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Short-term safety and effectiveness of a second-generation motion-guided total knee system

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ABSTRACT

Background: Modern knee prostheses are designed to more closely replicate normal knee kinematics. The JOURNEY II Bi-Cruciate Stabilized Total Knee System (Smith & Nephew Inc., Memphis, TN) is a second-generation motion-guided knee system that demonstrates axial rotation patterns during flexion, which resemble those of the normal knee. The aim of this study was to assess the short-term safety and effectiveness of this system in standard clinical practice.

Methods: A total of 186 subjects (209 primary total knee arthroplasties [TKAs]) were enrolled at 12 U.S. sites. Subjects were operated on between December 2011 and October 2013 and followed for 24 months. Radiographic, clinical, and patient-reported outcome data were collected at 6-, 12-, and 24-month postoperatively.

Results: At 24-month follow-up, the average objective Knee Society Score was 96.20 (standard deviation [SD] = 6.63), the average satisfaction score was 35.22 (SD = 6.63), the average expectation score was 10.91 (SD = 3.16), and the average functional activities score was 81.49 (SD = 14.65). On a 0-10 scale, pain level for walking was 0.79 (SD = 1.51) and 1.50 (SD = 1.97) for climbing stairs or inclines. The cumulative incidence of reoperation at 2-year follow-up was 1.48% (95% confidence interval [CI] 0.48%-4.52%). Ten TKAs in 7 patients were treated with closed manipulations for stiffness. Iliotibial band syndrome was reported in 2 TKAs. Two deep infections occurred, 1 requiring reoperation. No dislocations occurred in the study cohort.

Conclusions: In short-term follow-up, the JOURNEY II Bi-Cruciate Stabilized Guided Motion Total Knee System appears to be a safe and effective device for TKA.

Introduction

Arthritis of the knee is a source of joint pain and stiffness that can be severely debilitating. Total knee arthroplasty (TKA) is an effective treatment and is the current gold standard for providing symptomatic relief and the ability to return to daily activities for patients with end-stage knee arthritis [1-3].

A better understanding of knee anatomy and biomechanics has resulted in guided motion implants that simulate more natural knee kinematics to improve function [4,5]. The guided motion knee systems are characterized by anteroposterior stability and physiologic femoral rollback during flexion [6]. Earlier designs sought to replicate natural knee kinematics by implementing asymmetric surface geometry in the medial and lateral condyles as well as an asymmetric cam-post mechanism [7,8]. JOURNEY Bi-Cruciate Stabilized (BCS) Total Knee System (Smith & Nephew Inc., Memphis, TN) demonstrated axial rotation patterns (posterior translation of the femur and internal rotation of the tibia) during flexion, which resembled that of the normal knee [8]. JOURNEY II BCS is a second-generation model of the JOURNEY BCS system. Published clinical studies of this second-generation system are limited at present to a large series that assessed infections associated with

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intraarticular injections before TKA using a variety of prostheses [9] and a retrospective study that compared the effect of intraoperative valgus cut angle on postoperative coronal alignment [10]. The aim of this study was to assess the effectiveness and safety of this system at 2 years postimplantation.

Material and methods

We conducted a multicenter case series of consecutive patients. Key inclusion criteria were age ≥18 years with unilateral or bilateral knee disease requiring primary TKA. Patients with a well-functioning contralateral knee arthroplasty were also included. Patients were excluded if there was any other reason for an abnormal gait pattern such as an arthritic hip, a previous hip arthroplasty, a poorly functioning contralateral knee arthroplasty, or a pathologic foot and ankle deformity.

Patients were enrolled at 6 months after the TKA. Baseline operative and perioperative data were collected retrospectively. Six-, 12-, and 24-month data were collected prospectively during the in-clinic visit and included the 2011 version of the Knee Society Score (KSS) [11], radiographic assessments (anteroposterior, lateral and patella views) and treatment complications. The KSS is a validated system that consists of an objective physician component and a patient-reported component. The patient-reported component tracks patient outcomes across 3 dimensions of pain relief, functional abilities, and fulfillment of expectations.

Of 209 enrolled TKAs, 24-month follow-up information was available for 188 (89.95%). The average follow-up time across all TKAs was 23.4 months.

One subject was missing the 6-month KSS and pain evaluations. The missing 12- and 24-month follow-up values for KSS and pain evaluations were imputed using the last-value carry-forward approach.

All participating sites obtained approval from an institutional review board for this research. All patients provided written informed consent. Professional monitors visited the sites to assure that the data are true, accurate, and verifiable.

Statistical analysis

Descriptive statistical approaches included frequencies and percentages for qualitative variables and means and standard deviations for quantitative variables. Changes in KSS scores and Numeric Pain Rating Scale scores among the follow-up visits were analyzed by one-way repeated measures analysis of variance on imputed data sets. Revision incidence was estimated by Kaplan–Meier estimator [12] and as rate per 100 observed component years.

Results

Overall, 186 subjects (209 knees) were enrolled at 12 sites in the United States, between December 2011 and October 2013. The sites included both academic settings and community practices. Unilateral TKA was performed in 163 subjects (87.6%) and bilateral in 23 subjects (12.4%). Of the 23 bilateral subjects, 11 had the surgeries performed in 1 setting and 12 in a staged approach.

The average age at the index surgery was 61.1 years (standard deviation [SD] 7.7 years, range 39-85 years); 52.7% were female. The majority of subjects were Caucasian (169, 90.9%), 8 (4.3%) were Hispanic, 5 (2.7%) were African American, and 4 (2.2%) were Asian. The average body mass index at the time of surgery was 30.4 kg/m^2 (SD = 4.6; range 16.5-39.9).

Table 1
Distribution of patients by Charnley classification (N = 186).

Charnley classifications	
A Unilateral knee arthritis	100 (53.76%)
B1 Unilateral TKA, opposite knee arthritic	50 (26.88%)
B2 Bilateral TKA	33 (17.74%)
C1 TKR, but remote arthritis affecting ambulation	0
C2 TKR, but medical condition affecting ambulation	0
C3 Unilateral or bilateral TKA of bilateral THR	3 (1.61%)

TKR, total knee replacement; THR, total hip replacement.

Twenty-three of 163 unilateral TKA subjects (14.11%) had a history of TKA on a contralateral knee. One subject had diabetes. Most subjects had unilateral arthritis with no involvement of the contralateral knee (100/160, 53.8%). Fifty subjects (26.9%) received unilateral TKA but had arthritic involvement of the contralateral knee. Charnley class B2 (bilateral TKA) was reported in 33 subjects (17.7%), and 3 subjects (1.6%) were rated as Charnley class C3 (Table 1). The average surgery time (skin to skin) was 97.7 minutes (SD = 23.4, range 57-214 minutes). The mean length of hospital stay was 2.7 days (SD = 1.6 days, range from 1-15 days, median 2 days).

Average range of motion was 128.3 degrees (SD = 9.6, range 95-153 degrees) at 6-month follow-up and did not change at 12- and 24-month follow-up visits. Owing to the retrospective enrollment of subjects, baseline KSS scores were not available. The average objective KSS improved during the study. At 6-month follow-up, the average objective KSS was 93.74 (SD = 7.36), and at 24-month follow-up it was 96.20 (SD = 6.63) ($P \leq .0001$) (Table 2). After the imputation, patient scores were not available for 1 subject. Patient satisfaction score improved from 32.66 (SD = 7.22) at 6-month follow-up to 35.22 (SD = 6.63) at 24-month follow-up ($P \leq .0001$) (Table 3). Patient expectation score was 10.39 (SD = 2.93) at 6-month follow-up and 10.91 (SD = 3.16) at 24-month follow-up ($P = .0394$). Functional activities score improved from 75.40 (SD = 13.82) at 6-month follow-up to 81.49 (SD = 14.65) at 24-month follow-up ($P \leq .0001$) (Table 3).

There was an improvement in pain between 6- and 24-month postoperatively. Based on a Numeric Pain Rating Scale from 0 to 10, pain level while walking was 1.24 (SD = 1.73) at 6-month postoperatively. This improved to 0.79 (SD = 1.51) at 24-month postoperatively (Table 4). Pain level while climbing stairs or inclines improved from 2.41 (SD = 2.20) at 6-month postoperatively to 1.50 (SD = 1.97) at 24-month postoperatively. At 6-month follow-up, of the 103 subjects who were employed before the surgery, 93 (90.3%) had returned to work, 4 (3.9%) planned to return to work, and 6 (5.8%) did not return.

Two days after surgery, 1 subject (0.54%) developed a pulmonary embolism. Two subjects (1.07%) developed a deep venous thrombosis, which resulted in a pulmonary embolism in 1 of the subjects at 23 days postoperatively. Radiographic outcomes at 24-month were notable for 1 knee (0.48%), which showed a radiolucency of 2 mm or more in a tibial component. One case of device loosening and possible distal stress fracture was observed at the end of the

Table 2
Objective KSS Score by follow-up time.

Score	6 mo (N = 208)	12 mo (N = 208)	24 mo (N = 208)	*P*-value
Objective KSS Score	93.74 (7.36)	95.31 (6.84)	96.20 (6.63)	<.0001
Alignment score	24.5 (4.18)	24.83 (2.43)	24.83 (2.43)	.3688
Instability score	23.99 (2.34)	23.85 (2.58)	23.89 (2.69)	.6860
Joint motion score	25.57 (2.33)	25.92 (2.13)	26 (2.08)	.0009
Symptoms score	19.69 (4.37)	20.75 (4.36)	21.5 (4.07)	<.0001

Table 3
Patient-reported KSS scores.

Score	6 mo (N = 185)	12 mo (N = 185)	24 mo (N = 185)	*P*-value
Satisfaction score	32.66 (7.22)	34.46 (6.62)	35.22 (6.63)	<.0001
Expectation score	10.39 (2.93)	10.55 (3.00)	10.91 (3.16)	.0394
Functional activities score	75.40 (13.82)	79.59 (13.13)	81.49 (14.65)	<.0001
Walking and standing score	24.46 (6.09)	26.34 (5.30)	26.80 (5.26)	<.0001
Standard activity score	24.46 (4.00)	25.40 (4.06)	25.92 (4.45)	<.0001
Advanced activity score	14.00 (5.27)	15.39 (5.28)	16.05 (5.58)	<.0001
Discretional activity score	11.97 (2.78)	12.52 (2.55)	12.6472 (2.79)	<.0001

2-year follow-up period. There were reports of confirmed postoperative deep infection, at 31 days postoperative that resolved after treatment and at 204 days postoperatively that resulted in revision. One subject (0.54%) developed a postoperative ileus that resolved without sequelae. Two subjects (1.07%) developed Baker's cyst, one of which ruptured. Four subjects (2.15%) developed synovitis. Two knees (0.96%) developed iliotibial band syndrome (ITBS); 1 resolved without sequel and 1 was unresolved at 24-month follow-up.

Ten knees (4.8%) were treated with closed manipulations for stiffness. Of these, 7 (3.35%) were performed in 4 subjects (2.15%) who underwent bilateral TKA performed in one setting. Eleven subjects (5.91%) had bilateral TKA performed in one setting. Eleven subjects (5.91%) underwent knee aspiration for swelling and possible infection.

Three subjects (1.61%) underwent revision involving 3 knees (1.43%). One subject (0.54%) developed a deep wound infection which required drainage and replacement of the tibial liner and patella button 8.5 months after the index surgery. Another knee revision was due to a retained bone fragment that necessitated removal of the tibial liner for access and replacement 5 weeks after the index surgery. The third knee revision was performed at 14-month postoperatively due to a mismatched tibial insert implant size (size 4 insert in a size 5 tray). No cases involved revision of tibial or femoral components. The cumulative incidence of revisions at 24-month postoperative was 1.48% (95% confidence interval 0.48%-4.52%) (Fig. 1). The revision rate was 0.73 (95% confidence interval 0.19-2.00) per 100 observed component years.

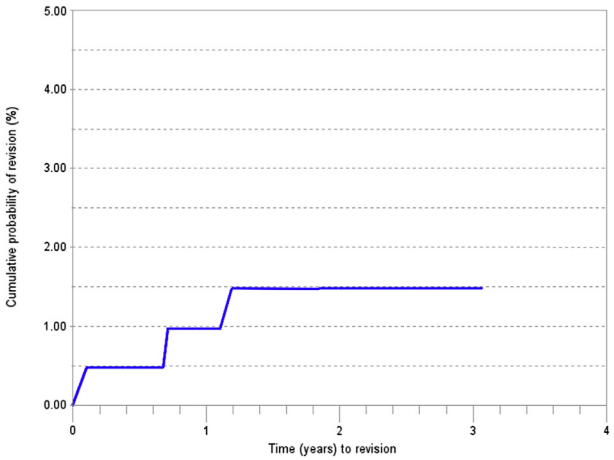

Figure 1. Cumulative incidence of revisions in JOURNEY II BCS implants.

Discussion

Subjects in this study demonstrated favorable objective and subjective outcomes after TKA using the second-generation JOURNEY BCS system. The mean objective KSS increased throughout follow-up intervals. This outcome score assesses knee alignment on anteroposterior radiographs, stability in the anteroposterior and mediolateral planes, joint range of motion, and pain with level-walking or stairs. A similar trend was demonstrated in patient-reported satisfaction, expectations met, and functional activity scores. Postoperative knee flexion at 2 years postoperative reached a mean of 130.5°. The pain scores at 2 years postoperative were low. Most subjects who were employed prior to TKA returned to work. Significant complications included 2 cases of pulmonary embolism, 2 deep infections, and 1 device loosening. There were 3 revisions, none of which involved the tibial or the femoral component.

JOURNEY II BCS is a second-generation JOURNEY BCS total knee system. While many surgeons noted good results with the first-generation system, complications reported included anterolateral and lateral knee pain, ITBS, and posterior cam-post dislocation [13,14]. Luyckx et al [13] reported a 7.2% rate of ITBS in a consecutive series of over 1000 JOURNEY BCS knees at a mean follow-up of 2.5 years. Despite this complication, the overall survivorship of the first-generation prosthesis was 98%. Sanz-Ruiz et al [15] reported a similar rate of ITBS at 6.6%. In our study, using the second-generation device, the rate of ITBS was 0.96%, suggesting that this complication is less common with the second-generation device.

Digennaro et al [5] compared long-term outcomes in the first-generation system to the Scorpio Non-Restrictive Geometry knee system (Stryker Orthopedics Inc., Mahwah, NJ), a similar but more constrained guided motion prosthesis. The first-generation system treated knees demonstrated significantly better Knee Injury and Osteoarthritis Outcome Scores but had a greater incidence of stiffness. The authors concluded that the greater posterior femoral rollback and physiologic knee kinematics of the first-generation system contributed to better clinical outcomes. In our study, about 1 in 20 knees required closed manipulation for stiffness. Interestingly, a majority of closed manipulations in our study were required for patients who underwent a bilateral TKA during the same surgery.

Another reported complication of the first-generation system was cam-post dislocation. Arnout et al [14] reported 4 such events of 1350 cases (0.3%). In all cases, the knees had an extremely high degree of knee flexion, which allowed the cam to dislocate over the post. There were no cam-post dislocations in our study.

Study limitations included retrospective collection of baseline clinical and operative data. As a result, outcome data could only be trended beginning at the 6-month postoperative time-point after which all subjects were followed prospectively. Inherent to retrospective studies, adverse events and complications during the initial hospital stay may be missed and under reported. However, a

Table 4
Pain level by follow-up.

Level of pain	6 mo (N = 185)	12 mo (N = 185)	24 mo (N = 185)	*P*-value
Pain with level walking	1.24 (1.73)	1.00 (1.66)	0.79 (1.51)	.0037
Pain with stair or inclines	2.41 (2.20)	1.85 (2.07)	1.50 (1.97)	<.0001

strict adherence to the investigational plan was observed and nearly 400 adverse events, most unrelated to the TKA, were captured and reviewed.

Conclusions

In short-term follow-up, the JOURNEY II BCS Guided Motion Total Knee System appears to be a safe and effective device for TKA.

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References

[1] Carr AJ, Robertsson O, Graves S, et al. Knee replacement. Lancet 2012;379:1331.
[2] Hawker G, Wright J, Coyte P, et al. Health-related quality of life after knee replacement. J Bone Joint Surg Am 1998;80:163.
[3] Talmo CT, Robbins CE, Bono JV. Total joint replacement in the elderly patient. Clin Geriatr Med 2010;26:517.
[4] Matsuzaki T, Matsumoto T, Muratsu H, et al. Kinematic factors affecting postoperative knee flexion after cruciate-retaining total knee arthroplasty. Int Orthop 2013;37:803.
[5] Digennaro V, Zambianchi F, Marcovigi A, et al. Design and kinematics in total knee arthroplasty. Int Orthop 2014;38:227.
[6] Walker PS. A new concept in guided motion total knee arthroplasty. J Arthroplasty 2001;16:157.
[7] Victor J, Mueller JKP, Komistek RD, et al. In vivo kinematics after a cruciate-substituting TKA. Clin Orthop Relat Res 2010;468:807.
[8] Victor J, Bellemans J. Physiologic kinematics as a concept for better flexion in TKA. Clin Orthop Relat Res 2006;452:53.
[9] Amin NH, Omiyi D, Kuczynski B, Cushner FD, Scuderi GR. The risk of a deep infection associated with intraarticular injections before a total knee arthroplasty. J Arthroplasty 2016;31:240.
[10] Davis JA, Hogan C, Dayton M. Postoperative coronal alignment after total knee arthroplasty: does tailoring the femoral valgus cut angle really matter? J Arthroplasty 2015;30:1444.
[11] Scuderi GR, Bourne RB, Noble PC, et al. The new knee society knee scoring system. Clin Orthop Relat Res 2012;470:3.
[12] Kaplan E, Meier P. Nonparametric Estimation from Incomplete Observations. J Am Stat Assoc 1958;53:457.
[13] Luyckx L, Luyckx T, Bellemans J, Victor J. Iliotibial band traction syndrome in guided motion TKA. A new clinical entity after TKA. Acta Orthop Belg 2010;76:507.
[14] Arnout N, Vandenneucker H, Bellemans J. Posterior dislocation in total knee replacement: a price for deep flexion? Knee Surg Sports Traumatol Arthrosc 2011;19:911.
[15] Sanz-Ruiz P, Carbo-Laso E, Alonso-Polo B, Matas-Diez JA, Vaquero-Martín J. Does a new implant design with more physiological kinematics provide better results after knee arthroplasty? Knee 2016;23:399.