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Effects of Coronal Limb Alignment and Ligament Balance on Pain and Satisfaction Following Total Knee Arthroplasty at Short-Term Follow Up

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ABSTRACT

Introduction: Few studies have evaluated the concomitant effect of both total knee arthroplasty (TKA) limb alignment and ligament laxity. Therefore, the primary aim of this study is to evaluate the impact of lower extremity alignment on the short-term outcome (one year) following TKA, including pain relief, function, and patient satisfaction. The secondary aim of the study is to evaluate the impact of ligament laxity and balance on early outcomes following TKA.

Materials and Methods: A prospective evaluation of mechanical alignment and ligament tension was performed for 110 consecutive TKAs using an identical surgical technique. Patients were evaluated with knee society score, visual analog pain score, and satisfaction one year following TKA. Linear regression analysis

was then performed to determine the effect of lower extremity alignment and ligament laxity.

Results: There was no significant relationship between lower extremity alignment and outcome measures. A significant relationship was identified between medial collateral laxity in full extension and knee society scores for function, but not for pain. There was also a significant relationship identified between lateral knee laxity at 90 degrees of flexion and knee society score and pain at one-year follow up.

Conclusion: Our results demonstrated no correlation between mechanical alignment restoration and pain or function. However, more interestingly, this study found patients with medial laxity in extension and lateral laxity in knee flexion, similar to normal physiologic knee laxity, to have less pain and greater function and satisfaction at one-year short-term follow up.

INTRODUCTION

As the number of patients undergoing total knee arthroplasty (TKA) is projected to increase substantially over the next two decades,[1,2] there has been an increasing focus on new surgical techniques to improve patient satisfaction, pain and function, as well as implant longevity.[3,4] Despite surgical advancements, only up to 80% of patients are satisfied following TKA.[5-12] Dissatisfaction after TKA is largely believed to be multifactorial and may be secondary to several factors including component malposition, malalignment, patient selection, and management of expectations.[13]

Classically, malalignment outside the traditional neutral mechanical axis ($\pm$ 3°) is believed to increase implant failure rates.[12,14] This is largely due to increased shear stress on polyethylene components resulting in increased wear and, ultimately, increased pain, decreased function, and early aseptic loosening.[15-21] Recently, several studies have questioned this central tenet of TKA by showing similar failure rates in TKAs left in neutral, varus, or valgus alignment at 15-year follow up.[20-23] Therefore, optimal alignment after TKA is yet to be fully established.

Similarly, improperly balanced TKAs are also known to be at an increased risk for complications including residual pain, instability, and, often, revision surgery.[12,24] Despite technological advances, the optimal degree of collateral tensioning in TKA has yet to be established. Tensioning collateral ligaments for a "snug" fit has been shown to have negative effects on both final knee motion and implant longevity.[25,26] Similarly, while some studies have shown improved clinical outcomes if TKAs are implanted with residual ligamentous laxity,[27-29] others have concluded medial laxity in flexion and extension to have increasingly poorer functional scores.[30]

The variability between TKA alignment and ligament balancing, as well as relative contribution of each to overall functional outcome following TKA, remains controversial.[16,22,23,31-33] Few studies have evaluated the concomitant effect of both TKA limb alignment and ligament laxity. Therefore, the primary aim of this study is to evaluate the impact of lower extremity alignment on the short-term outcome (one year) following TKA, including pain relief, function, and patient satisfaction. The secondary aim of the study is to evaluate the impact of ligament laxity and balance on early outcomes following TKA.

MATERIALS AND METHODS

After receiving institutional review board approval, a prospective study was performed to determine the effect of coronal limb alignment on pain and satisfaction at one-year follow up. All TKAs performed at our institution between 2009 and 2010 were identified from a prospective database. During this operative period, 110 unilateral TKAs were performed. All TKAs were performed for osteoarthritis and no patients were excluded without any early revisions.

All patients had anteroposterior (AP), lateral, sunrise of the knee, and three-foot hip to ankle lower extremity alignment radiographs preoperatively

Figure 1. Radiograph showing the mechanical alignment measurement. Varus is indicated by (-) and valgus is indicated by (+).

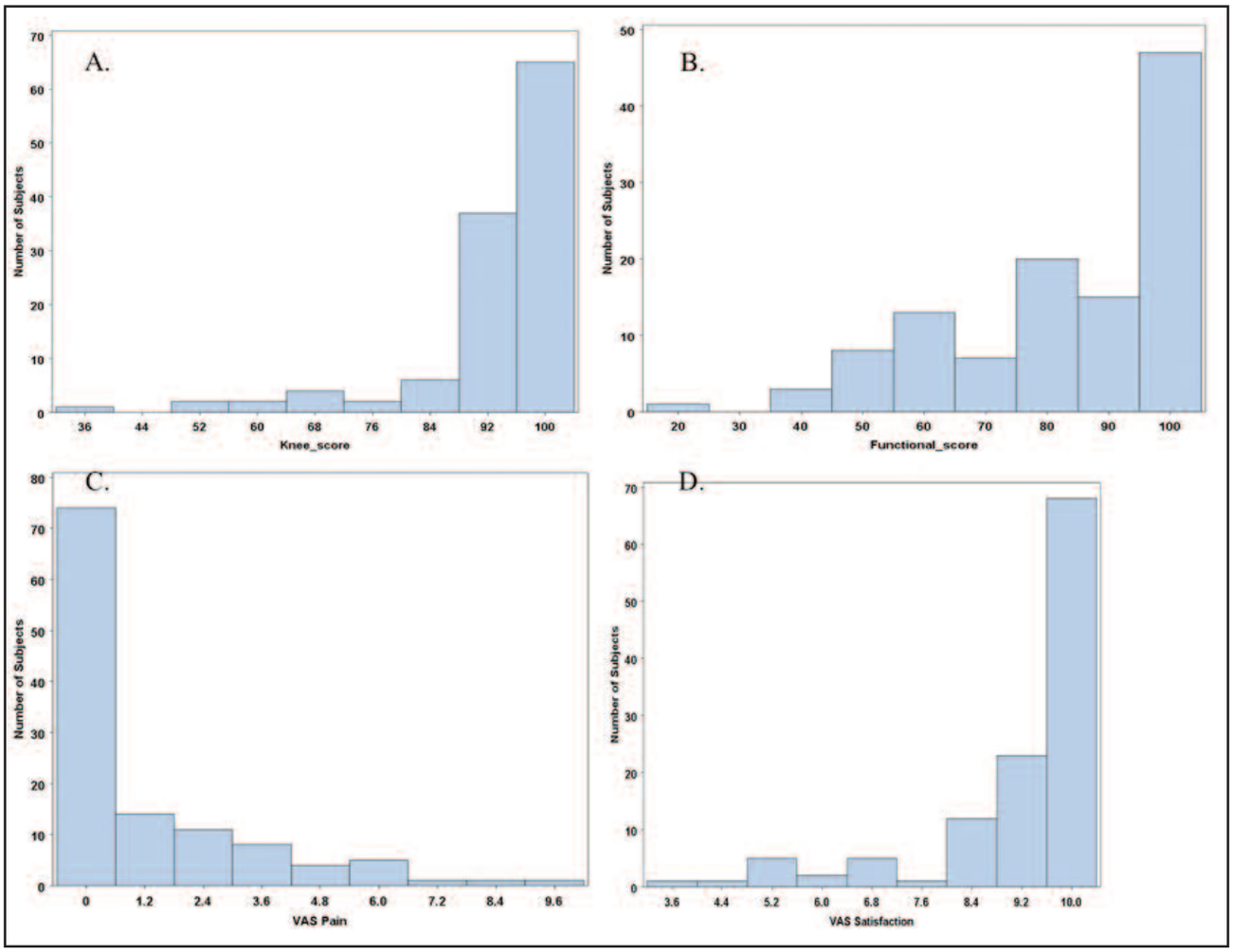

Figure 2. Distribution of data. 2a) knee score, 2b) function score, 2c) visual analog score (VAS) pain, and 2d) VAS satisfaction.

(~4 weeks) and postoperatively (~1 year). Radiograph measurements were performed on both the preoperative and postoperative three-foot hip to ankle radiographs. All measurements were performed by two independent observers (CTT and JVB). The two surgeons verified each other's measurements.

Laxity was assessed via pre- versus intraoperative physical exam by a fellowship-trained single examiner. Laxity was assessed on both the medial and lateral sides of the knee at 0, 30, and 90 degrees flexion and was recorded (in mm).

All patients underwent unilateral TKA by a single surgeon utilizing an identical prosthesis (Triathlon® CR, Stryker, Mahwah, New Jersey) and surgical technique, including a cemented cruciate retaining implant design. Intramedullary alignment guides for both femoral and tibial bony preparation was utilized in conjunction with preoperative templates with the goal of restoring a neutral overall mechanical alignment. A hybrid technique utilizing aspects of measured resection and gap balancing were utilized in all cases. A tensiometer was used for flexion gap balancing to help set femoral rotation for a symmetric gap.

Pain and function scores were assessed at one-year follow up post-surgery with the new knee society scores (KSS) and function score as well as the 10-point visual analog scores (VAS) for pain and satisfaction with the knee.[34] Physical examination was also performed to record passive range of motion and ligament balance and stability (0–7mm) at 0, 30, and 90 degrees of flexion by manual palpation. Coronal alignment films were reviewed and analyzed using IMPAX software (Afga, Inc., Arden, North Carolina) to accurately assess the overall mechanical alignment of the limb, as well as the femoral and tibial components (Fig. 1). Radiographs were also reviewed for evidence of loosening or mechanical failure.

Linear regression analysis was then performed to determine the effect of lower extremity alignment and ligament laxity on pain, knee society score, and patient satisfaction one year after TKA. A linear relationship between pre- and postoperative lower extremity mechanical alignment and component alignment were tested against the outcomes of knee score, function score, VAS pain, and VAS satisfaction. A tobit model (censored regression model) was also used to estimate linear relationships between variables, as the data skewed toward the higher end of the spectrum (Fig. 2). The tobit model is designed to estimate linear relationships between variables when there is either left- or right-censoring in the dependent variable. A similar analysis was performed for the ligament laxity

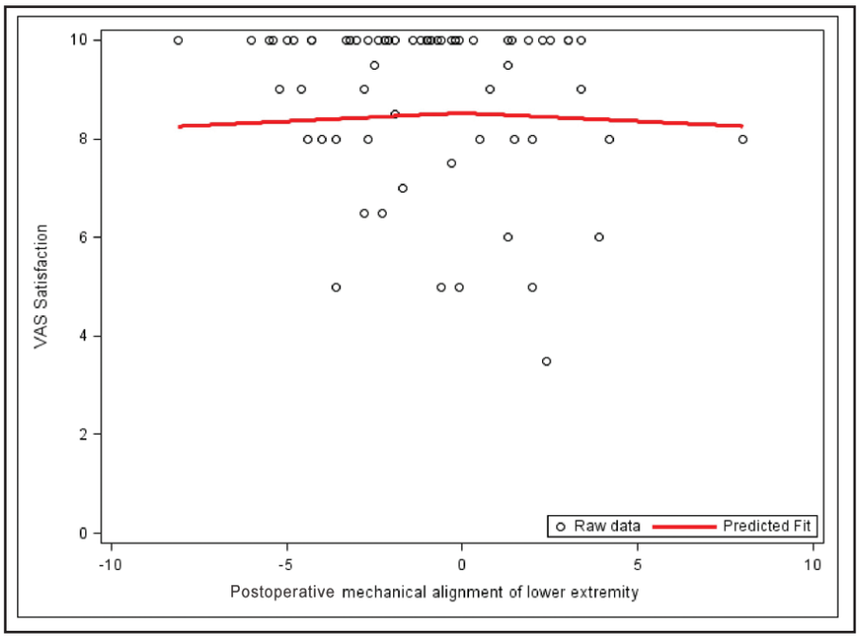

Figure 3. Raw data scatter plot of the association between postoperative mechanical alignment and VAS satisfaction.

variables. P-values <0.05 were considered statistically significant. SPSS v.20.0 software (SPSS Inc., Chicago, Illinois) for Windows® (Microsoft Corporation, Redmond Washington) was used to carry out descriptive analyses.

RESULTS

The average age of patients recruited was 62.1 years (range 49 to 72), with an average body mass index (BMI) of 31.44 (range 27 to 48). The average knee society score was 80.72 (range 73 to 90). The average knee function score was 80.28 (range 75 to 93). The average VAS pain score was 1.8 (range 0 to 5), and the average VAS satisfaction was 8.95 (range 7 to 9.8).

Alignment

There was no significant relationship identified between lower extremity alignment and KSS for pain or function and VAS for pain or satisfaction. There was no significant relationship between any of the alignment variables using their absolute values to test the linear relationship with any of the outcomes (Fig. 3).

For every one-degree increase (or decrease) in the mechanical alignment from neutral, there was a 0.03-point decrease in VAS satisfaction; however, this relationship was not statistically significant (p=0.896). A one-degree increase (or decrease) in postoperative tibial component alignment is associated with a 0.32-point increase in VAS satisfaction (p=0.434), also not significant.

Ligament laxity

A significant relationship was identified between medial collateral laxity and KSS for function, but not for pain, or VAS for pain or satisfaction. Improved knee society function scores were noted for patients with 0–2mm and more than 2mm of medial laxity when compared to patients with no measurable medial laxity. Compared to patients with no measurable medial collateral laxity, the functional score was 16.02 points higher for patients with a laxity of 0–2mm (p=0.02).

A significant relationship was also identified for knee society pain and function scores and VAS pain scores, as well as knee laxity at 90 degrees of flexion on the lateral side of the knee. There was no correlation between lateral laxity and VAS with patient satisfaction. The predicted knee society score was 13.71 higher for patients with knee laxity of ≥4mm when compared to those with knee laxity of <2mm (p=0.02). Compared to patients with lateral knee laxity of <2mm, patients with laxity of 2–4mm have better knee function (24.62 higher in functional score, p=0.01), as do patients with knee laxity ≥4mm (22.74 higher, p=0.02). We also found that patients with knee laxity ≥4mm have less reported pain on the VAS scale (2.05) than patients with knee laxity <2mm, (p=0.02).

No other statistically significant associations were noted between any of the outcome measures and knee laxity at 0, 30, and 90 degrees of flexion.

DISCUSSION

TKA neutral mechanical axis restoration has become the gold standard ever since Insall et al.'s[35] first description in 1985. Over the past decade, there has been growing interest in alternative alignments (i.e., constitutional and kinematic) in TKA as an effort to continue to improve patient outcomes.[4] Achieving optimal soft tissue balancing and stability has been a concomitant budding interest in the literature.[35-37] Manual tensiometer and technology-based intraoperative sensor inserts provide intraoperative metrics to assess soft tissue tensioning and balancing. However, despite surgical modifications and newer technology utilization, about 20% of patients continue to remain dissatisfied.[11] Despite a plethora of literature in both TKA mechanical alignment and soft tissue balancing and clinical outcomes, there are few studies evaluating both neutral axis restoration and ligament laxity in a single study. Therefore, we sought to evaluate the impact of lower extremity alignment and laxity on postoperative pain, function, and patient satisfaction at short-term follow up at one year. Our results demonstrated no correlation between mechanical alignment restoration and pain or function. However, more interestingly, this study found patients with medial laxity in extension and lateral laxity in knee flexion had less pain and greater function and satisfaction at one year.

This study is not without limitations. First, definitive conclusions cannot be made due to a small sample size. Second, longer-term studies are needed to evaluate the efficacy of residual TKA laxity on clinical outcomes and implant longevity. Third, laxity was determined clinically and may have poor inter-observable reliability. However, there is

no consensus regarding optimal ligament laxity as it is mostly based on a surgeon's personal experience. Additionally, LaPrade et al.[37] compared manual clinician-directed varus stress with a force application device and concluded both methods provided reproducible measures. Finally, this study utilized cruciate-retaining TKA implants with a mixed measured resection gap balancing technique and our results may not be extrapolated to other implant designs or surgical techniques.

Multiple studies have reported improved clinical and functional outcomes and increased implant longevity after TKA mechanical axis restoration.[14,16,17,19,32,38,39] However, Parratte et al.[22] challenged these established ideas by finding that TKAs placed outside of a few degrees from the mechanical axis in coronal plane had equal outcomes compared with knees placed within ±3 degrees of the mechanical axis. Vanlommel et al.[40] studied a cohort of 132 patients with preoperative varus alignment that was evaluated with a mean follow up of 7.2 years. Based upon the postoperative alignment, patients were stratified into three groups: neutral, mild varus, and severe varus. Knees that were left in mild varus scored significantly better for the KSS and the Western Ontario and McMaster Universities Arthritis Index (WOMAC) compared with knees that were corrected to neutral ($p=0.02$) and knees that were left in severe varus exceeding 6 degrees ($p=0.01$).

Our study found similar results with minimal patient outcome and satisfaction improvement at one year, with better mechanical alignment with no correlation between alignment and pain or function. These findings may be explained by a previous CT scanogram study that showed 98% of normal limbs did not have a neutral mechanical axis and 76% of normal limbs have deviation greater than 3 degrees from neutral.[41] Deep et al.[42] and Bellemans et al.[4] also indicated that the majority of normal individuals did not have neutral mechanical axis (mean 1.2 degrees varus, standard deviation [SD] 4 degrees, and mean 1.33 degrees varus, SD 2.34 degrees, respectively). TKA restoration to mechanical axis may not represent correction to normal alignment and, therefore, may have minimal influence on postoperative pain relief, function, and satisfaction.

Wide variability and significant controversy surrounds techniques for ligament balancing in TKA, as well as the recommended amount of medial and lateral ligament laxity following TKA. Knowledge of the normal knee collateral ligament laxity is essential to determine how tight TKA implants should be balanced. One study[41] evaluating collateral ligament laxity in young healthy individuals demonstrated a change of 3 degrees in full extension and 7 degrees in 15 degrees of flexion with a varus torque of 10Nm. On valgus torque of 10Nm, the mechanical axis changed by nearly 4.5 degrees in extension and 8 degrees in 15 degrees flexion. The study found greater laxity medially with valgus stress and in females. However, Aunan et al.[30] reported medial laxity of more than 2mm in extension and more than 3mm in flexion to have lower activity of daily living (ADL) scores, Knee injury and Osteoarthritis Outcome Score (KOOS) and Oxford Knee scores (OKS) with lateral laxity to be more forgiving in knees with neutral alignment at one-year follow up. Our findings are different from the previously reported study. We found the group of patients with slight laxity (0–2mm or 2–4mm medially in full extension and more pronounced lateral laxity 2–4mm or greater at 90 degrees of flexion with greater pain relief) had better KSS scores, and higher satisfaction at one year following TKA. The difference in our findings may be attributed to our ligamentous laxity assessment measure.

CONCLUSION

In conclusion, even though aim for mechanical axis restoration after TKA is the gold standard, there is inconclusive evidence regarding its effect on pain relief, function outcomes, and patient satisfaction. Additionally, appropriate soft tissue balancing is essential to prevent instability or stiffness, both of which are common reasons for revision arthroplasty. Our findings suggest that restoration of mechanical axis has minimal improvement in pain, function, and satisfaction. However, patients with slight medial laxity in extension with lateral laxity in flexion had significant improvement in pain, function, and overall satisfaction at one-year follow up. Although our findings cannot be generalized, we do recommend close attention to lower extremity limb alignment and its subsequent effect on ligament laxity to continue to improve functional outcomes after TKA. Long-term follow up with a large sample size is warranted for definitive conclusions.

AUTHORS' DISCLOSURES

Dr. Bono is a paid consultant and receives royalties from Stryker and Springer Healthcare.

All other authors have no conflicts of interest to disclose.

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