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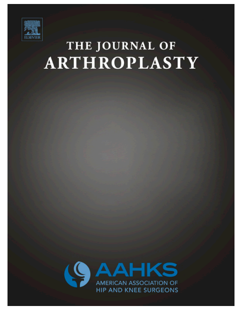

Impact of Component Alignment and Soft Tissue Release on 2 Year Outcomes in TKA

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Abstract

Introduction: The objective of this study was to investigate the impact of alignment and soft tissue release on patient outcomes following total knee arthroplasty (TKA).

Methods: In a multicenter study, soft tissue releases during TKA were prospectively documented in 330 robotic-assisted TKAs. Knee Injury and Osteoarthritis Outcome Scores (KOOS) were captured post-operatively. Delphi analysis was used to determine inlier and outlier component alignment boundaries: Tibia Coronal (TC): ±3°, Femur Coronal (FC): ±3°, Femoral Axial (FA): 3°Int-6°Ext, Hip-Knee-Ankle (HKA): 3°Val-4°Var, Tibiofemoral Axial (TFA): 3°Int-6°Ext. Kruskal-Wallis ANOVA tests were used to compare groups.

Results: No significant differences were found between any individual or grouped inlier and outlier alignment criterion and KOOS at any time point. Outlier alignment frequencies were: TC:0%, FC:12%, FA:8%, HKA:9%, TFA:8%, any:23%. Soft tissue releases were performed in 18% of cases. Knees with soft tissue releases reported significantly worse KOOS scores at: 6M: Symptoms (80.0 vs 75.3, p=0.03), ADL (86.2 vs 80.8, p=0.030), QOL (70.1 vs 60.9, p=0.008); 12M ADL (90.0 vs 85.1, p=0.023); and 24M ADL (91.9 vs 87.2, p=0.016). A higher proportion of patients achieved Minimally Clinically Important Difference (MCID) for pain at 6 months for those having no releases vs released (92.3% vs 81.0%, p = 0.021). No significant associations were found between pre-operative deformity, pre-operative or post-operative KOOS.

Conclusion: After trying to balance the TKA with bony cuts alone, the addition of soft tissue releases after bony cuts is associated with worse KOOS scores out to 2 years and was more prevalent in knees with worse deformity, while no such association was found for alignment.

Keywords: component alignment, soft tissue release, total knee arthroplasty, robotic assisted

Introduction

Total knee arthroplasty (TKA) has been shown to be an effective treatment for patients with end staged arthritis, but up to 20% of TKA patients are not satisfied post-operatively. [1–4] Historically, several technique related factors have been shown to play a role in TKA outcomes, including coronal alignment, proper soft tissue balancing, correct rotation of the femoral component, patellofemoral kinematics, and minimal change in the joint line.[5–9]

In the attempt to improve TKA outcomes, alternate strategies to balance ligaments and modify alignments have been explored. When targeting a balanced knee joint a compromise is often required between modifying component alignment versus soft tissue release. In the classic study by Parratte et al (with longer term follow-up by Abdel et al.), the authors found no difference in survivorship or Knee Society Scores (KSS) in a 20 year follow-up study of manually instrumented TKAs in mechanical alignment inlier or outlier alignments, however, the impact of soft tissue release was not investigated.[10,11] Murgier et al. also found that in addition, variable femoral rotation in navigated TKAs did not impact two year outcomes, indicating small deviations in component alignment and rotations to achieve soft tissue balance may not have an adverse impact on early TKA survivorship or outcome.[12] This is further supported by multiple studies regarding kinematic alignment, showing excellent clinical and functional outcomes in the short- and mid-terms.[13–15] Peters et al., however, reported that in cases where soft tissue releases are used to achieve neutral alignment, KSS scores were worse in valgus knees with 1-2 releases compared to TKAs with no releases. [16] And more recently, Golladay et al., and Wakelin et al., have found early patient outcomes are impacted by joint balance.[17,18]

Quantitative intraoperative soft tissue management remains challenging and requires the use of instruments such as tensors, distractors, spacer blocks, load sensors and navigation. Recently, digital load and gap balancing sensors integrated with robotic systems have provided a platform to further control joint balance either through component alignment or soft tissue release. The impact of alignment and soft tissue releases on early outcomes of balanced TKA's when using a digitally controlled joint tensioning device has not been investigated. Our research questions are: (1) when a surgeon chooses an outlier component alignment, is this associated with worse short-term outcomes? (2) Do soft tissue releases impact short-term outcomes? And (3) Is there a defined preference between alignment and soft tissue release when an intra-operative compromise is required

Methods

Patient enrollment

This was a prospective multi-center study across 4 sites with 4 different surgeons, approved by the New England Institutional Review Board (IRB 120170260). Patients undergoing a primary unilateral or bilateral TKA who were 18 years or older were enrolled in this study. Patients were excluded if they had body mass index (BMI) greater than 45 kg/m^2, history of mental or neurological disability, history of cancer or active infection. There were 330 robotic-assisted TKAs (288 unilateral TKAs and 21 bilateral TKAs) included in this study in 4 centers. The average age was 67 ± 8.5 years and average BMI was 31± 4.7 kg/m^2 (Table 1).

TKA Technique

All TKAs were performed using the OMNIBotics (Corin USA, Raynham, MA) robotic-assisted TKA platform with the BalanceBot digital ligament tensioning device. In all cases, the posterior cruciate ligament was resected, a cruciate retaining (CR) femoral component implant plus an ultra-congruent tibial insert was used, and the patella was resurfaced. In this cohort, 266 cases were performed with a tibia first workflow, and 64 cases performed with a femur first workflow. For tibia first (TF) cases, a neutral tibia resection was targeted within 2 degrees varus or valgus to the mechanical axis. Femoral and tibial osteophytes were removed prior to balancing. The ligament tensioner was inserted into the knee and the joint was taken through a range of flexion with 70 – 90 N tension force applied to each of the medial and lateral compartments. Pre-femoral resection joint balance was then used to plan the femoral component position and post-operative joint balance was captured. In femur first (FF) cases, femur and tibia resections were performed neutral to the mechanical axis within 2 degrees varus or valgus, and femoral rotation was set from 0 to 4 degrees external to the posterior condylar axis. Soft tissue releases were defined as any impact to the soft tissue above the surgeon's standard opening procedure and were performed in both TF and FF workflows as deemed necessary by the surgeon. Post-operative joint balance was reviewed by the surgeon after all resections to confirm acceptable final joint balance. In all cases, the surgeons were targeting equal rectangular gaps at 10° and 90° flexion.

PROMS

Knee injury and Osteoarthritis Outcome Scores (KOOS) were recorded pre-operatively and post-operatively at 3 months, 6 months, 1 year and 2 years. Data were captured electronically through an email with a unique link, or at the office visit using ORTECH (London, Canada). A minimal clinically important difference (MCID) of 8 points was used to compare KOOS pain and QOL, and 9 points to compare symptoms and ADL's.[19]

Definition of Alignment Outliers

The Delphi method [5] was used with the fellowship trained operating surgeons to determine clinically relevant inlier and outlier coronal (tibial, femoral and hip-knee-ankle (HKA)) and axial (femoral and tibiofemoral) alignments. Results of the method achieved the critical mean difference threshold of 1° after 2 cycles and revealed inlier and outlier component alignment boundaries (Tibia Coronal (TC): ±3°, Femur Coronal (FC): ±3°, Femoral Axial (FA): 3°Int-6°Ext, Hip-Knee-Ankle (HKA): 3°Val-4°Var, Tibiofemoral Axial (TFA): 3°Int-6°Ext) (Table 2).

Statistical Analysis

TKA's were divided into a number of groups for individual sub-analyses. To investigate the impact of alignment on outcome, knees were subdivided into those which satisfied the criteria defined from the Delphi analysis and those which did not. These knees are termed 'inliers' and 'outliers'. To compare the difference in soft tissue release rates based on TKA workflow, TKA's were classified as either TF workflow or FF workflow . Finally, to investigate the impact of soft tissue releases on outcome, TKA's were classified as those in which a soft tissue release was performed above the normal exposure procedure (Soft Tissue Release) and those in which it was not (No Soft Tissue Release).

All statistical analysis performed in R 4.0.4 (R Project, Vienna, Austria). Kruskal–Wallis one-way analysis of variance tests followed by post-hoc Mann-Whitney U tests were used to investigate demographics and outcome differences between inlier and outlier patients, and the impact of soft tissue releases on outcome. Chi-square tests were used to determine differences in gender proportion and release frequency. Spearman's Rank Correlations were also performed to identify rank correlations between alignment and outcome which may not be found using 'inlier' or 'outlier' thresholding. All PROMs Outcomes are visualized as boxplots in which the median score is shown surrounded by a 50%ile box and 95%ile whisker. Outliers are shown as individual points.

Results

Soft Tissue Release

Soft tissue releases were performed in 60 cases – 68% after tibial resection, 25% after femoral resection and 7% after the tibial and femoral resections. In this cohort, 51 cases had 1 release, 7 cases had 2 releases, and 2 cases had 3 releases. Releases occurred less frequently in TF knees (in 11% of TF cases, n = 30) than in FF knees (in 47% of FF cases, n = 30)($p < 0.0001$). In the TF group 11 (37%) releases occurred after tibial resection only and 15 (50%) after femoral resection and 4 (13%) after the tibia and then femur resections; whereas all 30 releases in the FF group occurred after both tibia and femoral resections. Majority of these releases were of the superficial MCL after the tibial resection (Figure 2).

Knees with soft tissue releases reported significantly worse KOOS scores at: 6M: Symptoms (80.0 vs 75.3, $p = 0.03$), QOL (70.1 vs 60.9, $p = 0.008$) and ADL (86.2 vs 80.8, $p = 0.030$); 1 Year: ADL (90.1 vs 85.1, $p = 0.023$); and 2 Year: ADL (91.9 vs 87.2, $p=0.016$) (Figure 3). No differences in pre-operative scores were found between the groups.

When subdivided by technique, the FF group retains significance in 6M QOL (73.0 vs 58.8, $p = 0.014$), 1-year symptoms (87.7 vs 82.7, $p = 0.034$) and additionally 2-year pain reported a significant improvement in knees without releases (91.6 vs 87.7, $p = 0.047$). The TF group does not have any significant differences in sub-analysis. As a combined cohort, there was a significant difference in achieving the MCID for pain at 6 months for those with no releases vs released (92.3% vs 81.0 %, p = 0.021). There were no MCID differences identified when sub-divided in TF and FF groups.

A significant association was found between pre-operative absolute coronal deformity and rate of soft tissue release after the tibial resection when all knees were combined. Knees with a coronal deformity of 10° or more (n = 55) from neutral were more likely to need a release than those with less deformity (n = 275) (32% vs 11%, p = 0.0002). However, no significant difference in KOOS score was found between highly deformed and neutral knees at any post-operative time point.

Impact of Alignment on PROMS

No significant differences were found between any individual inlier and outlier alignment criterion or by grouping knees with any outlier alignment vs knees with no outlier alignment and KOOS outcomes at any time point. Distribution of inliers versus outliers are shown in Figure 1. Outlier frequencies were as follows: TC: 0%, FC: 12%, FA: 8%, HKA: 10%, TFA: 8%, Any: 23% (Table 3). No significant association was found between pre-operative deformity or pre-operative outcomes and post-operative outcomes.

No significant differences in demographics were identified between inlier or outlier alignments. No significant Spearman Rank Correlations were identified between achieved femoral, tibial or tibiofemoral alignments and outcome. See appendix 1 for comparisons of outcome.

Reoperations and manipulations under anesthesia

One patient underwent a tibial insert exchange for instability 12 months after TKA. The participant reported KOOS pain > 90 pts at 1 yr and an outlier axial fem rotation of 6.5 deg external rotation. Three manipulations under anesthesia were performed, all were tibia first workflow performed by the same surgeon without soft tissue release. All component alignments were classified as inlier with low pre-operative coronal deformity (10°). The average time to manipulation was 47±36 days.

Discussion

We found that soft tissue releases statistically significantly impacted outcomes, however, alignment did not. Knees with soft tissue releases reported significantly worse KOOS Symptoms, ADL and QOL scores at six months, reaching the MCID difference for QOL. Differences in KOOS ADL remained at 1- and 2-year post-op. While a higher fraction of non-released patients achieved MCID for pain at six months, there was no significant difference in the absolute scores between groups. This study, therefore, suggests small changes to component alignment from neutral mechanical alignment may be preferrable to soft tissue releases to achieve joint balance.

During TKA surgery, there is inherent trauma that occurs from exposure and bony manipulations/cuts, including soft tissue trauma that heals during the post-operative period. The added trauma introduced by soft tissue release may only become apparent once the initial healing process is largely complete [27, 28, 29], and may explain why in our study there was no difference in PROMs in the early three-month post-operative recovery period. Additionally, the long-term effect on ligament health or integrity after soft tissue release has never been studied. Our results are similar to Peters et al., who found soft tissue releases impacted KSS outcome when 1 – 2 releases were performed in valgus knees. [16] Although the cohort was large (n = 1216), only 52% of knees had outcome scores and it was unclear if there was a selection bias associated with this low follow-up. Our finding that soft tissue releases impact outcome scores out to 2 years across all knee deformities suggest a different conclusion ~~– that small deviations in component alignment from neutral mechanical alignment may be preferable to soft tissue release to balance the joint.~~

Historically, three degrees has been the acceptable variation in alignment to maintain stability and survivorship, however, this is based on studies that analyzed older implant designs[15]. In recent years, implant designs have evolved both from a geometric design as well as from a materials perspective [30], which may allow some deviation to target function rather than mechanical stability. Recent studies found that patients who underwent a TKA with kinematic alignment had better functional outcomes in the early post-operative period.[20–22] Alternatively, a recent meta-analysis based on four randomized controlled trials with a minimum 2 year follow-up found that patients in the kinematic TKA group did not have superior clinical outcomes compared to those in the mechanical TKA group.[23]. While some studies found that there were no differences in clinical outcomes between mechanical and kinematic alignment TKA patients, other studies found that kinematically aligned TKA patients report improved outcomes, indicating non-neutral coronal alignment may be acceptable when preferencing a balanced joint with soft tissue releases. Similarly for femoral component rotation, Murgier et al analyzed 287 consecutive varus alignment TKA patients utilizing a navigated patient-specific alignment to assess component alignment impact on clinical outcomes.[12] Femoral rotation varied from 7 degrees of internal rotation to 8 degrees of external rotation and reported no significant difference in outcomes with respect to femoral alignment, also suggesting that when targeting a balanced knee, subtle modifications to alignment do not affect clinical outcomes.[12] There are some cases where kinematic alignment may be better for patients, however, in some cases there is no difference and the target alignment may be patient specific based on anatomy.

Our study supports this literature, and combined with modern accurate robotic techniques, indicates that successfully balanced knees with outlier alignment should not be considered an intra-operative compromise, but rather a deliberate decision to achieve balance without performing soft tissue releases.

Soft tissue releases were likely more prevalent in the FF group compared to the TF group due to both the neutral alignment target and reactive balance philosophy. While the TF technique may only require releases in the most highly deformed knees, the FF technique requires releases to balance mild to moderate deformities and provide insight into the impact of releases on more typical TKA subjects. High deformity knees reported a higher frequency of releases (32 %) compared to low and moderate deformities (11%), however no difference in outcome between these groups was found, indicating that worse outcomes associated with soft tissue release was not confounded by potentially poor outcomes associated higher deformities.

There are several limitations to our study. First, we did not report the accuracy of the balance achieved. Second, pre-op to 2-year outcomes show recovery, but may not be representative of long-term PROMS (e.g. ≥5 years). However, several studies have demonstrated that most of the improvement in outcomes scores occurs within the first year after surgery with relatively little change in the second year and beyond. [24–26] Third, all tibial resections were inliers – typical of gap balancing and measured resection techniques, and it is unknown if these trends extend to kinematic alignment or other alternate alignment techniques. Although data indicates small deviations from neutral may not adversely impact outcome, new boundaries for the small deviations have not been set, so caution must be taken clinically. Fourth, although a release was defined in this study as any impact to the soft tissue above standard opening and ACL/PCL resection, indications for soft tissue release and method of release were not controlled.

Each surgeon performed releases following their standard practice and were guided by the robotic assisted digital gap balancing tool. The variability inherent in soft tissue release technique and resulting trauma to the soft tissue is a limitation. A final limitation is that this is not a randomized controlled trial, as such it is not known explicitly if the knees which were released would have performed better if the component placement was modified to achieve balance. This study however, indicates that further investigation with a randomized controlled trial in which one group achieves balance only through component placement, and the other only through soft tissue releases is warranted.

After trying to balance the TKA with bony cuts alone, the addition of soft tissue releases after bony cuts is associated with worse KOOS scores out to 2 years and was more prevalent in knees with worse deformity, while no such association was found for alignment. ~~This suggests small deviations in component alignment from a neutral mechanical axis may be preferable to soft tissue releases to achieve joint balance for improved short-term outcomes following TKA.~~ A further randomized investigation of TKA's in which soft tissue releases or bone cuts and re-cuts are performed to achieve joint balance will substantiate or refute these findings.

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Appendix 1

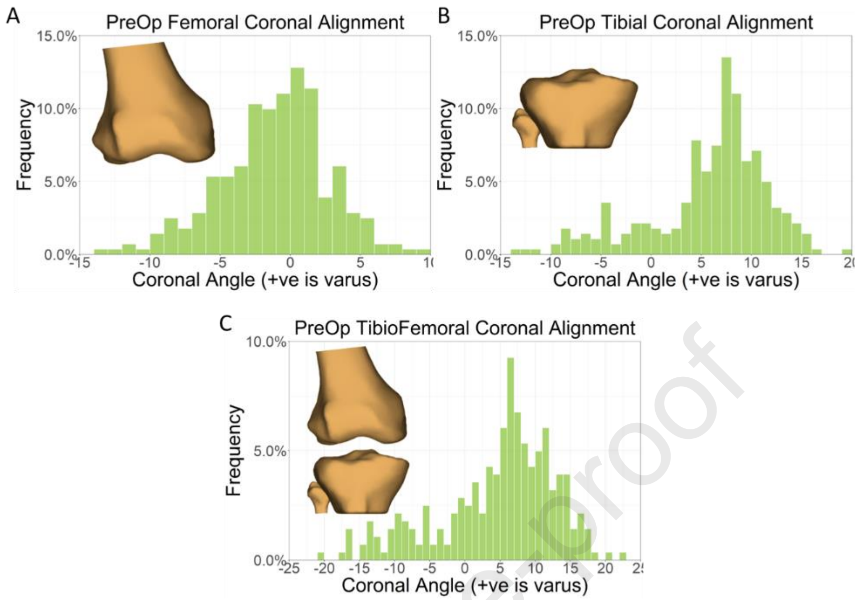


Figure 1 Pre-operative Alignment

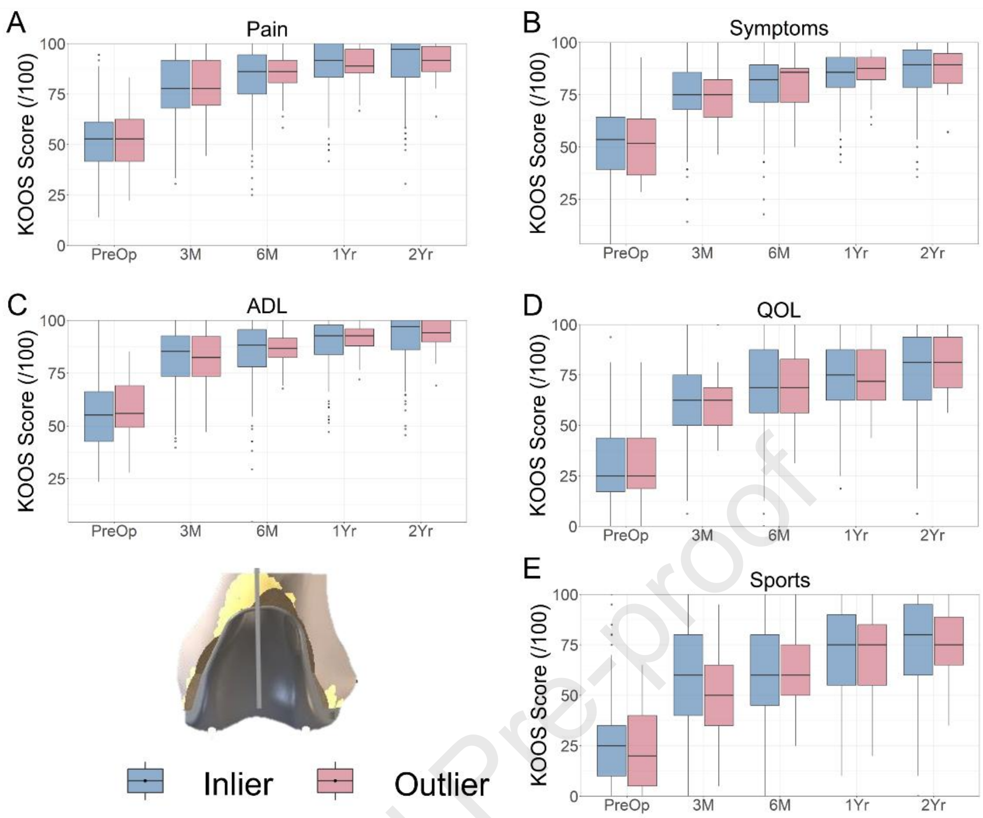


Figure 2 Impact of post-op femoral coronal angle on KOOS A) Pain B) Symptoms C) Activities of Daily Living (ADL) D) Quality of Life and E) Sports and Recreation scores from pre-op to 1 Yr post-op subdivided by inlier (Blue) and outlier (Red) alignments. No significant differences observed.

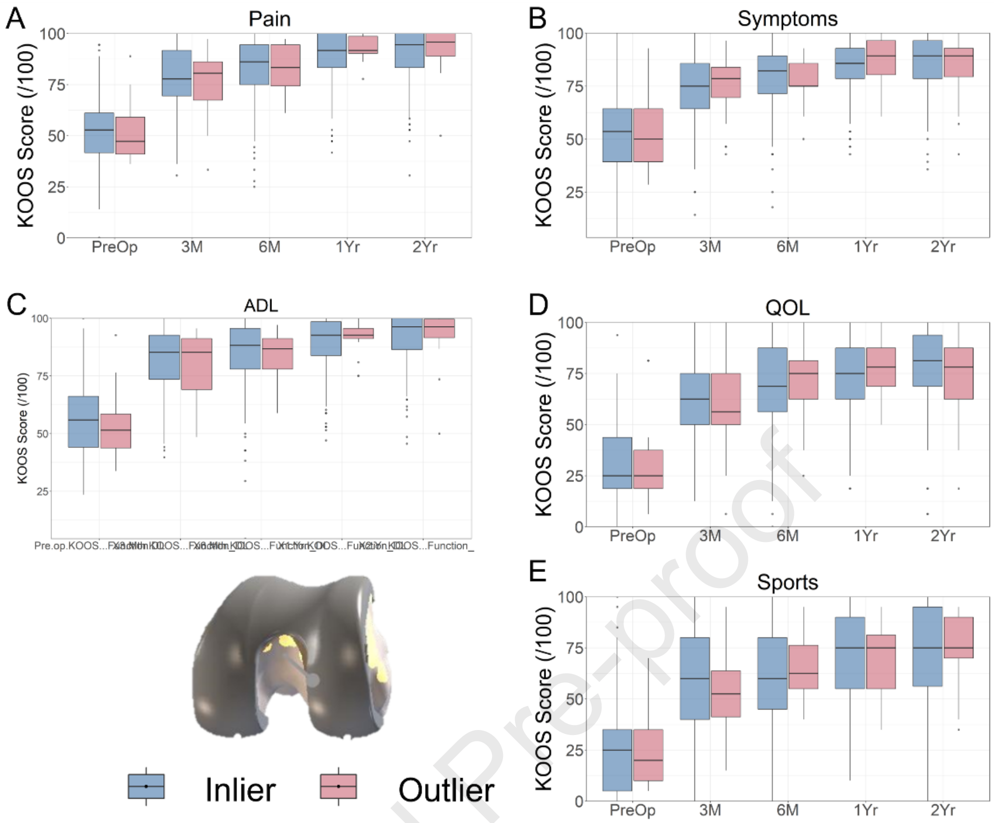


Figure 3 Impact of post-op femoral axial rotation on KOOS A) Pain B) Symptoms C) Activities of Daily Living (ADL) D) Quality of Life and E) Sports and Recreation scores from pre-op to 1 Yr post-op subdivided by inlier (Blue) and outlier (Red) alignments. No significant differences observed.

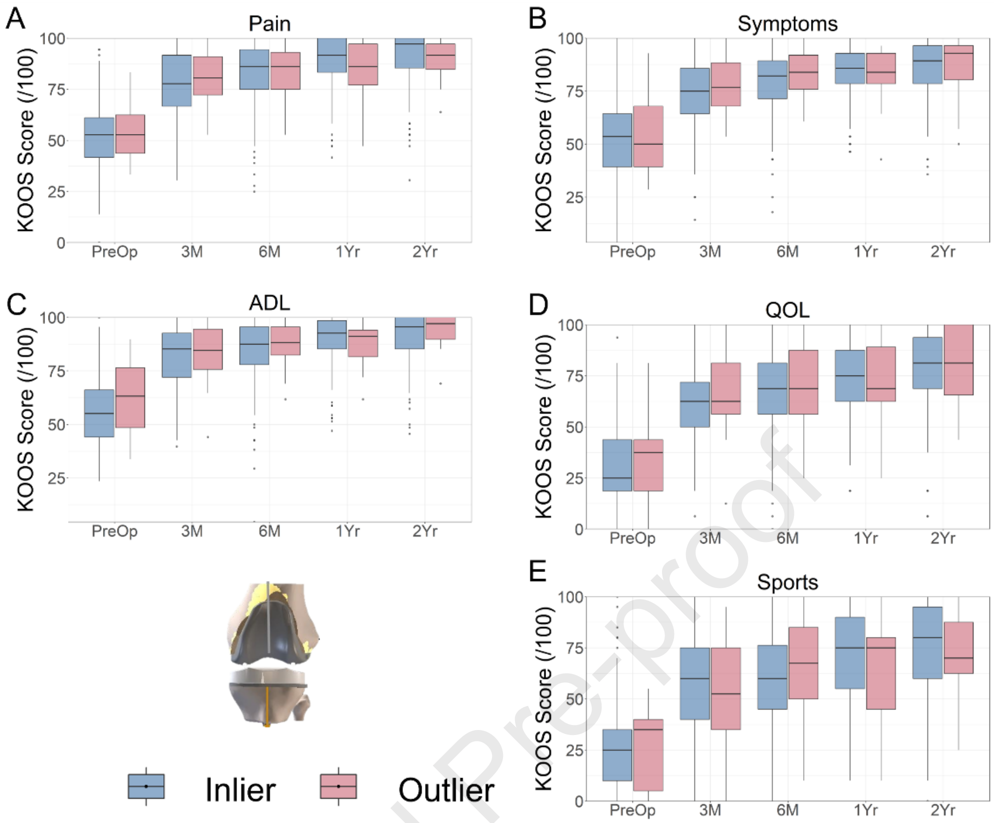


Figure 4 Impact of post-op tibio-femoral coronal alignment on KOOS A) Pain B) Symptoms C) Activities of Daily Living (ADL) D) Quality of Life and E) Sports and Recreation scores from pre-op to 1 Yr post-op subdivided by inlier (Blue) and outlier (Red) alignments. No significant differences observed.

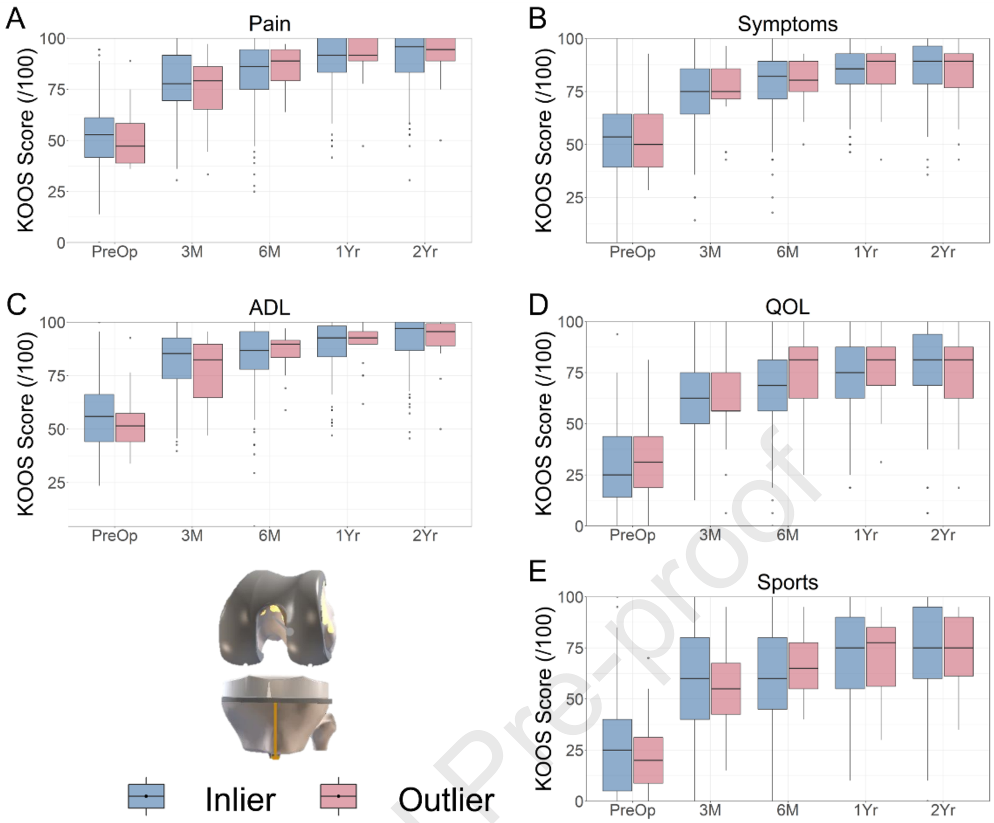


Figure 5 Impact of post-op tibio-femoral axial alignment on KOOS A) Pain B) Symptoms C) Activities of Daily Living (ADL) D) Quality of Life and E) Sports and Recreation scores from pre-op to 1 Yr post-op subdivided by inlier (Blue) and outlier (Red) alignments. No significant differences observed.

Table 1 Demographics

Demographic	Whole Cohort	Tibia First Only	Femur First Only
Age (Years)	67 ± 8.5	66.8±8.5	68.6±8.4
BMI (kg/m^2)	31± 4.7	31±3.6	32±4.9
Gender (% Female)	58	58	58
Deformity	4.7° ± 8.3° Varus	4.2° ± 9.9° Varus	4.8° ± 7.8° Varus

Table 2 Outlier Boundaries: Results of Delphi analysis of 6 fellowship trained orthopaedic surgeons

Angle	**'Inlier' Range**
Tibial Coronal	±3°
Femoral Coronal	±3°
Femoral Axial	3° Int to 6° Ext
Tibiofemoral Coronal	3° Valgus to 4° Varus
Tibiofemoral Axial	3° Int to 6° Ext

Table 3 Proportion of knees labelled as inlier or outlier for each alignment category

Angle	**inlier (%)**	**Outlier (%)**
Tibial Coronal	100	0
Femoral Coronal	88	12
Femoral Axial	92	8
Tibiofemoral Coronal	91	9
Tibiofemoral Axial	92	8
Any Criteria	77	23

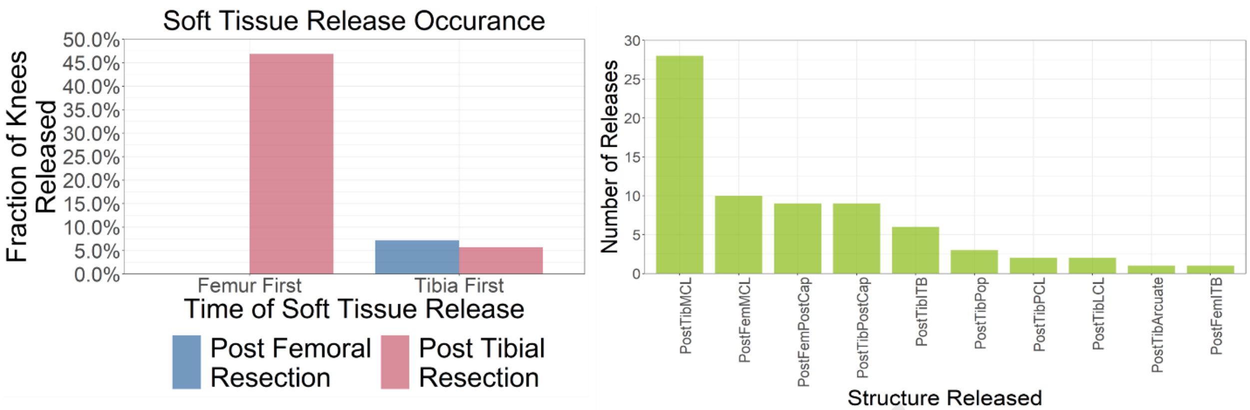


Figure 1 Point at which soft tissue releases were performed during TKA. B) Occurrence of soft tissue structures released during TKA

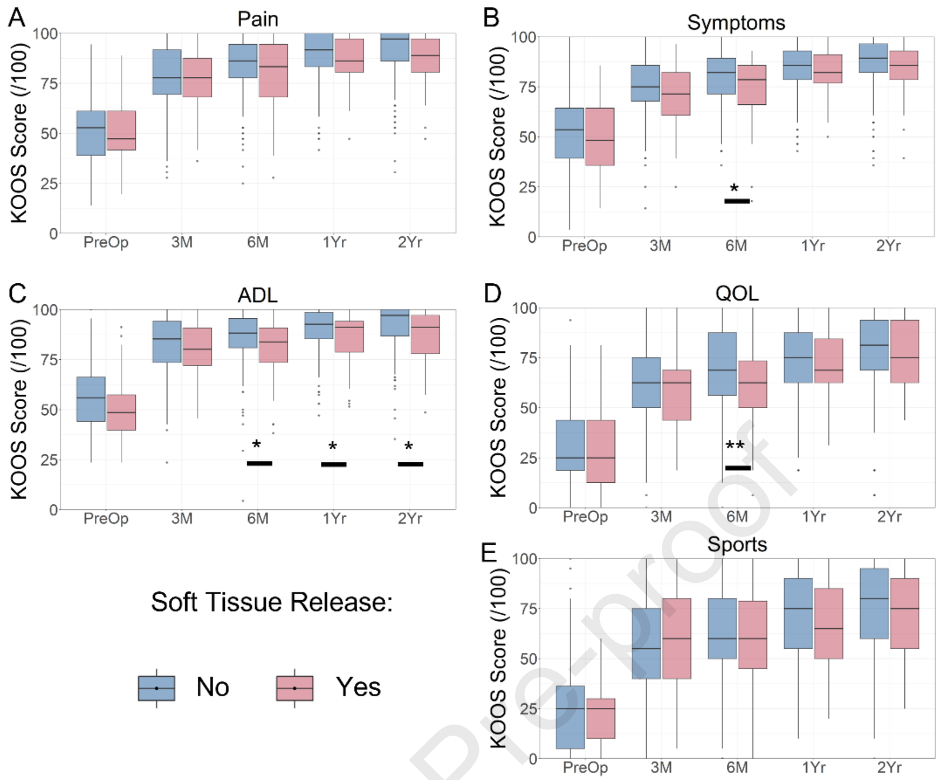
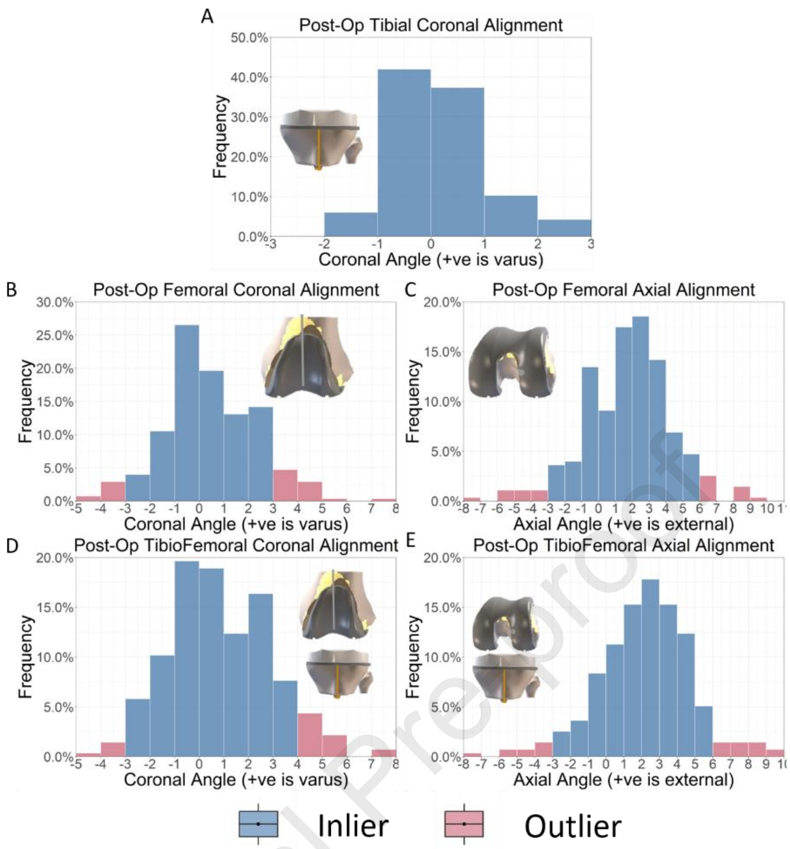


*Figure 3 Impact of soft tissue release after tibial resection on post-operative KOOS scores A) Pain B) Symptoms C) Activities of Daily Living and D) Sports and Recreation scores. *Knees which were not released are in blue, knees with releases in red. Significant difference in mean values: * p < 0.05, ** p < 0.01*

Figure 1 Distribution of achieved component alignments subdivided into inlier (Blue) and outlier (Red) groups. A) Tibial Coronal (0.4±0.9° Varus), B) Femoral Coronal (0.7±1.9° Valgus), C) Femoral Axial (2.0±2.6° Ext), D) Hip-Knee-Ankle (1.1±2.1° Varus) and E) Tibiofemoral Axial (2.4±2.6° Varus).

Figure 2 Point at which soft tissue releases were performed during TKA. B) Occurrence of soft tissue structures released during TKA

*Figure 3 Impact of soft tissue release after tibial resection on post-operative KOOS scores A) Pain B) Symptoms C) Activities of Daily Living and D) Sports and Recreation scores. *Knees which were not released are in blue, knees with releases in red. Significant difference in mean values: * p < 0.05, ** p < 0.01*



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