The Journal of Arthroplasty 38 (2023) S238–S245

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Proceedings of The Knee Society 2022

The Effect of Minor Adjustments to Tibial and Femoral Component Position on Soft Tissue Balance in Robotic Total Knee Arthroplasty

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ARTICLE INFO

Article history:
Received 13 November 2022
Received in revised form
2 March 2023
Accepted 9 March 2023
Available online 16 March 2023

Keywords:
alignment
balance
robotics
knee arthroplasty
knee replacement

https://www.kneesociety.org/

ABSTRACT

Background: Ideal goals for alignment and balance in total knee arthroplasty (TKA) remain controversial. We aimed to compare initial alignment and balance using mechanical alignment (MA) and kinematic alignment (KA) techniques and to analyze the percentage of knees that could achieve balance using limited adjustments to component position.

Methods: Prospective data on 331 primary robotic TKAs (115 MAs and 216 KAs) were analyzed. Medial and lateral virtual gaps were recorded in both flexion and extension. A computer algorithm was used to calculate potential (theoretical) implant alignment solutions to achieve balance within 1 millimeter (mm) without soft tissue release given an alignment philosophy (MA or KA), angular boundaries (±1, ±2, or ±3°), and gap targets (equal gaps or lateral laxity allowed). The percentage of knees that could theoretically achieve balance was compared.

Results: Less than 5% of TKAs were initially balanced. Limited adjustments to component position increased the percentage of TKAs that could be balanced in a graduated manner, with no difference between MA and KA start points: adjustments of ±1 (10% versus 6%, $P = .17$), ±2 (42% versus 39%, $P = .61$), or of ±3 (54% versus 51%, $P = .66$). A higher percentage of TKAs could be balanced when a greater range for lateral gap laxity was allowed. Balancing from KA resulted in increased joint line obliquity in the final implant alignment.

Conclusion: A high percentage of TKAs can be balanced without soft tissue release using minor adjustments to component position. Surgeons should consider the relationship between alignment and balance goals when optimizing component positioning in TKA.

Total knee arthroplasty (TKA) aims to restore limb alignment and soft tissue balance in the arthritic knee. Mechanical alignment (MA) technique targets a neutral limb alignment through perpendicular bone resections relative to the mechanical axis of the femur and tibia. It also aims for symmetrical and balanced gaps in flexion and extension, which may require soft tissue releases [1]. In contrast, kinematic alignment (KA) aims to restore the patient's native prearthritic knee anatomy through symmetrical bone resections after adjusting for wear, relative to the femoral and tibial joint lines. Advocates of KA argue that as this schema more closely replicates native anatomy, balanced gaps are more likely to be achieved without ligamentous release [2,3].

With the development of modern navigation and robotic technologies, surgeons can virtually position TKA components and assess balance and alignment prior to performing bone resections. This provides the opportunity to adjust tibial and femoral component position virtually to achieve gap balance, from either MA or KA initial start points, minimizing the need for soft tissue releases. This may be beneficial to TKA patients, with a recent study reporting reduced pain postoperatively in those without ligamentous releases versus those who had releases performed [4]. Surgeons may also consider individualized or unequal gap targets because knee laxity has been shown to vary between 0 and 90 of flexion, with lateral laxity increasing as the knee moves into flexion [5,6].

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to https://doi.org/10.1016/j.arth.2023.03.009.

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https://doi.org/10.1016/j.arth.2023.03.009

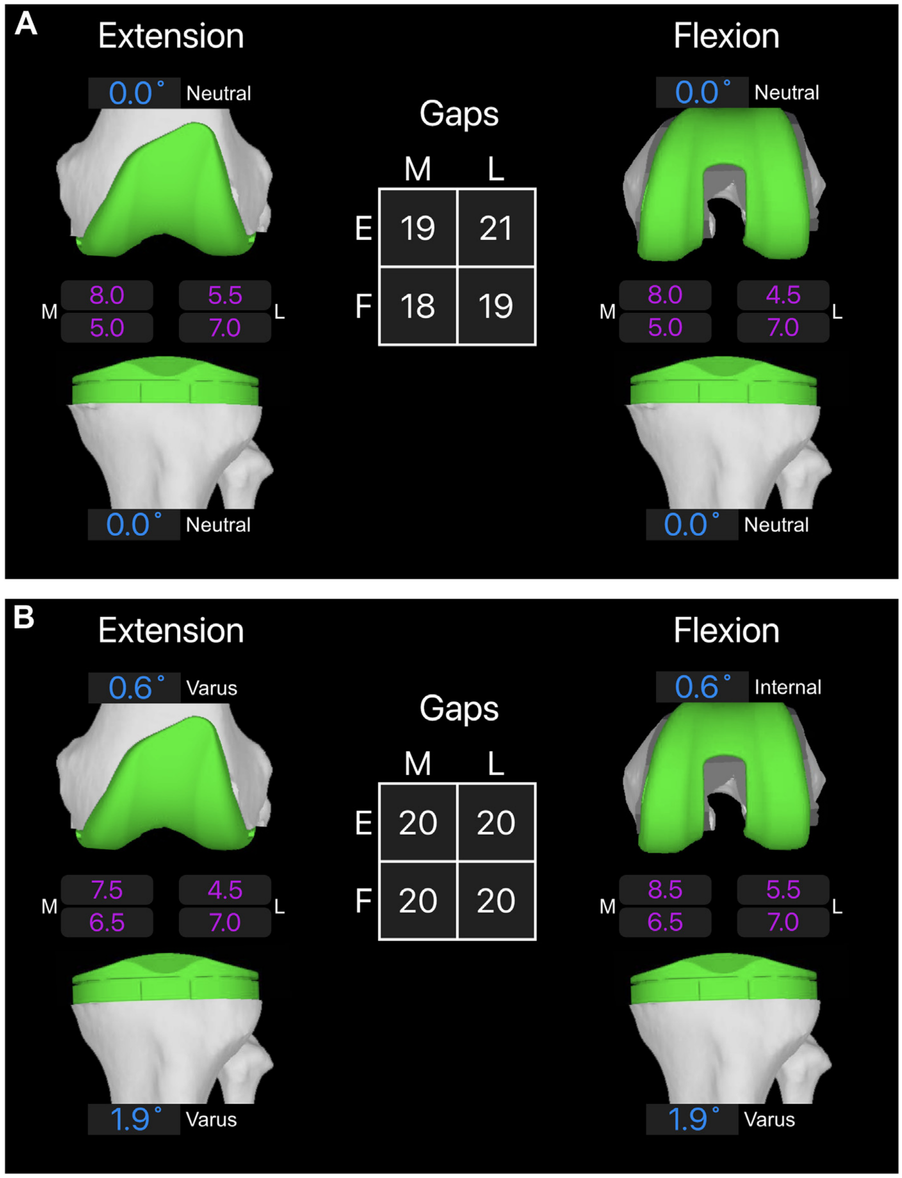

Fig. 1. Pictures of a computer application used to calculate all possible solutions for balancing a knee. Angulations are shown in blue, resections are shown in purple, and gaps are shown in white. The extension pose is on the left and the flexion pose is on the right. To calculate the likelihood of achieving balance using mechanical alignment, femoral and tibial components were set perpendicular to the mechanical axis, as shown in (A). (B) shows a potential solution for balancing the knee without soft tissue releases, with component boundaries of ±3 degrees and targeting equal gaps of 20 mm.

However, the ideal goals remain controversial, with some authors proposing both alignment and balance targets that more closely approximate the native knee [7].

To date, it is unclear what percentage of knees can achieve balance using limited adjustments to component position from either an MA or KA start plan (±1, ±2, ±3° from plan) or different balance targets (equal rectangular gaps or permitting a degree of lateral gap laxity). We aimed to (1) compare initial alignment and gap balance between MA and KA techniques and (2) to analyze the percentage of knees that could achieve balance using limited adjustments to component position.

Methods

Data were collected from 348 primary TKAs from 2 centers (6 surgeons) using a prospective primary TKA database. We excluded 17 knees with moderate or severe bone loss (Ahlbäck grade 4 or 5) or ligamentous injury and therefore analyzed 331 TKAs in his study. Patients consented to participation in the registry which received an institutional review board approval. All patients underwent a preoperative supine computed tomography (CT) scan in preparation for robotic arm–assisted surgery using the Mako Total Knee application (Mako TKA 1.0 software; Stryker, Stryker, Kalamazoo, Michigan). The robotic software was used to position a cruciate-retaining TKA implant design (Triathlon Total Knee System, Stryker, Kalamazoo, Michigan) using a 3-dimensional CT model of each patient's knee.

In 115 TKAs, implants were initially placed in MA (Fig. 1). Femoral components were planned 90 to the femoral mechanical axis with bone resections of 8 mm from the most distal and posterior points of the medial femoral condyle and femoral rotation aligned to the trans-epicondylar axis. Tibial components were planned 90 to the tibial mechanical axis with bone resections of 7 mm off the most proximal compartment of the tibia. In 216 TKAs,

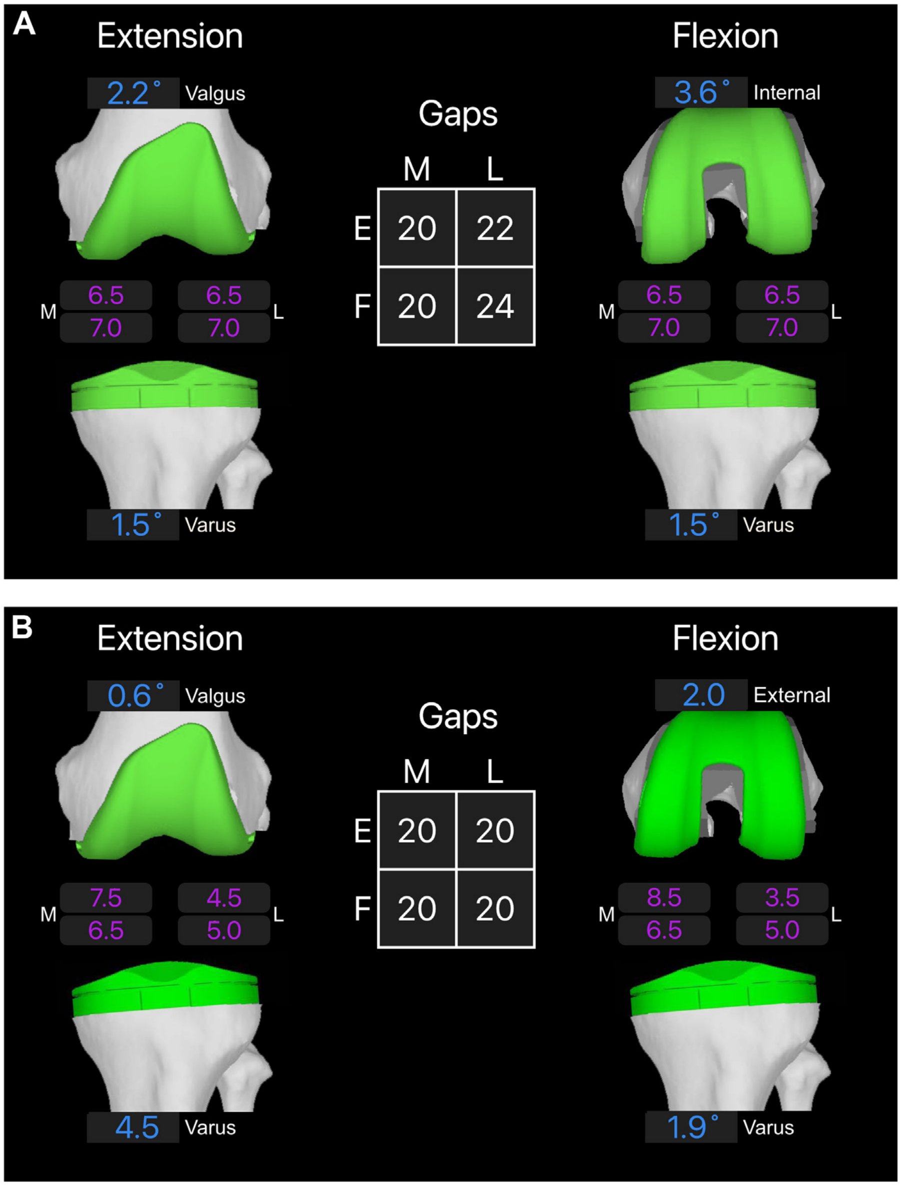

Fig. 2. Pictures of a computer application used to calculate all possible solutions for balancing a knee. Angulations are shown in blue, resections are shown in purple, and gaps are shown in white. The extension pose is on the left and the flexion pose is on the right. To calculate the likelihood of achieving balance with kinematic alignment, femoral and tibial components were aligned with equal resections from the distal femur and proximal tibia, as shown in (A). (B) shows a potential solution for balancing the knee without soft tissue releases, with component boundaries of ±3 degrees from the initial plan and targeting equal gaps of 20 mm.

implants were initially positioned in KA (Fig. 2). In all cases, KA was planned with 6.5 mm equal bone resections from the most distal and posterior points of the femoral condyles and 7 mm equal resections from the proximal tibia medially and laterally for all cases. Because posterior bone resections were equal, rotation of femoral component was parallel to posterior cortical axis. There

Table 1
Patient Demographics and Native Alignment Measures for 331 Total Knee Arthroplasties.

Parameter	MA (n = 115)	Range	KA (n = 216)	Range
Mean age (range)	67	49-86	67 ± 8	42-89
Mean Bone Mass Index (range)	32	20-53	32 ± 5	22-47
Sex (Men:Women)	61:54	-	113:103	-
Side (R:L)	62:53	-	98:118	-
LDFA	87.4 ± 2.5	81-96	87.3 ± 2.1	80-93
MPTA	86.7 ± 2.1	82-96	86.8 ± 1.7	83-93
aHKA	−1.2 ± 2.9	−9 varus to 8 valgus	−0.5 ± 2.6	−7 varus to 6 valgus
mHKA	−4.2 ± 4.0	−14 varus to 9 valgus	−3.5 ± 4.2	−15 varus to 7 valgus
TEA Relative to PCA	−2.2 ± 1.6	−7 internal to 0.4 external	−2.0 ± 1.9	−7 internal to 4 external

MA, mechanical alignment; KA, kinematic alignment; LDFA, lateral distal femoral angle; MPTA, medial proximal tibial angle; aHKA, arithmetic hip/knee/ankle angle; mHKA, measured hip/knee/ankle angle; TEA, transepicondylar line femur; PCA, posterior cortical axis.

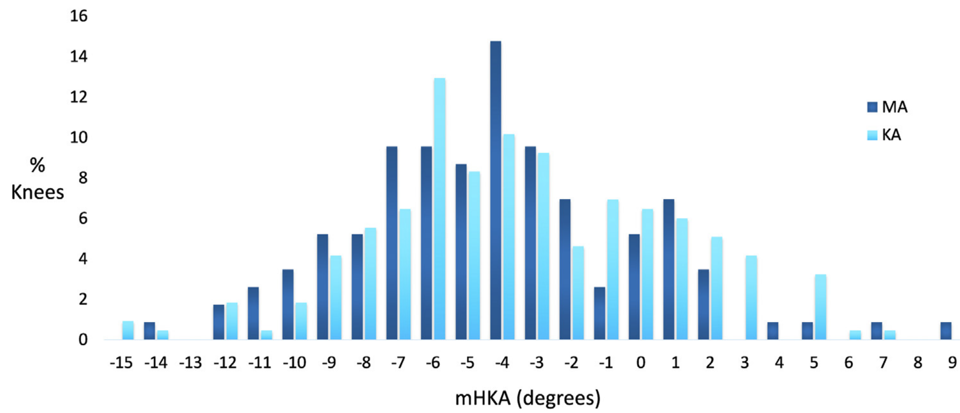

Fig. 3. Distribution of mechanical hip-knee-ankle (mHKA) angles in knees undergoing mechanically (MA) and kinematically aligned (MA) total knee arthroplasty.

was no difference in baseline demographics such as age, sex, body mass index, or alignment between MA and KA patient groups (Table 1 and Fig. 3).

After components were positioned virtually using KA or MA start points, varus/valgus manual tensioning was applied to the knee using a previously described method to obtain 4 maximal virtual gap measurements: (1) maximum medial extension gap; (2) maximum lateral extension gap; (3) maximum medial flexion gap; and (4) maximum lateral flexion gap [8]. Assessment took place with the patella inverted, following a medial parapatellar arthrotomy and anterior cruciate ligament resection under direct vision. Medial and lateral gaps were quantified by placing the knee at slightly less ($<5^\circ$) than full extension to relax the posterior capsule, then again at 90° flexion, while a manual maximal varus and valgus force was applied. Gaps were measured in mm as the distance between the planned femoral and tibial bone cuts. The use of this technique to assess mediolateral soft tissue tension in robotic TKA has been previously validated [9,10]. In addition, in a subset of 18 patients in our study manual, gap measures were collected on each knee by 2 separate observers to assess inter-rater reliability and by a single observer twice to assess intrarater reliability. The intraclass correlation coefficients (ICCs) for gap measurement errors are shown in Table 2. The lateral flexion gap was found to have "good agreement" between observers (ICC 0.89 to 0.9) and the other measures (lateral extension, medial extension, medial flexion) were found to have excellent reliability (ICC > 0.9) [11].

Implant alignment angulations, bone resections, and maximum gap measures were then entered into a computer application built using the Apple ecosystem (Swift–XCode–Apple Inc; Cupertino, California Fig. 1). The application applied a weighted iteration-based computer algorithm to calculate all potential solutions that achieved 4 balanced gaps (± 0.5 mm), using virtual angular and translational adjustments of the tibial and femoral components. The number of TKAs that could be balanced from the initial (MA or KA) position with equal gap values (medial and lateral extension, medial and lateral flexion gaps) was calculated. The algorithm was restricted in the amount of angular deviation permitted in all 3 planes (femoral coronal, femoral rotation, and tibial coronal) from initial MA or KA position by either ± 1, ± 2, or $\pm 3^\circ$. Hip-knee-ankle (HKA) angular boundaries were set, such that MA solutions required an overall HKA between 3° varus and 3° valgus, and KA solutions an HKA between 6° varus and 3° valgus for KA (Table 3). The HKA boundaries were chosen as ± 3 is a commonly described range in MA literature and 6° varus to 3° valgus are the Food and Drug Administration–approved boundaries for restricted KA [12,13]. A TKA was considered to have no solutions if there were no component positions where balanced gaps could be achieved within the set boundaries. In practice, these knees would require either a soft tissue release, component angulation boundaries extended, or acceptance of an unbalanced gap.

The algorithm provided a consistent method for balancing knees, with 'balance' defined as equal (20 ± 0.5 mm) virtual gaps in each quadrant to accommodate a minimum 9 mm polyethylene insert. Limits to the angular adjustments of tibial and femoral components were set at varying boundaries (± 1, ± 2, and $\pm 3^\circ$ from initial) and the percentage of knees that could achieve at least 1 balanced solution without soft tissue release was compared. As the native knee has greater laxity on the lateral side [5,6], particularly in flexion, we also analyzed the effect of a balance target with greater lateral gap ranges (20 to 21 mm lateral extension gap, 20 to 23 mm lateral flexion gap).

Statistical differences in continuous data were determined using *t*-tests and differences in number of balanced knees between MA and KA groups were examined using *Chi*-squared tests. Statistical significance was taken at the 5% level ($P < .05$).

Results

Initial gaps varied between across patients and varied between MA and KA starting plans (Fig. 4). The number of unique solutions possible to balance these gaps without soft tissue release varied depending on the amount of angular deviation and lateral laxity allowed. Less than 5% of MA or KA TKAs had all 4 compartments initially 'balanced' (Fig. 5A). Limited adjustments to component

Table 2
Intraclass Correlation Coefficients for Gap Measures.

Gap	Interobserver ICC	95% Confidence Interval [Lower Bound, Upper Bound]	Intraobserver ICC	95% Confidence Interval [Lower Bound, Upper Bound]
Medial Extension	0.92	[0.85, 0.96]	0.96	[0.90, 0.98]
Lateral Extension	0.90	[0.82, 0.95]	0.96	[0.90, 0.98]
Medial Flexion	0.98	[0.95, 0.99]	0.98	[0.94, 0.99]
Lateral Flexion	0.89	[0.80, 0.94]	0.97	[0.94, 0.99]

Table 3
Boundary Limits for Final Functional Alignment Using Balancing Algorithm.

Boundaries	Mechanical Functional	Kinematic Functional
Femoral coronal	3° varus to 3° valgus	3° varus to 6° valgus
Femoral rotational	3° from TEA	5° from TEA
Tibial coronal	3° varus to 3° valgus	6° varus to 3° valgus
HKA	3° varus to 3° valgus	6° varus to 3° valgus

position increased the percentage of TKAs with at least 1 balanced solution in a graduated manner (Fig. 5A), with no difference between MA and KA seen when targeting equal gaps: adjustments of ±1 (10% versus 6%, $P = .17$), of ±2 (42% versus 39%, $P = .61$) or of ±3 (54% versus 51%, $P = .66$).

A higher percentage of TKAs could be balanced when a greater range for lateral gap laxity (up to 1 mm lateral extension and 3 mm lateral flexion) was permitted. The percentage of MA ± 3° TKAs with a balanced solution increased from 54% with equal gaps to 79% with lateral gap laxity and the same trend was seen with KA (Fig. 5B). With lateral gap laxity allowed, there was no difference between MA and KA with adjustments of ±1° (MA 51% versus KA 58%; $P = .17$) or adjustments of ±2° (MA 77% versus KA 85%; $P = .10$). However, there was a higher number of TKAs that could be balanced with KA with ±3 adjustments with lateral gap laxity (MA 79% versus KA 88%; $P = .03$).

The MA group targeting equal gaps (20 mm) and allowing ±1° angular deviation had an average number of solutions of 87 (range, 60 to 105) in 15 TKAs, where balance without soft tissue release was possible. When the angular deviation was increased to MA ± 3°, there was a greater number of balancing solutions with an average of 594 solutions (range, 239 to 1,391) across 83 TKAs. There was a similar trend with KA, with an average of 102 solutions (range, 72 to 164) across 12 TKAs with KA ± 1° and an average of 564 solutions (range, 145 to 1,211) across 111 TKAs with KA ± 3°. There were even more solutions available when lateral laxity was allowed, with an average number of 4,432 solutions (range, 434 to 9,833) across 189 TKAs with KA ± 3.

When balancing from KA, the final balanced solutions were found to have 2.2° more femoral valgus (95% confidence interval [CI], lateral distal femoral angle [LDFA] 87.5 to 87.7°; $P < .01$) and to have 2.7 more tibial varus (95% CI, LDFA 86.2 to 86.3°; $P < .01$) than the final balanced solutions from MA. As a result, there was significantly greater joint line obliquity (JLO) (medial distal femoral angle + LDFA) [14] in the final implant position using a KA plan (95% CI, JLO 173.8 to 174°; $P < .01$; Fig. 6).

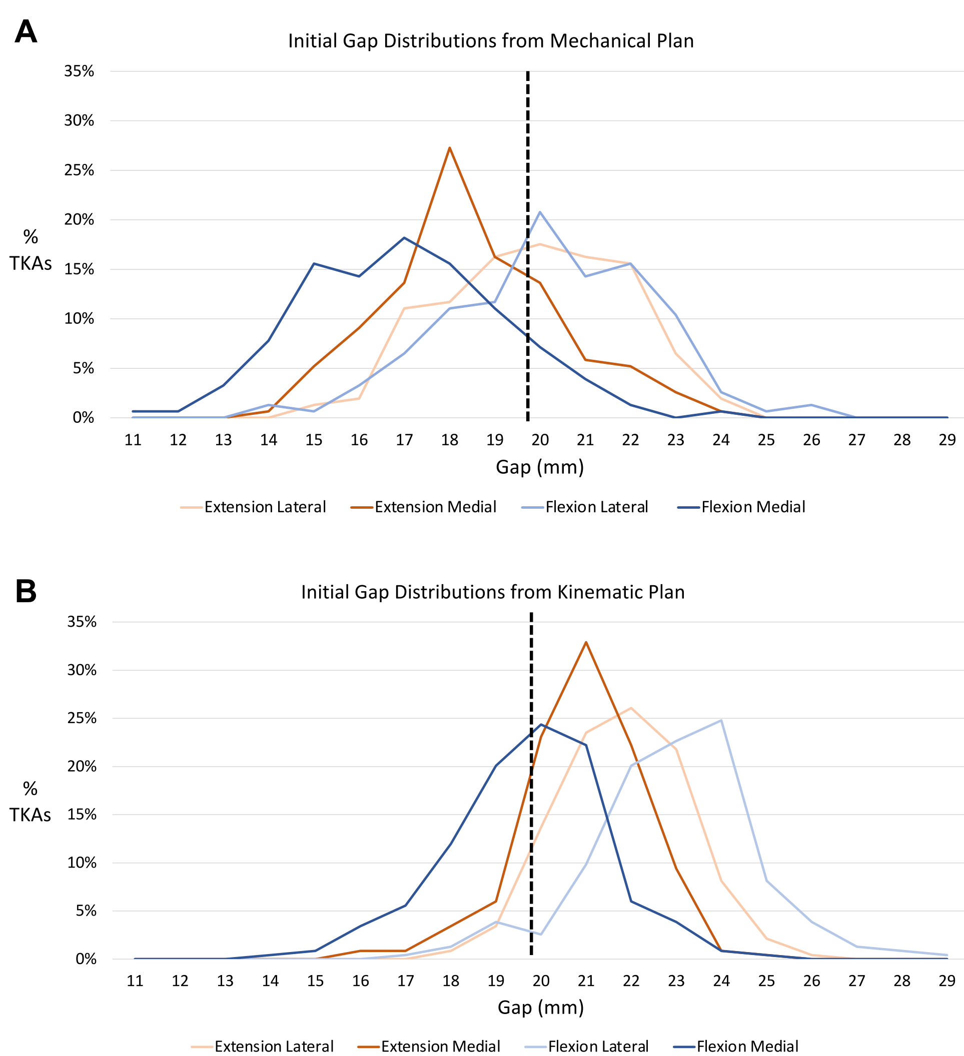

Fig. 4. (A) Initial gap distribution from mechanically aligned total knee arthroplasties. In general, medial extension and medial flexion gaps were tighter than the 20 mm target for balance, shown with the dotted line. (B) Initial gap distribution from kinematically aligned TKAs. In general, gaps were close to or looser than the 20 mm target for balance, shown with the dotted line.

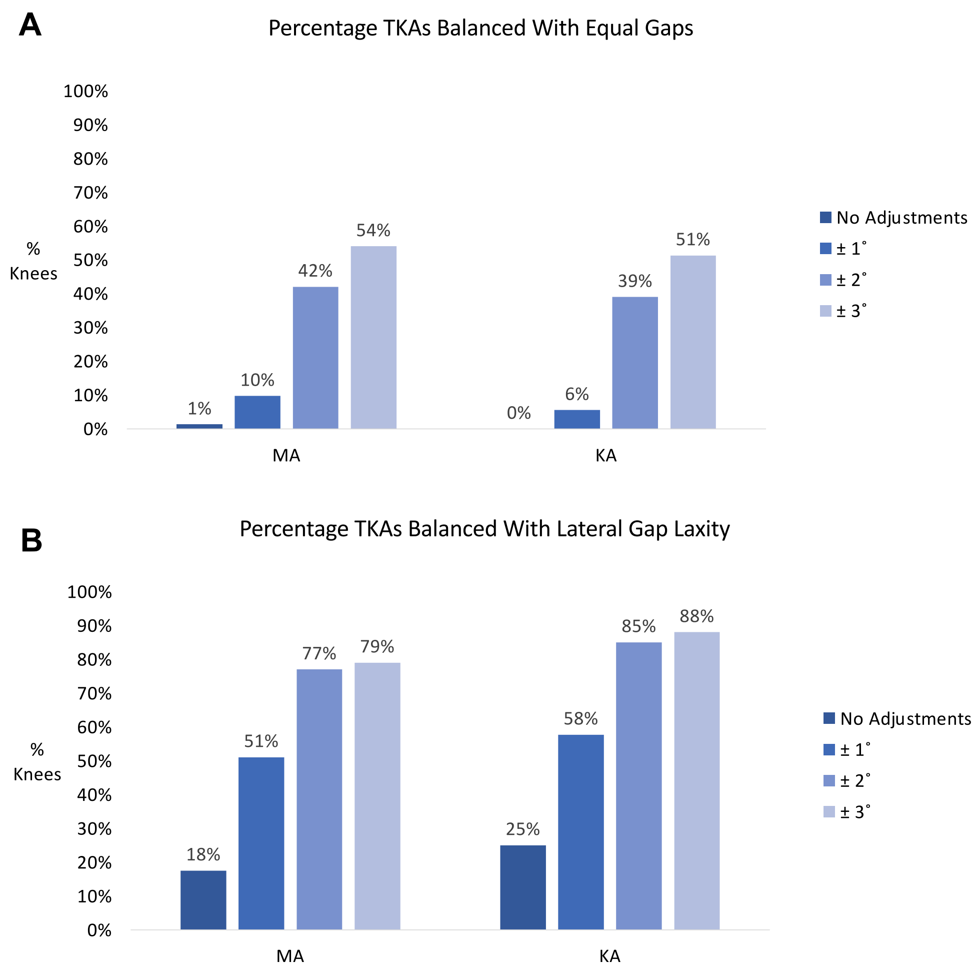

Fig. 5. Percentage of that could be balanced given an alignment philosophy (mechanical [MA] or kinematically [KA] aligned) and angular boundaries (±1, ±2, or ±3°). (A) shows the percentage of TKAs that could be balanced to equal gaps (20 mm) and (B) shows the percentage of TKAs that could be balanced when a greater range for lateral gap laxity (up to 1 mm lateral extension and 3 mm lateral flexion) was permitted. There was no difference between MA and KA with adjustments of ±1, ±2, or ±3° with equal gaps (A). However, there was a higher number of TKAs that could be balanced with KA with ±3 adjustments when lateral gap laxity was tolerated (MA 79% versus KA 88%; $P = .03$; (B)).

Discussion

In this study of 331 primary TKAs, a high percentage of TKAs achieved balanced gaps without soft tissue release using minor (±3°) adjustments to component position using both MA and KA initial positions. The KA positioning alone did not lead to a more balanced knee. In addition, we found the percentage of TKAs that achieved balanced gaps was higher when a greater range for lateral gap laxity was permitted.

The impact of KA or MA philosophies on clinical outcomes remains controversial [15,16]. However, regardless of alignment philosophy (MA or KA), most authors consider a key goal of TKA is to achieve a well-balanced joint through a full range of motion [1,2]. While MA with manual instruments relies on soft tissue release to achieve balance, and caliper-based KA seeks to restore the native bony anatomy through controlled resections, neither technique fully considers component positioning and balance simultaneously. Recently, a functional alignment technique has been described, which aims to 'position the components in the position that least compromises the soft tissue envelope of the knee' [12,17]. This is enabled by navigation that allows virtual component positioning and intraoperative assessment of soft tissue balance from either an MA or KA plan [18].

However, it remains unclear whether gap balance targets in TKA should aim for standardized, equal gaps in flexion and extension or

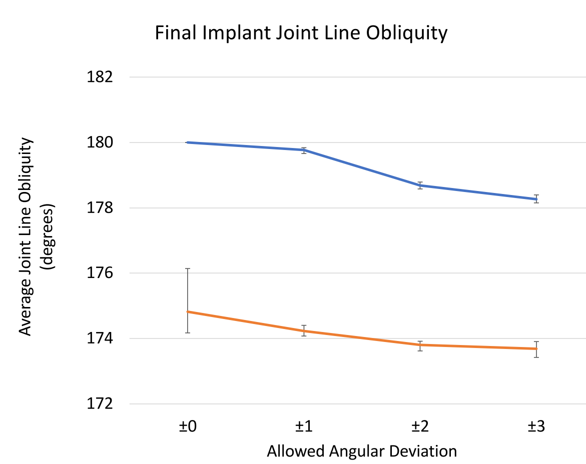

Fig. 6. Mean joint line obliquity for final implant alignment using mechanical alignment (MA) or kinematic alignment (KA). Joint line obliquity (JLO) is calculated as medial proximal tibial angle (MPTA) + lateral distal femoral angle (LDFA), as described by MacDessi et al [12]. A joint line obliquity (JLO) of 180 is a horizontal joint line, while a JLO < 180 is an apex distal joint line. There was significantly greater joint line obliquity in the final implant position using a KA plan compared to a MA plan ($P < .01$).

aim to more closely replicate the native knee with greater lateral laxity, particularly in flexion [19,20]. Many TKA authors advocate for equal flexion and extension gaps to reduce the incidence of stiffness [21] and instability [22] with posterior-stabilized implant designs [1,23]. However, recent studies evaluating cruciate-retaining TKA have reported improved patient-reported outcomes with looser flexion gaps [7,24]. This may be attributed to a greater lateral laxity (a trapezoidal flexion gap) occurring in normal knees [5]. Our findings support the concept of native lateral knee laxity, as when components were initially positioned in KA alignment, aiming to match the native joint line, we noted greater laxity in the lateral extension and particularly lateral flexion gaps (Fig. 4). While the impact of more closely targeting native gap laxities on clinical outcomes is uncertain, in this study we found a higher percentage of TKAs could be balanced when a greater range for lateral gap laxity (up to 1 mm lateral extension and 3 mm lateral flexion) was permitted.

To the best of our knowledge, this study is the first to demonstrate that there can be thousands of potential solutions to make implant adjustments to achieve balance in a knee depending on alignment philosophy, preferred boundaries for component position, and gap targets for desired laxity. When analyzing potential adjustments in the operating room to achieve balance, a standardized approach may be preferable to achieve reproducible results. While in this study we defined ‘balanced’ as cases with at least one potential solution within limits, many cases had multiple potential solutions. This clinical problem lends itself to an automated algorithm, as for some knees more than 4,000 solutions could be analyzed. The algorithm has the ability to rank these solutions as per criteria set by the surgeon, potentially aiding rapid intraoperative selection of the preferred solution [25]. Future research should focus on defining which solutions are more likely to optimize biomechanical function and clinical outcomes.

This study has several potential limitations. The manual gap assessment has potential for error. To consider this, we evaluated reliability in a small cohort of patients and found gap measures to have good or excellent reliability (Table 2). Also, while we have assessed the ability to achieve gap balance and alignment targets, we have not established a relationship between balanced gaps and clinical outcome, and this remains an area for further study. Additionally, while allowing increased lateral laxity (particularly in flexion) may more closely resemble the native knee [5], it is unclear if this is beneficial in TKA. However, alignment and balance goals are intimately related and establishing reproducible surgical techniques incorporating both aspects is required to investigate the effects on clinical outcome. Moreover, this study used a single radius, CR design and the posterior cruciate ligament was preserved when initial balance was assessed. Therefore, our findings may not apply when posterior stabilized and/or other designs are used. In addition, ‘optimum’ gap targets may be implant design dependent and potentially differ between posterior stabilized and CR implants. Furthermore, this study relied on a mathematical gap calculation method when making adjustments, and we could not clinically confirm that each solution provided by the algorithm would provide ‘balance’ after a TKA was implanted in one of these positions. In practice, other variables may impact this such as accuracy of bony cuts and stretching or injury to the soft tissue envelope during the course of the procedure. However an ongoing randomized controlled trial is underway to validate this [26], and a recent study reported 99% of knees were balanced at the completion of a robotic TKA if initial ‘virtual’ balance was achieved within 1 mm [18].

In conclusion, this study demonstrated that when using a computer algorithm to analyze potential (theoretical) changes, a high percentage of TKAs can be balanced without soft tissue release using minor adjustments to component position. Multiple possible solutions with variations of component position may exist to achieve balance. While the impact on clinical outcomes remains unclear, surgeons should consider the relationship between alignment and balance goals when optimizing component positioning in TKA.

Acknowledgments

We acknowledge the work was funded through a research grant provided by Stryker.

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