1. **CALLIESS T, BAUER K, STUKENBORG-COLSMAN C, WINDHAGEN H, BUDDE S, ETTINGER M.**

**PSI KINEMATIC VERSUS NON-PSI MECHANICAL ALIGNMENT IN TOTAL KNEE ARTHROPLASTY: A PROSPECTIVE, RANDOMIZED STUDY. KNEE SURG SPORTS TRAUMATOL ARTHROSC. 2017JUN;25(6):1743-1748.**

**Abstract**

**PURPOSE:**

Kinematic alignment in TKA is supposed to restore function by aligning the components to the premorbid flexion-extension axis instead of altering the joint line and natural kinematic axes of the knee. The purpose of this study was to compare mechanically aligned TKA to kinematic alignment.

**METHODS:**

In this study, 200 patients underwent TKA and were randomly assigned to 2 groups: 100 TKAs were performed using kinematic alignment with custom-made cutting guides in order to complete cruciate-retaining TKA; the other 100 patients underwent TKA that was manually performed using mechanical alignment. The WOMAC and combined Knee Society Score (KSS), as well as radiological alignment, were determined as outcome parameters at the 12-month endpoint.

**RESULTS:**

WOMAC and KSS significantly improved in both groups. There was a significant difference in both scores between groups in favour of kinematic alignment. Although the kinematic alignment group demonstrated significantly better overall results, more outliers with poor outcomes were also seen in this group. A correlation between post-operative alignment deviation from the initial plan and poor outcomes was also noted. The most important finding of this study is that applying kinematic alignment in TKA achieves comparable results to mechanical alignment in TKA. This study also shows that restoring the premorbid flexion-extension axis of the knee joint leads to better overall functional results.

**CONCLUSION:**

Kinematic alignment is a favourable technique for TKA.

**CLINICAL RELEVANCE:**

The kinematic alignment idea might be a considerable alternative to mechanical alignment in the future.

**LEVEL OF EVIDENCE:**

II.

1. **LAENDE EK, RICHARDSON CG, DUNBAR MJ.**

**A RANDOMIZED CONTROLLED TRIAL OF TIBIAL COMPONENT MIGRATION WITH KINEMATIC ALIGNMENT USING PATIENT-SPECIFICINSTRUMENTATION VERSUS MECHANICAL ALIGNMENT USING COMPUTER-ASSISTED SURGERY IN TOTAL KNEE ARTHROPLASTY. BONE JOINT J. 2019 AUG;101-B(8):929-940.**

**Abstract**

**AIMS:**

Patient-specific instrumentation of total knee arthroplasty (TKA) is a technique permitting the targeting of individual kinematic alignment, but deviation from a neutral mechanical axis may have implications on implant fixation and therefore survivorship. The primary objective of this randomized controlled study was to compare the fixation of tibial components implanted with patient-specific instrumentation targeting kinematic alignment (KA+PSI) versus components placed using computer-assisted surgery targeting neutral mechanical alignment (MA+CAS). Tibial component migration measured by radiostereometric analysis was the primary outcome measure (compared longitudinally between groups and to published acceptable thresholds). Secondary outcome measures were inducible displacement after one year and patient-reported outcome measures (PROMS) over two years. The secondary objective was to assess the relationship between alignment and both tibial component migration and inducible displacement.

**PATIENTS AND METHODS:**

A total of 47 patients due to undergo TKA were randomized to KA+PSI (n = 24) or MA+CAS (n = 23). In the KA+PSI group, there were 16 female and eight male patients with a mean age of 64 years (sd 8). In the MA+CAS group, there were 17 female and six male patients with a mean age of 63 years (sd 7). Surgery was performed using cemented, cruciate-retaining Triathlon total knees with patellar resurfacing, and patients were followed up for two years. The effect of alignment on tibial component migration and inducible displacement was analyzed irrespective of study group.

**RESULTS:**

There was no difference over two years in longitudinal migration of the tibial component between the KA+PSI and MA+CAS groups (reaching median maximum total point motion migration at two years of 0.40 mm for the KA+PSI group and 0.37 mm for the MA+CAS group, p = 0.82; p = 0.68 adjusted for age, sex, and body mass index (BMI) for all follow-ups). Both groups had mean migrations below acceptable thresholds. There was no difference in inducible displacement (p = 0.34) or PROMS (p = 0.61 for the Oxford Knee Score) between groups. There was no correlation between alignment and tibial component migration or alignment and inducible displacement. These findings support non-neutral alignment as a viable option with this component, with no evidence that it compromises fixation.

**CONCLUSION:**

Kinematic alignment using patient-specific instrumentation in TKA was associated with acceptable tibial component migration, indicating stable fixation. These results are supportive of future investigations of kinematic alignment. Cite this article: Bone Joint J 2019;101-B:929-940.

1. **DOSSETT HG, ESTRADA NA, SWARTZ GJ, LEFEVRE GW, KWASMAN BG.**

**A RANDOMISEDCONTROLLED TRIAL OF KINEMATICALLY AND MECHANICALLY ALIGNED TOTAL KNEEREPLACEMENTS: TWO-YEAR CLINICAL RESULTS. BONE JOINT J. 2014 JUL;96-B(7):907-13.**

We have previously reported the short-term radiological results of a randomised controlled trial comparing kinematically aligned total knee replacement (TKR) and mechanically aligned TKR, along with early pain and function scores. In this study we report the two-year clinical results from this trial. A total of 88 patients (88 knees) were randomly allocated to undergo either kinematically aligned TKR using patient-specific guides, or mechanically aligned TKR using conventional instruments. They were analysed on an intention-to-treat basis. The patients and the clinical evaluator were blinded to the method of alignment.

At a minimum of two years, all outcomes were better for the kinematically aligned group, as determined by the mean Oxford knee score (40 (15 to 48) versus 33 (13 to 48); p = 0.005), the mean Western Ontario McMaster Universities Arthritis index (WOMAC) (15 (0 to 63) versus 26 (0 to 73); p = 0.005), mean combined Knee Society score (160 (93 to 200) versus 137 (64 to 200); p= 0.005) and mean flexion of 121° (100 to 150) versus 113° (80 to 130) (p = 0.002). The odds ratio of having a pain-free knee at two years with the kinematically aligned technique (Oxford and WOMAC pain scores) was 3.2 (p = 0.020) and 4.9 (p = 0.001), respectively, compared with the mechanically aligned technique. Patients in the kinematically aligned group walked a mean of 50 feet further in hospital prior to discharge compared with the mechanically aligned group (p = 0.044).

In this study, the use of a kinematic alignment technique performed with patient-specific guides provided better pain relief and restored better function and range of movement than the mechanical alignment technique performed with conventional instruments.

Reports from Canada1 and England and Wales2 have shown that up to 20% of patients are not satisfied after total knee replacement (TKR). Recent developments have included the individualisation of alignment of the components using pre-operative imaging and computer software, with the goal of achieving pre-arthritic alignment through restoration of the axes of rotation.3-5 The outcomes of this alignment have been assessed in case series6-8 but so far no randomised controlled trial has compared the clinical results of kinematic alignment with the traditional technique of mechanical alignment.

This randomised controlled trial was designed to compare kinematically aligned TKR performed with patient-specific guides and mechanically aligned TKR performed with conventional instruments, with the null hypothesis that there would be no difference in pain, function or range of movement (ROM) at two years post-operatively between the two groups.

A secondary hypothesis was that there would be no difference between the two groups as assessed by blood loss, distance walked prior to discharge from hospital, length of stay, and frequency and type of further minor and major operations.

Some early results have been previously reported for 82 patients who completed a six-month follow-up evaluation.9 Here we have included the alignment information for the limb, knee and components for 88 patients who completed a two-year intention-to-treat follow-up, to ascertain whether a difference in alignment between the two groups is associated with a difference in pain, function and ROM.

Patients and Methods

The study had ethical approval and the patients provided informed consent. A total of 120 patients eligible for TKR with end-stage arthritis of the knee were prospectively enrolled in the study between January 2008 and August 2009. They were randomised by an opaque sealed envelope method to receive either kinematically aligned TKR with patient-specific guides or mechanically aligned TKR using conventional instruments. Exclusion criteria included previous fracture of the femur or tibia, infection, previous joint replacement or osteotomy involving the knee, or a medical condition precluding surgery. Patients who required a bilateral procedure and those who could not undergo MRI of the knee were also excluded. A total of 44 patients underwent kinematically aligned TKR and 44 underwent mechanically aligned TKR by two authors (HGD, GJS) who were trained in both approaches and who acted as surgical assistant to each other. Data were analysed on an intention-to-treat basis.

Outcome was assessed using the Oxford knee score (OKS, 0 to 48 worst to best),10 the Western Ontario and McMaster Universities Arthritis Index (WOMAC, 0 to 96 best to worst) score11 and the combined Knee Society score (KSS, 0 to 200 worst to best).12

In order to blind the patients, those in both groups had the same clinical evaluations and MRI scans of the knee pre-operatively. Standing coronal radiographs of the knee were performed with the patellae pointing forward and the anatomical alignment of the knee was recorded by the two surgeons using Picture Archiving and Communication system (PACS). A cemented posterior cruciate-retaining prosthesis with patellar resurfacing was used in all patients (Vanguard, Biomet, Inc. Warsaw, Indiana). The same length of incision, usually 16 cm and exposure were used for both groups. All patients underwent rotationally controlled post-operative CT scans of the lower limb during the hospital stay. Blood loss was calculated by subtracting the lowest post-operative haemoglobin recorded during the hospital stay from the pre-operative value. The distance walked prior to discharge was the furthest that the patient walked with a wheeled walker, as recorded by the physiotherapist. The frequency and type of further procedures were recorded. Major further operations involved the removal or revision of the components, and minor further operations included all other procedures in which the components were retained.

The concept of kinematic alignment is based on the kinematic axes of the knee and their relationship to the femoral condyles.3,4,13 The femoral and tibial components are introduced in such a way that the angle and level of the distal and posterior femoral joint lines and the tibial joint line are restored to the natural alignment for each patient using patient-specific guides.5,13,14 The process of creating these guides begins with a standardised MRI protocol of the knee. The projection of the knee in the MRI scanner is such that the plane of the oblique sagittal image is perpendicular to the primary axis in the femur, about which the tibia flexes and extends. Proprietary software is then used to create a three-dimensional model of the knee (Fig. 1). The ‘arthritic’ model is transformed into a ‘normal’ model by filling articular defects and equalising the gap between the medial and lateral compartments of the knee. Equalising the gap restores the joint line and the alignment of the knee and lower limb to the normal pre-arthritic state. An algorithm shape fits the best-fitting 3D model of the femoral component to the articular surface of the 3D model of the ‘normal’ femur, with a reproducibility of ± 0.5 mm for translations and ± 0.5º for rotations (OtisMed Inc., Alameda, California). The software sets the anteroposterior (AP) axis of the tibial component perpendicular to the flexion–extension axis of the femoral component, which kinematically aligns the two components. The tibia is centred kinematically beneath the tibial component. The guides which create the bone cuts are designed to fit onto the arthritic knee and are manufactured from medical-grade plastic.

The patient-specific guides were sterilised according to the manufacturer’s instructions, opened within the sterile field, and the specific patient identifiers on the guides were visually confirmed. Two trays of instruments and trials of the correct size were required for each procedure. The guides were made to fit to the patient’s knee in one specific position according to the arthritic anatomy, and were accurately placed by the surgeon on the femur and tibia. No release of the medial or lateral collateral ligaments was performed; however, the medial and lateral capsules were released at the margins of the menisci. The posterior cruciate ligament was retained. The distal femoral cut was made through the slot of the patient-specific guide. The conventional 4-in-1 cutting block that matched the size of the planned femoral component was placed into the two-guide pinholes in the distal femoral articular surface. The tibial patient-specific guide was then secured by drilling two pins through the pinholes on the proximal surface of the tibial guide, and and two in the anterior surface. The tibial cut was made through the slot in the guide, and marginal osteophytes were removed. Trial components were introduced, and the ROM of the knee, stability, rotation of the components, posterior cruciate ligament tension, patellar tracking (without applying any digital pressure) and flexion–extension gaps were checked. The tibial component was aligned parallel to the pinholes which had been drilled through the proximal surface of the guide. The definitive components were introduced with cement and a final check of the ROM etc was made.

The mechanically-aligned TKR was performed with the goal of achieving a neutral coronal mechanical limb alignment by making the femoral and tibial bone cuts perpendicular to the mechanical axes. The operation was conducted according to the manufacturer’s instructions (Biomet Inc). In all, nine instrument trays were used for each procedure. The distal femoral cut was made using an intramedullary alignment system, with the angle of the distal resection set at 5° valgus.15 The posterior femoral cuts were made with a referencing guide set at 3° of external rotation. The proximal tibial cut was made with an intramedullary alignment system (n = 43). An extramedullary system was used in one patient with severe varus bowing. Significant posterior osteophytes were removed. Trial components were introduced, and the ROM of the knee and other intra-operative parameters were checked as described above. Release of the collateral and retinacular ligaments was performed when necessary to balance the flexion and extension gaps, and provide satisfactory patellar tracking, at the discretion of the surgeons. In order to reduce intra-articular bleeding, the hole for the femoral intramedullary guide was plugged with bone. The definitive components were introduced with cement, and a final check of the ROM etc was made.

Post-operative management was identical for both groups. The patients, physiotherapists and nurses were blinded to method of alignment which had been used, as also was the radiologist (JC) who analysed the CT scans and the surgeon (BGK) who recorded the OKS, WOMAC and combined KSS scores. The limits of active extension and flexion were measured with a long-arm goniometer with the patient supine.

Statistical analysisThe mean, standard deviation (sd) and 95% confidence intervals (CIs) were determined for each measure in each group. Odds ratios (OR) were determined by logistic regression using Fisher’s scoring as the optimisation technique. The effect of the method of alignment (significance of the OR) was evaluated using Wald’s chi-squared test with 95% CIs. The difference in the means of the primary outcome measures between the groups were determined using the non-parametric Wilcoxon’s signed-rank test for non-normally distributed data, an unpaired t-test for normallydistributed data, OR and the chi-squared test using statisticalsoftware (SPSS Inc.v20, IBM Corp., Armonk, New York, and JMP v11,SAS, Cary, North Carolina). Statistical significance was set atp < 0.05. A power analysis was conducted on the intention-to-treat data.Given the mean OKS of 39.5 in the kinematically aligned group and33.4 in the mechanically aligned group, and a pooled sd of 10, α = 0.05, and power of 0.80, the sample size required for each group was 43.

Results

The number of patients allocated, treated, lost to follow-up and analysed on an intention-to-treat basis in each group is listed in a flow diagram based on CONSORT guidelines (Table I).

Comparison of pre-operative characteristics of the two groupsThe mean age, gender, BMI, American Society of Anaesthesiologists Score (ASA),16 pre-operative alignment of the knee, extension, flexion, OKS, WOMAC, Knee Society, knee function and combined Knee Society scores were similar in the two groups (Table II).

Comparison of post-operative alignment of the two groupsThe knee joint alignment for the kinematically aligned groupwas a mean of 1.9° more valgus compared with the mechanically alignedgroup (p < 0.001) (Table III). The femoral component was a meanof 2.2° more valgus in the kinematically aligned group (p < 0.001),and the tibial component a mean of 2.1° more varus (p < 0.001)in the kinematically aligned group compared with the mechanicallyaligned group. The alignment of the knee and limb were similar inthe two groups.

Comparison of clinical results of the two groupsThere was a statistically significant difference between the two groups for all the scores (Table III). The patients who underwent kinematically aligned TKR had significantly better scores for pain, function and ROM than those who underwent mechanically aligned TKR.

Those in the kinematically aligned group had less pain as assessed by the OKS and WOMAC scores (Table IV).

The mean active extension was similar for the two groups, but in the kinematically aligned group the mean flexion was greater by 8.5° (p = 0.002) (Table III).

Blood loss, length of stay and frequency and type of minor and major further operations was similar between the two groups. Patients in the kinematically aligned group walked a mean of 50 feet (15 to 400) further than the mechanically aligned group before discharge (Tables V and VI).

There was no statistically significant difference in the proportion of patients requiring further surgery in either group (Table VI).

Two patients in the kinematically aligned group required a manipulation under anaesthetic, one in a diabetic who had 90º of flexion at nine weeks post-operatively, and the other in a patient with chronic pain syndrome who had 85º of flexion at nine weeks post-operatively.17,18 In one patient in the mechanical group skin sloughing occurred, which was treated with local debridement and dressing changes.

Discussion

This study shows that an alignment technique based on restoring the normal kinematics for each patient’s knee can produce significantly better results two years post-operatively with regard to pain, function and ROM. We were thus able to reject the primary null hypothesis that there would be no difference in the pain, function and ROM between the two groups at two years. More patients were pain free in the kinematically aligned group at two years than in the mechanically aligned group.

The higher proportion of pain-free knees in the kinematically aligned group is important from both an individual patient and a global health system perspective, considering a recent report on the expense involved in investigating a painful TKR.19

With any method of alignment in TKR, there is a legitimate question about the survival of the prosthesis. Data from the New Zealand Joint Registry have shown that patients with a higher OKS are unlikely to require early revision.20,21 It is possible that the significantly higher OKSs in the kinematically aligned group in our study may be predictive of a lower rate of revision. Previously published alignment data for these patients9 showed that kinematic alignment did not preclude a neutral limb mechanical axis (Fig. 2). The mean alignment of both the limb and the knee in our patients was similar in both groups. The alignment of the components was different in the two groups, with a mean 2.2° more valgus for the femoral component and 2.1° more varus for the tibial component in the kinematically aligned knee group. A study of the Kinematic Condylar Prosthesis (Howmedica, Rutherford, New Jersey) with a mean varus alignment of the tibial component of 3° (sd 3) (similar to the mean 2.1° (sd 2.6) alignment of the tibial component in this study) showed a 96% survival of the prosthesis at ten years.22 A biomechanical study of the same prosthesis in 2° of tibial varus produced 51% to 49% mediolateral force distribution, consistent with symmetrical loading of the tibial component.23 In a study of 214 kinematically aligned knees with a mean follow up of 38 months (31 to 43), none had required revision of either component for loosening, wear or instability.6 The rate of further operation for any reason was 1.4%.

One explanation for the better pain relief, function and flexion in the kinematically aligned TKR could be the use of patient-specific instrumentation. This explanation is unlikely, however, as clinical trials and a comprehensive review article have shown no difference in function and alignment between patients treated with a mechanically aligned TKR performed with patient-specific guides, and those treated with a mechanically aligned TKR performed with conventional instruments.24-26

Another explanation is that the principle of kinematic alignment results in better pain relief, function and flexion than the principle of mechanical alignment. In our study, the kinematically aligned group varus-valgus angle of the femoral and tibial components was generally anatomical or in a natural alignment, which was significantly different from the mechanically aligned group, confirming that different alignment goals were achieved.

The second (null) hypothesis of this study was that there would be no difference between the two methods for blood loss, distance walked prior to discharge from hospital, length of stay, and rates of further minor and major operations. This hypothesis was confirmed for all except the distance walked. The kinematic group walked a mean of 50 feet further, indicating an earlier functional recovery in these patients.

This study has limitations. The population was primarily male, but the results are similar to those in the literature for kinematically aligned and mechanically aligned TKR in both men and women.6,27-29 The mean intention-to-treat OKS of 40 in the kinematically aligned group in our study is similar to the mean OKS of 43 reported in a case series of kinematically aligned TKRs in both men and women,6 and also similar to the mean of 42 reported in a series of 93 consecutive kinematically aligned TKRs performed with manual instruments.27

The mean intention-to-treat OKS of 33 in the mechanically aligned group in this study is similar to the mean OKS of 34 at two years in a large registry series of both men and women,28 and compares with a two-year mean OKS of 33 for fixed-bearing TKRs noted in the Knee Arthroplasty Trial.29

Another limitation of this study is that patients with post-traumatic osteoarthritic deformities were not included. The study does not show whether a kinematic alignment technique would be applicable to complex multilevel deformities.

This study involved only two surgeons at one site, and larger studies involving many sites and surgeons are needed to determine whether the results are generally applicable. Longer-term studies are also needed to investigate the survival of TKR using this technique of achieving alignment. Our findings should guide further research on kinematic alignment to assess wear, survival, clinical outcomes in women, outcomes with different designs of implant, and outcomes using different patient-specific guides.

This randomised controlled trial has shown that individualising a TKR using 3D imaging, and pre-operative computer planning to produce patient-specific guides in an attempt to replicate the kinematics of an individual’s knee, can significantly reduce pain and restore better function and movement two years post-operatively than a mechanical alignment technique using conventional instruments.

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1. **MACDESSI SJ, GRIFFITHS-JONES W, CHEN DB, GRIFFITHS-JONES S, WOOD JA, DIWAN AD,HARRIS IA.**

**RESTORING THE CONSTITUTIONAL ALIGNMENT WITH A RESTRICTIVE KINEMATIC PROTOCOL IMPROVES QUANTITATIVE SOFT-TISSUE BALANCE IN TOTAL KNEE ARTHROPLASTY: A RANDOMIZED CONTROLLED TRIAL. BONE JOINT J. 2020 JAN;102-B(1):117-124.**

**Abstract**

**AIMS**

It is unknown whether kinematic alignment (KA) objectively improves knee balance in total knee arthroplasty (TKA), despite this being the biomechanical rationale for its use. This study aimed to determine whether restoring the constitutional alignment using a restrictive KA protocol resulted in better quantitative knee balance than mechanical alignment (MA).

**METHODS**

We conducted a randomized superiority trial comparing patients undergoing TKA assigned to KA within a restrictive safe zone or MA. Optimal knee balance was defined as an intercompartmental pressure difference (ICPD) of 15 psi or less using a pressure sensor. The primary endpoint was the mean intraoperative ICPD at 10° of flexion prior to knee balancing. Secondary outcomes included balance at 45° and 90°, requirements for balancing procedures, and presence of tibiofemoral lift-off.

**RESULTS**

A total of 63 patients (70 knees) were randomized to KA and 62 patients (68 knees) to MA. Mean ICPD at 10° flexion in the KA group was 11.7 psi (SD 13.1) compared with 32.0 psi in the MA group (SD 28.9), with a mean difference in ICPD between KA and MA of 20.3 psi (p < 0.001). Mean ICPD in the KA group was significantly lower than in the MA group at 45° and 90°, respectively (25.2 psi MA vs 14.8 psi KA, p = 0.004; 19.1 psi MA vs 11.7 psi KA, p < 0.002, respectively). Overall, participants in the KA group were more likely to achieve optimal knee balance (80% vs 35%; p < 0.001). Bone recuts to achieve knee balance were more likely to be required in the MA group (49% vs 9%; p < 0.001). More participants in the MA group had tibiofemoral lift-off (43% vs 13%; p < 0.001).

**CONCLUSION**

This study provides persuasive evidence that restoring the constitutional alignment with KA in TKA results in a statistically significant improvement in quantitative knee balance, and further supports this technique as a viable alternative to MA.

Introduction

The causes of dissatisfaction following total knee arthroplasty (TKA) are likely to be multifactorial, with surgical factors such as instability, malalignment, patellofemoral maltracking, and stiffness reported to be significant contributors.1-4 Such dissatisfaction has led some surgeons to question the focus on creating the theoretically ideal mechanically aligned environment for the implant,5-8 suggesting instead ways to accurately recreate the constitutional (or pre-arthritic) alignment of the knee9 with a goal of improving patient satisfaction.10-12

The kinematic alignment (KA) method13 aims to restore the constitutional knee joint by creating bone resections parallel to the pre-disease surface of distal femur, posterior femur, and proximal tibia, as opposed to cuts oriented perpendicular to the long axis of each bone. The rationale is that a knee aligned to the patient’s native anatomy will be better balanced and therefore will require little, if any, adjustment of the soft-tissue envelope to more closely approximate normal knee kinematics.10 It remains unclear whether such kinematic techniques improve quantitatively measured knee balance when compared with mechanical alignment (MA), despite evidence that this technique may contribute to improved patient outcomes.13-17

The aim of this study was to assess whether restoring the patient’s constitutional alignment during TKA using a restrictive KA protocol results in better quantitative soft-tissue balance when compared with the conventional method of MA. The null hypothesis was that there would be no difference in mean intercompartmental pressure difference (ICPD) at 10° of knee flexion in patients who underwent TKA performed with a restrictive safe zone KA protocol when compared with those having surgery using MA. Additionally, we wished to test null hypotheses that a restrictive KA protocol would result in no difference in mean ICPDs at higher degrees of knee flexion, on the proportion of balanced knees, number of balancing procedures, and number of cases of tibiofemoral lift-off when compared with MA.

Methods

Study designWe conducted a randomized, controlled, parallel-group superiority trial comparing intraoperative soft-tissue balance in TKAs implanted using kinematic versus MA with a 1:1 ratio. Participants, assessors and statisticians were blinded in order to enable unbiased collection and analysis of patient-reported and functional outcomes. Allocation was performed via sequentially numbered, sealed opaque envelopes. Randomization was undertaken using computer-generated permuted blocks of four, with surgeons unaware of block size. Bilateral procedures were included and randomized once, with both sides being assigned to the same group. The study protocol was approved by Bellberry Ethics Committee (#2017-12-911) and was prospectively registered with the Australian New Zealand Clinical Trials Registry (#ACTRN12617001627347).

Participants Between February and August 2018, consecutive patients listed at our knee clinic to undergo primary TKA were screened for eligibility resulting in 125 participants and 138 knees (74 males, 51 females; mean age 67.5 years (36 to 89)). Patients were considered eligible for inclusion if they were scheduled for primary, unilateral or bilateral TKA for osteoarthritis, inflammatory arthritis, or post-traumatic osteoarthritis. Two knee arthroplasty surgeons (SJM, DBC) performed all procedures at one private hospital in Sydney, Australia. Each surgeon has been in clinical practice for 13 years and performs between 200 and 300 TKAs annually. Both surgeons routinely performed mechanically aligned TKAs, and prior to commencement of the study performed approximately 20 navigated KA TKAs to avoid a potential impact of the surgical learning curve on the study.

Patients were excluded if they had prior grade 3 ligamentous knee injury to posterolateral corner or lateral collateral ligament. Patients with previous grade 3 medial collateral ligament injuries treated conservatively were included if they were deemed by the surgeon to have healed with a maximum of grade 1 laxity. Patients with prior femoral, tibial, or patellofemoral osteotomies, or extra-articular femoral or tibial malunions with deformity greater than 5° in any plane were excluded.

Preoperative plans and groups Surgical planning was undertaken with weight-bearing, long leg alignment radiographs as per Paley.18 The hip-knee-ankle (HKA) angle, lateral distal femoral angle (LDFA), and medial proximal tibial angle (MPTA) were measured using a software-based measurement tool as per Bellemans et al.9

In the control group (MA), initial femoral and tibial bone resections were positioned perpendicular to the mechanical axis of each bone and at an HKA angle of 0°.5-8,19 Femoral component rotation was set parallel to the surgical transepicondylar axis with secondary rotational referencing perpendicular to the anteroposterior sulcus axis and 3° externally rotated to the posterior condylar axis.

In the intervention group (KA), bone resections were undertaken within a restrictive alignment safe zone of 4° valgus to 3° varus for recreation of the LDFA, 3° valgus to 4° varus for the MPTA, and 5° varus to 4° valgus for the HKA. If the preoperative plan required LDFA and MPTA resections that would lead to an HKA outside the safe zone, then LDFA and MPTA were incrementally adjusted until the final HKA did not exceed the boundaries of the safe zone. To reduce the risk of subsidence of the implant, patients with a history of medically treated osteoporosis, insufficiency fractures, or those aged over 80 years had the safe zones for LFDA and MPTA narrowed to 3° valgus to 3° varus, and HKA narrowed to 4° varus to 3° valgus. The angles bounding these safe zones were centred on means describing the normal distribution of these angles,9 as well as studies examining implant alignment in the context of survivorship.6-8,20 Femoral component rotation was initially set parallel to the native posterior condylar axis. If the planned tibial resection angle was reduced in order to bring it within the safe zone, the femoral component was externally rotated by the same amount in order to rebalance the flexion gap.

Surgical technique A posterior-stabilized, fully cemented total knee prosthesis was used with patellar resurfacing in all cases (Legion; Smith & Nephew, Memphis, Tennessee, USA). All TKAs were implanted using computer-assisted navigation (OrthoMap Precision Navigation; Stryker, Kalamazoo, Michigan, USA) to improve accuracy as well as to ensure consistency between groups. All implants were aligned according to group allocation. Trial components were inserted prior to any soft-tissue releases. During trialling, the surgeon determined the most suitable tibial insert size. The extensor mechanism was approximated using towel clips, and the knee cycled through a range of motion.21

ICPD assessments and balance The pressure sensor insert (VERASENSE; OrthoSensor, Dania Beach, Florida, USA) recorded initial knee ICPDs at 10°, 45°, and 90°, confirmed with computer-assisted navigation. Compartment pressures were recorded by the operating surgeon and surgical assistant. The absolute mean ICPD of the two readings constituted the primary endpoint.

The surgeon then undertook final balancing by standard surgical techniques, and utilizing the sensor as per Gustke et al.22 All knees were considered balanced if they achieved an ICPD of 15 psi or less at all three flexion angles.23,24 Improved one-year functional and satisfaction scores have been reported in patients with ICPDs less than 15 psi.24,25 Further bony resection was performed if the absolute pressure in one compartment was greater than 60 psi, or an ICPD was greater than 40 psi. If the ICPD was between 16 psi and 40 psi, a soft-tissue release was performed. The aim was to achieve a final ICPD of 15 psi or less, with a single compartmental pressure of 40 psi or less at the three flexion angles.

Endpoints at surgery and postoperative outcomes The primary endpoint with respect to improved knee balance was the difference of the mean ICPD at 10° of flexion between groups. This was recorded with trial implants in situ and prior to balancing procedures. A flexion of 10° was chosen as the primary endpoint as this is the position in which weight acceptance occurs during the gait cycle and walking on level ground is the most common activity after TKA. Additionally, the planning for KA was performed in the coronal plane to give distal femoral and proximal tibial resections and resultant extension gap, as opposed to a posterior femoral resection determining flexion gap balance. A primary endpoint measured at 10° (near extension) would therefore better reflect the different surgical technique in the KA cohort.

Secondary endpoints of mean ICPDs at 45° and 90° corresponded to mid- and high-flexion activities such as stair-climbing and rising from a seated position. We recorded the need for subsequent balancing procedures (further bony resection or soft-tissue releases) once pressures were recorded. We determined the proportions in each group that were balanced and recorded tibiofemoral ‘lift-off’ (no contact in one compartment with at least 20 psi of pressure in the contralateral compartment, agreed by both observers) as an indicator of significant imbalance.26,27 The requirement for a 20 psi minimum pressure of the contralateral side was to ensure that the zero reading was not due to an overall reduced joint tension, and instead reflected significant tightness of the collateral ligament on the contralateral side of the lift-off.26 Total operative time in minutes from skin incision to wound closure was recorded.

Radiological assessment of postoperative alignment was undertaken with CT using the Perth protocol.28,29 We analyzed the final postoperative CT alignment in both groups with respect to neutral MA and final target alignments (± 2° and ± 3°) for HKA, LDFA, and MPTA.

Finally, we recorded preoperative and one-year postoperative patient-reported outcome scores using the Knee Injury and Osteoarthritis Outcome Score 4 (KOOS4), the aggregated mean score of the subscales that are most specific to TKA recovery: pain, symptoms, function in daily living, and knee-related quality of life30,31 along with all five subscales of KOOS. In addition, we recorded the Forgotten Joint Score-12 (FJS-12), which focuses on patients’ awareness of their knees in everyday life,32 and the EuroQol five-dimension five-level questionnaire (EQ-5D-5L) as a standard measure of overall health status.33,34

Sample size We analyzed the ICPDs of 280 consecutive mechanically aligned TKAs and found a mean initial 10° ICPD of 30 psi (SD 30) prior to knee balancing. Given the recommended value of 15 psi in order to consider the knee balanced, we decided that a reduction of 15 psi would represent a clinically meaningful difference to achieve using KA prior to releases being performed. Using a 5% significance, a SD of 30 and an 80% power to detect a mean pressure reduction of 15 psi between groups, a sample size of 125 was required. As the primary endpoint was an intraoperative measurement, no loss to follow-up was included in the calculation.

Statistical analysis Independent-samples and paired t-tests were used to compare mean differences between continuous variables and reported with 95% confidence intervals (CIs). The Mann-Whitney U test was used to compare mean differences for non-normally distributed data. Chi-squared tests were used to compare proportions between groups. Intraclass correlation coefficients with 95% CIs were used to assess absolute agreement between the two observers with a two-way mixed effects model. Poor reliability was considered for values under 0.5, moderate reliability for 0.5 to 0.75, good reliability for 0.75 to 0.9, and excellent above 0.9. Statistical significance was set at p < 0.05.

Results

A total of 131 consecutive patients were eligible for inclusion. Two patients refused to participate, one patient did not meet the inclusion criteria, and three patients were excluded from final analysis due to inability to assess the primary endpoint. There were 62 patients (68 knees) in the MA group and 63 patients (70 knees) in the KA group who received the allocated intervention and were included in statistical analysis (Figure 1). There were no significant preoperative differences between groups (Table I).

Intercompartmental pressure difference at all knee flexion angles The mean ICPD in the MA group was almost twice that of patients undergoing the KA protocol at 45° and 90° of flexion of the knee (Table II).

Proportion of balanced knees between groups The proportion of knees that were unbalanced in each group was determined in order to calculate absolute risk, absolute risk reduction, and relative risk reduction. More than twice as many knees were balanced in the KA group at 10° (80%; 56/70 knees) when compared with the MA group (35%; 24/68 knees; p < 0.001, chi-squared test). The absolute and relative risks of having an unbalanced knee at each flexion angle are presented in Table III. In patients undergoing TKA with KA, there was a relative risk reduction of knee imbalance of 69%, 27%, and 48% at 10°, 45°, and 90°, respectively, when compared with MA group of patients. There was a significant relative risk reduction by undertaking a KA procedure at 10° and 90° of knee flexion compared with MA.

Requirements for subsequent knee balancing procedures Additional bony resection to alter the final alignment of the knee were more likely to be required in the MA group to achieve optimal knee balance (49% MA group, 9% KA group; p < 0.001, chi-squared test). The majority of such resections were made on the tibia (Table IV). A higher proportion of resections required additional soft tissue balancing in the MA group.

Presence of lift-off Prior to knee balancing, there was a significantly higher proportion of patients with lift-off in the MA group in at least one position (43% MA, 13% KA; p < 0.001, chi-squared test). The majority of these phenomena were noted in the lateral compartment (23/29 cases in MA group, 1/9 cases in KA group). When comparing two or more positions with lift-off, 27% had lift-off in the MA group compared with 4% in the KA group (p < 0.001, chi-squared test).

Operative time The mean total operative time was 78 minutes in the MA group (SD 12.3; 58 to 120) and 79 minutes in the KA group (SD 17.0; 58 to 160; p = 0.907; independent samples t-test).

Alignment The postoperative alignment was within 3° of the surgically recorded computer-assisted navigation resections in 94% of cases for both groups (Table V). The LDFA in the KA group had a greater mean valgus angulation (KA 89.2° (SD 1.8°; 85° to 93°), MA 90.6° (SD 1.5°; 86° to 93°); p < 0.001, independent samples t-test). By contrast, the MPTA in the KA group had a greater mean varus angulation (KA 88.9° (SD 1.8°; 84° to 95°), MA 90.0° (SD 1.9°; 85° to 94°; p = 0.003, independent samples t-test). There was no significant difference in the mean hip-knee-ankle (HKA) or the percentage of cases within ± 2° and ± 3° of neutral MA when comparing KA with MA with secondary balancing (including bone recuts).

Clinical outcomes Table VI presents a summary of patient-reported outcome scores. There were no statistically significant differences between groups when comparing baseline with one-year postoperative scores. It should be noted that a significant proportion of participants assigned to MA and KA groups underwent subsequent alignment changes and soft-tissue balancing procedures based on sensor pressures if required, hence these outcomes do not represent a direct comparison of MA and KA.

Discussion

This randomized controlled trial confirmed that recreating the constitutional alignment of the knee within a restrictive safe zone via kinematic alignment results in a lower mean ICPD at 10° of flexion compared with mechanical alignment. Significantly lower ICPDs were also seen at higher knee flexion angles in the KA group. At all knee positions, knees were found to have more equal mediolateral compartmental loads when KA was used, compared with MA. The ICPD decreased slightly between groups with increasing knee flexion. This may have been as a result of the coronal nature of the radiological planning of kinematic bone resections, leading to more pronounced differences near full extension than when in flexion.

The high rate of knee balancing noted in the current study is most likely multifactorial. The sensor may overestimate the requirement to undertake knee balancing because an optimal ICPD that correlates with patient outcomes has not been demonstrated by high-quality studies.25,35,36 Additionally, surgeon-defined assessment of knee balance is a poor predictor of the true soft-tissue balance compared with sensor data.37 Generally, it is likely that a high proportion of knees are left unbalanced despite surgeon assessment of appropriate balance.

Severe knee imbalance in this study was evidenced by the presence of lift-off, which indicates significant collateral ligament tightness on the contralateral side of the tibiofemoral joint separation and secondary unicompartmental load bearing.26,27,38,39 Although some degree of lateral tibiofemoral laxity is recognized to occur normally in flexion,40 the lift-offs recorded using our pre-defined criterion of high sensor pressures in the opposite compartment, particularly in extension, indicate that this phenomenon was most likely pathological. The rate of lift-off in our MA group using sensors was similar to that in other studies using different measures. The majority were noted to occur in the lateral compartment. This may suggest that iatrogenic overtightening of the medial collateral ligament results when a knee with constitutional varus develops relative valgus when positioned in neutral MA. Dennis et al26 fluoroscopically examined 40 successful TKAs and noted lift-off in 70% of cruciate-retaining and 80% of posterior-stabilized designs. Insall et al27 noted fluoroscopically demonstrated lift-off in 40% of TKAs in flexion, and Kim et al38 reported lift-off with axial radiographs in 18% of navigated and 45% of non-navigated TKAs.

Vandekerckhove et al41 examined 95 retrieved polyethylene inserts and noted more insert wear laterally in varus knees, which they felt may be due to lateral condylar lift-off inducing impact and shear loading. Li et al42 also reported that postoperative varus alignment predisposes to wear of both medial and lateral sides of retrieved polyethylene inserts, which may support the theory of lateral condylar lift-off as a cause of impaction wear. Although there is a concern regarding increased alignment outliers with KA,43 it is possible that the technique may actually reduce polyethylene wear through reduced incidence of lift-off. Our study did not find an increase in outliers with KA when compared with MA, despite KA significantly reducing lift-off.

The current study has several limitations. First, the one-year clinical results do not represent a true comparison of the two methods as both groups underwent balancing if indicated, due to the ethical conflict inherent in failing to address a knee confirmed by instrumentation to be unbalanced. Nearly half of all mechanically aligned knees subsequently underwent further bony resections that likely aligned them closer to their constitutional alignment. The results do indicate that both alignment strategies with subsequent knee balancing using sensor technology may produce similar early clinical outcomes. Kinematic alignment may, however, provide a potential surgical efficiency advantage in the absence of sensor technology as initial balance was achieved more readily and required significantly fewer balancing procedures. We used only one type of knee prosthesis with a posterior-stabilized design. As such, the results of this study may not be applicable to other implant designs, especially those with differing levels of stability or more anatomical articulations, as it is known that flexion laxities are altered with resection of the posterior cruciate ligament.44-47 Although patient blinding was undertaken, the surgeon was not blinded when sensor measures were recorded, and hence we cannot exclude measurement or treatment bias. For this reason, a second observer was used and intraclass correlations showed high levels of agreement between measures, thereby reducing the risk of measurement bias. Knee balancing procedures were performed based on the predefined sensor pressures, aiming to reduce the risk of treatment bias. The cost of the sensor technology used to determine and undertake knee balancing may prohibit widespread adoption. For the purposes of this study, however, the sensors provided an objective, quantifiable measure of knee balance.

The results of this study provide persuasive evidence that restoration of the patient’s constitutional alignment within a restrictive kinematic safe zone significantly improves knee balance, reduces knee balancing procedures, and may more closely restore native soft-tissue tension when compared with MA. Further high-quality randomized trials with long-term follow-up to evaluate efficacy, safety, and subsequent revision risk are needed to confirm the validity and efficacy of this approach.

Take home message

- Restoring the constitutional alignment of the knee using a restrictive kinematic protocol improves quantitative knee balance when compared to mechanical alignment.

- Twice as many patients undergoing kinematic alignment will have an optimally balanced knee when compared to mechanical alignment.

- Kinematic alignment significantly reduces the rate of tibiofemoral lift-off and the requirement for knee balancing procedures.

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1. **MCEWEN PJ, DLASKA CE, JOVANOVIC IA, DOMA K, BRANDON BJ.**

**COMPUTER-ASSISTED KINEMATIC AND MECHANICAL AXIS TOTAL KNEE ARTHROPLASTY: A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL OF BILATERAL SIMULTANEOUS SURGERY. J ARTHROPLASTY. 2020 FEB;35(2):443-450. DOI: 10.1016/J.ARTH.2019.08.064. EPUB 2019 SEP 5. PUBMED**

**Abstract**

**BACKGROUND:**

Randomized controlled trials of kinematic alignment (KA) and mechanical alignment (MA) in primary total knee arthroplasty (TKA) have to date demonstrated at least equivalence of KA in terms of clinical outcomes. No trial of bilateral TKA has been conducted so patient preference for one technique over the other is unknown.

**METHODS:**

Forty-one participants underwent computer-assisted bilateral TKA. The outcome measures were as follows: (1) joint range of motion and functional scores including the KOOS, the KOOS JR, Oxford Knee Score, and the Forgotten Joint Score at a minimum of 2 years; (2) preference and perception of limb symmetry; (3) intraoperative alignment data; (4) release and gap balance data; and (5) postoperative radiographic joint angles.

**RESULTS:**

There were no significant differences with respect to flexion range (P = .970) or functional scores (mean KOOS, P = .941; KOOS JR, P = .685; Oxford Knee Score, P = .578; FJS, P = .542). Significantly more participants who favored one knee preferred their KA TKA (P = .03); however, half of the patients had no preference and the overall numbers were small. Only 3 participants perceived any limb asymmetry (P < .001). More releases were required in the MA group (P = .018). Standing hip-knee-ankle angle means and frequency distributions were similar (P = .097 and P = .097, respectively).

**CONCLUSION:**

Clinical outcomes were equivalent at 2 years. Significantly more participants preferred their KA joint. Fewer releases were required using a KA technique. Participants were visually insensitive to modest hip-knee-ankle angle asymmetry.

**LEVEL OF EVIDENCE:**

Level 1.

1. **FRENCH SR, MUNIR S, BRIGHTON R.**

**A SINGLE SURGEON SERIES COMPARING THE OUTCOMES OF A CRUCIATE RETAINING AND MEDIALLY STABILIZED TOTAL KNEE ARTHROPLASTY USING KINEMATIC ALIGNMENT PRINCIPLES. J ARTHROPLASTY. 2020 FEB;35(2):422-428.**

Abstract

**BACKGROUND:**

Total knee arthroplasty (TKA) designs are developed to optimize kinematics and improve patient satisfaction. The cruciate retaining (CR) and medially stabilized (MS) TKA designs have reported good mid-term follow-up outcomes. However, reasons for consistently high rates of patient dissatisfaction following a TKA remain poorly understood. To further investigate this, we compared the short-term functional outcomes and quality of life, using patient-reported outcome measures (PROMs) and range of motion (ROM), between a CR and MS TKA.

**METHODS:**

A prospective comparison was made between 2 groups (44 CR-TKAs vs 46 MS-TKAs). The Knee Injury and Osteoarthritis Outcome Score (KOOS), KOOS-12, KOOS-Short form, KOOS-Joint Replacement, Oxford Knee Score, Western Ontario and McMaster Universities Osteoarthritis Index, UCLA Activity Scale, and EuroQuality of life - 5 Dimension were completed preoperatively and 1 year postoperatively. The Forgotten Joint Score (FJS) and Visual Analogue Scale-Satisfaction were completed at 1 year postoperatively. ROM was collected preoperatively and 1 year postoperatively.

**RESULTS:**

Patients who underwent an MS-TKA scored significantly better than the CR-TKA on the FJS (MS = 79.87, CR = 63.8, P = .005), the KOOS-12 Quality of Life subscale (MS = 82.8, CR = 74.4, P = .43), and the KOOS Quality of Life subscale (MS = 82.8, CR = 74.6, P = .44). There was no difference between the groups in all assessed PROMs or ROM, preoperatively and 1 year postoperatively.

**CONCLUSION:**

Patients who underwent the MS-TKA scored significantly better on the FJS and the quality of life subscale of the KOOS and KOOS-12 than those who underwent a CR-TKA. All other assessed PROMs and ROM were comparable between the 2 groups and demonstrated that both implants facilitated symptom relief and improved daily function at 1 year postoperatively. These findings suggest that at short-term follow-up, the MS device is more likely to allow a patient to "forget" that a joint has been replaced and restore their quality of life. Long-term assessment of MS-TKA design outcomes in larger cohorts is recommended.

1. **NIKI Y, NAGURA T, KOBAYASHI S, UDAGAWA K, HARATO K.**

**WHO WILL BENEFIT FROM KINEMATICALLY ALIGNED TOTAL KNEE ARTHROPLASTY? PERSPECTIVES ON PATIENT-REPORTED OUTCOME MEASURES. J ARTHROPLASTY. 2020 FEB;35(2):438-442.E2.**

Abstract

**BACKGROUND:**

Indications for kinematically aligned total knee arthroplasty (KA-TKA) have remained contentious. This study aimed at exploring preoperative characteristics of patients who were suitable for and benefited from KA-TKA, based on the assessment of patient-reported outcome measures (PROMs).

**METHODS:**

Subjects comprised 100 patients undergoing KA-TKA and 100 patients undergoing mechanically aligned (MA)-TKA due to end-stage osteoarthritis. Bone cuts were performed using portable navigation systems according to 3D planning data from computed tomography. At 2 years postoperatively, all 200 patients were assessed for PROMs, including Knee Society Score 2011, pain catastrophizing scale, and pain DETECT score. Multiple regression analysis was performed with activity subscore set as a dependent variable. Principal component analysis was used to evaluate patient satisfaction and function components transformed from the 3 PROMs and to compare these components between KA-TKA and MA-TKA.

**RESULTS:**

Male gender or use of KA technique positively affected advanced activity score, whereas age, body mass index, preoperative pain DETECT score, and preoperative femorotibial angle showed negative effects. In principal component analysis, 38 KA-TKA patients achieved a higher function score, with satisfaction scores comparable to those from MA-TKA. These 38 patients were characterized by a higher percentage of males, younger age, and higher preoperative total activity score.

**CONCLUSION:**

From the perspective of PROMs, KA-TKA should be favored over MA-TKA for young active males, because these patient groups achieved higher functional activity when undergoing KA-TKA.

1. **MATSUMOTO T, TAKAYAMA K, ISHIDA K, HAYASHI S, HASHIMOTO S, KURODA R.**

**RADIOLOGICAL AND CLINICAL COMPARISON OF KINEMATICALLY VERSUS MECHANICALLY ALIGNED TOTAL KNEE ARTHROPLASTY. BONE JOINT J. 2017 MAY;99-B(5):640-646.**

**Abstract**

**AIMS**

The aim of this study was to compare the post-operative radiographic and clinical outcomes between kinematically and mechanically aligned total knee arthroplasties (TKAs).

**PATIENTS AND METHODS**

A total of 60 TKAs (30 kinematically and 30 mechanically aligned) were performed in 60 patients with varus osteoarthritis of the knee using a navigation system. The angles of orientation of the joint line in relation to the floor, the conventional and true mechanical axis (tMA) (the line from the centre of the hip to the lowest point of the calcaneus) were compared, one year post-operatively, on single-leg and double-leg standing long leg radiographs between the groups. The range of movement and 2011 Knee Society Scores were also compared between the groups at that time.

**RESULTS**

The angles of orientation of the joint line in the kinematic group changed from slight varus on double-leg standing to slight valgus with single-leg standing. The mechanical axes in the kinematic group passed through a neutral position of the knee in the true condition when the calcaneus was considered. The post-operative angles of flexion and functional activity scores were significantly better in the kinematic than in the mechanical group (p < 0.003 and 0.03, respectively).

**CONCLUSION**

A kinematically aligned TKA results in a joint line which has a more parallel orientation in relation to the floor during single- and double-leg standing, and more neutral weight-bearing in tMA than a mechanically aligned TKA.

1. **WATERSON HB, CLEMENT ND, EYRES KS, MANDALIA VI, TOMS AD.**

**THE EARLY OUTCOME OF KINEMATIC VERSUS MECHANICAL ALIGNMENT IN TOTAL KNEE ARTHROPLASTY: A PROSPECTIVE RANDOMISED CONTROL TRIAL. BONE JOINT J. 2016 OCT;98-B(10):1360-1368.**

**Abstract**

**AIMS:**

Our aim was to compare kinematic with mechanical alignment in total knee arthroplasty (TKA).

**PATIENTS AND METHODS:**

We performed a prospective blinded randomised controlled trial to compare the functional outcome of patients undergoing TKA in mechanical alignment (MA) with those in kinematic alignment (KA). A total of 71 patients undergoing TKA were randomised to either kinematic (n = 36) or mechanical alignment (n = 35). Pre- and post-operative hip-knee-ankle radiographs were analysed. The knee injury and osteoarthritis outcome score (KOOS), American Knee Society Score, Short Form-36, Euro-Qol (EQ-5D), range of movement (ROM), two minute walk, and timed up and go tests were assessed pre-operatively and at six weeks, three and six months and one year post-

operatively.

**RESULTS:**

A total of 78% of the kinematically aligned group (28 patients) and 77% of the mechanically aligned group (27 patients) were within 3° of their pre-operative plan. There were no statistically significant differences in the mean KOOS (difference 1.3, 95% confidence interval (CI) -9.4 to 12.1, p = 0.80), EQ-5D (difference 0.8, 95% CI -7.9 to 9.6, p = 0.84), ROM (difference 0.1, 95% CI -6.0 to 6.1, p = 0.99), two minute distance tolerance (difference 20.0, 95% CI -52.8 to 92.8, p = 0.58), or timed up and go (difference 0.78, 95% CI -2.3 to 3.9, p = 0.62) between the groups at one

year.

**CONCLUSION:**

Kinematically aligned TKAs appear to have comparable short-term results to mechanically aligned TKAs with no significant differences in function one year post-operatively. Further research is required to see if any theoretical long-term functional benefits of kinematic alignment are realised or if there are any potential effects on implant survival.

1. **YOUNG SW, WALKER ML, BAYAN A, BRIANT-EVANS T, PAVLOU P, FARRINGTON B.**

**THE CHITRANJAN S. RANAWAT AWARD : NO DIFFERENCE IN 2-YEAR FUNCTIONAL OUTCOMES USING KINEMATIC VERSUS MECHANICAL ALIGNMENT IN TKA: A RANDOMIZED CONTROLLED CLINICAL TRIAL. CLIN ORTHOP RELAT RES. 2017 JAN;475(1):9-20.**

**Abstract**

**BACKGROUND**

Neutral mechanical alignment (MA) in total knee arthroplasty (TKA) aims to position femoral and tibial components perpendicular to the mechanical axis of the limb. In contrast, kinematic alignment (KA) attempts to match implant position to the prearthritic anatomy of the individual patient with the aim of improving functional outcome. However, comparative data between the two techniques are lacking.

**QUESTIONS/PURPOSES**

In this randomized trial, we asked: (1) Are 2-year patient-reported outcome scores enhanced in patients with KA compared with an MA technique? (2) How does postoperative component alignment differ between the techniques? (3) Is the proportion of patients undergoing reoperation at 2 years different between the techniques?

**METHODS**

Ninety-nine primary TKAs in 95 patients were randomized to either MA (n = 50) or KA (n = 49) groups. A pilot study of 20 TKAs was performed before this trial using the same patient-specific guides positioning in kinematic alignment. In the KA group, patient-specific cutting blocks were manufactured using individual preoperative MRI data. In the MA group, computer navigation was used to ensure neutral mechanical alignment accuracy. Postoperative alignment was assessed with CT scan, and functional scores (including the Oxford Knee Score, WOMAC, and the Forgotten Joint Score) were assessed preoperatively and at 6 weeks, 6 months, and 1 and 2 years postoperatively. No patients were lost to followup. We set sample size at a minimum of 45 patients per treatment arm based on a 5-point improvement in the mean Oxford Knee Score (OKS; the previously reported minimum clinically significant difference for the OKS in TKA), a pooled SD of 8.3, 80% power, and a two-sided significance level of 5%.

**RESULTS**

We observed no difference in 2-year change scores (postoperative minus preoperative score) in KA versus MA patients for the OKS (mean 21, SD 8 versus 20, SD 8, least square means 1.0, 95% confidence interval [CI], −1.4 to 3.4, p = 0.4), WOMAC score (mean 38, SD 18 versus 35, SD 8, least square means 3, 95% CI, −3.2 to 8.9, p = 0.3), or Forgotten Joint score (28 SD 37 versus 28, SD 28, least square means 0.8, 95% CI, −9.1–10.7, p = 0.8). Postoperative hip-knee-ankle axis was not different between groups (mean KA 0.4° varus SD 3.5 versus MA 0.7° varus SD 2.0), but in the KA group, the tibial component was a mean 1.9° more varus than the MA group (95% CI, 0.8°−3.0°, p = 0.003) and the femoral component in 1.6° more valgus (95% CI, −2.5° to −0.7°, p = 0.003). Complication rates were not different between groups.

**CONCLUSIONS**

We found no difference in 2-year patient-reported outcome scores in TKAs implanted using the KA versus an MA technique. The theoretical advantages of improved pain and function that form the basis of the design rationale of KA were not observed in this study. Currently, it is unknown whether the alterations in component alignment seen with KA will compromise long-term survivorship of TKA. In this study, we were unable to demonstrate an advantage to KA in terms of pain or function that would justify this risk.

**LEVEL OF EVIDENCE**

Level I, therapeutic study.

Introduction

Mechanical alignment (MA) in TKA aims to position femoral and tibial components perpendicular to the mechanical axis of each bone, aligning the hip-knee-ankle angle of the limb to neutral under static weightbearing conditions. This is a fundamental principle of TKA, aiming to achieve a more balanced load distribution within the medial and lateral compartments and minimize wear and component loosening [1, 3, 8, 18, 27, 30, 32, 39, 41]. Conventional TKA instrumentation is based around this principle, and computer navigation was introduced to aid accuracy in achieving this goal of a neutral mechanical axis [38, 40].

However, this situation differs from the native knee, in which the articular surface of the tibia averages 3° varus and that of the femur 2° to 3° of valgus relative to the mechanical axis [6]. Additionally, there is wide individual variation in limb alignment. A study of 250 young adults without arthritis found only 66% of males and 80% of females had a hip-knee-ankle angle within 3° of neutral with the majority of outliers demonstrating “constitutional varus” [7]. If such patients undergo TKA using MA principles, medial soft tissue releases are likely to be required [5, 6, 25]. In contrast, the kinematic alignment (KA) technique attempts to match implant position to recreate the anatomy of the prearthritic articular surface for the individual patient. Potentially this will improve ligament balancing and minimize the need for releases, because component alignment will more closely match each individual patient’s anatomy and the soft tissue envelope of the knee. Advocates of KA suggest that this will offer advantages over the MA technique in terms of pain and function. Additionally, recent studies suggest early patient-reported outcomes may be improved with KA [14, 15, 25, 34], but comparative data are lacking.

The aim of this randomized controlled trial was to ask: (1) Are 2-year patient-reported outcome scores enhanced in patients undergoing TKA with KA compared with an MA technique? (2) How does component alignment measured with postoperative CT scan differ between the two techniques? (3) Is the proportion of patients undergoing reoperation at 2 years different between the techniques?

Patients and Methods

Patients undergoing unilateral primary TKA at a single tertiary institution were eligible for enrollment in this prospective, randomized controlled trial. Ethical approval was obtained from the national ethical review board, and the trial and protocol were registered with the ClinicalTrials.gov (Identifier: NCT02527148). Inclusion criteria included a primary diagnosis of osteoarthritis suitable for a cruciate-retaining knee replacement (ie, posterior cruciate ligament intact) and the ability to undergo an MRI. Exclusion criteria were a history of previous osteotomy; gross deformity (> 15° varus/valgus deformity or fixed flexion contracture) that may require the use of stems, wedges, or augments during reconstruction; or instability for which the use of constrained implants was being considered. All procedures were performed by one of six fellowship-trained arthroplasty surgeons (BF, AB, TD-C, RS, DS, MLW), each of whom had performed > 500 TKAs. A pilot study of 20 TKAs was performed before this trial using the same patient-specific guides positioning in KA.

Between August 2011 and April 2013, 114 TKAs in 110 patients were enrolled by a trained research nurse (AJ) in an outpatient setting. Patients were randomized using computer-generated random allocations placed in numbered, opaque, sealed envelopes to either MA (n = 57) or KA (n = 56) groups. Seven patients in each group did not receive the allocated intervention (Fig. 1), leaving 49 TKAs in the KA group and 50 in the MA group for analysis. Mechanically aligned TKA was performed using an imageless computer navigation system (Stryker, Inc, Mahwah, NJ, USA), whereas kinematically aligned TKA was performed using patient-specific implant guides (OtisMed Inc, Alameda, CA, USA). All TKAs were performed using a cruciate-retaining, cemented, fixed-bearing implant (Triathlon; Stryker, Inc) implanted through a medial parapatellar approach. Patella resurfacing was performed selectively in cases where there was Grade 4 chondral loss on the patella or patellofemoral maltracking. Eleven TKAs in the in the KA group and six patients in the MA group underwent patella resurfacing. Both patients and independent outcome assessors collecting patient-reported outcome measures were blinded to the intervention. To maintain blinding, all patients underwent identical preoperative assessment, including full-length MRI scans of the affected limb. In the KA group, patient-specific cutting blocks were manufactured from individual MRI data using a previously described technique based on KA principles [14, 15, 21–23].

Briefly, the aim of the KA method used in this study is to recreate the prearthritic articular surface of the patient’s native knee using TKA components. In KA theory, three kinematic axes govern motion of the knee. The primary axis is a transverse axis passing through the center of a cylinder fit to the articular surface of the femoral condyles from 10° to 160° of flexion. The tibia flexes about the femur along this axis, and the patella about a second, parallel axes that are proximal and anterior. External and internal rotation of the tibia occurs along a third longitudinal axis perpendicular to the two transverse axes above. A standardized MRI protocol was used with the sagittal component of the MRI scan aligned perpendicular to the “primary flexion axis” of the femur about which the tibia flexes and extends [21]. Proprietary software then creates a three-dimensional knee model, which is transformed into a “prearthritic” model by removing osteophytes, filling articular defects, and equalizing the gap between the medial and lateral compartments of the knee [23]. A software algorithm selects the best-fitting femoral component to recreate the articular surface of the “prearthritic” knee with a reproducibility of ± 0.5 mm for translations and ± 0.5 for rotations [14] (OtisMed Inc). The coronal and sagittal alignment of the tibial component is positioned in a similar fashion with the rotational axis of the tibial component aligned perpendicular to the primary flexion axis of the femoral component [21]. Patient-specific cutting guides are then manufactured to fit the arthritic knee, which align bony cuts so coronal, sagittal, and rotational positioning of the TKA components matches that planned in the prearthritic knee model.

In the KA group, surgery was carried out according to the manufacturer-supplied surgical protocol. Patient-specific guides were opened within the sterile field and patient identifiers checked. Osteophytes were removed, and the distal femoral cut was made through the slot of the patient-specific guide. The guide was manufactured to match the patient anatomy of the preoperative MRI scan, which determined guide positioning [13]. Two pinholes in the guide were used to position a conventional four-in-one cutting block and set femoral rotation for anterior and posterior cuts. On the tibial side, the patient-specific guide was secured through pinholes on the proximal and anterior surface, and the tibial cut was made through the slot in the guide. Tibial component rotation was set through the pinholes in the proximal surface of the patient-specific guide in accordance with the preoperative plan.

A knee-balancing device (Stryker, Inc) was then inserted to measure the size and varus/valgus tightness of the flexion and extension gaps. In accordance with KA principles, ligamentous release was avoided but was performed if necessary to achieve symmetric ligament balance in both flexion and extension. Trial components were then positioned, and ROM, stability, posterior cruciate ligament tension, ligamentous balance, and patellar tracking were checked before definitive components were cemented in situ.

In the MA group, computer navigation was used according to the manufacturer’s surgical protocol to guide measured resection of bone with the goal of achieving overall neutral coronal limb alignment with tibial and femoral bony cuts perpendicular to the mechanical axis of each bone. Infrared trackers were secured to the tibia and femur and registration of bony landmarks performed. Navigation was used to position the distal femoral cutting guide at 90° to the mechanical axis of the femur. Posterior and anterior femoral cuts were then made with navigation assistance parallel to the surgical epicondylar axis with Whiteside’s line [2] and 3° external rotation relative to the posterior condylar axis used as additional references. Navigation was then used to position the tibial cutting guide at 90° to the mechanical axis of the tibia with 3° posterior slope. Tibial rotation was aligned to the junction of the medial and middle thirds of the tibial tubercle [29]. Osteophytes were removed, the knee balancer was inserted, and the size and varus/valgus tightness of the flexion and extension gaps checked. Ligament releases were performed where required to achieve symmetric ligament balance in both flexion and extension. Trial components were positioned and final checks of stability performed as described before cementation of the definitive components.

Postoperative management was identical between the two groups with physiotherapists blinded as to the intervention. All patients underwent CT scans of the lower limb according to the standardized Perth protocol [12], and detailed measurement of coronal, sagittal, and rotational alignment was performed by a blinded independent assessor (CG, SH). Patient-reported outcomes were assessed using the Oxford Knee Score (OKS, 0–48 worst to best) [33], the reduced WOMAC (0–100 worst to best) score [42], the pain and function components of the Knee Society Score (KSS, 0–100 worst to best) [26], the Forgotten Joint Score (FJS, 0–100 worst to best) [4, 31], EuroQol EQ-5D [11], and visual analog scales measuring pain at rest and when mobilizing (0–10 none to worst). Scores were measured preoperatively and at 6, 12, and 24 months postoperatively. Frequency and type of reoperations were recorded.

Statistical Analysis

Results were summarized using the mean, SD, range (minimum and maximum) for continuous variables, and frequencies and percentages for categorical variables by navigation (control) and kinematic patient groups. Baseline surgery and alignment data were evaluated using a chi-square test to compare the categorical response rates in each group and a paired t-test for the normally distributed data. The change from preoperative to the 2-year time point for the quality-of-life parameters was analyzed with analysis of covariance (ANCOVA) for repeated measurements. The repeated measurements were the four patients with bilateral knee replacements. The treatment effect was tested against between patient variance as estimated from the ANCOVA. The change from preoperative to the 2-year time point was adjusted for the baseline preoperative score, including the treatment group difference (kinematic—control); the 95% confidence interval (CI) for the treatment group difference was derived from between patient variance.

For each quality-of-life parameter, the absolute scores at 2 years were analyzed with analysis of variance for repeated measurements (ANOVA). The repeated measurements were the four patients with bilateral knee replacements. The treatment effect was tested against between patient variance as estimated from the ANOVA. The treatment group difference (kinematic—control) was the least squares mean (LSM) difference with 95% CI.

The significance level was set to 0.05 with no adjustment for multiple comparisons (SAS Version 9.3, Cary, NC, USA).

Power Analysis

The planned sample size for this study was 45 patients per treatment arm. This was based on a 5-point improvement in the mean OKS (the previously reported minimum clinically significant difference for the OKS in TKA [28]) from 37 (mean OKS reported in the New Zealand registry) to 42 (scoring category of excellent) with a pooled SD of 8, 80% power, and a two-sided significance level of 5%. An additional five patients per group (10%) have been included into the target patient number to allow for loss to followup, bringing the target to 50 patients per group.

Results

There was no difference in mean OKS at 2 years between the two groups (KA mean ± SD 42 ± 6 versus MA 41 ± 6, difference 1.0; 95% CI, −3.5 to 1.4; p = 0.4) nor in OKS change scores (2-year score minus preoperative score, KA 21 ± 8 versus MA 20 ± 8, LSM 1.0, 95% CI, −1.4 to 3.4, p = 0.4; Fig. 2). There was no difference in 2-year absolute or change scores for the KSS pain and function components, visual analog scale pain, WOMAC, or EQ-5D (Table 2). Similarly for the FJS, a score with a reduced ceiling effect specifically designed to differentiate between well-functioning implants, there was no difference in 2-year change scores (mean KA 28 ± 37 versus MA 28 ± 28, LSM 0.8, 95% CI, −9.1 to 11, p = 0.8). Intraoperative parameters did not differ significantly between groups (Table 3).

The mean overall mechanical limb axis (hip-knee-ankle angle) was similar between groups (KA 0.4° varus ± 3 versus MA 0.7° varus ± 2 varus, p = 0.6; Table 4), but there was greater variability in the KA group (KA: SD 3, range 11° varus to 6° valgus; MA: SD 2, range, 5° varus to 4° valgus; Fig. 3). In the KA group the tibial component was placed in a mean of 2° more varus than the MA group (95% CI, 1°–3°; p < 0.001) and the femoral component was placed in a mean of 1.6° more valgus (95% CI, 0.7°–2.5°; p = 0.003). In the KA group the femoral component was placed in a mean of 2° more internal rotation than the MA group (95% CI, 1°–3°; p < 0.001). In the KA group, 31% of tibias were in 5° or more of varus alignment compared with 4% in the MA group (Fig. 4).

There was no difference in the proportion of patients undergoing reoperation between groups (Table 5). Three patients in the KA and four patients in the MA group underwent reoperations. In the KA group, one patient sustained a patella dislocation 3 weeks postsurgery, which was treated with a patella realignment procedure. The patient then developed deep infection with Enterococcus faecalis successfully managed with débridement and polyethylene exchange with implant retention; OKS at 2 years was 45. Two patients underwent manipulation under anesthesia for stiffness. In one patient this was successful in restoring motion from 0° to 120°; the second patient continues to have reduced flexion (0°–80°) despite subsequent open débridement and exchange of the polyethylene liner with a smaller thickness. In the MA group, one patient sustained a distal femoral fracture 3 months after TKA treated with a lateral locking plate. He later developed a wound infection around the plate, which spread to involve the knee and was treated with a two-stage revision. One patient developed Streptococcus viridans deep infection 4 months postoperatively treated successfully with débridement and polyethylene exchange with implant retention. One patient developed recurrent hemarthroses with negative cultures, which resolved after open débridement. One patient fell 12 months after TKA and sustained a patella dislocation treated with open repair of the medial retinaculum and secondary patella resurfacing. The patient went on to develop recurrent patella instability, which was managed with a patella realignment procedure.

Discussion

Positioning components to achieve a neutral limb MA is a longstanding principle in TKA, aiming to provide more balanced load distribution and improve durability [1, 3, 8, 18, 27, 30, 32, 39, 41]. In contrast, KA aims to position TKA components to recreate the patient’s prearthritic articular surface anatomy, facilitating soft tissue balancing, which may, in turn, improve functional outcome [15, 25, 34]. Prospective data comparing MA with KA are limited to one previous trial [14], and given the excellent long-term results of MA, clear evidence of a functional advantage to KA is required before a change in technique can be recommended. In this prospective, randomized controlled trial, we were unable to demonstrate improved patient-reported outcome scores in KA versus the MA technique at 2-year followup.

This study has a number of limitations. First, the patient-specific instrumentation (PSI) guides used in the KA group were manufactured by a specific company using proprietary software analysis of the preoperative MRI scan. Other variants of KA such as using gap balancing or manual instrumentation to perform KA in TKA are described [25], and our results may not be generalizable to these techniques. However, the PSI guides were identical to those used in previous KA studies [14, 15, 22, 24, 34, 36], and their accuracy has been validated in a clinical study [13]. Currently, these guides are no longer commercially available in the United States nor elsewhere following a commercial decision by the manufacturing company. Second, 2-year followup is inadequate to assess long-term complications such as aseptic loosening, which may be affected by component alignment [18, 37]. Although positive 6-year results of the KA technique have been published [24], the long-term outcome remains unknown. Third, we did not control for patella resurfacing; however, we used set indications for patella resurfacing and the proportion resurfaced did not differ significantly between groups (22% KA versus 12% MA, p = 0.2). Fourth, although all surgeons involved in this study had considerable experience with the MA technique for TKA, experience with the KA technique was more limited. This did not appear to adversely affect the results of the KA group, because the 2-year change scores were as good or better as those of the KA group in a previous randomized trial [14]. Finally, although the main comparison of this study was KA versus MA component positioning, we used PSI in the KA group and computer navigation in the MA group. We do not believe this distinction compromises the results of the study, because both PSI and computer navigation merely represent techniques to enhance accuracy in achieving defined alignment goals.

Our findings contrast with the single previous randomized trial comparing the KA with the MA technique. Dossett et al. [14] randomized 88 patients undergoing TKA to either the KA technique with PSI or MA technique performed with manual instruments. At 2-year followup, there was a 7-point advantage in OKS to the KA group (mean OKS 40 versus 33, p = 0.005). This 2-year mean OKS for KA patients of 40 was comparable to the KA group in our study (mean OKS 42); however, outcomes for the MA group were very different: a mean OKS of 33 in the Dossett et al. trial versus 41 in this study. The reasons behind this are unclear. This previous study was performed on a unique population group of veterans (90% male), which may affect the generalizability of the results. Additionally, manual instrumentation was used for the neutral MA group compared with this study that used computer navigation. Although previous studies report no difference in patient-reported outcomes between TKAs performed with PSI versus manual instrumentation [35, 43], a meta-analysis of Level I studies did report a small functional advantage (mean 7-point increase in KSS score) for mechanically aligned TKAs performed with computer navigation versus manual instruments [38].

We found overall coronal limb alignment (hip-knee-ankle angle) to be similar in both KA and MA groups; however, in the KA group, the tibial component averaged 1.9° more varus and the femoral component 1.6° more valgus. This matches the findings of Dossett et al., who reported the tibial component to be in 2.1° more varus and the femoral component in 2.2° more valgus with the KA technique [14]. These findings are consistent with the stated goal of KA to more closely match the alignment of the native knee [6]. There was also more variation seen in overall limb alignment in the KA group (Fig. 2). The effect of these differences on component survival is currently unknown. Although there is strong biomechanical evidence that varus alignment of the tibial component causes increased load at the implant-bone interface [19, 20], clinical evidence of a negative effect on long-term survival is mixed [18, 37]. The amount of postoperative component varus or valgus alignment is likely to be important [20], but currently there are limited data with which to define what are “acceptable” postoperative parameters. Additionally, we found the femoral component was positioned in 2° more internal rotation in the KA group. This is to be expected, because a KA principle is to rotationally align the component to the cylindrical axis of the femur, which is distinct from the surgical transepicondylar axis used in the MA technique [16, 17].

We found no difference in the rate of short-term complications between the two groups. In particular we found no increase in the rate of patellofemoral complications in the KA group, similar to previous series using the KA technique [14, 15, 22, 24, 25]. The patellofemoral articulation is relevant because currently there is no implant specifically designed for use with KA; therefore, the relative internal rotation of the femoral component in KA versus the MA technique theoretically may adversely affect patellofemoral tracking [9, 10].

The KA technique used in this study required additional cost for preoperative MRI and PSI, although a KA technique using generic manual instruments has been described [25]. However, the main disadvantage of KA remains the uncertainty regarding the effects of the alignment changes on implant durability. Although 98% survivorship of KA has been reported at 6 years [24], long-term followup is lacking. Over 30% of the KA tibial components in our study were in 5° or more of varus (Fig. 4), and there is a risk that implant durability with KA will be adversely affected compared with MA. In this study, we were unable to demonstrate an advantage to KA in terms of pain or function, which would justify this risk.

In conclusion, we found no difference in 2-year patient-reported outcome scores in TKAs implanted using the KA compared with the MA technique. Currently, it is unknown whether the alterations in component alignment seen with KA will compromise TKA survivorship. Given the lack of a clear functional advantage to KA, until the long-term effect on implant durability is known, we recommend the technique be used with caution.

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