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Variability between the trial and final implant measurements during the sensor-guided total knee arthroplasty

Jong-Keun Kim[1] · Do Weon Lee[2] · Du Hyun Ro[2] · Hyuk-Soo Han[2] · Myung Chul Lee[2]

Abstract

Purpose Compartmental load-sensing technology has been used in the attempt to achieve optimal soft tissue balance during total knee arthroplasty (TKA). This study was conducted to investigate the validity of such use of intraoperative sensing technology.

Methods Ninety-three knees scheduled to undergo total knee arthroplasty for knee osteoarthritis with a tibial sensor were prospectively enrolled. Measurements were divided into three groups according to the three different time points of intraoperative load testing: group Trial (with the trial components), group Final (with the definitive cemented implants and an open joint capsule), and group Closed (with the definitive cemented implants and a closed joint capsule). Load measurements and component rotational alignments were documented at 10°, 30°, 45°, 90°, and 120° of flexion for all three groups, and compared. One year postoperatively, the joint line obliquity angle was obtained radiographically in the valgus and varus stress views at 10° and 30° flexion to evaluate the clinical instability. The Knee Society, Hospital for Special Surgery, and Western Ontario McMaster Universities Osteoarthritis Index scores were used to determine functional outcomes. The correlations of the above outcomes with intraoperative load were evaluated.

Results There were significant differences in medial and lateral loads at all flexion angles (except at a 120° lateral load) between group Trial and group Final ($p < 0.05$). Tibial trays were internally rotated to a significantly higher degree in group Final than in group Trial ($p = 0.010$). The lateral compartmental load significantly decreased after patellar inversion ($p = 0.037$). There were no correlations of intraoperative load with clinical instability and functional outcomes.

Conclusion Significant variability was observed between the trial and final implant measurements and intraoperative sensing data were not correlated with instability or functional outcomes over a 1-year period. Therefore, intraoperative sensor technology provides limited feedback and clinical efficacy in the adjustment of the soft tissue balance during TKA.

Level of evidence Level II.

Keywords Sensor · Intraoperative load-sensing technology · Soft tissue balance · Total knee arthroplasty · Validation study

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Abbreviations

HSS	Hospital for Special Surgery
KS	Knee Society
ROM	Range of motion
TKA	Total knee arthroplasty
WOMAC	Western Ontario McMaster Universities Osteoarthritis Index

Introduction

Compartmental load-sensing technology was also introduced in the attempt to achieve optimal soft tissue balancing during TKA [4, 21]. A tibial sensor increases the accuracy of soft tissue balancing by quantifying the obscure feeling of

load or tension and providing real-time data while the knee is taken through a range of motions (ROMs) during TKA [5]. This technology has yielded promising results related to improved objectivity in load measurement and improved clinical outcomes [3, 6, 13, 14].

However, many of the above-mentioned studies were conducted by the designers of the sensor technology, and the follow-up periods were relatively short [4, 21]. Furthermore, several issues related to the variability of measurements have been noted, such as movement of the sensor in the trial compartment and a mismatched point in the tibial contact location [2, 15, 16, 18]. Most of these studies also included a relatively low number of patients or biomechanical parameters. Hence, the validity of the tibial sensor in the assessment of soft tissue balance remains unknown. Therefore, this study was conducted with a relatively large number of patients to investigate the validity of such use of the tibial sensor by focussing on not only the presence of variability between measurements at different time points in the operation but also the clinical outcomes. The hypothesis of the present study was that the use of sensors would have limited validity in TKA.

Materials and methods

From May 2017 to February 2020, 93 knees scheduled to undergo TKA for knee osteoarthritis were enrolled, and the data were collected prospectively. Exclusion criteria were as follows: age < 50 years or > 85 years; rheumatoid or traumatic arthritis; previous knee surgery; severe sagittal or coronal deformity (preoperative flexion contracture > 20° or mechanical axis > 20°); neuromuscular disorders such as cerebral palsy, infarct, and parkinsonism (Fig. 1). Demographic characteristics of patients are summarised in Table 1.

The LPS standard posterior-stabilised system (Zimmer Biomet, Warsaw, IN) was used for all TKAs. The VERASENSE sensor device (OrthoSensor Inc., Dania Beach, FL) was used to measure the load and rotation between the tibial and femoral components. The VERASENSE device is a sensor-embedded tibial trial that can detect tibiofemoral contact points throughout the ROM to evaluate loads, component alignment, ligament tension, and rotation. OrthoSensor's Link Station and cloud-based iQ software were used to wirelessly communicate with the sensor to provide real-time data and feedback during the surgical procedure.

Surgical procedure using the intraoperative sensor

One experienced, senior surgeon (M.C.L) performed all TKAs with routine procedures regardless of the measurement on the sensor device. The modified gap technique was performed in all cases, with the goal of neutral mechanical
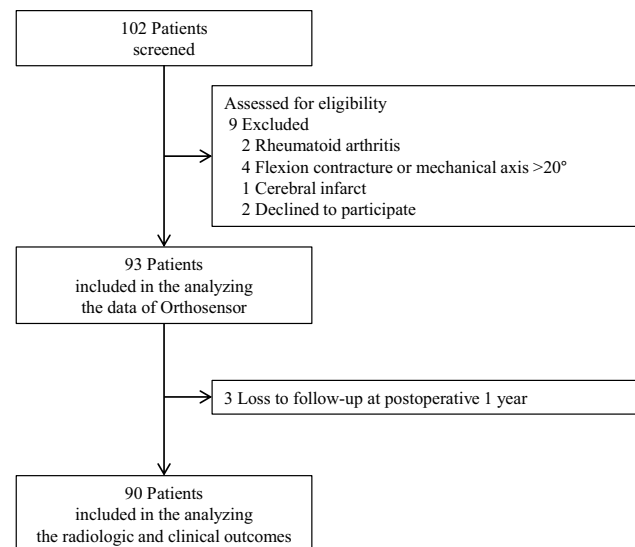

Fig. 1 Flowchart of patient eligibility and reasons for exclusion

Table 1 Summary of demographic characteristics

Number of patients	93
Age at surgery (year)	68.1 ± 5.0 (56–84)
Female/male (no.)	11/82
BMI (kg/m²)	27.1 ± 3.4 (18.9–34.6)
Right/left (no.)	45/48
Flexion contracture (°)	9.9 ± 7.8 (0–15)
Further flexion (°)	125.4 ± 14.3 (95–140)
Total range of motion (°)	113.6 ± 17.1 (90–140)
Mechanical axis (°)	9.1 ± 4.3 (-5.9–18.8)
Varus/valgus deformity (no.)	89/4
KS knee score	46.4 ± 15.8 (6–84)
KS function score	37.2 ± 14.7 (0–72)
HSS	63.5 ± 12.8 (24–86)
WOMAC pain	10.3 ± 3.2 (4–22)
WOMAC stiffness	4.2 ± 1.8 (1–9)
WOMAC function	35.9 ± 13.3 (12–69)

The values are presented as the mean and the standard deviation with the range in parentheses

BMI body max index, *KS* Knee Society, *HSS* Hospital for Special Surgery, and *WOMAC* Western Ontario and McMaster Universities Osteoarthritis index

alignment. Briefly, an anterior midline skin incision was made and medial parapatellar arthrotomy was performed with a tourniquet. As a preliminary step, medial soft tissue, such as the semitendinosus and deep medial collateral ligament, was released with removal of the medial osteophytes. Both the cruciate ligaments were resected. Distal femoral cutting was performed using an intramedullary guide perpendicular to the mechanical axis. Proximal tibial cutting was performed with an extramedullary guide perpendicular

to the mechanical axis. In the process of chamfer cutting, component rotation was determined with the modified gap technique, by tensioning the medial and lateral collateral ligaments in the direction of gravity. The Xcelerate Knee Balancer (Stryker Corporation, Kalamazoo, MI) was used to measure the tension of the medial and lateral soft tissue, and the femoral cutting block and alignment guide were used to measure the extension and flexion gaps. The medial and lateral gap differences were adjusted using a manual distraction device, and accepted when they were < 2 mm in size. Additional soft tissue, such as the semimembranosus and the popliteal tendon, was released to obtain equal-sized flexion and extension gaps and a rectangular flexion gap. The tibial rotation was determined by adjusting the tibial plate to the anterior border of the tibia and verifying its position upon knee extension when all trials (femur, insert, and tibia) were in position. Once the soft tissue balance was deemed adequate by the surgeon, the loads between the femoral and tibial trial components were measured by inserting the tibial sensor; these measurements were documented as 'Trial'. Loads were recorded in two compartments (medial and lateral) while taking the knee through the ROM. In addition, the angles of rotation between the femoral and tibial trial components were recorded through the ROM. The tibial trial components were free floating without pin insertion during measurements to allow positioning according to their natural movement. Subsequently, all trial components were removed and irrigation was performed. Thereafter, the bone was dried and the real components were fixed with cement (Palacos R + G pro, Heraeus Kulzer GmbH, Hanau, Germany) using a pressurisation technique, according to a previously described protocol [8]. The loads and rotations were measured in exactly the same way as for the Trial measurements; these results were documented as 'Final'. After resurfacing of the patella, the loads and rotations were measured again with relocation of the patella in the trochlear groove using two towel clips. These results were documented as 'Closed'. The trial components were placed after the final releases were performed following femoral and tibial resections, and no additional procedures related to soft tissue balancing were performed between each measurement phase.

Postoperative management and rehabilitation

Standardised postoperative rehabilitation and pain management were applied according to a previously described protocol [10]. Briefly, the knee was immobilised for the first day after the operation, and machine-assisted passive motion of the knee joint was begun within 24 h of the operation. Patients started walking from 24 h after the operation. From 48 h after the operation, the patients were encouraged to start supervised passive and active ROM exercises.

Outcome assessments

A clinical investigator blinded to the study, gathered all data. Measurements were divided into three groups: group Trial (with the trial components), group Final (with the definitive cemented implants and an open joint capsule), and group Closed (with the definitive cemented implants and a closed joint capsule). Compartment loads were measured in pounds (lbs). 'Quantifiably balanced' soft tissue was defined as that with a load difference between the mediolateral compartments of ≤ 15 lbs [7]. Component rotational alignments were also recorded at 10°, 30°, 45°, 90°, and 120° of flexion for all three groups, as the angle (°) between the femoral and tibial components.

To investigate the clinical validity of the sensor measurements, radiographs were obtained in the valgus and varus stress views at 10° and 30° flexion, 1 year after the operation. The correlation between the joint line obliquity angle in each view and the medial/lateral loads at 10° and 30° flexion was evaluated. At least two orthopaedic surgeons who specialise in knee surgery, all blinded to the surgery, repeatedly measured the joint line obliquity angle together to improve the reliability of measurement.

Functional outcomes in the form of the Knee Society (KS) score, Hospital for Special Surgery (HSS) score, and Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) score were evaluated 1 year after surgery [1, 9, 17]. The correlations between functional score and load difference between the medial and lateral compartments were evaluated to determine the load difference that could affect the clinical outcome.

Statistical analysis

Continuous variables are displayed as the mean ± standard deviation and were analysed with Student's t test (load, rotational angle, joint line obliquity angle, and functional score). Correlation and linear regression analyses were used to evaluate the association of the compartmental load with the joint line obliquity angle and functional outcomes. Statistical analyses were conducted using IBM SPSS Statistics for Windows (version 23.0; IBM Corp., Armonk, NY). A two-sided p value < 0.05 was considered statistically significant. A priori power analysis was performed based on the results of a previous study, in which the mean percentage of unbalanced knees was 13% [7]. Seventy-nine patients were required at a compensated alpha level of 0.05 and power of 80% (two-sided). Therefore, 93 patients were recruited to account for a 15% loss of participants.
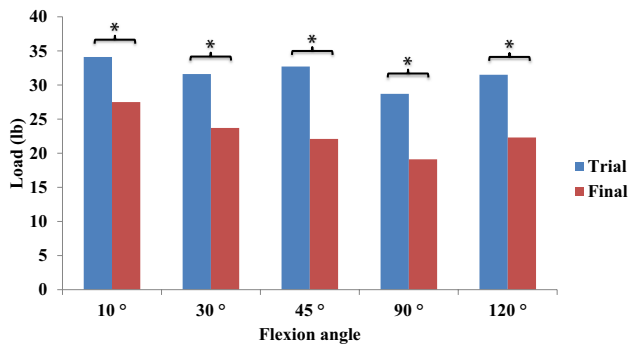
Fig. 2 Comparison of medial loads between groups Trial and Final. There were significant differences in medial loads in all flexion angles between groups Trial and Final
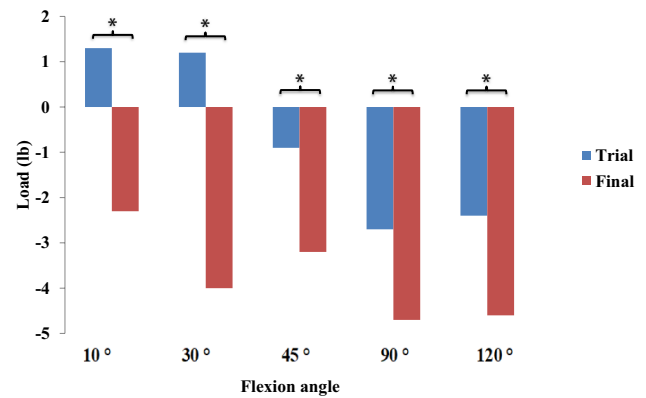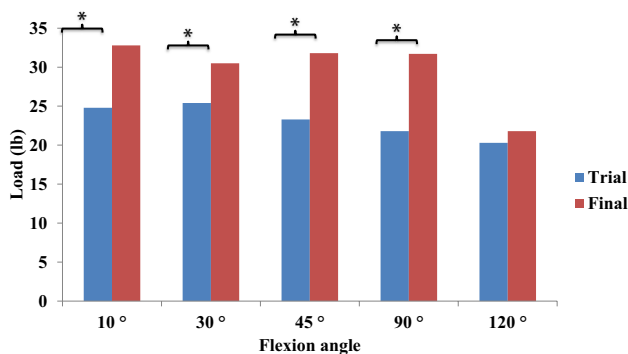

Fig. 3 Comparison of lateral loads between groups Trial and Final. There were significant differences in medial loads in all flexion angles (except 120°) between groups Trial and Final

Results

There were significant differences in medial and lateral loads at all flexion angles (except at a 120° lateral load) between group Trial and group Final (Figs. 2, 3). Medial loads were significantly higher in group Trial ($p = 0.016$),

Fig. 4 Comparison of rotation between groups Trial and Final. The tibial trays were positioned significantly more internally with the progression of knee joint flexion in both groups

whereas lateral loads were significantly higher in group Final ($p = 0.028$). Tibial trays were internally rotated to a significantly higher degree in group Final than in group Trial ($p = 0.010$) (Table 2). In addition, the tibial trays were positioned more internally with the progression of knee flexion in both groups (Fig. 4). The lateral compartmental load was significantly altered between group Final and group Closed, with a decreased lateral compartmental load after patellar inversion ($p = 0.037$) (Table 2, Fig. 5).

Only 90 patients were included for analyses because of loss to follow-up at 1 year after surgery (Fig. 1). No correlations between the intraoperative sensing data and any of the joint line obliquity angles were identified (Figs. 6, 7). In addition, there were no significant correlations between the load difference and the KS, HSS, or WOMAC scores (Fig. 8).

Table 2 Comparison of load and rotation between groups

	Trial	Final	Difference	*P* value
Medial load (lb)	31.8 ± 13	22.9 ± 16	10.2 ± 7	0.016
Lateral load (lb)	23.6 ± 8	30.7 ± 10	18.9 ± 9.9	0.028
Rotation (°)	−1.2 ± 0.7	−4.1 ± 2.1	2.6 ± 1.8	0.010
	Final	Close		
Medial load (lb)	22.9 ± 16	23.6 ± 16	1.2 ± 2	n.s
Lateral load (lb)	30.7 ± 10	27.3 ± 11	7.5 ± 3	0.037
Rotation (°)	−4.1 ± 2.1	−3.9 ± 2.2	0.1 ± 0.1	n.s

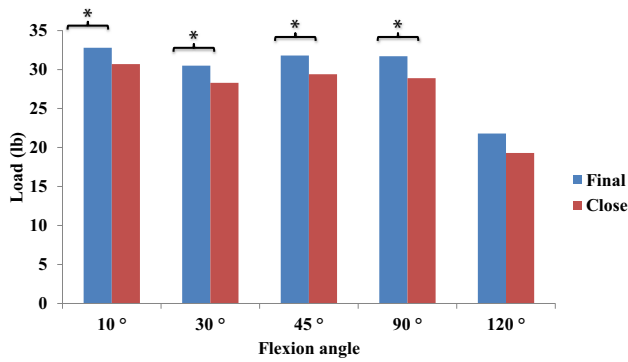The values are presented as the mean and the standard deviation

Fig. 5 Comparison of lateral loads between groups Final and Closed. Lateral compartment loads were significantly altered between groups Final and Closed, exhibiting decreased lateral compartment loads after the patella was everted
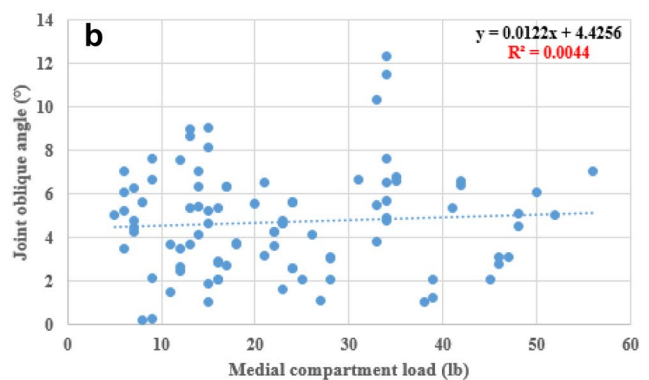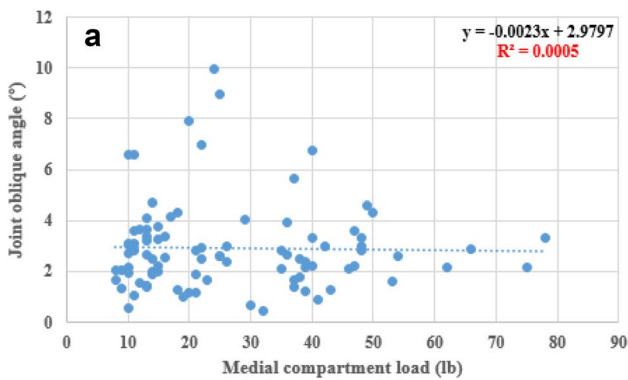
intraoperative load sensor was used during TKA. The main aim of this study was to investigate the validity of intraoperative sensor technology by evaluating the difference between the loads obtained when the sensor is used with the trial components and when it is inserted after implant cementation. To this end, an experienced, senior surgeon performed all TKAs while being blinded to the measurements of the sensor. Trials were placed after final releases were performed, and no additional balancing was performed between each measurement phase.

We observed unpredictable motion between the trial tibial plate and the cut surface of the tibial bone when the knee was flexed during TKA. Specifically, when the sensor was attached to the trial tibial plate, the measured load changed as the knee was flexed. Most balancing procedures should be performed before cementation, as the range of balanc-

Fig. 6 Correlation between valgus stress view and medial loads. There were no significant correlations in the 10° (**A**) and 30° (**B**) stress views
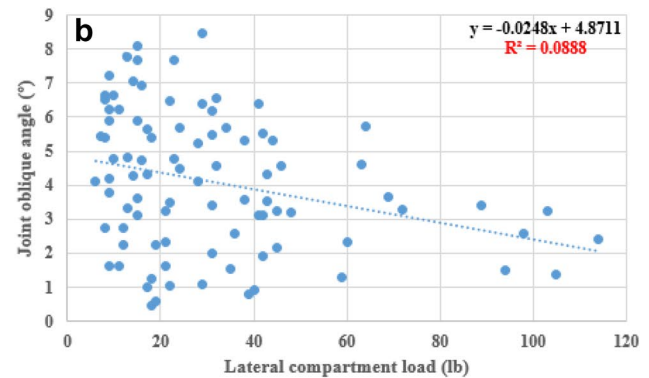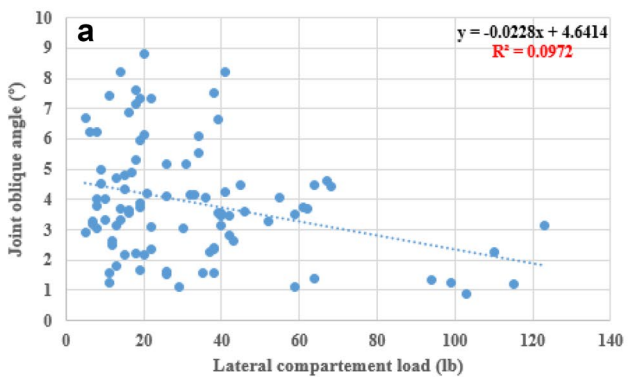

Fig. 7 Correlation between varus stress view and lateral loads. There were no significant correlations in the 10° (**A**) and 30° (**B**) stress views

Discussion

The most important finding of the present study is that statistically significant variations between the trial and final implant measurements were observed when the

ing is limited after cementing. Furthermore, modification of the rotational alignment is impossible after cementation. Therefore, the results of our study call into question the validity of the use of an intraoperative tibial sensor in the assessment of soft tissue balance and component rotational
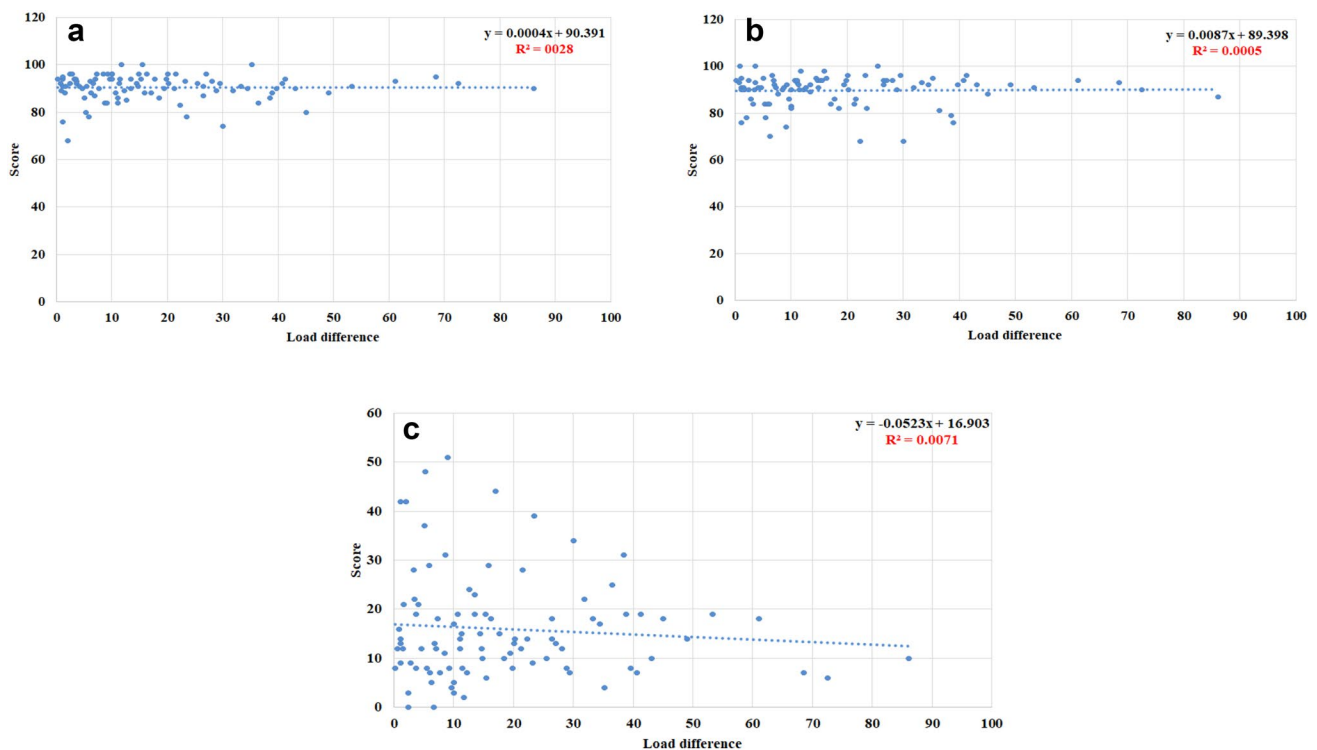
Fig. 8 Correlation between functional outcomes and load difference. There were no significant correlations in Knee Society Score (**A**), Hospital for Special Surgery score (**B**), and Western Ontario McMaster Universities Osteoarthritis Index (**C**)

alignment. Previous studies yielded similar results [2, 15, 16, 18]. Nodzo et al. [16] reported on a change in the load in the lateral compartment after cementation. Roche et al. [18] observed a statistically significant change in tibial rotational alignment after cementation. On the other hand, in another study, no statistically significant change in load was observed after cementation [23]. However, the authors of that study noted that the sample size might have been too small to detect such differences. In addition, a recently published biomechanical study revealed that the sensing area is smaller than the final tibial baseplate, which impair the accuracy of the trial measurement, as the contact location during flexion may be outside the sensing area [15].

The tibial trials were free floating without pin insertion during measurements to allow positioning according to their natural movement. Some surgeons recommend that a pin should be placed in either an anteromedial or an anterolateral position to stabilise the translational motion [7]. However, the unilateral insertion of a pin is not enough to fix the tibial; in fact, it is more likely to generate undesirable rotation along the axis of the pin. Furthermore, anterolateral pin placement may irritate the patellar tendon, affecting the load differences. On the other hand, pin insertion only on the anterior side may result in the lift-off of the posterior side of tibia plate during normal ROM.

The variability of the load in the lateral compartment was determined before and after patellar eversion in the present study. The lateral compartmental load statistically significantly increased after the patella was everted. After cement fixation, the expected results were obtained based on the physical position of the patella. Previous studies have yielded results similar to those of the present study [19, 20]. Furthermore, internal rotation of the tibial tray increased with flexion once the components were cemented in place, manifesting as lateral femoral condyle rollback and pivoting. These findings imply that firm fixation of the sensor to the tibial baseplate resulted in a more accurate reflection of the anatomical position of the knee and natural kinematics, justifying the results of the present study.

To the best of our knowledge, this is the first study in which the correlation between postoperative instability and intraoperative sensing data were investigated. The joint line obliquity angles were measured radiologically to assess the degree of instability. However, no clinical correlations were observed. This suggests that postoperative instability cannot be accurately predicted from the measurements obtained with the sensor. Moreover, none of the clinical scores we used was correlated with the intraoperative sensing data. Satisfactory soft tissue balance, as defined using intraoperative sensing data, was reportedly associated with positive clinical outcomes [6, 7, 14].

However, in multiple recently published studies, no specific correlations were reported [11, 12, 22]. One of the reasons for this discrepancy could be the fact that, other than the teams of the sensor technology designers, clinical research teams from around the world have also started to publish studies, providing abundant data for the objective evaluation and validation of the sensor technology.

This study has several limitations. First, the results may not be generalisable because of its single-centre nature and involvement of only one surgeon. The intraoperative sensing data may be biased because of the way in which the surgeon performed knee flexion, as an axial load from the ankle to the knee joint is inevitably generated during knee flexion. In the effort to overcome the limitations of the sensor during open-chain kinematic measurements, it is possible that the surgeon increased the axial load to the contact area, inducing an unexpected locking motion in the tibial baseplate. This motion could explain why the medial load was higher in group Trial. Furthermore, the higher lateral load in group Final suggests that the results of our procedure, conducted by one surgeon, may not be generalisable. We are currently working on solving this conundrum to ensure a balanced TKA. Further studies should be conducted to account for differences in the axial force applied by different surgeons. Second, the follow-up period was relatively short; therefore, long-term evaluation of knee stability and clinical outcomes was not possible. Specifically, instability may accumulate over time. Longer term studies of large sample size should be conducted to determine the correlation between intraoperative sensing data and clinical outcomes.

Conclusion

Most soft tissue balancing procedures should be completed before cementation; however, in the present study, statistically significant variability was observed between the trial and final implant measurements, and intraoperative sensing data were not correlated with the instability and functional outcome of TKA over a 1-year period. Therefore, intraoperative sensor technology provides limited feedback in adjusting soft tissue balance and clinical efficacy.

Declarations

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