Intraoperative pressure sensors improve soft-tissue balance but not clinical outcomes in total knee arthroplasty: a multicentre randomized controlled trial

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Aims

Intraoperative pressure sensors allow surgeons to quantify soft-tissue balance during total knee arthroplasty (TKA). The aim of this study was to determine whether using sensors to achieve soft-tissue balance was more effective than manual balancing in improving outcomes in TKA.

Methods

A multicentre randomized trial compared the outcomes of sensor balancing (SB) with manual balancing (MB) in 250 patients (285 TKAs). The primary outcome measure was the mean difference in the four Knee injury and Osteoarthritis Outcome Score subscales ($\Delta KOOS_4$) in the two groups, comparing the preoperative and two-year scores. Secondary outcomes included intraoperative balance data, additional patient-reported outcome measures (PROMs), and functional measures.

Results

There was no significant difference in $\Delta KOOS_4$ between the two groups at two years (mean difference 0.4 points (95% confidence interval (CI) -4.6 to 5.4); p = 0.869), and multiple regression found that SB was not associated with a significant $\Delta KOOS_4$ (0.2-point increase (95% CI -5.1 to 4.6); p = 0.924). There were no significant differences between groups in other PROMs. Six-minute walking distance was significantly increased in the SB group (mean difference 29 metres; p = 0.015). Four-times as many TKAs were unbalanced in the MB group (36.8% MB vs 9.4% SB; p < 0.001). Irrespective of group assignment, no differences were found in any PROM when increasing ICPD thresholds defined balance.

Conclusion

Despite improved quantitative soft-tissue balance, the use of sensors intraoperatively did not differentially improve the clinical or functional outcomes two years after TKA. These results question whether a more precisely balanced TKA that is guided by sensor data, and often achieved by more balancing interventions, will ultimately have a significant effect on clinical outcomes.

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Introduction

Although clearly a multifactorial issue, a commonly cited reason for dissatisfaction following total knee arthroplasty (TKA) is failure to restore the soft-tissue balance.[1-4] Instability following TKA is also a leading cause of early revision, and ensuring more precise soft-tissue balance may reduce revision rates and improve outcomes.[5,6] While computer-assisted navigation can quantify the angular positioning of implants and align the limb precisely,[7] historically no such instruments have been available to quantify the soft-tissue balance.

In order to address this issue, intraoperative pressure sensors were introduced for use during TKA. They have been demonstrated to reliably and accurately quantify soft-tissue balance,[8-10] and are used to direct ligamentous releases and bony

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readjustments.[11] While several studies have reported improvements in outcomes with the use of sensors, others have shown no significant correlation.[12-18] Despite their ability to improve soft-tissue balance, it is not clear whether sensors improve early clinical and functional outcomes in TKA. Furthermore, despite precise balance being considered an important determinant of outcome, it has not been established that it, in fact, improves outcomes compared with TKAs that are not balanced.

The aim of this study, therefore, was to determine whether the use of sensors to attain soft-tissue balance in TKA improved outcomes compared with manual balancing techniques. Secondary aims were to determine if attaining precise balancing, regardless of the use of sensors, improved outcomes. The primary null hypothesis was that in patients undergoing primary TKA, achieving soft-tissue balance with the use of sensors would not lead to a greater improvement in the aggregated mean Knee injury and Osteoarthritis Outcome Score subscales ($\Delta KOOS_4$)[19] up to two years after surgery compared with those in whom manual balancing techniques were used. Secondary null hypotheses were that other patient-reported outcome measures (PROMs), functional measures, and quantitative measures of soft-tissue balance would not differentially improve with use of sensors, and that achieving balance, regardless of method, would not improve PROMs. If it can be shown that using sensors to achieve balance improves clinical outcomes in patients undergoing TKA, their routine use may be justified.

Methods

A multicentre, randomized controlled trial (RCT) was undertaken comparing the outcomes of sensor balancing (SB) in patients undergoing TKA, compared with manual balancing (MB). Patients, assessors, and statisticians were blinded to group allocation. Ethical approval was obtained from South Eastern Sydney Local Health District (Approval No. HREC/18/POWH/320). The study was prospectively registered in the Australian New Zealand Clinical Trials Registry (ACTRN#12618000817246p). The protocol was published prior to the start of the trial.[20]

Eight surgeons undertook operations at 11 sites in public and private Australian hospitals between October 2018 and March 2019. They had been in practice for between eight and 13 years, and each performed between 50 and 300 TKAs per annum. At the beginning of the trial, five surgeons had used pressure sensors for at least one year. The remaining three had used them intermittently in previous TKAs, but then intensively for 15 to 30 cases prior to the start of the study, experience which has been shown to mitigate any learning curve.[21]

A pragmatic approach was used for the inclusion of patients: all those aged between 20 and 85 years who were scheduled for primary TKA to treat primary osteoarthritis, inflammatory arthritis, or post-traumatic arthritis were eligible. Those undergoing unilateral or bilateral procedures, those with extra-articular deformity from previous fracture or osteotomy, and those with severe stiffness were also included, but those who required constrained prostheses due to significant ligament deficiencies, and those undergoing TKA for acute fracture or tumour, were excluded.

A total of 250 patients underwent 285 TKAs. At two years, 227 patients (90.8%) had complete follow-up. Figure 1 shows the details of the groups at each timepoint. There were 124 patients (141 TKAs) in the MB group and 126 (144 TKAs) in the SB group who received the allocated intervention and whose data were analyzed. There were no significant differences in the baseline or surgical characteristics between groups (Table I).

After the eligible patients were identified and consent was obtained, they were allocated randomly (1:1) to the MB or SB group using a remote, centralized telephone service. Surgeons were notified of the allocation only after the intraoperative soft-tissue balance was documented, and prior to any balancing procedures. Allocation was stratified according to surgeon and the age and sex of the patient. For patients undergoing bilateral TKA or sequential unilateral TKA on different days, both knees were allocated to the same treatment arm, as randomization was done at the level of the patient, not the knee.

Surgeons used sensor data to balance the knee in the SB group, and in the MB group, they used their usual balancing method, including manual laxity assessments in varying knee positions and spacer block techniques. They remained blinded to the sensor pressures at all times. Pressures were recorded by non-surgical staff both during and after balancing the knee, with the computer screen turned away from the surgical field.

All TKAs were performed using the Legion/Genesis II system (Smith & Nephew, USA). In order to maintain the pragmatism of the study, no restrictions were placed on the technique, including the use of alignment instruments (conventional instruments, patient-specific guides, computer-assisted navigation, or robotic-assisted surgery); alignment strategy (mechanical (MA) or kinematic alignment (KA)); the stability of the prosthesis (cruciate-retaining or posterior-stabilized); the method of fixation (cemented or cementless); and the decision to resurface the patella.

The measurements of compartmental pressures and tibiofemoral congruence were standardized using the following protocol: the arthrotomy was temporarily clipped and the patella reduced; the heel was then supported with one hand while the other hand cradled the posterior aspect of the distal femur; excessive varus, valgus, or compressive forces on the knee were avoided. Compartmental pressures in both groups were recorded once per patient at three positions of flexion of the knee (10°, 45°, and 90°), before and after balancing. In a previous study, we reported high reliability of the sensor measurements between observers at 10°, with reliability decreasing slightly at higher angles of flexion.[8] "Balance" in this study was defined as an absolute intercompartmental pressure difference (ICPD) of $\leq$ 15 psi with a compartmental pressure of between 5 and 40 psi in at least two of three positions of the knee.[11] Tibiofemoral congruence was recorded as the angular match between the femoral component and the sensor, with "optimal rotation" defined as $\leq 5°$ difference at two of three positions of the knee.

In the SB group, balancing was performed as described by Roche et al.[22] If an absolute pressure in any one compartment was $\geq$ 60 psi, or if there was an ICPD $\geq$ 40 psi, the bone was re-cut. Otherwise, for ICPDs of between 16 and 40 psi, soft-tissue releases were performed. The aim was to achieve a final ICPD of $\leq$ 15 psi, with individual compartmental pressures of

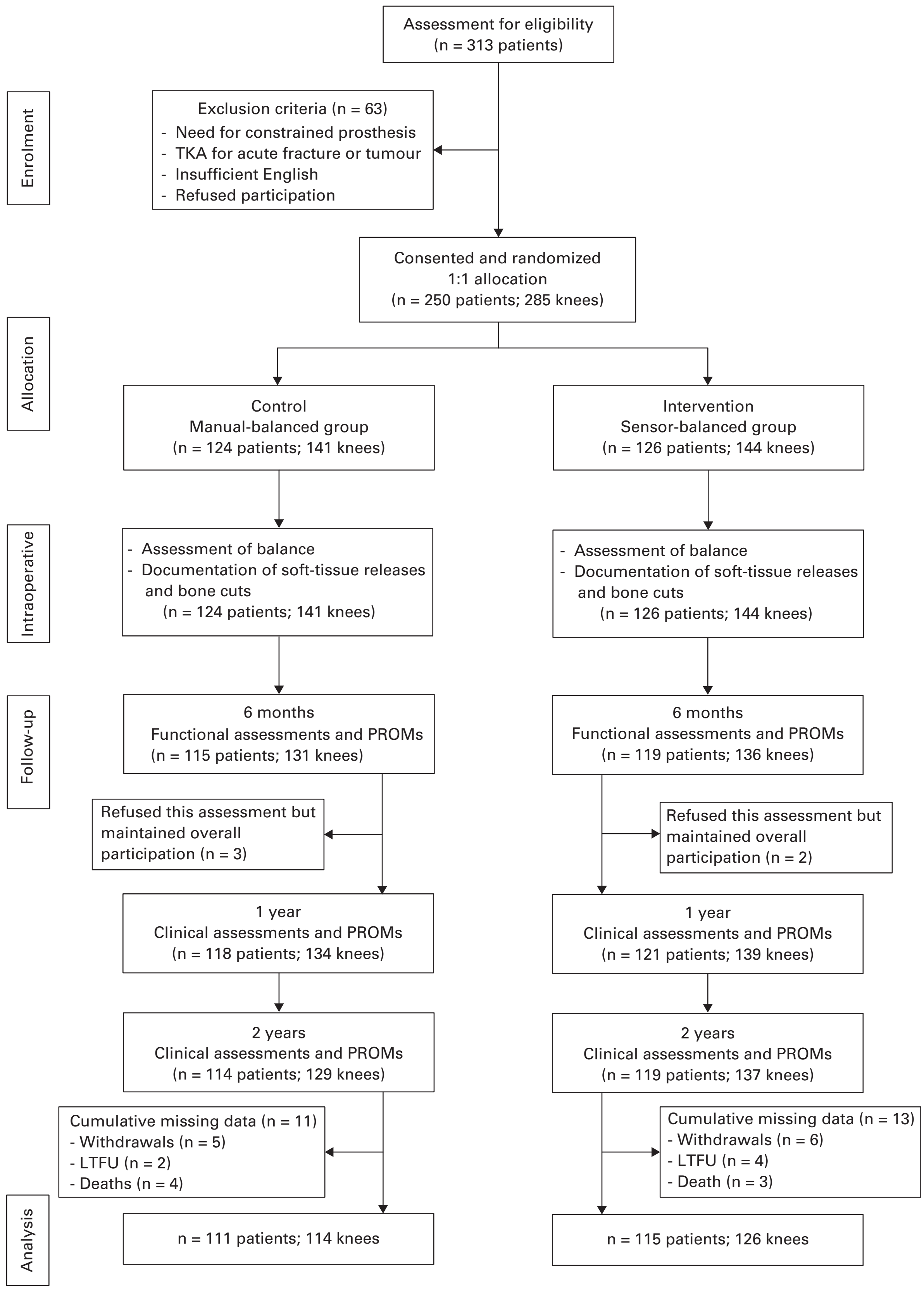

Fig. 1

Flow diagram showing recruitment and allocation of patients. LTFU, lost to follow-up; PROMs, patient-reported outcome measures; TKA, total knee arthroplasty.

Table I. Details of the patients in the study.

Variable	Manual balance	Sensor balance	p-value
Total, n	141	144	
Mean age, yrs (SD)	69.2 (8.1)	68.9 (8.7)	0.787*
Mean BMI, kg/m² (SD)	31.4 (5.4)	31.7 (7.6)	0.664*
Sex, n (%)			
Female	83 (58.9)	85 (59.0)	> 0.999†
Male	53 (37.6)	59 (41.0)	
Side, n (%)			0.781†
Left	64 (45.4)	62 (43.1)	
Right	77 (54.6)	82 (56.9)	
Preoperative alignment, n (%)			0.746†
Neutral	30 (21.3)	26 (18.1)	
Varus	79 (56.0)	86 (59.7)	
Valgus	28 (19.9)	27 (18.8)	
Operating time, mins (SD)	74.5 (17.6)	75.8 (18.6)	0.544*
Alignment strategy, n (%)			0.575†
MA	116 (82.3)	123 (85.4)	
KA	25 (17.7)	21 (14.6)	
Alignment referencing method, n (%)			0.230†
IM femur + tibia	44 (31.2)	43 (29.9)	
IM femur/EM tibia	21 (14.9)	20 (13.9)	
Patient-specific instrumentation	21 (14.9)	35 (24.3)	
Computer-assisted	46 (32.6)	42 (29.2)	
Robotic-assisted	9 (6.4)	4 (2.8)	
Femoral fixation, n (%)			> 0.999†
Cemented	139 (98.6)	142 (98.6)	
Non-cemented	2 (1.4)	2 (1.4)	
Tibial fixation, n (%)			
Cemented	141 (100)	144 (100)	N/A
Patellar implant, n (%)			0.270†
Oval	118 (83.7)	126 (87.5)	
Round	6 (4.3)	1 (0.7)	
Inset	9 (6.4)	10 (6.9)	
Not resurfaced	8 (5.7)	7 (4.9)	
Prosthetic stability, n (%)			0.572†
Posterior-stabilized	124 (87.9)	130 (90.3)	
Cruciate-retaining	17 (12.1)	14 (9.7)	

*Independent-samples *t*-test.
†Chi-squared test.
EM, extramedullary guide; IM, intramedullary guide; KA, kinematic alignment; MA, mechanical alignment; N/A, not applicable; SD, standard deviation.

between 5 and 40 psi at all angles of flexion, values that have been associated with improved outcomes.[12-16]

In the MB group, balancing was performed using the same techniques, but decisions about when to perform balancing and which interventions to use were at the surgeon's discretion.

The primary outcome measure was the difference in the aggregated mean of the four subscales of the KOOS ($\Delta KOOS_4$) between the preoperative values and those two years after surgery. These four subscales (pain, symptoms, function in daily living, and knee-related quality of life) are considered the most specific to recovery after TKA.[19] The fifth subscale, function in sport/recreation, has a significant floor effect in these patients and was therefore not included. The $KOOS_4$ scores range from 0 (worst) to 100 (best).

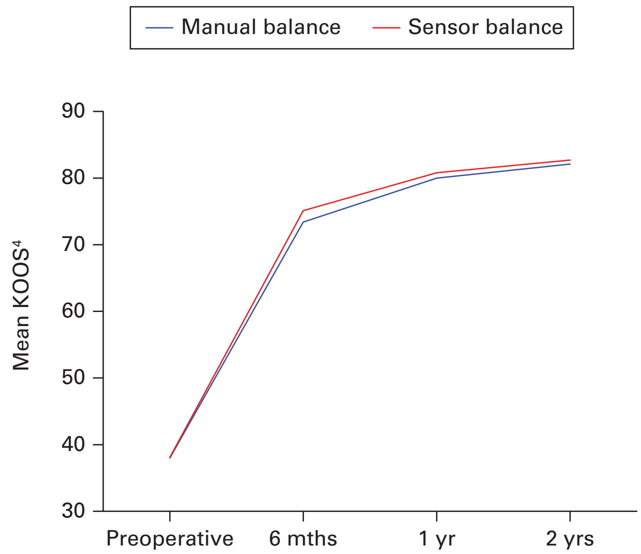

Fig. 2

Change in the aggregated mean of four subscales of the Knee injury and Osteoarthritis Outcome score ($KOOS_4$) over two years comparing the manually and sensor balanced groups.

In order to gain a more holistic view, several secondary outcomes were assessed. Additional PROMs, recorded at six months and one and two years postoperatively, included all five subscales of KOOS;[19,23] the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC);[24] the Forgotten Joint Score (FJS-12);[25] and, as a measure of overall health status, the EuroQol five-dimension five-level questionnaire (EQ-5D-5L).[26,27]

Functional outcome measurements were recorded at six months postoperatively by research physiotherapists at each site who were blinded to the patients' allocations. Tests included the Timed Up and Go test (TUG),[28] Six-Minute Walk Test (6MWT),[29] and active range of motion (ROM) of the knee.

Intraoperatively, the proportions of unbalanced knees between the groups were compared after grading them as "mildly unbalanced" (ICPD > 15 psi, or individual compartmental pressure outside 5 to 40 psi in two or more positions of flexion); "moderately unbalanced" (ICPD > 40 psi in at least one position); or "severely unbalanced" (ICPD > 60 psi in at least one position).

Quantitative ICPDs and balancing procedures (soft-tissue releases and bone recuts) were compared between the groups. Finally, differences in clinical outcomes were compared based on the degree of imbalance of the TKA (mildly, moderately, or severely unbalanced), regardless of group assignment.

Adverse events were recorded at all timepoints.

The study was powered for the secondary analysis (balanced versus unbalanced knees, assuming a ratio of 3:1), knowing this would over-power the study for the primary analysis (intention-to-treat, with 1:1 allocation). This ratio was based on previous research, which showed that nearly all patients who underwent sensor-guided balancing were truly balanced, while fewer than half of those who were considered balanced with manual assessment were.[30] A sample size of 200 (assuming 150 patients

Table II. Mean Knee Osteoarthritis Outcome Scores and other patient-reported outcome measures for the manually balanced and sensor-balanced groups.

Outcome	Mean score (SD)				Mean between-group difference at 2 yrs (95% CI)	p-value*
	Preoperative	6 mths	1 yr	2 yrs		
KOOS4						
MB	38.0 (14.3)	73.4 (16.9)	80.0 (15.7)	82.1 (15.5)	0.4 (-4.6 to 5.4)	0.869
SB	38.1 (15.0)	75.1 (14.6)	80.8 (14.6)	82.7 (15.1)		
KOOS symptoms						
MB	42.5 (20.4)	70.5 (18.1)	78.7 (15.7)	81.9 (14.4)	2.4 (-3.3 to 8.1)	0.402
SB	43.6 (18.1)	73.0 (16.8)	79.6 (15.1)	81.7 (16.4)		
KOOS pain						
MB	39.3 (15.9)	78.8 (17.4)	84.7 (14.5)	86.6 (15.3)	1.7 (-3.8 to 7.1)	0.548
SB	39.6 (18.2)	79.5 (15.6)	85.7 (16.0)	86.4 (14.9)		
KOOS ADL						
MB	43.1 (17.2)	78.9 (17.6)	83.5 (18.1)	85.0 (15.6)	-0.6 (-6.0 to 4.8)	0.836
SB	43.3 (20.0)	80.9 (14.1)	85.3 (15.5)	86.7 (14.8)		
KOOS QoL						
MB	24.8 (16.2)	65.1 (23.7)	73.1 (22.5)	75.1 (23.0)	0.0 (-6.5 to 6.5)	0.993
SB	24.5 (14.0)	67.3 (20.6)	72.6 (19.5)	76.1 (20.9)		
KOOS sports						
MB	15.1 (18.2)	50.2 (24.0)	57.4 (28.3)	54.6 (29.2)	-3.6 (-11.1 to 3.9)	0.344
SB	14.7 (16.1)	52.5 (25.1)	58.8 (25.4)	59.0 (27.0)		
FJS-12						
MB	12.8 (15.5)	47.6 (28.4)	57.9 (29.6)	63.6 (29.0)	2.2 (-5.4 to 9.8)	0.563
SB	11.8 (14.5)	47.6 (26.0)	53.9 (30.5)	60.0 (29.2)		
EQ-VAS						
MB	71.1 (19.0)	82.1 (12.6)	81.8 (13.7)	80.1 (15.9)	-2.5 (-7.3 to 2.4)	0.325
SB	69.5 (19.4)	80.8 (13.6)	82.0 (14.8)	81.3 (14.8)		
WOMAC total						
MB	54.6 (15.7)	20.7 (16.3)	15.7 (15.6)	14.0 (14.4)	0.1 (-4.9 to 5.1)	0.971
SB	54.5 (18.1)	18.8 (13.1)	14.2 (14.1)	13.0 (13.8)		

*Independent-samples *t*-test.
ADL, activities of daily living; CI, confidence interval; EQ-VAS, EuroQol visual analogue scale; FJS-12, Forgotten Joint Score; KOOS, Knee injury and Osteoarthritis Outcome Score; MB, manual balance; PROMs, patient-reported outcome measures; QoL, quality of life; SB, sensor balance; SD, standard deviation; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

Table III. Measures of functional outcome in the manually and sensor balanced groups, six months postoperatively.

Outcome	Manual balance	Sensor balance	p-value*
Mean Timed Up and Go test, secs (SD)	10.0 (2.4)	9.7 (4.5)	0.580
Mean Six Minute Walk Test, metres (SD)	366.2 (89.3)	395.3 (96.3)	0.015
Mean active ROM, ° (SD)			
Extension	8.7 (5.5)	8.7 (6.1)	0.868
Flexion	114.1 (10.7)	113.8 (12.1)	0.832
Arc of motion	105.3 (12.9)	105.3 (15.07)	0.960

*Independent-samples *t*-test.
ROM, range of motion; SD, standard deviation.

balanced and 50 unbalanced) would provide 90% power to detect an eight-point (minimum clinically important) $\Delta KOOS_4$, with a standard deviation of 15 and a level of significance of 0.05.[19] This sample size would provide 96% power for the primary analysis. Assuming a 10% loss to follow-up, a sample size of 222 patients was set.

Statistical analysis. Descriptive statistics were used to characterize differences in baseline demographics and intraoperative measurements. Chi-squared tests and independent-samples *t*-tests were used for comparison of differences between groups. Intention-to-treat analysis was used when analyzing the results. Linear regression models were used to adjust for different baseline and surgical covariates when considering the effect of group assignment (MB or SB) on PROM outcome variables. Covariates included age, sex, BMI, the side of the surgery, surgeon, alignment technique, alignment strategy (KA or MA), and operating time. Significance was set at $p < 0.05$.

Results

The difference in the mean $\Delta KOOS_4$ between the preoperative and two years postoperative values was 44.9 points (-15 to 86) in the MB group and 44.5 points (-10 to 93) in the SB group. The mean difference in the change in $KOOS_4$ score between the groups was not significant (0.4 points (95% confidence interval (CI) -4.6 to 5.4); p = 0.869, independent-samples *t*-test). Multiple regression of the effect of group allocation on the primary outcome measure, adjusting for baseline and surgical covariates showed that the use of sensors was not associated with a statistically significant or clinically important $\Delta KOOS_4$ (0.2-point increase (95% CI -5.1 to 4.6); R^2 6.7%; p = 0.924). The assumptions for linear regression were satisfied.

There were no differences between MB and SB groups when comparing preoperative, postoperative, or change of score at

Table IV. Proportion of patients with an unbalanced total knee arthroplasty in the manual balance and sensor balance groups in three positions of knee flexion (10°, 45°, and 90°).

Definition	Manual balance, n (%)	Sensor balance, n (%)	p-value
Mildly unbalanced in 2 of 3 knee positions (ICPD ≥ 15 psi)	50 (36.8)	13 (9.4)	< 0.001*
Moderately unbalanced (ICPD ≥ 40 psi)	15 (11.0)	1 (0.7)	< 0.001†
Severely unbalanced (ICPD ≥ 60 psi)	4 (2.9)	0 (0.0)	0.125†

*Chi-squared test.
†Fisher's exact test.
ICPD, intercompartmental pressure difference; psi, pounds per square inch.

Table V. Intercompartmental pressure differences between the manual balance and sensor balance groups at 10°, 45° and 90° of knee flexion.

Knee flexion	Mean ICPD, psi (SD)		p-value*
	Manual balance	Sensor balance	
10°	19.9 (17.3)†	7.6 (6.8)	< 0.001
45°	15.7 (13.9)†	8.5 (9.1)	< 0.001
90°	12.2 (8.8)	8.4 (6.8)	< 0.001

*Independent-samples *t*-test.
†Mean ICPDs ≥ 15 psi were defined as "unbalanced".
ICPD, intercompartmental pressure difference; psi, pounds per square inch; SD, standard deviation.

six months, one year, and two years for KOOS subscales, FJS-12, WOMAC, and EQ visual analogue scale for general health (Table II and Figure 2). Furthermore, when assessing the effect of group allocation and adjusting for baseline and surgical covariates, no significant differences in FJS-12, WOMAC, and EQ5D-5L scores were found.

Six months postoperatively, those in the SB group had a significantly longer mean walking distance for the 6MWT (366 metres MB group, 395 metres SB group; mean difference 29 m; p = 0.015, independent-samples *t*-test). There were no significant differences in the mean TUG test or active ROM of the knee between groups (Table III).

As indicated in Table IV, four times as many TKAs in the MB group were "mildly unbalanced" compared with the SB group (50 vs 13; p < 0.001, chi-squared test). The mean ICPDs were significantly higher in the MB group at all angles of flexion, with mean ICPDs outside the balanced range at 10° and 45° (Table V and Figure 3). The use of sensors increased the rate of medial soft-tissue releases, all soft-tissue releases, and bone recuts (Table VI).

Regardless of group, TKAs with any degree of imbalance (mild, moderate, or severe) showed no significant differences in PROMs at six months or one or two years when compared with balanced knees.

Six TKAs (4.8%) the MB group and three (2.4%) in the SB group were treated with a manipulation under anaesthesia (MUA) (Table VII). One patient in each group underwent a soft-tissue release postoperatively for iliotibial band pain. One patient in the MB group had a debridement with implant retention for deep infection. There were six unrelated deaths during the study period, three in each group.

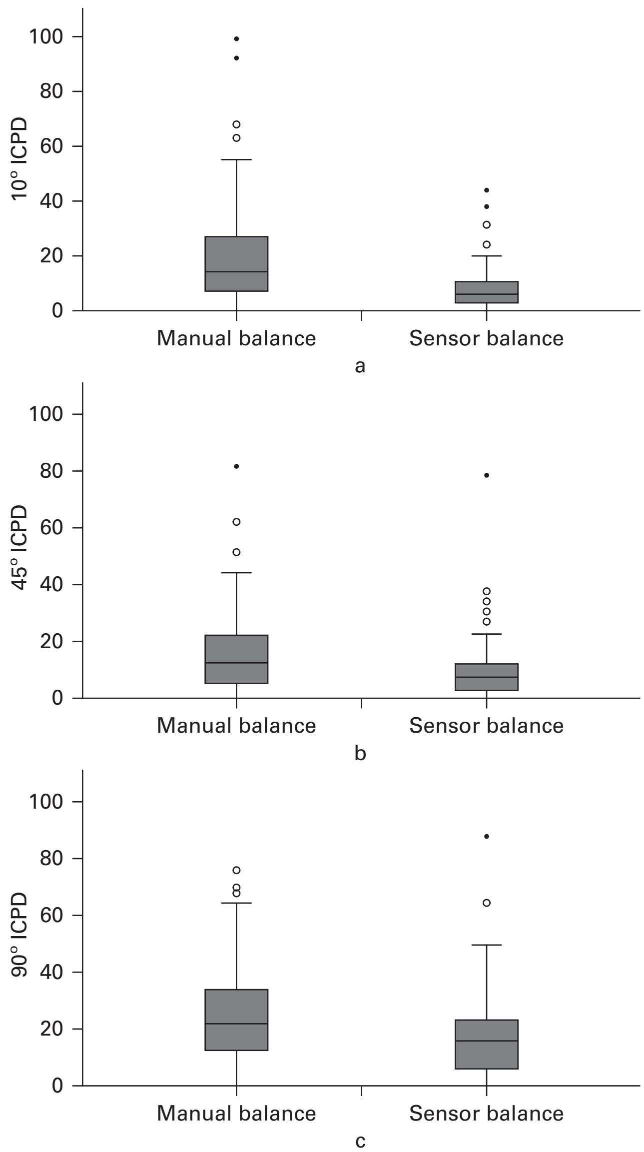

Fig. 3

Box plots of intercompartmental pressure differences (ICPD; pounds per square inch) comparing manually balanced and sensor balanced groups at a) 10°, b) 45°, and c) 90° of knee flexion.

Discussion

The null hypothesis could not be rejected on the basis of these results, in that the use of sensors intraoperatively did not lead to a greater improvement in $KOOS_4$ scores when compared with manual balancing at two years postoperatively. Furthermore, none of the other knee-specific or general health outcomes improved with the use of sensors when compared with MB. Sensors did, however, reduce the proportion of unbalanced knees four-fold, improve the quantitative balance of the knee by increasing the rates of balancing procedures that were undertaken, and increase the six-minute walking distance.

One secondary outcome of specific note is that there were no differences in any outcomes when quantitatively balanced

Table VI. Difference in proportions of balancing procedures between the manual balance and sensor balance groups.

Balancing procedure	Manual balance (%)	Sensor balance (%)	p-value*
Medial soft-tissue release	10	25.4	0.013
Lateral soft-tissue release	19.3	18.3	0.595
Any soft-tissue release	28.6	40.1	0.045
Any bone recut	8.6	21.1	0.004

*Chi-squared test.

Table VII. Differences between manually and sensor-balanced groups in rates of adverse events.

Adverse event	Manual balance, n (%)	Sensor balance, n (%)
Manipulation under anaesthesia	6 (4.8)	3 (2.4)
Tendon release	1 (0.8)	1 (0.8)
Superficial SSI requiring oral antibiotics	4 (3.2)	3 (2.4)
Superficial SSI requiring parenteral antibiotics	1 (0.8)	1 (0.8)
SSI requiring debridement and liner exchange	1 (0.8)	0 (0)
Death (unrelated cause)	3 (2.4)	3 (2.4)

SSI, surgical site infection.

knees were compared with knees with mild, moderate, or severe imbalance. This challenges the long-standing belief that precisely balanced TKAs, with or without ligament releases, result in better outcomes. This finding is of particular importance with the growing adoption of KA, a technique that results in better soft-tissue balance than MA, while also reducing the requirements for ligament releases.[31,32]

There are several key features that support the strength of these findings compared with the literature to date.[12-14,18,30,33] First, they are likely to be more generalizable because they are from a multicentre trial that included numerous surgeons, a variety of operating techniques, and broad inclusion criteria. Secondly, it is the first study to report two-year outcomes, the postoperative time at which maximal improvement occurs, particularly when considering joint awareness.[34] Thirdly, regression was used to control for the effects of potential confounding factors in the analysis of outcomes. Fourthly, functional outcomes were analyzed as another important and practical measure of surgical success. Lastly, this is the first study to examine whether precise soft-tissue balance, independent of the use of sensors, contributes to improved clinical outcomes.

Two previous observational studies comparing MB to SB showed conflicting clinical results at six months after surgery.[13,17] In a non-randomized trial, Golladay et al[14] found that patients with a quantifiably balanced knee at six months had significantly higher satisfaction and better mean FJS-12 scores. A recent RCT by Wood et al,[18] which compared MB with SB in 152 TKAs, found no differences in the PROMs (Knee Society Scores[35] and Oxford Knee Scores[36]), between the groups at one year postoperatively. Previous cohort studies suggested a correlation between intraoperative sensor measurements and clinical outcomes.[12,16] In the current study, no differences were found in any outcome score when incremental ICPD boundaries were applied to define balance.

Several previous studies have also found that SB improves soft-tissue balance by increasing the rates of balancing procedures, which are used.[30,37] Similar rates of imbalance were reported by Wood et al[18] (MB group 36%, SB group 5.3%) to our findings (MB 36.8%, SB 9.4%). This provides further support for the view that sensors reduce soft-tissue imbalance, but they do so by increasing the numbers of balancing interventions required. Whether the use of robotic technologies also reduces the rates of imbalance by reducing the rates of ligament release through virtual pre-resection positioning of the components remains to be seen. Another important metric is the reduced rates of MUA that have been documented with the use of sensors in TKA.[13,38] In the current study, although twice as many patients in the MB group required a MUA, the difference was not statistically significant.

The SB group had a longer mean 6MWT by 29 metres, which is within the reported minimum clinically important difference (MCID) threshold of between 14 and 30 m.[39] This test has been shown to be an excellent predictor of capacity for longer, more functional walking after TKA.[29] This may be a spurious statistical finding, however, as other functional measures were not improved, and the degree of soft-tissue imbalance did not influence the outcome of this test when analyzed separately.

The study had limitations. First, the surgeons were high-volume arthroplasty surgeons with significant experience in balancing techniques including KA and gap balancing, and this may not be representative of routine orthopaedic practice. Second, it is possible that the current definitions of soft-tissue balance do not correlate with constitutional joint laxities, which vary in different angles of knee flexion.[40] Thirdly, only one prosthetic system was used, and clinical outcomes may vary with other systems and levels of implant stability. Fourth, the broad inclusion criteria and variation between the surgeons' operating techniques increase the study's pragmatism, and therefore, potentially, the generalizability of the findings, but they may reduce the overall sensitivity of the results when making direct comparisons between the groups. Fifth, there were small numbers of unbalanced knees, and because the study was not powered to tease out the secondary endpoint of patient outcomes in balanced versus unbalanced TKAs, the true effect of precise balance theoretically could have been underestimated. Finally, potentially deleterious effects of increased rates of ligament release and corresponding damage to the soft-tissue envelope cannot be ignored when interpreting these findings. Further research should investigate whether kinematically aligned TKAs may have better outcomes than the ligament lengthening often required in more neutrally aligned TKAs.

Although it is clear that sensors significantly improve intraoperative soft-tissue balance, we found that their use was not more effective than manual techniques in improving the clinical outcomes of TKA two years postoperatively. As a corollary, these results question whether a more precisely balanced

TKA that is guided by sensor data, and often achieved by an increased rate of balancing interventions, will ultimately have a significant effect on clinical outcomes. Future research is required to examine the long-term benefit from precise soft-tissue balance, including the evaluation of prosthetic survival and joint biomechanics.

Take home message

- Although it is clear that sensors significantly improve intraoperative soft-tissue balance, this study found their use was not more effective than manual techniques in improving the clinical outcomes of total knee arthropalsty (TKA) two years after surgery.
- These results question whether a more precisely balanced TKA that is guided by sensor data, and often achieved by more balancing interventions, will ultimately have a significant effect on clinical outcomes.

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