Clin Orthop Relat Res (2018) 00:1-8
DOI 10.1097/CORR.0000000000000600

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

Clinical Research

Is There a Force Target That Predicts Early Patient-reported Outcomes After Kinematically Aligned TKA?

Trevor J. Shelton MD, MS, Stephen M. Howell MD, Maury L. Hull PhD

Received: 13 May 2018 / Accepted: 19 November 2018 / Published online: 0, xxxx

Abstract

Background Four mechanical alignment force targets are used to predict early patient-reported outcomes and/or to indicate a balanced TKA. For surgeons who use kinematic alignment, there are no reported force targets. To date the usefulness of these mechanical alignment force targets with kinematic alignment has not been reported nor has a specific force target for kinematic alignment been identified.

Questions/purposes (1) Does hitting one of four mechanical alignment force targets proposed by Gustke, Jacobs, Meere, and Menghini determine whether a patient with a kinematically aligned TKA had better patient-reported Oxford Knee and WOMAC scores at 6 months? (2) Can a new force target be identified for kinematic alignment that determines whether the patient had a good/excellent Oxford Knee Score of ≥ 34 points (48 best, 0 worst)?

Methods Between July 2017 and November 2017, we performed 148 consecutive primary TKAs of which all were treated with kinematic alignment using 10 caliper measurements and verification checks. A total of 68 of the 148 (46%) TKAs performed during the study period had intraoperative measurements of medial and lateral tibial compartment forces during passive motion with an instrumented tibial insert and were evaluated in this retrospective study. Because the surgeon and surgical team were blinded from the display showing the compartment forces, there was no attempt to hit a mechanical alignment force target when balancing the knee. The Oxford Knee Score and WOMAC score measured patient-reported outcomes at 6 months postoperatively. For each mechanical alignment force target, a Wilcoxon rank-sum test determined whether patients who hit the target had better outcome scores than those who missed. An area under the curve (AUC) analysis tried to identify a new force target for kinematic alignment at full extension and 10°, 30°, 45°, 60°, 75°, and 90° of flexion that predicted whether patients had a good/excellent Oxford Knee Score, defined as a score of ≥ 34 points.

Results Patients who hit or missed each of the four mechanical alignment force targets did not have higher or

One of the authors certifies that he (SMH) has received personal fees, during the study period, in an amount of USD 100,001 to USD 1,000,000, from Zimmer Biomet (Warsaw, IN, USA); personal fees from ThinkSurgical (Fremont, CA, USA) in an amount of USD 10,000 to USD 100,000; and personal fees from Medacta (Castel San Pietro, Strada Regina, Switzerland) in an amount of USD 100,001 to USD 1,000,000, all outside the submitted work. One of the authors certifies that he (MLH) has received grants, during the study period, in an amount of USD 100,001 to USD 1,000,000, from Zimmer Biomet.

All ICMJE Conflict of Interest Forms for authors and *Clinical Orthopaedics and Related Research*® editors and board members are on file with the publication and can be viewed on request.

Clinical Orthopaedics and Related Research® neither advocates nor endorses the use of any treatment, drug, or device. Readers are encouraged to always seek additional information, including FDA approval status, of any drug or device before clinical use.

Each author certifies that his institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

This work was performed at the University of California, Davis, Sacramento, CA, USA.

T. J. Shelton, M. L. Hull Department of Orthopaedic Surgery, University of California, Davis, Sacramento, CA, USA

S. M. Howell, M. L. Hull Department of Biomedical Engineering, University of California, Davis, Davis, CA, USA

M. L. Hull Department of Mechanical Engineering, University of California, Davis, Davis, CA, USA

T. J. Shelton ✉ Department of Orthopaedic Surgery University of California, Davis 4860 Y Street Suite 3800 Sacramento, CA 95817, USA email: tjshelton@ucdavis.edu

Wolters Kluwer

lower Oxford Knee Scores and WOMAC scores at 6 months. Using the Gustke force target as a representative example, the Oxford Knee Score of 41 ± 6 and WOMAC score of 13 ± 11 for the 31 patients who hit the target were not different from the Oxford Knee Score of 39 ± 8 (p = 0.436) and WOMAC score of 17 ± 17 (p = 0.463) for the 37 patients who missed the target. The low observed AUCs (from 0.56 to 0.58) at each of these flexion angles failed to identify a new kinematic alignment force target associated with a good/excellent (≥ 34) Oxford Knee Score.

Conclusions Tibial compartment forces comparable to those reported for the native knee and insufficient sensitivity of the Oxford Knee and WOMAC scores might explain why mechanical alignment force targets were not useful and a force target was not identified for kinematic alignment. Intraoperative sensors may allow surgeons to measure forces very precisely in the operating room, but that level of precision is not called for to achieve a good/excellent result after calipered kinematically aligned TKA, and so its use may simply add expense and time but does not improve the results from the patient's viewpoint.

Level of Evidence Level III, therapeutic study.

Introduction

TKA relieves pain and restores high and durable function for patients with end-stage arthritis; however, approximately 20% of patients express some level of dissatisfaction [1, 2, 23]. Malalignment, stiffness, and instability are potential avoidable causes for early patient dissatisfaction and failure [35]. Measurement of intraoperative forces in the medial and lateral tibial compartments with instrumented tibial inserts is now possible [8, 10]. The assumption is that the development and use of force targets will guide surgeons when performing soft tissue releases, bone cuts, and selecting insert thickness. Aligning forces within the target might lower the risks of patient dissatisfaction and revision [8, 10, 16, 20, 21].

Although the appropriate level of force and the best range of differential force between compartments are not known, four force targets are being used with mechanically aligned TKA. Four studies have proposed different mechanical alignment force targets for balancing posterior cruciate-retaining (CR) and posterior-stabilized (PS) TKAs in an attempt to predict early patient-reported outcome measures [8, 10, 16, 20, 21]. Gustke's force target for a CR and PS TKA is a < 15-pound absolute difference in force between tibial compartments at 10°, 45°, and 90° of flexion [8, 10]. Jacobs' force target for a CR TKA is a > 10-pound force in the medial compartment at full extension [16]. Meere's force target for a CR TKA is a 0.35 to 0.65 ratio of medial to total compartment force between 0° and 90° of flexion [20]. Meneghini's force target for a CR and PS TKA is a < 60-pound absolute difference in force between tibial compartments averaged over 0°, 45°, and 90° of flexion [21].

Kinematic alignment is of interest because three randomized trials and a national multicenter study showed that patients treated with kinematically aligned TKA reported better pain relief, function, flexion, and a more normal-feeling knee than patients treated with mechanically aligned TKA [3, 4, 19, 23], whereas two randomized trials showed similar clinical outcomes [41, 42].

Tibial compartment forces measured during the kinematic alignment technique that used 10 caliper measurements for verification checks without ligament release are comparable to those of the native knee without evidence of compartment overload [32, 37]. To date the usefulness of these mechanical alignment force targets with kinematic alignment has not been reported nor has a specific force target for kinematic alignment been identified. Intraoperative tibial compartment forces have been measured after kinematically aligned TKA [12, 14, 25]; although the risk of compartment overload is low, a kinematic alignment force target that predicts early patient-reported outcomes has not been identified and would be of clinical interest.

Accordingly, the present study asked two questions: (1) Does hitting one of four mechanical alignment force targets proposed by Gustke, Jacobs, Meere, and Menghini determine whether a patient with a kinematically aligned TKA had better patient-reported Oxford Knee and WOMAC scores at 6 months? (2) Can a new force target be identified for kinematic alignment that determines whether the patient had a good/excellent Oxford Knee Score of ≥ 34 points (48 best, 0 worst)?

Patients and Methods

An institutional review board approved this retrospective study of patients. Between July 2017 and November 2017, we performed 148 primary TKAs with kinematic alignment using 10 serial caliper measurements and sequential verification checks. A total of 68 of the 148 (46%) TKAs performed during the study period had intraoperative measurements of medial and lateral tibial compartment forces during passive motion with an instrumented tibial insert (Verasense™; Orthosensor Inc, Dania Beach, FL, USA) and were evaluated in this retrospective study. The availability of the orthopaedic resident (TJS) determined the days on which patients were studied making the selection of patients a "convenience" and nonrandomized sample. The indications for TKA included disabling symptoms that had not resolved after conservative knee treatment, radiographic evidence of Kellgren-Lawrence Grade 2 to 4 arthritic changes or osteonecrosis, any severity of varus or valgus deformity as measured when nonweightbearing with a goniometer, and any severity of flexion contracture. On those surgical days that the orthopaedic resident (TJS) was available for data collection, 68 patients were selected for intraoperative measurement of tibial compartment forces. We excluded patients with inflammatory arthroplasty, prior knee infection, prior arthroplasty, evidence of dementia, or an inability to comprehend English. Before surgery, each patient completed a written questionnaire consisting of the Oxford Knee Score (48 best, 0 worst) and WOMAC (0 best, 96 worst) questionnaires in the preoperative waiting area before signing the surgical consent.

Kinematic alignment was performed using 10 sequential caliper measurements and a series of verification checks with manual instruments using a previously described technique by a single surgeon (SMH) using a midvastus approach [13, 15, 22, 24, 26]. A posterior cruciate ligament-retaining implant and patella button were implanted with cement (Vanguard® cruciate-retaining; Zimmer Biomet, Warsaw, IN, USA). The following steps are detailed because tibial compartment forces are affected by the settings of the femoral and tibial components.

For the femoral component, the varus-valgus orientation and proximal-distal location were set coincident with the native joint line by adjusting the thickness of the distal medial and distal lateral femoral resections as measured with a caliper to within 0 ± 0.5 mm of the thickness of the femoral component condyles after compensating for cartilage wear and kerf of the saw blade. The internal-external orientation and AP location were set based on the native joint line by adjusting the thickness of the posterior medial and posterior lateral femoral resections as measured with a caliper to within 0 ± 0.5 mm of the thickness of the femoral component condyles after compensating for cartilage wear and kerf. These steps set the femoral component with a bias of 0.3° and precision of ± 1.1° with respect to the flexion-extension plane of the knee and reliably aligned the flexion-extension axis of the femoral condyle to the flexion-extension axis of the knee [24, 29].

For the tibial component, the varus-valgus orientation was set coincident with the native joint line using the following two verification checks. First, the thickness of the medial and lateral tibial resections measured at the base of the tibial spines with a caliper was adjusted within 0 ± 0.5 mm. Second, with the knee in full extension, the varus-valgus angle of the tibial resection was adjusted working in 1° to 2° increments until the varus-valgus liftoff of the trial tibial component on the femoral component was negligible. These verification checks restore the native rectangular extension space, laxities, and alignments of the limb and femoral and tibial joint lines [17, 26, 30, 31]. The internal-external rotation of the tibial component was set using a kinematic tibial template with a negligible bias of 0.1° external and a precision of ± 3.9° [28, 32]. The slope was set coincident with the native joint line, working in 1° to 2° increments, using the following two verification checks with the knee in 90° of flexion. First, the offset of the anterior tibia from the distal medial femoral condyle with trial components matched that of the knee at exposure after adjusting for cartilage wear on the femur. Second, the passive internal-external rotation of the tibia on the femur approximated 14°, which restored the native laxity [11, 12, 31]. Ligament releases were not performed. Alignment references such as the femoral and tibial mechanical axes, transepicondylar axis, and tibial tubercle border were not used when performing kinematic alignment [13]. All components were cemented. The tibial insert was opened but not implanted.

The tablet screen that displayed compressive force in the medial and lateral tibial compartments measured in pounds by a commercially available instrumented tibial insert was activated and rotated away from the view of the surgeon and surgical team (Verasense; Orthosensor Inc) [6, 7]. The sensor was assembled using the thickness of the insert to be implanted. The sensor was zeroed and inserted in the knee. Towel clips applied proximal and distal to the patella provisionally closed the extensor mechanism. Passively cycling the knee from the limits of full extension to full flexion three times preconditioned the knee. The orthopaedic resident (TJS) activated a video camera in a smartphone and simultaneously recorded the tablet screen showing the medial and lateral tibial compartment forces and flexion-extension position of the knee during three cycles of passive motion. The tablet screen faced away from the surgeon's view, and his assessment of the forces took place after wound closure. The method of applying the passive motion minimized varus or valgus and internal or external rotational moments at the knee by placing the dorsal aspect of the other hand under the heel and by placing one hand on the posterior aspect of the thigh away from the popliteal fossa so that flexion was not limited. Because the surgeon and surgical team were blinded from the display showing the compartment forces, they were not available for use when balancing the knee. The medial and lateral compartment forces from three cycles of passive motion were averaged at full extension and 10°, 30°, 45°, 60°, 75°, and 90° of flexion. The intraclass correlation coefficient for the medial tibial compartment force was 0.95 at full extension, 0.96 at 45°, and 0.97 at 90° of flexion, and for the lateral tibial compartment force was 0.89 at full extension, 0.82 at 45°, and 0.96 at 90° of flexion [37].

At 6 months, all 68 patients filled out the written questionnaire consisting of the Oxford Knee Score and WOMAC score.

Statistical Analysis

A power analysis estimated the minimum sample size needed to observe a significant difference between patients who hit or missed a mechanical alignment force target. The analysis used a clinically important difference in the Oxford Knee Score of 5 points, a SD of 7 points, $\alpha = 0.05$, and a power = 0.80 [23]. Sixty-four patients achieve this degree of power, which indicates the selection of the 68 patients provided adequate power.

Continuous variables were reported as mean ± SDs and categorical variables were reported as a number or a percentage of patients. Patients were grouped according to whether they hit or missed the mechanical alignment force targets of Gustke et al. [7, 8], Jacobs et al. [16], Meere et al. [20], and Meneghini et al. [21]. A Wilcoxon rank-sum test determined whether the Oxford Knee Score and WOMAC score were different between groups 6 months postoperatively. To identify a kinematic alignment force target, a logistic regression with a binary outcome computed the area under the curve (AUC) of the receiver operating characteristic to determine whether the difference in tibial compartment force (that is, medial minus the lateral) at full extension and 10°, 30°, 45°, 60°, 75°, and 90° of flexion predicted either a better (≥ 34) or worse (≤ 33) 6-month Oxford Knee Score. The binary outcome was derived by combining the excellent (> 41) with the good (41 to 34) and the fair (33 to 27) with the poor (< 27) Kalairajah classifications [18]. The value of this binary outcome is that a person with a 6-month Oxford score of > 41 or a 41 to 34 score has a 0.45% and a 0.73% risk of revision within 2 years, which are significantly less than the 1.43% risk and 5.67% risk with a score of 33 to 27 and < 27, respectively, according to the New Zealand arthroplasty registry [39].

Based on a rough classifying system, AUC can be interpreted as follows: 90 to 100 = excellent; 80 to 90 = good; 70 to 80 = fair; 60 to 70 = poor; and 50 to 60 = fail [34]. The computations were performed with statistical software (JMP Pro, 13.0; SAS Institute Inc, Cary, NC, USA). Significance was set at $p < 0.05$.

Results

Descriptive statistics of preoperative clinical characteristics, knee conditions, and function of selected (n = 68) and not selected (n = 80) patients are shown (Table 1). Preoperatively, there were no significant differences in age, proportion of women, body mass index, extension, flexion, varus or valgus deformities, Oxford Knee Score, Knee Society Score, or Knee Function Score between selected and not selected patients.

Descriptive statistics for the medial and lateral tibial compartment forces recorded in pounds at full extension and 10°, 30°, 45°, 60°, 75°, and 90° of flexion are listed (Table 2). The mean (± SD) force computed as the average of the forces at 0°, 45°, and 90° in the present study of 21 ± 17 pounds and 7 ± 8 pounds for the medial and lateral tibial compartments was not different from the 14 ± 7 pounds and 6 ± 3 pounds reported by Verstraete et al. for the medial and lateral tibial compartments of the native knee, respectively ($p = 0.520$; $p = 0.819$) [40]. At 6 months, the mean Oxford Knee Score was 40 ± 7 and the mean WOMAC score was 15 ± 14.

Overall, the 6-month Oxford Knee Score and the WOMAC scores of patients grouped accordingly to whether hit or missed a mechanical alignment force target were not significantly different. For the Gustke force target of < 15 pounds, the absolute difference in force between tibial compartments at 10°, 45°, and 90° of flexion [8, 10] and the mean Oxford Knee Score of 41 ± 6 and WOMAC score of 13 ± 11 for the 31 patients who hit the target were

Table 1. Comparisons of preoperative clinical characteristics, knee conditions, and function for patients selected (N = 68) and not selected (N = 80) for enrollment in the present study between July 2016 and November 2016

Parameters	Selected (N = 68)	Not selected (N = 80)	p value
Preoperative clinical characteristics			
Age (years)	69 ± 7	68 ± 9	0.319
Sex (male) N (%)	35 (51%)	30 (38%)	0.099
Body mass index (kg/m^2)	29 ± 5	30 ± 5	0.156
Preoperative knee conditions			
Knee extension (°)	11 ± 7	10 ± 8	0.413
Knee flexion (°)	112 ± 11	112 ± 9	0.924
Valgus (-)/varus (+) deformity (°)	1 ± 13	-3 ± 13	0.191
Preoperative function			
Oxford Knee Score	23 ± 8	22 ± 8	0.350
Knee Society Score	32 ± 13	34 ± 16	0.560
Knee Society function	52 ± 16	48 ± 21	0.184

Values are mean ± SD; Wilcoxon rank-sum test determined p values; significance set at $p < 0.05$.

Table 2. Mean, SD, median, minimum, and maximum values of the medial and lateral tibial compartment forces at full extension and 10°, 30°, 45°, 60°, 75°, and 90° of flexion

Variable	Mean	SD	Median	Minimum	Maximum
Medial tibial compartment force (pounds)					
Full extension	27	23	22	0	89
10° flexion	29	23	23	0	83
30° flexion	24	19	19	0	69
45° flexion	22	18	35	0	63
60° flexion	19	17	13	0	62
75° flexion	17	16	12	0	61
90° flexion	15	15	10	0	58
Lateral tibial compartment force (pounds)					
Full extension	12	14	7	0	68
10° flexion	12	13	9	0	64
30° flexion	9	11	7	0	56
45° flexion	7	9	4	0	50
60° flexion	5	8	3	0	44
75° flexion	4	7	1	0	37
90° flexion	4	6	1	0	28

not different from the Oxford Knee Score of 39 ± 8 (p = 0.436) and WOMAC score of 17 ± 17 (p = 0.463) for the 37 patients who missed the target (Fig. 1). For the Jacobs force target of a > 10-pound force in the medial compartment at full extension [16], the mean Oxford Knee Score of 40 ± 7 and WOMAC scores of 18 ± 16 for the 32 patients who hit the target were not different from the Oxford Knee Score of 40 ± 7 (p = 0.887) and WOMAC scores of 13 ± 13 (p = 0.382) of the 36 patients who missed the target (Fig. 2). For the Meere force target of a 0.35:0.65 ratio of medial-to-total compartment force between 0° and 90° of flexion [20], the mean Oxford Knee Score of 39 ± 8 and WOMAC scores of 17 ± 16 for the 40 patients who hit the target were not different from the Oxford Knee Score of 41 ± 6 (p = 0.453) and WOMAC score of 13 ± 13 (p = 0.221) of the 28 patients who missed the target (Fig. 3). For the Meneghini force target of < 60-pound absolute difference in force between tibial compartments averaged over 0°, 45°, and 90° of flexion [21], 67 of 68 patients hit this force target, so the comparison of patient-reported outcome measures could not be performed.

A new force target for kinematic alignment was not identified at full extension or 10°, 30°, 45°, 60°, 75°, and 90° of flexion. The low observed AUCs (from 0.56 to 0.58)

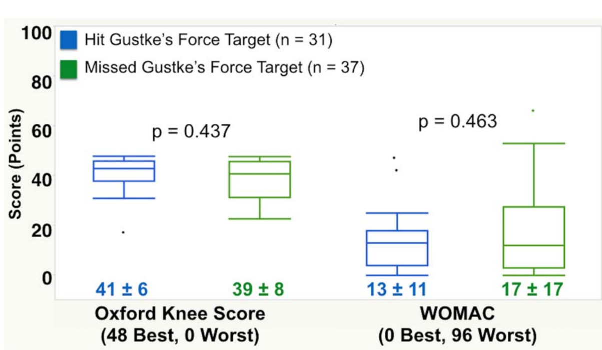

Fig. 1 Quantile box plots show the 6-month Oxford Knee Scores and WOMAC scores for patients who hit or missed Gustke's mechanical alignment force target of an absolute difference in force < 15 pounds at 10°, 45°, and 90° of flexion (n = number of patients) [10, 11]. Patients who hit or missed the force target had no differences in Oxford Knee Scores (41 versus 39; p = 0.437) and WOMAC scores (13 versus 17; p = 0.463).

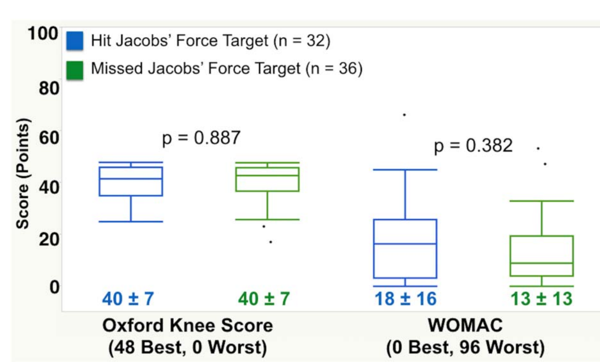

Fig. 2 Quantile box plots show the 6-month Oxford Knee Score and WOMAC scores for patients who hit or missed Jacobs' force target of 10 pounds greater force in the medial compartment at full extension [17]. Patients who hit or missed the force target had no differences in Oxford Knee Scores (40 versus 40; p = 0.887) and WOMAC scores (18 versus 13; p = 0.382).

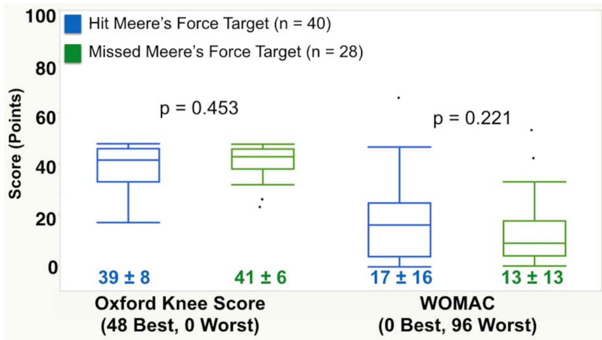

Fig. 3 Quantile box plots show the 6-month Oxford Knee Scores and WOMAC scores for patients who hit or missed Meere's force target of a ratio of medial to total force (medial + lateral force) of 0.35 to 0.65 at 0°, 30°, 30°, 60°, and 90° of flexion [21]. Patients who hit or missed the force target had no differences in Oxford Knee Scores (39 versus 41; p = 0.453) and WOMAC scores (17 versus 13; p = 0.221).

at each of these flexion angles failed to identify a force target associated with a better (≥ 34) or worse (≤ 33) Oxford Knee Score.

Discussion

The clinical value of an instrumented tibial insert is that force measurements in the medial and lateral tibial compartments can be used intraoperatively to balance the TKA and to hit a force target that predicts a better patient-reported outcome score [8, 10, 16, 21]. Kinematic alignment without ligament release restores tibial compartment forces comparable to those reported for the native knee, which explains why the four mechanical alignment force targets were not useful and a force target was not identified when the Oxford Knee and WOMAC scores determined clinical outcome. Therefore, intraoperative sensors may allow surgeons to measure forces very precisely in the operating room, but that level of precision is not called for to achieve a good/excellent result after calipered kinematically aligned TKA, and so its use may simply add expense and time but does not improve the results from the patient's viewpoint.

Several limitations might affect the generalization of the findings. First, the convenience sampling of 68 of 148 consecutive patients based on the availability of the resident might have caused selection bias with preoperative characteristics differing between selected and nonselected patients or transfer bias where treatment was not consistent across groups. We found no evidence for either, because there were no significant differences in preoperative clinical characteristics, knee conditions, or function between the selected and not selected patients (Table 1). A transfer bias was not detected because all patients were treated with calipered kinematically aligned TKA. Second, the present study used a postoperative interval of 6 months for determining whether the four mechanical alignment force targets predicted the Oxford Knee and WOMAC scores after kinematically aligned TKA. The 6-month interval was comparable to the 6-month interval used by Gustke et al. [8, 10] and Jacobs et al. [16] and the 4-month interval used by Meneghini et al. [21]. The 6-month interval was necessary for determining whether the mechanical alignment force targets predict clinical outcome after kinematically aligned TKA and was reasonable for defining a force target for kinematically aligned TKA. The 6-month Oxford Knee Score has long-term implications because it predicts the risk of implant failure and the patient's score at 2 years [33, 39]. Hence, the use of a 6-month interval did not affect the generalizations of the findings. Third, insufficient sensitivity of the Oxford Knee and WOMAC scores resulting from a "ceiling effect" might explain the inability to differentiate the clinical outcomes between those patients who hit or missed each target. However, the ceiling effect of these outcome scores did not compromise the findings of those randomized clinical trials that showed kinematic alignment restored better clinical outcomes than mechanical alignment [3, 4]. Fourth, the results of the present study represent one design of a CR implant and might not be generalizable to other implant designs such as posterior cruciate ligament-substituting, which are reported to have higher lateral compartment forces than CR knees [21].

There are several reasons for the inability of the four mechanical alignment force targets to predict early patient-reported outcome scores and the inability to identify a new kinematic alignment force target. One reason is that the forces in the medial and lateral compartments of the kinematically aligned TKA without ligament release were comparable to those of the native knee and three to six times lower than those of a mechanically aligned TKA in which soft tissue releases were performed [9, 10, 16, 20, 21, 40]. Hence, the effectiveness of the mechanical alignment force targets might depend on whether the compartment forces are greater than those of the native knee. The sensitivity of the Oxford Knee and WOMAC scores might have been insufficient to detect a difference in outcome when compartment forces are restored to those of the native knee. The WOMAC score was sufficiently sensitive because "balanced" patients, according to the Gustke mechanical alignment force target, had an 8-point higher score than "unbalanced" patients [7]. Accordingly, the use of mechanical alignment forces targets cannot be recommended with kinematic alignment when contact forces are restored to those of the native knee and outcomes are measured with the Oxford Knee and WOMAC scores.

The value of intraoperatively measuring compartment forces increases when the forces are higher than those of the native knee. Knowing that a kinematically aligned TKA has native tibial compartment forces reassures the surgeon that the articular surfaces of the components were set geometrically coincident with the native joint lines and that ligament release is not needed. In contrast, mechanical alignment changes the native joint lines in most patients, which requires the setting of the femoral and tibial components outside or inside the bounds of the native joint line [5, 27, 38]. Setting a component outside the bound without setting the opposing component equally inside the bound distracts the joint. Resecting less bone distally than posteriorly or posteriorly than distally on a femoral condyle either distracts or slackens the ligamentous sleeve in extension and flexion, which is a common imbalance in mechanical alignment that is uncorrectable with a ligament release [5]. A 2-mm distraction increases the tibial force 30 pounds, which, being double that of the native knee, causes 3° extension loss, 3° flexion loss, and 3-mm anterior translation of the tibia at 90° of flexion indicating stiffness [36]. Hence, there is value in measuring tibial compartment forces when they are higher than those of the native knee as the surgeon is notified that the ligamentous sleeve is overtensioned and there is a need to either change the orientations and positions of the components or release a ligament to lower the risks of motion loss, anterior tibial translation, and stiffness.

In summary, the use of mechanical alignment force targets with kinematic alignment cannot be recommended. Intraoperative sensors may allow surgeons to measure forces very precisely in the operating room, but that level of precision is not called for to achieve a good/excellent result after calipered kinematically aligned TKA, and so its use may simply add expense and time but does not improve the results from the patient's viewpoint.

Acknowledgments We thank Jessica De Anda and Paloma Batres for sending out and collecting outcome questionnaires.

References

1. Baker PN, van der Meulen JH, Lewsey J, Gregg PJ; National Joint Registry for England and Wales. The role of pain and function in determining patient satisfaction after total knee replacement. Data from the National Joint Registry for England and Wales. *J Bone Joint Surg Br*. 2007;89:893-900.
2. Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron KDJ. Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? *Clin Orthop Relat Res*. 2010; 468:57-63.
3. Calliess T, Bauer K, Stukenborg-Colsman C, Windhagen H, Budde S, Ettinger M. PSI kinematic versus non-PSI mechanical alignment in total knee arthroplasty: a prospective, randomized study. *Knee Surg Sports Traumatol Arthrosc*. 2017; 25:1743-1748.
4. Dossett HG, Estrada NA, Swartz GJ, LeFevre GW, Kwasman BG. A randomised controlled trial of kinematically and mechanically aligned total knee replacements: two-year clinical results. *Bone Joint J*. 2014;96:907-913.
5. Gu Y, Roth JD, Howell SM, Hull ML. How frequently do four methods for mechanically aligning a total knee arthroplasty cause collateral ligament imbalance and change alignment from normal in white patients? *J Bone Joint Surg Am*. 2014;96:e101.
6. Gustke K. Use of smart trials for soft-tissue balancing in total knee replacement surgery. *J Bone Joint Surg Br*. 2012;94: 147-150.
7. Gustke KA. Soft-tissue and alignment correction: the use of smart trials in total knee replacement. *Bone Joint J*. 2014;96: 78-83.
8. Gustke KA, Golladay GJ, Roche MW, Elson LC, Anderson CR. A new method for defining balance: promising short-term clinical outcomes of sensor-guided TKA. *J Arthroplasty*. 2014;29: 955-960.
9. Gustke KA, Golladay GJ, Roche MW, Elson LC, Anderson CR. Primary TKA patients with quantifiably balanced soft-tissue achieve significant clinical gains sooner than unbalanced patients. *Adv Orthop*. 2014;2014:628695. doi: 10.1155/2014/628695. Epub 2014 Aug 18.
10. Gustke KA, Golladay GJ, Roche MW, Jerry GJ, Elson LC, Anderson CR. Increased satisfaction after total knee replacement using sensor-guided technology. *Bone Joint J*. 2014;96:1333-1338.
11. Heesterbeek P, Keijsers N, Jacobs W, Verdonschot N, Wymenga A. Posterior cruciate ligament recruitment affects antero-posterior translation during flexion gap distraction in total knee replacement. An intraoperative study involving 50 patients. *Acta Orthop*. 2010;81:471-477.
12. Howell SM, Howell SJ, Kuznik KT, Cohen J, Hull ML. Does a kinematically aligned total knee arthroplasty restore function without failure regardless of alignment category? *Clin Orthop Relat Res*. 2013;471:1000-1007.
13. Howell SM, Hull ML, Mahfouz MR. Kinematic alignment in total knee arthroplasty In: W Scott, ed. *Insall and Scott Surgery of the Knee*. 6th ed. Philadelphia, PA, USA: Elsevier; 2017: 1784-1796.
14. Howell SM, Papadopoulos S, Kuznik K, Ghaly LR, Hull ML. Does varus alignment adversely affect implant survival and function six years after kinematically aligned total knee arthroplasty? *Int Orthop*. 2015;39:2117-2124.
15. Howell SM, Papadopoulos S, Kuznik KT, Hull ML. Accurate alignment and high function after kinematically aligned TKA performed with generic instruments. *Knee Surg Sports Traumatol Arthrosc*. 2013;21:2271-2280.
16. Jacobs CA, Christensen CP, Karthikeyan T. Greater medial compartment forces during total knee arthroplasty associated with improved patient satisfaction and ability to navigate stairs. *J Arthroplasty*. 2016;31:87-90.
17. Johnson JM, Mahfouz MR, Midillioglu MR, Nedopil AJ, Howell SM. Three-dimensional analysis of the tibial resection plane relative to the arthritic tibial plateau in total knee arthroplasty. *J Exp Orthop*. 2017;4:27.
18. Kalairajah Y, Azurza K, Hulme C, Molloy S, Drabu KJ. Health outcome measures in the evaluation of total hip arthroplasties–a comparison between the Harris hip score and the Oxford hip score. *J Arthroplasty*. 2005;20:1037-1041.
19. Matsumoto T, Takayama K, Ishida K, Hayashi S, Hashimoto S, Kuroda R. Radiological and clinical comparison of kinematically versus mechanically aligned total knee arthroplasty. *Bone Joint J*. 2017;99:640-646.
20. Meere PA, Schneider SM, Walker PS. Accuracy of balancing at total knee surgery using an instrumented tibial trial. *J Arthroplasty*. 2016;31:1938-1942.
21. Meneghini RM, Ziemba-Davis MM, Lovro LR, Ireland PH, Damer BM. Can intraoperative sensors determine the 'target'

ligament balance? Early outcomes in total knee arthroplasty. *J Arthroplasty*. 2016;31:2181-2187.
22. Nam D, Lin KM, Howell SM, Hull ML. Femoral bone and cartilage wear is predictable at 0 degrees and 90 degrees in the osteoarthritic knee treated with total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc*. 2014;22:2975-2981.
23. Nam D, Nunley RM, Barrack RL. Patient dissatisfaction following total knee replacement: a growing concern? *Bone Joint J*. 2014;96:96-100.
24. Nedopil AJ, Howell SM, Hull ML. Does malrotation of the tibial and femoral components compromise function in kinematically aligned total knee arthroplasty? *Orthop Clin North Am*. 2016;47:41-50.
25. Nedopil AJ, Howell SM, Hull ML. What mechanisms are associated with tibial component failure after kinematically-aligned total knee arthroplasty? *Int Orthop*. 2017;41:1561-1569.
26. Nedopil AJ, Singh AK, Howell SM, Hull ML. Does calipered kinematically aligned TKA restore native left to right symmetry of the lower limb and improve function? *J Arthroplasty*. 2018;33:398-406.
27. Niki Y, Sassa T, Nagai K, Harato K, Kobayashi S, Yamashita T. Mechanically aligned total knee arthroplasty carries a risk of bony gap changes and flexion-extension axis displacement. *Knee Surg Sports Traumatol Arthrosc*. 2017;25:3452-3458.
28. Paschos NK, Howell SM, Johnson JM, Mahfouz MR. Can kinematic tibial templates assist the surgeon locating the flexion and extension plane of the knee? *Knee*. 2017;24:1006-1015.
29. Riviere C, Iranpour F, Harris S, Auvinet E, Aframian A, Chabrand P, Cobb J. The kinematic alignment technique for TKA reliably aligns the femoral component with the cylindrical axis. *Orthop Traumatol Surg Res*. 2017;103:1069-1073.
30. Roth JD. How Well Does Kinematically Aligned Total Knee Arthroplasty Prevent Clinically Important Changes in Passive Knee Function? An In Vitro Biomechanical Study of Tibiofemoral Laxities and Contact. Davis, CA, USA: University of California, Davis: ProQuest Dissertations Publishing; 2016.
31. Roth JD, Howell SM, Hull ML. Native knee laxities at 0 degrees, 45 degrees, and 90 degrees of flexion and their relationship to the goal of the gap-balancing alignment method of total knee arthroplasty. *J Bone Joint Surg Am*. 2015;97:1678-1684.
32. Roth JD, Howell SM, Hull ML. Kinematically aligned total knee arthroplasty limits high tibial forces, differences in tibial forces between compartments, and abnormal tibial contact kinematics during passive flexion. *Knee Surg Sports Traumatol Arthrosc*. 2018;26:1589-1601.
33. Rothwell AG, Hooper GJ, Hobbs A, Frampton CM. An analysis of the Oxford hip and knee scores and their relationship to early joint revision in the New Zealand Joint Registry. *J Bone Joint Surg Br*. 2010;92:413-418.
34. Safari S, Baratloo A, Elfil M, Negida A. Evidence based emergency medicine; part 5 receiver operating curve and area under the curve. *Emerg (Tehran)*. 2016;4:111-113.
35. Schroer WC, Berend KR, Lombardi AV, Barnes CL, Bolognesi MP, Berend ME, Ritter MA, Nunley RM. Why are total knees failing today? Etiology of total knee revision in 2010 and 2011. *J Arthroplasty*. 2013;28:116-119.
36. Shelton TJ, Howell SM, Hull ML. A total knee arthroplasty is stiffer when the intraoperative tibial force is greater than the native knee. *J Knee Surg*. 2018 Nov. 9. [Epub ahead of print]
37. Shelton TJ, Nedopil AJ, Howell SM, Hull ML. Do varus or valgus outliers have higher forces in the medial or lateral compartments than those which are in-range after a kinematically aligned total knee arthroplasty? limb and joint line alignment after kinematically aligned total knee arthroplasty. *Bone Joint J*. 2017;99:1319-1328.
38. Singh AK, Nedopil AJ, Howell SM, Hull ML. Does alignment of the limb and tibial width determine relative narrowing between compartments when planning mechanically aligned TKA? *Arch Orthop Trauma Surg*. 2018;138:91-97.
39. The New Zealand Joint Registry 18 Year Report: January 1999 to December 2016. Available at: https://nzoa.org.nz/system/files/DH7827_NZJR_2017_Report_v4_26Oct17.pdf. Accessed October 5, 2018.
40. Verstraete MA, Meere PA, Salvadore G, Victor J, Walker PS. Contact forces in the tibiofemoral joint from soft tissue tensions: implications to soft tissue balancing in total knee arthroplasty. *J Biomech*. 2017;58:195-202.
41. Waterson HB, Clement ND, Eyres KS, Mandalia VI, Toms AD. The early outcome of kinematic versus mechanical alignment in total knee arthroplasty: a prospective randomised control trial. *Bone Joint J*. 2016;98:1360-1368.
42. Young SW, Walker ML, Bayan A, Briant-Evans T, Pavlou P, Farrington B. The Chitranjan S. Ranawat Award: No difference in 2-year functional outcomes using kinematic versus mechanical alignment in TKA: a randomized controlled clinical trial. *Clin Orthop Relat Res*. 2017;475:9-20.