



# Kinematic alignment in total knee arthroplasty

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- Kinematic alignment (KA) is an alternative philosophy for aligning a total knee replacement (TKR) which aims to restore all three kinematic axes of the native knee.
- Many of the studies on KA have actually described non-KA techniques, which has led to much confusion about what actually fits the definition of KA.
- Alignment should only be measured using three-dimensional cross-sectional imaging. Many of the studies looking at the influence of implants/limb alignment on total knee arthroplasty outcomes are of limited value because of the use of two-dimensional imaging to measure alignment, potentially leading to inaccuracy.
- No studies have shown KA to be associated with higher complication rates or with worse implant survival; and the clinical outcomes following KA tend to be at least as good as mechanical alignment.
- Further high-quality multi-centre randomized controlled trials are needed to establish whether KA provides better function and without adversely impacting implant survival.

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## Introduction

Over 100,000 total knee replacements (TKR) are performed annually for painful end-stage osteoarthritis (OA) in the UK.<sup>1</sup> The main reason for undertaking a TKR is to provide pain relief as well as improving function and mobility. Up to 20% of patients annually (20,000 patients) who have a TKR are not satisfied with the outcome.<sup>2,3</sup> A significant proportion complain about restricted knee flexion, residual pain and limitations in performing day-to-day activities such as level walking, kneeling, walking up an incline, and pivoting the knee. Despite the many advancements to improve the precision and accuracy of TKR, functional

outcomes can remain disappointing.<sup>4</sup> Therefore, alternative ways of aligning a TKR have gained interest.

## What are the different ways of aligning a TKR?

### Anatomical alignment (AA)

In 1985, Hungerford and Krackow described the anatomical alignment technique of performing a TKR, with the aim of creating an oblique joint line (2–3° valgus) relative to the mechanical axis of the lower limb, using a 'systematic approach'.<sup>5</sup> AA aims for a neutral limb alignment with an oblique joint line relative to the mechanical axis of the limb.<sup>6</sup> This was thought to provide better load distribution in the tibial component as well as to improve patellofemoral biomechanics.<sup>4</sup> Although short-term outcomes were good, in a significant proportion of cases (5%), there was catastrophic wear of the polyethylene, resulting in a need for further intervention and early revision surgery.<sup>7</sup> Such wear is unlikely to occur with modern-day polyethylene and implants. A study by Yeo et al comparing AA with mechanical alignment (MA) showed comparable clinical, radiological and functional outcomes. The authors originally stated that the study compared KA versus MA but issued a correction stating that in fact, it was an AA technique that was performed.<sup>8</sup>

### Mechanical alignment (MA)

In the 1970s, Freeman and Swanson developed the Freeman–Swanson bicompartmental prosthesis using MA to prioritize mechanical stability over anatomical function, with the cruciate ligaments being sacrificed as a result.<sup>9</sup> In 1985, Insall further popularized the MA technique<sup>10</sup> and following the failures of AA, MA in TKR has been the gold standard for decades.<sup>11</sup> This technique places the femoral component perpendicular to the coronal mechanical axis of the femur.<sup>12</sup> The aim is to create a neutral lower limb alignment to achieve a balanced load distribution between the medial and lateral compartments.<sup>11</sup> Only

0.1% of patients have a neutral mechanical axis, even though the mean of the population as a whole is neutral, therefore MA TKR inevitably alters almost every patient's native anatomy.<sup>13</sup> Balancing of soft tissues has been shown to increase patient satisfaction.<sup>14,15</sup> However, this requires soft tissue releases which are technically difficult, at times inaccurate and can affect the natural knee kinematics.<sup>16–18</sup>

#### *Kinematic alignment (KA)*

As implant technology has improved, the issue of component wear and loosening has dissipated, and the concept of restoring a patient's native anatomy has gained increasing traction in the orthopaedic community. KA is true 'resurfacing' of the knee joint in which the aim is for the implant thickness to replace the exact amount of 'bone/cartilage' removed and therefore restore the highly variable pre-arthritis knee joint orientation. KA is thought to improve function whilst also reducing the incidence of pain associated with TKR.<sup>12</sup> KA aims to restore the pre-arthritis alignment of the knee by positioning the femoral and tibial components to restore native joint lines, theoretically without limit the amount of post-operative correction.<sup>11,19,20</sup> What constitutes the acceptable 'safe' limits for knee alignment is, in reality, defined by the surgeon who performs a KA TKR. Some surgeons may undertake KA TKR in more extreme constitutional varus/valgus alignments whereas others may choose, in the same situation, to perform a restricted KA (rKA) knee replacement. This does not create gap imbalances and therefore ligament releases are not required.<sup>11,20</sup> Provided accurate femoral resurfacing has been achieved, balancing of a KA TKR is achieved through osteophyte removal and tibial bone resection as described by the decision tree of Howell et al (Table 1).<sup>21</sup>

#### *Restricted kinematic alignment (rKA)*

Some patients may have an inherently biomechanically inferior knee anatomy, and as such recreating this may have negative consequences for the mechanics of the TKR and wear patterns.<sup>13,22</sup> A 'safe' range has been proposed in which independent tibial and femoral cuts must be within 5° of the mechanical axis and the overall alignment must be within ±3° of neutral.<sup>13,22</sup> This is known as restricted kinematic alignment. To execute rKA precisely, intra-operative technology such as patient-specific instrumentation (PSI), computer-aided surgery (CAS) or robotics is required. The original rKA protocol was first described by Hutt et al

in 2016 using CAS,<sup>22</sup> with the aim of performing KA for most cases but adjusting bone resections in patients who lie outside the 'safe' range. For surgeons who routinely perform KA TKR, rKA is usually a part of their normal surgical practice, and both can be considered part of the same family. With more research, what constitutes the 'safe' range may also change in time.

## **What are the potential benefits of KA?**

By being more physiological and restoring the three kinematic axes of the knee, it is thought KA provides a superior outcome to MA. The three axes are the transverse axis (otherwise known as the trans-epicondylar or cylindrical axis) in the femur, about which the tibia flexes and extends; the transverse axis in the femur, about which the patella flexes and extends; and the longitudinal axis in the tibia, about which the tibia internally and externally rotates on the femur (Fig. 1). The key principle of the KA approach is that restoration of these three axes, the joint line orientation angle (JLOA) and physiological soft tissue balancing will improve gait, feel of the knee and range of motion (ROM); and thus, result in superior patient outcomes.

#### *Joint line orientation angle (JLOA)*

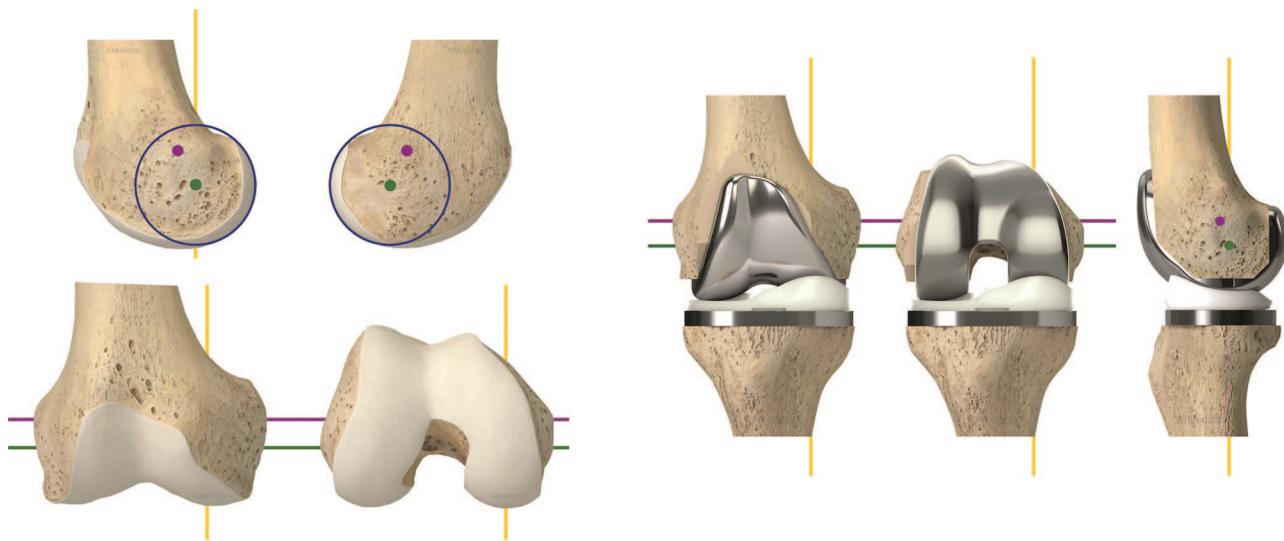
It has been reported that the JLOA in the coronal plane in the native knee after skeletal maturity is parallel to the floor and perpendicular to the weight-bearing axis of the body in bipedal stance, irrespective of varus deformity.<sup>23</sup> Ji et al<sup>24</sup> compared JLOA following MA and KA. The authors demonstrated that JLOA was horizontal to the floor in most KA and in MA the JLOA was in valgus. Similarly, Matsumoto et al<sup>25</sup> found that patients with KA stand with their knees more parallel to the floor and bear weight more centrally in the knee during gait when compared to MA. This in turn should improve gait with a KA TKR and this contradicts the long-held principle that a JLOA of 180° will protect the implant. In this study, although described as a KA technique, the authors performed a tibial osteotomy with systematic 3° varus and 7° posterior slope, and hence does not meet the definition of KA or rKA described above. We will refer to this technique as 'pseudo KA'.<sup>25</sup>

#### *Gait*

Gait studies analysing KA have shown conflicting results, with some studies suggesting KA knees had better gait

**Table 1.** Step-by-step actions for balancing the knee with a kinematically aligned femoral component

Tight in extension and flexion	Tight in extension	Tight in flexion	Tight medial	Tight lateral
Remove more tibia	Remove posterior osteophytes Strip posterior capsule Decrease posterior tibial slope	Increase posterior tibial slope	Remove medial osteophytes Recut tibia in more varus Lateralise tibial component	Remove lateral osteophytes Recut tibia in more valgus Medialise tibial component



**Fig. 1** The orange vertical lines demonstrate the longitudinal axis; the purple horizontal lines represent the transverse axis, about which the patella flexes and extends; and the green horizontal lines represent the transverse axis, about which the tibia flexes and extends.

parameters, reproducing the native knee kinematics more closely compared to MA, whilst others showed no difference. A retrospective case-control study compared gait parameters between 18 rKA TKRs and a matched control group of MA TKRs.<sup>26</sup> The authors found the knee kinematics in KA were more similar to normal healthy controls when compared to MA.<sup>26</sup> Niki et al<sup>27</sup> compared data from 21 knees in 18 patients who underwent KA TKR to a matched group of 21 knees with MA TKR. Smaller knee adduction moment (KAM) was found in KA, this was attributed to significantly decreased ground reaction force (GRF) frontal lever arm in KA.<sup>27</sup>

### What are the potential disadvantages of KA?

TKR was first introduced in the 1970s. In the early years, due to poor precision of instruments, errors were frequent. Therefore, MA was introduced as a simple, reproducible method to maximize implant survival by creating a neutral limb axis. Although some studies<sup>28–30</sup> have suggested that outliers to neutral alignment have a higher rate of revision and that MA is associated with an improved primary TKR survivorship, these studies are fundamentally flawed as they rely on two-dimensional (2D) radiographs (which includes long-leg views) to assess post-operative alignment, which is an inaccurate method.<sup>28</sup> It is only with cross-sectional three-dimensional (3D) imaging that true limb alignment and JLOA can be measured. There are several studies that have shown that preserving constitutional alignment after TKR does not lead to early implant failure.<sup>31,32</sup> Furthermore, unicompartmental knee

replacements (UKR) have been carried out for 30 years or more using fixed-bearing implants with great success.<sup>33</sup> Nevertheless, there are still concerns with regard to asymmetrical forces between the lateral and medial tibial plateau as well as patellofemoral joint (PFJ) complications, based primarily on computer modelling (rather than clinical studies).<sup>34</sup> These complications were associated only with the extremes of anatomical variation (severe varus/valgus deformities) which may be managed with an rKA technique. The question of what the acceptable limb alignment and JLOA is after TKR remains unanswered.

#### Compartment overload

There is a concern that restoring constitutional varus/valgus of the knee may cause overload in the medial/lateral compartment respectively, which may lead to early failure. In a study of 67 patients with KA TKR, the varus/valgus outliers (defined using MA criteria) were identified. The intra-operative forces in the medial and lateral compartments of patients with outlier alignment were comparable with those with in-range alignment, with no evidence of overload of the medial or lateral compartments of the knee.<sup>35</sup> The limitation of this study is that this was an intra-operative assessment checking passive ROM, and limb alignment may be influenced by dynamic loading of the knee when the patient bears weight. In MA the forces in the medial and lateral tibial compartment are three to six times higher at 0°, 45° and 90° of flexion when compared to the native knee and KA TKR.<sup>36</sup> This may be due to poor soft tissue and ligament balancing as a result of using MA to try and correct an ‘unbalanceable’ knee.<sup>37–39</sup>

In MA TKR, varus alignment causing medial compartment overload is thought to be the mechanism of tibial component failure. It remains unclear as to what the influence of alignment is on the performance of a TKR. On plain radiographs, what looks like varus alignment may indeed be a fixed flexion deformity (FFD) of the implanted knee associated with a slight external rotation of the ipsilateral hip.<sup>40</sup> It may be that a residual FFD is the main driver of component loosening rather than varus alignment. Nevertheless, there is concern amongst some surgeons that KA implants, particularly tibial component in varus, may be associated with early loosening and implant subsidence. However, loosening of the varus tibial component in KA has been reported as 0.3% at 2 to 10 years, which is lower than in MA.<sup>32,41</sup> This could be related to the lower KAM found in KA.<sup>27</sup> It could also be due to reduced intensity and frequency of dynamic edge loading (lift off) seen in KA knees. The tibial component failures that have occurred in KA have been associated with excessive, unphysiological posterior slope rather than varus alignment.<sup>41</sup>

Similarly, Laende et al<sup>31</sup> showed that KA and MA knees had similar migration patterns using radiostereometric analysis (RSA) suggesting an equal and low risk of aseptic loosening for both groups. RSA has been proven to predict long-term implant survival and two-year data on implant migration in KA vs. MA TKR is indeed suggestive of similar behaviours for the two design philosophies in terms of implant subsidence and loosening.<sup>42</sup>

Ten-year implant survivorship data have been published by Howell et al.<sup>32</sup> Revision for aseptic loosening at 10 years is reported at 1.5% for a study group of 220 patients following KA TKR. This is not dissimilar to (and in fact lower than) the incidence of aseptic loosening following MA TKR at 10 years.<sup>43</sup> However, it should be recognized that the current long-term data with KA are based on a single-surgeon series, and independent validation is needed to support these findings.

#### *PJF complications*

There is concern that KA of the femoral component may delay the capture of the patella by the trochlear groove during early knee flexion and increase the risk of PFJ instability.<sup>34</sup> A study simulated the femoral component (Vanguard, Biomet) in MA and KA. The study found that the femoral component in KA reduced the lateral reach of the trochlea by a mean of 3 mm, which may lead to increased PFJ component instability. Studies looking at the PFJ in KA TKR have shown that both KA and MA knee replacements have a tendency to undersuff the PFJ, creating a prosthetic groove that is more valgus than the native trochlea.<sup>44,45</sup> The authors conclude that a more specific KA knee implant with a femoral component that more closely restores the native trochlea anatomy may help improve patient outcomes.<sup>44,45</sup> A recent randomized-controlled

trial (RCT), however, which also used the Vanguard implant, found no difference in any complications (including those associated with the PFJ) between MA and KA.<sup>19</sup> A recent meta-analysis also found no difference in PFJ instability between MA and KA.<sup>46</sup> Howell et al reported a 0.4% incidence of PFJ instability at 1 to 10 years after KA and reported an association between increased femoral component flexion and PFJ instability.<sup>32</sup> In summary, KA is safe with contemporary TKR implants, but outcomes may be optimized with a dedicated TKR designed with the KA technique in mind.

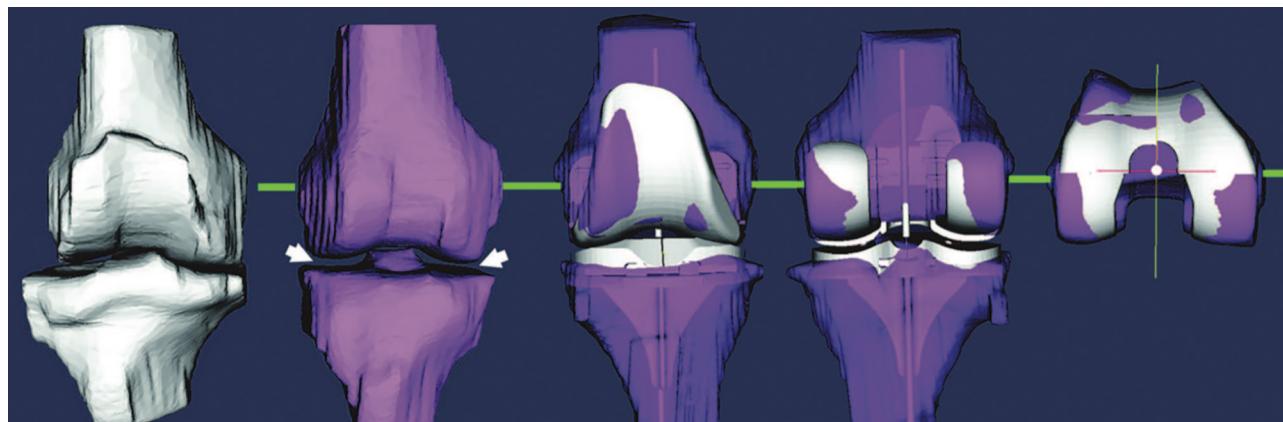
#### **How is KA performed?**

KA requires a precise surgical technique which can be achieved by caliper verification, PSI, CAS or robotics.<sup>11</sup>

Caliper verification is a technique developed by Howell.<sup>36</sup> This technique uses manual instruments with measurements to guide bony cuts, followed by caliper verification of bone resections to ensure the correct amount has been removed.<sup>36</sup> The technique allows intra-operative assessments and instruments to recut the bone(s) in the desired orientation if required. The technique has been recently approved by the US Food and Drug Administration to perform KA TKR and has received CE marking certification.

PSI is made using magnetic resonance imaging (MRI) or computed tomography (CT) scans of the patient's knee. Using the 3D image of the knee, a plan for the operation can be created by the surgeon. This includes a plan of the implant size and alignment. Bespoke cutting blocks are then made to guide the bony cuts during the operation. When considering the use of PSI in KA, the most commonly used system in published RCTs is the OtisMed system (rebranded as ShapeMatch, Stryker but recalled in 2013 due to concerns about surgical imprecision) which uses MRI scans to create a 3D reconstruction of the knee joint (Fig. 2) as well as a scan of the whole limb to assess the limb alignment. Howell and Hull recommend that PSI is used with caliper verification intra-operatively before cementing the prosthesis.<sup>21</sup>

Two studies using either OtisMed or ShapeMatch technology reported on the accuracy of this PSI system but the same limitations of imprecise measurement using 2D imaging remain. Laende et al found a deviation of 1.4° from the planned alignment using PSI.<sup>31</sup> Calliess et al found a deviation from the initial plan using PSI in KA was  $2^\circ \pm 2^\circ$ .<sup>47</sup> There were five outliers with a Knee Society Score (KSS) < 150 points and this was associated with a deviation from the planned alignment.<sup>47</sup> In the same study there were six outliers with Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores > 40 in KA. A higher WOMAC score was associated with high flexed femoral component possibly caused by



**Fig. 2** Composite showing a three-dimensional model of an 'arthritic' knee (first on the left), a model of a normal knee (second from the left), and a femoral component shape-fitted to anterior, posterior and axial projections of the femur (last three to the right). Shape-fitting the femoral component aligns its flexion-extension axis in the femur, about which the tibia flexes and extends with the femoral component.

Source: Reproduced with permission and copyright © of The British Editorial Society of Bone & Joint Surgery.<sup>19</sup>

use of PSI.<sup>47</sup> However, a study by Howell et al reporting 10-year outcomes did not report any complications related to PSI,<sup>32</sup> which could be related to the additional intra-operative caliper verification carried out in this study.

CAS has been shown to improve the accuracy and precision of component alignment in TKR.<sup>48</sup> However, no RCTs have reported on the use of CAS for KA and its use in KA TKR remains unproven. A small RCT<sup>25</sup> comparing 'pseudo KA' versus MA using navigation showed that navigation provided accurate bone resections but the study excluded patients with severe valgus or varus deformities. Although there is a study reporting the role of CAS in KA TKR,<sup>22</sup> further research with RCTs into the role of CAS in KA is required.

## What are the clinical outcomes of KA from the literature?

In a telephone survey of 661 patients taken at, on average, 2.6 years post-surgery, KA patients were three times more likely to report their knee felt normal compared to MA patients.<sup>49</sup> All patients in this survey had a KA using PSI.

There are three retrospective studies comparing KA/rKA with MA (Table 2). Two showed improved clinical outcomes in KA and one demonstrated no difference:

1. In a retrospective analysis of 78 patients who previously had an MA TKR followed by a contralateral KA TKR on average seven years later, patients tended to favour the KA TKR and felt the recovery was faster.<sup>50</sup> The median forgotten joint score (FJS) was 15 points higher in the KA TKR with a comparable Oxford Knee Score (OKS).<sup>50</sup>
2. In a retrospective case-control study, Niki et al found no difference in Knee Society Score (KSS) knee, KSS function or ROM. This study was primarily designed to show a difference in gait patterns.<sup>27</sup>
3. Blakeney et al showed a significantly better Knee Injury and Osteoarthritis Outcome Score (KOOS) in rKA patients when compared to MA patients.<sup>26</sup> This study, however, was powered to show a difference in gait and not KOOS.

There has also been a recent prospective comparison study involving 103 patients who had either a cruciate-retaining TKR (CR-TKR) or a medially stabilized TKR (MS-TKR), in both groups the KA technique was used.<sup>51</sup> The study demonstrated a substantially better FJS with the MS-TKR at one year, but also showed that the KA principle was safe and effective using both CR and MS-TKR.<sup>51</sup>

**Table 2.** Summary of retrospective studies comparing rKA/KA versus MA TKR

Author	Year	Type	Knees	Patients	F/up	Implant	Incision	Favours rKA/KA	Favours MA	No difference
Shelton et al	2019	Retrospective case-control	156	78	18 m	Persona	Mid-vastus	FJS	-	OKS
Niki et al	2017	Retrospective case-control	21	18	20 m	LPS-Flex	Mid-vastus	-	-	KS
Blakeney et al	2018	Retrospective case-control	18	15	12 m	Triathlon	Medial parapatellar	KOOS	-	-

Note. KA, kinematic alignment; MA, mechanical alignment; FJS, forgotten joint score; OKS, Oxford Knee Score; KS, Knee Society; KOOS, Knee Injury and Osteoarthritis Outcome Score.

**Table 3.** Summary of RCTs comparing KA versus MA TKR

Author	Year	Knees	Patients	F/up	Implant	KA technique	MA technique	Favours KA	Favours MA	No difference
Waterson et al	2016	71	71	12 m	Triathlon	PSI	Manual	–	–	KOOS, AKSS, UCLA, EQ-5D, TUG, ROM
Young et al	2016	99	95	24 m	Triathlon	PSI	CAS	–	–	OKS, WOMAC, KSS, FJS, EQ-5D, Visual Analog score
Dossett et al	2014	120	120	24 m	Vanguard	PSI	Manual	OKS, WOMAC, KSS	–	–
Calliess et al	2016	200	200	24 m	Triathlon	PSI	Manual	KSS, WOMAC	–	–

Note. RCT, randomized controlled trial; KA, kinematic alignment; MA, mechanical alignment; TKR, total knee replacement; PSI, patient-specific instrumentation; KOOS, Knee Injury and Osteoarthritis Outcome Score; AKSS, American Knee Society Score; UCLA, University of California at Los Angeles; EQ-5D, EuroQol; TUG, time up and go; ROM, range of motion; CAS, computer-aided surgery; OKS, Oxford Knee Score; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; KSS, Knee Society Score; FJS, forgotten joint score.

Four RCTs, using an unrestricted protocol for KA, were powered to show a difference in clinical outcome (Table 3). Two demonstrated no difference between MA and KA, two showed improved clinical outcomes in KA:

1. Waterson et al conducted an RCT of 71 patients; in the KA group ( $n=36$ ) PSI was used, standard instruments were used for MA ( $n=35$ ).<sup>52</sup> All patients had patella resurfacing carried out. The study was powered for a difference in the KOOS. At one year the authors found no difference in the KOOS, American Knee Society Score (AKSS), University of California at Los Angeles (UCLA) score or EuroQol (EQ)-5D scores. There was also no difference in ‘time up and go’ (TUG) or timed up and down stairs. The ROM was also similar in the two groups. The accuracy of PSI was not commented on in this study.
2. Young et al, in an RCT of 99 TKRs, compared CAS MA with PSI (OtisMed) KA.<sup>53</sup> Patients and assessors were blinded to the intervention. The study was powered to show a difference in the OKS. The authors found no significant difference in the OKS, WOMAC, KSS, FJS, EQ-5D or visual analogue score five years post surgery. The authors did not comment on whether the pre-operative alignment plan was achieved using PSI in KA. Ligament releases were also performed to achieve symmetric ligament balance in flexion and extension for both alignment groups (KA and MA). The CAS MA knee replacements were performed by surgeons who were experts in MA compared to surgeons in their learning curve with KA.
3. Calliess et al randomly allocated 200 patients to two groups: KA using PSI (ShapeMatch Technology) or manual TKR.<sup>47</sup> Twelve-month KSS and WOMAC scores were significantly better for KA. However, the patients were not blinded to the intervention in this study. This study was powered to show a difference in KSS.
4. Dossett et al conducted an RCT of 120 patients with 1:1 allocation between PSI (OtisMed) KA and MA

using standard instruments.<sup>19</sup> The patients and assessors were blinded in this study. The study was powered to show a difference in OKS. The authors found significantly better OKS, WOMAC, and KSS scores in KA. Patients also had improved flexion following KA. There was a higher proportion of pain-free knees in KA. Complication rates were similar for both groups. This study, however, had a high rate of missed allocation (26%).

A further study demonstrated no difference between MA and KA, but was not powered to show a difference in clinical outcome. An RCT of 47 patients comparing PSI (OtisMed) KA with CAS MA,<sup>31</sup> the authors of this study found no difference in OKS, Satisfaction or UCLA activity score.<sup>31</sup> This study was designed to show a difference between the fixation of the tibial component. Ligament releases were also performed in the KA group.<sup>31</sup> Ligament release is problematic as in the KA technique, by definition, no ligament release should be performed, and soft tissue balance is achieved by removing bone and osteophytes as appropriate.

## What are the clinical outcomes of rKA from the literature?

Two RCTs employ the rKA protocol to compare to MA. However, only one of these RCTs measured patient-reported outcome measures (PROMs), and this study demonstrated no significant difference in PROMs between KA and MA (Table 4).<sup>54</sup>

1. In an RCT of 45 patients undergoing bilateral simultaneous surgery, the patients identified their most symptomatic knee which was then randomized to either MA or KA.<sup>54</sup> The correction was achieved using a restricted protocol from 6° varus to 3° valgus, ligament releases were also carried out in KA knees. At two years there was no significant difference in ROM, KOOS, KOOS Joint Replacement (JR), OKS, or FJS scores, the authors question whether

**Table 4.** Summary of RCTs comparing rKA versus MA TKR

Author	Year	Knees	Patients	F/up	Implant	rKA technique	MA technique	Favours rKA	Favours MA	No difference
McEwen et al	2019	90	45	24 m	Triathlon	CAS	CAS	–	–	ROM, KOOS, KOOS JR, OKS, FJS

Note. RCT, randomized controlled trial; rKA, restricted kinematic alignment; MA, mechanical alignment; TKR, total knee replacement; CAS, computer-aided surgery; ROM, range of motion; KOOS, Knee Injury and Osteoarthritis Outcome Score; OKS, Oxford Knee Score; FJS, forgotten joint score.

this could be due to a ceiling effect in these scores.<sup>54</sup> However, more patients expressed a preference for KA and this was associated with fewer releases and achieving functional JLOA.<sup>54</sup>

2. In an RCT of 125 patients (138 knees), there were 70 knees in the rKA group and 68 knees in the MA group, with optimum knee balance being the primary outcome measure, as defined by an intercompartmental pressure difference (ICPD) of 15 psi or less using a pressure sensor.<sup>55</sup> The primary endpoint was the mean intra-operative 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. The study showed that the rKA protocol led to a significantly better-optimized knee balance.<sup>55</sup>

A further two studies exist which claim to use a KA protocol. However, in the study by Yeo et al<sup>56</sup> the protocol is more closely associated with AA which has been described above, and therefore this study has not been included in the analysis. In this study the tibial cut was planned at 2° varus to the mechanical axis and the femoral cut was planned at 2° valgus to the mechanical axis.<sup>56</sup> A correction has since been published.<sup>8</sup> The study by Matsumoto et al<sup>25</sup> has been discussed above. In this ‘pseudo KA’ group the tibial osteotomy was performed with 3° varus in relation to the mechanical axis. Sixty patients were listed for navigated TKR with 1:1 randomization to ‘pseudo KA’ or MA. Significantly better flexion was demonstrated in patients following ‘pseudo KA’.<sup>25</sup> The mean objective and functional 2011 KSS scores were significantly better in this group at one year. There was no difference in other components of KSS.<sup>25</sup> Ligament releases were also performed in the ‘pseudo KA’ group.<sup>25</sup>

## Meta-analyses

There are six published meta-analyses comparing KA and MA. Due to variations in the patient selection criteria, operative technique and/or statistical analysis, all meta-analyses have limitations. Takahashi et al, in a recent meta-analysis, showed KA resulted in better WOMAC scores, OKS, KSS, and post-operative ROM. However, the WOMAC, KSS, and ROM analysis included studies using rKA,<sup>25</sup> unblinded patients<sup>47</sup> or had a high dropout rate.<sup>19</sup>

Yoon et al found no difference in JLOA or tibial component slope but TKRs with KA resulted in better overall function. However, in the analysis of functional outcome scores the same study was used twice from Dossett et al<sup>19,57</sup> For KSS and Knee Society Function Scores (KSFS) they extrapolated data from an incomplete study.<sup>58</sup> Luo et al<sup>59</sup> concluded KA achieved functional, radiological and perioperative results similar to those of MA without an increase in the complication rates. This paper did have some significant flaws in that the forest plots were incorrect due to an error in how the outcomes scores (WOMAC, OKS and KSS) were interpreted, and the meta-analysis included studies with different techniques for TKR alignment including KA, rKA and AA. In addition, for the functional outcome scores the authors used data from Yeo et al which has been discussed in a previous paragraph and is not actually KA. Data from studies using KA and studies using rKA (Blakeney et al<sup>26</sup>) were combined in this analysis. The forest plots (with the correct interpretation of the outcome scores) actually favour the KA group compared to the MA group. Li et al<sup>60</sup> concluded KA provided better functional outcomes. However, in the analysis as well as using the same study twice, the authors included a study of revision surgery for patients with a UKR being converted to TKR. Courtney and Lee, and Woon et al analysed only the studies performing ‘true’ KA.<sup>46,61</sup> One paper concluded that the PROMs were similar in both groups,<sup>61</sup> whereas the other concluded functional outcomes (KSS) favoured KA.<sup>46</sup>

## Conclusion

The literature on KA is complex and there is misunderstanding about the definition, principles and technique of KA. This makes comparisons very difficult and therefore reviews and meta-analyses do not provide strong, reliable data. As well as this, we must also consider how the choice of post-operative analysis and outcome measures may affect the results.

The majority of studies used weight-bearing long-leg radiographs to judge alignment of the lower limb. However, radiographic measurements of limb alignment are prone to error due to the rotation of the lower limb and magnification errors.<sup>62–64</sup> As little as 3° of rotation can lead to a significant difference in the measured alignment.<sup>64</sup> Furthermore, residual FFD of the prosthetic knee is very

common and can significantly influence measuring frontal alignment on a 2D radiograph. Therefore, 2D imaging cannot be relied on to accurately measure lower limb alignment. CT has been shown to be superior in assessing limb alignment and component position.<sup>65</sup> However, there may be some deviation in alignment in the standing position when compared to supine.<sup>66</sup> With newer technologies, accurate measurement of alignment with 3D images in a weight-bearing patient is now possible.<sup>67</sup>

Clinical outcomes following orthopaedic surgery are often assessed using PROMs. However, as techniques and surgical procedures improve, ceiling effects may become apparent. Ceiling effects occur when a considerable proportion of patients achieve either the best or worst score and as such it is not possible to distinguish any difference between these patients. If 15% of patients, or more, attain the highest score, a ceiling effect of the scoring system becomes a concern.<sup>68</sup> One study found the AKSS and OKS to have ceiling effects of 53% and 33% respectively.<sup>69</sup> This may explain why a large multicentre RCT was unable to demonstrate a difference between UKR and TKR.<sup>70</sup> Similarly in another study the KSS score was unable to differentiate between high-functioning UKR patients and patients with a TKR.<sup>71</sup> One study compared the OKS with the FJS and demonstrated a much lower ceiling effect of 16% for the FJS.<sup>72</sup> The ceiling effect for KOOS was found to be approximately 20% for pain and approximately 15% for quality of life.<sup>73</sup> In the same study, the WOMAC score had ceiling effects of approximately 30% and 10% for pain and function respectively.<sup>73</sup> Careful consideration of the choice of PROMs is required when comparing high-functioning patients.

Finally, it is unclear whether KA can be safely used for all patients irrespective of the nature and extent of the constitutional coronal and/or sagittal plane deformities. The majority of the reported studies comparing MA and KA have excluded knees with a pre-operative valgus deformity. At present, the range of safe pre-operative deformity and post-operative correction for patients undergoing KA TKR has not been established.

At present, there is no consensus on which philosophy is superior, although most comparative studies have generally shown that KA patients have superior clinical outcomes compared to MA patients. The existing data are difficult to compare due to the varied methodologies employed, some of which do not comply with the principles of KA. The use of recalled PSI further complicates matters. There is considerable variability of the choice of outcome measures, some of which have considerable ceiling effects. In conclusion, further high-quality multicentre RCTs are required to assess whether there is any difference in clinical outcomes between KA and MA and to identify the best technique for performing a KA TKR, in order to make the operation accurate and reproducible. It is important going forward that there is a single agreed definition

of KA to allow reliable comparison and well-structured studies. Otherwise, inappropriate data may undermine this potentially transformative technique, resulting in it being prematurely discarded.

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#### ICMJE CONFLICT OF INTEREST STATEMENT

CR reports consultancy for Medacta; a pending patent for TKA design for kinematic implantation, all outside the submitted work.

ME reports consultancy for Zimmer-Biomet as an implant design surgeon educational consultant; an educational contract with Medacta; is a designer surgeon for a hip replacement implant for Zimmer-Biomet; has an educational contract for lectures and teaching with Zimmer-Biomet; is a clinician consultant attending expert meetings to discuss novel approaches to arthroplasty for Depuy Synthes, International, all outside the submitted work.

HP reports consultancy for Depuy Synthes, Zimmer-Biomet, Medacta Int, GSK, BMS, JRI, Smith and Nephew and Meril Life; consultancy for Kennedy's Law for work related to metal-on-metal hips from Kennedy's Law (representing Depuy Synthes and Stryker); that their institution has received/will receive (pending) grant support from Depuy Synthes, ZimmerBiomet, Medacta Int, GSK and Pacira Pharmaceuticals; and that their institution has received funding from NIHR (RFPB, HTA) for conducting randomized controlled trials, all outside the submitted work. HP is a National Institute for Health Research (NIHR) Senior Investigator.

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#### LICENCE

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