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Publication Date

2023-06-01

DOI

10.1016/j.artd.2023.101127

Peer reviewed

Arthroplasty Today 21 (2023) 101127

Contents lists available at ScienceDirect

Arthroplasty Today

journal homepage: http://www.arthroplastytoday.org/

Systematic Review

Patient-Reported Outcomes of Kinematic vs Mechanical Alignment in Total Knee Arthroplasty: A Systematic Review and Meta-analysis of Randomized Controlled Trials

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ARTICLE INFO

Article history:
Received 22 August 2022
Received in revised form
28 January 2023
Accepted 27 February 2023
Available online xxx

ABSTRACT

Background: Total knee arthroplasty (TKA) is an effective treatment method for severe osteoarthritis of the knee. Poor alignment of a knee replacement has been associated with suboptimal clinical results. Traditionally, mechanical alignment (MA) has been considered the gold standard. In light of reports of decreased satisfaction with TKA, a new technique called kinematic alignment (KA) has been developed. The purpose of this study is to (1) review the results of KA and MA for TKA in randomized controlled trials based on the Western Ontario and McMaster Universities Arthritis Index score, the Oxford Knee Score, and the Knee Society Scores, (2) perform a meta-analyses of the randomized controlled trials with baseline and follow-up values of these parameters, and (3) discuss other shortcomings of this literature from the perspective of study design and execution.

Methods: Two independent reviewers performed a systematic review of the English literature using the Embase, Scopus, and PubMed databases searching for randomized controlled trials of MA vs KA in TKA. Of the initial 481 published reports, 6 studies were included in the final review for meta-analysis. The individual studies were then analyzed to evaluate for risks of bias and inconsistencies of methodology.

Results: A majority of studies demonstrated low risk of bias. All studies had fundamental technical issues by utilizing different techniques to achieve KA vs MA. There was no significant difference between KA and MA in these studies.

Conclusions: There is no significant difference in any outcomes measured between KA and MA in TKA. Both statistical and methodological factors diminish the value of these conclusions.

Introduction

Rationale

Total knee replacement is a widely performed tool in the treatment of knee osteoarthritis. Traditionally, knee replacements have been performed using the technique of mechanical alignment (MA) advocated by Insall [1]. In MA, the objective is to place the femoral and tibial components in neutral alignment relative to the femoral and tibial axes, respectively. This technique has been very popular, due to its reproducibility and its ability to correct severe coronal deformities of the knee.

In spite of the success of mechanically aligned (MA) total knee replacement, a substantial portion of total knee patients remain dissatisfied [2]. Potential explanations for this have included stiffness, instability, undiagnosed infection, and alterations in nerve transmission.

The kinematic alignment (KA) technique aims to place the femoral component spatially on this cylindrical axis of rotation of the native knee as defined by Eckhoff et al [3] on both its distal and posterior dimensions rather than on any mechanical axis defined by the hip and ankle as in MA. Similarly, in the KA technique, the

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https://doi.org/10.1016/j.artd.2023.101127

tibial implant is placed spatially in the same orientation as the native tibial articular surface. By replacing the amount of cartilage/bone removed with an appropriately sized implant thickness, the KA technique aims to restore the individual native tibio-femoral joint line orientation so that the collateral ligaments and posterior cruciate ligament are balanced throughout the arc of motion.

The randomized controlled trial (RCT) has been viewed as the "gold standard" in decision-making in medicine. In surgery, there are other variables that can introduce bias including variations in surgical technique for each surgeon during different procedures and between surgeons. In research on TKA, these concerns have been partially addressed by having the same surgeon perform the same procedure while maintaining the operating room, implants, and technique the same.

Objectives

The goals of the current study are 3-fold. The first objective is to review and summarize the results of KA and MA in TKA based on clinical scores from RCTs including the Western Ontario and McMaster Universities Arthritis Index (WOMAC), the Oxford Knee Score, and the Knee Society Pain, Function, and Combined scores. The second goal is to perform a meta-analysis of the RCTs including both their baseline values and follow-up values. The third and final goal is to explore and discuss other nonstatistical characteristics of the studies that could compromise the conclusions drawn.

Material and methods

Protocol and registration

We followed the Preferred Reports Items for Systematic Reviews and Meta-Analyses guidelines. Methods of the analysis and inclusion criteria were specified in advance and documented in a PROSPERO registered protocol, registration number: CRD42021219365.

Eligibility criteria

The studies included were all RCTs comparing unilateral KA to MA in TKA.

Information sources

We performed electronic searches using the Embase, PubMed, Scopus, and Cochrane databases from database inception to 14 November 2022. This portion was performed with collaboration of all the authors with the exception of SLS (Fig. 1).

Search

The databases were searched with the following terms in all fields (title, keywords, abstract, and so on) "kinematic" OR "mechanical" AND "alignment" AND "total knee replacement."

Study selection

Exclusion criteria included preliminary reports of RCTs or reports with less than 6-month minimum follow-up, non-English language studies, conference abstracts, case series, cohort studies, case-control series, studies that utilized a "restricted kinematic alignment" rather than true "kinematic alignment" [4], bilateral knee replacement, and any study that was not a RCT. Two senior authors (AJ and DD), both fellowship-trained orthopaedic knee replacement surgeons independently performed the study selection. Duplicates were removed, and additional search was performed for the terms "kinematic" AND "knee" in all fields. This narrowed the potential list to 481 manuscripts. The 2 senior

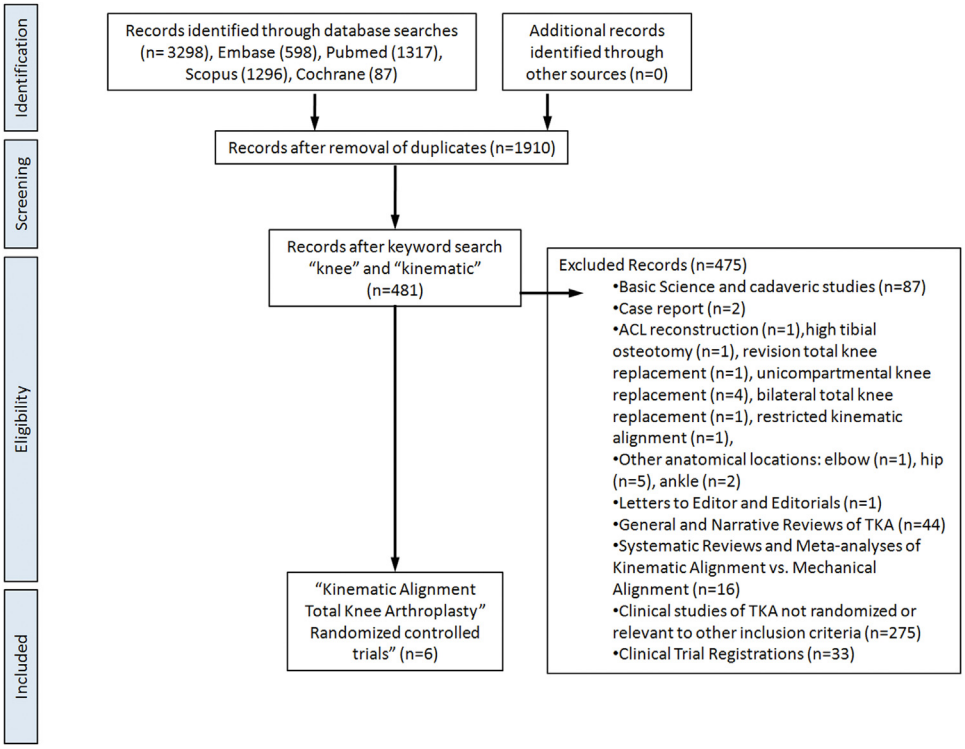

Figure 1. Four-phase PRISMA flow diagram of the literature reviewed and selected. PRISMA, Preferred Reports Items for Systematic Reviews and Meta-Analyses.

authors reviewed these abstracts and manuscripts to confirm the final list of RCTs comparing KA and MA. Discrepancies between the 2 reviewers were minimal and were resolved by consensus. A 4-phase flow diagram of the literature selection was prepared according to guidelines of the "preferred reporting items for systemic reviews and meta-analyses."

Data collection process and data items

For the RCTs, data were tabulated in a spreadsheet. Data for outcome measures were entered into RevMan software (Review Manager, version 5.3. Cochrane Collaboration).

Summary measures

The principal summary measures were the baseline and follow-up WOMAC (0 to 96, best to worst), Oxford Knee score (0 to 48, worst to best), and Knee Society Pain, Function, and Combined scores at 6 months, 12 months, and 24 months.

Risk of bias in individual studies

The Cochrane Collaboration's tool, ROB2, was used to evaluate the studies that met the inclusion criteria for risk of bias [5]. Data were analyzed independently by both senior authors and in cases of deviation, a consensus was reached.

Method of analysis

All data analyzed in this study were continuous variables. The WOMAC is traditionally on a scale of 0-96 (best to worst) [6–8]. Young et al. [9] utilized the "reduced WOMAC," on a scale of 0-100 (worst to best) which is highly correlated with the standard WOMAC. The scores from the study by Young et al. were converted to the Standard WOMAC and incorporated into the meta-analyses using the formula, Standard WOMAC Score = 0.96 × (100-Reduced WOMAC).

The Oxford score is traditionally presented as a scale from 0-48 (worst to best) [10]. Dossett et al (2012) [11] presented their data as 0-48 (best to worst) and in 2014 as 0-48 (worst to best) [12]. The scores were standardized to the original scoring using the formula: Oxford score (worst to best) = 48 - Oxford Score (best to worst).

In the case of the KSS-Combined score, the calculation is the sum of the KSS-Pain and KSS-Functional measurements [13]. However, if the standard deviation for KSS-Combined score was not explicitly given, it was calculated using the formula:

$$St.\,Deviation\,(X+Y)\Big| = SQRT\{\,Variance(X) + Variance(Y) + 2\,Covariance(X,Y)\} = SQRT\Big\{(St.\,Deviation(X))^2 + (St.\,Deviation(Y))^2 + 2\,Correlation(X,Y)*(St.\,Deviation(X))*(St.\,Deviation(Y))\Big\}$$

All information needed for the aforementioned conversion was available in the manuscripts except for the correlation of the KSS-Pain and KSS-Function. For this, we referred to the work by Jacobs and Christensen [14] who determined that knee pain and function scores were correlated r = 0.49. We used this as the estimate when the standard deviation of the combined KSS was not available. This method was applied to the article by Dossett et al (2012) and the study by Young et al.

For the meta-analysis of the visual analog scale, data were available from 2 articles, by Laende et al. and Young et al. There were some differences in the terminology used in obtaining these values. Laende et al. used a "visual analog scale for satisfaction (unsatisfied to satisfied = 0 to 100)". In contrast, Young et al. used a "visual analog scales measuring pain at rest and when mobilizing (0-10 none to worst)." In the meta-analysis, we selected the pain at rest VAS rather than the VAS when mobilizing. We further converted the 0-10 none-to-worst scale to the 0-100 scale with 0 being worst and 100 being no pain by multiplying both the mean and standard deviation by 10.

Meta-analysis was performed using random-effects models. Inverse variance weighted standardized mean differences were used to estimate pooled effect sizes with 95% confidence intervals. Statistical heterogeneity was assessed by χ^2 tests using the Q statistic, with the I^2 statistic to quantify heterogeneity.

Forest plots were generated for the meta-analysis. The meta-analysis was performed at 6-month, 12-month, and 24-month follow-up periods if available for each parameter. In the articles by Dossett where the same or nearly same study group of patients was included, we did not include both studies in the baseline meta-analysis. This avoided counting the same patients twice in the same analysis.

Technical analysis of the studies

To assess for consistency between the groups, we scrutinized the manuscripts to determine if the following requirements were met: (1) Did the authors disclose preoperative and postoperative alignment measurements from each group to confirm that they achieved the desired alignment objectives? (2) Did the studies describe whether the knee replacements had resurfaced or non-resurfaced patellae? (3) Was the alignment method in each group clinically appropriate and reliable based on scientific and regulatory guidelines of the manufacturer and government agencies? and (4) Did the authors use the same surgical cutting technique (eg, navigation, rapid prototype cutting blocks, manual, and so on) and change just 1 variable (KA vs MA) or was each alignment method performed with a different surgical cutting technique?

Results

Literature search

The total number of references for each database was Embase – 598 abstracts, PubMed – 1317 abstracts, and Scopus – 1296 abstracts. The Cochrane Library was searched for the terms "kinematic total knee replacement" with an additional 87 trials identified. This led to a total of 3298 abstracts for review. A total of 1910 abstracts were eliminated after removal of duplicates leaving 481 abstracts in the analysis. Of these, 475 were eliminated due to being basis science or cadaveric studies (n = 87), being a case report (n = 2) involving other surgeries such as ACL reconstruction (n = 1), high tibial osteotomy (n = 1), revision total knee replacement (n = 1), unicompartmental knee replacement (n = 4), involving total

Table 1
Summary data from RCTs of kinematic vs mechanical alignment for total knee replacement.

Author	Title	Year	Study type	Single/ Double blinding	Radiographic criteria for OA	Implant	Number of surgeons	Method of KA	Method of MA
Calliess, T., et al. [15]	PSI kinematic vs non-PSI mechanical alignment in total knee arthroplasty: a prospective, randomized study. Knee Surg Sports Traumatol Arthrosc, 2017. 25(6): p. 1743-1748.	2017	RCT	None	Not specified	Triathlon (Stryker)	2	OtisMed Shape Match Technology	Manual Instrumentation
Dossett, H.G., et al. [11]	Kinematically vs mechanically aligned total knee arthroplasty. Orthopedics, 2012. 35(2): p. e160-9.	2012	RCT	Double	Not specified	Vanguard (Biomet)	2	OtisMed Shape Match Technology (Not explicitly specified)	Manual Instrumentation
Dossett, H.G., et al. [12]	A randomized controlled trial of kinematically and mechanically aligned total knee replacements: 2-year clinical results. Bone Joint J, 2014. 96-B(7): p. 907-13.	2014	RCT	Double	Not specified	Vanguard (Biomet)	2	OtisMed Shape Match Technology (Not explicitly specified)	Manual Instrumentation
Laende, E.K., C.G. Richardson, and M.J. Dunbar [16]	A randomized controlled trial of tibial component migration with kinematic alignment using patient-specific instrumentation vs mechanical alignment using computer-assisted surgery in total knee arthroplasty	2019	RCT	Double	Not specified	Triathlon (Stryker)	3	OtisMed Shape Match Technology (Not explicitly specified)	Imageless computer navigation (Stryker)
Waterson, H.B., et al. [17]	The early outcome of kinematic vs mechanical alignment in total knee arthroplasty: a prospective randomized control trial. Bone Joint J, 2016. 98-B(10): p. 1360-1368.	2016	RCT	Double	Not specified	Triathlon (Stryker)	3	OtisMed Shape Match Technology (Not explicitly specified)	Manual Instrumentation
Young, S.W., et al. [18]	The Chitranjan S. Ranawat Award: No Difference in 2-year Functional Outcomes Using Kinematic vs Mechanical Alignment in TKA: A Randomized Controlled Clinical Trial. Clin Orthop Relat Res, 2017. 475(1): p. 9-20	2017	RCT	Double	Not specified	Triathlon (Stryker)	6	OtisMed Shape Match Technology (Not explicitly specified)	Imageless computer navigation (Stryker)

knee replacement performed bilaterally (n = 1) or with a restricted kinematic alignment protocol (n = 1). Eight of the 475 studies were eliminated for involving other anatomic areas such as the elbow (n = 1), hip (n = 5), or ankle (n = 2). One abstract was a letter to the editor and was not included. Forty-four of the 475 studies were eliminated as they were general or narrative reviews of total knee replacement. Sixteen abstracts involved kinematic vs mechanical alignment in total knee replacement but were systematic reviews or meta-analyses rather than primary controlled trials and were eliminated. Two hundred seventy-five of the 475 studies were eliminated as they were clinical studies of total knee replacement that were not randomized or did not meet the inclusion criteria we had specified. Thirty-three abstracts were actually protocols and clinical trial registrations and were excluded. This process provided 6 RCTs of kinematic vs mechanical alignment in total knee replacement that fit our inclusion criteria.

Results of individual studies

Table 1 summarized the data from RCTs of KA vs MA for TKA.

Study characteristics and concerns for bias

The study characteristics of the 6 studies included are provided in Table 1 [11,12,15–18]. The majority of studies were well designed from a statistical perspective and demonstrated low bias (Fig. 2). The exception was the study by Calliess et al [15]. According to these authors, “due to high overall costs, patient blinding was not performed in this study.”

All studies had areas of concern regarding the technical orthopaedic aspects. These data are summarized in Figure 3.

All studies included preoperative and postoperative alignment information. Calliess et al. [15] did not specify whether the knees in their study had patellar resurfacing or if there was a difference in patellar resurfacing between the KA and MA groups. Young et al. [18] had a mixture of resurfaced and nonresurfaced patellae. The alignment techniques proved to be the most concerning aspect of these RCTs. Specifically, there is concern about the rapid prototype technology used in all of these studies to achieve KA. In all studies, the instrumentation used was made by the US company, OtisMed, who developed rapid prototype blocks to achieve kinematic alignment. The proprietary technologies used in preparing these

Complications	Patellar resurfacing	Cruciate retaining/ stabilized	Experimental group	Control group	Total patients	Males	Females	Experimental group total patients	Experimental group Genders (M/F)	Control group total patients	Control group Genders (M/F)	Age in years (Exp group)	Age in years (control group)	Followup range
2 multidirectional instabilities in KA, 1 instability in MA.	Not specified	CR	KA	MA	200	82	118	100	39/61	100	43/57	67 ± 8	70 ± 8	12 months
KA: 1 hematoma, w MUA, 1 patellar subluxation, MA. 1 hematoma treated closed, 1 hematoma evacuation, 1 patella fracture	All resurfaced	CR	KA	MA	82	74	8	41	39/2	41	35/6	65 ± 8	66 ± 8.2	6 months
3 total: (KA group) 2 MUAs; (MA group) One Skin slough	All resurfaced	CR	KA	MA	88	79	9	44	41/3	44	38/6	66 ± 7.7	66 ± 8.6	24 months
Not specified	All resurfaced	CR	KA	MA	47	14	33	24	8/16	23	6/17	64 ± 8	63 ± 7	24 months
1 extensor tendon rupture	All resurfaced	CR	KA	MA	71	N/A	N/A	36	N/A	35	N/A	N/A	N/A	6, 12 months
3 kinematic, 4 mechanical	Both, equal proportion, 11in MA and 6MA had resurfacing of patella	CR	KA	MA	99	48	51	49	24/25	50	24/26	72 ± 6.5	70 ± 7.5	24 months

KA custom cutting guides are a source of concern due to the lack of clear validation and reliability of the achieved KA alignment. The final technical concern among these studies was the use of a different alignment technique for the KA and MA groups. This can introduce yet another source of bias in the results of each group, thus diminishing the conclusions that can be drawn from the studies. In all studies, the KA technique was performed with the OtisMed cutting blocks. In 4 studies, the MA technique was performed with manual instruments. In 2 studies, the MA technique was achieved with an imageless navigation system.

Pooled outcomes

The results of the meta-analysis are presented in Figures 3-9. For the WOMAC, the limited number of studies demonstrated a significantly better outcome at 6 months and at 12 months for KA. For the Oxford Knee score, there was no significant advantage for either surgical technique at 6 months, 12 months, or 24 months. For the Knee Society Pain score, there was no significant advantage for either surgical technique at 6 months, 12 months, or 24 months. For the Knee Society Function score, there was a significant advantage at 6 months, but this only reflected 1 study [11]. At 24 months, there was no significant advantage for either approach. For the Knee Society Combined score, there was a significant advantage for KA at 6 months and at 12 months, but this only reflected from 1 study each [11,15]. At 24 months, there was no advantage for either approach. For the VAS, there was no significant advantage for either approach at 6 months, 12 months, or 24 months.

Baseline data demonstrated that some of the studies demonstrated better patient-reported outcomes in the KA group at time 0 indicating a potential source of bias in the later reported outcomes [11,12,15]. None of these baseline differences reached statistical significance.

Discussion

KA has been developed as a method to address the sources of dissatisfaction and early revision from total knee replacement, namely persistent pain, instability, and stiffness. Intuitively placing knee replacement implants in the identical spatial position as the native knee would lead to the ligaments being under physiological tension throughout the range of motion. In this study, we performed a systematic review and meta-analysis of RCTs that compared KA and MA. The results indicate that there is no

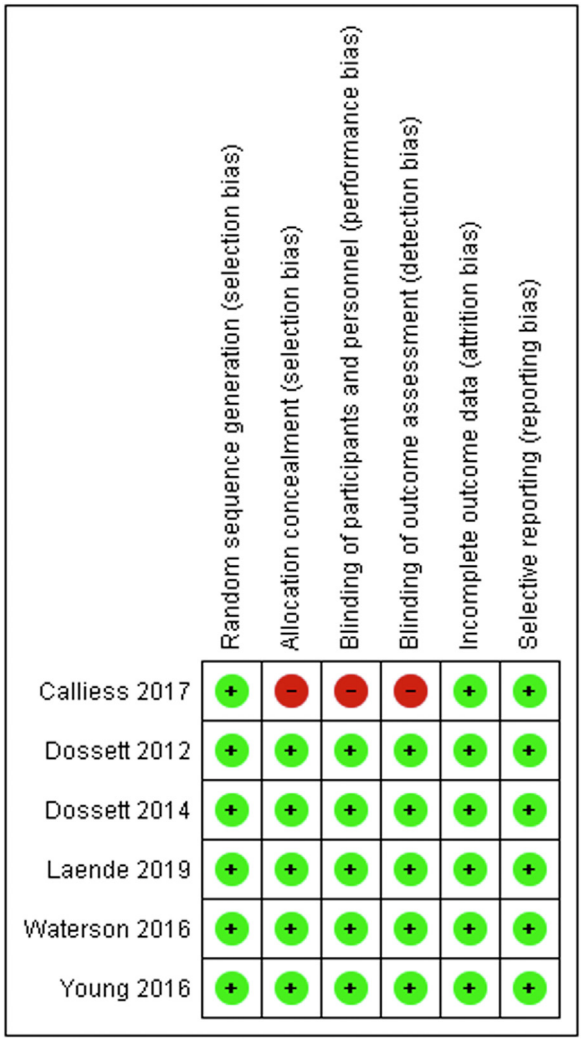

Figure 2. Summary assessment of statistical risk of bias using the ROB2 score in randomized controlled trials of kinematic vs mechanical alignment for total knee replacement.

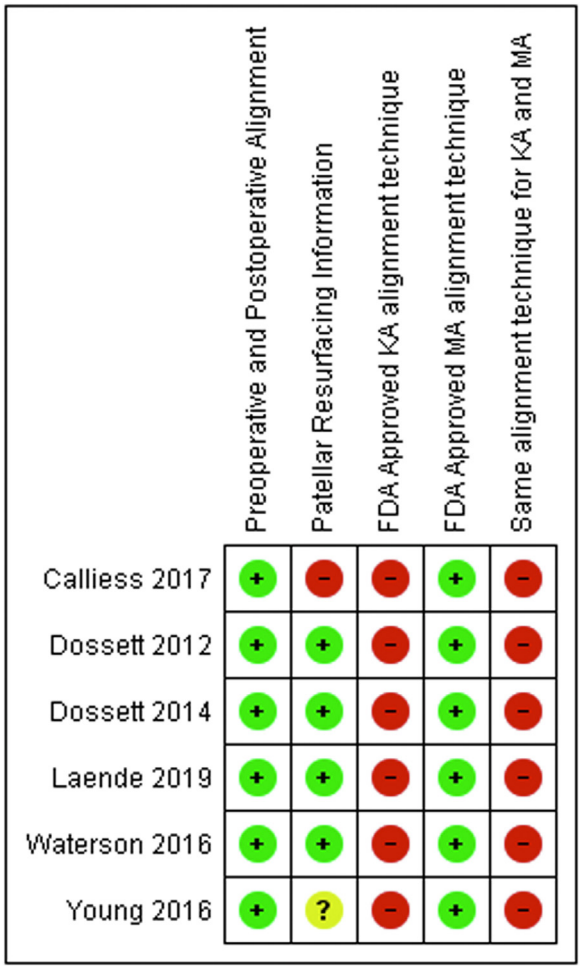

Figure 3. Summary assessment of bias resulting from technical factors in RCTs of KA vs MA in total knee arthroplasty. KA, kinematic alignment; MA, mechanical alignment; RCT, randomized controlled trial.

significant difference in any outcome measure between KA and MA as defined in these studies.

The next step in our analysis was to explore sources of bias. From a statistical perspective, we evaluated the patient-reported outcomes at specific time points for each outcome measure including at baseline to determine if the 2 groups were truly matched. The data indicate that there was some asymmetry of the patient-reported outcomes at baseline between the 2 groups in a number of articles, but this was most pronounced in the 2 articles by Dossett et al. [11,12]. The RCTs were otherwise well designed from a statistical point of view with the exception of the study by Calliess et al. [15] where the participants and the examiners were not blinded to the assigned group.

We also found that the potential biases are not only restricted to statistical factors but also to the surgical methodology used. We were concerned that these studies used 2 different techniques to achieve each of the alignment methods, thereby introducing additional variables into the analysis. The first of these was that the studies used a controversial rapid prototype technology, the OtisMed system which was initially performed without Food and Drug Administration approval and was ultimately removed from the market.

Historically, OtisMed marketed a method of alignment in total knee replacement through the use of 3-dimensionally printed rapid prototype guides from magnetic resonance imaging data. The company had difficulty with obtaining Food and Drug Administration clearance for the guides. OtisMed was eventually acquired by Stryker which continued with the approval process. Ultimately, the OtisMed guides, now named Stryker ShapeMatch were approved by the Food and Drug Administration on May 24, 2011. However, in November 2012, Stryker issued a statement for surgeons to stop using the ShapeMatch guides. It issued a voluntary recall of the guides on April 10, 2013 [19]. These are the same custom cutting guides used for KA in these studies.

The OtisMed rapid prototype cutting blocks have demonstrated a broad range of accuracy in the literature in achieving the desired alignment. Klatt et al. [20] reported on 4 knees with major malalignment from desired values using the OtisMed system as measured by an intraoperative navigation system. Clark et al. [21] also evaluated the intraoperative reliability of the OtisMed ShapeMatch cutting guides in a series of 24 patients undergoing TKA. They placed the cutting guides on the joint surfaces and then determined the planned cuts using an intraoperative navigation system. They then completed each cut with the navigation system. They found that the guides performed well in matching the navigation system and were within 0.5 degrees in 96% of cases for the distal femoral cut and within 0.5 degree in 92% of cases for the

Figure 4. Meta-analysis of RCTs providing data on the WOMAC score at baseline to 24 months of follow-up. RCT, randomized controlled trial.

proximal tibial coronal cut. More recently, Zambianchi et al [22] had less favorable findings after evaluating the performance of the OtisMed guides and those of a similar technology (Visionaire, Smith and Nephew) based on measurements of the bone resections. They found that the guides performed best on the distal femur with 90% of cuts within 2 degrees of the plan and less well on the posterior femur and tibial coronal cut with only 78% and 68% within the 2 degree range of the plan. Thus, the use of the OtisMed guides is a

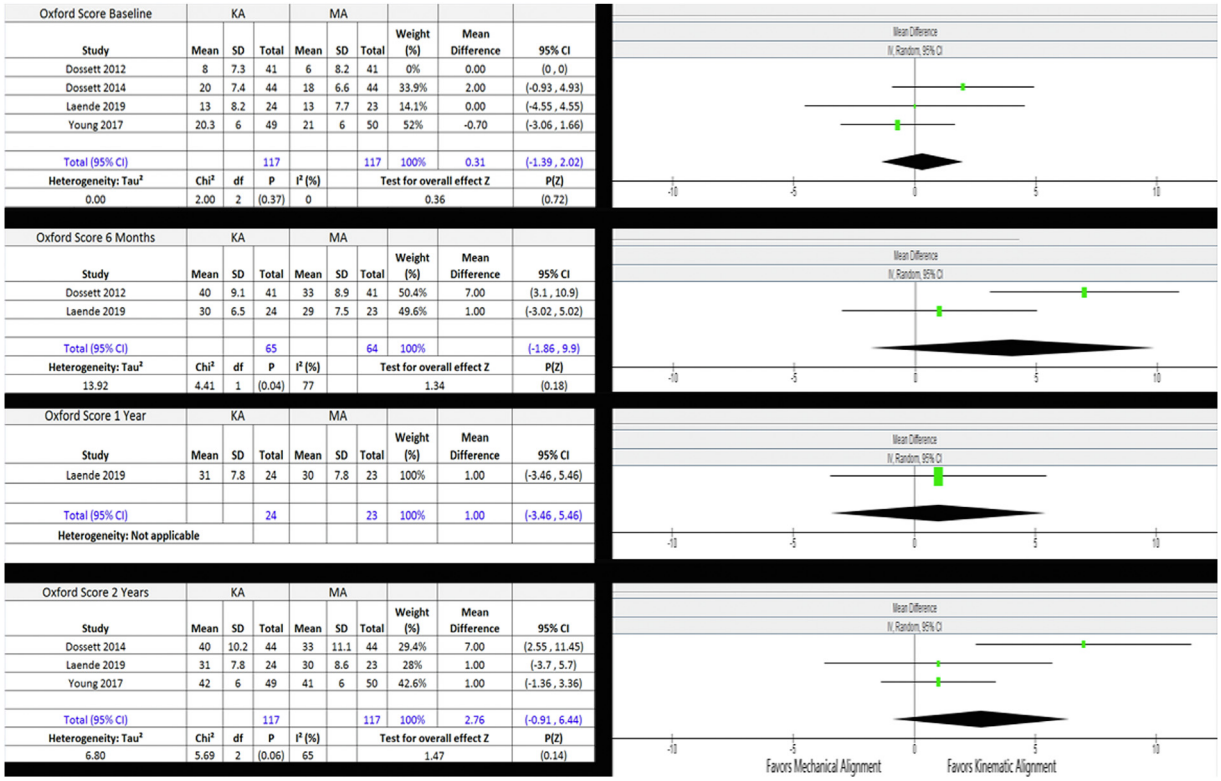

Figure 5. Meta-analysis of RCTs providing data on the Oxford knee score at baseline to 24 months of follow-up. RCT, randomized controlled trial.

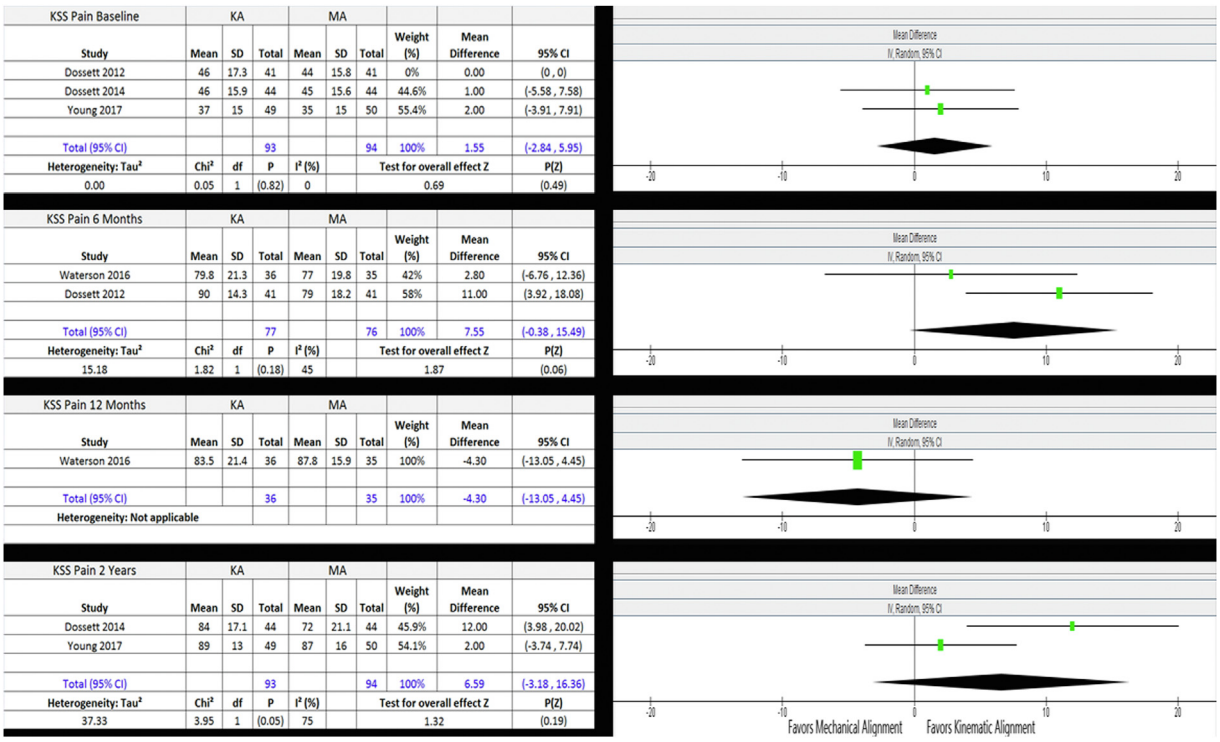

Figure 6. Meta-analysis of RCTs providing data on the Knee Society Pain scores at baseline to 24 months of follow-up. RCT, randomized controlled trial.

potential source of error in achieving the desired KA alignment for total knee replacement based on a wide range of results from the literature. Meanwhile, in the mechanical alignment groups included in the studies reviewed here, several cutting techniques were used, thereby, confounding the true effect of KA vs MA. Additionally, some of the studies either had a mixture of resurfaced or nonresurfaced patellae or did not specify how many patellae were resurfaced, introducing yet another factor that could affect the clinical outcome between the KA and MA groups.

A number of previous systematic review and meta-analyses have been performed on this topic. Their methodology is similar to those of our study with a number of notable exceptions.

Liu et al. [23] published a meta-analysis on this same topic. Their inclusion criteria were slightly different than those of the current study. For example, they included an abstract from Belvidere et al. in their analysis. Although inclusion of an abstract in a meta-analysis does have the advantage of minimizing publication bias, the lack of detail can be a point of concern relative to a standard manuscript. It is not clear why an abstract with 144 patients at 4 centers would not be published in a standard manuscript after 7 years unless there was some other methodological issue. Furthermore, and more concerning, the authors included 2 articles from Matsumoto at al. in the analysis. A close reading of those articles would reveal that both of those articles were not true

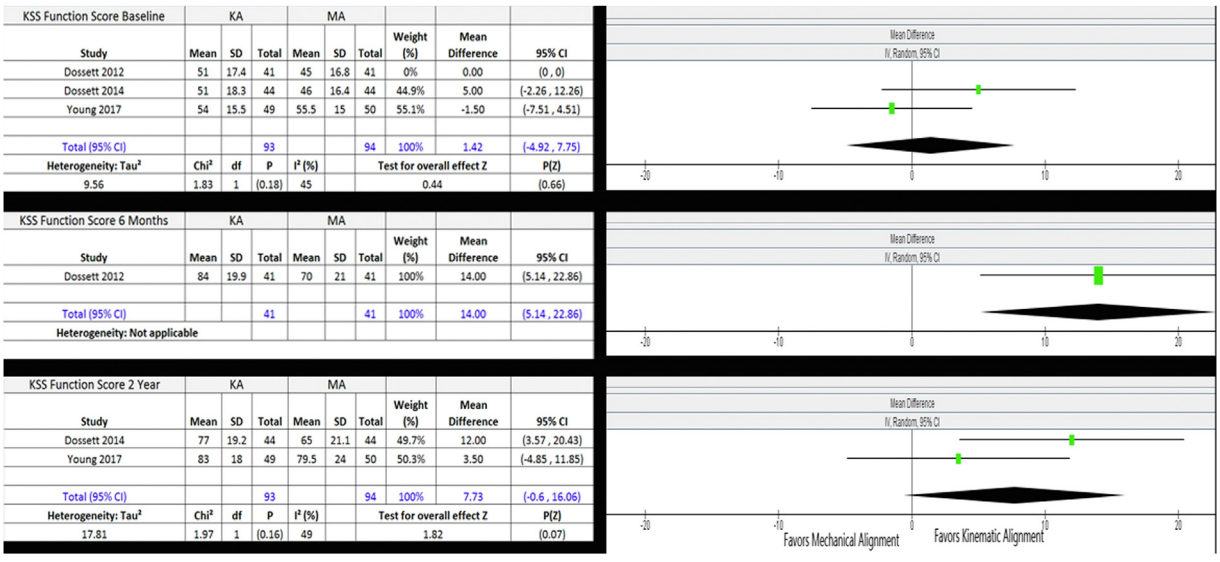

Figure 7. Meta-analysis of RCTs providing data on the Knee Society Function scores at baseline to 24 months of follow-up. RCT, randomized controlled trial.

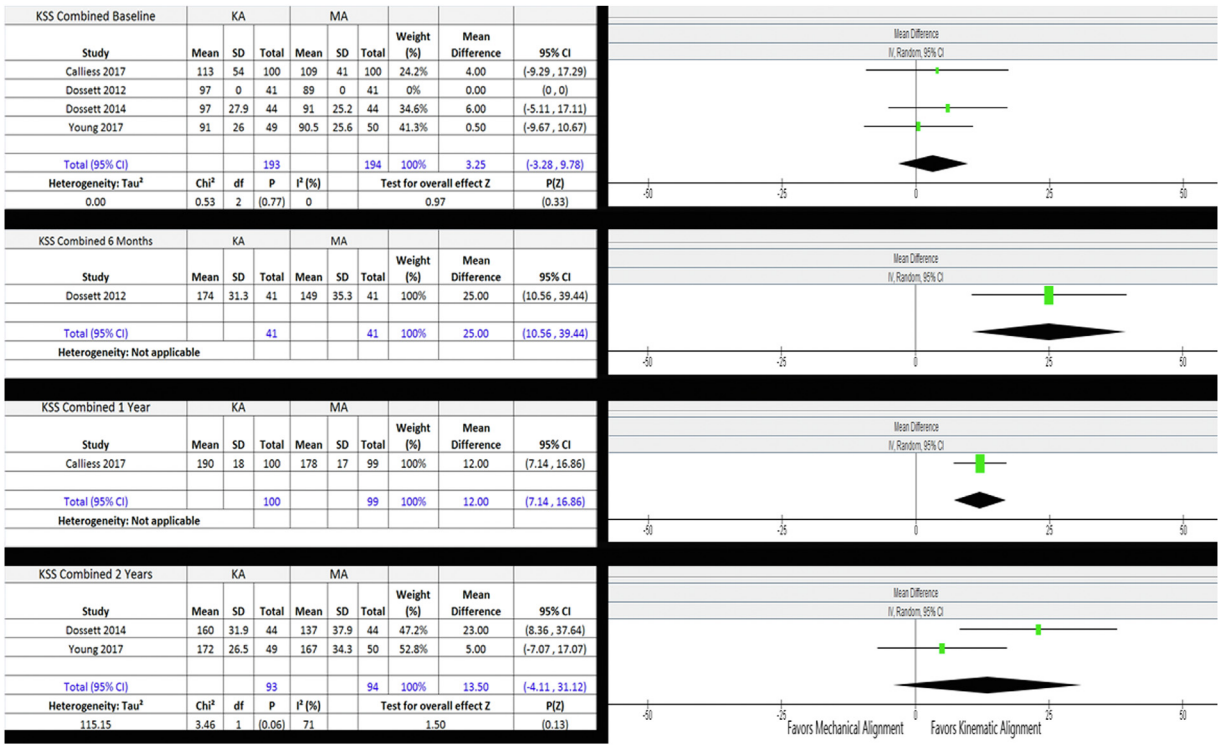

Figure 8. Meta-analysis of RCTs providing data on the Knee Society Combined scores at baseline to 24 months of follow-up. Note that standard deviations were calculated rather than provided for Dossett et al in their 2012 article. RCT, randomized controlled trial.

kinematic alignment but rather a "modified kinematic" alignment where all knees were placed in 3° of tibial varus based on population means of native tibial alignment rather than based on matching the preoperative alignment parameters of each patient as in the true kinematic technique. Liu et al also included the article by Yeo et al., which once again assigned standardized coronal cuts, of 2° varus on the tibia and 2°valgus on the femur relative to the mechanical axis of each bone using a robotic system, again not consistent with the true kinematic alignment technique. Finally, the authors included the 2 articles by Dossett at al. with the same patient population in the same meta-analysis, increasing the relative contribution of those patients to the overall results. Overall, these oversights compromise the conclusions that can be drawn from this meta-analysis.

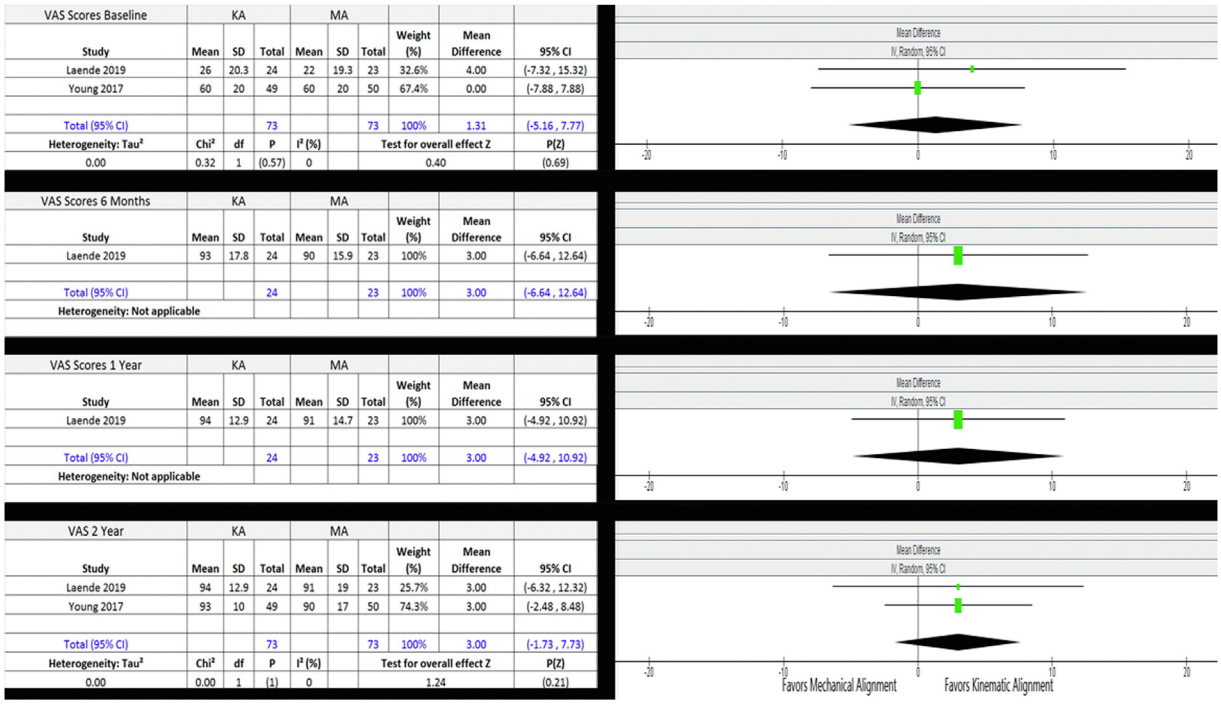

Figure 9. Meta-analysis of RCTs providing data on the visual analog scale (VAS) scores at baseline to 24 months of follow-up. RCT, randomized controlled trial.

Luo et al. [24] published a meta-analysis similar to this study. Their study included both randomized controlled trials as well as noncontrolled trials. Unfortunately, they also included the article by Yeo et al. as well as the articles by Dossett in the same meta-analysis. For example, in 1 forest plot, they included Dossett's 6-month results with Caliess's 12-month result with Dossett's and Young's 24-month result.

Gao et al. [25] reported on this same topic with an article with similar concerns. They also included the articles by Yeo and Matsumoto, not representative of kinematic alignment. They included Dossett's papers in the same meta-analysis thereby duplicating the contribution of those patients, albeit at different time points. These authors also included articles that even within their title indicated that they were “restrictive kinematic alignment” rather than true kinematic alignment as well an article with bilateral total knee replacements, one side done with mechanical and the other with kinematic alignment within the same meta-analysis with other articles with kinematic alignment [26,27].

The strengths of this study compared to previous systematic reviews and meta-analyses on KA vs MA are the inclusion of baseline data and the highlighting of methodological flaws in the studies due to the use of varying surgical cutting techniques.

The limitations of our study, similar to other reviews on this topic, are the paucity of studies available for inclusion, the use of a variety of patient reported outcomes in these studies, and the variations in time points for reporting for these studies. For example, in many of the time points in our meta-analysis, only 1 or 2 studies were included. This clearly limits the value of the meta-analysis but is unavoidable since all qualifying publications have been included.

In summary, this study highlights some of the methodological challenges in the available RCTs comparing KA to MA for TKA. We find it impossible to draw any meaningful conclusions from this literature in light of these deficiencies. Future RCTs will likely be able to avoid some of these pitfalls through the use of validated alignment techniques such as measured bone resections or through the use of the same navigation or robotic system for both techniques.

Conflicts of interest

Danton Dungy is a part of Speakers Bureau for Johnson & Johnson, Ethicon Division for suture and wound closure teaching; is a paid consultant for evaluating knee replacement instruments in Johnson & Johnson/DePuy; is a paid consultant for feedback about a proposed new hip implant in DJO Surgical. All other authors have no conflicts to declare.

For full disclosure statements refer to https://doi.org/10.1016/j.artd.2023.101127.

References

[1] Insall JN, Easley ME. In: Insall JN, Scott WN, editors. Surgery of the knee. Philadelphia: Churchill Livingstone; 2001. p. 1555.

[2] Kahlenberg CA, Nwachukwu BU, McLawhorn AS, Cross MB, Cornell CN, Padgett DE. Patient satisfaction after total knee replacement: a systematic review. HSS J 2018;14:192–201.

[3] Eckhoff DG, Bach JM, Spitzer VM, Reinig KD, Bagur MM, Baldini TH, et al. Three-dimensional mechanics, kinematics, and morphology of the knee viewed in virtual reality. J Bone Joint Surg Am 2005;87(Suppl 2):71–80.

[4] Riviere C, Iranpour F, Auvinet E, Howell S, Vendittoli PA, Cobb J, et al. Alignment options for total knee arthroplasty: a systematic review. Orthop Traumatol Surg Res 2017;103:1047–56.

[5] Sterne JAC, Savovic J, Page MJ, Elbers RG, Blencowe NS, Boutron I, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ 2019;366:l4898.

[6] Bellamy N, Goldsmith CH, Buchanan WW, Campbell J, Duku E. Prior score availability: observations using the WOMAC osteoarthritis index. Br J Rheumatol 1991;30:150–1.

[7] Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. J Rheumatol 1988;15:1833–40.

[8] Bellamy N. Pain assessment in osteoarthritis: experience with the WOMAC osteoarthritis index. Semin Arthritis Rheum 1989;18(4 Suppl 2):14–7.

[9] Whitehouse SL, Lingard EA, Katz JN, Learmonth ID. Development and testing of a reduced WOMAC function scale. J Bone Joint Surg Br 2003;85:706–11.

[10] Murray DW, Fitzpatrick R, Rogers K, Pandit H, Beard DJ, Carr AJ, et al. The use of the Oxford hip and knee scores. J Bone Joint Surg Br 2007;89:1010–4.

[11] Dossett HG, Swartz GJ, Estrada NA, LeFevre GW, Kwasman BG. Kinematically versus mechanically aligned total knee arthroplasty. Orthopedics 2012;35:e160.

[12] Dossett HG, Estrada NA, Swartz GJ, LeFevre GW, Kwasman BG. A randomised controlled trial of kinematically and mechanically aligned total knee replacements: two-year clinical results. Bone Joint J 2014;96-B:907–13.

[13] Scuderi GR, Bourne RB, Noble PC, Benjamin JB, Lonner JH, Scott WN. The new knee society knee scoring system. Clin Orthop Relat Res 2012;470:3–19.

[14] Jacobs CA, Christensen CP. Correlations between knee society function scores and functional force measures. Clin Orthop Relat Res 2009;467:2414–9.

[15] 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 2017;25:1743–8.

[16] Laende EK, Richardson CG, Dunbar MJ. A randomized controlled trial of tibial component migration with kinematic alignment using patient-specific instrumentation versus mechanical alignment using computer-assisted surgery in total knee arthroplasty. Bone Joint J 2019;101-B:929–40.

[17] 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;98-B:1360–8.

[18] 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;475:9–20.

[19] Eisner W. FDA classifies stryker ShapeMatch recall class I. Orthopedics This Week. Beaverton, OR: RRY; 2013. https://ryortho.com/breaking/fda-classifies-stryker-shapematch-recall-class-i/. [Accessed 9 April 2023].

[20] Klatt BA, Goyal N, Austin MS, Hozack WJ. Custom-Fit total knee arthroplasty (OtisKnee) results in malalignment. J Arthroplasty 2008;23:26–9.

[21] Clark G, Leong A, McEwen P, Steele R, Tran T, Trivett A. Intra-operative reliability of ShapeMatch cutting guide placement in total knee arthroplasty. Comput Aided Surg 2013;18:159–65.

[22] Zambianchi F, Colombelli A, Digennaro V, Marcovigi A, Mugnai R, Fiacchi F, et al. Assessment of patient-specific instrumentation precision through bone resection measurements. Knee Surg Sports Traumatol Arthrosc 2017;25:2841–8.

[23] Liu B, Feng C, Tu C. Kinematic alignment versus mechanical alignment in primary total knee arthroplasty: an updated meta-analysis of randomized controlled trials. J Orthop Surg Res 2022;17:201.

[24] Luo Z, Zhou K, Peng L, Shang Q, Pei F, Zhou Z. Similar results with kinematic and mechanical alignment applied in total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc 2019;28:1720–35.

[25] Gao ZX, Long NJ, Zhang SY, Yu W, Dai YX, Xiao C. Comparison of kinematic alignment and mechanical alignment in total knee arthroplasty: a meta-analysis of randomized controlled clinical trials. Orthop Surg 2020;12:1567–78.

[26] 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;35:443–50.

[27] MacDessi SJ, Griffiths-Jones W, Chen DB, Griffiths-Jones S, Wood JA, Diwan AD, et al. 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;102-B:117–24.