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Influence of Total Knee Arthroplasty Alignment on Soft-Tissue Balance and Pivot Patterns: A Randomized Controlled Trial of Kinematic Versus Mechanical Alignment

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A B S T R A C T

Background: Over the last decade alternative alignment techniques in primary total knee arthroplasty (TKA) have been developed in the hope to allow knee prostheses to better replicate normal knee kinematics and improve clinical outcomes. The purpose of this study was to quantify prosthesis soft-tissue balance and pivot patterns based on a restricted kinematic alignment (KA) or mechanical alignment (MA) surgical technique.

Methods: A total of 109 primary cruciate retaining TKAs were randomized to either a mechanical or KA technique. Medial and lateral compartmental pressures and contact point patterns were quantified at 10, 45, and 90 degrees of flexion using an insert pressure sensor.

Results: A significantly greater proportion of KA knees were balanced through a full range of motion (ROM) after the initial bone resections (61 KA versus 12% MA, $P < 0.001$) and the differences were significant at all positions of ROM. For the unbalanced prostheses, the MA knees required significantly more soft-tissue releases ($P = 0.008$) and bone alignment adjustments ($P < 0.001$). The initial and final rollback pivot patterns were not significantly different between techniques (initial $P = 0.29$, final $P = 0.29$). The primary driving factor for the pivot patterns was not alignment, but instead the differential pressure between the medial and lateral compartments at 45 and 90 degrees flexion (45° $P < 0.001$, 90° $P < 0.001$), with the knee pivoting on the tighter compartment in flexion.

Conclusions: In primary cruciate retaining TKA a restricted KA technique achieves a balanced prosthesis with significantly fewer soft-tissue releases or bone recuts. The knee's natural medial pivot pattern can be replicated with a prosthesis by controlling the soft tissue balance to achieve a non-symmetrical flexion gap: equal balance in extension, with medial ligament tension maintained through ROM while allowing increased lateral soft-tissue laxity in flexion. The trial and protocol were registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616001705471).

Kinematic alignment (KA) in total knee arthroplasty (TKA) has gained popularity as an alternative to the mechanical alignment (MA) technique, with the goals of restoring the native knee and limb alignment, and the native soft-tissue laxity of the of the knee [1]. Achieving a balanced knee is one of the key principles of TKA, as soft

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tissue imbalance has been associated with various complications including instability, stiffness, and aseptic loosening [2]. Recently, a study utilized a novel pressure sensor during TKA to quantify the medial and lateral soft-tissue balance; the authors demonstrated that patient satisfaction was significantly higher in patients with a balanced soft-tissue envelope [3].

In a randomized trial of bilateral TKA, with patients receiving MA and KA in each of their knees, McEwen et al. found a major patient preference to the KA aligned joint [4]. A possible explanation of these results would be the ability of KA to produce a better-balanced knee. This theory is supported by a study performing measurements with an intraoperative sensor, which reported significantly better quantitative knee balance of the KA compared to MA technique [5].

The traditional model of a TKA motion, involving a symmetrical rollback of both femoral condyles on the tibia during flexion has been proven to not replicate the native joint kinematics [6]. Instead, the medial condyle remains stable throughout flexion with the medial tibiofemoral contact point (CP) only moving slightly posteriorly during the first 30° of flexion, while the lateral condyle and the lateral CP move posteriorly throughout flexion from 0° to 120° [6,7]. This produces an internal rotation of the tibia around a medial center, a pattern known as medial pivot (MP) [8].

This study aimed to compare and quantify the balance and CP patterns of primary TKAs performed following KA and MA techniques. The hypothesis of the study was that KA technique would be more likely to achieve the goals of providing a balanced knee and MP natural kinematics, without the need for additional soft tissue releases or bone cut adjustments.

Materials and Methods

Ethics and Registration

This study was approved by the regional review board (approval reference HREC/16/QTHS/205) and conducted in accordance with the Declaration of Helsinki. The trial and protocol were registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616001705471). All recruited individuals gave written informed consent to participate.

Study Design

This study was a prospective randomized controlled trial. Participants were assigned to either a KA group or to a MA group at the time of the consent using computer-generated random allocations. All procedures were performed using patient-specific instrumentation (PSI). Participants were blinded to the intervention; surgeons were not, as they had to plan cutting guides according to the group allocations in advance.

Participants

Patients were recruited and operated on at two institutions by two knee surgeons with extensive experience in MA and KA techniques and in PSI technology (BP, MW). Inclusion criteria were: patients undergoing primary TKA for the treatment of knee osteoarthritis. Exclusion criteria included: arthritis secondary to osteonecrosis or inflammatory conditions, incompetent collateral ligaments, previous fracture and/or surgery that altered native limb alignment, and inability to consent due to language or cognitive barriers. There were 200 consecutive knees with end stage arthritis assessed for suitability in the study. Out of these, 125 knees were enrolled in the study with 109 undergoing a primary TKA (KA 59, MA 50) (Figure 1). Patient characteristics are summarized in Table 1.

Surgical Planning and Technique

Preoperative standing weight bearing long-leg radiographs were obtained to determine the hip knee ankle angle (HKAA), mechanical lateral distal femoral angle (mLDFA) and mechanical medial proximal tibial angle [9]. A preoperative magnetic resonance imaging (MRI) scan was performed as per the PSI protocol to produce a three-dimensional model of the knee, from which the prosthesis alignment plan and PSI cutting blocks were created (Zimmer Patient Specific Knee System, Zimmer Inc, Warsaw, Indiana).

All participants received a cemented cruciate retaining (CR) TKA prosthesis with a CR poly bearing (Persona, Zimmer Inc, Warsaw, Indiana). Patella resurfacing was performed in all cases. Tourniquet was not used. All procedures were planned and performed with the use of PSI guides. A medial parapatellar approach was employed for all knees. During the exposure of the knee, an effort was made to preserve native medial collateral ligament and medial soft-tissue constraints by only exposing the proximal 7 to 10 mm of the medial tibial plateau for tibial resection preparation. The posterior cruciate ligament (PCL) insertion on the tibial plateau was preserved using a 10 mm osteotome to create a U-shaped bone island.

For the MA group, the coronal tibial and femoral cuts were performed perpendicular to the mechanical axis of each bone in order to produce a HKAA of 0°. The femoral component rotation was set at 3° of external rotation to the posterior condylar axis. The posterior tibial slope was set to 7° as per implant recommendations by the manufacturer for the CR bearing. For the bony resections, 9 mm of distal femoral bone/cartilage and 10 mm of proximal tibial bone/cartilage was planned to match prosthesis thickness (when measured from a normal cartilage surface; if the reference point was worn through to bare bone, 2 mm less resection was planned).

In the restricted KA group, cuts were performed to recreate the individual patient prearthritic HKAA, medial proximal tibial angle, and mLDFA. The preoperative MRI and long leg radiographs were used to assist in determining the individual's native alignment. If the opposite limb did not have arthritis, it was also used as a secondary guide for planning. Due to the lack of long-term outcomes on implant survivorship in unrestricted KA techniques, the employed kinematic technique was restrictive in the limits of deviation away from the neutral axis: limits were set for the postoperative HKAA (3° varus to 3° valgus), the medial proximal tibial angle (3° valgus to 3° varus) and mLDFA (3° valgus to 3° varus). Femoral component rotation was set parallel to the native posterior condylar axis. Tibial posterior slope was set to 7° as per implant recommendations by the manufacturer for the CR bearing. For the femoral bony resections, 9 mm (bone and cartilage) or 7 mm (bone only) were planned on the MRI images from both distal and posterior condyles. If the native distal femoral alignment was greater than 3°, the prosthesis alignment was set at 3° and a slightly thinner distal resection was made on one condyle. Tibial component alignment was determined from a combination of preoperative long-limb radiographs, cartilage and bone wear measurements from the MRI planning and the necessary tibial component alignment to achieve the target hip-knee-ankle after taking into account the femoral component alignment. A planned thickness of 10 mm (bone and cartilage) was resected from the proximal tibia if there was normal joint surface to reference from. In the event of cartilage and bone loss from both tibial condyles, a best estimate of depth of resection was planned at the determined

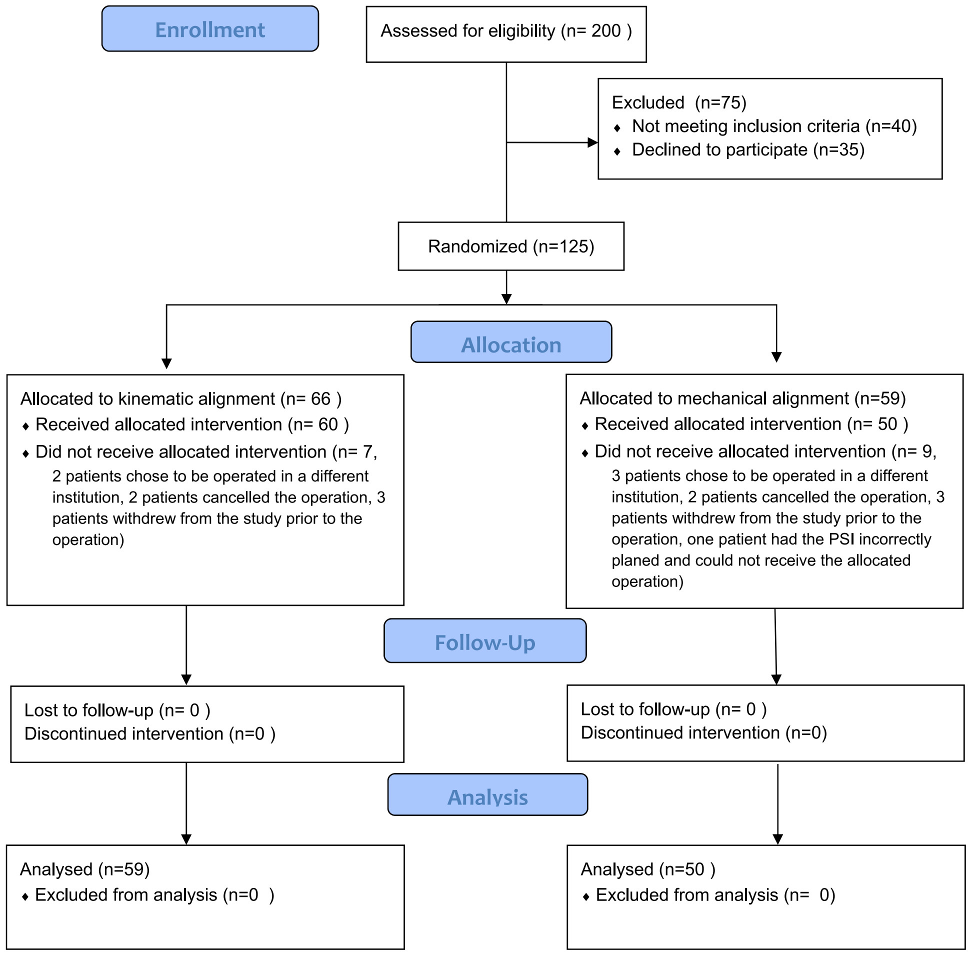

Figure 1. Consolidated Standards of Reporting Trials 2010 flow diagram.

varus/valgus alignment target for that patient. The planned femoral and tibial component alignments for the KA knees are shown in Figure 2.

In both MA and KA cohorts, tibial component rotation was set by using a combination of landmarks and intra-operative checks. The reference landmarks used were: (1) the line from the PCL to mid-to medial-third of the tibial tubercle; and (2) matching the anatomic tibial tray to the anterior tibial cortex to provide maximal plateau coverage of the asymmetric tibial tray while ensuring the tibial trial was appropriately orientated against the femoral trial with the knee fully extended.

After the initial bony cuts were made and the trial implants positioned, a pressure sensor (Verasense Knee System, Ortho-Sensor Inc, Dania Beach, Florida) was inserted, the knee reduced and the extensor mechanism approximated using towel clips. The knee was passed through a range of motion (ROM) from 0 to 120 degrees flexion. The medial and lateral compartment pressures were measured at 10, 45, and 90° of flexion. Target pressures for a balanced knee were defined as an absolute compartmental value less than 40 pounds per square inch (psi), as well as an inter-compartmental pressure difference (ICPD) of less than 15 psi, except at the 90° flexion measurement, where a medial ICPD exceeding the lateral pressure by any amount was accepted, provided the absolute medial pressure was < 40 psi (i.e., aim to replicate the native asymmetrical flexion gap balance with greater medial compartment pressure than lateral). The compartmental CPs were separated into three categories according to the pattern of the movement within each compartment: MP (lateral rollback > medial rollback), neutral pivot (lateral rollback = medial rollback) and lateral pivot (lateral rollback < medial rollback).

In the cases where the initial ROM evaluation found the compartmental measurements were within the balanced target limits, no soft-tissue releases or bony alignment adjustments were performed and the definitive component were implanted. If however, the knee was unbalanced, soft tissue releases and/or further bony cuts (up to two degrees coronal tibial and femoral or

Table 1
Demographic Information and Baseline Data for KA Versus MA TKA.

	KA Group	MA Group	*P*-Value	χ2
Sex				
Men	24/59	26/50	0.24	1.39
Women	35/59	24/50		
Side				
Left	29/59	22/50	0.59	0.2
Right	30/59	28/50		
Age in years	66 ± 7.74	66 ± 7.42	0.52	
BMI	31.68 ± 5.91	30.96 ± 4.92	0.45	
Preop mHKA	−5.81 ± 5.97	−5.63 ± 6.09	0.59	
Preop PROMS				
KOOS JR	47.8 ± 15.3 (3 to 91)	49.5 ± 12.0 (21 to 79)	0.52[a]	
OKS	22.3 ± 8.6 (8 to 40)	23.5 ± 7.8 (8 to 43)	0.45[a]	

KA, kinematic alignment; MA, mechanical alignment; KOOS JR, Knee injury and Osteoarthritis Outcome Score; OKS, Oxford Knee Score; BMI, body mass index; mHKA, mechanical hip-knee-ankle angle.
[a] Student *t*-test.

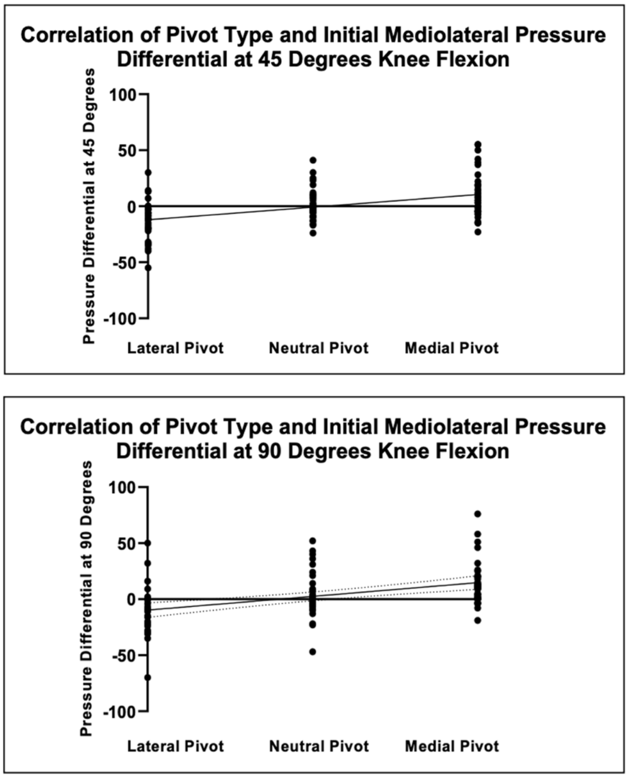

Figure 2. Effect of compartmental pressure differences on prosthesis pivot patterns (prior to balancing).

sagittal tibial adjustments) were performed in a standardized technique to achieve a balanced knee [10]. The final data measurements were repeated after the balancing procedures. The use of bone recuts to balance some knees resulted in the two alignment groups no longer remaining distinctly MA or KA. This was done for the clinical need of the patients to ensure their prosthesis was balanced at the end of the procedure. The primary study data and findings are based on the initial bone cuts before any balancing techniques were undertaken.

Outcomes

The primary outcome measure for this study was the presence of a balanced or unbalanced TKA after the planned bony resections as quantified by the medial and lateral compartmental pressures at 10, 45, and 90° flexion. The secondary outcome measures were the compartmental contact patterns recorded during knee ROM and the amount of soft-tissue releases and/or bone cut adjustments required to balance those knees that were initially unbalanced.

Patient-reported outcome measures (PROMs) were collected preoperatively and at a minimum of 2 years postoperatively (Tables 1 and 2).

Power Analysis

A priori calculation was conducted using a statistical software (G*Power 3.1.9.2; Heinrich-Heine-Universität, Düsseldorf, Germany) with ICPDs treated as the primary outcome measure. Accordingly, a total sample size of 102 knees were required (51 in each group) with an anticipated effect size of 0.5 (clinically meaningful differences of 15 psi and an expected measure of dispersion of 30 psi), an alpha level of 0.05 and a power of 0.8. To account for potential technology issues with capturing intraoperative data and cases not proceeding to surgical intervention, it was aimed to recruit a total of 130 cases.

Table 2
Postoperative Clinical Outcome Measures.

	KA Group	MA Group	*P*-Value
FJS	78.2 ± 20.5 (35 to 100)	79.3 ± 24.3 (0 to 100)	0.80[a]
KOOS JR	83.2 ± 12.0 (50.1 to 100)	82.3 ± 12.4 (54.8 to 100)	0.49[a]
OKS	42.7 ± 5.1 (22 to 48)	44.0 ± 5.4 (26 to 48)	0.94[a]

Values are shown as mean ± SD (range).
KA, kinematic alignment; MA, mechanical alignment; FJS, Forgotten Joint Score; KOOS JR, Knee injury and Osteoarthritis Outcome Score; OKS, Oxford Knee Score.
[a] Student *t*-test.

Data Analyses

Statistical analyses were performed using GraphPad Prism (version 10.3.0) for MacOS (GraphPad Software, La Jolla, California). Continuous variables were analyzed for normality using the D'Agostino-Pearson normality tests. Central tendencies were analyzed using 2-tailed Student *t*-tests (paired and unpaired) for normally distributed data and the Mann-Whitney *U*-tests as appropriate. Correlations were examined using Spearman correlation coefficients using data cleaned for outliers using the robust regression and outlier removal method. Categorical data was analyzed using *Chi*-square and Fisher's exact tests. All dependent measures were reported as means, standard deviations (SD), and ranges; alpha level was set at 0.5.

Results

A significantly greater proportion of KA knees were balanced through a full ROM after the initial bone resections (61 KA versus 12% MA, $P < 0.001$). The differences in knee balance were significant at all positions of ROM (10, 45, and 90 degrees) (Table 3). For the unbalanced knees, the MA prostheses required significantly more soft tissue releases ($P = 0.008$) and bone alignment adjustments ($P < 0.001$) (Table 4). After balancing and implantation of the definitive prosthesis, a higher percentage of KA knees were balanced through ROM, but this difference did not reach statistical significance (KA 85 versus MA 72% $P = 0.16$). The differences in final prosthesis balance were only significant at 90 degrees, with all KA knees balanced in this position compared to 88% of MA knees (Table 5).

The initial and final rollback pivot patterns were not significantly different between MA and KA knees (initial $P = 0.29$, final $P = 0.29$). The driving factor for the pivot patterns in both cohorts was correlated to the differential pressure between the medial and lateral compartments at 45 and 90 degrees (45^0 $P < 0.001$, 90^0 $P < 0.001$). The pressure difference at 10^0 did not correlate to the pivot patterns ($P = 0.16$). The pivot patterns in both initial and final assessments (if balancing steps were undertaken) were determined by a greater compartmental pressure in one compartment (Figures 2 and 3). A tighter medial compartment at 45 and 90^0 was

Table 3
Initial Percentage of Balanced Knees After Planned Resections.

	10°	45°	90°	Balanced in all Positions
KA (%)	80	73	86	61
MA (%)	36	50	54	12
P-value	<0.001	0.017	<0.001	<0.001

KA, kinematic alignment; MA, mechanical alignment.

Table 4
Summary of Balancing Procedures Undertaken.

	KA (23 of 59 Knees)	MA (44 of 50 Knees)	*P*-Value
Soft-tissue release	25	33	0.008
Bone recut	12	33	<0.001
Both soft-tissue release and bone recut	7	22	<0.001

associated with a MP and the opposite pattern was associated with a lateral pivot. Knees with equal rollback demonstrated comparable medial and lateral compartmental pressures through ROM.

Clinical Outcomes

There were significant improvements for both PROMs outcome scores for both groups following surgery (MA pre- to post-Knee injury and Osteoarthritis Outcome Score for Joint Replacement 49.5 versus 87.3 $P = 0.0001$; MA pre to post Oxford Knee Score 23.5 versus 44.0 $P = 0.0001$; KA pre- to post-Knee injury and Osteoarthritis Outcome Score for Joint Replacement 47.8 versus 78.2 $P = 0.0001$; KA pre to post Oxford Knee Score 22.3 versus 42.7 $P = 0.0001$). There were no significant post-operative differences between the groups for any clinical outcome measure (Table 2).

Discussion

This study has demonstrated two important findings for knee arthroplasty surgeons. Using a restrictive KA technique achieves a more balanced prosthesis with significantly fewer soft-tissue or bone cut adjustments than the traditional MA. Also, the pivot pattern of the condyles through knee flexion is determined by the difference between the soft tissue tension of each compartment. As an example, a MP can be reliably reproduced by creating an asymmetrical flexion gap that maintains medial tension and allows increased lateral laxity. To our knowledge, this is the first randomized controlled trial reporting the use of a pressure sensor device in the assessment of compartment pressures and pivot patterns in TKAs with conventional CR bearings.

The pivot pattern findings of this study will be of particular interest as currently there is a trend to try and replicate the native knee MP during flexion. Design modifications to the polyethylene inserts have been developed by many companies in an attempt to recreate the MP; however a 2022 systematic review an metanalysis concluded that MP inserts are not clinically superior to conventional posterior stabilized (PS)-CR designs [11], and another in 2023 found MP designs only superior to PS in terms reduced of patellar clunk and crepitus incidence [12]. The findings of the present study support the idea of recreating a “soft tissue” MP, with theoretically beneficial biomechanical implications.

The classic concept of symmetric gap balancing in both flexion and extension may no longer be dogmatic [13]. Previous

Table 5
Final Percentage of Balanced Knees After Soft Tissue and Bone Cut Adjustments.

	10°	45°	90°	Balanced in all Positions
KA (%)	93	88	100	85
MA (%)	96	86	88	72
P-value	0.69	0.78	0.008	0.16

KA, Kinematic Alignment; MA, mechanical alignment.

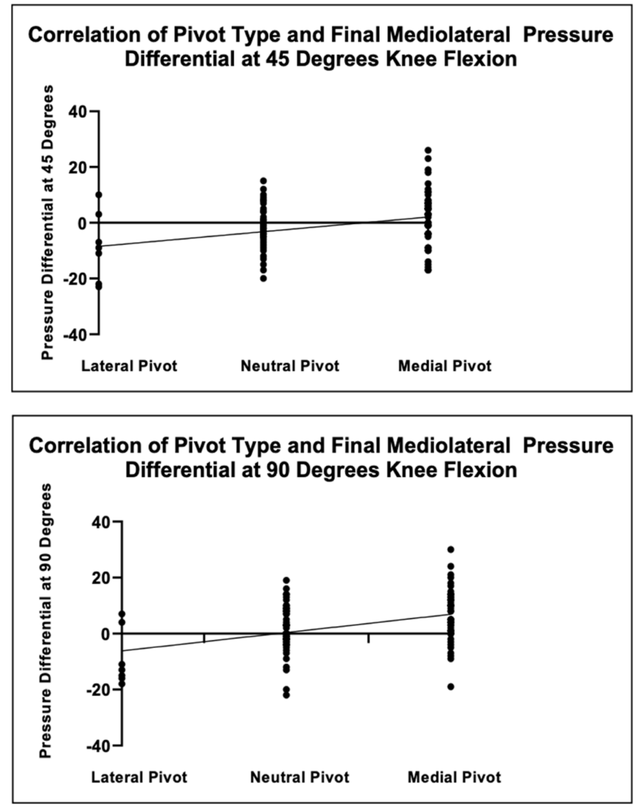

Figure 3. Effect of compartmental pressure differences on prosthesis pivot patterns (final after balancing).

studies have demonstrated that soft-tissue balance in flexion is an important driver of the prosthesis pivot pattern. Matsuzaki et al., found that creating an asymmetrical flexion gap with increased lateral laxity in a CR prosthesis achieved a MP [14]. Kamenaga et al., similarly demonstrated that keeping the medial gap tight through flexion in a posterior-stabilized prosthesis played an important role in creating a MP which was correlated with greater postoperative knee flexion [15]. Valpiana et al. recently demonstrated that an asymmetric gap balancing technique with certain lateral laxity in flexion provides closer to natural gait biomechanics, as well as higher flexion compared to symmetric balancing [16]. In support of this balancing concept, multiple recent studies have demonstrated improved clinical outcomes for TKAs with an asymmetrical flexion gap compared to the traditional equal flexion gap [10,17,18].

This study has demonstrated that maintaining soft-tissue tension through flexion on a compartment creates stability during rollback and controls the pivot pattern of the knee. To achieve a MP with the prosthesis, it may be recommended to aim for a symmetrical extension gap with an asymmetrical flexion gap – maintain a uniform medial soft-tissue tension through range (i.e., lateral compartment gap becomes looser in flexion). All prostheses in this study utilized a standard nonstabilized CR bearing with PCL retention; caution should be taken in applying these results to other types of polyethylene bearings, particularly PCL-substituting designs. Prior studies have demonstrated the importance of retaining the PCL to produce a MP and to minimize the risk of flexion instability [19,20], but others have found increased mid-flexion sagittal stability in MP implants when compared radiographically to PS TKAs [21].

These balancing goals could be considered reachable for all arthroplasty surgeons. Cochetti et al. suggested that intraoperative pressure sensors provided useful feedback for achieving MP TKA kinematics, despite this not having significant clinical relevance in their study [22]. For most surgeons without sensor availability, manual balancing techniques are sufficient to achieve the desired gap configuration [23]. Robotic surgery technology may provide tools for more precise alignment and balancing control than conventional surgery techniques, but it has not proven clinical nor functional superiority to date [24].

This study found that restrictive KA makes it "easier" to achieve balanced gaps, requiring less soft-tissue interventions and additional bony cuts. This is in keeping with one of the most commonly mentioned drawbacks of MA, the usual need for ligaments and/or tendons tension modification [25,26].

This study did not demonstrate a clinical outcome difference in PROMs between MA and KA techniques. This is hardly a surprise, as the knees that were not "balanced" on initial assessment were adjusted through bone recuts and soft-tissue releases to achieve the same final prosthesis balance target.

This study, as any other, has potential limitations. The use of pressure sensors intraoperatively to quantify prosthesis balance provided a reliable technique for this study however these results may not accurately reflect actual prosthesis balance and pivot patterns of the knee during weight bearing activities under active muscular control. Other techniques to quantify prosthesis biomechanics such as gait analysis and force plate measurements could provide further insights into the function of a total knee prosthesis that may help improve our understanding on the effect of intraoperative techniques to postoperative functional outcomes. It is possible that the debate over the last decade around the potential superiority of different alignment techniques to achieve "knee balance" is not the answer. Instead of focusing on prosthesis alignment, determining what is the optimal soft-tissue balance of a prosthesis might be the more important variable to achieve improved clinical outcomes, and this may prove to be independent of specific bone alignment techniques.

Conclusions

The knee's natural MP pattern can be replicated in CR TKAs by maintaining medial collateral ligament tension through ROM while allowing the native asymmetrical flexion gap: equal extension laxity, with increased lateral soft-tissue laxity in flexion. The restrictive KA alignment technique proved a more reliable method to achieve this goal, with fewer bony cuts and soft-tissue corrections than the traditional MA alignment technique.

CRediT authorship contribution statement

Sergio Barroso Rosa: Writing – review & editing, Validation. **Petros Ismailidis:** Investigation. **Kenji Doma:** Formal analysis. **Andrea Grant:** Project administration. **Peter McEwen:** Visualization, Investigation, Conceptualization. **Matthew Wilkinson:** Investigation. **Benjamin Parkinson:** Writing – review & editing, Writing – original draft, Investigation, Conceptualization.

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