Achieving More Natural Motion, Stability, and Function With a Dual-Pivot ACL-substituting Total Knee Arthroplasty Design

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Summary: Reports demonstrate up to 20% of total knee arthroplasty (TKA) patients are not satisfied and claim their knee does not feel normal. Failure to replicate native anterior cruciate ligament (ACL)-intact knee tibiofemoral kinematics and stability may contribute to this dissatisfaction. Originally described as medial-pivot pattern throughout flexion, recent studies have elucidated the more modern understanding of a complex motion pattern in ACL-intact knees, where walking and early flexion activities near extension exhibit a lateral-pivot pattern and medial-pivot pattern is observed in deeper flexion. A contemporary TKA design (EMPOWR 3-D; DJO Global, Vista, CA) has the potential to promote natural motion and stability by incorporating a conforming spherical lateral compartment to recreate the dual-pivot kinematics. In vivo fluoroscopic studies have confirmed this optimal kinematic pattern of medial-pivot motion during squatting and kneeling activities, with a lateral-pivot motion during walking. Further, near normal knee strength and minimized hamstrings co-contraction provide evidence for optimal intrinsic tibiofemoral stability. Emerging clinical results have been encouraging and support the modern dual-pivot kinematic understanding and in vivo function studies. Recent studies have revealed intraoperative dual-pivot femoral contact patterns optimize patient outcomes. Clinical results comparing the dual-pivot TKA and a traditional TKA design demonstrate patients with the dual-pivot TKA experience a higher level of function and a greater likelihood of a normal feeling knee. Merging the modern understanding of kinematics in ACL-intact knees with a contemporary dual-pivot TKA design may improve outcomes through optimal knee motion and stability, which may narrow the elusive 20% of TKA patients currently not satisfied.

Key Words: dual-pivot—ACL substituting—total knee arthroplasty—kinematics—lateral-pivot.

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It is widely accepted that total knee arthroplasty (TKA) is an extremely important tool for the treatment of diseased knees, resulting in high patient satisfaction in 75% to 90% of cases.[1–5] In those patients reporting incomplete satisfaction, a variety of factors have been identified as potentially contributing to less than optimal outcomes. Joint instability, weakness, low endurance, giving way, and other complaints of a mechanical nature are often cited,[6,7] and potentially could be improved through enhanced implant design or surgical techniques that directly affect postoperative knee mechanics. Which elements of knee joint mechanics are generally deficient or need to be improved remains an open question.

Approximately US$8 billion is spent annually in the United States reconstructing the anterior cruciate ligament (ACL) in the young and active population.[8] A myriad of studies demonstrate the efficacy of ACL reconstruction in terms of clinical and functional outcomes.[8–10] The ACL provides primary anterior-posterior (AP) joint stability in the early flexion arc, and knees with a deficient ACL manifest instability, weakness, giving way and dynamic muscular compensation.[11–13] Yet the ACL, if present, is sacrificed in the vast majority of TKA procedures. It appears reasonable, therefore, to suspect ACL deficiency as a contributor to abnormal joint stability in knees with TKA in general, and in knees with suboptimal outcomes related to instability in particular.

Retaining the ACL with knee arthroplasty has been practiced for roughly 50 years.[14,15] Although patient satisfaction and functional outcomes can be very good,[16–20] the more technically demanding surgical procedure and relatively less consistent[21] outcomes have resulted in a small percentage of TKA surgeries performed with ACL retention. An alternative to ACL retention is substitution with a prosthesis designed to mimic the joint stabilizing influence of the ACL. The purpose of this manuscript is to describe 1 design rationale for unique contemporary ACL-substituting TKA intended to provide closer-to-natural knee stability in addition to replication of native dual-pivot knee kinematics, and to report modern functional and clinical results.

DESIGN CONCEPT

An ACL-substituting TKA design (EMPOWR 3-D Knee System; DJO Global Inc., Vista, CA) was developed by creating a lateral compartment that is spherically conforming from −15 to 65-degree flexion, with increasing AP laxity at higher flexion angles (Fig. 1). This articulation forces the lateral condyle to the tibial AP center in extension, and permits posterior translation with deeper flexion—approximately substituting for the ACL, and providing definitive AP knee stability over the flexion arc for most ambulatory activities. The medial tibial articulation is sagittally curved to provide control of the medial condyle translation in flexion. The thickest aspect of the posterior condyles occurs later in the flexion arc to maintain the femoral posterior condylar offset and natural range of motion.[22] Large tibiofemoral contact areas are achieved with the spherical articulation in the lateral compartment and a widened (more anatomic) medial compartment, which has the secondary benefit of lateralizing the patellar groove by several millimeters. Standardized laboratory testing of this prosthesis demonstrates 4.4 mm^3 wear per million cycles with direct compression

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FIGURE 1. The anterior cruciate ligament-substituting total knee arthroplasty 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. full color online

molded ultra-high molecular weight polyethylene, and 1.9 mm^3 wear per million cycles with vitamin E blended, moderately cross-linked ultra-high molecular weight polyethylene.[23]

IN VIVO FUNCTION

Kinematics of healthy, ACL-intact knees have been studied extensively across a range of passive and functional activities. For passive flexion and activities including squatting, kneeling, lunging, and deep-knee bends, the femur typically is observed to externally rotate and posteriorly translate with respect to the tibia with increasing flexion.[24–29] This combination of rotation and translation corresponds to the medial condyle undergoing little translation while the lateral condyle moves progressively more posterior with flexion, giving rise to the common description of the knee as a so-called medial-pivot articulation. However, studies over the past decade have shown healthy knees manifest a very different pattern of motion during ambulatory activities. During pivoting, level walking and downhill running activities, the lateral condyle moves very little, whereas the medial condyle translates with knee axial rotations.[30–33] Thus, for these ambulatory activities performed predominantly near extension, characterizing the healthy knee as having a lateral pivot is a more apt description. Indeed, Meneghini et al[34] recently showed that TKAs have superior clinical outcomes when they exhibit this dual-pivot pattern of motion, lateral in extension and medial in flexion, during intraoperative kinematic pattern assessment. The question is whether the ACL-substituting TKA design provides the correct joint stability to support this healthy, dual-pivot pattern of motion in functional activities?

Mikashima et al[35] used fluoroscopy to study a cohort of 10 subjects with the ACL-substituting design and compared them to a similar cohort of subjects with a traditional symmetric posterior cruciate-retaining TKA design. During a weight-bearing squat activity, subjects with the ACL-substituting TKA prosthesis showed statistically greater maximum knee flexion (124 vs. 110 degrees), tibial internal rotation (17 vs. 10 degrees), and posterior lateral condyle translation (11 vs. 6 mm) than was observed in knees with the traditional prosthesis. Mikashima et al[35] noted the medial condyle remained within 1 mm of the AP center of the tibia in both groups during the maximally flexing squat activity. Ginsel et al[36] performed a

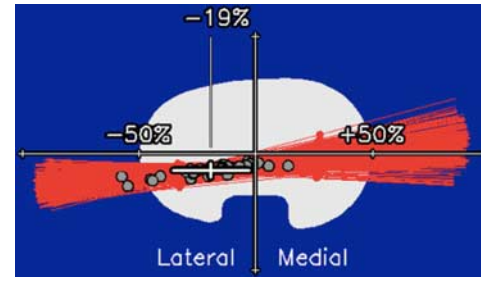

FIGURE 2. Knees with anterior cruciate ligament-substituting total knee arthroplasty show a consistent lateral center of rotation during treadmill walking. The image shows 366 frames of data for 13 knees, where each red line connects the centers of the medial and lateral femoral condyles as projected onto the tibial insert. The 13 knees exhibited an average of 4.5-degree tibial rotation during the stance phase of gait. full color online

similar fluoroscopy study on a cohort of 20 ACL-substituting knees during a maximum flexion kneeling activity, and reported mean flexion of 131 degrees, tibial internal rotation of 10 degrees, and the medial and lateral condyles were an average of 2 and 10 mm posterior to the tibial AP center, respectively. In a separate study, Mikashima et al[37] studied 13 subjects with ACL-substituting TKA during treadmill walking. They observed a repeatable lateral center of rotation during the stance phase of gait (Fig. 2), consistent with the spherical lateral articulation. Finally, Mitchell et al[38] reported a gait laboratory study of subjects having 10 ACL-substituting TKAs who were closely matched to subjects from a prior study.[39] During a step-up and over activity, the ACL-substituting knees exhibited 85% of their normal contralateral knee strength, comparable to the best-performing cohort from the prior study.[39] Based upon electromyography, subjects with the ACL-substituting TKA showed no evidence of elevated hamstrings co-contraction, indicating they were not abnormally recruiting hamstrings as dynamic knee stabilizers.[38]

These functional studies demonstrate the ACL-substituting TKA prosthesis performs as designed—providing intrinsic joint stability that supports patterns of motion similar to the healthy knee. In squatting and kneeling activities the observed motions were consistent with a medial center or rotation, whereas in gait there was a clear lateral center of rotation. This dual-pivot pattern of knee motion has been observed in healthy knees and suggests the prosthesis provides sufficient stability that patients do not develop muscular adaptations typical of unstable knees. The observed close-to-normal knee strength, and lack of elevated hamstrings co-contraction, support these observations. Of course these laboratory studies do not predict if knees with these mechanical characteristics will exhibit superior clinical outcomes.

CLINICAL OUTCOMES

Although the design concept of this ACL-substituting dual-pivot TKA design is sound and based on established and scientifically proven kinematic patterns that exist in normal native knees in vivo and also appear to behave as intended by fluoroscopic studies as described previously, true value and patient benefit must be realized and corroborated in clinical outcomes. An initial endeavor to determine a correlation between kinematic patterns and clinical outcomes, sensor-embedded tibial insert trials were used to determine intra-operative kinematic patterns and subsequent clinical

outcomes.[34,40] Although traditionally developed and utilized to obtain objective force measurements within the medial and lateral compartments intraoperatively to assess balance,[41] the sensor-embedded tibial insert trials have the capacity to display femoral contact points on the tibial surface and the subsequent kinematic pattern.

In a study of 141 TKAs, Warth et al[40] utilized sensor-embedded tibial insert trials to obtain intraoperative kinematics and identify those patients with a medial-pivot pattern based on accepted criteria. At a minimum 1-year follow-up, Knee Society scores (KSS) and University of California Los Angeles activity level did not differ based on medial-pivot versus non-medial-pivot patterns ($P \geq 0.29$).[40] In further investigation and analysis, Meneghini et al[34] reported on 120 consecutive TKAs with detailed intraoperative sensor-derived kinematic pattern determinations. Lateral-pivot and medial-pivot pattern designations were based on the center of rotation within 3 flexion zones and KSS, pain scores, and patient satisfaction were analyzed in relation to kinematic patterns. The authors reported the Knee Society function scores were higher in TKAs with early lateral-pivot/late medial-pivot intraoperative kinematics compared with all other kinematic patterns ($P = 0.018$), and there was a greater decrease in the proportion who reported that their knee never feels normal ($P = 0.011$). Early lateral/late medial pivot had greater function scores at 1 year ($P < 0.001$) and improvement from preoperative baseline ($P = 0.008$) compared with those with the least ideal pattern. All patients with the most ideal pattern compared with none of the least ideal pattern reported they were very satisfied ($P = 0.003$). The authors concluded that patients with an intraoperative early lateral-pivot pattern followed by medial-pivot motion in later flexion, reported higher functional outcome scores along with higher overall patient satisfaction.[34] This data suggests that an intraoperative dual-pivot pattern, as observed with an ACL-intact native knee, may produce superior clinical outcomes compared with other less natural kinematic patterns.

Although fluoroscopic and intraoperative sensor-derived kinematic pattern assessment and clinical correlation support a foundational basis of support for a TKA design that facilitates and guides a dual-pivot kinematic pattern, ultimately it is the clinical outcomes that must confirm such a notion. A retrospective analysis of the prospectively collected clinical outcome registry database at our institution, 126 dual-pivot TKAs (EMPOWR 3-D Knee System; DJO Global Inc.) were demographically and functionally matched with 126 traditional nonconforming TKAs with identical perioperative protocols. To ensure the highest level of scientific rigor, it was confirmed there was no differences in the prevalence of established confounding variables of fibromyalgia, lumbar spine disease, depression, preoperative narcotic use ($P \geq 0.14$) or preoperative outcome scores ($P \geq 0.26$). At early follow-up of 4 months, the dual-pivot TKA patients reported better postoperative assessment of whether their knee feels normal ($P = 0.04$), as well as higher postoperative activity levels as assessed with the University of California Los Angeles activity score ($P = 0.04$). In addition, was a trend for more patients with dual-pivot TKAs to rate their satisfaction at the highest classification of "very satisfied" compared with the traditional TKA patients ($P = 0.11$).

A unique aspect of the conforming polyethylene and enhanced topography of the dual-pivot TKA design is the inherent knee stability it affords in the absence of the posterior-cruciate ligament (PCL), which has been supported in clinical studies.[42,43] Watanabe and colleagues reported a clinical series of the original dual-pivot TKA design (3D; DJO Surgical, Austin, TX), where 56 TKAs were studied using dynamic radiography at a minimum 1-year follow-up with 27 TKAs retaining the PCL and 29 TKAs sacrificing the PCL. Although patient-reported outcomes were not reported in this series, the authors reported that PCL-sacrificing knees showed more anterior femoral condylar positions, as would be expected; however, the PCL-sacrificing TKAs demonstrated an average 7-degrees greater knee flexion during kneeling.[43] In a series of clinical and functional outcomes of the original dual-pivot TKA design described above, Harman and colleagues reported on 116 dual-pivot TKAs with PCL retention compared with 43 TKAs where the PCL was resected. The PCL-resected group exhibiting an average of 5 degrees greater flexion ($P = 0.002$); however, the PCL-retained group demonstrated greater mean KSS function scores compared with the PCL-sacrificed patient group ($P = 0.003$). The authors also performed a fluoroscopic analysis of 33 knees within this series, which revealed stable tibiofemoral translations.[42] While minimal clinically meaningful differences do not appear to exist with this conforming dual-pivot TKA design, it does appear that retaining the PCL may impart a benefit to patient function, albeit with less knee flexion.

DISCUSSION AND CONCLUSIONS

Modern TKA does not satisfy all patients, despite being an extremely successful and important treatment that is widely popular and utilized. A plausible explanation for the seemingly larger than expected proportion of unsatisfied TKA patients, is the loss of normal and potentially native tibiofemoral joint stability in those unsatisfied patients. One approach to restoring a more normal and natural knee stability is through a dual-pivot ACL-substituting TKA design. Effective knee stability and motion that replicates ACL substitution can be accomplished in a TKA design with a conforming polyethylene that has a spherical lateral compartment from extension to mid-flexion to drive lateral-pivot motion in early flexion angles that occur in the ACL-intact native knee during walking or running. There is supporting scientific evidence that knees with a dual-pivot ACL-substituting design exhibit the dual-pivot kinematic pattern as intended with the geometrical design. Further, emerging clinical evidence suggests that patients who receive the dual-pivot TKA design may experience a higher level of physical function and a feeling their knee feels more normal compared with traditional contemporary TKA designs. This ACL-substituting TKA design restores patterns of motion and inherent stability approximating healthy knees and may provide incremental benefit over traditional TKA designs that do not consistently provide the same intrinsic stability due to less conforming polyethylene.

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