Knee

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Clinical outcomes of kinematic alignment versus mechanical alignment in total knee arthroplasty: a systematic review

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- Although mechanical alignment (MA) has traditionally been considered the gold standard, the optimal alignment strategy for total knee arthroplasty (TKA) is still debated.
- Kinematic alignment (KA) aims to restore native alignment by respecting the three axes of rotation of the knee and thereby producing knee motion more akin to the native knee.
- Designer surgeon case series and case control studies have demonstrated excellent subjective and objective clinical outcomes as well as survivorship for KA TKA with up to 10 years follow up, but these results have not been reproduced in high-quality randomized clinical trials.
- Gait analyses have demonstrated differences in parameters such as knee adduction, extension and external rotation moments, the relevance of which needs further evaluation.
- Objective improvements in soft tissue balance using KA have not been shown to result in improvements in patient-reported outcomes measures.
- Technologies that permit accurate reproduction of implant positioning and objective measurement of soft tissue balance, such as robotic-assisted TKA and compartmental pressure sensors, may play an important role in improving our understanding of the optimum alignment strategy and implant position.

Keywords: alignment; clinical outcome; kinematic; mechanical; total knee arthroplasty

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Introduction

Since the development of the total condylar prosthesis during the 1970s,[1] the optimal implant alignment for total knee arthroplasty (TKA) has been recognized as an important factor determining outcome,[2] and is still a matter of debate.[3,4]

Hungerford and Krackow proposed anatomical alignment, striving to achieve a neutral hip-knee-ankle (HKA) angle with the anatomical joint line orientation of 2–3° from the horizontal to bring the joint line parallel to the floor during single leg stance.[5] Insall, on the other hand, focussed on restoring neutral mechanical alignment (MA) with orthogonal femoral and tibial resections, subsequently balancing flexion and extension gaps with soft tissue releases (Fig. 1).[1] The orthogonal implant position was intended to evenly distribute load through the implant–bone interface and minimize laterally directed ground reaction force (GRF) during gait in the hope that this would achieve longevity, though at the cost of normal knee kinematics.[1,6–11]

MA has been regarded as the gold standard alignment strategy and is supported by biomechanical studies, finite element analyses, and clinical studies.[1,2,9,10,12–18] However, closer inspection reveals that much of this data is based on small numbers of patients, rudimentary component designs, and variable methods of determining alignment,[2,3,7,9,16,19] and the majority of the population do not have a perfectly neutral MA.[16] A study of 250 healthy, young adults revealed that 32% of males and 17% of females have constitutional varus > 3°.[20] Furthermore, an orthogonal distal femoral resection may raise the medial joint line and cause mid-flexion instability.[21]

Our understanding of native knee motion has evolved.[22] Three axes of rotation have been described, namely the primary femoral axis (tibio-femoral flexion and extension), the secondary femoral axis (patella-femoral flexion and extension), and the longitudinal tibial axis (tibial internal and external rotation), all of which are intricately related to and influenced by implant position.[23]

This evolving understanding, coupled with the desire to improve TKA performance and recent evidence that

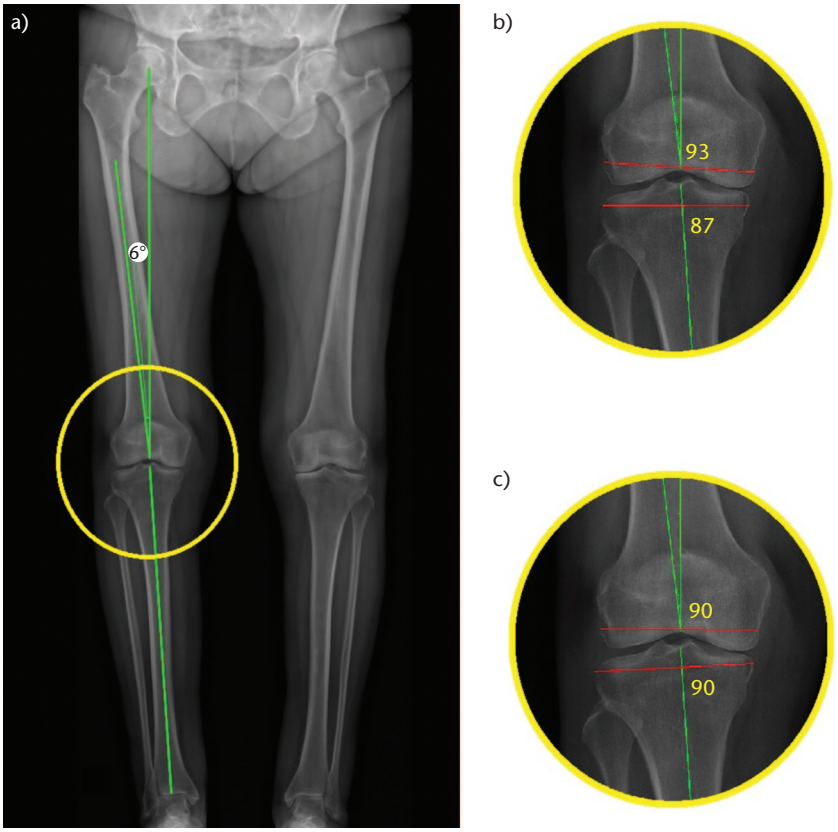

Fig. 1 Long-leg standing radiograph demonstrating the mechanical axis (MA) relative to the anatomical axis (AA) of the lower extremity (a). Note the joint line forms an angle that is 93° with the MAT, or 3° of varus. Anatomical alignment (b) mimics the native joint line of 3° varus to the mechanical axis of the tibia corresponding 3° valgus to the AA. Mechanical alignment (c) involves resections perpendicular to the mechanical axis of the tibia and distal femur.
Note. mLDFA, mechanical lateral distal femoral angle; aLDFA, anatomical lateral distal femoral angle; MPTA, medial proximal tibial angle.

variance in alignment beyond the traditional safe zone of neutral ± 3° may not impact survival as originally thought,[19,24–26] has provided the impetus to revisit the alignment strategy.

Kinematic alignment (KA), an alternative alignment method in TKA, is based on a three-dimensional appreciation for the three axes of rotation of the knee.[27–29] Here, the objective is to position the implants so as to restore the pre-arthritic knee anatomy,[29,30] permitting motion more akin to the native knee. The pre-arthritic alignment is estimated pre-operatively with the use of proprietary software to create patient-specific cutting guides (PSGs) based on cylinders of best fit for the femoral condyles, or intra-operatively by resecting the femoral condyles symmetrically (distally and posteriorly), after correcting for cartilage and bone wear.[29,31–33] This provides an individualized primary femoral axis of rotation, which has been shown to deviate from the transepicondylar axis by as much as 11.3° (Fig. 2).[28] In the coronal plane, the mechanical distal femur valgus and mechanical proximal tibia varus are restored to pre-arthritic alignment, which will vary from patient to patient, and incorporates a joint line orientation angle that may or may not be orthogonal to the mechanical axis.[23,28] The HKA angle is usually restored to neutral (0° ± 3° from neutral in 73% of patients according to Howell et al[34]) and, in theory, accommodates for the proportion of the population that has pre-arthritic constitutional varus or valgus alignment.[20,28,29,34] Furthermore, restoration of left-to-right symmetry of the lower limb HKA is achieved in 95% of patients within ± 3°, according to a recent study by Nedopil et al.[35] Of note, the studies by Howell et al[34] and Nedopil et al[35] utilized non-weight-bearing CT scanograms to measure alignment.

In the sagittal plane, since the implants most frequently used in KA TKA are cruciate retaining (CR), a sufficient posterior tibial slope to protect the posterior cruciate ligament (PCL) (5–7°) is required. Restoring the antero-posterior position of the tibial component is necessary to achieve correct tension in the PCL and thereby facilitate more native motion.[29] Flexion of the femoral component is largely determined by the design of the implant and the avoidance of 'notching' the distal femur in both techniques.

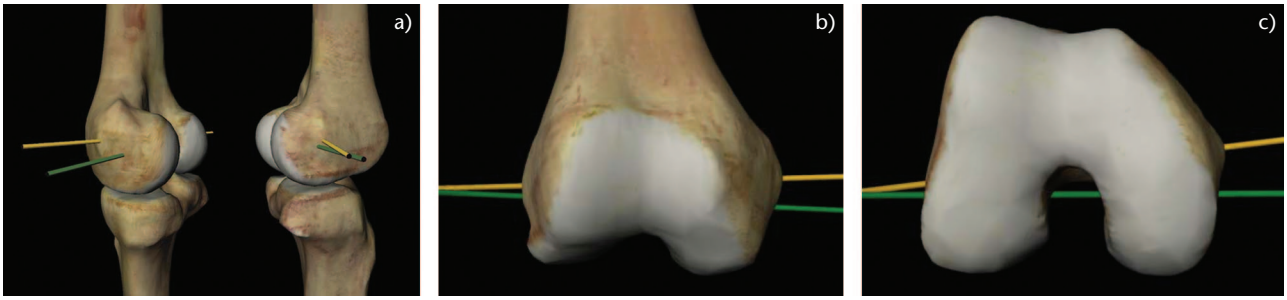

Fig. 2 Three-dimensional knee model constructed from the Visible Human database (University of Colorado Center for Human Simulation), demonstrating the differences between the epicondylar (yellow) axis, which is the basis of MA TKA, and the axis derived from cylinders of best fit for the femoral condyles (green), which is the basis of KA TKA.
Reproduced with permission from: Eckhoff DG, Bach JM, Spitzer VM, Reinig KD, Bagur MM, Baldini TH, Flannery NM. Three-dimensional mechanics, kinematics, and morphology of the knee viewed in virtual reality. *J Bone Joint Surg (Am).* 2005 Dec 1;87(suppl_2):71-80.

In the axial plane, the two strategies may differ somewhat. Proponents of MA tend to aim for slight external rotation of the femoral components to prevent patella maltracking, which accommodates for the relatively greater lateral tibial resection with a 90° tibial bone cut,[1,4] whereas the KA strategy aims to achieve symmetrical posterior condylar resections of the distal femur after correcting for the cartilage wear, which would place the implant in a native, rotationally neutral position.[29] In both techniques, cross referencing with alternative landmarks, including Whiteside's line and the transepicondylar axis, may be required in cases with extreme deformity, although the reliability of the transepicondylar axis has been questioned.[27,28] Proponents of KA believe that this strategy may require less soft tissue release, preserve bone, reduce post-operative pain, and improve post-operative function, thereby reducing the proportion of patients who remain discontent following TKA.[29,36]

Whether these changes in prosthetic alignment translate to improvements in subjective or objective outcomes or have an impact on survivorship of the TKA remains unknown. In this systematic review, we will present and critique the current clinical evidence to determine whether, compared to MA, KA (1) translates to improvement in subjective patient-reported outcomes or objective measures of knee function following TKA and (2) has an impact on implant survivorship.

Methods

In keeping with the Preferred Reporting Items for Systematic review and Meta-analysis (PRISMA) guidelines, we conducted a literature search on PubMed, Embase and Cochrane databases for publications between 1975 and January 2020, using the following criteria for titles and abstracts: "(kinematic alignment) AND ((total knee arthroplasty) OR (total knee replacement))". This yielded 592 results. After duplicates were removed, a fellowship-trained orthopaedic surgeon screened the titles and abstracts for relevance. The full texts of 23 publications were selected and assessed for appropriateness by two authors (both fellowship-trained orthopaedic surgeons), who then independently performed the quality assessment for each of the 15 selected studies. The authors then discussed the quality assessments to ensure agreement.

Eligibility criteria included full-text articles written in English that reported clinical and/or radiological outcomes comparing KA and MA TKA. Case reports, letters, unpublished data, cadaver studies and studies of revision arthroplasty were excluded (Fig. 3).

Quality assessment of individual studies was performed using the revised tool to assess Risk of Bias in randomized trials (ROB 2.0),[37] and Risk of Bias for Non-randomized Studies of Interventions (ROBINS-I) for all other non-randomized studies identified.[38]

Owing to the small numbers of randomized controlled trials (RCTs) identified, quality of the methodology, and heterogeneity of outcome reporting, the data were not pooled.

Results

Twenty-three clinical articles were analysed, including two meta-analyses,[39,40] one systematic review,[41] eight RCTs,[11,42–48] six case control studies,[30,33,36,49–51] and six case series[29,31,32,34,52,53] (six level I, four level II, seven level III, and five level IV). Fifteen original research papers reporting clinical results and survivorship were included in the systematic review, summarized in Table 1 and Table 2.

Quality assessment

The assessment for risk of bias for the 15 studies included (Table 3 and Table 4), revealed that all studies had at least moderate risk of bias and one had serious risk of bias.

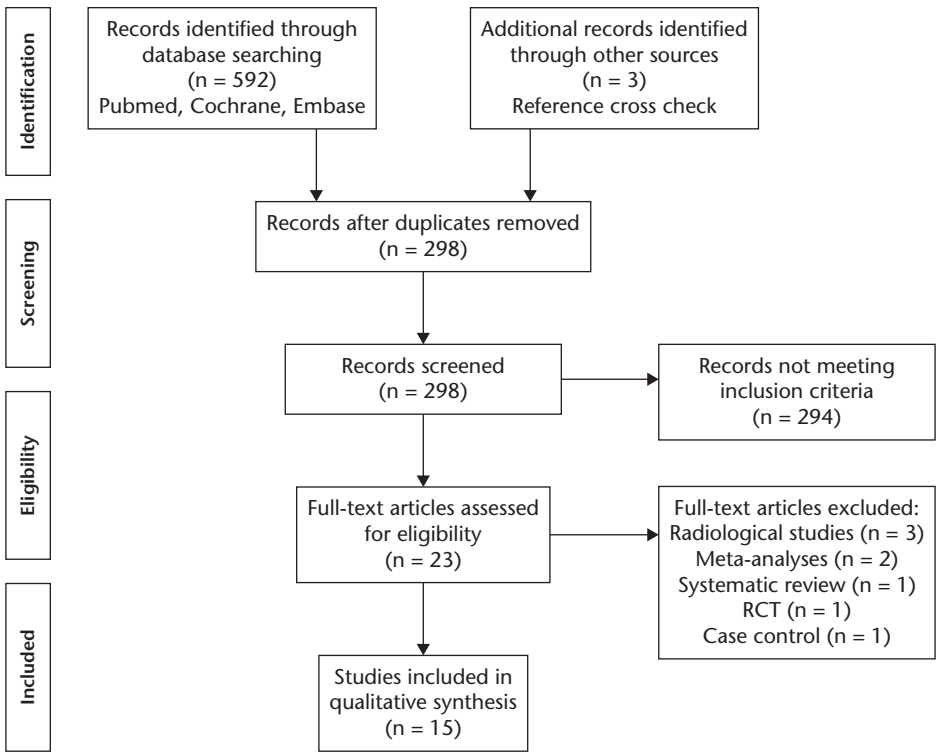

Fig. 3 PRISMA Flow Diagram
Note. RCT, randomized controlled trial.

Table 1. Overview of the design characteristics of the article included in this review

Author, year	Design	Level of evidence	Blinding	Single surgeon	Follow up in months		*N* TKAs (patients)	Implant		Guide
								PS/CR	Patella resurfacing	
MacDessi, 2020	RCT	I	Double	No	12	MA	68 (62)	PS	Standard	Navigation
						KA	70 (63)	PS	Standard	Navigation
McNair, 2018	RCT	II	Double	No	> 24	MA	15 (15)	CR	Selective	Navigation
						KA	14 (14)	CR	Selective	PSG
Young, 2017	RCT	I	Double	No	24	MA	50 (50)	CR	Selective	Navigation
						KA	49 (49)	CR	Selective	PSG
Calliess, 2017	RCT	II	No	No	12	MA	100 (100)	CR	NR	Conventional
						KA	100 (100)	CR	NR	PSG
Waterson, 2016	RCT	I	Double	No	12	MA	35 (27)	CR	Standard	Conventional
						KA	36 (28)	CR	Standard	PSG
Dossett, 2014	RCT	I	Double	Yes*	> 24	MA	44 (44)	CR	Standard	Conventional
						KA	44 (44)	CR	Standard	PSG
Dossett, 2012	RCT	I	Double	Yes*	6	MA	41 (41)	CR	Standard	Conventional
						KA	41 (41)	CR	Standard	PSG
Blakeney, 2019	Case control	III	No	Yes	34 (12–96)	MA	18 (17)	CR	NR	Navigation
						KA	18 (15)	CR	NR	Navigation
Niki, 2018	Case control	III	No	Yes	35 ± 5	MA	21 (19)	PS	NR	Conventional
					26 ± 6	KA	21 (18)	PS	NR	Conventional
Spencer, 2009	Case control	IV	No	Yes	6	MA	30 (30)	CR	None	Conventional
						KA	21 (21)	CR	None	PSG
Howell, 2018	Case series	III	No	Yes	120	KA	207 (203)	CR	Standard	PSG
Howell, 2015	Case series	III	No	Yes	76 (70–86)	KA	219 (214)	CR	Standard	PSG
Howell, 2013 CORR	Case series	IV	No	Yes	38 (31–43)	KA	214 (198)	CR	Standard	PSG
Howell, 2013 KSSTA	Case series	IV	No	Yes	6–9	KA	101 (101)	CR	Standard	Conventional
Howell, 2008	Case series	IV	No	Yes	3	KA	48 (48)	CR	Standard	PSG

Note. RCT, randomized controlled trial; CR, cruciate retaining; KA, kinematic alignment; MA, mechanical alignment; *N*, number; NR, not reported; PS, posterior stabilized; PSG, patient-specific guide; TKA, total knee arthroplasty; CORR, Clinical Orthopaedics and Related Research; KSSTA, Knee Surgery, Sports Traumatology, Arthroscopy.
*Single team of two surgeons.

Table 2. Overview of the results of the controlled articles included in this review

Author, year	Functional tests e.g. - gait lab analysis - timed-up-and-go test - ICPD	Complications and/or implant survival in favour of	PROMs in favour of									
			WOMAC	OKS	AKSS	cKSS	FJS	VAS	EQ-5D	SF-36	KOOS	UCLA
MacDessi, 2020	Improved quantitative knee balance with KA						N		N		N	
McNair, 2018	Neither		N	N								
Young, 2017		Neither	N	N		N	N	N	N			
Calliess, 2017		Neither	KA			KA						
Waterson, 2016	KA: better peak quadriceps torque up to three months				N				N	N	N	N
Dossett, 2014	KA: 8.5° greater flexion at two years	Neither	KA	KA		KA						
Dossett, 2012	KA: 5° greater flexion at six months		KA	KA		KA						
Blakeney, 2019	KA: better resembles healthy knee gait parameters than MA										KA	
Niki, 2018	KA: reduced first peak of KAM during gait at 2.2 years					N						
Spencer, 2009		Neither										

Note. AKSS, American Knee Society Score; cKKS, combined Knee Society Score; EQ-5D, EuroQol 5-dimensional health questionnaire; FJS, Forgotten Joints Score; ICPD, intercompartmental pressure difference; KA, kinematic alignment; KAM, knee adduction moment; KOOS, Knee injury and Osteoarthritis Outcome Score; MA, mechanical alignment; N, neither; OKS, Oxford Knee Score; PROMs, patient-reported outcome measures; SF-36, Short Form 36; VAS, Visual Analog Scale; WOMAC, Western Ontario and McMaster Universities Arthritis Index; UCLA, University of California at Los Angeles (UCLA) Activity Score.

Table 3. Risk of bias assessment in randomized trials (ROB 2.0)

Domain	Dosset, 2012	Dosset, 2014	Waterson, 2016	Calliess, 2017	Young, 2017	McNair, 2018	MacDessi, 2020
Randomization	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns
Deviations from intended intervention	Low	Low	Some concerns	Some concerns	Low	Low	Some concerns
Missing data	Low	Low	Low	Low	Low	Low	Low
Measurement of outcomes	Low	Low	Low	Low	Low	Low	Low
Selection of the reported result	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Low	Low
Overall bias	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns

Table 4. Risk of bias for non-randomized studies of interventions (ROBINS-I)

Domain	Howell, 2008	Spencer, 2009	Howell, 2013 CORR	Howell, 2013 KSSTA	Howell, 2015	Niki, 2018	Blakeney, 2019
Confounding	Moderate	Moderate	Moderate	Low	Moderate	Moderate	Low
Selection of participants	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
Classification of interventions	Low	Low	Low	Low	Low	Moderate	Low
Deviations from intended intervention	Low	Low	Low	Low	Low	Low	Low
Missing data	Moderate	Low	Low	Low	Low	Low	Low
Measurement of outcomes	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Low
Selection of the reported result	Moderate	Moderate	Moderate	Moderate	Moderate	Low	Serious
Overall bias	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Serious

Note. CORR, Clinical Orthopaedics and Related Research; KSSTA, Knee Surgery, Sports Traumatology, Arthroscopy.

Challenges in the randomization process were recognized in all studies, some of which are inherent to the nature of the research. For example, the inability to blind the treating surgeons who perform either KA or MA TKA, and incomplete blinding of participants – only Young et al,[11] McNair et al[46] and Dossett et al[43,44] conducted magnetic resonance imaging (MRI) on all patients regardless of the intervention, and MacDessi et al introduced a second observer to reduce the risk of measurement bias.[48]

Outcome measures were heterogeneous and included the use of pain and functional indices, and 10 different patient-reported outcome measures (PROMs, Table 2).

The Knee Society Score (KSS) was the most commonly used outcome measure.[11,42–45,50] One study also reported the intercompartmental pressure difference measured intra-operatively using a pressure sensor insert (VERASENSE; OrthoSensor, Dania Beach, Florida, USA).[48]

The measurement of alignment pre-operatively and post-operatively also varied among the studies, utilizing long leg standing radiographs,[42,45] or supine computed tomography (CT),[11,34,43,44,49] while one RCT utilized standing long leg radiographs pre-operatively and CT post-operatively.[48] However, methods of determining component alignment as well as overall limb alignment were standardized.

Gait analysis studies were performed in a similar manner in studies looking at kinematic and kinetic parameters, such as walking speed, range of motion (ROM), ground reaction force (GRF), and knee adductor moment (KAM), while patients were allowed to walk trials at a self-selected speed.[46,50,51]

Potential confounding variables include the use of PSGs for KA TKAs and comparing these to MA TKAs performed with conventional instrumentation,[42–45] or computer navigation.[11] CR, cemented implants and patella resurfacing were utilized in all studies, except for Young et al and McNair et al who reported selective resurfacing, Blakeney et al, Niki et al, and Calliess et al who did not mention patella resurfacing, Niki et al who used posterior stabilized (PS) TKAs with an uncemented trabecular metal tibial tray, and MacDessi et al who utilized cemented posterior stabilized implants. Notably, most studies reported the use of a proprietary system (OtisMed Inc., Alameda, California) for PSGs, which is no longer commercially available.[11,29,31,34,43–45,49,52]

The proportion of follow up (FU) for each study was good (> 90%), although the duration of FU was short in all RCTs – MacDessi et al, Waterson et al and Calliess et al reported one year results, while Dossett et al and Young et al reported two year results. Medium-term results were only available from Howell et al, who reported results after 5.8–7.2 years FU in 2015,[52] and subsequently reported their results at 10 years FU in 2018.[34] While this group's series have been well constructed, an inherent risk of bias will always exist in single, designer surgeon case series.

Statistical methods were questionable for all RCTs. Numerous variables were measured, yet no Bonferroni correction was performed in any of the studies reviewed, except for Blakeney et al.[51] They were conducted with small numbers of patients in each group, ranging from 14–100 patients. This is a result of researchers performing power analyses based on a single variable, e.g. Oxford Knee Score (OKS)[11,43,44] or Knee Injury and Osteoarthritis Outcome Score (KOOS),[42] and in at least one instance, the use of a two-tailed test for level of significance.[11]

Does kinematic alignment translate to improvement in patient-reported outcomes or objective measures of knee function following TKA in comparison to mechanical alignment?

Significant improvements in PROMs or objective knee function following KA TKAs have been reported in five case series and two case control studies. However, results reported in the six RCTs and another case control study are less convincing, with small numbers of patients, short duration of FU, and methodological concerns. Formal gait analysis was performed in three comparative studies (one RCT and two case control studies), which reported subtle differences in parameters such as the knee adduction, extension and external rotation moments. The clinical relevance of this needs further evaluation.

Howell et al demonstrated an improvement in the mean OKS from 20 pre-operatively to 43 post-operatively, and post-operative Western Ontario and McMaster Universities (WOMAC) scores averaging 92 points in a case series of 198 patients undergoing 214 KA TKAs at a minimum FU of 31 months.[31] They concluded that KA TKAs restore a high level of function despite 75% of patients in the study group having tibial component varus, defined as > 0° varus. All patients in this study received CR, fixed-bearing, cemented implants with patella resurfacing using PSGs. In another series, Howell et al reported similar clinical outcomes at 6–9 months in 101 patients undergoing KA TKAs using the same implants this time with conventional instrumentation, and showed post-operative OKS and WOMAC scores of 42 and 89 respectively.[32] In 2015, Howell's group reported on the results of 214 patients undergoing 219 KA TKAs at a median FU of 6.3 years (5.8–7.2 years) with post-operative OKS and WOMAC scores of 42.7 and 91.1 respectively.[52] At 10 years FU, the group reported OKS scores of 43 (48 best) and WOMAC scores of 7 (0 best).[34] Notably, any severity of pre-operative varus, valgus and flexion deformity was included in these case series. Spencer et al reported no complications or re-operations at six months FU in a small case control study of 21 patients undergoing KA TKAs using PSGs, with lower tourniquet time and similar blood loss and ROM in comparison to 30 MA TKAs performed with conventional instrumentation.[49]

In 2012, Dossett et al published the first RCT of 41 KA versus 41 MA TKAs using CR cemented implants with patella resurfacing.[43] At six months FU, they reported that the WOMAC score was 16 points better, OKS 7 points better, combined Knee Society Score (cKSS) 25 points better, and flexion 5° greater in the KA group. In 2014, the same group published their two year FU results for 44 KA versus 44 MA TKAs, again reporting significantly better mean

scores for the KA group. At two years, the KA group consisted of a greater proportion of pain-free patients (52% versus 18%).

In 2016, Waterson et al, compared 36 KA TKAs, performed with PSGs, and 35 MA TKAs, performed with conventional instrumentation.[42] They found no significant difference in any of the pain and functional indices or health and quality of life (QoL) scores, including ROM, the timed up-and-go test, two-minute walking test, timed up and down stairs test, peak quadriceps strength test, American Knee Society Score (AKSS), KOOS, Short-Form (SF)-36, University of California at Los Angeles activity score (UCLA) and EuroQol (EQ-5D) at one year FU. CR, cemented implants with patella resurfacing were used by three surgeons for all patients, who were not blinded. Some of the exclusion criteria are worth taking note of: patients with pre-operative varus or valgus > 10° or flexion contracture > 20°, patients who suffered a complication that could have influenced the functional outcome and 7 patients with class 1 device recall (KA group).

In 2017, Calliess et al reported that at one year FU, greater improvements in the KSS (190 versus 178) and WOMAC score (16 versus 26) were found in 100 patients undergoing KA versus 100 patients undergoing MA TKAs, but also noted a greater number of outliers (six patients) with poor functional scores (WOMAC > 40) in the KA group.[45] Patients with varus or valgus deformity > 10°, body mass index (BMI) > 40, post-traumatic osteoarthritis, and previous surgery were excluded from the trial; no mention was made of the proportion of patients with patella resurfacing, and patients were not blinded. In the same year, Young et al reported on the comparison of 49 KA TKAs (PSGs) with 50 MA TKAs (computer navigation) all performed by six fellowship-trained arthroplasty surgeons using CR, fixed-bearing, cemented implants with selective patella resurfacing.[11] Both groups underwent pre-operative MRI scans to ensure blinding. At two years FU, no difference was found in the OKS, KSS, visual analogue score (VAS), forgotten joint score (FJS), WOMAC or EQ-5D scores. Similar complications, including patella maltracking, were found in both groups. As a continuation of this study, patients with a non-arthritic, native contralateral knee with at least two years of FU were approached to participate in 3-D gait analysis on this topic.[46] Twenty-nine patients were enrolled, i.e. 15 with a MA TKA and 14 with a KA TKA. Kinematic and kinetic variables were collected while patients performed five trials of walking at a self-selected pace and overall were found to be similar. The only difference was that the KA group showed significantly lower internal rotation moments and a trend towards increased extensor moments during the mid to late stance phase, which is of uncertain clinical significance. Of note in this study, KAM, the main component of frontal knee kinetics, was lower than typically observed after TKA for both groups.

Niki et al conducted a gait analysis study focusing specifically on KAM,[50] as varus joint line orientation is perceived as a risk factor for premature tibial loosening. They matched a cohort of 21 MA TKAs (18 patients) against 21 KA TKAs (18 patients). For this Asian population, a posterior stabilized TKA with a cementless tibial tray was implanted via mini subvastus approach. Despite slight varus alignment, reduced KAM was found for KA TKAs compared to MA TKAs ($p = 0.021$) after a median FU of 2.6 years, and was attributed to a shorter lever arm ($p = 0.028$). Clinical outcome scores (Knee Society) did not differ between the two groups.

Recently, Blakeney et al performed a retrospective case control study in which 18 KA TKAs (15 patients) were matched against 18 MA TKAs (17 patients).[51] Both groups underwent gait analysis before inclusion and kinematic parameters were compared to those of a non-matched group of healthy controls (170 knees in 95 participants). The KA group showed no significant differences in knee kinematics compared to healthy controls. The MA group displayed several significant differences in knee kinematics compared to healthy controls, i.e. less sagittal plane ROM ($p = 0.020$), less maximum flexion ($p = 0.002$), adduction during the initial swing phase ($p = 0.010$), and knee external tibial rotation in mid-stance ($p = 0.008$). However, when comparing MA and KA groups directly, no significant differences in kinematics parameters could be shown. PROMs were significantly better for the KA group compared to the MA group at mean FU of 33.5 (12–96) months (KOOS).

MacDessi et al demonstrated that KA TKA with navigation results in significantly lower mean intercompartmental pressure difference at 10°, 45° and 90° knee flexion and less soft tissue release, but this did not translate into a difference in PROMs after one year follow up.[48] The authors acknowledged that using the pressure sensors resulted in intra-operative adjustments of bony resection and soft tissue balancing, which may encumber the comparison of clinical outcomes.

Two meta-analyses have been performed for KA versus MA TKAs. Li et al found that the group of 280 KA TKAs achieved better WOMAC, KFS, OKS and flexion, reduced operative time and increased walking distance to discharge in comparison to 281 MA TKAs, with similar KSS, VAS, post-operative haemoglobin, and length of hospital stay in both groups.[39] However, the authors included KA TKA revision of unicompartmental knee arthroplasty in the analysis. Courtney and Lee conducted a meta-analysis of four RCTs comparing 229 KA and 229 MA TKAs and reported higher post-operative KSS in the KA group, but no difference in complication rate (3.9% in KA group versus 4.4% in MA group).[40]

Does kinematic alignment have an impact on implant survivorship when compared to mechanical alignment?

Currently, long-term survivorship (10 years) has been reported for KA TKAs in one designer surgeon case series, with RCTs reporting six to 24-month survivorship.

In their series of 101 patients undergoing KA TKA using conventional instrumentation, Howell et al reported no re-operations at 6–9 months FU.[32] Another case series of 214 KA TKAs using PSGs conducted at the same institution showed no revisions for loosening, wear or instability at 31–43 months FU,[31] and the group subsequently published their medium-term results for 219 KA TKAs after 5.8–7.2 years FU with implant survivorship of 97.5% and revision rate per 100 component years of 0.40.[52] Failures included two loose patella components, one loose tibial component, one with patella instability and one deep infection. At 10 years, the group reported implant survivorship of 97.5% for revision for any reason and 98.4% for aseptic loosening (number at risk 141 and 140 respectively).[34] Reasons for revision included PJI (two knees), patella instability/loosening (two knees), and tibial component loosening (one knee), and an additional two knees required arthroscopic lateral release for patella instability within the first year.[34]

In their RCT, Calliess et al reported similar early revision rates in the KA (2%) and MA groups (1%) at one year FU, all for instability.[45] In 2012, Dossett et al reported similar complication rates and no revisions at six months.[43] In 2014, the same group reported one revision for infection in the KA group of 44 patients and one revision for instability in the MA group of 44 patients after two year FU.[44] Waterson et al excluded patients with complications that could affect functional outcome, and therefore were unable to report on survivorship in their RCT.[42] Young et al reported similar proportions of re-operations in the KA group (3 in 49 patients) and the MA group (4 in 50 patients), which included one patient with patella instability in both groups.[11]

Courtney and Lee pooled the survival data of 877 KA TKAs from nine studies and reported a survivorship of 97.4% at a weighted FU of 38 months.[40] Patellofemoral problems was the most frequent reason for revision (8 patients, 1.2%).[40] However, when comparing the revision rate for patellofemoral complications in a meta-analysis of 229 KA and 229 MA knees, there was no difference between the two groups (1.3% versus 1.3%).[40]

Discussion

This systematic review identified 15 studies evaluating the subjective and objective functional outcomes and survivorship of KA TKA, 10 of which compared KA to MA TKA. We chose to analyse these studies without pooling data because (1) all studies contained methodological concerns, including challenges in randomization, risk of bias, and inability to control confounding variables; (2) substantial heterogeneity in outcome measures was apparent, with 10 different PROMs utilized; (3) non-standardized objective measures of knee function were performed; and (4) the included clinical trials had 6–24 months FU and relatively small numbers of participants even when collated: MA 353 knees (339 patients) versus KA 354 knees (339 patients). Despite this, there are salient findings that are worthy of noting, which may be less apparent by pooling data in this instance.

Firstly, it is clear that excellent clinical and functional outcomes for KA TKA have been achieved in designer series, even at 10 years FU.[34] Secondly, the currently available level I and II evidence suggests that KA TKA appears to show equivalent or improved PROMs, objective measures of knee function, and implant survival.[11,42–46] Thirdly, although the technique described in designer series may be difficult to reproduce given the unavailability of the property software used for determining the implant position and the use of PSG, it has been successfully reproduced with standard instrumentation and computer navigation.[32,48]

Proponents of KA TKA suggest that correcting the arthritic deformity to the native or pre-arthritic alignment by positioning the tibial, femoral and patellar components in a manner that respects the three axes of rotation of the knee, as well as the native distal and posterior joint lines,[34] improves functional outcome and patient satisfaction. The studies reported herein demonstrate that PROMs such as OKS, WOMAC, AKSS, cKSS and KOOS appear equivalent or in favour of KA TKA,[11,43–46,51] while FJS, VAS, EQ-5D, SF-36, and UCLA scores appear equivocal.[11,42] Since these PROMs have recognized limitations in terms of responsiveness and ceiling effects, comparative studies focussing on PROMs as the primary outcome may be unable to detect a meaningful difference.[54,55] Only four comparative studies reported on objective measures of knee function (none of which are standardized measures) including peak quadriceps torque, degrees of flexion, KAM and gait kinematics, which were in favour of KA TKA.[42–44,50] The lower KAM seen in KA TKA suggests that this technique may be particularly suitable for patients with increased varus tibial bowing.[34,50] The proposed soft tissue benefits of KA that may be responsible for improvements in pain, function and patient satisfaction[29,44,49,52] were only quantified in one RCT, which showed reduced intercompartmental pressure difference in KA knees, but this did not translate into improvements in PROMs at 1 year follow up.[48]

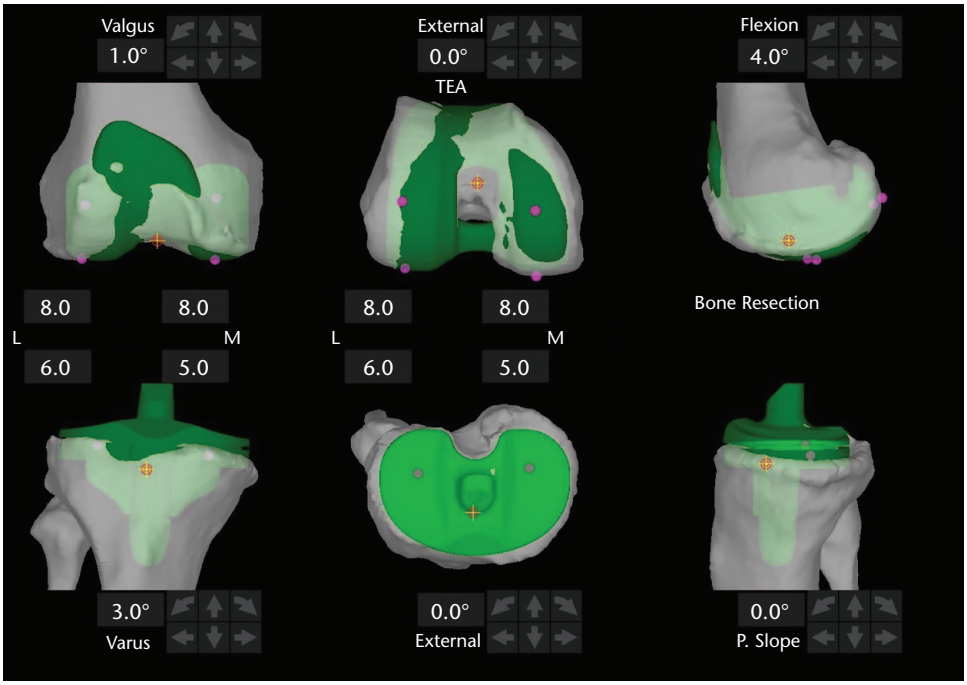

Fig. 4 Operative plan for a robotic-assisted, kinematically aligned TKA. Note that the implant alignment is based on symmetrical 8 mm distal and posterior resections of the femoral condyles. The tibial resection is aligned to the native proximal tibial joint line, taking into consideration 1mm of asymmetrical bone loss from osteoarthritis.

Studies reporting the outcomes in TKA tend to focus on static coronal alignment, but one should also appreciate the importance of sagittal and axial alignment. Femoral component flexion > 3° and tibial slope of 7° have been noted as risk factors for failure[56,57] Optimal axial rotation of the femoral component is important in obtaining balanced flexion gaps, as well as tibiofemoral and patellofemoral congruency,[58–60] and it has been shown that external rotation of the femoral or tibial components of < 2° or > 5° is associated with increased risk of failure and patellar maltracking.[56,61–64] Only two studies identified in this review commented on the sagittal alignment of the components,[34,43] and none of them reported the axial alignment objectively.

Patient selection criteria for KA TKA need to be clearly defined. While one would expect that it may be inappropriate for patients with large deformities, Howell et al included a range of 14° varus to 20° valgus, and any degree of flexion deformity.[34] The fact that poor clinical results are still reported in both KA and MA groups, suggests that careful evaluation of which patients benefit from either strategy is required.[65]

The relationship between alignment and survivorship is unclear. Fang et al correlated the anatomical tibiofemoral angle with survivorship in 6070 TKAs and reported that the best survival rate (99% at 20 years) was seen for patients with post-operative anatomic knee alignment of between 2.4° and 7.2° valgus (which represents a nearly neutral or varus mechanical axis).[10] They showed that neutrally aligned TKAs (+/- 5°) showed significantly better survivorship compared to varus and valgus TKAs.[10] Other contemporary studies have recognized that patient age, polyethylene shelf age, and BMI may play an important role in survivorship of TKA.[66,67] In reality, the durability of TKA is to be multifactorial, and far more complex than a dichotomous description of 'well aligned' or 'malaligned' based on historical perspectives.[3] The utilization of modern technologies, especially robotics in TKA, will likely play a pivotal role in improving our understanding about optimal, functional alignment and implant position (Fig. 4).[68,69] Not only do they provide us with the ability to plan and position the implants with greater precision, taking into consideration the alignment, joint line and soft tissue balance, but will also assist in the collection of data through the acquisition of lower limb alignment and 3-D CT imaging required for pre-operative planning, and collection of intra-operative data regarding soft tissue balancing, which can then be evaluated with post-operative radiological and functional assessment. Robotic TKA also avoids the unique complication of incorrect seating of the PSG, which can cause symptomatic malalignment requiring revision.[34] Dynamic, in vivo methods of assessing alignment and quantifying joint contact pressures may be valuable adjuncts to quantifying the soft

tissue balance and correlating functional outcome with alignment strategies.[70–72]

The main limitation of this study was that data from comparative studies was not pooled. This was deliberate, since it is our view that the studies were too heterogenous in design, methodology, surgical technique and reported outcome measures, and would still contain relatively few numbers to make relevant statistical inference.

In conclusion, there is some compelling evidence showing that using a KA strategy has equivalent or improved clinical outcomes, without increased risk of failure in the short, medium and even long term. However, further studies are warranted to determine reproducibility of the encouraging clinical results reported by the designer surgeons. Future RCTs should control for confounders such as surgical technique (PSGs, navigation or conventional instrumentation), perform adequate blinding of patients and outcome measurers, utilize outcomes measures that are less susceptible to a ceiling effect, and improve the integrity of the statistical methods by adjusting for the number of variables tested. The use of robotics and objective measures of soft tissue balance may play an important role in these future studies.

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