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No differences in clinical outcomes or isokinetic performance between cruciate-substituting ultra-congruent and posterior stabilized total knee arthroplasties: a randomized controlled trial

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Abstract

Purpose Whether ultra-congruent (UC) or posterior cruciate ligament-stabilized (PS) inserts should be used in posterior cruciate ligament (PCL)-sacrificing total knee arthroplasty (TKA) remains debatable. Therefore, the aim of this prospective randomized controlled study was to compare the isokinetic performance and clinical outcomes of these inserts in PCL-sacrificing TKA.

Methods Sixty-six patients diagnosed with primary knee osteoarthritis were randomly assigned to either the UC or the PS group. There were no significant differences between the groups in terms of age, body mass index or sex. The Knee Society score (KSS) and isokinetic performance results for each patient were recorded preoperatively and at 3, 6 and 12 months postoperatively. The physiatrist that performed the isokinetic tests and the patients were blinded to the study groups.

Results There were no significant differences between the groups in terms of the preoperative KSS or isokinetic performance. Gradual improvement in the KSS was observed in both groups, but no significant differences were detected between the groups during the whole follow-up period. The UC and PS groups exhibited similar peak extension and flexion torque values normalized to body weight at 3, 6 and 12 months postoperatively ($p > 0.05$).

Conclusion The use of UC or PS inserts in TKA did not affect the clinical outcomes or isokinetic performance.The clinical relevance of this study is that the potential differences in clinical outcomes and isokinetic performance between UC and PS inserts do not need to be considered when sacrificing the PCL in TKA.

Level of evidence I.

Keywords Ultra-congruent · Insert · Isokinetic · Total knee replacement · Posterior stabilized

Introduction

Posterior cruciate ligament (PCL) retention versus sacrifice is one of the main topics related to total knee arthroplasty (TKA) that is debated, and which method is selected depends on the individual preference of the surgeon during the surgery [4]. The outcomes of PCL retention and sacrifice have been compared in many studies; however, the superiority of one method over the other has not been demonstrated [14]. Most authors recommend sacrificing the PCL in cases of flexion contracture or PCL insufficiency [19]. Whenever a surgeon decides to sacrifice the PCL, another controversial question arises regarding the type of tibial insert. PCL-stabilized (PS) and ultra-congruent (UC) inserts allow the PCL to be sacrificed, and UC inserts are only available in certain TKA systems, such as the Stryker Triathlon, DePuy Synthes Attune, Zimmer Biomet Persona and Vanguard knee systems.

PS inserts are associated with some disadvantages, such as additional bone resection, breakage or dislocation of the post and patellar clunk syndrome [3, 7, 9, 16, 20, 21]. UC inserts were designed to prevent bone loss, as well as the other disadvantages of the conventional PS inserts previously mentioned [9, 16, 22, 28]. However, there are also many concerns about UC inserts, such as paradoxical

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anterior translation, limited rotation of the femur, decreased sagittal tibial stability, an increased patellar tendon angle and anterior patellar translation, all of which lead to altered knee kinematics and potentially poor clinical outcomes [1, 3, 5, 7, 11, 16]. The clinical translation of these different inserts has been compared in the relatively small number of studies in the literature, because UC inserts were only recently incorporated in clinical practice [3, 16, 17]. The superiority of either type of insert has not been shown clearly, and a recent meta-analysis provided additional inconsistent information. Bae et al. reported greater tibial laxity in the sagittal plane and a smaller range-of-motion (ROM) for UC inserts and that the clinical outcomes were equivalent between UC and PS inserts [3]. These inconsistent findings raise doubt regarding the clinical outcomes and functional results of UC inserts.Although they provided inconsistent findings, the authors of all of the previous studies have agreed on one point: there is a need for new high-quality randomized controlled trials (RCTs) comparing UC and PS inserts.

Quadriceps muscle strength is an important predictor of the functional abilities of patients undergoing TKA [14], and the isokinetic modality has been shown to be valid and reliable in the assessment of the quadriceps muscles in these patients [15, 24]. While previous studies have used knee scores, ROM and complications in comparisons, this study included isokinetic performance as a new comparison parameter to objectively evaluate muscle strength after TKA. The aim of this prospective RCT was to compare the isokinetic performance and clinical outcomes of UC and PS inserts in PCL-sacrificing TKA. The hypothesis of the present study was that compared with the PS inserts, the UC inserts are associated with poorer clinical outcomes and isokinetic performance following TKA.

Materials and methods

All 117 patients admitted to our clinic were screened for eligibility. Patients with Kellgren-Lawrence grade 3–4 knee osteoarthritis who were aged between 55 and 80 years and scheduled to undergo unilateral TKA for primary knee osteoarthritis were included in the study. The exclusion criteria were patients who could not achieve 0 to 110 degrees of flexion–extension ROM preoperatively, had a valgus deformity (tibio-femoral angle > 10°), had rheumatological joint diseases, previously underwent knee surgery, had neuromuscular diseases, underwent bilateral TKA, or had insufficiency of the collateral ligaments. Among 117 patients, 32 patients were excluded according to the exclusion criteria, 19 patients declined to participate, and 66 patients were enrolled in the study (Fig. 1). Written and informed consent was obtained from all participants.The patients were randomized in a 1:1 ratio via computer-generated randomization, which was performed using Microsoft Excel 2016 (Microsoft Corporation, Seattle, WA, USA), to either the UC insert or PS insert group before the operation (Fig. 1). Unblinded senior resident was responsible for the randomization of the patients. The patients and the physiatrists performing the isokinetic measurements were blinded to group allocation. All patients randomly assigned to a group underwent the corresponding procedure.

During the UC and PS operations, a Vanguard® Complete Knee System prosthesis (Zimmer Biomet Inc., Warsaw, IN, USA) was implanted, and the same surgical technique was used in all patients. The Vanguard anterior-stabilized (AS) insert is a UC deep-dish design with a 10 mm prominent anterior lip and 5 mm posterior lip (Fig. 2). The prominent anterior lip of this bone-conserving design prevents anterior femoral subluxation. The design of the insert allows it to be used with the Vanguard cruciate-retaining femoral component, and the highly congruent articulating surface increases rotational stability. The contact area between the femoral component and the weight-bearing surface is large to decrease the shear stress between the femur and polyethylene insert.

A tourniquet was inflated to a pressure of 300 mmHg after spinal anaesthesia was induced. All operations were performed with the same surgical technique by a single senior surgeon. A straight, longitudinal midline skin incision and medial parapatellar arthrotomy were performed. The patella was not everted. Patellar resurfacing was performed in all patients by the freehand resection method. Lateral release was performed in three patients in the UC group and in four patients in the PS group. Both the femoral and tibial prostheses were implanted with pressured bone cement. All patients underwent the same postoperative protocol, including pain control medication and physiotherapy which was guided by one therapist who was blinded to the assigned surgical procedure. The patients were mobilized with full weight-bearing under the supervision of the physical therapist on the day following surgery. The patients were discharged on postoperative day 3, and they were evaluated during postoperative week 4 to ensure that they were performing the exercises effectively. All patients were examined by the same physiatrist at the regular 3-, 6-, and 12-month follow-up visits.

The primary outcome was isokinetic performance, and the peak torque value was defined as the maximum acting torque, which was the highest point on the torque curve generated by a muscle contraction [27]. These peak torque values were normalized by body weight. The measurements were performed preoperatively and at the 3-, 6-, and 12-month follow-up examinations under the supervision of the same senior physiatrist using a Biodex System III isokinetic dynamometer, version 3.03 (Biodex Medical Inc., Shirley, NY, USA), which has beenreported

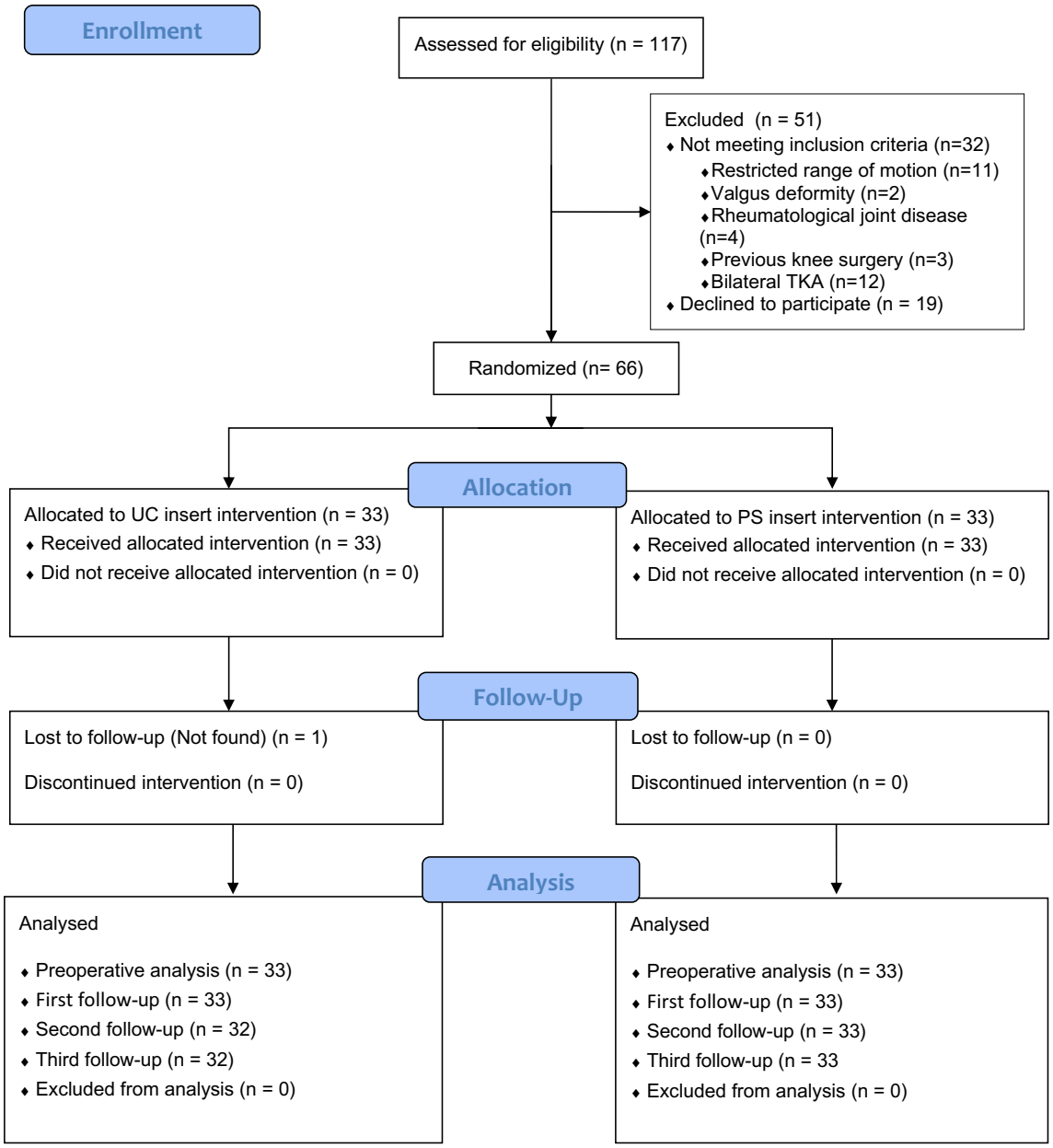

Fig. 1 Consolidated Standards of Reporting Trials (CONSORT) diagram. *UC* ultra-congruent, *PS* posterior cruciate ligament-stabilized

to bereliable [24]. The patients sat on the dynamometer with the hip flexed to 90° for the knee flexion and extension measurements. Lateral movements of the knee were prevented during full extension and flexion of the knee by a thigh strap on the operated leg. The physical therapist helped the patients achieve proper positioning before each test. Concentric isokinetic knee flexion–extensions were assessed at a predetermined velocity of 60°/s over a range of motion of 0° to 110° for both parameters. Prior to the measurement of baseline muscle strength, ten flexion–extension repetitions were completed by each patient, which allowed them to become familiar with the isokinetic test. The instructions were provided once more, and one more trial repetition was performed by all patients before the last baseline muscle strength measurements were taken. At the same time points, the Knee Society score (KSS), the secondary outcome, was also evaluated by the same physiatrist. The intraclass correlation coefficient (ICC) was calculated to estimate the test–retest reliability of the Biodex measurements. The estimated ICCs (two-way mixed single measures) for the peak extensor torque and peak flexor torque were 0.827 and 0.834, respectively. The ICC values indicated good reliability and consistency in the measurements.

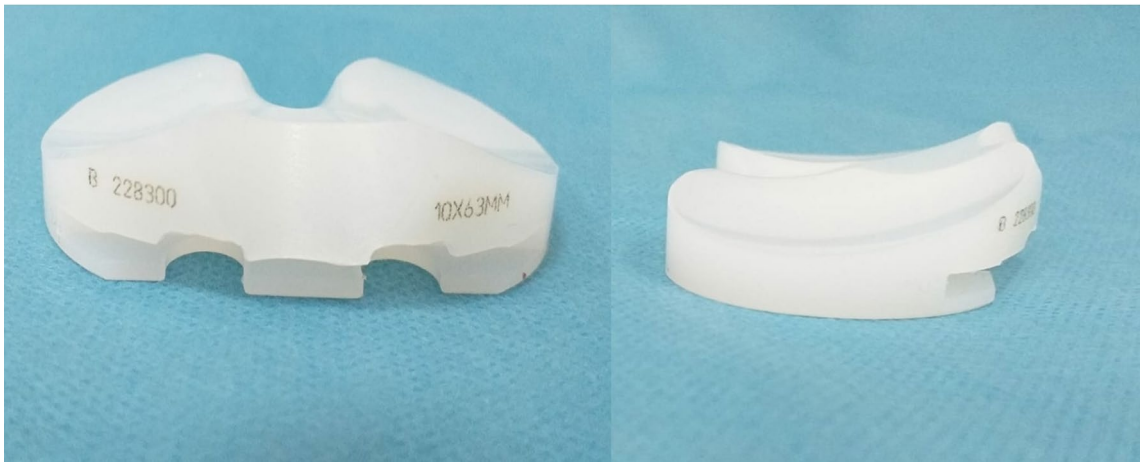

Fig. 2 AP and lateral view

The study was approved by the ethics committee of Ankara Numune Training and Research Hospital, with ID number E-17-1585.

Statistical analysis

Sample size estimation was performed using the mean knee extensor peak torque at one year postoperatively, 53.9 Nm, and the standard deviation, 12, reported in a prior study [10] and G*Power (version 3.1.9.6.) software. A total of 66 patients were estimated to be needed to achieve a power of 95% in detecting a 10 Nm difference in the extensor peak torque, with a standard deviation of 12, 4 measurements, an effect size of 0.41 and a significance level (alpha) of 0.05 using two-way repeated measures ANOVA. All the data are presented as means and standard deviations. Two-way repeated measures ANOVA was used for the statistical analysis of the repeated measurements in the two groups. The statistical calculations were performed with SPSS 22.0 software (IBM SPSS Statistics for Windows, version 22.0. Armonk, NY: IBM Corp.). Values of $p < 0.05$ were considered statistically significant.

Results

UC inserts were used in 33 patients, and PS inserts were used in 33 patients. The age, sex and body mass index distributions of the groups are shown in Table 1. No significant differences were detected between the groups with respect to the anthropometric and demographic data. Of the 66 patients included in the current study, 1 patient in the UC insert group was lost to follow-up at 6 months and excluded from the 6th and 12th month analyses in the study but was included in the 3rd month analysis. Thus, the study was completed with 32 patients in the UC group and 33 patients in the PS group. The postoperative complications included one superficial infection and two cases of symptomatic deep vein thrombosis, which were cured with drug treatment.

Table 1 Demographic characteristics of the patients

	UC insert group	PS insert group	*p* value
Sex (*n*)			n.s.
Female	29	26	
Male	4	7	
Age (years)	69.2 ± 8.6	67.7 ± 8.1	n.s.
BMI (kg/m^2)	29.9 ± 3.4	30.8 ± 3.7	n.s.

There was gradual improvement in the KSS inboth groups, but there were no statistically significant differences in the knee or functional KSSs between the groups at all follow-up examinations at postoperative months 3, 6 and 12 (Figs. 3, 4). At the preoperative and 3-, 6- and 12-month postoperative examinations, the mean degrees of flexion in the UC group were 121.2°, 126.3°,128.2° and 128.7°, respectively. At the preoperative and 3-, 6- and 12-month postoperative examinations, the mean degrees of flexion in the PS group were 119.3°, 128.5°, 132.4° and 133.9°, respectively. There were no statistically significant differences in the peak extensor torque normalized to body weight or peak flexor torque normalized to body weight between the groups during the whole follow-up period (Table 2). The UC and PS groups exhibited similar isokinetic performance of the knee at all time points (flexion and extension) ($p > 0.05$).

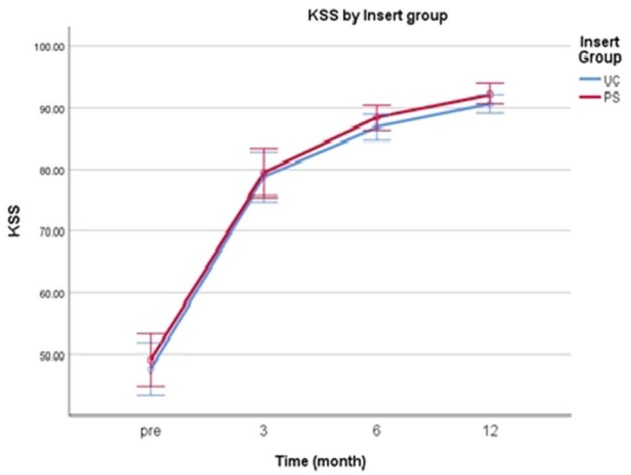

Fig. 3 Preoperative and follow-up KSSs (Knee Society scores) for the knee

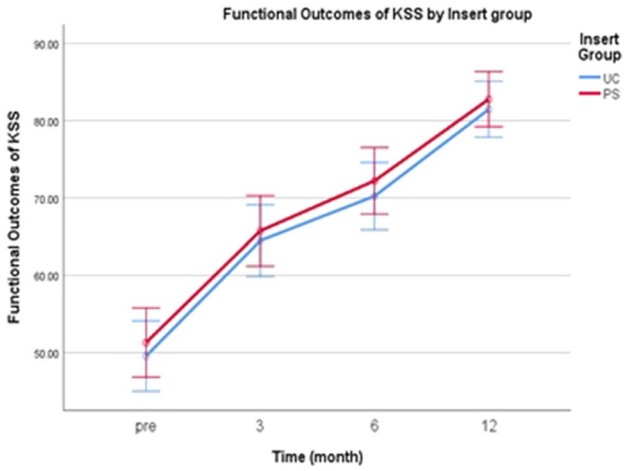

Fig. 4 Preoperative and follow-up KSSs (Knee Society scores) for knee function

Discussion

The most important finding of the present study was that UC and PS inserts are associated with similar levels of isokinetic performance and clinical outcomes after TKA. Mobile-bearing vs fixed-bearing [12], posterior-stabilized vs condylar-stabilized [23], cruciate-retaining (CR) vs UC [6, 17, 22, 25], and UC vs PS [1–3, 7, 9, 11, 16, 21, 28] tibial inserts have been compared in many recent studies with different designs. Preserving the PCL is one of the major factor of tibial insert design, and whether the PCL should be retained or sacrificed remains controversial [4, 6, 9, 16, 22]. Although larger degrees of flexion and ranges of motion were reported with the use of PS inserts than with CR inserts in a recent meta-analysis [4], the need for high quality RCTs was emphasized. With respect to PCL retention or sacrifice, surgeons should choose the surgical technique with which they are most comfortable [4]. Despite the preference of the surgeon, PCL sacrifice is sometimes necessary, and the PCL can be substituted by a UC or PS insert in this situation [7].

Although CR and PS inserts have been evaluated in many studies for decades, there are few studies in the literature that have compared UC and PS inserts because UC inserts have only recently become clinically available [3, 9]. Different intraoperative kinematics and stability results between UC and PS inserts have been previously reported [1–3, 7, 9, 11, 16, 21, 23, 26]. Lützner et al. showed in an RCT that the KSS and Oxford knee score (OKS) improved with both UC and PS inserts, but the improvements in the scores for the OKS pain and OKS functional components were significantly larger in the UC group [16]. In contrast, in a recent meta-analysis, Bae et al. reported similar clinical outcomes and knee scores between groups; however, the UC group was reported to have significantly greater tibial laxity in the sagittal plane and a smaller ROM [3]. Moreover, UC inserts have been reported to yield less anterior–posterior stability, paradoxical anterior translation and internal rotation of the femur; sagittal laxity; an increased patellar tendon angle; and reduced posterior femoral rollback [1, 3, 7, 11, 16, 26]. As a result of these differences, it has been concluded that UC inserts yield worse knee function [26] and inferior clinical scores than do PS inserts [1]. However, some other studies have reported that there are no differences in knee function orclinical outcomes and have suggested that UC inserts are considered an alternative to

Table 2 Preoperative and follow-up peak extensor torque (PET) and peak flexor torque (PFT) normalized tobody weight for the operated knee

	Preoperative	3 months	6 months	12 months	*p* value
PET per body weight (Nm/kg)					
UC insert	70.7 ± 15.2	56.6 ± 13.2	68.1 ± 15.0	75.3 ± 15.5	n.s.
PS insert	74.1 ± 19.1	57.8 ± 13.3	66.6 ± 14.8	78.0 ± 19.4	
PET per body weight (Nm/kg)					
UC insert	48.3 ± 14.1	40.6 ± 14.5	46.2 ± 15.0	51.0 ± 15.7	n.s.
PS insert	51.2 ± 14.7	37.0 ± 10.8	44.6 ± 12.6	52.3 ± 14.4	

PS inserts [3, 16, 23]. Furthermore, postoperative hyperextension is known to cause poor clinical outcomes, and the knees of patients have been reported to gradually extend while the postoperative extension angle has been reported to decrease for 2 years after the operation with an UC insert [13]. Nevertheless, how the aforementioned differences in kinematics between the two inserts affect patient function, as well as flexor and extensor strength, remains largely unknown.

Quadriceps muscle strength is an important predictor of function in patients undergoing TKA [18]. Isokinetic tests have been shown to provide valid and reliable data for the assessment of quadriceps strength in patients who have undergone TKA, and from a practical point of view, quadriceps strength tests have been concluded to be reliable for use in both clinical practice and research settings [15]. Therefore, in the current study, isokinetic tests were performed to objectively evaluate the functional differences in patients receiving UC and PS inserts. No previous studies have compared isokinetic performance differences between UC and PS inserts. The KSS was also evaluated for the UC and PS groups. No significant difference were determined in the peak isokinetic torque normalized to body weight during knee extension-flexion or the KSS. Therefore, the choice between UC or PS inserts did not affect the isokinetic performance or the KSS. Our findings can help resolve concerns about the clinical outcomes and isokinetic performance related to the use of UC inserts owing to these inserts being introduced to the industry relatively recently. The data presented here can helps surgeons select either the UC or PS insert during TKA.

This study has some limitations. First, the patients in the present study had primary knee osteoarthritis, and cases of knee osteoarthritis secondary to other disorders, such as rheumatological disorders, were not evaluated. Second, we analysed the data collected at the 1-year follow-up, and we acknowledge that the inclusion of data collected over longer follow-up periods may yield different results; additional studies are warranted. In addition, satisfactory results of navigation-assisted TKA using UC inserts have been reported [28]. Therefore, the use of an additional system, such as computer-assisted surgery and navigation-assisted gap balancing techniques, may also influence the results. Moreover, although fixed insert designs were compared in the current study, differences in kinematics in patients receiving mobile UC and mobile PS inserts have been reported [11], so the conclusions drawn from the current study cannot be applied to the mobile UC insert design. Finally, this study evaluated the results of TKA using the inserts of only one company and only one design. UC insert designs of other companies should be evaluated to acquire more generalizable results.

Conclusion

Compared with PS inserts, UC inserts do not influence clinical outcomes or isokinetic performance after TKA. When the type of insert to be used during PCL-sacrificing TKA is considered, the potential differences in clinical outcomes and isokinetic performance between the two inserts can be disregarded.

Author contributions The study was conceived by D.C. D.C. performed all the surgeries. D.K. performed all the isokinetic tests. D.C., E.A.S. and S.A. performed the analyses and D.C. and E.A.S. wrote the initial draft. All authors contributed to the interpretation of the data and to revision of the manuscript. All the authors read and approved the final manuscript.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This study was approved by the institutional review board (IRB) by the "Ankara Numune Training and Research Hospital Clinical Research Ethics Committee" ethical committee (1585/2017) and was performed in accordance to the 1964 Helsinki Declaration and its amendments.

Informed consent Written informed consent was acquired for all participants prior to their participation.

Trial registration number and date of registration ClinicalTrials.gov NCT04419311, 05 June 2020 (Retrospectively registered).

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