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Tibiofemoral dynamic stressed gap laxities correlate with compartment load measurements in robotic arm-assisted total knee arthroplasty

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Aims

It is unknown whether gap laxities measured in robotic arm-assisted total knee arthroplasty (TKA) correlate to load sensor measurements. The aim of this study was to determine whether symmetry of the maximum medial and lateral gaps in extension and flexion was predictive of knee balance in extension and flexion respectively using different maximum thresholds of intercompartmental load difference (ICLD) to define balance.

Methods

A prospective cohort study of 165 patients undergoing functionally-aligned TKA was performed (176 TKAs). With trial components in situ, medial and lateral extension and flexion gaps were measured using robotic navigation while applying valgus and varus forces. The ICLD between medial and lateral compartments was measured in extension and flexion with the load sensor. The null hypothesis was that stressed gap symmetry would not correlate directly with sensor-defined soft tissue balance.

Results

In TKAs with a stressed medial-lateral gap difference of ≤ 1 mm, 147 (89%) had an ICLD of ≤ 15 lb in extension, and 112 (84%) had an ICLD of ≤ 15 lb in flexion; 157 (95%) had an ICLD ≤ 30 lb in extension, and 126 (94%) had an ICLD ≤ 30 lb in flexion; and 165 (100%) had an ICLD ≤ 60 lb in extension, and 133 (99%) had an ICLD ≤ 60 lb in flexion. With a 0 mm difference between the medial and lateral stressed gaps, 103 (91%) of TKA had an ICLD ≤ 15 lb in extension, decreasing to 155 (88%) when the difference between the medial and lateral stressed extension gaps increased to ± 3 mm. In flexion, 47 (77%) had an ICLD ≤ 15 lb with a medial-lateral gap difference of 0 mm, increasing to 147 (84%) at ± 3 mm.

Conclusion

This study found a strong relationship between intercompartmental loads and gap symmetry in extension and flexion measured with prostheses in situ. The results suggest that ICLD and medial-lateral gap difference provide similar assessment of soft-tissue balance in robotic arm-assisted TKA.

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Keywords: Restricted kinematic alignment, Functional positioning, Virtual gap balancing, Load sensor, Total knee arthroplasty, Robot-assisted TKA

Introduction

While total knee arthroplasty (TKA) is the treatment of choice for advanced osteoarthritis, revision rates remain high. The factors driving this are numerous, but among them is soft tissue imbalance, which may manifest as instability, stiffness and pain. Instability has been cited as the cause for around

20% of revisions, while stiffness and pain underlie up to 10%.¹⁻⁴ Kinematic alignment (KA) protocols that restore constitutional alignment produce a quantitative improvement in soft tissue balance when compared with mechanical alignment.⁵ Furthermore, KA TKA results in unequal medial and lateral gap laxities⁶ reflecting the soft

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tissue laxity characteristics of the native knee in its pre-arthritis state.⁷⁻¹⁰ The concept of ‘functional’ alignment has evolved from KA: it positions implants with minimal compromise of the soft tissue envelope by maintaining the obliquity of the native joint line, while adhering to accepted safe limits for implant and limb alignment. Using computer navigation or robot-assisted TKA, precise information is available both for limb alignment and the medial and lateral tibiofemoral gaps in extension and at 90° of flexion, allowing an individualized approach to achieving a balanced knee.¹¹

The intraoperative use of load sensors to determine soft tissue balance has been described.¹² However, the relationship between osteotomised joint gaps and compartmental loads remains unclear. While modelling has demonstrated a linear relationship between ligament forces and tibiofemoral contact forces during congruent articulation, increased joint distraction force *in vivo* is associated with increased varus knee alignment.^{13,14} It remains to be determined whether the stressed gaps (the maximum medial and lateral tibiofemoral gaps under valgus and varus loads) which are used currently to functionally position TKA implants are predictive of soft tissue balance.

This study sought to establish the relationship between maximum gap laxity and compartment loads in functionally aligned, robotic arm-assisted TKA. The aim was to investigate whether symmetry of the stressed extension and flexion gaps is predictive of evenly distributed loads, and therefore, predictive of soft tissue balance. The null hypothesis was that ‘balance’, as defined by incremental medial-lateral gap differentials in extension and flexion, would not correlate with ‘balance’, as determined by maximum ICLD values for extension and flexion.

Methods

Study design. We undertook a prospective cohort study of 187 patients aged 48 to 89 years undergoing robotic arm-assisted TKA, using an intraoperative load sensor and robotic gap measurements to assess soft tissue balance (200 TKA). Ethics approval was granted by the Hunter New England Local Health District Human Research Ethics Committee (authorization number EX202005-03) and patients provided written consent to have their operative data analyzed.

Study group. All patients underwent TKA between August 2018 and March 2020 by one of two fellowship-trained knee surgeons (SM, DC) in a private hospital (St George Hospital, Sydney, Australia). A consecutive series of 200 TKAs was assessed, excluding those procedures for which data were incomplete or posterior stabilized implants were used (24 TKAs in 22 patients excluded).

Operative technique. All 200 cases employed the Stryker Triathlon system (Stryker, USA) with onlay patellar resurfacing. Alignment and virtual gap balancing were

undertaken using the Mako robotic arm-assisted system (Stryker), with sensor loads recorded using the Verasense load monitoring insert (OrthoSensor, USA).

Both surgeons followed a standardised operative protocol employing a restricted kinematic philosophy to reproduce functional alignment. As described in the coronal plane alignment of the knee (CPAK) classification,¹⁵ the medial proximal tibial angle (MPTA) and lateral distal femoral angle (LDFA) were measured from four-foot standing radiographs. From these values, the constitutional alignment (arithmetic hip-knee-ankle angle; aHKA) and the obliquity of the joint line (joint line obliquity; JLO) were calculated for each patient.^{16,17} These four values were used to inform the starting point from which subsequent gap balancing was undertaken for individual patients. Restricted safe zones were set between -6° to +3° for the final aHKA, -6° to 3° for the tibial resection, and +6° to -3° for the distal femoral resection. Femoral component rotation was set parallel to the posterior condylar axis with incremental rotational adjustments based on any difference between MPTA and tibial resection angle up to a maximum of 6° of internal or external rotation. Tibial component rotation was set primarily perpendicular to the virtually transposed surgical transepicondylar axis, and secondarily parallel to Akagi’s line.¹⁸

Following joint mapping and alignment registration, virtual gap balancing was undertaken with the extensor mechanism approximated with a towel clip.¹⁹ Controlled varus and valgus forces were manually applied in extension and flexion, and the Mako navigation software calculated the maximum medial and lateral dimensions of the simulated extension and flexion spaces. The extension stressed gaps were measured at 10° of knee flexion to relax the posterior capsular structures, while the flexion stressed gaps were measured at 90° of knee flexion. Next, the femoral and tibial components were virtually translated and rotated with six degrees of freedom, and component size was adjusted when necessary, so that the dimensions of the extension and flexion gaps were approximately equal at 19 mm to 20 mm. Constitutional HKA and JLO were restored as much as possible while respecting restricted safe zone boundaries, and care was taken to avoid patellofemoral overstuffing, anterior femoral notching or compromised bone coverage. The planned bone resections were then executed with the robot-assisted cutting arm and trial components inserted.

After bone resections were complete and with trial components in place, data capture was undertaken for subsequent analysis. As conducted previously during the virtual gap balance assessment, the ‘stressed gap’ measurements were determined through the sequential application of varus and valgus forces in extension and flexion, and the maximum medial and lateral tibiofemoral gaps were recorded.

The trial tibial insert then was exchanged for a Verasense insert of the same size, and the knee was cycled through a range of motion. The medial and lateral compartment loads were recorded at 10° and 90° of flexion for subsequent analysis.²⁰ Note that while the Verasense insert allows load measurements at three points in the arc, the Mako protocol only requires these two measurements.

At this juncture, if the knee was not adequately balanced (with balance defined by an intercompartmental load difference (ICLD) of 15 lb or less and an absolute load of 40lb or less in both compartments at 10°, 45°, and 90° of knee flexion), soft tissue releases or bone recuts were made as required.

Outcome measures. In the first analysis, only TKAs with final medial-lateral gap laxity differentials of ≤ 1 mm were considered (that is, TKAs in which the difference between the medial and lateral stressed gaps was no more than 1 mm). The number of these TKAs that were ‘balanced’ based on compartmental loads was determined. ICLDs of ≤ 15 lb, ≤ 30 lb, and ≤ 60 lb were used sequentially to define soft tissue balance based on prior studies reporting improved outcomes using these ICLD values as the definition of balance.^{21,22} Extension (10°) and flexion (90°) balance were considered separately.

In the second analysis, a stepwise increase of the medial-lateral gap laxity differential was permitted starting from 0 mm (that is, a medial stressed gap measurement equal to the lateral stressed gap; a medial stressed gap measurement that was no more than 1 mm larger or smaller than the lateral stressed gap; a medial stressed gap measurement that was no more than 2 mm larger or smaller than the lateral stressed gap, etc). For each gap increment, the proportion of TKAs defined as balanced using load parameters was determined. Again, ICLDs of ≤ 15 lb, ≤ 30 lb, or ≤ 60 lb were used to define soft-tissue balance. As previously, extension (10°) and flexion (90°) balance were considered separately.

Statistical analysis. Descriptive analyses included means, standard deviations, and frequencies and were performed using Excel 2018 (Microsoft, USA).

Result

From 200 TKAs performed, 176 were included (165 patients). Of those, 164 were unilateral TKAs (159 patients), and 12 were bilateral TKAs (six patients). Cruciate-retaining implants were used in all procedures (Figure 1). The baseline demographics are shown in Table I.

Firstly, only TKAs in which the difference between the stressed medial and stressed lateral gaps was ≤ 1 mm were considered. As shown in Table II, 89% were balanced in extension and 84% were balanced in flexion using an ICLD of ≤ 15 lb as the load threshold that defined balance. If the maximum permitted ICLD was increased

to ≤ 60 lb, 100% of TKAs with a stressed medial-lateral gap laxity of ≤ 1 mm were balanced in extension and 99% in flexion.

Next, sequential increases in the stressed medial-lateral gap difference in extension were considered. For this part of the analysis, an ICLD of ≤ 15 lb was used as the load threshold defining balance. When the stressed medial-lateral gap differential in extension was 0 mm, 91% of TKAs were balanced. This decreased to 88% for as the gap asymmetry increased from ≤ 1 mm to ≤ 3 mm (Table III).

The same analysis was performed with incremental changes in the stressed medial-lateral gap differential in flexion, again using an ICLD of ≤ 15 lb to define balance. As the stressed flexion gap differential increased from 0 mm to 5 mm, the proportion of balanced knees increased from 77% to 84% (Table IV).

Increasing the ICLD threshold used to define balance to ≤ 30 lb or ≤ 60 lb was associated with an increase in the number of balanced TKAs in both extension and flexion, regardless of gap differential (Tables III and IV).

Discussion

If an osteotomised gap is defined as symmetrical when the stressed medial-lateral laxity difference is within 1 mm, and soft tissue balance is defined as an intercompartmental load difference of ≤ 15 lb, 89% of functionally aligned TKAs in this study were balanced in extension and 84% in flexion. Almost 100% of TKAs in this study were balanced in extension and flexion when the ICLD ceiling for balance increased to ≤ 60 lb.

When an ICLD of ≤ 15 lb or ≤ 30 lb was used to define soft-tissue balance, a marginal reduction in the percentage of TKAs found to be balanced was noted when the extension gap was asymmetrical when compared with equal medial and lateral extension gaps. The converse was found in flexion where medial-lateral gap asymmetry was associated with an increase in the percentage of knees found to be balanced using the load sensor when compared with equal medial and lateral flexion gaps.

The ability to discern balance and imbalance intraoperatively through surgeon assessment alone has been shown to be poor, but accuracy can be markedly improved with the use of intraoperative load sensors.^{23,24} Virtual gap balancing provides an alternative method to achieve soft tissue balance during functional TKA.^{25,26} The inter-relationship between these two well-established balancing techniques has not been widely explored.

Through their use of a test rig modelling an artificial knee joint, Sanz-Pena et al¹⁴ demonstrated a linear relationship between tibiofemoral contact forces measured with a load monitoring insert and collateral ligament tensile forces measured with load cells. With equal medial and lateral contact forces, the varus or valgus moments required to cause lift-off were equal. That is, symmetrical compressive forces are proportional to symmetrical

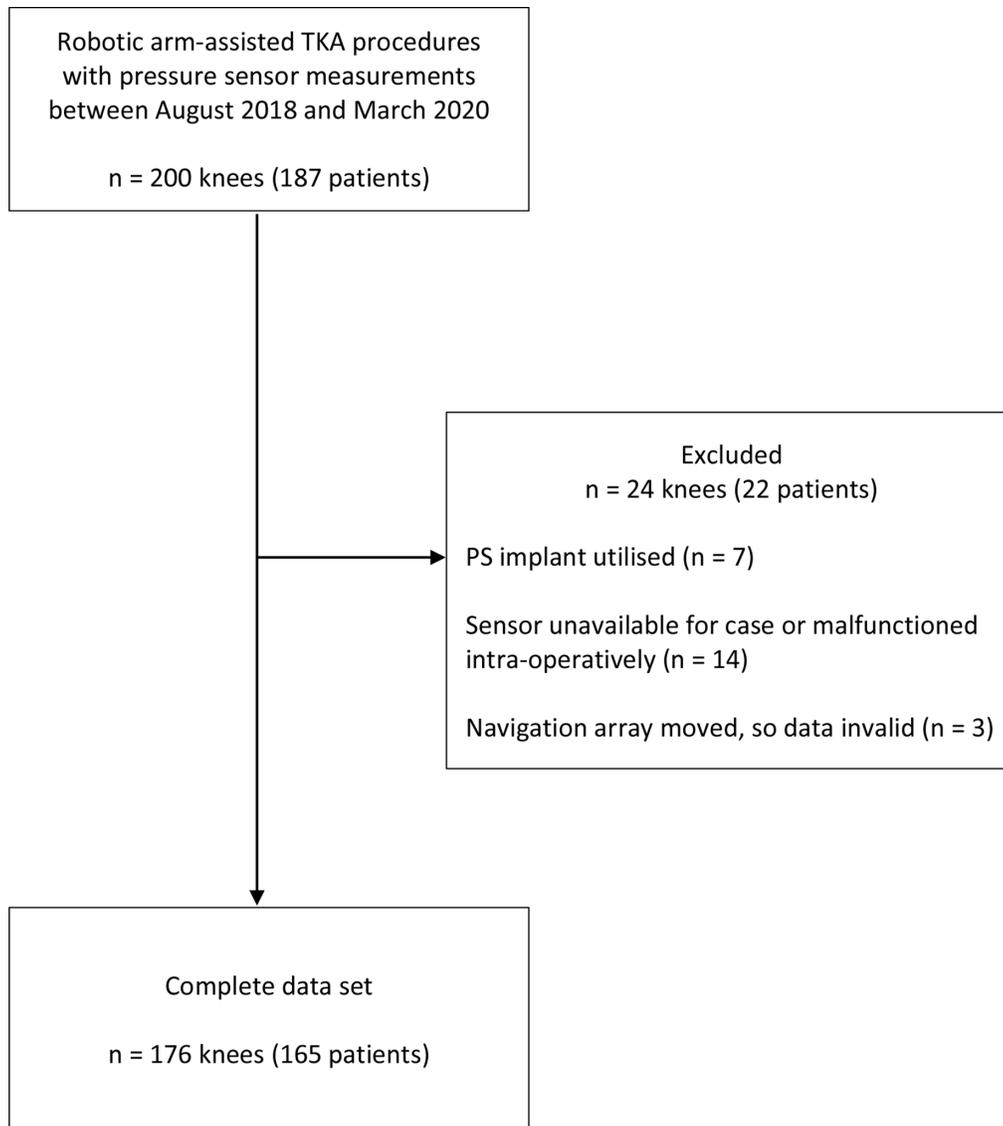


Fig. 1

Study flowchart. PS, posterior stabilized; TKA, total knee arthroplasty.

tensile forces. However, once lift-off has occurred, the laxity angle is dependent on the relative stiffness of the tight medial or lateral structures. This is supported by Wasielewski et al,²⁷ who reported an association between intraoperative medial-lateral compartmental load imbalance and fluoroscopically-demonstrated lift-off during deep knee bend postoperatively.

Nagai et al¹³ found that increasing distraction forces of 20 lb, 40 lb, and 60 lb perpendicular to either the extension or flexion space intraoperatively correlated with increasing varus knee alignment. While they reported the medial structures to be stiffer at all flexion angles from 0° to 135°, in vitro biomechanical studies have found the lateral collateral and medial collateral ligament in isolation to be of comparable stiffness when axial tension forces are applied.²⁸ However, biomechanical studies

of individual ligaments such as these do not reflect the complex in vivo anatomy of the collateral ligaments, the recruitment of different bundles under tension, nor the combined kinematics of the ligamentous structures about the knee.²⁹⁻³¹ Furthermore, the anterior cruciate ligament (ACL) contributes to the stability of the lateral compartment, while the posterior cruciate ligament (PCL) acts as a lateral stabilizer for the medial compartment. As such, sectioning the ACL while preserving the PCL with cruciate-retaining implants may contribute to soft tissue imbalance with increased loads in the medial compartment.³²

Collectively, these studies suggest that balanced medial and lateral compartment loads correlate with balanced static (non-stressed) medial and lateral gaps. However, when varus or valgus loads are applied (such

Table I. Patient characteristics.

Variable	Data
Mean age, yrs, (SD; range)	68.0 (7.5; 48 to 89)
Mean BMI, kg/m ² (SD; range)	29.7 (5.3; 19.6 to 47.4)
Sex, n (%)	
Male	77 (43.8)
Female	99 (56.2)
Laterality, n (%)	
Right	102 (58.0)
Left	74 (42.0)
Intraoperative navigation-derived angles°, mean (SD; range)	
Initial HKA	-3.4 (4.3; -12.0 to 12.0)
Initial knee extension	4.0 (5.2; -9.0 to 23.0)
Initial LDFA	1.9 (1.6; -3.1 to 5.0)
Initial MPTA	-2.3 (2.0; -6.0 to 6.0)
Final HKA	-1.2 (2.3; -7.0 to 5.0)
Final knee extension	2.5 (2.2; -2.0 to 9.0)
Final LDFA	1.4 (1.6; -3.1 to 5.0)
Final MPTA	-2.6 (1.8; -6.0 to 4.0)

HKA, hip knee ankle angle; LDFA, lateral distal femoral angle; MPTA, medial proximal tibial angle; SD, standard deviation.

Table III. Proportion of total knee arthroplasties balanced in extension with increasing increments of medial-lateral gap difference. Balance defined at three different intercompartmental load difference thresholds.

Medial-lateral gap difference, mm (n)	ICLD ≤ 15 lb, n (%)	ICLD ≤ 30 lb, n (%)	ICLD ≤ 60 lb, n (%)
0 (113)	103 (91)	111 (98)	113 (100)
≤ 1 (165)	147 (89)	157 (95)	165 (100)
≤ 2 (175)	155 (89)	167 (95)	175 (100)
≤ 3 (176)	155 (88)	167 (95)	175 (99)

ICLD, intercompartmental load difference.;

as for the assessment of stressed gaps), the relative stiffnesses of the medial and lateral ligament complexes influence the size of the resultant medial and lateral gaps for a given applied moment.

The anticipated non-linear relationship between stressed gap size and compartment load is borne out in vivo. Song et al³² assessed soft tissue balance with a load sensor while undertaking measured resection TKA employing conventional gap-balancing using a tensiometer and with the patella reduced. With equal, rectangular extension and flexion gaps, coronal load imbalance was found in 56% of TKAs in extension and 32% in flexion. Furthermore, load imbalance between the extension and flexion gaps affected the medial compartment in 36% of TKAs, but the lateral compartment in only 4%. Such soft-tissue imbalance in the presence of equal medial-lateral gaps has been described previously by such authors as Manning et al.³³ Several explanations have been offered for discrepancies between an apparently balanced soft tissue envelope when using a tensiometer and imbalance when trial implants are situated, many of which propose that trial components tension the posterior structures,

Table II. Proportion of total knee arthroplasties with medial-lateral gap difference of ≤1 mm. Balance defined at three different intercompartmental load difference thresholds.

Medial-lateral gap difference ≤ 1 mm (n)	ICLD ≤ 15 lb, n (%)	ICLD ≤ 30 lb, n (%)	ICLD ≤ 60 lb, n (%)
Extension (165)	147 (89)	157 (95)	165 (100)
Flexion (134)	112 (84)	126 (94)	133 (99)

ICLD, intercompartmental load difference.;

Table IV. Proportion of total knee arthroplasties balanced in flexion with increasing increments of medial-lateral gap difference. Balance defined at three different intercompartmental load difference thresholds.

Medial-lateral gap difference, mm (n)	ICLD ≤ 15 lb, n (%)	ICLD ≤ 30 lb, n (%)	ICLD ≤ 60 lb, n (%)
0 (61)	47 (77)	55 (90)	61 (100)
≤ 1 (134)	112 (84)	126 (94)	133 (99)
≤ 2 (164)	136 (83)	154 (94)	163 (99)
≤ 3 (171)	142 (83)	161 (94)	170 (99)
≤ 4 (175)	146 (83)	165 (94)	174 (99)
≤ 5 (176)	147 (84)	166 (94)	175 (99)

ICLD, intercompartmental load difference.;

especially those at the posterolateral corner.³⁴⁻³⁶ However, this has not been borne out by intraoperative findings.³² Song et al³² acknowledged that their study assessed the size and symmetry of osteotomized gaps, but then measured the load balance with trial components in place. In contrast, our study reports both gap size and soft-tissue balance with the trial components in place.

Defining an ICLD threshold for imbalance is difficult. Some studies have demonstrated faster rates of recovery³⁷ and greater satisfaction with a sensor-guided intraoperative ICLD of ≤15lb.^{12,21,38,39} However, Meneghini et al²² analyzed 189 TKAs performed using load sensors and found that an ICLD of less than 60 lb was associated with a greater improvement in University of California Los Angeles Activity Score at four months.²² In the absence of a consensus for the ICLD that should define imbalance, we analyzed the data sequentially using ICLDs of ≤ 15 lb, ≤ 30 lb, and ≤ 60 lb as the threshold for imbalance.

Gordon et al⁴⁰ describe undertaking robotic arm-assisted TKA with virtual gap balancing to determine the extension space, and a tensiometer to determine the flexion space, before assessing intercompartmental balance with a load sensor. In a subset of cases in which equal-sized medial and lateral planned gaps were possible, they found 86.1% of cases were balanced in extension and 71.3% in flexion using an ICLD of 15 lb to define balance. This is comparable with our results of 91% and 77%, respectively. Gordon et al⁴⁰ permitted significant variation in final HKA. However, in contrast to our study, they applied very tight restrictions of -2° to 2° to LDFA and MPTA. Overall, only 65% of TKAs in their study were balanced at the 15 lb ICLD threshold throughout the range of motion, with the remainder requiring recuts, soft tissue release, or cement adjustments at

component implantation. Using wider restricted boundaries, our study found 74% of TKAs to be balanced at the 15 lb threshold throughout the range of motion without releases or recuts, likely through more consistent restoration of native JLO. Although Bellemans' work does not specifically cite the statistic,²² application of restricted boundaries to Bellemans' original data set confirms that only 93/500 (18.6%) of normal knees have an LDA and MPTA within 2° of neutral. Therefore, in light of the tight restricted boundaries applied in the study by Gordon et al,⁴⁰ their conclusion that mediolaterally symmetrical flexion and extension gaps achieved through virtual gap balancing "are a poor surrogate for load sensor-defined intercompartmental balance" should be interpreted with some caution.⁴⁰

Our study explores the relationship between intercompartmental loads and stressed extension and flexion gap laxities with implants in situ. The key findings are:

1. When undertaking functionally aligned TKA, a medial-lateral gap difference of ≤ 1 mm is associated with an intercompartmental load difference of ≤ 15 lb in extension in 89% of cases, and in 84% of cases in flexion.
2. As medial-lateral gap asymmetry increases, the percentage of TKA that are balanced decreases in extension, but increases in flexion at both the 15 lb and 30 lb load sensor-determined threshold for balance.

Study limitations. However, our study is not without limitations. The technique employed in this study followed a functional alignment philosophy constrained by restricted safe zone boundaries. Consequently, if a patient's constitutional alignment fell beyond these parameters, the knee would be left in a state of relative imbalance unless soft tissue releases (or further bone cuts) were undertaken. Gap assessments were subjective: the varus and valgus forces applied during testing were surgeon-dependent, varying between surgeons, between cases and potentially within cases. Furthermore, assessment of stressed gap size is more difficult in flexion than in extension and with larger legs. The moments applied during measurement of gap laxity were likely less than those found under maximum physiological load. Lastly, it is recognised that in normal knees, lateral joint laxities are greater than medial laxities, particularly in flexion.^{7,41} This study aimed for symmetrical gap balance; hence, we cannot extrapolate from our findings to the relationship of physiological ligament laxities and compartment loads.

In conclusion, this study demonstrates an association between medial-lateral gap balance and medial-lateral intercompartmental load balance. Load sensors may be used as a complement to virtual gap balancing to determine knee balance in robotic-assisted TKA using CR implants.



Take home message

- When undertaking functionally aligned total knee arthroplasty (TKA), a medial-lateral gap difference of ≤ 1 mm is associated with an intercompartmental load difference of ≤ 15 lb in extension in 89% of cases, and in 84% of cases in flexion.
- This study found a strong relationship between intercompartmental loads and gap symmetry in extension and flexion measured with prostheses in situ.
- The results suggest that intercompartmental load difference and medial-lateral gap difference provide similar assessment of soft-tissue balance in robotic arm-assisted TKA.

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