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Dual-pivot bearings improve ambulation and promote increased activity levels in Total knee arthroplasty: A match-controlled retrospective study

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ABSTRACT

Background: Modern understanding of native knee kinematics reveals more complex pattern of lateral-pivot in early flexion activities, and medial-pivot in deeper flexion (i.e. dual-pivot). The purpose of this study was to compare patient outcomes with a contemporary dual-pivot TKA, designed to replicate anterior-cruciate substitution and stability, with a traditional TKA.

Methods: One hundred eighty-three dual-pivot TKAs were matched with 183 traditional non-conforming TKAs. All TKAs were cemented and performed with identical perioperative protocols. Patients were matched on age, sex, BMI, and ASA score. Patient-reported outcome measures were prospectively obtained and compared at minimum one-year follow-up.

Results: Study cohorts were identical with 72% female, average age of 68 years, and BMI of 33 kg/m^2. There were no differences in prevalence of fibromyalgia, depression, preoperative narcotic use, or femoral component alignment ($p \geq 0.105$). Dual-pivot TKA patients had a greater prevalence of lumbar spine disease ($p = 0.012$) and more reported their knee never feels normal preoperatively ($p = 0.012$). Dual-pivot TKA patients reported less walking pain at latest follow-up ($p = 0.022$). Trends for greater level of participation in very active activities or impact sports ($p = 0.067$) and more reporting their knee feels normal ($p = 0.091$) were observed in dual-pivot TKAs.

Conclusion: Patients with dual-pivot knees reported less walking pain despite greater lumbar spine disease, supporting the potential benefit of lateral-pivot motion in early flexion activities. However, the groups were similar in overall satisfaction suggesting the nuances and potential ceiling-effect of patient satisfaction warrants further study.

1. Introduction

Total knee arthroplasty (TKA) is a highly successful surgery in terms of implant longevity and survivorship. Despite this, patients continue to report postoperative pain, stiffness, or an unnatural feeling to the joint with approximately 20% reporting they are not satisfied with their knee replacement [1–3]. It has been hypothesized that knee arthroplasty systems that replicate kinematic patterns of the native knee with an intact anterior cruciate ligament (ACL) will reproduce normal knee motion and po-

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tentially optimize patient function, outcomes, and satisfaction after TKA. While various implant designs and types have been studied with respect to kinematic patterns [4–17], no one design has emerged to consistently produce superior patient outcomes.

Historically, studies have demonstrated a predominantly medial-pivot kinematic pattern throughout native knee flexion [11,18–20]. Since 2008, a more modern understanding of native knee kinematics has revealed a more complex kinematic pattern of differing pivot motions in the various knee flexion ranges [21–24]. While modern kinematics continues to support a medial-pivot pattern in deeper flexion, it is now understood that the motion pattern in an ACL-intact native knee in earlier flexion angles, occurring with activities like walking, running, or pivoting, is characterized by a lateral-pivot pattern [21–25]. Furthermore, studies have shown that patients who demonstrated an early lateral-late medial-pivot pattern intraoperatively had higher function and satisfaction scores and were less likely to report that their knee never feels normal postoperatively [26]. The purpose of this study was to determine whether patients report superior outcomes after receiving a dual-pivot designed TKA compared to a traditional non-conforming TKA design, which does not facilitate or promote a specific kinematic pattern. The hypothesis of the study was that the dual-pivot TKA system would have superior patient-reported outcomes compared to the traditional TKA design with a symmetric non-conforming bearing articulation.

2. Material and methods

Institutional Review Board approval from the Office of Research Compliance was obtained to retrospectively analyze prospectively collected patient-reported outcomes for 204 dual-pivot primary TKAs performed between January 20, 2016 and March 6, 2017. The dual-pivot TKA (EMPOWR 3D Knee® system; DJO Global, Inc., Vista, CA) was designed to more closely replicate the early flexion lateral-pivot and late flexion medial-pivot, characterized as a "dual-pivot" kinematic pattern, of native knees with an intact ACL. The femoral component has a single radius of curvature, which decreases posteriorly to allow lateral condyle femoral posterior rollback in deeper flexion (Figure 1). The medial condyle is widened and the polyethylene has a conforming lateral compartment to help drive early lateral-pivot motion during early flexion, mimicking native knee motion with an intact ACL. The medial side of the polyethylene is also conforming to a degree, but less so than the lateral side.

Twenty-one dual-pivot knees were excluded for the following reasons: first, dual-pivot cases performed potentially reflecting a learning curve ($n = 3$); simultaneous bilateral procedures ($n = 2$); orthopedically complex ($n = 1$); hip fracture within one year ($n = 1$); manipulated postoperatively ($n = 1$); chronic superficial infection ($n = 2$); revision within one year ($n = 5$), Parkinson's disease ($n = 1$); expired prior to one year follow-up ($n = 2$); and lost to one year follow-up ($n = 3$).

The remaining 183 dual-pivot knees were matched based on age, body mass index (BMI), sex, and American Society of Anesthesiology Physical Classification (ASA PS) score to 183 traditional primary TKAs with non-conforming polyethylene bearings (traditional non-conforming TKAs; Triathlon®, Stryker Orthopedics, Mahwah, NJ) performed between November 7, 2011 and July 18, 2016. Identical exclusion criteria were used for traditional non-conforming knees and were not considered for matching. Traditional non-conforming knees were cruciate substituting but the posterior cruciate ligament (PCL) was routinely preserved in all patients and an anterior lipped polyethylene component was used. The dual-pivot TKAs utilized cruciate retaining bearings, in

Figure 1. The ACL-substituting TKA design incorporates a lateral tibiofemoral compartment that is spherically conforming in extension, which becomes progressively more lax in flexion to allow the condyle to translate posteriorly.

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which the PCL was retained whenever possible in the majority of patients unless an excessively tight flexion space necessitated PCL-release to optimize kinematics and motion.

All procedures were performed by a single surgeon in a designated hip and knee center located in an academic tertiary care hospital. All patients were radiographic grade 4 end-stage osteoarthritis. A median parapatellar approach was used for all procedures. Standard coronal plane femoral bone cuts were made with computer-aided navigation (Stryker Navigation, Kalamazoo, MI) while the tibial cuts were performed with the aid of extramedullary referencing, both targeting neutral mechanical alignment in general. The tibial component target goal was essentially neutral mechanical axis, using extramedullary alignment guides to place the implant perpendicular to the anatomic axis of the tibia and reproducing the native tibial slope. For knees with substantial tibial vara, the tibial component was allowed to be placed in one to two degrees of anatomic varus; however, intentionally leaving knees in varus or targeting so-called kinematic alignment was not performed. A measured resection technique was employed in all procedures, with laminar spreaders utilized to ensure flexion-extension gaps in the medial and lateral compartments were balanced to within one millimeter. The patella was resurfaced in all cases. All tibial, femoral, and patella components were cemented with standard medium viscosity cement.

The same perioperative pain control, clinical, and rehabilitation protocols were used for all patients. All patients underwent medical clearance within four weeks of surgery by a perioperative internal medicine specialist whose practice focuses exclusively on TJA. Patients and family members received comprehensive perioperative education and postoperative care by the surgeon, internal medicine specialist, and a multidisciplinary care team. Expectations for discharge were communicated to patients in all educational materials and by all physicians, nursing staff, physical therapists, and discharge planners involved in patient care. The same rehabilitation protocol with physical therapy evaluation and ambulation in the afternoon on the day of surgery was used for all patients.

A multimodal preoperative pain protocol was used in all cases. Patients took acetaminophen (1000 mg PO TID) 24 h before surgery. Oxycodone (10 to 20 mg PO), celecoxib (200 mg PO unless contraindicated), and pregabalin (75 mg PO) were administered immediately prior to surgery. Postoperative pain control protocols included acetaminophen (1000 mg PO TID), OxyContin (10 to 20 mg PO q12 hours), celecoxib (200 mg PO bid unless contraindicated), oxycodone (five to 10 mg hourly prn for mild pain and 10–20 mg hourly prn for moderate pain), or hydromorphone (0.5 mg IV q20 minutes prn for severe pain). Surgeries were performed with standardized light general anesthesia and a low-dose intrathecal, single-shot spinal. A periarticular injection of ropivacaine, epinephrine, clonidine, and ketorolac was used immediately following component fixation. Ketorolac was removed for patients with renal insufficiency.

2.1. Patient-reported outcomes and covariates

Patient-reported outcomes were prospectively evaluated preoperatively and at minimum one-year postoperatively utilizing the short form of the modern Knee Society (KS) questionnaire [27], the University of California Los Angeles (UCLA) Activity Level scale [28,29], and Likert scale satisfaction. KS questions included pain with level walking (0 = none to 10 = severe), pain with stairs or inclines (0 = none to 10 = severe) and does this knee feel normal to you (always, sometimes, never). In addition to evaluation of mean KS pain scores, pain scores were transformed to assess clinically meaningful categories of pain with 0 equating to no pain, 1–3 classified as mild pain, 4 to 7 classified as moderate pain, and 8 to 10 classified as severe pain. The UCLA Activity Level scale asks patients to choose their highest level of current activity, ranging from zero (Wholly Inactive: dependent upon others, cannot leave residence) to 10 (Regularly participate in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labor, or backpacking). Likert scale satisfaction asks patients to report their current level of satisfaction with their knee replacement surgery, rated as very satisfied, satisfied, neutral, dissatisfied, or very dissatisfied.

Table 1
Cohort demographics and covariates.

	Dual-pivot TKA	Traditional non-conforming TKA	Statistic	*p*
% Female	72.7	72.1	$X^2 = 0.014$	1.000
Mean age (SD) in years	67.8 (7.9)	67.7 (7.8)	$t = 0.160$	0.876
Mean BMI (SD) in kg/m^2	33.4 (6.5)	33.1 (6.4)	$t = 0.41$	0.679
ASA Classification				
▪% normal healthy patient	0.5	1.6	$X^2 = 1.376$	0.711
▪% mild systemic disease	25.1	26.8		
▪% severe systemic disease	72.7	69.4		
▪% severe systemic disease that is a constant threat to life	1.6	2.2		
% with RA or PA	8.2	10.9	$X^2 = 0.790$	0.478
% with fibromyalgia/SLE	4.4	5.5	$X^2 = 0.234$	0.810
% with lumbar spine disease	20.0	10.1	$X^2 = 6.831$	**0.012**
% with depression[a]	25.1	26.8	$X^2 = 0.128$	0.812
% with preoperative narcotic use	19.1	26.5	$X^2 = 2.826$	0.105
Tibial component alignment (°)	−2.3 (2.1)	−1.5 (2.0)	$t = 3.6$	<0.001[b]
Femoral component alignment (°)	−5.6 (2.2)	−5.4 (2.8)	$t = 0.9$	0.396

[a] Depression was controlled with medication in all but two patients, both with traditional non-conforming TKAs

[b] Tibial component alignment was statistically significant; however, a difference between groups of 0.77 degrees was not clinically meaningful. 100% of cases for Dual-Pivot and Traditional Non-conforming TKAs were classified as either varus or neutral for tibial component alignment ($X^2 = 1.0$, Fisher's $p = 0.623$).

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Table 2
Preoperative patient-reported outcome scores.[a]

	Dual-pivot TKA	Traditional non-conforming TKA	Statistic	p
Mean (SD) pain with level walking	5.74 (2.35)	5.68 (2.41)	t = 0.230	0.822
Pain with level walking				
▪% None	1.8	1.8	$X^2 = 0.297$	0.961
▪% Mild	18.2	17.4		
▪% Moderate	56.5	59.3		
▪% Severe	23.5	21.6		
Mean (SD) pain with stairs or inclines	7.67 (2.09)	7.38 (2.35)	t = 1.22	0.222
Pain with stairs or inclines				
▪% None	0.0%	1.2%	a	a
▪% Mild	4.7%	7.1%		
▪% Moderate	34.7%	36.3%		
▪% Severe	60.6%	55.4%		
Does this knee feel normal to you?				
▪% always	0.6	6.5	$X^2 = 8.904$	**0.012**
▪% sometimes	34.1	33.9		
▪% never	65.3	59.5		
Mean (SD) UCLA Activity Level Score	4.03 (1.72)	3.90 (1.57)	t = 0.690	0.491
% Regularly participate in very active events or impact sports (UCLA 8 to 10)	4.6	2.6	$X^2 = 0.971$	0.388

[a] X^2 approximation invalid due to low cell counts

Preoperative history and physical examinations performed by the same perioperative internal medicine specialist for all patients were examined to record the presence of rheumatoid arthritis (RA), psoriatic arthritis (PA), fibromyalgia, systemic lupus erythematosus (SLE), lumbar spine disease, depression, and preoperative narcotic use.

Femoral and tibial component alignment was measured on four-week postoperative radiographs. A uniform standardized measurement protocol was used defined by the Modern Knee Society Radiographic Evaluation System [30]. If the radiograph was not available or suboptimal views of the implant were accessed, the next available radiograph closest to the date of surgery was used for the most accurate measurements.

2.2. Data analysis

Minitab® 18 was used for all statistical analyses. Normally distributed continuous variables were analyzed with Student's two-sample t-test (t) and non-normally distributed continuous variables were compared with the Mann–Whitney (W) test adjusted for ties. Pearson's Chi-Square (X [2]) test was used to test independence among categorical variables, with Fishers Exact test *p* values reported for 2×2 contingency tables. A significance level of 0.05 was used for all statistical analyses.

3. Results

As shown in Table 1, dual-pivot and traditional non-conforming knee cohorts did not differ in terms of sex ($p = 1.000$), age ($p = 0.876$), BMI ($p = 0.679$), or ASA PS classification ($p = 0.711$). 72.7% (133/183) and 72.1% (132/183) of the cohort was female for the dual-pivot and traditional non-conforming knees, respectively. Average age was 67.8 (SD 7.9, range 47.0–91.4) years and 67.7 (SD 7.8, range 42.9–89.0) years, and average BMI was 33.4 (SD 6.5, range 20.0–49.0) kg/m^2 and 33.1 (SD 6.4, range 18.0–49.0) kg/m^2 for the dual-pivot and traditional non-conforming knee cohorts. Approximately 70% of patients in each cohort were classified as patients with severe systemic disease (ASA PS = 3). Table 1 also shows that there were no group differences in the prevalence of RA or PA ($p = 0.478$), fibromyalgia or SLE ($p = 0.810$), depression ($p = 0.812$), preoperative narcotic use ($p = 0.105$), or postoperative femoral component alignment ($p = 0.396$). Postoperative tibial component alignment was significantly more varus for the dual-pivot TKA due to small variation in the data (mean −2.3 vs −1.5, $p < 0.001$); however, 100% of both groups were classified as varus or neutral; therefore, this finding was deemed to not be a clinically meaningful difference. Significantly more patients with dual-pivot TKA (20%) than those with traditional non-conforming TKA (10%) reported a history of lumbar spine disease ($p = 0.012$).

Preoperative patient-reported outcomes in dual-pivot and traditional non-conforming TKA patient groups are compared in Table 2. There was only one significant difference in preoperative outcome scores between the two groups – more patients with traditional non-conforming TKAs reported their knee always felt normal prior to surgery (6.5% vs. 0.6%, $p = 0.012$).

The length of postoperative follow-up was equivalent for the two groups (median 12.6 months for dual-pivot and median 12.9 months for traditional non-conforming knees, W = 30,823.0, $p = 0.129$). As shown in Table 3, at minimum one-year, mean pain scores while walking on a level surface were significantly lower in dual-pivot knees (0.88) compared to traditional non-conforming knees (1.37) ($p = 0.022$). Table 3 additionally shows that these mean differences reflect that significantly more traditional non-conforming knee patients had severe pain (4.4% vs. 0.6%), whereas significantly more dual-pivot patients had no pain (68.8% vs. 58.5%), at latest follow-up ($p = 0.050$). With the numbers available, the two groups did not differ at latest follow-up in terms of pain with stairs or inclines ($p = 0.256$), the proportions reporting that their knee always, sometimes, or never feels normal ($p = 0.865$), or mean UCLA Activity Level score ($p = 0.302$). There was, however, a potentially clinically

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Table 3
Postoperative patient-reported outcome scores.

	Dual-Pivot TKA	Traditional Non-Conforming TKA	Statistic	*p*
Mean (SD) pain with level walking	0.88 (1.72)	1.37 (2.30)	t = 2.30	**0.022**
Pain with level walking				
▪% None	68.8%	58.5%	$X^2 = 7.819$	**0.050**
▪% Mild	21.6%	26.8%		
▪% Moderate	9.1%	10.4%		
▪% Severe	0.6%	4.4%		
Mean (SD) pain with stairs or inclines	1.57 (2.22)	1.84 (2.30)	t = 1.14	0.256
Pain with stairs or inclines				
▪% None	48.3%	42.6%	$X^2 = 1.563$	0.668
▪% Mild	36.2%	38.8%		
▪% Moderate	10.9%	14.2%		
▪% Severe	4.6%	4.4%		
Does this knee feel normal to you?				
▪% always	53.1%	50.8%	$X^2 = 0.289$	0.865
▪% sometimes	38.9%	39.9%		
▪% never	8.0%	9.3%		
Mean (SD) UCLA Activity Level Score	5.31 (1.85)	5.12 (1.68)	t = 1.03	0.302
% Regularly participate in very active events or impact sports (UCLA 8 to 10)	12.2	6.2	$X^2 = 3.905$	0.067

relevant trend for more patients with dual-pivot knees to regularly participate in very active activities or impact sports (12.2% vs. 6.2%, $p = 0.067$, Table 3).

As shown in Figure 2, there also was a potentially clinically relevant trend for more patients with dual-pivot TKAs to report better postoperative assessments of whether their knee feels normal (including changes from never to sometimes or always, and sometimes to always feels normal after surgery) ($X^2 = 3.134$, $p = 0.091$). There was no difference in the proportions of the two groups (89%) who reported that they were satisfied or very satisfied in response to the question, "what is your current level of satisfaction with your knee replacement?" ($X^2 = 0.043$, $p = 0.836$).

4. Discussion

Modern understanding of native knee kinematics reveals a complex kinematic pattern of differing pivot motions in the various knee flexion ranges [21–24]. While modern kinematics continues to support a medial-pivot pattern with deeper flexion activities, it is now understood that the motion pattern in an ACL-intact native knee in earlier flexion angles is characterized by a lateral-pivot pattern [21–25]. The dual-pivot TKA was designed to induce an early lateral-pivot during low flexion activities such as walking followed by a late medial-pivot kinematic pattern with greater flexion to replicate the kinematic pattern and stability of an ACL-intact native knee. In theory, such a design could lead to better patient outcomes and improved satisfaction. We observed that patients with a dual-pivot TKA with conforming polyethylene reported significantly less mean pain while walking ($p = 0.022$) at minimum one-year follow-up despite a significantly greater prevalence of lumbar spine disease. Significantly more dual-pivot patients reported no pain and significantly fewer dual-pivot patients reported severe pain with level walking at latest follow-up ($p = 0.050$). Based on the modern understanding of kinematics that support a lateral-pivot motion in early flexion activities observed in native knees with an intact ACL, the clinical findings in this study of statistical superiority in pain scores during

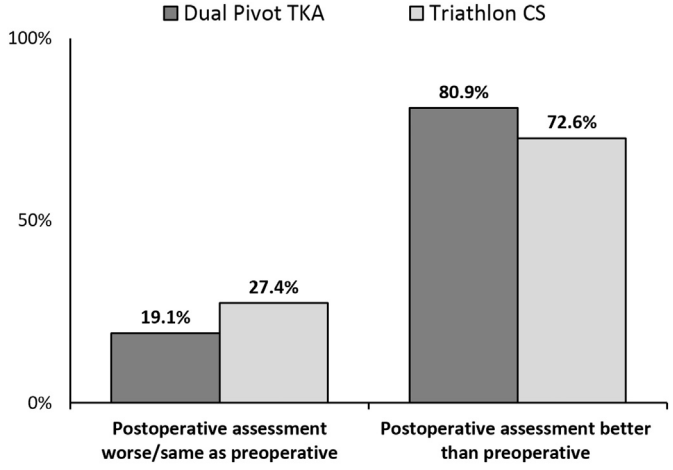

Figure 2. Trend ($p = 0.091$) for more patients with dual-pivot TKAs to report better postoperative assessments of whether their knee feels normal.

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early flexion walking, provide supportive clinical evidence of this dual-pivot TKA design intent. There may be further clinically-based support for this reported in a study with intraoperative sensors [31]. In a recent report describing intraoperative measurement of kinematics using force-sensing trial inserts with a traditional symmetric TKA design, it was demonstrated that knees showing a lateral-pivot in early flexion and a medial-pivot in later flexion had greater functional scores, more improvement from preoperative baseline, and higher satisfaction compared to patients who did not show dual-pivot kinematics during surgery [31].

Superior outcomes for the dual-pivot TKA system confirmed our hypothesis for the majority of patient-reported outcomes. There were statistical trends for a greater level of participation in very active activities or impact sports ($p = 0.067$) and better postoperative assessments of whether their knee feels normal ($p = 0.091$) in dual-pivot TKA patients. Regarding the latter observation, 81% of patients with dual-pivot knees had better postoperative assessments of whether their knee feels normal compared to 72% of patients with traditional non-conforming TKAs ($p = 0.012$, Figure 2), despite the fact that dual-pivot patients were significantly less likely to feel that their knee felt normal prior to surgery. Despite having less pain than patients with traditional non-conforming TKA, patients with dual-pivot knees in the current study were not more or less satisfied overall. Eighty-nine percent of each group reported they were satisfied or very satisfied with their TKA ($p = 0.836$). Recent research suggests that patient satisfaction following TKA varies depending on the question being asked (satisfaction with pain, work, activity levels, etc.) [32]. It is possible, therefore, that our Likert ordinal scale question asking about overall satisfaction with TKA was not sensitive enough to detect differences in overall satisfaction, yet, the statistical trends with respect to specific activities represent clinically relevant improvements and an evolution in TKA designed to replicate native knee motion and stability.

Strengths of our study include the prospective collection of outcomes, the use of modern patient-reported outcome measures, and the fact that TKAs in the two study cohorts were performed by the same surgeon with identical surgical selection criteria and perioperative protocols. In addition, potential confounds known to influence outcomes after TKA such as fibromyalgia [33], lumbar spine disease [34], preoperative narcotic use [35], and depression [36] were controlled for in the two study groups. Our study also has limitations including its retrospective design which we attempted to mitigate by matching the two groups based on age, BMI, sex, and ASA-PS classification. In addition, more patients with traditional non-conforming TKAs reported their knee always felt normal prior to surgery which may have influenced the outcomes in terms of that patient group not having the same disease severity, which could have resulted in less than optimal outcomes postoperatively. However, every other metric and demographic data were very tightly matched. Further, the outcome metric “does your knee feel normal” is more applicable to postoperative assessment as knees that are painful with end-stage degenerative disease preoperatively, by definition do not feel “normal.” So it is unclear why any patient would ever answer that question “yes” preoperatively and therefore the authors do not feel that particular preoperative metric is a substantial confound. The effect sizes (i.e. differences in group means or percentages) for null results were small, thus resulting in low statistical power to detect an actual difference despite 183 subjects in each group and our tightly matched control study design. Consequently, our conclusions and discussion avoid emphasizing null results as it is possible they reflect a type-II error with power as low as 20.4% for null results. Although the dual-pivot TKA is designed to replicate early lateral-pivot kinematics, we were unable to confirm that patients were actually functioning in this manner in vivo due to the lack of fluoroscopically or radiographically confirmed kinematic assessment. Further, it may be the conforming nature of this polyethylene knee design that imparts more general knee stability, rather than specifically replicating a particular and more complex kinematic pattern, resulting in improved patient outcomes. Future studies of this cohort will involve gait lab kinematic analysis to determine if this TKA design indeed reproduces and/or facilitates the intended pattern and if patients with an early lateral-pivot continue to report higher outcome scores.

5. Conclusions

Maximizing clinical outcomes and patient satisfaction after TKA is a common goal of total joint arthroplasty surgeons. Healthcare cost containment initiatives have proposed patient satisfaction as the leading metric by which to evaluate the quality and value of TKA. However, a recent meta-analysis of 208 studies on patient satisfaction with TKA published between 2007 and 2017 documented that 62% were lower level of evidence studies, satisfaction metrics were multifarious, and only 13% of studies used a validated measure of satisfaction [3]. Thus, in the joint replacement field itself, patient satisfaction is not well understood. Future research should focus on the evaluation of patients with the highest outcome scores and those who report their knees “always” felt normal to determine if a correlation exists between patient-reported optimal outcomes and kinematic patterns. Clinical findings in this study demonstrate statistical superiority in pain scores during early flexion walking activities, providing supportive evidence that dual-pivot TKA may replicate kinematic patterns and stability inherent in the ACL-intact native knee.

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The authors would like to acknowledge Dr. Andrew Hodge for his creative and innovative inception and development of the dual-pivot total knee arthroplasty design, based on ACL-intact native knee kinematics and stability. We are privileged to study a design that while almost 15 years in existence, is improving care and outcomes for TKA patients in a time where patient satisfaction and function are paramount to surgeons and patients.

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Declaration of competing interest

Two authors (SAB and RMM) are paid consultants for, and receive royalties from the company (DJO Surgical) that designed this dual-pivot TKA design; however, neither were involved in data collection, compilation, or analysis.

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