate logistic regression models were used to assess the association between covariates, such as host or spacer factors, and the risk of mechanical failure. A P value ≤ 0.05 was considered statistically significant.

Results

In total, 186 patients, including 75 with n-PS, 61 with C-PS, and 50 with PC-PS spacers, were included. One knee from each patient was used. The mean follow-up duration was 55.3 months. A Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) flowchart detailing the study design is shown in Fig. 2. There were no significant differences in demographic data, except in the postoperative follow-up period (Table 1).

The outcomes of patients treated with n-PS, C-PS, and PC-PS spacers are shown in Table 2. The intraclass correlation coefficient of the radiographic coding of mechanical complications was 0.990 (range, 0.980–0.996; $P < 0.001$). No mechanical complications occurred with PC-PS spacer use. The overall mechanical complication rates for n-PS, C-PS, and PC-PS spacers were 20%, 19.7%, and 0%, respectively. Between-cohort comparisons of major mechanical complications are shown in Fig. 3. The rate of unstable joints after femoral cam fracture was highest in patients with n-PS spacers (17.3%; Fig. 4a–d). In contrast to n-PS spacers, there was no femoral cam fracture in patients with C-PS spacers after reinforcement of the femoral cam; however, there were higher rates of tibial spacer dislodgement (9.8%; Fig. 4e–h) and unstable joints after tibial post fracture (9.8%; Fig. 4i–l). Moreover, the rate of spacer exchange was lower in PC-PS spacers than in n-PS and C-PS spacers (0%, 16.0%, and 13.1%, respectively). No rotating-hinge knee (RHK) revision prosthesis was required in patients with the PC-PS spacers compared to patients with the other two spacers. All RHKs required for the n-PS and C-PS spacers were knees with mechanical complications. However, all spacers could control the infection.

The details of patients with n-PS and C-PS spacers who had mechanical complications are shown in Table 3. Most (26/27, 96.3%) of the mechanical complications were nontraumatic mechanisms, with 88.9% (24/27) failures occurring ≤ 6 weeks after spacer use.

Tables 4 shows univariate risk factors for mechanical complications. After multivariate logistic regression adjusted, body mass index (BMI) ≥ 25 kg/m², femoral spacer size ≤ 2 , and intra-operative maximum flexion $\geq 110^\circ$ were identified as independent risk factors (Table 5).

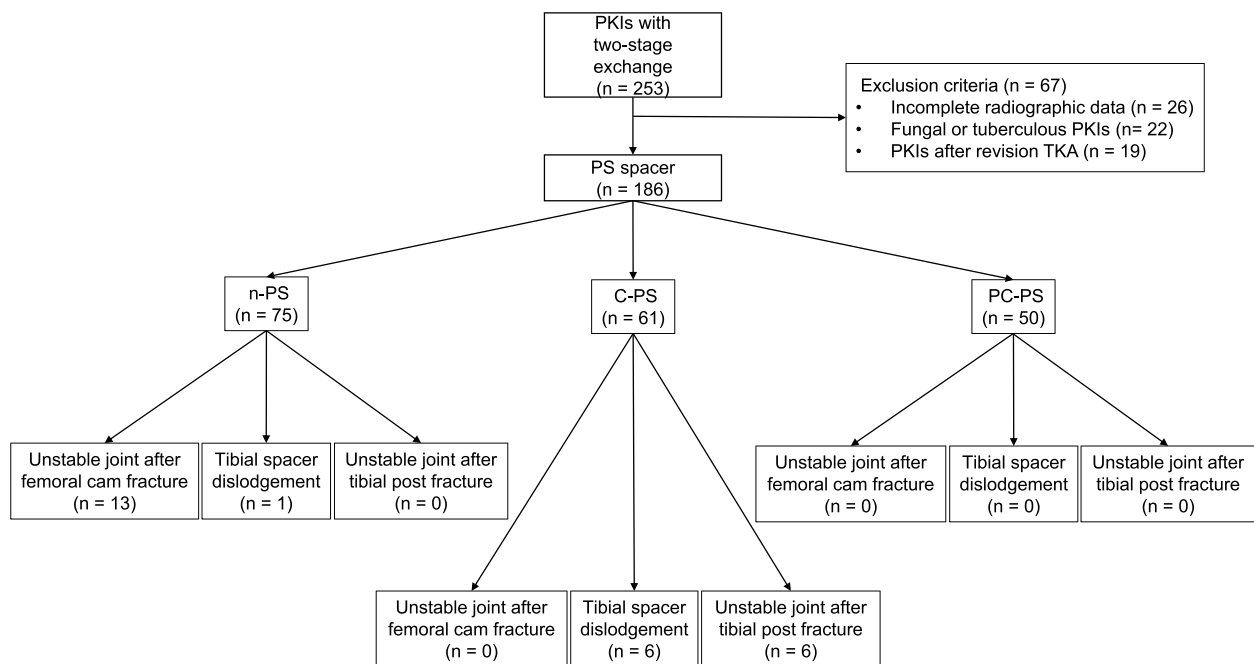


Fig. 2 The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) flowchart detailing the study design. PKI, prosthetic knee infection; PS, posterior-stabilized; n-PS non-reinforced; C-PS, cam-reinforced alone; PC-PS, post- and cam-reinforced

Discussion

This retrospective cohort study compared the mechanical effects of endoskeleton-reinforced post and cam in PS spacers and analysed the risk factors for mechanical failure. Notably, all three spacers effectively controlled infections. However, compared to n-PS and C-PS spacers, the novel PC-PS spacer showed neither mechanical complications nor reoperations during the interim period, and a high-level constraint revision prosthesis was not required. Independent risk factors for mechanical complications included a higher BMI, smaller femoral spacer size, and greater knee flexion.

The post-cam mechanism of the PS spacer stabilizes the knee during flexion, enhances femoral rollback, and thus increases the range of flexion compared with the CR spacer [6, 15]. However, unstable joints after femoral cam fractures are the major mechanical complications observed in patients with n-PS spacers. This is likely because the cross-sectional area and volume of the femoral cam are smaller than those of the tibial post, making the femoral cam more susceptible to failure. The PS spacer is composed of cement with high-dose antibiotics, which have detrimental effects on various mechanical properties of the cement, including bending, shearing, compressive and tensile strength, and fracture toughness [16]. Moreover, the unstable biomechanical environment in PKI after resection may result in a higher risk of post-cam failure due to increased stress concentration during

post and cam engagement and impingement [8]. This could explain why nearly all mechanical complications occurred within few weeks after surgery without a traumatic mechanism.

No femoral cam fractures were observed after the metal-reinforced cam was placed in the C-PS spacer. Lin et al. reported that metal not only acts as a reinforced endoskeleton for the cam to prevent fracture but also serve as a “salvage” metal cam in cement cam fracture [8]. However, complications of unstable joints after tibial post-fractures have been reported. In primary PS TKA, a polyethylene tibial post fracture occurred at the posterior base and propagated anteriorly when the lift-off force generated by the metal femoral cam exceeded the structural integrity of the post [17]. Based on the same principle, the constrained loading was shifted, leading to tibial post fracture under repeated impingement between the metal-reinforced cam and cement-unreinforced post in the C-PS spacer. Another tibial spacer-related complication is dislodgement. The cement-bone junction is recognized as the weakest component in the prostheses-cement-bone assembly, particularly in the tolerance of shearing strength [16]. Therefore, the tibial spacer can easily become dislodged following mechanical debonding of the spacer-cement–bone interface. The shearing stress is transferred from the reinforced cam to the unreinforced post during deep flexion, making the post a fulcrum and leveraging the tibial spacer dislodgement

Table 1 Demographic data of patients with n-PS, C-PS, and PC-PS spacers

Variables	Spacer type			P value
	n-PS (n = 75)	C-PS (n = 61)	PC-PS (n = 50)	
Age, years (95% CI)	68.7 (61–81)	69.1 (58–84)	67.6 (60–80)	.681
Female sex, n (%)	42 (56.0)	34 (55.7)	30 (60.0)	.410
BMI, kg/m ² (95% CI)	27.8 (20.4–35.1)	28.1 (22.2–33.5)	28.5 (20.9–34.8)	.606
Right laterality, n (%)	37 (49.3)	32 (52.5)	24 (48.0)	.319
Constraint of the original prosthesis				
Cruciate-retaining, n (%)	28 (37.3)	23 (37.7)	18 (36.0)	.552
Posterior-stabilized, n (%)	47 (62.7)	38 (62.3)	32 (64.0)	.843
Smoking status				
Never smokers, n (%)	36 (48.0)	29 (47.5)	23 (46.0)	.537
Current or former smokers, n (%)	39 (52.0)	32 (52.5)	27 (54.0)	.538
Insurance status				
Insured, n (%)	75 (100.0)	60 (98.4)	50 (100.0)	.493
Uninsured, n (%)	0 (0.0)	1 (1.6)	0 (0.0)	.695
Socioeconomic status				
Low, n (%)	29 (38.7)	24 (39.3)	18 (36.0)	.538
Middle, n (%)	29 (38.7)	25 (41.0)	20 (40.0)	.421
High, n (%)	17 (22.7)	12 (19.7)	12 (24.0)	.344
Charlson Comorbidity Index				
0, n (%)	35 (46.7)	29 (47.5)	23 (46.0)	.560
1–2, n (%)	26 (34.7)	22 (36.1)	18 (36.0)	.414
3+, n (%)	14 (18.7)	10 (16.4)	9 (18.0)	.683
McPherson host grade				
Uncompromised, n (%)	35 (46.7)	29 (47.5)	23 (46.0)	.443
Compromised, n (%)	25 (33.3)	23 (37.7)	17 (34.0)	.467
Significantly compromised, n (%)	15 (20.0)	9 (14.8)	10 (20.0)	.363
Microorganisms				
Staphylococcus species, n (%)	27 (36.0)	21 (34.4)	18 (36.0)	.485
Streptococcus species, n (%)	14 (18.7)	12 (19.7)	9 (18.0)	.534
Gram-positive cocci, n (%)	10 (13.3)	8 (13.1)	8 (16.0)	.360
Gram-negative species, n (%)	14 (18.7)	9 (14.8)	8 (16.0)	.327
Polymicrobial, n (%)	5 (6.7)	5 (8.2)	4 (8.0)	.501
Culture negative, n (%)	5 (6.7)	6 (9.8)	3 (6.0)	.468
Spacer information				
Femoral spacer size, No. (95% CI)	3.9 (2–5)	3.7 (2–5)	3.8 (2–5)	.622
Tibial spacer size, No. (95% CI)	3.8 (2–5)	4.0 (2–5)	3.9 (2–5)	.458
Tibial spacer thickness, mm (95% CI)	13.5 (10–20)	13.4 (10–18)	13.1 (9–22)	.306
Associated costs of spacer ^a , USD (95% CI)	380.1 (321–683)	384.7 (337–672)	386.3 (331–680)	.593
Surgical time of resection arthroplasty, min (95% CI)	166.7 (135–193)	169.1 (141–189)	168.3 (140–195)	.477
Intra-operative range of motion ^b , degree (95% CI)	97.8 (83–113)	95.7 (85–109)	96.3 (86–111)	.403
Maximum extension, degree (95% CI)	3.2 (0–8)	2.9 (1–10)	3.1 (1–9)	.555
Maximum flexion, degree (95% CI)	109.2 (88–121)	110.8 (93–120)	111.7 (90–119)	.374
Interim period ^c , weeks (95% CI)	12.4 (10–18)	11.5 (9–17)	11.7 (9–17)	.491
Follow-up period, months (95% CI)	67.8 (42–93)	56.2 (37–75)	36.7 (24–47)	<.001^d

n-PS non-reinforced posterior-stabilized, C-PS cam-reinforced alone posterior-stabilized, PC-PS post- and cam-reinforced posterior-stabilized, CI confidence interval, BMI body mass index, n number, No. number

^a Including antibiotics, bone cement, endoskeleton, and sterilizing medical instruments

^b Range of motion recorded at the end of operation after spacer insertion and wound closure

^c Six patients with permanent spacers and three with above-knee amputations were excluded from the interim period calculations

^d Bold values are set at $P < .05$

Table 2 Outcomes of patients with n-PS, C-PS, and PC-PS spacers

Parameters	Spacer type			P value
	n-PS	C-PS	PC-PS	
	(n = 75)	(n = 61)	(n = 50)	
Overall mechanical complication rate, n (%)	15 (20.0)	12 (19.7)	0 (0.0)	.003^a
(A) Femoral spacer dislodgement, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	.999
(B) Unstable joint after femoral cam fracture, n (%)	13 (17.3)	0 (0.0)	0 (0.0)	<.001^a
(C) Tibial spacer dislodgement, n (%)	1 (1.3)	6 (9.8)	0 (0.0)	.009^a
(D) Unstable joint after tibial post fracture, n (%)	0 (0.0)	6 (9.8)	0 (0.0)	.007^a
(E) Spacer fracture besides post or cam, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	.999
(F) Peri-spacer fracture, n (%)	1 (1.3)	0 (0.0)	0 (0.0)	.475
(G) Extensor mechanism disruption, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	.999
Spacer exchange rate, n (%)	12 (16.0)	8 (13.1)	0 (0.0)	.011^a
Unexpected early reimplantation rate, n (%)	2 (2.7)	3 (4.9)	0 (0.0)	.281
Constraint choice of revision prosthesis rate				
(A) Legacy constrained condylar knee, n (%)	59 (83.1) ^b	50 (84.7) ^c	47 (100) ^d	.013^a
(B) Rotating-hinge knees, n (%)	12 (16.9) ^b	9 (15.3) ^c	0 (0.0) ^d	.013^a
Infection eradication rate, n (%)	63 (88.7) ^b	51 (86.4) ^c	42 (89.4) ^d	.881

n-PS non-reinforced posterior-stabilized, C-PS cam-reinforced alone posterior-stabilized, PC-PS post- and cam-reinforced posterior-stabilized, n number

^a Bold values indicate $P < .05$

^b Total $n = 71$, after excluding two with permanent spacers and two with above-knee amputations

^c Total $n = 59$, after excluding two with permanent spacers

^d Total $n = 47$, after excluding two with permanent spacers and one with an above-knee amputation

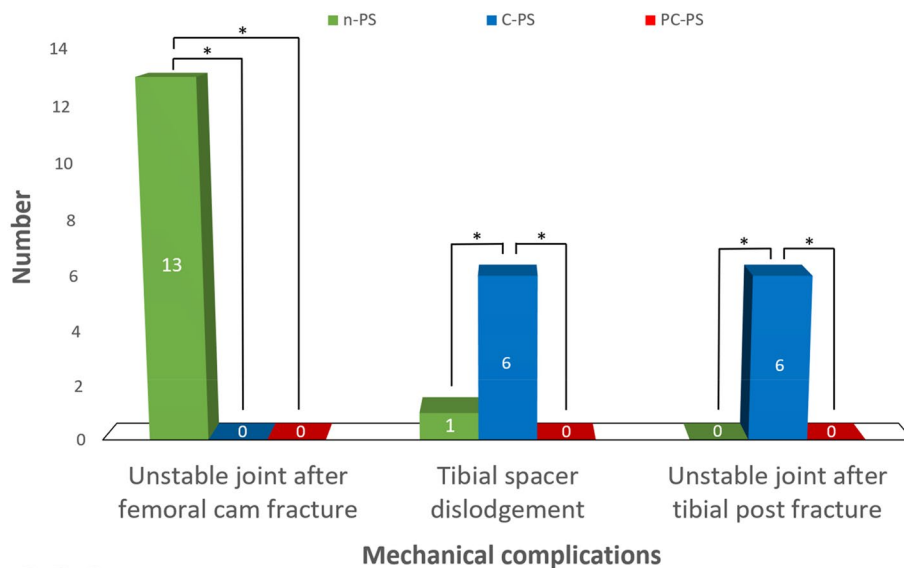


Fig. 3 Distribution of the different major mechanical complications among the three cohorts. The symbol “*” denotes statistically significant differences ($P < 0.05$) between the cohort

from the bone. However, there was no report of failure of tibial spacers in a series by Lin, who used the “line”-shaped Kirschner wire in the cam and posterior condyles [8], compared to the present “saddle” type. Moreover, the authors did not know why some tibial spacer failures

were post-fracture types and others tibial spacer dislodgements, including one case of the n-PS spacer. Therefore, further biomechanical testing is required to evaluate the effect of the cam endoskeleton configuration and clarify the failure mode of the tibial spacer.

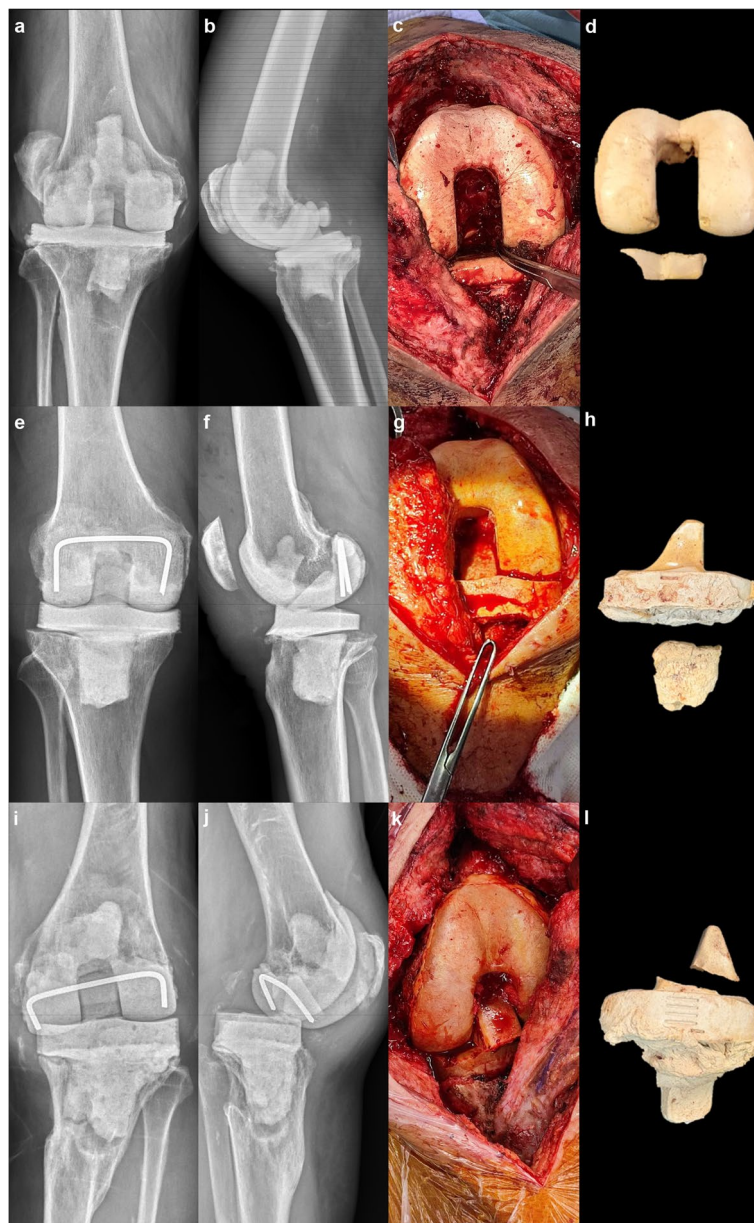


Fig. 4 **a-d.** Mechanical complication 3 weeks after n-PS spacer use in a 77-year-old male. **a** Anteroposterior and **(b)** lateral radiographs of the knee showing an unstable joint after femoral cam fracture; **c** intra-operative view; **d** joint side view of retrieved femoral spacer and fractured cam. **e-h.** Mechanical complication 6 weeks after C-PS spacer use in a 64-year-old male. **e** Anteroposterior and **(f)** lateral radiographs of the knee showing tibial spacer dislodgement; **g** intra-operative view; **h** lateral view of retrieved tibial spacer and cement stem. **i-l.** Mechanical complication 6 weeks after C-PS spacer use in a 65-year-old female. **i** Anteroposterior and **(j)** lateral radiographs of the knee showing unstable joint after tibial post fracture; **k** intra-operative view; **l** lateral view of retrieved tibial spacer and fractured post

Building upon the mould of the mechanical complications of the C-PS spacer and integrating the rationale of locking screw to stem extension of the constrained condylar knee (CCK) [18], the tibial post, spacer, and cement stem were merged with the screw in the novel PC-PS spacer. The screw acts as a reinforced endoskeleton for the tibial post, compression force of the

spacer-cement-bone junction, and “locking screw”-like force between the spacer and cement stem. With mechanics optimization, there was no post fracture, cam fracture, or tibial spacer dislodgement after applying the novel PC-PS spacer, which is strong enough to counteract the mechanical disadvantage of n-PS or C-PS spacers, thereby decreasing the reoperation rates. Compared to

Table 3 Details of patients with mechanical complications associated with n-PS and C-PS spacers

Patient No	Age (years)	Sex	Mechanism	Timing after spacer (weeks)	Radiographic finding	Intervention
n-PS spacer						
1	77	M	Nontraumatic	3	Unstable joint after femoral cam fracture	Femoral spacer exchange
2	62	M	Nontraumatic	4	Unstable joint after femoral cam fracture	Femoral spacer exchange
3	71	M	Nontraumatic	5	Unstable joint after femoral cam fracture	Femoral spacer exchange
4	83	F	Nontraumatic	5	Unstable joint after femoral cam fracture	Femoral spacer exchange ^a
5	63	F	Nontraumatic	3	Unstable joint after femoral cam fracture	Femoral spacer exchange ^a
6	67	F	Nontraumatic	5	Unstable joint after femoral cam fracture	Femoral spacer exchange ^a
7	65	M	Nontraumatic	6	Unstable joint after femoral cam fracture	Femoral spacer exchange ^a
8	64	M	Nontraumatic	3	Unstable joint after femoral cam fracture	Both spacers exchange ^b
9	79	F	Nontraumatic	2	Unstable joint after femoral cam fracture	Both spacers exchange ^a
10	63	F	Nontraumatic	5	Unstable joint after femoral cam fracture	Both spacers exchange ^a
11	78	F	Fall	2	Unstable joint after femoral cam fracture	Both spacers exchange ^a
12	64	M	Nontraumatic	7	Unstable joint after femoral cam fracture	Unexpected early reimplantation
13	77	F	Nontraumatic	8	Unstable joint after femoral cam fracture	Unexpected early reimplantation
14	62	F	Nontraumatic	6	Tibial spacer dislodgement	Hinged knee brace
15	73	M	Nontraumatic	3	Peri-spacer fracture	Tibial spacer exchange
C-PS spacer						
16	68	M	Nontraumatic	3	Tibial spacer dislodgement	Tibial spacer exchange
17	78	M	Nontraumatic	5	Tibial spacer dislodgement	Tibial spacer exchange ^c
18	64	M	Nontraumatic	6	Tibial spacer dislodgement	Tibial spacer exchange ^c
19	94	M	Nontraumatic	2	Tibial spacer dislodgement	Both spacers exchange ^d
20	71	M	Nontraumatic	7	Tibial spacer dislodgement	Unexpected early reimplantation
21	74	M	Nontraumatic	3	Tibial spacer dislodgement	Hinged knee brace
22	63	F	Nontraumatic	6	Unstable joint after tibial post fracture	Tibial spacer exchange ^c
23	69	M	Nontraumatic	3	Unstable joint after tibial post fracture	Tibial spacer exchange ^c
24	64	F	Nontraumatic	4	Unstable joint after tibial post fracture	Tibial spacer exchange ^c
25	66	F	Nontraumatic	2	Unstable joint after tibial post fracture	Both spacers exchange ^c
26	58	F	Nontraumatic	6	Unstable joint after tibial post fracture	Unexpected early reimplantation
27	65	F	Nontraumatic	6	Unstable joint after tibial post fracture	Unexpected early reimplantation

n-PS non-reinforced posterior-stabilized, C-PS cam-reinforced alone posterior-stabilized, M male, F female

^a Revision to the femoral spacer with endoskeleton-reinforced cam

^b Due to recurrent infection

^c Revision to the tibial spacer with endoskeleton-reinforced post

^d Permanent spacer retention

the current endoskeleton design, the femoral cam of the PROSTALAC spacer (DePuy Synthes) has an exoskeleton design that may lead to fractures at the cement-femoral component edge anterior to the femoral skids, resulting in fragment detachment. In addition, dislodgement of the tibial post of the PROSTALAC spacer has been reported, although it is stabilized by an intramedullary stem to reduce motion at the cement–bone interface [14].

A higher BMI is directly associated with increased tibiofemoral compression and shear forces, as well as greater posterior muscle forces during gait [19]. Obesity affects knee joint mechanics and is associated with an increased risk of perioperative and postoperative complications,

including revisions following primary TKA and resection arthroplasty [8, 20]. This could explain why a higher BMI is a risk factor for mechanical complications with the use of PS spacers, composed of cement and not metal or polyethylene, in TKA.

A smaller femoral spacer corresponds to a smaller cam cement volume, enhancing the collision possibility between the condyles and post and triggering stress risers formed on the spacers [8]. This might explain why, in the present study, metal was used in the C-PS spacer to reinforce the weaker cam to decrease the cam fracture rate. New concepts of anterior-lipped ultracongruent spacers and refined round posts may help address the

Table 4 Univariate analysis for risk factors associated with the mechanical complications of PS spacers

Variables	No complication (n = 159)	Complication (n = 27)	Odds ratio (95% CI)	P value
Age ≥ 65 years, n (%)	84 (52.8)	16 (59.3)	1.99 (0.21–4.48)	.216
Female sex, n (%)	90 (56.6)	13 (48.1)	0.83 (0.13–1.83)	.663
BMI ≥ 25.0 kg/m ² , n (%)	37 (42.1)	18 (66.7)	7.20 (3.61–46.7)	.002^a
Right laterality, n (%)	82 (51.6)	13 (48.1)	0.97 (0.06–1.94)	.267
Constraint of the original prosthesis				
Cruciate-retaining, n (%)	56 (35.2)	13 (48.1)	4.02 (1.11–19.6)	.057
Posterior-stabilized, n (%)	103 (64.8)	14 (51.9)	0.56 (0.02–1.44)	.064
Smoking status				
Never smokers, n (%)	76 (47.8)	12 (44.4)	0.98 (0.22–2.02)	.526
Current or previous smokers, n (%)	83 (52.2)	15 (55.6)	1.25 (0.20–2.02)	.531
Insurance status				
Insured, n (%)	158 (99.4)	27 (100.0)	1.02 (0.17–2.88)	.528
Uninsured, n (%)	1 (0.6)	0 (0)	0.97 (0.09–2.01)	.567
Socioeconomic status				
Low, n (%)	59 (37.1)	12 (44.4)	2.08 (0.11–6.07)	.140
Middle, n (%)	62 (38.9)	12 (44.4)	2.01 (0.15–6.01)	.159
High, n (%)	38 (23.9)	3 (11.1)	0.67 (0.03–1.94)	.082
Charlson Comorbidity Index				
0, n (%)	74 (46.5)	13 (48.1)	1.03 (0.16–3.21)	.344
1–2, n (%)	56 (35.2)	10 (37.0)	1.06 (0.23–3.87)	.272
3+, n (%)	29 (18.2)	4 (14.8)	0.91 (0.10–2.71)	.290
McPherson host grade				
Uncompromised, n (%)	76 (47.8)	11 (40.7)	0.92 (0.16–3.11)	.344
Compromised, n (%)	55 (34.6)	10 (37.0)	1.18 (0.19–3.30)	.521
Significantly compromised, n (%)	28 (17.6)	6 (22.2)	1.89 (0.18–3.48)	.297
Microorganisms				
Staphylococcus species, n (%)	58 (36.5)	8 (29.6)	0.89 (0.08–2.16)	.277
Streptococcus species, n (%)	30 (18.9)	6 (22.2)	1.14 (0.17–3.42)	.433
Gram-positive cocci, n (%)	22 (13.8)	4 (14.8)	1.01 (0.20–3.14)	.561
Gram-negative species, n (%)	27 (17.0)	4 (14.8)	0.91 (0.06–2.98)	.476
Polymicrobial, n (%)	12 (7.5)	2 (7.4)	0.99 (0.06–2.62)	.673
Culture negative, n (%)	10 (6.3)	3 (11.1)	2.39 (1.27–5.55)	.101
Spacer information				
Femoral spacer size ≤ 2, n (%)	50 (31.4)	18 (66.7)	11.4 (5.18–61.4)	<.001^a
Tibial spacer size ≤ 2, n (%)	49 (30.8)	13 (48.1)	5.96 (2.61–27.7)	.032^a
Tibial spacer thickness ≥ 13 mm, n (%)	79 (49.7)	14 (51.9)	1.28 (0.24–4.71)	.372
Associated costs of spacer ≥ 380 USD, n (%)	52 (32.7)	8 (29.6)	0.92 (0.06–2.45)	.438
Surgical time of resection arthroplasty ≥ 160 min, n (%)	115 (72.3)	19 (70.4)	0.95 (0.11–2.81)	.390
Intra-operative range of motion ^b ≥ 95 degrees, n (%)	98 (61.6)	20 (74.1)	4.73 (2.47–22.6)	.040^a
Maximum extension ≤ 5 degrees, n (%)	82 (51.6)	13 (48.1)	0.96 (0.10–2.62)	.407
Maximum flexion ≥ 110 degrees, n (%)	75 (47.2)	26 (96.3)	21.7 (8.81–76.3)	<.001^a
Interim period ^c , weeks (95% CI)	11.9 (10 to 17)	12.0 (9 to 17)	1.10 (0.16–2.48)	.527
Follow-up period, months (95% CI)	53.7 (28–84)	61.3 (38–81)	4.02 (2.47–19.6)	.047^a

PS posterior-stabilized, BMI body mass index, CI confidence interval

^a Bold values are set at $P < 0.05$ ^b Range of motion recorded at the end of operation after spacer insertion and wound closure^c Six patients with permanent spacers and three with above-knee amputations were excluded from the interim period calculations

Table 5 Multivariate analysis for risk factors associated with the mechanical complications of PS spacers

Variables	Adjusted odds ratio (95% CI)	P value
BMI ≥ 25.0 kg/m ²	6.34 (3.09–41.4)	.007^a
Femoral spacer size ≤ 2	9.87 (4.73–56.1)	.002^a
Tibial spacer size ≤ 2	3.96 (1.84–15.3)	.074
Intra-operative range of motion ≥ 95 degrees	3.51 (1.62–13.9)	.083
Intra-operative maximum flexion ≥ 110 degrees	19.3 (6.77–69.8)	<.001^a
Follow-up period, months	3.03 (1.06–10.0)	.089

PS posterior-stabilized, BMI body mass index, CI confidence interval

^a Bold values are set at $P < 0.05$

issues associated with the post-cam design in future studies [21, 22].

Furthermore, femoral cam-posterior post impingement occurs at knee flexion $> 80^\circ$ [23], leading to severe deformation in the posterior part of the post in specific hyperflexion clinical sequelae $> 130^\circ$ [24]. In addition, morphology affects the risk of fracture of the tibial post. Compared with the round design, the squared design causes higher peak contact stresses corresponding to a smaller contact area, especially in deep flexion-internal rotation of the tibia [22]. Therefore, greater knee flexion increases the risk of mechanical complications in PS spacers.

All three spacers effectively controlled infection. However, additional reoperations with spacer exchanges or unexpected early reimplantation were required in cases with the n-PS and C-PS spacers. Maintaining knee joint stability in the interim not only reduces mechanical complications but also reduces the need for high-level constrained revision prostheses [6, 8, 25]. RHK demonstrated 10-year survivorship rates and patient-reported outcomes similar to CCK [26–28]; however, it was associated with higher proximal tibial stress over the stem tip, leading to micromotions of the prostheses and early loosening [29]. With the novel PC-PS spacers, CCK was used for all revision prostheses without the need for a high-level constrained RHK, which was required in 16.9% and 15.3% of cases using n-PS and C-PS spacers, respectively. In addition, all RHKs required for n-PS and C-PS spacers were knees with mechanical complications. All three risk factors, including a higher BMI, smaller femoral spacer size, and greater knee flexion, can be compensated by the novel PC-PS spacers to prevent mechanical complications, spacer exchange, and the need for high-level constraint revision prostheses.

This study had several limitations. First, as a retrospective cohort study, a higher-level prospective randomized

controlled study was required to determine the effects of the endoskeleton. Second, we examined three generations of spacers developed using maturing techniques, which contributed to fewer mechanical complications and better outcomes observed in the latest novel PC-PS spacers. This may potentially cause a learning curve bias, even for a single surgeon. Furthermore, although the surgical protocol, debridement technique, and reimplantation criteria were consistent, minor improvements in the clinical workflow, such as expedited preoperative workups and standardized consultations with infectious disease specialists for antibiotic stewardship, may have occurred over the extended study period. These changes were not formally quantified and may have had a limited effect on clinical outcomes. Third, there were no comparative biomechanical tests among the three spacers configurations. Finally, there were no data on the longevity of PC-PS spacers because the present study focused on the interim stage. This provides a scope for future research to determine whether the novel PC-PS spacer is a better mechanical indication for the prolonged time needed for spacer retention or a permanent spacer if the patient is medically unfit [30].

The present study is the first single-surgeon series and has the largest cohort of patients with PS spacers in the literature, with adequate reliability for evaluation. Through the advancements of different generations of spacers, the novel PC-PS spacers have achieved better clinical outcomes than the n-PS and C-PS spacers. A simple and effective method using a Kirschner wire and screw endoskeleton can enhance clinical application.

Conclusions

This is the first single-surgeon series of a two-stage exchange for PKIs that assessed endoskeleton PS spacers in three configurations: non-reinforced, cam-reinforced alone, and post- and cam-reinforced. Although all three spacers effectively controlled infection, the novel PC-PS spacers prevented mechanical complications, spacer exchange, and the need for high-level constraint revision prostheses. We recommend the use of novel PC-PS spacers in a two-stage exchange for chronic PKIs, especially in patients with a high BMI, small femoral spacer size, and high knee flexion.

Abbreviations

PS	Posterior-stabilized
PKI	Prosthetic knee infections
n-PS	Non-reinforced posterior-stabilized
C-PS	Cam-reinforced alone posterior-stabilized
PC-PS	Post- and cam-reinforced posterior-stabilized
TKA	Total knee arthroplasty
CR	Cruciate-retaining
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
BMI	Body mass index
CCK	Constrained condylar knee

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Authors' contributions

C.W.Y. and C.Y.K. wrote the main manuscript text. C.H.T. and Y.C.F. collected and analyzed the data. H.Y.C. interpreted the results. H.T.C. contributed to data collection and analysis. T.L.L. supervised the study, critically reviewed the manuscript, and provided revisions. All authors reviewed and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This study was approved by the Research Ethics Committee (IRB number, CMUH107-REC3-130) of China Medical University Hospital and conducted in accordance with the Declaration of Helsinki. All study participants provided informed consent.

Consent for publication

Patients with typical cases of the disease presented in the manuscript agreed to the publication of their medical data (including medical records, photographs, and imaging data).

Competing interests

The authors declare no competing interests.

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